

Suboptimal reporting of randomized controlled trials on non-pharmacological therapies in Chinese medicine

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Abstract With the successive release of the CONSORT extensions for acupuncture, moxibustion, cupping, and Tuina/massage, this review aims to assess the reporting characteristics and quality of randomized controlled trials (RCTs) based on these specific guidelines. A comprehensive review was conducted by searching multiple databases, including Embase, Ovid MEDLINE(R), All EBM Reviews, AMED, CNKI, VIP Chinese Medical Journal Database, and Wanfang Data, for publications from January 1 to December 31, 2022. Two reviewers independently evaluated the eligibility of the records, extracted predetermined information, and assessed the reporting based on the STRICTA, STRICTOM, STRICTOC, and STRICTOTM checklists. Among the included 387 studies (acupuncture, 213; Tuina/massage, 85; moxibustion, 73; cupping, 16), the overall reporting compliance averaged 56.0%, with acupuncture leading at 62.6%, followed by cupping (60.2%), moxibustion (53.1%), and Tuina/massage (47.9%). About half of the evaluated items showed poor reporting (compliance rate < 65%). Notably, international journals demonstrated significantly higher reporting quality than Chinese journals ($P < 0.05$). Although acupuncture trials had relatively higher compliance rates, deficiencies persist in reporting non-pharmacological therapies of Chinese medicine, particularly in areas like treatment environment details and provider background information.

Keywords CONSORT; Chinese medicine; reporting guideline; STRICTA; STRICTOM; STRICTOC; STRICTOTM

Introduction

Nonpharmacological treatments (NPT) encompass non-invasive approaches, including surgical and behavioral techniques, as well as complementary and alternative medicine (CAM) modalities [1,2]. Nonpharmacological treatments in Chinese medicine (NPTCM) hold a significant position as an integral part of CAM. These treatments have evolved over thousands of years, deeply rooted in the philosophy and holistic approach of Chinese medicine (CM). Over time, NPTCM diversified, and gained recognition globally, with modern research

supporting its efficacy for various health conditions and cost-effectiveness in clinical practice [3–5]. Among the various NPTCM therapies, acupuncture, cupping, moxibustion, and Tuina are the most frequently employed physical modalities [6,7]. For example, the American College of Physicians advocates for the use of NPTs, such as acupuncture and Tuina/massage, as first-line treatments for low back pain [8]. Research from previous studies has illustrated the efficacy of moxibustion in treating a wide array of ailments, including fetal malposition, diarrhea, and colitis [9]. Cupping therapy has demonstrated potential benefits in alleviating neck pain, knee osteoarthritis, plaque psoriasis, chronic urticaria, and migraines [10]. These interventions exhibit their therapeutic efficacy by enhancing local circulation of qi and blood, relieving pain associated with qi

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stagnation, or modulating autoimmunity through various methods targeting meridians, acupoints, and specific anatomical sites [11–14]. The operational conditions of each component or provider involved can significantly influence the success of an NPT interventional trials [15]. Several studies assessing the quality of trial results have highlighted a tendency toward lower grade in CM modalities [16,17]. Many randomized controlled trials (RCTs) lack sufficient descriptions of interventions, details of blinding, or evidence of significant interstudy heterogeneity [18]. Therefore, it is imperative to adhere to specific reporting guidelines to ensure accurate documentation of non-pharmaceutical trials.

To address this, several CONSORT (Consolidated Standards of Reporting Trials) extension guidelines have been developed, focusing on acupuncture, moxibustion, cupping, and Tuina/massage interventions. These guidelines aim to ensure accurate reporting of non-pharmacological trials in the field of CM. A significant contribution to this field is the revised STAndards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) statement, published in 2010 [19]. STRICTA has offered valuable guidance for researchers conducting acupuncture trials. Since its publication, there has been increasing endorsement and adoption among various stakeholders. Moreover, STRICTA has proven to be a valuable tool for assessing the quality of RCTs included in systematic reviews and meta-analyses [20,21]. Building on the success of STRICTA, additional CONSORT extensions have been developed for moxibustion, cupping, and Tuina/massage, namely STRICTOM (STAndards for Reporting Interventions in Clinical Trials Of Moxibustion) [22], STRICTOC (STAndards for Reporting Interventions in Clinical Trials Of Cupping) [23], and STRICTOTM (STAndards for Reporting Interventions in Clinical Trials Of Tuina/Massage) [24]. These guidelines strive to establish thorough reporting standards that encompass diverse facets of interventions. This includes elucidating the rationale behind the intervention, presenting operational details, outlining the background of intervention providers, describing the control or comparator interventions employed, and specifying precautionary measures undertaken. Adhering to these checklists ensures that researchers report non-pharmacological trials in CM consistently and accurately, thereby enhancing the quality and reliability of research in this field.

Given the temporal disparities in the publication of the four reporting guidelines for NPTCM, we have chosen to evaluate reports published within the same year (the most recent) to assess the reporting quality of each intervention, following the respective guidelines. Except for the infrequent assessment of cupping RCTs' reporting quality, previous studies have focused on evaluating the reporting quality of acupuncture and moxibustion clinical

trials using the CONSORT, STRICTA, or STRICTOM [25–27]. The latest review for assessing Tuina/massage RCTs using CONSORT was published in 2021 [17]. These studies, however, were published no later than 2021, with search dates for included literature before or until 2020. There have been no updated reviews on RCTs involving these four types of NPTCM interventions after 2021. Therefore, this study has opted to examine RCTs involving acupuncture, moxibustion, cupping, and Tuina/massage interventions published in the most recent year, 2022, as representative examples. This decision was made considering the current status of NPTCM studies, despite the guidelines of STRICTOC and STRICTOTM were newly released.

The objective of this study is to perform a comprehensive analysis of both Chinese and English articles to identify and compare the reporting characteristics and quality of four types of interventional trials. Factors such as journal quality (whether published in Chinese or English journals) and the issuing years of various guidelines are taken into consideration to provide recommendations for the future endorsement and promotion of CONSORT extensions for NPTCM. Additionally, drawing insights from the application effects of earlier guidelines like STRICTA and STRICTOM, this study seeks to inspire effective strategies for familiarizing and disseminating the latest guidelines of STRICTOC and STRICTOTM in the upcoming period.

Overview of the study design

The study was undertaken by Chinese EQUATOR Centre at Hong Kong Baptist University. This review was designed following a standard methodology framework [28,29]. The study has been registered in Open Science Framework, and the protocol has been pre-designed. This review was initiated in February 2023 and completed in November 2023. This study aimed to include RCTs that investigated acupuncture, moxibustion, cupping, and Tuina/massage interventions. Eligible publications in either English or Chinese within January 1, 2022 to December 31, 2022 were considered for inclusion.

