

Reporting quality of randomized controlled trials on acupuncture and manipulation for greater occipital neuralgia evaluated using the CONSORT statement and STRICTA checklist

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<https://doi.org/10.12307/2025.930>

Received:

October 11, 2024

Peer review started:

October 23, 2024

Accepted:

November 26, 2024

Published online:

January 13, 2025

Abstract

OBJECTIVE: In recent years, the number of clinical research reports on acupuncture and manipulation for the treatment of greater occipital neuralgia has gradually increased, but the quality is uneven. There is currently no literature evaluating the quality of published reports, which is not conducive to the promotion of clinical use of these therapies. Therefore, this article assessed the reporting quality of randomized controlled trials on acupuncture and manipulation for greater occipital neuralgia.

METHODS: Cochrane Library, PubMed, Web of Science, Embase, China National Knowledge Infrastructure (CNKI), VIP, WanFang Data, and Chinese BioMedical Literature Database (CBM) from inception to May 20, 2024 were searched. The reporting quality of included randomized controlled trials was independently evaluated by two investigators using the CONSORT statement, STRICTA checklist, and Cochrane bias of risk assessment tool. A third investigator resolved any disagreement.

RESULTS: A total of 62 articles were included. Based on the CONSORT statement, 59.46% (22/37) of all entries had a reporting rate of less than 50%, mainly including "Identification as a randomized trial in the title (1/62, 1.61%)," "How sample size was determined (7/62, 11.29%)," "Implementation (1/62, 1.61%)," "Blinding (1/62, 1.61%)," and "Reports of Funding (4/62, 6.45%)." According to the STRICTA checklist, 29.41% (5/17) of all entries had a reporting rate of less than 50%, mainly including "Details of other interventions (7/58, 12.07%)," "Setting and context of treatment (0/58, 0%)," and "Description of participating acupuncturists (0/58, 0%)."

CONCLUSION: The reporting quality of randomized controlled trials on acupuncture and manipulation therapy for greater occipital neuralgia remains low. Future researchers need to make greater efforts to strictly adhere to the CONSORT statement and STRICTA checklist during trial design, implementation, and reporting. This will facilitate the standardization of research in this field and enhance the reliability and reproducibility of the research results.

Key words: reporting quality; acupuncture; manipulation; CONSORT statement; STRICTA checklist; ROB; clinical randomized controlled trials; greater occipital neuralgia

INTRODUCTION

Greater occipital neuralgia (GON) refers to paroxysmal pain within the distribution range of the greater occipital nerve, which can radiate to the vertex, mastoid process, or external ear^[1]. This disease is characterized by a high incidence rate and a wide range of affected populations, and in recent years, the onset of the disease has shown a trend of younger age^[2]. Modern medical anatomy reveals that the occipital nerve's long path and extensive distribution render it susceptible to various neck factors, leading to compression and occipital neuralgia due to local damage, scarring, adhesion, or enlarged lymph node compression^[3]. Therefore, relieving the compression during the greater occipital nerve is the key to treating occipital neuralgia. Multiple treatment options exist for GON, including acupuncture, autonomy, manipulation, oral medication, and surgery. While oral medicines offer swift pain relief, it often accompanies significant side effects. Moreover, surgical intervention is invasive and may not be well-received by patients.

As traditional Chinese medicine's comprehension of GON evolves, there is a growing emphasis on incorporating its therapies into clinical practice. Acupuncture, a prevalent clinical treatment for GON, enhances local blood circulation, facilitates inflammation absorption, and alleviates pain, exhibiting notable clinical efficacy^[4]. Furthermore, manipulation techniques can rectify misaligned joints, address neck muscle imbalances, relax tense or spasmodic neck muscles and fascia, and ease nerve entrapment symptoms^[5].

