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Evaluation on quality of clinical trials reports about treating acute peripheral facial palsy with acupuncture by using CONSORT and STRICTA

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Abstract: *In order to improve the reporting quality of randomized controlled studies on acupuncture treatment of acute peripheral facial paralysis, a search was conducted on CNKI, Wanfang database, VIP, and PubMed databases for randomized controlled studies on acupuncture treatment of acute peripheral facial paralysis. The search period was from January 2016 to present. Evaluate the quality of reports included in the literature using the CONSORT statement and the sub items in the STRICTA standard. A total of 290 randomized controlled studies were included in this article. Among them, 18 articles (82.8%) reported random sequence generation methods, and 12 articles (55.5%) reported allocation concealment. There is no literature that provides a detailed description of the experimental design, and 22 articles (100%) reported baseline data in accordance with the requirements of CONSORT. In the description of intervention measures, all included studies did not describe the reasons for the selection of acupuncture methods or the background of therapists. From this, it can be concluded that although the number of randomized controlled studies on acupuncture treatment of acute peripheral facial paralysis is increasing, the quality of most clinical research reports is poor. Evaluation results based on the CONSORT statement show that most literature has not standardized reporting on sample size, randomization, blinding, allocation concealment, adverse events, etc. as required; The evaluation results based on the STRICTA standard showed that most literature did not provide standardized reports on treatment plan basis, treatment details, other methods, physician background, and the rationality of the control group as required. This indicates that most researchers have failed to attach importance to the standardized reporting of clinical research. Future researchers should pay attention to the design of research protocol details and strictly follow international reporting standards for reporting.*

Keywords: *Peripheral facial paralysis; The acute phase; Acupuncture; Reporting quality; CONSORT; STRICTA*

1. Introduction

Peripheral facial nerve paralysis (PFP) is a common clinical disease characterized by unilateral facial paralysis. Epidemiological data show that the incidence rate of the disease in China is 4.26%, accounting for 10% of nervous system diseases [1]. A considerable number of patients missed the treatment in the acute phase and left facial nerve dysfunction symptoms such as facial muscle weakness, facial muscle synkinesis, facial muscle spasm or crocodile tears, which not only affected the work and life of patients, but also had a negative impact on patients' psychology. The acute phase of PFP is generally 3 to 7 days after the onset. Western medicine usually uses corticosteroids, antiviral drugs, B vitamins and other drugs to improve the neuroedema injury and promote the recovery of facial nerve function [2]; Traditional Chinese medicine chooses traditional acupuncture therapy on this basis to dispel wind, dredge collaterals, and regulate meridians and tendons. A large number of clinical studies have shown that giving facial nerve benign stimulation in the acute phase of PFP will greatly improve the cure rate. A large number of clinical studies have shown that giving facial nerve benign stimulation in the acute phase of PFP will greatly improve the cure rate. Traditional Chinese medicine uses acupuncture therapy for mild and superficial stimulation in the treatment of acute phase PFP, mainly by selecting distal acupoints, which can effectively shorten the treatment cycle. With the increasing number of PFP patients and the

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recognition of acupuncture efficacy at home and abroad, the number of clinical reports on acupuncture intervention in the acute phase of PFP has increased, and has always been a hot topic in clinical research. The use of internationally recognized CONSORT statements and STRICTA standards to evaluate the quality of RCT literature reports on acupuncture treatment of acute phase PFP can help promote the standardization of such research reports and enhance the international recognition of the effectiveness of acupuncture early intervention in PFP treatment.

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 PFP. The retrieval time is limited to all documents included in each database from January 1, 2018 to December 31, 2022. Search strategy: the Chinese key words are "acupuncture " and "acute facial neuritis, acute peripheral facial paralysis, acute facial nerve paralysis, acute Bell facial paralysis include 'clinical research'", and use high-level retrieval method combined with subject words. The operation of restriction methods varies according to different databases ". The English search words include: acute facial nerve paralysis and acupuncture. (See Figure 1)

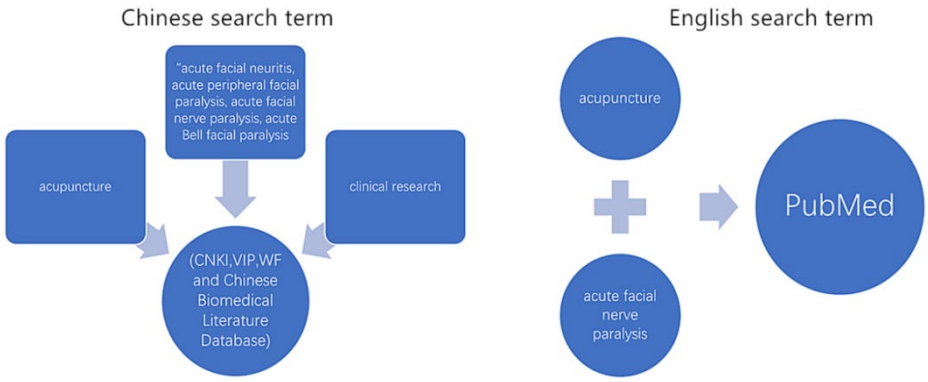

Figure 1: Retrieval strategy flow chart

2.2. Inclusion criteria of literature

(1) Research type: RCT; (2) Research object: Diagnosed acute phase patients with PFP, i.e. 3-7 days of onset; (3) Intervention measures in the experimental group: simple acupuncture, excluding acupuncture combined with traditional Chinese medicine, Western medicine, moxibustion and other treatments. (Except for basic treatment in both the experimental and control groups)

