

## Literature Research

## Approach to Assess Adequacy of Acupuncture in Randomized Controlled Trials: A Systematic Review\*

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**ABSTRACT** **Objective:** To summarize and identify the available instruments/methods assessing the adequacy of acupuncture in randomized controlled trials (RCTs) for proposing a new improved instrument. **Methods:** A systematic literature search was carried out in 7 electronic databases from inception until 21st November 2022. Any study evaluating the adequacy or quality of acupuncture, specifying specific acupuncture treatment-related factors as criteria of subgroup analysis, or developing an instrument/tool to assess the adequacy or quality of acupuncture in an RCT was included. Basic information, characteristics and contents of acupuncture adequacy assessment were presented as frequencies and percentages. **Results:** Forty studies were included in this systematic review. Thirty-five studies (87.50%) were systematic reviews, none of which used formal methods to develop the assessment instruments/methods of acupuncture adequacy; of 5 methodological studies, only 1 study used a relatively formal method. Thirty-two studies (82.05%) assessed the components of acupuncture, while 7 (17.95%) assessed the overall quality of acupuncture. An independent assessment instrument/method was used to assess acupuncture adequacy in 29 studies (74.35%), whereas as one part of a methodological quality assessment scale in 10 (25.65%). Only 9 (23.00%) studies used the assessment results for subgroup analysis, sensitivity analysis or the criteria for inclusion in the meta-analysis. **Conclusion:** Assessment contents for adequacy or quality of acupuncture in RCTs hadn't still reached consensus and no widely used assessment tools appeared. The methodology of available assessment instruments/scales is far from formal and rigorous. A new instrument/tool assessing adequacy of acupuncture should be developed using a formal method.

**KEYWORDS** acupuncture, adequacy assessment, quality, randomized clinical trial, systematic review

Randomized controlled trials (RCTs) are considered as the highest level of evidence among the current hierarchy of primary studies for evaluating the effect of medical interventions, therefore they are used to test the efficacy and effectiveness of acupuncture.<sup>(1)</sup> Over the past several decades, the number of acupuncture RCTs have increased rapidly.<sup>(2,3)</sup> However, acupuncture's treatment effect varies largely across trials, even the results between RCTs on the same topic/disorder are conflicted.<sup>(4)</sup> The reasons of the variations include methodological and clinical factors, such as risk of bias, eligibility criteria of participants, comparator type, dose (adequacy) of acupuncture.<sup>(5)</sup> Internal validity assessed by risk of bias has generated a considerable number of instruments/checklists to assess the scientific rigour of an RCT.<sup>(6)</sup> The Cochrane risk-of-bias tool is extensively used to evaluate the methodological quality by systematic reviewers and clinical guideline developers.<sup>(7)</sup> Trials with high risk of

bias usually overestimate the intervention effect.<sup>(8)</sup> As for clinical factors such as participants, interventions and outcomes representative of external validity or generalizability, fewer studies have explored these issues with no consensus on the approach.<sup>(9)</sup> Whatever regimens or techniques of acupuncture used in an RCT, the conclusion of an acupuncture's RCT

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was generalized to acupuncture therapy regardless of their regimen, technique or practitioners. As known, acupuncture is a complex intervention including large number of components influenced by practitioners' expertise and skills. If the internal validity of an RCT is of high quality, but acupuncture regimen, techniques or dose (adequacy) of acupuncture is suboptimal, the conclusion will not reflect the true effect of acupuncture and the evidence will not be interpreted appropriately. Therefore, whether the adequacy of acupuncture used in RCTs is optimal or appropriate need to be assessed.

Experts have been working on how to assess the adequacy or quality of acupuncture used in RCTs since the 1990s. Several approaches have been reported on the assessment of the adequacy or quality of acupuncture in existing studies, such as assessments of description/reporting,<sup>(10)</sup> components of acupuncture,<sup>(11)</sup> and overall quality of acupuncture.<sup>(12)</sup> Some of them set the assessment criteria based on the specific aspects involved in the process of acupuncture treatment, while others made the assessment based on the subjective judgment of the assessors. Among existing instruments, even fewer scales and checklists have been developed using rigorous methods.

