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Evaluation of acupuncture treatment based on CONSORT and STRICTA quality evaluation of randomized controlled trial report on neurogenic tinnitus

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Abstract: *Objective: To evaluate the methodological quality, report quality and intervention measure report quality of randomized controlled trial of acupuncture treatment for neurogenic tinnitus. Methods: The randomized controlled trial of acupuncture treatment of neurogenic tinnitus included in PubMed, CNKI, the full text database of Chinese scientific and technological journals of Vip, Wanfang data resource system, and the Chinese biomedical literature database from January 1, 2013 to December 31, 2022 was searched by computer. Refer to CONSORT expansion statement and STRICTA list for data extraction. The methodological quality and report quality of the included study were evaluated based on the CONSORT expansion statement, and the intervention report quality was evaluated based on the STRICTA list. Results: A total of 72 articles were included in the evaluation, including 69 Chinese articles and 3 English articles. After reading the literature, it was found that most of the literature had problems such as irregular randomization, insufficient process of subjects, general lack of blind related design, outcome evaluation to be improved, acupuncture details to be further described, and no details of acupuncture and moxibustion teacher qualifications. Conclusion: At present, the quality of clinical randomized controlled trials of acupuncture treatment for neurogenic tinnitus is generally poor, which has a certain impact on the reliability and reference value of the research results. It is suggested that in the future clinical trial research, the design, implementation and literature report of clinical trial should be described in strict accordance with the CONSORT statement and STRICTA standard.*

Keywords: *Nervous tinnitus; Acupuncture treatment; Report evaluation; CONSORT; STRICTA*

1. Introduction

Nervous tinnitus (NT) is a common clinical disease. It refers to the abnormal sound sensation produced by people without any external stimulation, such as cicadas and buzzing in the ear, which can exist temporarily or continuously, causing people to be disturbed [0]. Epidemiological studies show that the incidence of tinnitus in adults is about 10% to 15%, and 20% of patients need clinical intervention [0]. In recent years, modern medicine has mainly treated the disease by nourishing nerves, improving circulation drugs, surgery and other methods, while the external treatment of Chinese medicine represented by acupuncture and moxibustion has achieved good clinical effects [0].

Randomized controlled trials (RCTs) are the authoritative design scheme for the human medical community to verify the efficacy judgment of intervention measures. The quality of research and report can have a direct impact on the efficacy judgment of intervention measures [0]. The CONSORT statement (2010 version) is applicable to randomized parallel controlled trials and has gained more and more support and recognition [0]. STRICTA standard is an effective reporting guide for acupuncture clinical trial intervention measures [0]. For the items in the list, the size of the implementation degree determines the sample size of the report quality. The RCTs report quality of acupuncture treatment of tinnitus is evaluated based on the CONSORT statement and STRICTA standard. The research results are reported as follows.

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2. Data and methods

2.1. Document retrieval method

Computer retrieval of Chinese databases: Chinese Journal Full-text Database (CNKI), Vip Chinese Science and Technology Journal Full-text Database (VIP), Wanfang Data Resource System (WF), Chinese Biomedical Literature Database, and the English database PubMed RCT literature on acupuncture treatment of NT. The retrieval time is limited to all documents included in each database from January 1, 2013 to December 31, 2022. Search strategy: the Chinese key words are "nervous tinnitus" and“Needle, Acupuncture, Electroacupuncture, Needleknife, Auricular needling, Sunken cord”.The English search words include: nervus tinnitus and acupunture, needle. (See Figure 1)