Seven databases, including All EBM Reviews, AMED (Allied and Complementary Medicine), Embase, Ovid MEDLINE(R), CNKI (Chinese National Knowledge Infrastructure), VIP Chinese Medical Journal Database, and Wanfang Database, were searched on February 14 (for acupuncture interventional studies), February 22, 2023 (for Tuina/massage interventional studies), and March 13, 2023 (for moxibustion and cupping interventional studies), respectively. We provided the detailed search strategy of each database in supplementary file 1. All identified studies underwent screening using EndNote 20 (Clarivate Analytics, PA, USA), adhering to the

pre-defined inclusion and exclusion criteria outlined in Table 1. Specifically, four reviewers (Yao Wang, Yaxin Lin, Han Li, and Yumeng Liu) independently assessed the publications during two phases. The first phase involved reviewing the titles and abstracts, while the second phase involved reviewing the full text of the selected studies. The inclusion and exclusion criteria were applied during both phases. Throughout the entire process, two reviewers conducted a double check to ensure accuracy. Any disagreements between the reviewers were resolved through discussion or consultation with the third reviewer (Nana Wang).

For data extraction, a pre-designed form was developed. Two independent reviewers (Dongni Shi and Nana Wang) were responsible for extracting data from each article. To ensure accuracy and consistency, training sessions on the data extraction rules were conducted by a senior reviewer (Xuan Zhang). To evaluate the effectiveness of the extraction process, a pilot test was conducted on a randomly selected set of ten articles. Any ambiguities encountered during the pilot test were thoroughly discussed and resolved. Following the data extraction rules outlined in supplementary file 2, relevant data were extracted from the articles, including: (1) information of included articles, journals, and corresponding authors (e.g., publication language, type of journal, etc.); (2) participants (e.g., type of diseases/patterns, sample size, etc.); (3) study design (e.g., number of assigned groups, trial setting/center, randomization, blinding, etc.); (4) types of interventions; (5) types of comparisons; (6) outcome (e.g., CM-related outcomes, adverse effects, etc.); and (7) funding, registration and protocol information. Additionally, a double-check procedure was implemented to verify the accuracy of the extracted data. In cases where

inconsistencies arose, the two reviewers engaged in discussions to reach a consensus and resolve any discrepancies.

For quality assessment, the reporting completeness of each included study were evaluated in accordance with its respective CONSORT extension, including STRICTA checklist for acupuncture, STRICTOM checklist for moxibustion, STRICTOC checklist for cupping, and STRICTOTM checklist for Tuina/massage (Boxes 1–4). A specially designed assessment form was pre-developed based on the original reporting checklist of each guideline. Each reporting item was reformulated into one or more questions to facilitate the evaluation. For example, the reporting checklist item 1c of STRICTA statement (*Acupuncture rationale: Extent to which treatment was varied*) is subdivided into Q4 (*Whether the acupuncture treatment was individualized was reported?*), Q5 (*If the individualized acupuncture was “Fully reported” in Q4, whether the possible variations for individualized were described?*), and Q6 (*If the individualized acupuncture treatment was “Fully reported” in Q4, whether the reason/rationale was reported?*). Each question was scored with three possibilities: “1” for “fully reported,” “0” for “partially reported” or “not reported,” and “NA” for “not applicable.” Details of the standard operating procedures (SOP), including the original items and specific questions, scoring rules and examples are presented in supplementary file 3. All reviewers were trained by a senior reviewer (Xuan Zhang) and participated in pilot evaluations of ten randomly selected articles from each type of NPTCM to ensure consistency in scoring. Each question was scored by two independent reviewers (e.g., acupuncture articles, Han Li and Yumeng Liu; moxibustion articles, Nana Wang and Dongni Shi;

Table 1 Full inclusion and exclusion criteria

| | Inclusion criteria | Exclusion criteria |
|------------|---|--|
| Population | Studies will be included if they are: <ul style="list-style-type: none"> • Human studies without any limitation on age, geography, gender, and type of disease | Focus exclusively on: <ul style="list-style-type: none"> • Non-human studies |
| Concept | Studies will be included if they are: <ul style="list-style-type: none"> • RCTs of any one of four NPTCM (e.g., acupuncture, moxibustion, cupping, or Tuina/massage) | Focus exclusively on: <ul style="list-style-type: none"> • Study interventions other than the four NPTCM (e.g., acupuncture, moxibustion, cupping, or Tuina/massage). <i>OR</i> • Combined more than two studied interventions, or combined any other types of NPTCM interventions. <i>OR</i> • Non-randomized or quasi-randomized controlled trials. <i>OR</i> • Non-controlled trials. <i>OR</i> • Observational studies. <i>OR</i> • Case reports. <i>OR</i> • Study protocols. <i>OR</i> • Reviews |
| Context | Studies were included if they are: <ul style="list-style-type: none"> • Published in English or Chinese. <i>AND</i> • Published from 01/01/2022 to 31/12/2022 | Focus exclusively on: <ul style="list-style-type: none"> • Studies without abstracts or full text are not available. <i>OR</i> • Repeat publications |

BOX 1 Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA)

The Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) was initially published in 2001, followed by a revised version in 2010 as an extension of the CONSORT statement. This comprehensive framework aimed to enhance the reporting standards of acupuncture trials, comprising six main items with 17 sub-items. These items include guidelines for reporting the rationale behind acupuncture interventions, specific details regarding needling techniques, treatment regimens, other adjunctive components of treatment, practitioner qualifications, and descriptions of control or comparator interventions. Moreover, the necessity of individualized treatment based on the characteristics of acupuncture was also considered.

BOX 2 Standards for Reporting Interventions in Clinical Trials Of Moxibustion (STRICTOM)

The Standards for Reporting Interventions in Clinical Trials Of Moxibustion (STRICTOM) was introduced in 2013 with the aim of enhancing the reporting quality of moxibustion trials, thereby facilitating their interpretation and reproducibility. The STRICTOM checklist comprises seven main items and 16 sub-items, which cover various aspects such as the rationale behind moxibustion, specific details of moxibustion techniques, treatment regimens, additional components of treatment, qualifications of treatment providers, descriptions of control and comparator interventions, and precautionary measures. Similar to STRICTA, STRICTOM also emphasizes the importance of reporting individualized treatment approaches.

BOX 3 Standards for Reporting Interventions in Clinical Trials Of Cupping (STRICTOC)

The Standards for Reporting Interventions in Clinical Trials Of Cupping (STRICTOC) was published in 2020 to enhance the reporting standards of various clinical studies involving cupping interventions, including but not limited to RCTs, uncontrolled outcome studies, and case reports. The STRICTOC checklist comprises six main items and 16 sub-items, which cover essential aspects such as the rationale behind cupping, specific details of cupping techniques, treatment regimens, additional components of treatment, qualifications of treatment providers, and descriptions of control or comparator interventions. Notably, the inclusion of a description of sham cupping in the rationale for the control group setting contributes to a more rational trial design, facilitating the demonstration of differences between cupping therapy and control measures.