The assessment of adequacy of acupuncture used in RCTs depends on full reporting, which has improved since the introduction of the STRICTA guidelines (Standards for Reporting Interventions in Controlled Trials of Acupuncture).<sup>(13,14)</sup> Thus, it made the assessment feasible because the assessment of adequacy of acupuncture used in RCTs focuses on whether the dose of acupuncture, including but not limited to components of acupuncture treatment such as the regimen, techniques, frequency of the acupuncture treatment used, was optimal.

Therefore, identification of a reliable and valid method/instrument to assess the adequacy of acupuncture improves the design of acupuncture regimens in RCTs. We conducted a systematic review to summarize the content, construction, development methods, assessors and application of instruments used to assess the adequacy of acupuncture, in order to develop an appropriate instrument to be applied widely with scientific rigor.

## METHODS

This study followed the Preferred Reporting

Items for Systematic Review and Meta-Analyses (PRISMA).<sup>(15)</sup>

### Definition

Adequacy of acupuncture<sup>(16)</sup> refers to the dose or quality of the intervention that enables the full therapeutic effect of the acupuncture intervention administered in randomized trials, that is, the extent to which the real acupuncture in the treatment group can most benefit patients and this is often associated with the design and delivery of acupuncture protocol, as well as the sham acupuncture as a control producing minimal effect when applied in trials.

### Eligibility Criteria

Any study evaluating the adequacy or quality of acupuncture, selecting particular acupuncture related factors as criteria for subgroup analysis, or developing an instrument/tool to assess the adequacy or quality of acupuncture in an RCT was included. No limitations on interventions, patients, or language were applied.

The studies aiming to evaluate the reporting quality of acupuncture's RCTs were excluded. When a study produced multiple publications as data collection and analysis progressed, the most recent version was selected and the others were placed as supplementary documents for data extraction.

### Search Strategy

The search included 7 databases including China National Knowledge Infrastructure (CNKI), Wanfang, VIP Database for Chinese Technical Periodicals (VIP), China Biology Medicine disc (CBM), PubMed, EMBASE and the Cochrane Library from inception to 21st November 2022. Keywords such as acupuncture, randomized controlled trials and adequacy/quality/dose were used. In addition, the references in included studies and the cited studies of early assessment tools were reviewed to find eligible studies. Appendix 1 provides details of search strategies.

### Literature Selection and Data Extraction

All citations were exported to Endnote X9.0 for eligibility screening. Two researchers (Jiao RM and Xiu WC) independently conducted the title and abstract screening on studies except for systematic reviews. The full text of all systematic reviews were screened. After the full text screening, the references and cited literature of included studies were also reviewed for

eligibility (Shi LJ and Hu XY<sup>a</sup>). A calibration exercise prior to ensure screening quality was conducted. All disagreements were resolved by consulting the third arbiter (Gang WJ).

Standardized forms for data extraction were developed. One researcher (Hu XY<sup>b</sup>) extracted data, and the other researcher (Tian ZY) checked. Discrepancies were resolved by consensus after discussion or consulting the third arbiter (Gang WJ). Data related to assessment details, assessors and its application were extracted. In addition, the results of adequacy assessment for acupuncture used in RCTs in the included systematic reviews were collected.

**Data Analysis**

All collected data, including general information and details of acupuncture adequacy or quality assessments, were summarized descriptively per included study. Basic information of the included studies and characteristics, development methods and content of included instruments/methods to assess adequacy or quality of acupuncture were presented as frequencies and corresponding percentages.

**RESULTS**

The databases search yielded 15,691 records, of which 1,141 studies were eligible through title and abstract screening. We retrieved and screened the full texts, excluded 1,109 ineligible studies, and included 32 studies. Subsequently the references of 32 included studies were screened and a further 3 studies were included. Moreover, 5 studies were included by reviewing the cited literature. Finally, 40 studies were included in this study (Appendix 2).

