



Bibliometric analysis of publication trends in global acupuncture clinical research protocol

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Background: This bibliometric analysis focused on the acupuncture clinical research protocol to reveal the existing trends and predict the future of acupuncture clinical research.

Methods: The WoS database was accessed through the Library of China Academy of Chinese Medical Sciences on Aug 14, 2017. All records of acupuncture clinical research protocol were included, without limitation of publication years and languages.

Results: Finally, 182 records were included, all included protocols were journal articles, and were identified as type of randomized controlled trial (RCT). The number of acupuncture protocols gradually increased to a peak of 30 from 2000 until the middle of 2017; pain was the most commonly studied topic, accounting for 15% of identified protocols, followed by internal diseases including stroke (8.8%), arthritis (7.5%), insomnia (5%), depression (5%), and polycystic ovary syndrome (5%); China (186, 47.2%) was the country responsible for the most published acupuncture protocols; Trials (102, 56%) published the most acupuncture clinical research protocol; Kyung Hee University published the most acupuncture protocols (25, 13.7%).

Conclusions: Acupuncture clinical research protocols are gradually valued by researchers in worldwide, increasing number of protocols have been accepted by various academic journals. In addition to RCT protocols, observational research such as cohort study and registry study protocol are needed.

Keywords: Acupuncture; bibliometric analysis; clinical research protocol; Web of Science (WoS)

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Introduction

As one of the most commonly used complementary and alternative medicine, acupuncture research has markedly grown. Consequently, summaries of acupuncture clinical research status have been reported (1-3), and several well-designed clinical trials that evaluated the effectiveness and safety of acupuncture for diseases such as migraine, constipation, incontinence, and polycystic ovary syndrome have been completed recently (4-7). According to the survey

of Ma and colleagues, more than 7017 articles related to acupuncture clinical research including case reports, case series studies, non-randomized or randomized controlled trials have been published on academic journals from 1995 to 2014 (8). Despite ascending acupuncture-related research are arising, the bibliometric analysis for acupuncture clinical research protocol remain underexplored. Bibliometric analysis could be valuable to reveal historical development, existing research hot-point and predict the future of acupuncture clinical research as well. Hence, we

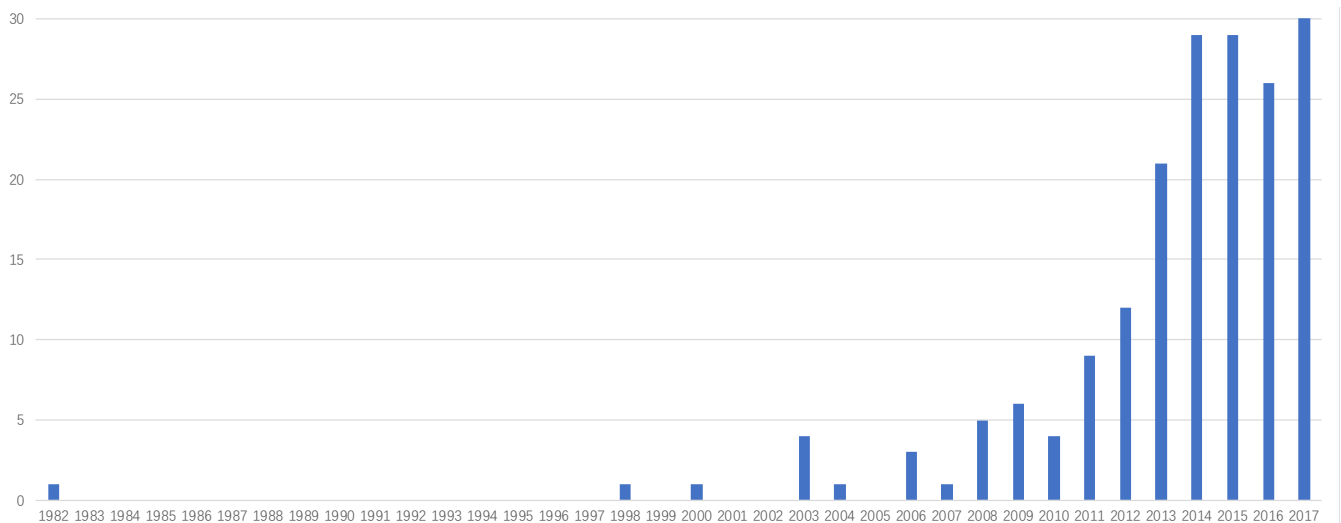


Figure 1 Publication trends of acupuncture clinical research protocols from 1982 to 2017.

conducted this study using Web of Science (WoS) database to summarize the productivity, performance, and structural trends of researchers, institutes, and research fields.

Methods

The WoS database was accessed through the Library of China Academy of Chinese Medical Sciences on 14th August, 2017. The search strategy comprises three steps. We used ‘acupunct*’ and ‘electroacupunct*’ as title words for the 1st step; ‘protocol’, ‘proposal’ and ‘design’ as titles words for the 2nd step; The 3rd step was the combination of step 1 and 2. All records of acupuncture related clinical research protocol were included. Excluded criteria were (I) original articles, (II) letter, (III) review, (IV) systematic review protocol, (V) abstract, and (VI) design of device. There were no publication year and language restrictions. All results were manually checked by two authors (Zongshi Qin and Jiani Wu) independently, and retrieval results were downloaded using export function of WoS website. Following aspects including publication trends, country/areas, authors (including all authors), journal name of published articles, organization which published articles, and main health conditions addressed were analyzed. To simplify analyses, only top-10 ranking results of each respect were listed.