BOX 4 Standards for Reporting Interventions in Clinical Trials Of Tuina/Massage (STRICTOTM)

The Standards for Reporting Interventions in Clinical Trials Of Tuina/Massage (STRICTOTM) was published in early 2023 to enhance the reporting quality and transparency of Tuina/Massage clinical research. The STRICTOTM checklist comprises seven main items and 16 sub-items, covering essential aspects such as the rationale behind Tuina/massage, specific details of Tuina/massage techniques, intervention regimens, additional components of the intervention, qualifications of Tuina/massage providers, descriptions of control or comparator interventions, and precautionary measures. Furthermore, the STRICTOTM guidelines emphasize the importance of clearly defining the design principles and operational procedures of sham massage measures.

Tuina/massage articles, Hanzhi Tan and Yumeng Liu; cupping articles, Shufeng Luo and Hanzhi Tan). Cohen's kappa was used to identify the level of agreement, including poor agreement (0–40%), moderate agreement (41%–60%), substantial agreement (61%–80%), and almost complete agreement (81%–100%) [30]. Any inconsistencies were resolved by the panel of senior reviewers (Xuan Zhang, Juan Wang, and Chung Wah Cheng).

For data analysis, descriptive statistics were performed to analyze the characteristics and reporting compliance of the included articles. Categorical variables were summarized using frequencies and percentages, while continuous variables were presented as mean and standard deviation (SD). To assess the reporting quality, each item or question was evaluated based on the number of reports that received a score of “1” out of the total number of included reports (excluding items that were

marked as “not applicable”). Reference to previous relevant studies [31,32], the compliance level was then categorized into three groups: excellent compliance (> 90%), good compliance (between 65% and 90%), and poor compliance (< 65%). Furthermore, subgroup analyses were conducted to compare the reporting quality in the following groups: (1) publications in English versus in Chinese, and (2) RCTs with CM patterns versus without CM patterns. Considering that the quality of publications can be impacted by the caliber of journals, both English international journals and Chinese journals were deemed as influence factors [33]. Therefore, we devised the first subgroup for comparison. Besides, pattern differentiation is a crucial aspect of CM diagnosis and treatment, including both herbal interventions and non-pharmacological therapies. Previous studies have highlighted the significance of channel pattern differentiation, such as *Jing Luo Bian Zheng*, in

acupuncture-moxibustion pattern identification. This is particularly pertinent in addressing various types of *jing-jin* (channel sinews within the *jing-luo* system) diseases and *zang-fu* diseases [34,35]. In addition, some scholars have underscored the importance of designing and reporting CM patterns in NPTCM clinical trials [36,37]. Hence, in this review, we designed the second subgroup comparisons between RCTs with and without CM patterns to offer additional evidence in this domain. The *t*-tests and/or Mann–Whitney U tests were used for conducting these comparisons. Statistical data were recorded in Microsoft Office Excel 365, while the subsequent data analysis was carried out utilizing SPSS software, version 26.0.

Characteristics of the included studies

The initial search yielded a total of 5703 records, from which 487 relevant studies were retained after excluding duplicates and screening the titles and abstracts. Following a thorough review of full-text articles, we identified 387 eligible RCTs, including 213 acupuncture studies, 85 Tuina/massage studies, 73 moxibustion studies, and 16 cupping studies (Fig. 1). Details of the literature screening process for each type of interventional studies are provided in supplementary file 4. Included RCTs for analysis in this review are listed in supplementary file 5.

This study analyzed a total of 387 trials published in 2022, with the majority (91.7%) appearing in Chinese journals. The geographical distributions of the included trials were involving 14 countries, with 94.8% hailing from China (Table 2). The most frequently studied condition was musculoskeletal system or connective tissue disorders (22.5%). Additionally, 19.1% of the included trials adopted CM patterns, with 2.8% falling under the category of qi stagnation and blood stasis. 68.2% of the trials included 51–100 participants, and 92% of the studies included two parallel groups. The primary purpose of the trials was to assess efficacy, accounting for 74.2% of the total. Only a small proportion (6.5%) of the studies included a multicenter design, and simple randomization (95.1%) was the most commonly used method for randomization. Blinding methods were employed in only 12.9% of all the trials. Regarding the type of CM intervention, 49.9% utilized a single intervention, while the remaining 50.1% involved complex interventions. Placebo controls were utilized in 5.9% of the trials. Approximately 30.4% of the studies included CM-related indicators in their outcome measurements. Safety assessment was included in 14.8% of the articles. Of these trials, 37.3% reported that the occurrence of adverse events (AEs) (e.g., 39.9% were skin damages) was related to the intervention, with all being acupuncture. Only a small percentage (9.3%) of the

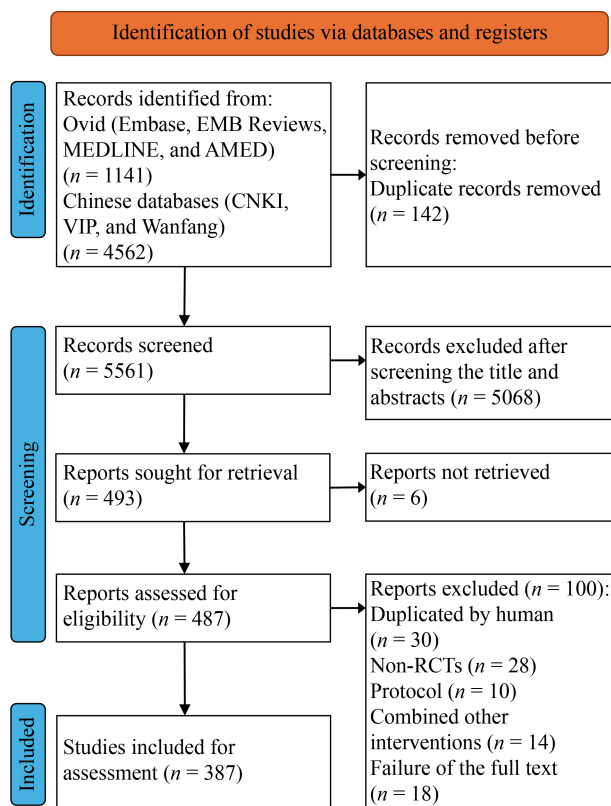


Fig. 1 Overall flow chart of the search and selection process.

Table 2 Geographical distribution of the included studies (n = 387)

| Geographical distribution | n (%) |
|---------------------------|------------|
| China | 368 (95.1) |
| South Korea | 4 (1.0) |
| USA | 3 (0.8) |
| Iran | 2 (0.5) |
| Spain | 2 (0.5) |
| Austria | 1 (0.3) |
| Egypt | 1 (0.3) |
| Germany | 1 (0.3) |
| Indonesia | 1 (0.3) |
| Lebanon | 1 (0.3) |
| Malaysia | 1 (0.3) |
| Pakistan | 1 (0.3) |
| Poland | 1 (0.3) |
| Turkey | 1 (0.3) |

included RCTs were registered, and an even lower percentage (6.5%) included a protocol. More details are provided in Tables 3 and 4 and supplementary file 6.

