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Review Article

Non-standard reporting of sex and ethnicity terms in acupuncture randomized controlled trials

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ABSTRACT

Background: Methodological rigor in acupuncture randomized controlled trials (RCTs) requires adequate consideration of demographic factors that influence treatment outcomes. However, researchers frequently neglect sex/gender and race/ethnicity, despite increasing evidence of their impact on treatment responses. This study systematically examines how acupuncture RCTs consider and report sex/gender and race/ethnicity.
Methods: We systematically searched seven databases (MEDLINE, EMBASE, CENTRAL, CBM, CNKI, Wanfang, and VIP). Two authors independently performed study screening and eligibility assessment, and any disagreements were resolved by a senior reviewer. We included RCTs of acupuncture published between 1 January 2014 and 31 May 2025. Two authors independently extracted data and evaluated the reporting and analysis of sex/gender and race/ethnicity using 27 predefined items.
Results: In total, 567 studies were included. Reporting of sex information increased over time but remained incomplete. Among English-language studies that used sex- or gender-related terminology ($n = 180$), only 42.8 % (77/180) correctly distinguished between the terms "sex" and "gender". Although 73.8 % of studies (418/567) reported participants' sex distribution, very few examined its association with treatment efficacy, and only 5.3 % (30/567) reported any information on race or ethnicity. Furthermore, only two studies examined the intersectional effects of sex and race, and none considered nonbinary gender categories.
Conclusions: Acupuncture RCTs show substantial deficiencies in reporting and analyzing sex/gender and race/ethnicity. Inconsistent terminology and limited analytical integration reduce evidence generalizability and clinical applicability. Researchers should adopt standardized reporting frameworks and systematically incorporate these variables as key analytical factors to improve rigor and equity.
Protocol registration: Open Science Framework (Registration ID: 10.17605/OSF.IO/6SXE5).

1. Introduction

Acupuncture, a traditional medicine cornerstone, is increasingly used globally for many conditions,[1] including pain management, neurological disorders, and mental health.[2,3] As its application expands, the demand for rigorous, high-quality evidence to validate its efficacy has grown commensurately.[4] Randomized controlled trials (RCTs) are recognized as the gold standard for evaluating therapeutic interventions,[5] and consequently, the number of acupuncture RCTs has surged in recent decades.[6]

High-quality clinical research should consider demographic factors that can impact treatment outcomes.[7] While age is routinely reported, other demographic variables are often inconsistently defined and insufficiently reported.[8] Sex, based on biological attributes, and gender, shaped by sociocultural roles and identities, are particularly important.[9,10] Evidence shows significant differences between males and

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females in pain perception, nerve conduction, and hormonal regulation,[11–13] which may influence acupuncture responses.[14,15] Accordingly, major scientific journals and regulatory agencies such as the U.S. Food and Drug Administration (FDA) require reporting and analysis of sex and gender in clinical research to improve population applicability. However, reporting quality in acupuncture RCTs remains inadequate. Our group previously found poor adherence to Consolidated Standards of Reporting Trials (CONSORT) and Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines, frequent spin, and underreporting of patient-reported outcomes and adverse events, indicating persistent deficiencies in methodological transparency and safety reporting.[16,17]

Race and ethnicity, which encompass shared genetic, cultural, and social characteristics, may influence health behaviors, treatment access, and potentially treatment response.[18,19] Preliminary studies suggest that acupuncture compliance and efficacy may differ across racial and ethnic groups.[20,21] Sociocultural factors such as treatment expectations and health beliefs, may also influence acupuncture responses.[22] Despite their importance, reviews in other medical fields have consistently identified poor reporting and under-representation of diverse populations.[23,24] In East Asian regions with relatively homogeneous populations, race and ethnicity are often omitted from clinical trial reports, potentially limiting the generalizability of findings.[25,26] This raises the question of whether similar deficiencies exist in acupuncture research.