Randomized controlled trials (RCTs) are widely regarded as the gold standard in clinical research, representing the primary form of interventional study^[6]. These trials effectively mitigate selection and confounding bias, which is crucial for conducting high-quality clinical research^[7]. The methodologies employed, the quality of reporting, and the chosen outcome indicators in RCTs directly impact the authenticity and validity of systematic evaluation evidence^[8]. Previous meta-analyses have shown that the number of clinical research reports on acupuncture and manipulation therapies for the

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Funding: National Natural Science Foundation of China, No. 81874511 (to WS); Guangdong Province Famous Chinese Medicine Inheritance Studio Construction Project, No. 102018007 (to FZY); Guangdong Province Fourth Batch of Famous Chinese Medicine Apprenticeship Project, No. 102018105 (to WS)

How to cite this article: LIU LG, QIU MW, HUANG YL, FAN ZY, WU S, GUO RS. Reporting quality of randomized controlled trials on acupuncture and manipulation for greater occipital neuralgia evaluated using the CONSORT statement and STRICTA checklist. *Zhongguo Zuzhi Gongcheng Yanjiu*. 2025;29(30):6566-6573.



treatment of GON has gradually increased^[9]. However, the quality of these reports is inconsistent. What is more, notably, there is a lack of literature dedicated to evaluating the quality of the published reports, which hinders the advancement and adoption of these therapies. To address this gap, our study utilizes the consolidated standards of reporting trials (CONSORT) statement and the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) checklist to evaluate the reporting quality of RCTs involving acupuncture and manipulation for GON^[10-11]. We conducted an in-depth analysis and discussion of the results, aiming to improve the integrity of related clinical trials and promote the standardization of clinical research reporting.

MATERIALS AND METHODS

Search strategy

Study types

Publicly published RCTs, limited to Chinese and English languages.

Databases

China National Knowledge Infrastructure (CNKI), VIP, WanFang Data, China BioMedical Literature Database (CBM), Cochrane Library, PubMed, Web of Science, and Embase.

Search terms

Chinese search terms were "Tuina, bone setting, spinal correction, manipulation, massage, acupuncture, electroacupuncture, greater occipital neuralgia, occipital neuralgia, clinical observation, randomized controlled trial, efficacy." English search terms were "massage, manipulation, Tuina, acupuncture, electroacupuncture, auricular, moxibustion, greater occipital neuralgia, randomized controlled trial, random."

Search timeframe

From inception to May 20, 2024.

Strategy

The details of the search strategy (PubMed) can be found in **Table 1**.

Table 1 | Search strategy

PubMed
#1 "Greater occipital neuralgia" [MeSH Terms]
#2 (Massage [MeSH Terms]) OR (Manipulation) OR (Tuina) OR (Acupuncture [MeSH Terms]) OR (Electroacupuncture) OR (Acupuncture therapy) OR (Moxibustion)
#3 ("Randomized Controlled Trial" [Publication Type]) OR (Randomized [Title/Abstract])
#4 #1 AND #2 AND #3

Inclusion and exclusion criteria

Studies considered for inclusion were required to fulfill the following criteria: Publicly published RCTs, limited to Chinese and English languages; the subjects must be over 18 years old, with no restrictions on gender, age, or case source; there is a transparent and standardized diagnostic criterion for GON^[12]; the treatment group was treated with acupuncture or manipulation therapy alone or acupuncture, manipulation combined with other interventions, while the control group receives interventions such as traditional Chinese medicine, medicine, acupuncture, and manipulation.

Studies meeting any of the following criteria were excluded: those that were republished, contained data that could not be extracted or lacked access to the full text.

Study selection and data extraction

Two researchers independently gathered and sorted through the literature, utilizing Note Express 3.2 to handle the collected documents. Initially, any duplicate documents were eliminated. Following this, documents that needed to meet the inclusion criteria were excluded upon reviewing their titles and abstracts. Afterward, the remaining documents underwent a comprehensive reading, allowing for selecting those that adhered to the set criteria. Microsoft Excel 2016 was utilized to construct a data table, compiling details like the title, author, publication year, CONSORT statement, and STRICTA checklist. Two researchers first conducted a pre-extraction round to improve the extraction form's design and unify extraction standards. Then, they extracted the data independently and completed the data entry after cross-checking. The whole methodology employed was systematically outlined using a flowchart.