**Basic Information of Included Studies**

The basic information of the included studies is presented in Table 1. Forty studies were published between 1990 and 2020 (median 2009). The period with the peak of research publications between 2016 and 2020, with 12 publications (30.00%). Nineteen studies (47.50%) were published in journal with impact factor between 6 to 10 points. Thirty-six studies were published in journals which ranked by Journal Citation Reports, and 25 (62.50%) studies were published in the top quarter of high-ranking impact factor journals. Thirty-five (87.50%) was systematic reviews, which assessed the adequacy or quality of acupuncture intervention used. Thirty-nine studies (97.50%)

were published in English. There were a total of 245 authors in the 40 studies with different specialties, and the proportion of authors' specialties varied a lot in studies, with the largest range among acupuncturists (13.33%–100.00%). Europe (15, 37.50%) had the largest number of first authors, followed by America, Oceania, and Asia.

**Table 1. Basic Information of Forty Included Studies**

Characteristics	Study [n (%)]	Characteristics	Study [n (%)]
Publication year		Study type	
1990–1995	3 (7.50)	Systematic review	35 (87.50)
1996–2000	5 (12.50)	Methodological study	5 (12.50)
2001–2005	4 (10.00)	Location of first authors	
2006–2010	8 (20.00)	Asia	6 (15.00)
2011–2015	8 (20.00)	Europe	15 (37.50)
2016–2020	12 (30.00)	America	11 (27.50)
Journal impact factor		Oceania	8 (20.00)
≤3	13 (32.50)	Proportion of authors' specialty <sup>2</sup>	
>3, ≤6	4 (10.00)	Methodologist	12.50–33.33
>6, ≤10	19 (47.50)	Statistician	8.33–44.44
>10	4 (10.00)	Epidemiologist	6.66–66.67
Rank for journal IF <sup>1</sup>		Acupuncturists	13.33–100.00
Q1	25 (62.50)	Other doctors	14.29–100.00
Q2	6 (15.00)	Other	6.66–16.67
Q3	3 (7.50)	Complementary medicine	8.33–50.00
Q4	2 (5.00)	No report	7.69–42.86
Publication language			
English	39 (97.50)		
Other language	1 (2.50)		

Notes: <sup>1</sup>n=36, 4 articles were published in journals without rank. IF: impact factor; Q: quarter. <sup>2</sup>The lowest and highest percentages of experts of each specialty in each article

**Characteristics of Included Instruments/Methods on Assessing Adequacy of Acupuncture**

Table 2 presents the characteristics of included instruments/methods on assessing adequacy or quality of acupuncture intervention. Thirty-nine studies were analyzed in this step, while 1 study was not included due to lack of information on characteristics of acupuncture.<sup>(17)</sup>

An independent assessment instrument/method was used to assess acupuncture adequacy in 29 studies (74.35%), whereas acupuncture adequacy was assessed as one part of methodological quality assessment scale in 10 (25.65%). Most of the studies did not distinguish the styles of acupuncture, and

**Table 2. Basic Characteristics of Included Instruments/Methods on Assessing Adequacy of Acupuncture (n=39)<sup>1</sup>**