Reporting quality of the included studies

For all 387 included trials, the average reporting rate was

Table 3 Information of the included studies (*n* = 387)

| Information | Acupuncture <i>n</i> (%) | Moxibustion <i>n</i> (%) | Tuina/massage <i>n</i> (%) | Cupping <i>n</i> (%) | Total <i>n</i> (%) |
|--|-----------------------------|-----------------------------|-------------------------------|-------------------------|-----------------------|
| Part 1 Information of included articles and journals | | | | | |
| Language of publications | | | | | |
| English | 22 (5.7) | 2 (0.5) | 8 (2.1) | 0 | 32 (8.3) |
| Chinese | 191 (49.4) | 71 (18.3) | 77 (19.9) | 16 (4.1) | 355 (91.7) |
| Type of journals ^a | | | | | |
| English journal (SCIE), with impact factor > 3 | 8 (2.1) | 0 | 3 (0.8) | 0 | 11 (2.8) |
| Chinese core journal | 25 (6.5) | 3 (0.8) | 1 (0.3) | 1 (0.3) | 30 (7.8) |
| Part 2 Participants | | | | | |
| Type of disease/pattern(s) (top 3) ^b | | | | | |
| Diseases of the musculoskeletal system or connective tissue | 51 (13.2) | 14 (3.6) | 18 (4.7) | 4 (1.0) | 87 (22.5) |
| Diseases of the nervous system | 59 (15.2) | 7 (1.8) | 6 (1.6) | 3 (0.8) | 75 (19.4) |
| Symptoms, signs or clinical findings, not elsewhere classified | 35 (9) | 7 (1.8) | 17 (4.4) | 2 (0.5) | 61 (15.8) |
| Including CM pattern(s) | 34 (8.8) | 25 (6.5) | 9 (2.3) | 6 (1.6) | 74 (19.1) |
| Type of CM pattern(s) (top 3) ^c | | | | | |
| Pattern(s) of qi stagnation and blood stasis | 6 (1.6) | 1 (0.3) | 2 (0.5) | 2 (0.5) | 11 (2.8) |
| Pattern(s) of liver and kidney depletion | 4 (1.0) | 0 | 1 (0.3) | 0 | 5 (1.3) |
| Pattern(s) of qi deficiency with blood stasis | 3 (0.8) | 0 | 1 (0.3) | 0 | 4 (1.0) |
| Age design of participants | | | | | |
| < 18 years old | 4 (1.0) | 6 (1.6) | 18 (4.7) | 3 (0.8) | 31 (8.0) |
| ≥ 18 years old | 209 (54.0) | 67 (17.3) | 66 (17.1) | 12 (3.1) | 354 (91.5) |
| Any age | 0 | 0 | 1 (0.3) | 1 (0.3) | 2 (0.5) |
| Total sample size | | | | | |
| ≤ 50 | 19 (4.9) | 9 (2.3) | 9 (2.3) | 1 (0.3) | 38 (9.8) |
| 51–100 | 147 (38) | 53 (13.7) | 52 (13.4) | 12 (3.1) | 264 (68.2) |
| 101–200 | 38 (9.8) | 10 (2.6) | 19 (4.9) | 3 (0.8) | 70 (18.1) |
| > 200 | 9 (2.3) | 1 (0.3) | 5 (1.3) | 0 | 15 (3.9) |
| Part 3 Study design | | | | | |
| Study purpose | | | | | |
| Efficacy | 147 (38.0) | 55 (14.2) | 71 (18.3) | 14 (3.6) | 287 (74.2) |
| Both (efficacy and safety) | 66 (17.1) | 18 (4.7) | 14 (3.6) | 2 (0.5) | 100 (25.9) |
| Number of assigned groups | | | | | |
| 2 | 193 (49.9) | 70 (18.1) | 78 (20.2) | 15 (3.9) | 356 (92.0) |
| 3 | 18 (4.7) | 3 (0.8) | 5 (1.3) | 1 (0.3) | 27 (7.0) |
| 4 | 2 (0.5) | 0 | 2 (0.5) | 0 | 4 (1.0) |
| Trial participating center | | | | | |
| Single center | 198 (51.2) | 68 (17.6) | 82 (21.2) | 14 (3.6) | 362 (93.5) |
| Multicenter | 15 (3.9) | 5 (1.3) | 3 (0.8) | 2 (0.5) | 25 (6.5) |
| Type of randomization ^d | | | | | |
| Simple randomization | 201 (51.9) | 72 (18.6) | 79 (20.4) | 16 (4.1) | 368 (95.1) |
| Others | 12 (3.1) | 1 (0.3) | 6 (1.6) | 0 | 19 (5.0) |
| Type of blinding | | | | | |
| Open label | 3 (0.8) | 0 | 0 | 0 | 3 (0.8) |
| Blinding | 38 (9.8) | 7 (1.8) | 4 (1.0) | 1 (0.3) | 50 (12.9) |

| | <i>(Continued)</i> | | | | |
|---|-----------------------------|-----------------------------|-------------------------------|-------------------------|-----------------------|
| Information | Acupuncture <i>n</i> (%) | Moxibustion <i>n</i> (%) | Tuina/massage <i>n</i> (%) | Cupping <i>n</i> (%) | Total <i>n</i> (%) |
| Not reported | 172 (44.4) | 66 (17.1) | 81 (20.9) | 15 (3.9) | 334 (86.3) |
| Part 4 Interventions | | | | | |
| Types and duration | | | | | |
| Single intervention | 120 (31) | 34 (8.8) | 32 (8.3) | 7 (1.8) | 193 (49.9) |
| Complex interventions | 93 (24) | 39 (10.1) | 53 (13.7) | 9 (2.3) | 194 (50.1) |
| Treatment duration (week, mean) | 4.9 | 4.1 | 5.2 | 3.1 | 4.8 |
| Part 5 Comparisons | | | | | |
| Type of controls ^e | | | | | |
| Including placebo control | 20 (5.2) | 1 (0.3) | 2 (0.5) | 0 | 23 (5.9) |
| Part 6 Outcomes | | | | | |
| Including CM pattern-related outcome(s) | 16 (4.1) | 6 (1.6) | 6 (1.6) | 4 (1.0) | 32 (8.3) |
| Part 7 Funding, registration, and protocol | | | | | |
| Including funding supports | 147 (38.0) | 42 (10.9) | 40 (10.3) | 8 (2.1) | 237 (61.2) |
| Including registration | 22 (5.7) | 5 (1.3) | 8 (2.1) | 1 (0.3) | 36 (9.3) |
| Including protocol | 17 (4.4) | 2 (0.5) | 6 (1.6) | 0 | 25 (6.5) |

^aThe journal types and impact factors of English journals were based on the latest data on the official website of Journal Citation Reports. Chinese core journals were according to the latest data of CNKI official website. Detailed rules are presented in supplementary file 6.1. ^bAccording to the International Classification of Diseases 11th Revision (ICD-11) in 2023. More details are presented in the supplementary file 6.3. ^cThis item is based on the 74 studies which reported type of CM pattern(s). The total number of patterns 94 exceeded 74 because more than one type of pattern was reported in several studies. The percentage was based on the number of included studies 387. More details are presented in the supplementary file 6.4. ^dOther types of randomization included stratified randomization, central randomization, and minimization randomization. ^eThe total number of control types 394 exceeded the number of included studies 387 because several studies have more than two control groups. The percentage was based on the number of included studies 387. More details are presented in the supplementary file 6.5.