2.3. Document exclusion criteria

(1) The research subjects were patients with central facial paralysis, Hunt's facial paralysis, or PFP during the remission period; (2) The intervention measures in the experimental group include not only acupuncture, but also medication treatment; (3) Unable to obtain full text literature; (4) Historical controlled studies, animal experiments, case study studies, reviews, theoretical discussions, reviews, and other non clinical trial reports.

2.4. Literature Screening and Data Extraction

Step: Import the search literature title into NoteExpress3.0 according to the inclusion and exclusion criteria above, identify and delete the same literature between and within the literature library; Read the titles and abstracts of the remaining literature and exclude clearly unrelated literature; Finally, read through the remaining literature and select the literature that meets the inclusion criteria, becoming the final literature that needs to be studied. The content of data extraction includes: author, year of publication, CONSORT statement, STRICTA standard entries, etc. Record the above extracted data in an Excel 2021 table.

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2.5. Literature quality evaluation methods

Using an Excel spreadsheet to extract literature, extract sub items from the CONSORT statement and STRICTA standard as the subject matter. Two evaluators will evaluate the included RCTs individually based on each sub item. If consensus cannot be reached, a third evaluator will arbitrate. Finally, calculate the number of articles reported for each item in the CONSORT statement and STRICTA standard, as well as the percentage of reported articles in the total included literature.

3. Results

3.1. Literature search results

A total of 290 articles were detected, 32 duplicate articles were screened out, 116 significantly unrelated articles were screened out through reading questions and abstracts, 80 articles met the inclusion criteria were screened through full text reading, 51 articles were excluded based on exclusion criteria, and 22 Chinese articles and 0 English articles were ultimately included. (The specific situation is shown in Table 2, 3)

3.2. CONSORT statement

The quality of included literature reports was evaluated using the CONSORT statement, as shown in Table 1.

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

Thesis part, theme and project	describe		Chinese literature (22)		English literature (0)	
			Number of articles (n)	Percentage	Number of articles (n)	Percentage
Title and abstract	Random control of text prompts		0	0	0	0
	Structured Summary		21	95.5	0	0
Foreword	Background and purpose		18	82.2	0	0
method	Experimental design		22	100	0	0
	Research object		22	100	0	0
	Location of data collection		22	100	0	0
	Intervening measure		22	100	0	0
	Outcome indicator		22	100	0	0
Sample size	Specify how the sample size is determined		2	9.0	0	0
	Random sequence generation	Random type	18	82.8	0	0
		Allocation concealment	12	55.5	0	0
		Implementation of hidden allocation	1	4.5	0	0
Blinding			4	18.2	0	0
Statistics			22	100	0	0
Result	Subject mobility		9	40.9	0	0
	Baseline data and clinical features		22	100	0	0
	data analysis		22	100	0	0
	Outcome and Evaluation		22	100	0	0
	Auxiliary analysis		0	0	0	0
	AEs		11	50	0	0
Discuss	boundedness		15	68.2	0	0
	Universal significance: the significance of experimental results		21	95.5	0	0
	Explanation: Explain the results and consider other evidence		17	77.3	0	0
additional information	Registration: Name and registration of the experiment		0	0	0	0
	Test plan: inform where to find the complete test plan		0	0	0	0
	Fund projects		2	9	0	0

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3.3. 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

project	describe	Chinese literature (22)		English literature (0)	
		Number of articles (n)	Percentage	Number of articles (n)	Percentage
Theoretical basis for acupuncture	Acupuncture type	20	90.9	0	0
	Basis for the mechanism of acupuncture	18	81.8	0	0
Acupuncture treatment details	Acupoint name	21	95.5	0	0
	Number of needles	2	9	0	0
	Needle depth	15	68.2	0	0
	Induced body reaction	6	27.3	0	0
	Acupuncture stimulation mode	2	9	0	0
	Retention time	4	18.2	0	0
	Needle type	22	100	0	0
Treatment plan Number of treatment units	Treatment plan	22	100	0	0
	Number of treatment units	22	100	0	0
Other interventions	Basic treatment	10	45.5	0	0
	Treatment site and relevant information	0	0	0	0
Background of the therapist	Physician qualifications	1	4.5	0	0
Control or control intervention	Cite data to explain the rationality of the selection of comparison	6	27.3	0	0
	Accurately describe the comparison or comparison measures	19	86.4	0	0

4. Conclusion

4.1. CONSORT evaluation

We evaluated the report quality of acupuncture treatment for peripheral facial paralysis RCTs using the CONSORT statement entry. As a result, most of the items have to varying degrees, as follows:

4.1.1. Sample quantity calculation

In the literature included in this study, there are 39 samples, 1 [2] (4.5%); the maximum sample quantity is 90 cases, 2 [3,4] (9%), of which the sample quantity is ≥60 There are 19 examples (86.4%); only 2 [3,5] (9%) simply report the estimated method of the sample, but the detailed formula or calculation method is not mentioned. Objects and related clinical data are estimated through SPASS and MEDSCI sample calculation software and other estimates to improve the scientificity of clinical research.