Despite growing recognition of demographic variables, inconsistencies in reporting sex, gender, race, and ethnicity remain common. In acupuncture RCTs, “sex” and “gender” are often used interchangeably,[27] while race and ethnicity are frequently conflated with nationality,[28] potentially affecting interpretation and generalizability.[29–31] These issues may be particularly important in acupuncture research, as treatment responses are shaped by both biological and sociocultural factors.[32] For instance, a study found that age, sex, region, and social class significantly influenced healthcare-seeking behaviors. Without precise differentiation of these factors, it becomes difficult to accurately assess the social determinants influencing the effectiveness and promotion of acupuncture.[33]

To date, no systematic evaluation has examined how sex/gender and race/ethnicity are reported and analyzed in acupuncture RCTs.[34] Therefore, this study assessed such reporting and analysis in acupuncture RCTs over the past 12 years, evaluated reporting completeness and accuracy, and identified major deficiencies to improve future research quality and generalizability.

2. Methods

This study employed a systematic analysis approach to evaluate the reporting of sex/gender and race/ethnicity in acupuncture RCTs published between 2014 and 2025. The entire study protocol, including the research questions, search strategy, inclusion and exclusion criteria, and preliminary data extraction sheet, was pre-specified and registered via the Open Science Framework (OSF) (Registration ID: 10.17605/OSF.IO/6SXE5). Any deviations from the pre-registered protocol have been thoroughly documented and are publicly accessible on the OSF platform.

2.1. Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting, or dissemination plans in this study.

2.2. Identification and selection of articles

We comprehensively searched for acupuncture RCTs between 1 January 2014 and 31 May 2025 in three English databases: MEDLINE, Excerpta Medica Database (EMBASE), Cochrane Central Register of Controlled Trials (CENTRAL), and four Chinese databases including Chinese Biomedical Literature Service System (CBM), China National Knowledge Infrastructure (CNKI), Wanfang Data and VIP Chinese Medical Journal Database. The search strategy for all databases is available in the online supplement.

We included studies that met the following criteria: (1) RCTs in which acupuncture therapy was applied as the sole intervention in the experimental group, without combination with other traditional Chinese medicine or conventional Western medicine treatments; (2) Acupuncture therapies based on traditional medicine (TM) principles, regardless of variations in instrument type, stimulation sites, or needling techniques (e.g., body acupuncture, auricular acupuncture); (3) Control groups involving no intervention, placebo intervention, sham acupuncture, Western medicine, waiting-list control, or other interventions guided by modern medical theory; (4) Two-arm parallel-group studies conducted involving humans; and (5) Studies published in English or Chinese in peer-reviewed journals.

We excluded studies with: (1) Non-clinical therapeutic objectives (e.g., cost-effectiveness analyses, diagnostic studies); (2) Acupuncture procedures in which needles did not penetrate the skin; (3) Full text unavailable; (4) Duplicate publications; (5) Sample size $\leq$10 participants per group; (6) Fewer than three authors. Studies with fewer than three authors were excluded because they often lack sufficient multidisciplinary collaboration and independent oversight, which may increase the risk of bias and incomplete reporting.

All identified Chinese publications were imported into EndNote (version X7.1), and English publications into Rayyan (https://www.rayyan.ai/) for duplicate removal. Following this, two researchers (HL and YF) independently screened all titles, abstracts, and full texts. Any discrepancies were resolved through discussion or consultation with two senior investigators (YDe and YDu) when necessary.

2.3. Data extraction

We categorized data extraction into three categories: general characteristics, sex/gender factors, and race/ethnicity factors. Three standardized data extraction tables were created using Microsoft Excel 2019 (Microsoft Excel 2019 MSO 2210 Build 16.0.15726.20188 32). The data extraction sheets were developed by the research team to align with the objectives of this study, specifically to evaluate the extent and depth of gender and race reporting. Three rounds of pre-testing were conducted on a random sample of 10 studies to ensure the accuracy and reliability of the extraction process.

Two researchers (HL and YF) independently extracted data on general characteristics, with any discrepancies resolved by a senior reviewer (YDe). The general characteristics included: (1) title, (2) authors, (3) language, (4) country, (5) year of publication, (6) publication journal, (7) journal impact factor, (8) single-center or multi-center trials, (9) sample size, (10) source of funding (industry, independent or none), (11) conflict of interest, (12) registry information, (13) outcomes type, (14) types of acupuncture, (15) sex/gender reporting, (16) race/ethnicity reporting.