Assessment of reporting quality

Two researchers evaluated the quality of each RCT using the CONSORT 2010 Statement and the STRICTA checklist. The CONSORT 2010 Statement consists of six sections, including Title and Abstract, Introduction, Methods, Results, Discussion, and Other Information, and is divided into 25 items and 37 sub-items. The STRICTA checklist^[10-11], an extended version of the CONSORT Statement, is mainly used to evaluate the reporting norms of intervention measures in acupuncture RCTs. It includes six sections: Rationality of Acupuncture Treatment, Details of Needling, Treatment Regimen, Other Interventions, Therapist Background, and Control or Comparator Interventions, and is further divided into six items and 17 sub-items. Based on whether each item was reported in the article, the two researchers made a judgment of "reported" or "not reported" item by item. After completing the evaluation, the two researchers cross-checked each other's work. In case of disagreement, a third party could participate in the adjudication. Finally, the number and percentage of reported articles for each item were calculated. Cohen's κ -statistic was quantified to evaluate the interrater agreement^[13]. Agreement levels were categorized as follows: 0.20 or less was deemed "poor," greater than 0.20 but less than 0.40 as "low," values between 0.40 and 0.60 were considered "moderate," those between 0.60 and 0.80 were labeled as "substantial," above 0.80 was classed as "good," and a perfect score of 1 indicated "perfect" agreement. Items with any disagreement were subject to specific examination to facilitate consensus. The calculation of Cohen's κ -statistic and the determination of the 95% confidence interval (95%CI) for each item were executed using PASW Statistics for Windows, version 18.0 (SPSS Inc., Released 2009, Chicago, IL, USA).

Risk of bias assessments

The quality of the included literature was evaluated using the Cochrane Collaboration's tool for assessing the risk of bias^[14]. Two researchers independently assessed each item as "low risk," "unclear risk," or "high risk" based on criteria such as the random allocation method, allocation concealment, blinding of subjects, blinding in outcome assessment, completeness of outcome data, selective reporting, and other potential sources of bias. In case of any disagreement during the evaluation, a third researcher was consulted to reach a consensus.

Main observational indicators

Quality of the studies.

RESULTS

Search results

The initial search yielded 1 020 studies, which were reduced to 479 after removing duplicates. Through preliminary screening of titles and abstracts, 128 relevant studies were selected. After further full-text screening, a total of 62 studies were ultimately included^[15-76]. Among them, 60 reports were written in Chinese, and two reports were written in English; however, all reports were published by Chinese researchers. The flow diagram of literature selection is shown in **Figure 1**.

Information on published papers per year

All the studies were published between 2007 and 2024, with an overall increasing trend in the number of publications. The peak was reached in 2019, with a total of 8 articles published. Details can be found in **Figure 2**.

Quality of the studies

Risk of bias

The quality of the included literature was evaluated using the Cochrane Collaboration's tool for assessing the risk of bias. The results indicated that most items were classified as "low risk of bias," while the proportion of "high risk of bias" items was the lowest, primarily concentrated in the "Random sequence generation" and "Binding of participants and personnel" sections. Specifically, some studies mentioned randomization but did not describe the method used to generate the randomization results, thus being rated as "high risk of bias." Moreover, although some studies reported the implementation of single blinding in their respective articles, blinding of participants and personnel was deemed impractical considering the designs of the included studies, thereby increasing the potential for performance bias. Low-quality RCTs will produce evidence and results that lack credibility and may even mislead readers and affect the implementation of clinical decision-making. A