Table 4 Adverse events identified in the included studies (*n* = 387)

| Classification | Acupuncture <i>n</i> (%) | Moxibustion <i>n</i> (%) | Tuina/massage <i>n</i> (%) | Cupping <i>n</i> (%) | Total <i>n</i> (%) |
|---|-----------------------------|-----------------------------|-------------------------------|-------------------------|-----------------------|
| Including adverse events (AEs) assessment in the study ^a | 42 (11.1) | 6 (1.6) | 7 (1.9) | 1 (0.3) | 56 (14.8) |
| Including AEs reports in the experimental group ^b | 39 (70.0) | 6 (10.7) | 5 (8.9) | 1 (1.8) | 51 (91.2) |
| AEs related to the intervention ^c | 19 (37.3) | 0 | 0 | 0 | 19 (37.3) |
| Specific syndromes ^d | | | | | |
| Skin damage (e.g., rash, itching, etc.) | 26 (17.2) | 2 (1.3) | 1 (0.7) | 1 (0.7) | 30 (19.9) |
| Digestive system damage (e.g., nausea, vomiting, diarrhea, constipation, abnormal liver function, etc.) | 7 (4.6) | 5 (3.3) | 2 (1.3) | 0 | 14 (9.3) |
| Urinary system damage (e.g., hematuria, renal dysfunction, etc.) | 0 | 1 (0.7) | 0 | 0 | 1 (0.7) |
| Systemic damage (e.g., anaphylactic shock, fever, etc.) | 15 (9.9) | 3 (19.9) | 3 (2.0) | 0 | 21 (13.9) |
| No AE was identified in the experimental group | 3 (2.0) | 0 | 2 (1.3) | 0 | 5 (3.3) |

^aThe percentage was based on the number (387) of included studies. ^bThe percentage was based on the number (56) of studies including AEs reports in the experimental and control groups. ^cThe percentage was based on the number (51) of studies including AEs reports in the experimental group. ^dThe number of AEs in the experimental and control groups was 151 from the 56 studies that reported the AEs. It exceeded 56 because more than one type of AE was reported in several studies. The percentage was based on the number (151) of AEs in the experimental group. More details of AEs in the control group are presented in the supplementary file 6.6.

56.0%. Specifically, acupuncture demonstrated the highest reporting rate at 62.6%, followed by cupping at 60.2%, moxibustion at 53.1%, and Tuina/massage at 47.9%. The inter-rater agreement for each item exceeded 85% among the two reviewers (supplementary file 7). Concerning the compliance level, RCTs of cupping were categorized as demonstrating excellent compliance, while

RCTs of Tuina/massage displayed poor compliance (Fig. 2). Focusing on specific items, the reporting of treatment regimens exhibited a relatively higher rate of 79.9%, particularly in the RCTs of moxibustion. Conversely, the reporting rate for practitioner background displayed the lowest average compliance rate, standing at a mere 14.9%. Among the four interventions, the

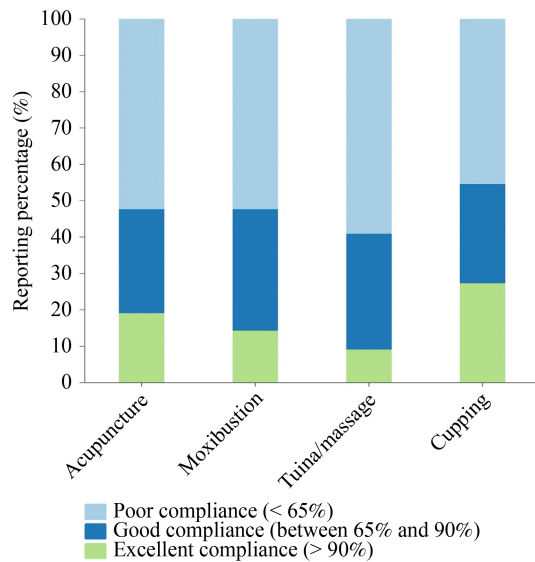


Fig. 2 Level of reporting compliance of the included studies.

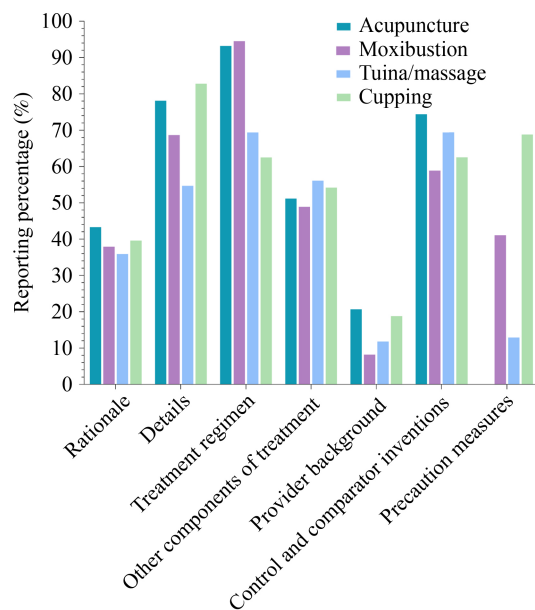


Fig. 3 Reporting percentage of different sections of the reporting checklists.

descending order of reporting rates for this item was as follows: acupuncture, cupping, Tuina/massage, and moxibustion (Fig. 3).