Two researchers (HL and YF) also independently extracted data related to sex/gender and race/ethnicity factors, with discrepancies resolved by a senior reviewer (YDe). The specific sex-related reporting elements included: (1) basic reporting (whether participant sex information was provided and the correct differentiation between "sex" and "gender"); (2) demographic characteristics (sex distribution proportions overall and within subgroups); (3) methodological considerations (whether sex-stratified randomization was used or sex-based subgroup analyses were performed); (4) results and discussion (whether sex differences in treatment efficacy were explored and whether the impact of sex on outcomes was discussed); and (5) whether non-binary participants were considered and included. The scoring system comprised 15 items across modules, with four scoring options: 0 = Not reported, 1 = Yes, 2 = No, NA = Not applicable. The specific race-related reporting elements included: (1) basic reporting (whether race/ethnicity

information was reported and the accurate distinction between "race" and "ethnicity"); (2) classification standards (specific racial/ethnic categorization criteria used); (3) demographic characteristics (overall and subgroup racial/ethnic distribution proportions); and (4) results analysis and discussion (whether racial/ethnic subgroup analyses were conducted, efficacy differences explored, and the impact of race/ethnicity on outcomes discussed). The scoring system consisted of 12 items across 4 modules, using the same scoring options: 0 = Not reported, 1 = Yes, 2 = No, NA = Not applicable.

2.4. Data analysis

We summarized the general characteristics and reporting status of studies that reported sex and race among the included articles. For general characteristics, descriptive statistics were used, and data are presented as counts (n) and percentages (%) in figures. To examine temporal trends in the use and accurate reporting of sex-related terminology, we performed two separate logistic regression analyses. The dependent variables were: (1) the use of sex/gender terminology (yes/no) and (2) correct reporting (yes/no), with publication year as the