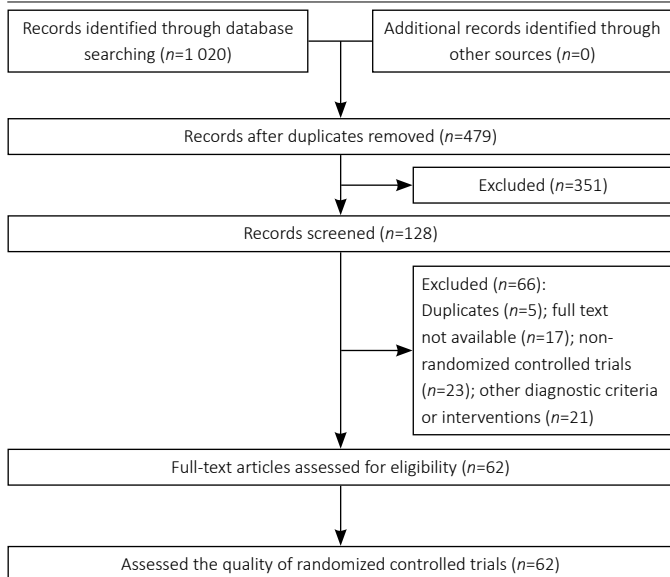


Figure 1 | Flow diagram of literature selection

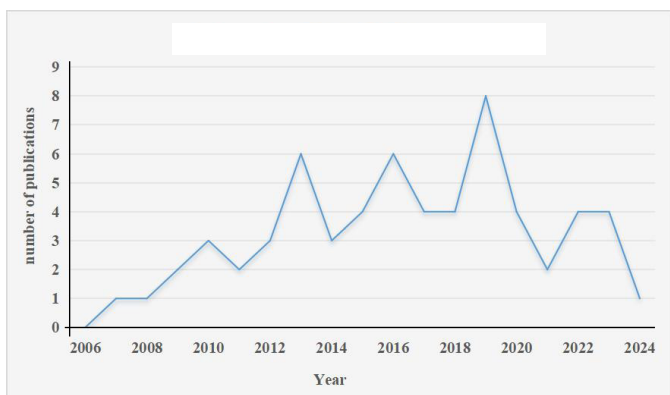


Figure 2 | Information of published papers per year

few items were rated as “unclear risk of bias” due to incomplete reporting of information, as detailed in Figure 3.

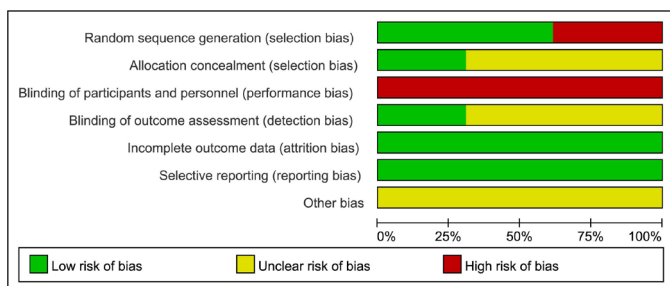


Figure 3 | Risk of bias of all included studies

CONSORT statement

We conducted a quality report on the 62 included studies according to the CONSORT statement (Table 2). Among the 37 items encompassed within the eight criteria, 15 items had a reporting rate exceeding 50%, with 1 item achieving a 100% reporting rate. Meanwhile, nine items had a reporting rate of 0%, but it is important to note that most of these items are only required

to be reported when necessary and are not mandatory. Therefore, their low reporting rates do not necessarily reflect the quality of reporting. Additionally, items with a reporting rate below 50% were mainly concentrated in the following aspects: “Identification as a randomized trial in the title” (1/62, 1.61%), “How sample size was determined” (7/62, 11.29%), “Implementation” (1/62, 1.61%), “Blinding” (1/62, 1.61%) (2/62, 3.23%), “Losses and exclusions after randomization” (19/62, 30.65%), “A table showing baseline data” (21/62, 33.87%), “Reports of Harms” (16/62, 25.81%), “Reports of limitations” (20/62, 32.26%), and “Reports of funding” (4/62, 6.45%). It remains unclear what factors may reduce the credibility of the research results or even lead to misleading conclusions. In the evaluation of the 37 items by two reviewers, 31 items had kappa values greater than 0.8, and the kappa values of the remaining six items were all within the range of 0.6 to 0.8, indicating good overall consistency.