Characteristics	Study [n (%)]
Assessment approach	
Independent assessment instruments/methods	29 (74.36)
Part of the methodological quality assessment scale	10 (25.64)
Style of acupuncture assessed	
Chinese medical acupuncture	1 (2.56)
Western medical acupuncture	1 (2.56)
Not reported	37 (94.87)
Assessment content involvement	
Component of acupuncture	32 (82.05)
Overall quality of acupuncture	7 (17.95)
Basis of assessment	
Evaluation instruments/methods <sup>2</sup>	26 (66.66)
Reporting the specific acupuncture aspect	13 (33.33)
Similarity with the assessor's acupuncture treatment <sup>2</sup>	5 (12.82)
Methods or sources for assessment instruments/methods	
Previous methods	21 (53.85)
Specific methods	
Formal	1 (2.56)
Informal	17 (43.59)
Assessor	
Systematic reviewer	24 (61.54)
Experienced acupuncturist	11 (28.21)
Not reported	4 (10.26)
Blind assessment	
Yes	13 (33.33)
No	1 (2.56)
Not reported	25 (64.10)
Grading method of assessing results	
Experience of assessors	5 (12.82)
Assessment score	2 (5.13)
Similarity with assessors' treatment	8 (20.51)
Predefine minimal criteria	1 (2.56)
Application of assessment results	
Subgroup analysis	3 (7.69)
Sensitivity analysis	4 (10.26)
Criteria for inclusion in the meta-analysis	2 (5.13)
Not reported	30 (76.92)
Use of existing instruments/methods <sup>3</sup>	
NICMAN scale	5 (12.82)
G Ter Riet scale	4 (10.26)

Notes: <sup>1</sup>One study considered acupuncture therapy regardless of characteristics of acupuncture due to significant variability and lack of standardization.<sup>(17)</sup> <sup>2</sup>Five studies used both 1 and 3 as the assessment criterion. <sup>3</sup>Only 9 studies used existing evaluation instruments/methods. NICMAN: National Institute for Complementary Medicine Acupuncture Network

1 study clearly put forward that it focused on Western medical acupuncture and 1 for Chinese medicine acupuncture. For assessment content, 32 studies (82.05%) assessed the component of acupuncture, while 7 (17.95%) assessed the overall quality of acupuncture. As for the assessment basis, 26 studies (66.66%) were based on the evaluation criteria, 13 (33.33%) assessed on the basis of whether they reported the specific acupuncture aspect, and 5 (12.82%) of which also considered the similarity with the assessors' acupuncture treatment at the same time. The assessment process of these 5 studies<sup>(18-22)</sup> was divided into two parts: one part was to assess the similarity between the treatment regimen and assessors' own experience, and the other was to evaluate the degree of confidence that acupuncture was applied in an appropriate manner on a visual analog scale (VAS).

Methods or sources for assessment instrument/method varied. Twenty-one studies (53.85%) directly used previous methods, 17 (43.59%) assessed acupuncture adequacy or quality using instruments/methods developed without rigorous methods, and only 1 study (2.56%) used rigorous methods to develop the instruments including Delphi method and reliability testing. Of the 17 studies, 7 specified assessment items arbitrarily<sup>(10,11,18,23-25)</sup> or by data analysis,<sup>(26)</sup> 8 by citing published studies such as STRICTA,<sup>(27-34)</sup> and the remaining 2 by referring to the acupuncturist experience.<sup>(35,36)</sup>

As for the assessors, acupuncture adequacy was assessed by designated reviewers in 24 studies (61.54%), and by experienced acupuncturists in 11 studies (28.21%). And only 4 (10.26%) did not mention the assessors. Of the studies, 13 (33.33%) reported the assessors were blinded to the publication and the results, and only one study explicitly stated that the blinding of assessors was not used. The remaining 25 studies did not report on the blinding of assessors. Sixteen studies graded the assessment results. Of these studies, 5 classified the assessment results according to the experience of assessors,<sup>(10,25,28,32,35)</sup> 2 according to assessment score,<sup>(11,12)</sup> 8 according to the similarity between treatment of assessors and that of the study,<sup>(18-22,26,37,38)</sup> and 1 based on predefined minimal criteria.<sup>(23)</sup>

The assessment results were applied as basis

for subgroup analysis in 3 studies (7.69%), for sensitivity analysis in 4 studies (10.26%) and as the criteria for inclusion in the meta-analysis in 2 studies (5.13%). The remaining 30 studies (76.92%) did not report the application of the assessment results. Appendix 3 presented the assessment results of adequacy or quality of acupuncture and the number of RCTs included by each included systematic review.