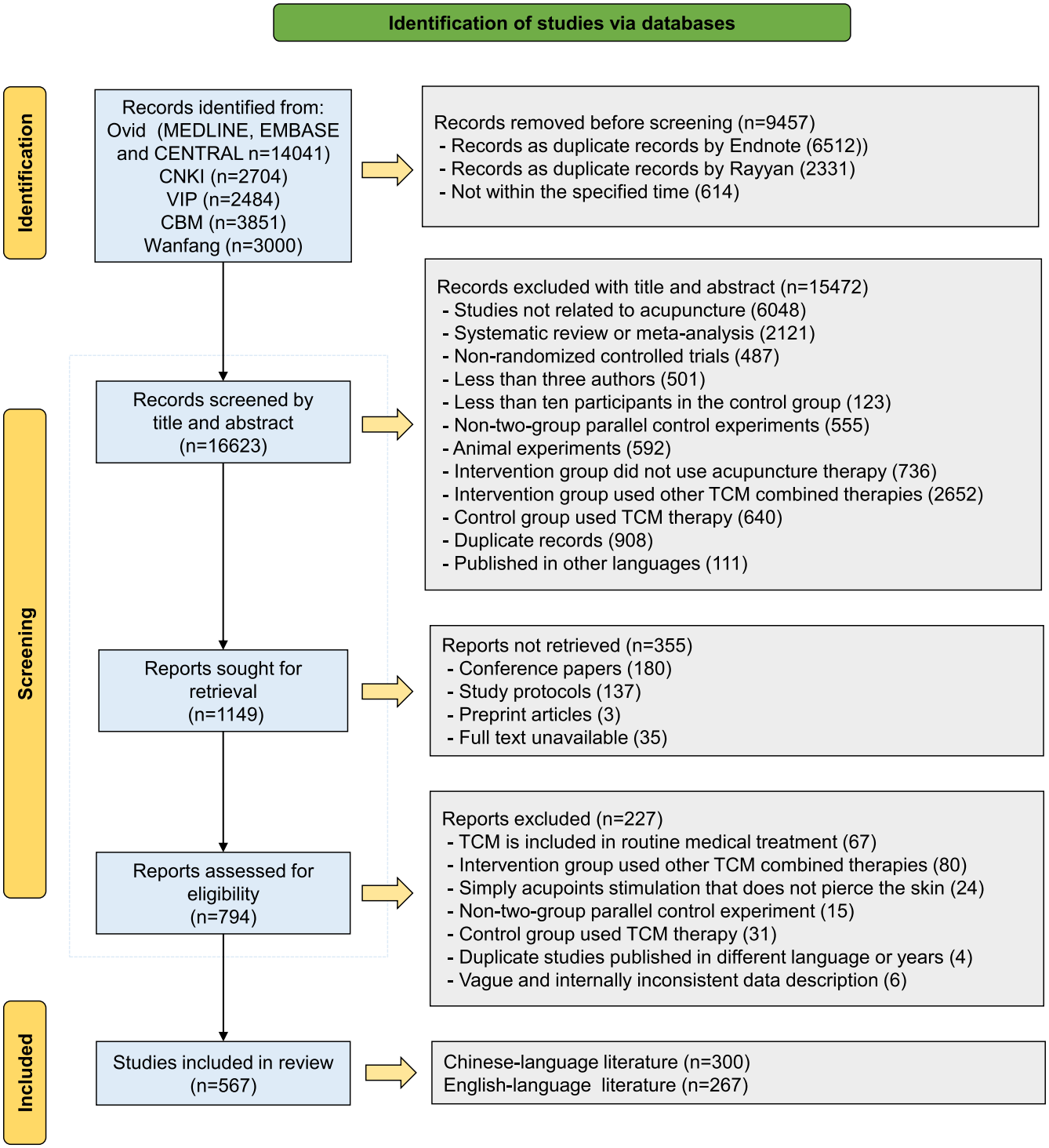


Fig. 1. Identification of studies.

independent variable. In these analyses, β_1 denotes the change in log odds per year, p represents the significance level, and the odds ratio (OR) with its 95 % confidence interval (95 % CI) reflects the strength and precision of the association. For participant sex representation in RCTs, we conducted a one-tailed Wilcoxon signed-rank test. All statistical analyses were performed using MATLAB software (R2024a, MathWorks, Natick, MA, USA), and a significance level of $p = 0.05$ (one-sided) was adopted.

3. Results

In total, 567 studies were included in the final sample (Fig. 1), comprising Chinese- and English-language publications. All studies included in the review and the data extracted for each article are available on the OSF.

3.1. Proportion and accuracy of sex/gender reporting

Table 1 summarizes the general characteristics of the included studies, as well as the characteristics of studies that reported sex or gender and race/ethnicity information. Additionally, Table 2 details the reporting frequencies of these demographic variables stratified by specific clinical conditions. Overall, most studies mentioned sex or gender (Fig. 2A). Among the English-language studies that reported participant sex or gender information, the majority used sex- or gender-related terminology (Fig. 2B). Fig. 2B illustrates the proportion of studies that used such terminology, while Fig. 2C further breaks down the accuracy of this usage. Although these terms were commonly used, fewer than half of the studies applied them correctly according to accepted definitions.

3.2. Temporal trends in sex/gender reporting

In addition, logistic regression analysis was implemented to investigate temporal variations in the appropriate utilization and application of sex/gender-related terminology as indicators of reporting quality over time (Fig. 3). The results showed a significant increase in the use of sex/gender-related terminology over time (Fig. 3A, $\beta_1 = 0.1147$, SE = 0.045, $p = 0.0116$). The corresponding odds ratio was 1.12 (95 % CI [1.03, 1.23]), indicating that the odds of using sex/gender-related terminology increased by approximately 12.2 % per year. In contrast, logistic regression analysis showed no significant temporal change in the correct use of sex/gender-related terminology (Fig. 3B, $\beta_1 = -0.014$, SE = 0.052, $p = 0.7893$). The corresponding odds ratio was 0.99 (95 % CI [0.89, 1.09]), indicating that the likelihood of correct term usage did not change significantly over time.

Table 1
General characteristics of included studies.