For acupuncture studies, excellent compliance was observed in 19.1% of cases, good compliance in 28.6%, and poor compliance in 52.4%. Notably, the reporting rates for three items were below 30%, including the reason/rationale for individualized acupuncture, treatment environment, and the characteristics of acupuncture providers. Details are shown in Fig. 4 and supplementary file 8. For moxibustion studies, excellent compliance was

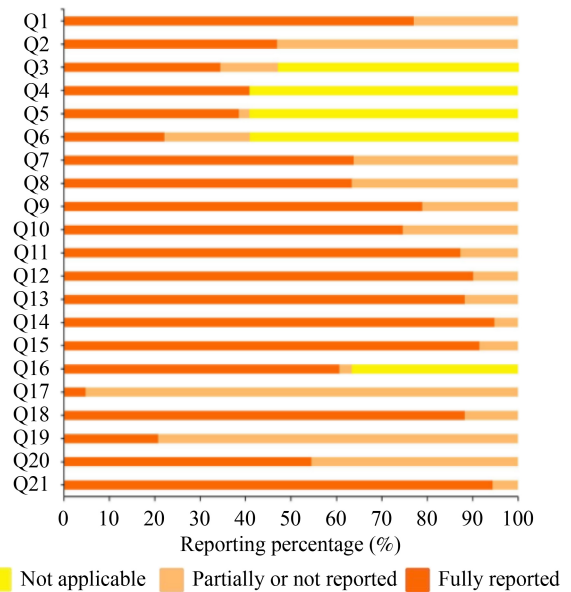


Fig. 4 Reporting quality assessment of acupuncture RCTs.

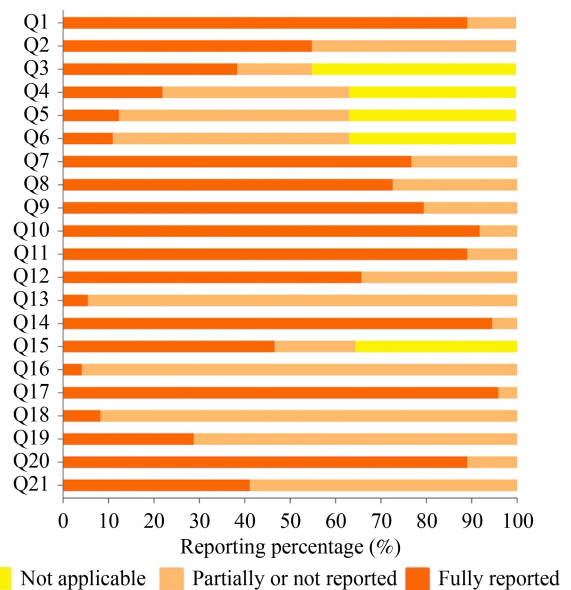


Fig. 5 Reporting quality assessment of moxibustion RCTs.

observed in 14.3% of cases, good compliance in 33.3%, and poor compliance in 52.4%. The reporting rate of seven items was below 30%, including the report of individualized moxibustion and its rationale, patient posture, place of treatment, the characteristics of moxibustion treatment provider(s), and the rationale for the choice of control. Details are shown in Fig. 5 and supplementary file 9. For Tuina/massage studies, excellent compliance was observed in 9.1% of cases, good compliance in 31.8%, and poor compliance in 59.1%. Seven items were below 30%, indicating inadequate reporting. These issues encompassed

precautionary or managerial measures for adverse events, the characteristics of Tuina/massage treatment providers, individualized reporting and its rationale, as well as the media employed for Tuina/massage. Details are shown in Fig. 6 and supplementary file 10. For cupping studies, excellent compliance was observed in 27.3% of cases, good compliance in 27.3%, and poor compliance in 45.5%. Seven items of individualized reporting and its rationale, the cupping setting or environment, and the characteristics of cupping treatment providers were below 30%, indicating inadequate reporting. Details are shown in Fig. 7 and supplementary file 11.

In the subgroup analysis, the reporting score of publications in Chinese was significantly lower compared to those in English ($P < 0.05$). When comparing the included trials with and without CM pattern(s), there was no statistical significance between the two groups ($P > 0.05$). The results of each group are shown in Fig. 8 and supplementary file 12.

Major deficiencies identified in this study

In this review, we identified various characteristics of the included RCTs of NTPCM.

First, clinical practitioners, in China, widely employ non-pharmacologic therapies to effectively treat musculoskeletal or connective tissue disorders, resulting in a considerable volume of related clinical research and publications in this domain [38,39]. The four NPTCMs discussed in this paper play a pivotal role in disease treatment by facilitating hemodynamic circulation, alleviating blood stasis, promoting meridian flow, and enhancing positive qi retention [40].

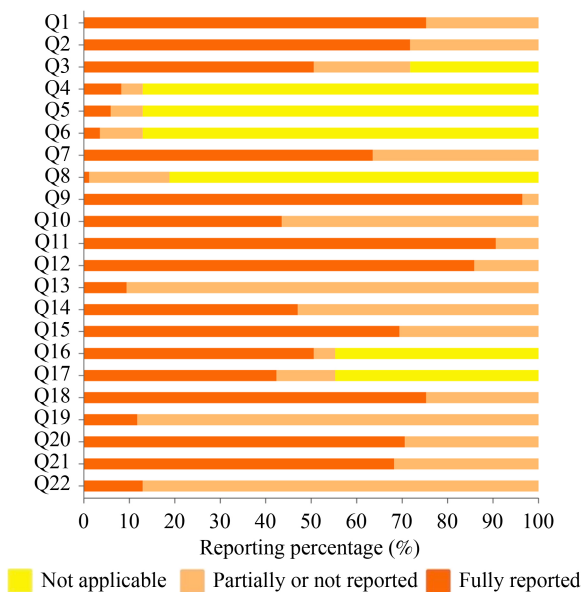


Fig. 6 Reporting quality assessment of Tuina/massage RCTs.

Secondly, NPTCMs present unique advantages in clinical practice, demonstrating a lower incidence of AEs and a high level of safety [41–44]. Among the included studies, no serious adverse events (SAEs) were identified in any of the trials. The primary AEs were limited to minor skin damage, such as subcutaneous bleeding. These findings align with the previous study investigating AEs associated with NPTCM [45]. Notably, in addition to being influenced by study design and intervention features, the prevention of AEs can also be regulated by the proficiency and expertise of the operators [46]. Consequently, NPTCMs were found to be remarkably secure, with unfavorable occurrences being manageable.

Thirdly, the research design of RCTs with NPTCM

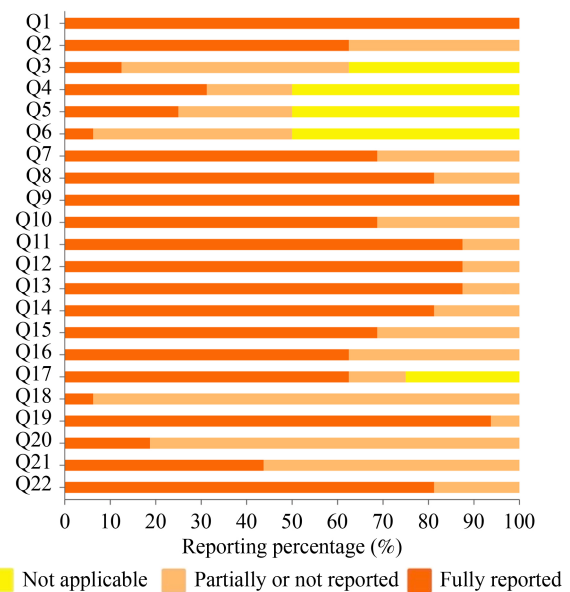


Fig. 7 Reporting quality assessment of cupping RCTs.