4.1.2. Subject

The included documents all reported the qualified standards of the subjects, the place and place of data collection. Most of the literatures were relatively uniform in the diagnostic standards of target research diseases, and they all adopted the standards of Chinese and Western medicine diagnostic standards. However, in the nearly half of the literature, the recruitment and flow of the subject were not stated. This suggests that clinical research should fully record the information that the subject is included in the ending to ensure the credibility of the test results.

4.1.3. Random distribution hidden

Among the 22 documents included, 18 documents [6-24] (82.8%) describe specific random distribution

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methods; all research only 1 literature [3] (4.5%) The person who implemented hidden allocation was told as researchers. This shows that all documents incorporated in this study are inadequate in implementing random distribution hidden. In order to avoid selective bias and enhance the comparability of the group, researchers should pay attention to the randomization of experiments, improve the learning capacity of random distribution, and clear the random distribution methods and personnel in the literature.

4.1.4. Blind method

Due to the particularity of clinical research on acupuncture, and acupuncture efficacy is related to operating physicians' methods, it is difficult to implement blind methods for subjects and acupuncture doctors. In the literature, 4 articles [3,10,12-13] (13.64%) informed the implementation of the blind method and the measurement of blind objects and blind measures, but only one [3] was a double-blind method, and the rest was used by single blindness. Law. This prompts that this study is incorporated into the literature in the implementation of blind methods. Although acupuncture clinical trials are indeed difficult to implement blind method, especially the double-blind method, subjects and data statisticians have less intersection, and they can implement blind method.

4.1.5. Ending and evaluation

The income of the literature describes the effect size and accuracy of the ending, α=0.05.

4.2. STRICTA evaluation

4.2.1. Principle of acupuncture

Most of the literatures included in the types of acupuncture and acupuncture mechanisms are reported.

4.2.2. Acupuncture details

Including 21 articles (95.4%) mentioned the name of the acupoint, only one [22] is a local skin with plum blossom needle stabbing disease. Most of the stimulus methods, needle types. Among them, the needle retention time is mentioned 18 (82.8%), and the remaining 4 articles are not mentioned because there is no need to leave a needle; there are 14 in depth of the needle [6,8,10-11,13-22] (64.6%). And, the triggered body response was only 6 [14-16, 21-22], and the number of needles was only 2 [3,4] clearly mentioned. None of the treatment venues and related information were explained. Although acupuncture details are only a small part of the clinical trial report of acupuncture, they are neglected to regulate during acupuncture operations. Such research has no practical reference or practical significance in clinical practice.

4.2.3. Acupuncture therapist's background

Only one article included in the document [13] (4.5%) mentioned the qualifications of acupuncture physicians, and only mentioned that the surgeon is a uniform trainer who has not mentioned the professional background. The degree of proficiency of acupuncture physician skills and the level of professionalism in the art will have a direct impact on the test results, so it should be introduced in detail during the literature report.

4.2.4. Contrast intervention measures

The included literature is more accurately described by the control measures, but none of them quoted the information to select the rationality of the control. RCTS usually has a test control. Compared with clinical and similar treatment measures, reasonable choice of control intervention measures can be an objective explanation of improvement of research efficacy.

5. Conclusion

CONSORT declares and its expansion version of STRICTA as a reference and recommendation of the report standards in clinical scientific research methods. Its principles and methods have universal guiding significance. It is not only suitable for modern medicine, but also for the combination of Chinese medicine and traditional Chinese and Western medicine. It can promote the further development of the clinical trials of Chinese medicine, make the research results of traditional Chinese medicine more reliable, objective and argumenting intensity, and promote Chinese medicine to the world [25]. In all included documents, they did not fully meet the Consort statement and Stricta standards. In the CONSORT statement, most literature issues are concentrated in these aspects: the article does not indicate that the article is a random control test, lacks specific sample calculations, does not explain the

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hidden embodiment of random distribution. The ending evaluation, auxiliary analysis, and the source of the test plan, registration. The problem in the STRICTA standard entry is: without explanation of the treatment venues and related information, the specific number of acupunctures is not indicated, and the lack of the background introduction of the appliance physician. In addition, the author considers that this study has not been retrieved in English literature, which is related to the controversial intervention in the acute period of PFP. This suggests that researchers should refer to the Consort statement and Stricta standards in the clinical study of acupuncture in PFP acute period to enrich the structure and content of the article, improve the quality of the article, and expand the influence of the research results. The shortcomings may exist in this study: the standards of literature are strict, and the number of literatures is limited, which may cause results bias. I hope that in the future, researchers will complete the quality report of articles with larger samples under the allowable conditions of manpower and material resources to better guide researchers to researchers We carried out research reports in related fields.

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