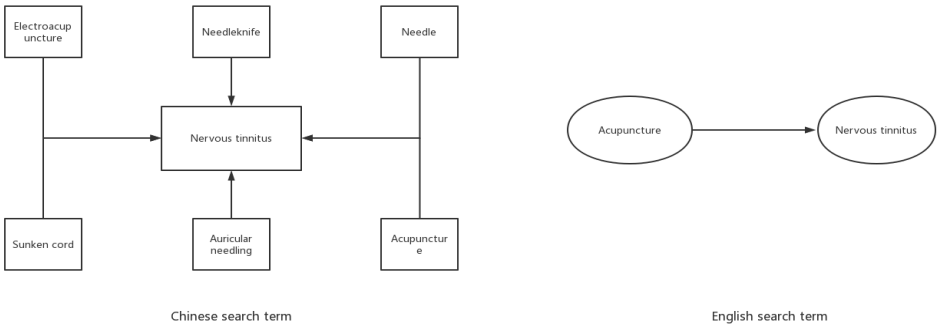

Figure 1: Retrieval strategy flow chart

2.2. Document inclusion criteria

At the same time, the following criteria are met: (1) RCT of NT treated by acupuncture has prompt words such as "random distribution", "random" and "control" in the literature; (2) The subjects were divided into different treatment groups by two or more intervention measures; (3) The experimental group adopted acupuncture or acupuncture therapy combined with other therapies (including ear acupuncture, electroacupuncture, catgut embedding, etc.) as its intervention means. (4) Academic journals.

2.3. Exclusion criteria of literature

Meet one of the following criteria: (1) Does not meet the inclusion criteria; (2) Repeated publication or detection of literature; (3) Historical control study; (4) Review, comment, discussion and other non-clinical trials; (5) Animal experiment; (6) Case review and retrospective study; (7) Non-Chinese and English literature; (8) The full text of the literature cannot be obtained.

2.4. Literature screening and data extraction

Import all the detected documents into NoteExpress 3.5, first eliminate the duplicate detected documents, then read the literature title and abstract to screen out the obviously unrelated documents, then read the full text to screen out the documents that meet the inclusion criteria, and finally include the documents that meet the research criteria. Extract the published year, published journal, author and CONSORT statement, STRICTA standard entries from the original text and enter them into Excel 2003.

2.5. Quality evaluation method

25 standards of CONSORT (2010) and 6 standards of STRICTA were used to evaluate the quality of literature reports. Select two researchers who have no direct interest to answer "yes" or "no" to the report item by item and cross-check it. When the results are different, they will negotiate to solve it. Finally, count the number of literature reports of each item in CONSORT and STRICTA standards and the percentage of the total number of articles.

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3. Results

3.1. Literature search results

A total of 669 (15) papers were detected, 322 duplicate papers were screened, 187 papers that were obviously unrelated were screened through reading topics and abstracts, 160 papers that met the inclusion criteria were screened through reading the full text, and 85 papers were excluded according to the exclusion criteria, including 7 papers published repeatedly, 19 non-randomized control experiments, 62 other experiments, and 72 papers were finally included. (See Figure 2).

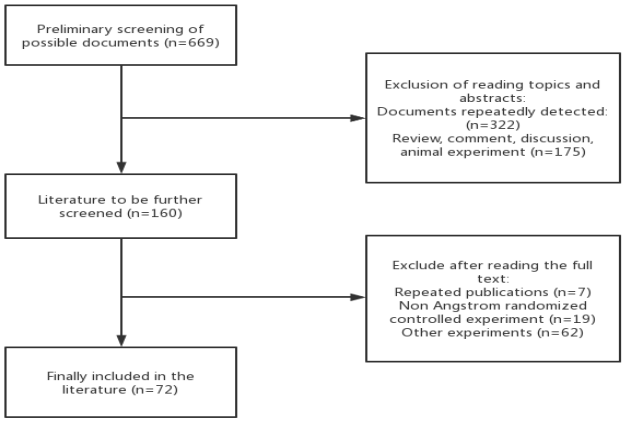

Figure 2: Document retrieval flow chart

3.2. Included in annual distribution

From 2013 to 2020, the number of documents issued increased, and then decreased. (See Figure 3)

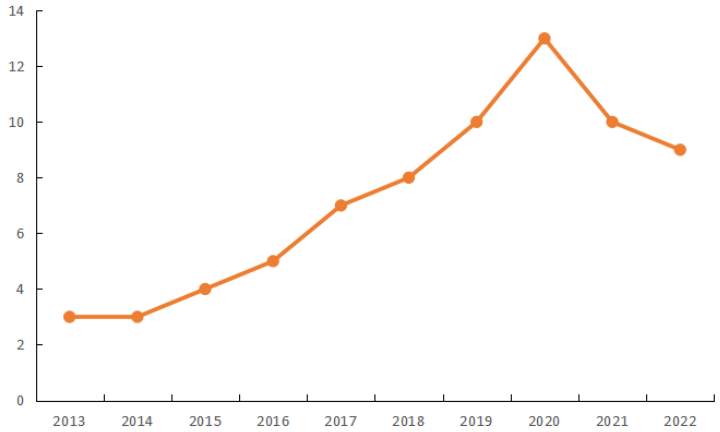

Figure 3: Annual document issuance trend

3.3. CONSORT statement

According to the latest version of the 2010 CONSORT statement, a total of 37 items were evaluated for the quality of 72 literature reports. The results are shown in Table 1.