Characteristic	Total No. (%) (*N* = 567)	Sex/Gender Reporting No. (%) (*N* = 538)	Race/Ethnicity Reporting No. (%) (*N* = 30)
Publication language			
Chinese	300 (52.9)	289 (53.5)	0 (0.0)
English	267 (47.1)	249 (46.5)	30 (100.0)
Publication year			
2014–2015	46 (8.1)	44 (8.2)	2 (6.7)
2016–2017	70 (12.3)	69 (12.8)	5 (16.7)
2018–2019	69 (12.2)	68 (12.6)	5 (16.7)
2020–2021	86 (15.1)	83 (15.4)	4 (13.3)
2022–2023	163 (28.7)	160 (29.7)	8 (26.7)
2024–2025	133 (23.3)	114 (21.2)	6 (20.0)
Type of study centre			
Single-centre	250 (44.1)	232 (43.1)	14 (46.7)
Multi-centre	317 (55.9)	306 (56.9)	16 (53.3)
Acupuncture type			
Manual acupuncture	318 (56.1)	302 (56.1)	16 (53.3)
Electro-acupuncture	185 (32.6)	173 (32.2)	11 (36.7)
Small needle-knife	29 (5.1)	28 (5.2)	0 (0.0)
Others	35 (6.2)	35 (6.5)	3 (10.0)
Registration			
Prospective registration	187 (33.0)	169 (31.4)	23 (76.7)
Retrospective registration	40 (7.1)	38 (7.1)	6 (20.0)
Unregistered	340 (60.0)	331 (61.5)	1 (3.3)
Funding			
Institutional funding	444 (78.3)	423 (78.6)	28 (93.3)
Individual funding	1 (0.2)	1 (0.2)	0 (0.0)
Mixed funding	1 (0.2)	1 (0.2)	0 (0.0)
None	121 (21.3)	113 (21.0)	2 (6.7)

Table 2
Reporting of sex/gender and race/ethnicity stratified by clinical conditions.

Disease Category	Total No. (%) (*N* = 567)	Sex/Gender Reporting* No. (%) (*N* = 538)	English-language studies No. (%) (*N* = 267)	Race/Ethnicity Reporting in English-language studies† No. (%) (*N* = 30)
Endocrine system	39 (6.9 %)	39 (100.0 %)	18 (6.7 %)	0 (0.0 %)
Reproductive system	47 (8.3 %)	47 (100.0 %)	25 (9.4 %)	5 (20.0 %)
Motor system	94 (16.6 %)	91 (96.8 %)	37 (13.9 %)	4 (10.8 %)
Circulatory system	24 (4.2 %)	23 (95.8 %)	12 (4.5 %)	1 (8.3 %)
Respiratory system	23 (4.1 %)	22 (95.7 %)	11 (4.1 %)	1 (9.1 %)
Immune system	21 (3.7 %)	20 (95.2 %)	9 (3.4 %)	2 (22.2 %)
Nervous system	186 (32.8 %)	177 (95.2 %)	77 (28.8 %)	7 (9.1 %)
Digestive system	75 (13.2 %)	70 (93.3 %)	38 (14.2 %)	7 (18.4 %)
Urinary system	23 (4.1 %)	20 (87.0 %)	14 (5.2 %)	2 (14.3 %)
Mental health	29 (5.1 %)	24 (82.8 %)	21 (7.9 %)	1 (4.8 %)
NA	6 (1.1 %)	5 (83.3 %)	5 (1.9 %)	0 (0.0 %)

NA, Not applicable - This category includes trials involving healthy volunteers, conditions that do not fit into the primary physiological systems listed (e.g., ophthalmological diseases like glaucoma), or studies with mixed/unspecified clinical conditions.

* Percentages for sex/gender reporting were calculated using total number of studies (N = 567) as the denominator.

† Percentages for race/ethnicity reporting were calculated using English-language studies (N = 267) as the denominator.