STRICTA checklist

Using the STRICTA checklist, a quality assessment was conducted on the 58 included studies related to acupuncture, as shown in Table 3. Among the 17 items encompassed by the 6 Criteria, 12 items had a reporting rate exceeding 50%, with two items achieving a 100% reporting rate. There were five items with a reporting rate below 50%, among which two items had a 0% reporting rate, precisely “Needle type” (22/58, 37.93%), “Details of other interventions” (7/58, 12.07%), “Setting and context of treatment” (0/58, 0%), “Description of participating acupuncturists” (0/58, 0%), and “Rationale for the control or comparator” (21/58, 36.21%). It remains unknown what factors reduce the reproducibility and authenticity of the research. In the assessment of the 17 detailed items by two evaluators, 14 items had kappa values greater than 0.8, and 3 items ranged from 0.6 to 0.8, indicating good overall consistency.

DISCUSSION

Our research findings indicate that the reporting quality of RCTs on GON is mostly low. Many researchers pay inadequate attention to crucial elements such as title writing rules, methods for determining sample size, allocation concealment of interventions, blinding, complete trial reporting, detailed intervention implementation, and trial registration. Addressing these shortcomings, we identify the following reasons: (1) Trial designers and executors lack standardized and unified training in clinical trial fundamentals, leading to inadequate awareness of clinical trial reporting. (2) Human subjects introduce numerous uncontrollable factors into trials. (3) Researchers tend to reference literature with low reporting quality excessively. The abundance of low-quality literature poses significant challenges for researchers in understanding the rationality of study designs. In response, we propose the following recommendations.

Before initiating trials, clinical trial executors should undergo standardized training in fundamental clinical trial knowledge. The title format should be standardized, incorporating terms like “randomized” to avoid misdetections or misleading information that could impair readers’ interpretation and utilization of research results. Emphasis should be placed on sample size calculation to prevent credibility reduction due to insufficient sample sizes or unnecessary waste from excessive inclusion^[77]. Accurate and comprehensive recording of all trial data, including patient conditions, intervention details, adverse reactions during the trial, and follow-up situations, enhances the reliability of trial results and enables readers to evaluate them more objectively.

The principles of randomization and blinding are the cornerstones of clinical trials, capable of eliminating chance bias to a great extent and crucial for ensuring the credibility of intervention outcomes^[78-79]. However, most of the RCTs in this study needed more rigor in their execution and provided inadequate reporting on the randomization and blinding components required by the CONSORT statement. Some studies merely mentioned the terms “Randomization” and “Blinding” without describing the specific randomization methods and the success of blinding implementation in detail. Studies have shown that different randomization methods and their strict implementation processes significantly impact trial results, and a lack of sufficient allocation concealment may lead to an exaggeration of intervention effects by 30%–40%^[80]. We recommend adopting random schemes such as computer-generated random number tables and random lot drawings for randomization in future RCTs. For blinding implementation, acupuncture trials should include a sham acupuncture group for blinded control, using specially designed needles to conceal the specific intervention from both operators and patients. While

Table 2 | Overall quality of reporting: rating using items based on the 2010 CONSORT statement (n=62)