As for the use of existing instruments/methods, most of the existing assessment instruments/methods were embedded in the systematic review without forming independent assessment tool and seldom reused by other studies. Only G Ter Riet scale and National Institute for Complementary Medicine Acupuncture Network (NICMAN) scale were applied after development. The former assessed the adequacy of acupuncture within the methodological quality assessment, while the latter was a specially developed tool to assess the adequacy or quality of acupuncture. Among them, G Ter Riet scale has been used for 3 times,<sup>(10,39,40)</sup> and used once after adaptation.<sup>(41)</sup> The NICMAN scale has been verified once<sup>(42)</sup> and applied for 4 times.<sup>(37,43-45)</sup>

### Assessment Contents for Adequacy of Acupuncture

Assessment contents on the acupuncture/quality of acupuncture involved components of acupuncture treatment, information related to control group and other issues, such as study design. Appendix 4 provides summaries on the content of assessment.

For control groups assessed, either sham acupuncture (18, 46.15%) or existing/routine treatment modality (4, 10.26%) was used as assessment items. The remaining 18 studies did not assess the control group. As for the components of acupuncture treatment, the number of treatments (21, 53.85%) was the most frequently assessed item, followed by choice of acupoints (19, 48.71%), needling technique (14, 35.90%), needle sensation induced (13, 33.33%). Additionally, half of the studies assessed the acupuncturists' experience (20, 51.28%). Other aspects of assessment contents, such as population description (6, 15.38%), intervention description (6, 15.38%), comparator description (6, 15.38%), outcome description (6, 15.38%), study design appropriateness (6, 15.38%), were mainly from the NICMAN scale studies, 5 of which were derived

from the PICOS principle (population, intervention, comparator, outcome and setting).

## DISCUSSION

A total of 40 studies were identified on the adequacy or quality of acupuncture from 7 databases from inception to 21st November 2022, most of which were systematic reviews and only a few methodological studies. Of these, in the systematic reviews, no rigorous methods were used to develop the assessment instruments/methods of acupuncture adequacy; as for methodological study, only 1 study used rigorous methods including Delphi method and reliability testing. These studies focused on how to assess and develop assessment criterion of the adequacy of acupuncture used in RCTs, and most of them assessed components of acupuncture, and a few assessed the overall quality of acupuncture. The assessment of the components of acupuncture usually defined the eligibility thresholds as 'adequacy', and the overall quality of acupuncture mostly depended on the personal experience of the assessors. The adequacy or quality assessment of acupuncture in most studies was one step of systematic review without definite assessment method, and a few were one aspect of methodological quality assessment or independent assessment tools, such as NICMAN scale.<sup>(46)</sup> Although the results of acupuncture adequacy assessment were occasionally used as the basis for subgroup analysis, sensitivity analysis or criteria for inclusion in the meta-analysis, most of the results were only used as supporting evidence in discussion rather than as data analysis.

Twenty-one studies (53.85%) used previous instruments/methods to assess acupuncture adequacy and 18 developed new instruments/methods, 17 of the latter (94.44%) did not use rigorous methods to develop the instruments/methods, whereas only 1 study (5.56%) used rigorous methods. It is a complex process to develop acupuncture adequacy assessment tools, and the research methods should be standardized as much as possible. For example, the NICMAN scale was used after it was first developed, then verified and modified to form the final version of the assessment tool. Until now, although there is no methodological guidance specifically for the development of quality assessment tools, we suggested to refer to the guidance for developers of health research reporting guidelines in the future studies.<sup>(47)</sup>

Thirty-two studies (82.05%) assessed the components of the acupuncture treatment, and 7 (17.95%) judged directly from the overall perspective based on the experience of the assessors. Due to the complexity of acupuncture manipulation and numerous influential factors, most studies attempted to standardize the eligibility threshold of these influential factors such as at least 6 treatments,<sup>(27)</sup> at least 1 session per week,<sup>(30)</sup> and the use of standardized acupuncture manipulation,<sup>(46)</sup> but the results were not fully satisfactory. However, if the assessors directly judged from the overall perspective only based on their own experience, it is hard to understand for readers and difficult to repeat for future research. Therefore, it is unrealistic to define the eligibility thresholds for each factor, and it is impossible to develop a unified and effective treatment standard for each disease and different patients in clinical practice. A tool considering the design and implementation of acupuncture regimen should be developed to assess the adequacy of acupuncture, so that experienced acupuncturists can make a comprehensive assessment based on their own experience. Due to the heterogeneity of acupuncture and target diseases or conditions, this tool could include the previous research base and the formulation of the acupuncture regimen, the practitioners skills and expertise, and the rationale of sham acupuncture rather than specific components of the acupuncture treatment.