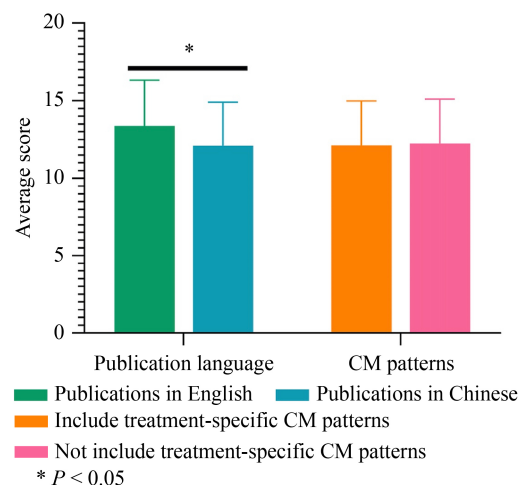


Fig. 8 Subgroup analysis.

interventions, however, should take into account the distinctive features of CM. This entails the consideration of CM pattern types in diagnostic criteria and the selection of CM-related outcome indicators. Unfortunately, this review found that 80.9% of the included trials did not include CM patterns, and 69.6% did not adopt CM-related indicators in the outcomes. In previous studies, some scholars advocate for the precise identification of CM pattern types and the use of corresponding acupoints, suggesting that this approach can yield favorable therapeutic effects [47]. Other research has indicated a strong correlation between the differentiation of syndromes and the effectiveness of NPTCMs [48]. Additionally, the foundation of CM pattern diagnosis is a crucial element in individualized NPTCM treatment [49]. Thus, based on clinical practice and previous evidence-based studies [50,51], it is recommended to incorporate TCM characteristics into the design of NPTCM RCTs.

Fourthly, this study discovered the inadequacy in implementing blinding, which was found to be influenced by the specific characteristics of NTPCM. The unregulated use of blinding was particularly challenging, as achieving double blinding was hindered by the visibility of NTPCM treatment to both physicians and patients [26]. It is noteworthy that, among the four interventions, only acupuncture trials had a sham-controlled reporting guideline developed [52]. The limitations and challenges associated with NPTCMs in conducting double-blind placebo-controlled clinical trials significantly compromised the quality of clinical research. As a result, RCTs of NPTCM face considerable obstacles in gaining recognition and publication in high-impact international journals. Besides, it is crucial that all clinical trials be registered, and study protocols be made publicly available to enhance transparency and minimize duplication of effort among study teams [53,54]. However, it is imperative to acknowledge that there is room for improvement in both areas.

Suboptimal reporting of the included studies

Among four interventional studies, acupuncture trials demonstrated the highest reporting compliance according to the STRICTA checklist, consistent with previous research findings [26]. Following acupuncture, cupping, moxibustion, and Tuina/massage exhibited descending levels of reporting compliance based on STRICTOC, STRICTOM, and STRICTOTM. It is important to note that the recent release of STRICTOTM for Tuina/massage studies may have impacted the findings, as more time is required for its widespread adoption and understanding. While the higher compliance rate for

acupuncture trials observed in this review could be linked to the earlier issuance of STRICTA, the quality of reporting for more specific and detailed items did not fully correlate with the publication years of the various guidelines. For example, generally, the reporting of treatment regimen and operation details of four NPTCM interventions was relatively comprehensive. Regarding the treatment regimen, it was essential to provide information on the number, frequency, and duration of sessions. Detailed descriptions should include the names and numbers of acupoints/meridians/locations used for NPTCM, materials employed for moxibustion, participants' posture, media used for Tuina/massage, devices employed for cupping, depth of insertion, sought responses, and other relevant factors. Similar to the findings in previous research, adequate reporting on these items is crucial not only for reflecting the rigor and scientific nature of the trial design but also for enhancing the credibility of research conclusions and ensuring the objectivity of clinical efficacy evaluations [55,56].

However, the absence of reporting rates concerning practitioners' backgrounds among the four studied interventions was notably conspicuous, mirroring findings from a previous study evaluating reporting completeness in acupuncture studies [57]. Existing requirements for medical journal reporting on physician qualifications are inadequate, as only a limited number of editors explicitly demand the disclosure of information regarding the individuals implementing the treatment. However, the professional background and practices of practitioners play a crucial role in the clinical outcomes of NPTCM. Strict adherence to the four checklists proposed in this study could provide a viable avenue to enhance the reporting of practitioner experiences, which also helps standardize the qualifications of practitioners in clinical research and practice [58].

Regarding different assessment tools, distinct characteristics were observed.

First, for acupuncture studies using STRICTA, a total of 3 items including the rationale of individualised acupuncture, the location of treatment, and the characteristics of participating acupuncturists were scored as poor reporting. The efficacy of acupuncture is not solely determined by the details of the procedure; the characteristics of the practitioner play an equally crucial role, with the quality of the practitioner directly influencing the achievement of satisfactory results [59]. Prior research has noted similar levels of underreporting regarding this specific STRICTA item [60,61], echoing findings from acupuncture RCTs in the Korean literature [62]. Furthermore, there has been no discernible improvement in the reporting of this item over time [63].

Secondly, for cupping studies using STRICTOC, the absent reporting focused on the background of providers,

treatment setting/environment, and the rationale of individualized treatment. Providing information about the intervention environment is crucial for ensuring the safety of cupping treatments, especially since certain modalities involve the use of an open flame for heating the canister [64]. However, this study underscored the inadequate documentation by investigators regarding site selection and reporting in the included trials, a concern not previously identified in prior studies. This lack of information hampers readers' ability to make informed judgments regarding treatment safety. Implementing cupping in a controlled environment with fire-resistant ventilation and the absence of flammable materials can effectively reduce the risk of adverse burn incidents in clinical practice [65].

Thirdly, for moxibustion studies using STRICTOM, seven items displayed low reporting rates, including the individualized moxibustion and its rationale, patient's posture, treatment environment, characteristics of the moxibustion treatment provider, and the rationale for the choice of control. Some of these finding aligns with previous studies [66,67]. Considering that moxibustion is believed to induce nonspecific effects, such as psychological reactions influenced by the treatment environment, patient posture during treatment, and the relationship with the treatment provider, it is essential for researchers to report information regarding patient posture and treatment environment [68]. Additionally, careful attention should be given to reporting the response to moxibustion treatment. Despite a reporting rate of 66% for this item, it has been easily overlooked. Sensations such as heating, burning, warming, feelings, or other phenomena like redness and peak temperature could serve as target responses, and reporting on these aspects is crucial [27]. Furthermore, it should be noted that the reporting of moxibustion trials was lower than cupping trials, despite the issuance year of STRICTOM being seven years earlier than that of STRICTOC.