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Table 1: CONSORT evaluation results of 72 articles on acupuncture treatment of neurogenic tinnitus

Thesis part, theme and project	describe	Chinese literature (69)		English literature (3)	
		Number of articles (n)	Percentage	Number of articles (n)	Percentage
Title and abstract					
1a	Random control of text prompts	0	0	2	66.6
1b	Structured Summary	68	98.55	2	33.3
Foreword					
Background and purpose					
2a	Background and principle explanation	52	75.36	3	100
2b	Specific purposes and assumptions	12	17.39	3	100
method					
Experimental design					
3a	Describe the experimental design method (such as parallel design, factorial design),inclusive distribution ratio	8	11.59	3	100
3b	Significant changes in the test method after the start of the test are given (if qualified standard changes) and reasons	0	0.00	0	0
Subjects					
4a	Eligibility criteria for participants	100	100	3	100
4b	Place and place of data collection	100	100	3	100
Intervention 5	Describe the exact details of each group of interventions in order to repeat the trial, how and when these interventions were implemented	68	98.55	3	100
Final result					
6a	Clearly define the main and secondary outcome indicators, including how and when to evaluate them	63	91.30	3	100
6b	All changes and causes of test outcome indicators after the start of the test	2	2.90	0	0
Sample size					
7a	Specify how the sample size is determined	61	88.41	2	66.6
7b	Explain the interim analysis and the criteria for terminating the test as much as possible	2	2.90	0	0
Randomized sequence generation					
8a	Method of describing random distribution order	43	62.32	2	66.6
8b	Describe the type of randomization and any restrictions (such as the sample size of each partition group and each partition group)	8	11.59	2	66.6
Assign Hidden 9	Describe the method of using random allocation (such as consecutively numbered containers) to hide the allocation steps before implementing the intervention	4	5.80	3	100
Implementation 10	Who generated the allocation order, who recorded the participants, and who assigned the participants to each group	2	2.90	1	33.3
Blind method					
11a	Describe as much as possible who is set up after the intervention (such as evaluators, subjects, medical staff) and how to do it	3	4.35	2	66.6
11b	Describe similarities between interventions	0	0	0	0
Statistical methods					
12a	Statistical methods for comparing primary and secondary outcomes in each group	60	86.96	3	100
12b	Methods of recording additional analysis such as subgroup analysis and adjustment analysis	0	0	0	0
Result					
Subject flow					
13a	Record the number of people in each group randomly assigned to receive the expected treatment and analyze the main outcome	55	79.71	3	100
13b	Describe the number and reason of randomization withdrawal and elimination in each group	3	4.35	2	66.6
Recruitment of subjects					
14a	Record recruitment and follow-up dates	11	15.94	2	66.6
14b	Record the reasons for ending and terminating the test	0	0	0	0
Baseline data 15	Describe the baseline data and clinical characteristics of each group with tables	12	17.39	3	100
Number of people analyzed 16	Record the number of participants (denominator) of each group entering the analysis, and whether the analysis is conducted between the originally designed groups	64	92.75	3	100
Outcome and evaluation					
17a	Summarize the primary and secondary outcome indicators of each group, the magnitude and	65	94.20	3	100

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	accuracy of the evaluation effect (such as 95% CI)				
17b	For the secondary outcome indicators, it is recommended to state the absolute and relative effects	1	1.45	1	33.3
Auxiliary analysis 18	Report all other analysis results, such as subgroup analysis and adjustment analysis, and point out the pre-specified part and exploratory part	1	1.45	1	33.3
Hazard 19	Any hazards or unexpected effects of each group	6	8.70	2	66.6
Discuss					
Limitations 20	Point out the limitations, potential bias, imprecision and diversity of analysis of the test	7	10.14	3	100
Universal significance 21	Point out the universal significance of the test results (external effectiveness, applicability)	62	89.86	3	100
Interpretation 22	Explain the results, weigh the interests and consider other evidence	30	43.48	3	100
Other information					
Registration 23	Test name and registration number	0	0	1	33.3
Test plan 24	Try to tell where to find the complete test plan	0	0	1	33.3
Funding 25	The source of sponsorship or other support (such as providing drugs), and the role of sponsors	16	23.19	1	33.3

3.4. STRICTA standard

The quality of 72 literature reports was evaluated according to 17 items of 6 items in the latest version of STRICTA standard. The results are shown in Table 2.