3.3. Participant sex representation in RCTs

In our study, a total of 290 publications reported the sex/gender composition of participants before dropout, encompassing over twenty-seven thousand individuals, with a slight overall predominance of female participants (Fig. 4A). At the individual study level, the median number of male participants was 34.5 (IQR = 28.0), and that of female participants was 37.5 (IQR = 27.0) (Fig. 4B). The number of female participants was significantly higher than that of males ($p = 0.015$, one-tailed Wilcoxon signed-rank test). Furthermore, we calculated the female-to-male participant ratio (F/M ratio) for each study as a standardized indicator of sex representation balance across trials. This ratio was significantly greater than 1 (Fig. 4C, $p = 5.21 \times 10^{-6}$, one-tailed Wilcoxon signed-rank test). Similarly, we conducted the same analysis for the sex composition of participants after dropout. A total of 147 publications reported post-dropout sex composition, including 12,530

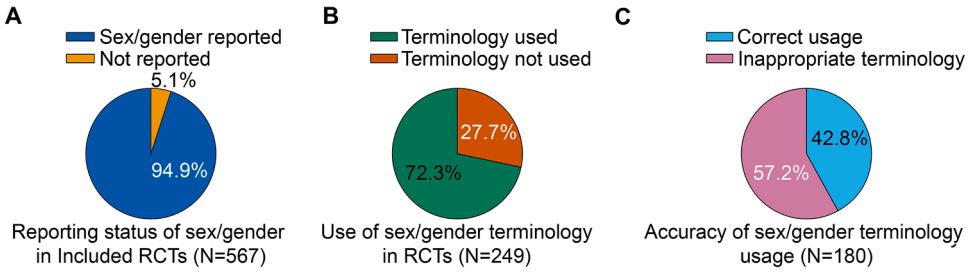


Fig. 2. (A) Sex/gender reporting status,(B) Prevalence of sex/gender terminology reporting, and (C) accuracy of sex/gender terminology use in included randomized controlled trials.

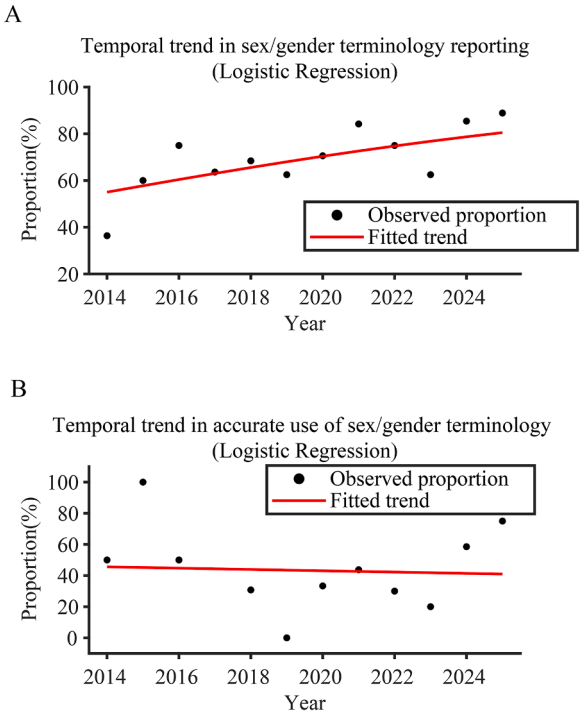


Fig. 3. Temporal trends in the (A) use, and (B) accurate use of sex/gender-related terminology.

participants in total. At the individual study level, the median number of male participants was 34.0 (IQR = 27.0), and that of female participants was 39.0 (IQR = 22.0) (Fig. 4D). The number of female participants remained significantly higher than that of males ($p = 0.028$, one-tailed Wilcoxon signed-rank test). In addition, the female-to-male participant ratio after dropout was also significantly greater than 1 (Fig. 4E, $p = 2.17 \times 10^{-5}$, one-tailed Wilcoxon signed-rank test). The predominance of female participants was consistently observed in all studies, regardless of whether they dropped out before or after. Nevertheless, sex-stratified or subgroup analyses were infrequently reported (2.1 %), suggesting a discrepancy between the analytical reporting at the study level and the composition of the participant population.