Criteria	Code of item	Description	Number of positive trials	Percentage of papers adequately reporting (%)	Cohen's κ coefficient	95%CI
Title and abstract	1a	Identification as a randomized trial in the title	1	1.61	1.00	1.00
	1b	Structured summary of trial design, methods, results, and conclusions	57	91.93	1.00	1.00
Introduction		Background and objectives				
	2a	Scientific background and explanation of rationale	34	54.83	0.85	0.57 to 1.13
Methods	2b	Specific objectives or hypotheses	41	66.12	0.77	0.59 to 0.94
		Trial design				
	3a	Description of trial design, including allocation ratio	35	56.45	0.66	0.04 to 1.27
	3b	Essential changes to methods after trial commencement with reasons	0	0	1.00	1.00
		Participants				
	4a	Eligibility criteria for participants	57	91.96	1.00	1.00
	4b	Settings and locations where the data were collected	60	96.77	0.7	0.41 to 0.98
		Interventions				
	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	62	100	1.00	1.00
		Outcomes				
Randomization	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	43	69.35	0.87	0.73 to 1.02
	6b	Any changes to trial outcomes after trial commencement, with reasons	0	0	1.00	1.00
		Sample size				
	7a	How sample size was determined	7	11.29	0.73	0.57 to 0.89
	7b	When applicable, explanation of any interim analyses and stopping guidelines	0	0	1.00	1.00
		Sequence generation				
	8a	Method used to generate the random allocation sequence	35	56.45	0.87	0.77 to 0.96
	8b	Type of randomization; details of any restriction	29	46.77	0.76	0.22 to 1.15
		Allocation concealment mechanism				
	9	Mechanism used to implement the random allocation sequence, describing any steps taken to conceal the sequence until interventions were assigned	10	16.13	0.94	0.86 to 1.01
		Implementation				
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	1	1.61	1.00	1.00
		Blinding				
	11a	If done, who was blinded after assignment to interventions and how	2	3.23	0.81	0.61 to 0.98
	11b	If relevant, a description of the similarity of interventions	1	1.61	0.89	0.79 to 0.99
	Statistical methods					
12a	Statistical methods used to compare groups for primary and secondary outcomes	54	87.10	0.68	0.42 to 0.95	
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	0	0	1.00	1.00	
	Participant flow					
13a	For each group, the number of participants who were randomly assigned received intended treatment and were analyzed for the primary outcome	60	96.77	1.00	1.00	
13b	For each group, losses and exclusions after randomization, together with reasons	19	30.65	0.92	0.84 to 0.98	
	Recruitment					
14a	Dates defining the periods of recruitment and follow-up	50	80.65	0.84	0.75 to 0.95	
14b	Why the trial suspended or was stopped	2	3.23	1.00	1.00	
	Baseline data					
15	A table showing baseline demographic and clinical characteristics for each group	21	33.87	1.00	1.00	
	Numbers analyzed					
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	60	96.77	1.00	1.00	
	Outcomes and estimation					
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision	0	0	1.00	1.00	
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	0	0	1.00	1.00	
	Ancillary analyses					
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	0	0	1.00	1.00	
	Harms					
Discussion	19	Important harms or unintended effects in each group	16	25.81	1.00	1.00
		Limitations				
	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	20	32.26	0.91	0.82 to 0.97
		Generalizability				
21	Generalizability of the trial findings	58	93.55	0.86	0.78 to 0.95	
	Interpretation					
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	60	96.77	0.84	0.79 to 0.98	
Other information		Registration				
	23	Registration number and name of trial registry	0	0	1.00	1.00
		Protocol				
	24	Where the full trial protocol can be accessed, if available	0	0	1.00	1.00
		Funding				
25	Sources of funding and other support role of funders	4	6.45	1.00	1.00	

Table 3 | Overall quality of reporting: rating using items based on the STRICTA checklist (n=58)