Table 2: STRICTA evaluation results of literature on acupuncture treatment of neurogenic tinnitus

Intervention project	detailed catalogue	Chinese literature (69)			English literature (3)	
		Number of articles (n)	Percentage		Number of articles (n)	Percentage
Rationality of acupuncture treatment						
1a	Types of acupuncture treatment	69	100		3	100
1b	Reasons for acupuncture treatment	50	72.46		3	100
1c	Literature basis of acupuncture treatment principle	40	57.97		0	0
Details of acupuncture						
2a	Number of needles per treatment unit for each subject	0	0		0	0
2b	Acupoint name	69	100		3	100
2c	Needle depth	42	60.87		1	33.3
2d	Induced body reaction	48	69.57		3	100
2e	Acupuncture stimulation mode	63	91.30		3	100
2f	Retention time	61	88.41		2	66.6
2g	Needle type	62	89.86		3	100
Treatment plan						
3a	Number of treatment units	62	89.86		3	100
3b	Frequency and duration of treatment units	52	75.36		3	100
Other interventions						
4a	Details of other intervention measures applied to acupuncture group	48	69.57		2	66.6
4b	Treatment site and relevant information	0	0		0	0
Background of the therapist 5		2	2.90		3	100
Control or control intervention						
6a	Cite data to explain the rationality of the selection of comparison	0	0		1	33.3
6b	Accurately describe the comparison or comparison measures	51	73.92		3	100

4. Discussion

4.1. The results of CONSORT evaluation

CONSORT evaluation Use the items of the CONSORT statement to evaluate the report quality of acupuncture treatment of neurogenic tinnitus. The results show that most of the items have problems of different degrees, as follows.

4.1.1. Sample size estimation

Sample size estimation refers to the estimation of the number of observation objects required in the scientific research experiment with reliable conditions or data in the process of clinical experimental

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research and investigation and research, and reflects the principle of repeatability in the research design. If the sample size is too small, the overall accuracy is poor, and the test efficiency is low, which has an impact on the demonstration strength of the real outcome and the overall difference; If the sample size is too large, it will introduce more confounding factors and consume unnecessary manpower, material resources and time. Therefore, scientific sample size estimation is an essential and important step in the clinical trial process [0]. Among the documents included in this study, 61 (88.40%) Chinese documents described the sample size estimation, and 2 (66.66%) English documents described the sample size estimation.

4.1.2. Subjects

The 72 articles included clearly informed the eligibility criteria of participants, the place and place of data collection, but most of the articles focused on the diagnostic criteria of NT, and the inclusion criteria and exclusion criteria of the study were not discussed. In the detailed classification, only 12 (17.39%) of the Chinese literature used tables to describe the data of the subjects, while the English literature was mentioned. In addition, the Chinese and English literature did not report the subject flow chart, indicating that there are still deficiencies in this aspect. In the future, researchers need to pay enough attention to increase the reliability of the test.

4.1.3. Hidden random distribution

Most of the 72 included literatures mentioned "random", but 43 of them (62.32%) described the specific random distribution method in Chinese literature and 2 of them (66.66%) in English literature; As for the description of the specific implementer of the random allocation sequence, all the studies have not been reported. Only 4 (5.80%) of the Chinese literature have reported the implementation of allocation concealment, while the English literature has reported. This shows that the 69 Chinese literatures included are insufficient in the implementation of random allocation and grouping concealment, while the English literatures are more comprehensive by comparison. Randomized allocation and grouping concealment can largely avoid subjective selective bias, enhance the comparability between groups, and make the clinical trial design and implementation process more rigorous and standardized [0]. In the process of writing and discussing in the future, researchers should pay attention to the study of random hidden knowledge, strengthen the integrity of scientific research ideas, and master the types and methods of random reporting, and the grouping hidden measures such as consecutively numbered containers.