Fourthly, for Tuina/massage studies using STRICTOTM, less than 30% primarily addressed critical aspects such as the media employed, individualized treatment rationale, patient posture, number of acupoints/meridians/locations, responses sought from participants, and precautionary or managerial measures for adverse events. The therapeutic posture assumed by the patient plays a pivotal role in massage therapy, with different postures yielding distinct therapeutic effects [69]. Therefore, the inclusion of detailed posture information should not be overlooked in the report. It is crucial to maintain comprehensive records of the number of acupoints stimulated during massage therapy. Some points may require bilateral stimulation, while others necessitate unilateral stimulation on the affected side [70]. Thus, when point names are mentioned without

specifying their quantity, it becomes challenging for readers to accurately replicate the procedure. Comprehensive documentation of patient-specific responses concurrently plays a pivotal role in effectively mitigating the occurrence of adverse events within a specified timeframe [71]. This ensures procedural safety and demarcates the termination point of treatment. Moreover, documenting the massage duration for each position in massage therapy offers a more comprehensive record in clinical practice, delineating specific time allocations for different diseases and patient conditions. These records are of significant reference value, facilitating necessary adjustments to the massage duration based on the individual patient's actual condition [72].

In this review, we also conducted a subgroup analysis based on language, revealing a higher reporting score in English publications compared to Chinese ones. Specifically, detailed reporting of the sites where NPTCMs were implemented, the characteristics of the providers, and the rationale for the control were more prevalent in English publications. In contrast, a majority of the Chinese publications lacked these specific details. However, NPTCM RCTs in Chinese exhibited notable advantages. First, they encompassed various styles of NPTCM interventions, including the fire needle, moxa burner moxibustion, Zang-fu meridians massage, medicated cupping, and numerous others, a feature also identified in previous studies [59]. Secondly, owing to the extensive history of CM inheritance in China and the wealth of medical practice experience summaries, Chinese researchers provided more detailed information regarding the operational procedures of NPTCM. This observation aligns with our previous study [17]. For instance, Chinese literature described the use of different acupoints for different syndrome types, whereas English literature used fewer acupuncture points [73]. Additionally, a recent study has illustrated that the report rate of items, including needle retention time, frequency, duration of treatment sessions, details of other interventions administered to the acupuncture group, setting, and context of treatment in Chinese RCTs, were higher than in English RCTs [74].

As the concept of "Treatment based on pattern differentiation" is a distinctive feature of CM [49], this study conducted a subgroup analysis that compared trials with and without consideration of CM patterns among the included trials. The results revealed no significant differences between these two groups in terms of reporting quality. In comparison, numerous studies have explored the correlation between NPTCM and TCM patterns in clinical practice [48,75]. Furthermore, CM approaches the understanding of diseases from a holistic perspective and tailors individualized treatments based on variations in pathogenesis [76,77]. Specifically, during

the process of evaluating some of these studies, three items related to individualization scored high in two specific situations: one when intervention(s) were administered based on the location of uncomfortableness (e.g., pain), and the other when the treatment plan was adjusted in response to changes in CM pattern types. For example, modifying acupuncture point prescriptions or adjusting massage techniques is based on changes in pattern types. However, the average reporting rate for these individualization-related items in the studies was less than 30%. In trials with poor reporting quality, there was a lack of information regarding the diagnosis and treatment of CM patterns. Some scholars have believed that incorporating CM patterns into the study design of NPTCM RCTs not only supports the achievement of individualized treatments but also enhances the overall reporting quality of RCTs [78,79]. However, the subgroup analysis in this review did not identify a significant difference, which may be related to the limited number of studies (e.g., 19.1% of the included trials) that adopted the CM pattern in their design. Therefore, although previous studies have suggested that incorporating CM pattern diagnosis and outcome measures may reflect a higher methodological quality for CM interventional studies, the impact on reporting quality remains to be further investigated in future research. This may require more baseline data and evidence comparisons.

Limitations of this study

First, this review identified the NPTCM RCTs published in 2022 from the targeted 7 databases. Any records not included in these databases by the specified cutoff period were excluded. Additionally, only articles written in English and Chinese were considered, introducing a potential limitation as trials published in other languages might have been overlooked. Second, the issued time of different assessment tools may have distinct effects on studies published in 2022. Notably, the checklist for acupuncture interventions was released earliest, contributing to the highest reporting compliance within the included RCTs. While acknowledging these potential limitations, it is asserted that the findings presented in this study reflect significant and reliable trends.

Recommendations

Based on the above deficiencies identified in this review, we recommend the following actions to promote the reporting quality of NPTCM interventional studies:

1) The reporting of safety assessments should be enhanced, incorporating the checklist provided in the CONSORT Harms guideline [80] and the specific details

outlined in STRICTA, STRICTOM, STRICTOC, and STRICTOTM. This is particularly important for addressing the following items: (1) clearly stating precautionary measures for potential adverse events as outlined in the study protocol; (2) describing the method(s) used to assess safety during NPTCM interventions; (3) outlining actions taken to manage adverse effects, such as specified stopping criteria; (4) detailing the method(s) used to determine the relationship between observed harm/adverse effects and the studied intervention.

2) Standardized reporting of CM pattern-related diagnostic criteria and outcome evaluation is essential. Several studies aimed at standardizing syndrome criteria, establishing core outcome sets within the CM field, and developing a reporting checklist for CM pattern differentiation have been completed or are currently underway [81–83]. These efforts are expected to significantly impact the design and reporting of CM clinical trials that include CM pattern-related elements. Therefore, we advocate for the incorporation of CM pattern considerations in the design of NPTCM clinical trials, where applicable.

3) For items with obvious poorly reporting, such as details about the treatment environment and provider background information in NPTCM trials, more research should be dedicated. This research should focus on identifying the underlying reasons for such omissions, as well as the difficulties and challenges faced in clinical practice, through surveys, interviews, and other user-based methods. Feasible solutions should then be explored based on expert consultations.

4) The core value of reporting guidelines lies in its application. Journals should strengthen the endorsement to reporting guidelines of CM, especially for Chinese journals. Recently, our research team has devised a checklist of “Consensus-based Seven Approaches to Promote the Application of CM Reporting Guidelines” [84]. For instance, the “Pilot Journals Endorsement Program” garnered considerable approval from the editors we surveyed. Further details on this checklist will be published in the near future, offering valuable insights for promoting and implementing reporting guidelines of CM, including the four checklists featured in this study.

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Compliance with ethics guidelines

Conflicts of interest Xuan Zhang, Han Li, Hanzhi Tan, Nana Wang, Chung Wah Cheng, Juan Wang, Dongni Shi, Lin Zhang, Yumeng Liu, Yao Wang, Shufeng Luo, Yaxin Lin, Lihan Hu, Xuanqi Zhang, Ji Li, Fei Han, Ping Wang, Aiping Lyu, and Zhaoxiang Bian declare that they have no conflict of interest.

This article does not contain any studies with human or animal subjects.

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