Criteria	Code of item	Description	Number of positive trials	Percentage of papers adequately reporting (%)	Cohen's κ coefficient	95%CI
Acupuncture rationale	1a	Style of acupuncture	58	100	1.00	1.00
	1b	Reasons for acupuncture provided	30	51.72	0.65	0.05 to 1.27
	1c	Extent to which treatment was varied	42	72.41	1.00	1.00
Details of needling	2a	Number of needles inserted per subject per session	54	93.10	0.95	0.92 to 1.01
	2b	Names of points used (uni-/bilateral)	48	82.76	1.00	1.00
	2c	Depth of insertion	49	84.48	0.90	0.82 to 0.98
	2d	Responses sought	45	77.59	0.92	0.85 to 0.99
	2e	Needle stimulation	58	100	1.00	1.00
	2f	Needle retention time	49	84.48	0.93	0.84 to 1.01
	2g	Needle type	22	37.93	1.00	1.00
Treatment regimen	3a	Number of treatment sessions	55	94.83	0.95	0.88 to 1.02
	3b	Frequency and duration of treatment sessions	56	96.55	0.94	0.86 to 1.02
Other components of treatment	4a	Details of other interventions administered to the acupuncture group	7	12.07	0.92	0.85 to 1.01
	4b	Setting and context of treatment	0	0	1.00	1.00
Practitioner background	5	Description of participating acupuncturists	0	0	1.00	1.00
Control or comparator interventions	6a	Rationale for the control or comparator in the context of the research question (s)	21	36.21	0.61	0.02 to 1.21
	6b	Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details for items 1–3 above	51	87.93	0.79	0.61 to 0.97

blinding implementation in massage-related clinical trials is challenging, efforts should still be made, as partial implementation is preferable to none.

Trial registration should be prioritized to enhance research transparency and help reduce publication bias and overestimating effect sizes^[81-82]. Despite the increasing number of clinical trials in China in recent years, the attention given to trial registration among clinical trial researchers remains low^[83]. In this study, none of the included studies reported the name or registration number of the clinical registration authority. This lack of information prevents readers from tracing the trial process and results, making it difficult to assess whether incomplete or selective reporting exists^[84]. We recommend that researchers register their trials with the Chinese Clinical Trial Registry and that research institutions strengthen the supervision of trial registration and encourage researchers to register their trials.

The details of acupuncture interventions should be reported more thoroughly. According to the evaluation results of the STRICTA checklist, the included literature is lacking in reports on aspects such as "Needle type," "Details of other interventions," "Setting and context of treatment," "Description of participating acupuncturists," and "Rationale for the control or comparator," which is consistent with some current research findings^[85]. Given the specificity of different acupuncture points due to their locations, the selected needles and manipulation methods also vary, and these details need to be reported in detail. Otherwise, it will be unfavorable for trial reproducibility and limit the ability of clinicians to implement acupuncture treatments recommended in research reports^[86]. Additionally, the years of practice experience of participating acupuncturists significantly impact treatment outcomes. Research indicates that differences in clinical experience among acupuncturists may influence treatment effects, and doctors with more experience and training are positively correlated with better treatment outcomes^[87]. What is more, during the diagnosis and treatment process, communication between doctors and patients, as well as the environment provided for treatment, can enhance or reduce the overall effectiveness of the intervention^[88], and the rationality of control measures is also related to the value that trial results can demonstrate^[89]. Therefore, these details should all be reported in detail.

Finally, journals should also undertake the task of reviewing paper reporting quality. As a crucial step in paper acceptance and publication, journals should strive to minimize the acceptance of poorly reported papers. One specific measure could be to require authors to provide a CONSORT evaluation report of their articles during submission.

This study has its own deficiencies. (1) This study did not include clinical studies conducted abroad, indicating a possible problem of insufficient representation of foreign literature. (2) RCTs were only searched in Chinese and English databases, so RCTs in other languages may be missed.

Based on our assessment, while there are numerous RCTs on acupuncture and manipulation for GON, their reporting quality remains low, falling short of relevant regulatory requirements. This significantly hinders the development of acupuncture and manipulation for GON. Future researchers need to make

greater efforts to strictly adhere to the CONSORT statement and STRICTA checklist during trial design, implementation, and reporting. By doing so, we can achieve high-quality reporting of randomized controlled trials and provide more reliable evidence for clinical decision-making.