4.1.4. Blind method

Because the results of the test are closely related to the degree of implementation of blind method, it can effectively avoid information bias due to the research design. The verification of blind method is gradually attracting attention and is recommended to be included in the unified standard CONSORT statement of the test report [0]. The clinical trial of acupuncture and moxibustion has its particularity, and the evaluators cannot understand whether the patients have received the correct filiform acupuncture, so it is difficult to blind the subjects and acupuncture and moxibustion, but the indicator evaluators and data statisticians can be blinded according to the grouping of the subjects [0]. Only 3 (4.35%) of the Chinese literature included in the evaluation reported that the blind method was implemented, while all the English literature described it.

4.1.5. Outcome and evaluation

With the continuous improvement of scientific research methods and conditions, mainstream academic journals at home and abroad require a detailed description of the outcome of the experiment, the effect size and accuracy of the outcome, so as to further strengthen the level of the test results and demonstration strength [0]. Among the 72 articles included, the Chinese literature [0] and the English literature [0] each have 1 article describing the effect size and accuracy of the outcome, accounting for 1.45% and 66.66% respectively. In future research work, it is necessary to describe the relative effects of outcomes and evaluation.

4.1.6. Selective report

The 72 Chinese and English documents included did not mention the trial registration number, trial protocol and funding, and the report of clinical trial background and specific information was missing, which was not conducive to the transparency of acupuncture clinical trial and reduced the quality of acupuncture clinical trial research, and should be enriched in future research reports.

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4.2. STRICTA evaluation

4.2.1. Acupuncture theoretical basis and acupuncture details

Among the 72 documents included in the evaluation, all Chinese and English documents describe the types of acupuncture treatment in terms of acupuncture theoretical basis; There were 50 Chinese (72.46%) and 3 English (100.00%) articles describing the reasons for acupuncture treatment; There are 40 articles (57.97%) in Chinese literature describing the literature basis of acupuncture treatment principle, but the English literature does not cover this item. In terms of acupuncture details, 62 Chinese literatures (89.86%) and 3 English literatures (100.00%) described the specific information of the needles used in the study, including specifications, dimensions, manufacturers and materials; There are 42 Chinese literatures (60.87%) and 1 English literature (33.33%) describing the depth of each acupuncture point; There were 48 Chinese (69.57%) and 1 English (33.33%) articles describing the body response induced by acupuncture. Acupuncture details determine the rigor of the experimental design, and also reflect the scientific research literacy of scientific researchers. Whether or not to master the acupuncture details will directly affect the credibility of the conclusions drawn by the research institute [0]. In this study, we need to pay attention to one point. The number of needles used for each treatment unit of each subject is not mentioned in the Chinese and English literature included in the evaluation. We should improve this.

4.2.2. Control intervention measures

The included literatures describe the control measures accurately, but only one (33.33%) English literature cited data to explain the rationality of the selection of control measures, while the Chinese literature did not mention them. The control test is one of the methods to verify the systematic error in the design of the measurement method. In the process of clinical research, in order to test the therapeutic effect of some therapies, the trial control will be set up. The intervention measures of the trial control are recognized as clinically effective measures [0]. Therefore, it is suggested that future researchers can further describe the trial control intervention measures in clinical research practice, including its theoretical support, design source, etc.

4.2.3. Qualification of acupuncture and moxibustion

Among the 72 literatures included in the evaluation, 2 (2.90%) in Chinese described the time acupuncture and moxibustion received relevant training, the length of clinical practice, and the reserve of disease expertise in this field, while the English literature mentioned it [0]. The qualifications of acupuncture and moxibustion play a very important role, so it is necessary to explain this aspect in future literature reports.

5. Conclusion

To sum up, the quality evaluation results of the clinical randomized controlled trial of acupuncture treatment of neurogenic tinnitus using the CONSORT statement and STRICTA standard show that there are some problems in the quality of the Chinese and English literature reports. Generally speaking, the Chinese literature is more prominent than the English literature. However, due to the uneven sample size of the Chinese and English literature, the quality evaluation results will be greatly deviated. Therefore, this gives readers doubts about the scientific nature of the clinical trial design, the correctness of the implementation and the authenticity of the conclusions reported in these documents, and has low reference value for researchers who intend to carry out research in this direction in the future. In view of the above deficiencies and reasons, improve the quality of literature report on acupuncture treatment of neurogenic tinnitus RCTs.

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