Only half of included studies had assessed the rationale for the control groups. The rationale of the control group mainly depended on whether the control group matched the purpose of the study. Sham acupuncture as a comparator is usually used in explanatory RCTs, mainly to verify the causal effect under ideal conditions, which is suitable for an efficacy study.<sup>(48)</sup> However, sham acupuncture often included several types, such as superficial needling and non-penetration acupuncture, needling at non-acupoints or acupoints not targeting the intended diseases. Which type and how to implement sham acupuncture is usually associated with the effect size of acupuncture RCTs. Therefore, sham acupuncture should also be considered in assessing the adequacy of acupuncture in RCTs.

Sixteen studies (41.03%) have graded the assessment results of acupuncture adequacy, 9 (23.08%) of which applied assessment results for further analysis, such as subgroup analysis,<sup>(26,29,49)</sup>

sensitivity analysis,<sup>(25,33,35,37)</sup> and inclusion criteria for meta-analysis.<sup>(12,30)</sup> If the grading and application of the results are not displayed, readers cannot reach a unified understanding of the assessment results. The acupuncture adequacy grading can be used as one aspect of evaluation of validity and generalizability of the results from RCT studies; in systematic review/meta-analysis, it can be used as the basis for subgroup/sensitivity analysis or included meta-analysis or evidence strength judgment basis.

The quality of RCTs of acupuncture has come under scrutiny since it appeared in 1970s. STRICTA provided reporting guideline and improved reporting of acupuncture interventions in RCTs. In contrast, although the assessment of adequacy or quality of acupuncture used in RCTs has been conducted since 1990 and varying instruments/methods were used by different studies as above mentioned, there is still no a widely accepted instrument/tool. This systematic review summarized the content, construction, development methods, assessors and application of instruments/methods used to assess the adequacy of acupuncture, which would contribute to develop new instruments/tools in the future.

In addition, based on the assessment results of this study, several suggestions are made for the design of acupuncture adequacy evaluation tools. First, rigorous methods should be used. Second, both the rationality of the design and adequacy of the implementation of the acupuncture regimens can be assessed. Third, both the real and sham acupuncture groups should be considered. Finally, the experience and expertise of practitioners is also an important influencing factor.

Our study also has some limitations. We did not search gray literature or databases other than in English or Chinese, which might lead to missing of some eligible studies. Due to term limits, our search strategy may have missed some studies, however, we further reviewed the cited literature and references of included studies. Therefore, readers are encouraged to notify us of any missing eligible studies. This study was not registered in advance because of its scope focusing on assessment instrument/methods of acupuncture used in RCTs which is not covered by PROSPERO.

In conclusion, increasing attention has been paid to assess the adequacy of acupuncture in RCTs since

1990s. Although improvements have been made, the content of how to assess this has not reached consensus and no assessment tools were widely used. Furthermore, the development methods of assessment tools were far from rigorous and were still in an exploratory stage.

### Conflict of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

### Author Contributions

Shi LJ and Gang WJ contributed to the conception and design of the study. Shi LJ, Jiao RM, Xiu WC, Hu XY<sup>a</sup>, Hu HY<sup>b</sup> and Tian ZY contributed to study selection, data extraction and analysis. Shi LJ contributed to writing the draft. Gang WJ, Robinson N, and Jing XH revised the manuscript critically for important intellectual content. All data were generated in-house, and no paper mill was used. All authors agree to be accountable for all aspects of work ensuring integrity and accuracy.

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