3.4. Consideration of sex/gender and race/ethnicity in study design and analysis

Table 3 summarizes the reporting and analysis of sex/gender and race/ethnicity considerations in the included acupuncture RCTs. Only a very small subset of studies implemented gender-stratified randomization, and subgroup analyses by sex/gender were infrequent. Similarly, reporting of sex/gender-based differences in treatment efficacy and discussion of sex/gender as an interpretative factor was limited in scope. Notably, no studies reported inclusion of participants with non-binary gender identities. With respect to race and ethnicity, reporting was highly uneven across language groups. While English-language studies occasionally provided race/ethnicity information, this was absent in Chinese-language publications. Even among studies that did report these variables, only a minority clearly distinguished between race and ethnicity as separate constructs. Analytical use of race/ethnicity was

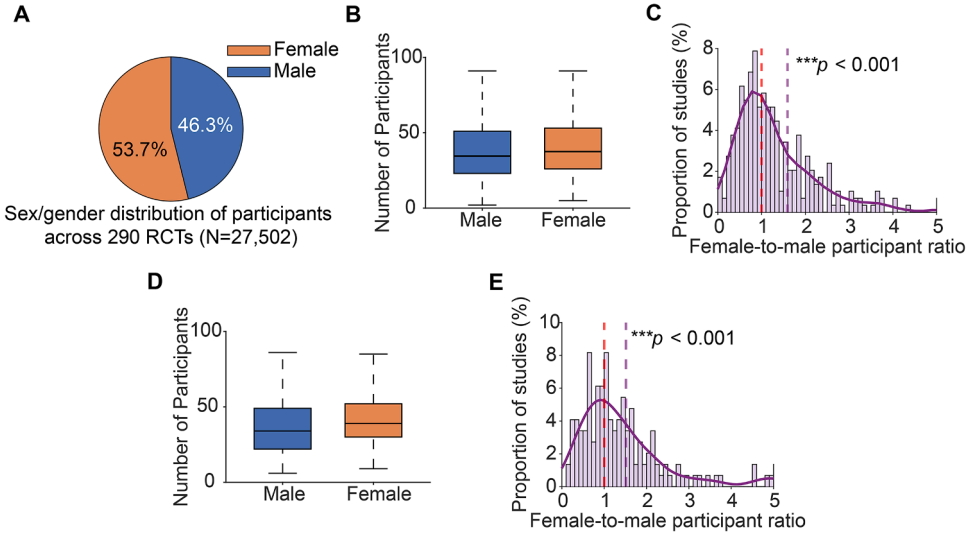


Fig. 4. (A) Sex distribution, (B) box plot of participants, and (C) distribution of female-to-male participant ratio in included RCTs before dropout; (D) box plot of participants, and (E) distribution of female-to-male participant ratio in included RCTs after dropout.

Table 3
sex/gender and race/ethnicity reporting and analyses in included acupuncture RCTs.

Item	Number of Studies (%)
Sex/Gender reporting	
Total studies with gender reporting*	$N = 420$
Gender-stratified randomization	1 (0.2)
Gender-specific subgroup analysis	9 (2.1)
Reported gender differences in treatment effectiveness	12 (2.9)
Discussed the influence of gender	30 (7.1)
Reporting of non-binary gender	0 (0.0)
Race/Ethnicity reporting	
Total studies mentioning race or ethnicity	$N = 30$
Distinguished between race and ethnicity	9 (30.0)
Race/ethnicity-specific subgroup analysis	2 (6.7)
Discussed the influence of race/ethnicity on study outcomes	2 (6.7)

RCTs: Randomized controlled trials.
* Excluding single-gender studies and studies without gender information.

also rare, with very few studies conducting subgroup analyses or evaluating differential treatment effects across groups.

4. Discussion

4.1. Summary of key findings

The reporting and analytical use of sex/gender and race/ethnicity in acupuncture RCTs were identified as substantial deficiencies in this study. Despite the fact that the use of sex/gender-related terminology has increased over time, there has not been a corresponding improvement in correct or conceptually appropriate usage. This suggests a persistent disparity between the quantity and quality of reporting. It is crucial to note that these variables are rarely included as effect modifiers in statistical analyses, which restricts the capacity to assess subgroup differences and restricts the generalizability of the results.

4.2. Comparison with previous studies

Our findings are consistent with previous research indicating that sociodemographic variables are frequently treated as descriptive characteristics rather than analytical factors in RCTs. Similar limitations have been documented in high-impact medical journals, where the insufficient collection and reporting of such data may obfuscate disparities in recruitment and outcomes and undermine external validity.[8]

This issue is also present in acupuncture studies. For example, a randomized trial of electroacupuncture for dry eye disease observed no significant efficacy differences when stratified by gender.[35] However, this result does not definitively rule out a potential gender-related effect on therapeutic outcomes. The statistical power of the study was likely reduced by the limited sample size, and the absence of gender-related social variables precluded the assessment of their moderating effects on treatment outcomes.