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(责任编辑: WJ, ZN, QY, ZLJ)

基于 CONSORT 声明和 STRICTA 清单评价针灸推拿治疗枕大神经痛的随机对照试验报告质量

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中图分类号:

R459.9; R318; R246.6

文章编号:

2095-4344(2025)30-6566-08

文献标识码: A

文章快速阅读: 枕大神经痛随机对照试验的报告质量分析

检索:

国内外 8 大中英文数据库;

时间:

所有数据库建库至 2024-05-20;

收集:

针灸、推拿疗法治疗枕大神经痛的临床随机对照试验报告

报告质量评价工具:

(1) CONSORT 声明;
(2) STRICTA 清单;
(3) Cochrane 风险偏倚评估工具。

纳入文献报告质量偏低

主要存在的问题:

(1) 标题书写不规范;
(2) 缺乏样本量计算;
(3) 未实施随机化和盲法;
(4) 试验报告不完整;
(5) 干预措施细节不足;
(6) 缺乏试验注册。

文题释义:

CONSORT声明: 是一个旨在提高随机对照试验报告质量的国际性倡议, 它提供了一套详细的指南, 用于指导临床试验作者在撰写研究报告时应该包含哪些关键信息, 包括标题和摘要、引言、方法、结果、讨论以及其他信息, 并细化为多个具体项和子项。

STRICTA清单: 是专门针对针灸的临床试验报告规范。STRICTA清单包括6个主要部分: 针灸治疗的合理性、针刺的详细信息、治疗方案、其他干预措施、治疗师背景和对照或比较干预措施。

摘要

目的: 近年来, 针灸推拿疗法治疗枕大神经痛的临床研究报告逐渐增多, 但质量参差不齐。目前尚未有文献对已发表报告进行质量评价, 这不利于这些疗法的临床使用推广。为此, 文章评价了针灸和推拿疗法治疗枕大神经痛随机对照试验的报告质量。

方法: 计算机检索 Cochrane Library、PubMed、Web of Science、Embase、中国知网、维普、万方和中国生物医学文献数

据库, 检索时间从各数据库建库至 2024-05-20, 由2名研究者使用 CONSORT 声明、STRICTA 清单和 Cochrane 风险偏倚评估工具独立评估纳入随机对照试验的报告质量, 由第三位研究者负责解决过程中产生的分歧。

结果: 共纳入62篇文献。在 CONSORT 声明的评估中, 报告率< 50%的条目占全部条目的59.46%(22/37), 主要包括“文题能识别是随机临床试验(1/62, 1.61%)”“如何确定样本量(7/62, 11.29%)”“随机的实施(1/62, 1.61%)”“盲法(1/62, 1.61%)”和“资金来源(4/62, 6.45%)”等项目。在 STRICTA 清单的评估中, 报告率< 50%的条目占全部条目的29.41%(5/17), 主要包括“针刺细节(7/58, 12.07%)”“治疗的环境和背景(0/58, 0%)”和“针灸师的相关描述(0/58, 0%)”等项目。

结论: 针灸和手法治疗枕大神经痛的随机对照试验报告质量偏低, 提示未来的研究人员需要在试验设计、实施和报告过程中严格遵守 CONSORT 声明及 STRICTA 清单的要求, 这将促进该领域研究的规范化和标准化, 增强研究结果的可靠性和可重复性。

关键词: 报告质量; 针灸; 推拿; CONSORT 声明; STRICTA清单; ROB; 临床随机对照试验; 枕大神经痛

作者贡献: 刘利国和郭汝松进行文章设计。刘利国进行论文撰写。刘利国和范志勇进行了文献数据检索。丘明旺和黄艳玲分别独立进行质量评价, 出现分歧则由吴山评估解决。郭汝松和吴山审核论文。

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基金资助: 国家自然科学基金(81874511), 项目负责人: 吴山; 广东省名中医传承工作室建设项目(102018007), 项目负责人: 范志勇; 广东省第四批名中医承项目(102018105), 项目负责人: 吴山

引用本文: 刘利国, 丘明旺, 黄艳玲, 范志勇, 吴山, 郭汝松. 基于 CONSORT 声明和 STRICTA 清单评价针灸推拿治疗枕大神经痛的随机对照试验报告质量 [J]. 中国组织工程研究, 2025, 29(30):6566-6573.