Emerging neuroimaging evidence further suggests that sex/gender differences in acupuncture response may exist at the neural level.[36] Functional imaging studies have demonstrated sex-related differences in pain perception and brain connectivity during acupuncture stimulation, as well as distinct patterns of regional brain activity despite similar subjective responses.[37] These findings indicate that the lack of subgroup analyses in clinical trials may overlook biologically meaningful heterogeneity.

In addition, previous research has found insufficient reporting of race/ethnicity, particularly in regions with relatively homogeneous populations.[38] However, in the context of increasingly globalized research, inconsistent reporting standards continue to be a barrier to cross-population comparison and generalizability.[39,40]

4.3. Clinical and scientific implications

The limited integration of sex/gender and race/ethnicity into statistical analyses reduces the interpretability of current acupuncture evidence.[41] Without examining these variables, it is uncertain whether treatment effects vary across populations, which restricts the generalizability of findings and their relevance to clinical practice.[42,43]

Furthermore, the absence of such analyses limits comprehension of the mechanisms that underlie the effects of acupuncture and the variability in treatment response.[44] Therefore, it is imperative that sociodemographic variables be integrated into the design of future studies and the development of statistical models, rather than being regarded as mere baseline characteristics.

4.4. Strengths and limitations

The strengths of this study include the inclusion of RCTs covering a wide range of disease types and published in various journals, which provides a comprehensive reflection of the current reporting practices regarding sex/gender and race/ethnicity information in acupuncture RCTs. This study not only evaluates the basic completeness of reporting but also delves deeper into how gender and racial data are utilized in statistical analysis. By combining a systematic descriptive analysis with bibliometric methods, we offer a reference for establishing future reporting standards.

However, this study also has several limitations. The conclusions are entirely based on published literature, which may suffer from incomplete reporting or selective outcome reporting, thus introducing the potential for reporting bias. In addition, our analysis of race and ethnicity was constrained by the extremely limited availability of such data in the included trials, which restricted the depth of examination and may have led to an underestimation of the true extent of deficiencies in this domain. Finally, only studies published in Chinese and English were included, which may have resulted in the omission of evidence from other regions or cultural contexts, thereby limiting the generalizability of the findings.

4.5. Conclusions and future research

This study demonstrates a significant lack of consistency in the reporting and analysis of sex/gender and race/ethnicity, particularly in the definition and integration of these variables into statistical analyses. Despite increasing international emphasis on demographic transparency, implementation remains limited and uneven, underscoring the need for standardized reporting and analytical frameworks to improve the transparency, reproducibility, and interpretability of future acupuncture research. Future studies should clarify conceptual distinctions between sex and gender, and race and ethnicity;[45,46] advance methodological approaches by treating sociodemographic variables as important research factors rather than merely as confounding variables;[47,48] and strengthen interdisciplinary collaboration with fields such as epidemiology, sociology, and medical anthropology to better understand how demographic factors influence acupuncture efficacy.[49]

Author contributions

Conceptualization: YDuan, LY. Methodology: HL, YDeng. Formal analysis: HL. Investigation: HL, YF, YDeng. Resources: HY, YC, ZX, SW, LS, ZZ. Data curation: HL, YF. Writing – Original Draft: HL. Writing – Review & Editing: YDuan, YDeng, LS, EL. Visualization: HL. Supervision: YDuan, LY. Project administration: YDuan, LY, ZX. Funding acquisition: YDuan, LY.

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Ethics statement

No ethical approval was required as this study did not involve human participants or laboratory animals.

Data and code availability

Data are available in a public, open-access repository. The datasets used and/or analysed during the current study have been provided in the supplement and are available via Open Science Framework at: https://osf.io/zxae9.

Declaration of competing interest

The authors declare no competing interests.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imr.2026.101353.

Supplement 1. Search strategy.

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