Results

A total of 295 records for acupuncture research were

retrieved in the database. We excluded 90 records based on the titles and abstracts and 23 records were excluded after scanning full-text, of which 14 indicated the design of placebo needle or other devise, 9 were letters, 24 were original articles, 25 were reviews, 25 were systematic review protocols, and 18 were treatment protocol instead of the trial design. Finally, 182 records were included. All included protocols were journal articles, and were identified as type of randomized controlled trial.

Publication trends

In 1982, the first acupuncture clinical trial protocol, which reported acupuncture for primary headache was published (9), after that, no record arose until 1998 Margolin *et al.* described the rationale and design of acupuncture for cocaine alternative treatments study (10). The number of acupuncture protocols gradually increased to a peak of 30 from 2000 until the middle of 2017. Owing to the publication for 2017 was still in process, the final number was not yet available. During the last 5 years, the annual amount of protocols was higher than 20, and the average of annual publications equals to the total amount from 1982 to 2010. *Figure 1* shows the growth in numbers of acupuncture clinical research protocols from 1982 to 2017.

Research fields

Table 1 shows the research fields that last 3 years acupuncture clinical research protocols focused. Pain was the most

Table 1 Research fields of acupuncture clinical research protocol over last 3 years

Focus areas	Records	%
Pain	12	15
Stroke	7	8.8
Arthritis	6	7.5
Insomnia	4	5
Depression	4	5
Polycystic ovary syndrome	4	5
Post-chemotherapy symptoms	4	5
Functional dyspepsia	3	3.8
Urinary incontinence	3	3.8
Obesity	3	3.8
Menopausal	3	3.8
Fertilization	2	2.5
Drug requirement	2	2.5
Diabetes	2	2.5
Vertigo	1	1.3
Urinary retention	1	1.3
Stable angina pectoris	1	1.3
Sjogren syndrome	1	1.3
Precompetition nervous syndrome	1	1.3
Parkinson's disease	1	1.3
Irritable bowel syndrome	1	1.3
Hyperlipidemia	1	1.3
Heart failure	1	1.3
Gastroesophageal reflux disease	1	1.3
Inflammation	1	1.3
Colic	1	1.3
Cognitive impairment	1	1.3
Chronic prostatitis	1	1.3
Bell's palsy	1	1.3
Attention deficits	1	1.3
Atrial fibrillation	1	1.3
Asthma	1	1.3
Alzheimer's disease	1	1.3
Rhinitis	1	1.3

Table 2 Top ten prolific areas that published acupuncture clinical research protocols

Country/area	Records	%
China	86	47.2
South Korea	42	23.1
USA	23	12.6
Germany	13	7.1
Australia	11	6
Sweden	8	4.4
UK	7	3.8
Switzerland	6	3.3
Canada	5	2.7
Spain	5	2.7

commonly studied topic, accounting for 15% of identified protocols. Other research fields of focus included stroke (8.8%), arthritis (7.5%), insomnia (5%), depression (5%), polycystic ovary syndrome (5%), and post-chemotherapy symptoms such as nausea and vomiting (5%). Besides, less commonly studied health conditions included vertigo, urinary retention, hyperlipidemia, heart failure, sjogren syndrome, colic, cognitive impairment.

Country/areas

Table 2 illustrates the list of top ten areas of articles published related to acupuncture clinical research protocols. China (86, 47.2%) was the country responsible for the most published acupuncture protocols, and the amount of the acupuncture protocol came from China is higher than the total of South Korea (42, 23.1%), USA (23, 12.6%), and Germany (13, 7.1%). Following by South Korea, USA, and Germany.

Authors

Table 3 shows the list of top ten authors who published acupuncture clinical research protocols. Lee S from South Korea published the most acupuncture protocols (17, 9.3%), followed by Liu ZS (13, 7.1%), Choi SM (10, 5.5%), and Li Y (10, 5.5%).

Journals

Table 4 lists the top ten journals which published acupuncture

Table 3 Top ten prolific authors who published acupuncture clinical research protocols

Authors	Records	%
Lee S	17	9.3
Liu ZS	13	7.1
Choi SM	10	5.5
Li Y	10	5.5
Kim AR	9	4.9
Kim JH	9	4.9
Zheng H	9	4.9
Jung SY	8	4.4
Kim TH	8	4.4
Liang FR	8	4.4

Table 4 Top ten journals that published acupuncture clinical research protocol

Journals	Records	%
<i>Trials</i>	102	56
<i>BMC Complementary and Alternative Medicine</i>	24	13.2
<i>BMJ Open</i>	13	7.1
<i>Evidence-based Complementary and Alternative Medicine</i>	8	4.4
<i>Journal of Alternative and Complementary Medicine</i>	5	2.7
<i>Contemporary Clinical Trials</i>	3	1.6
<i>Forschende Komplementarmedizin und Klassische Naturheilkunde</i>	2	1.1
<i>Journal of Acupuncture and Meridian Studies</i>	2	1.1
<i>Journal of Integrative Medicine (JIM)</i>	2	1.1
<i>Journal of Pharmacopuncture</i>	2	1.1

clinical research protocols. It shows that *Trials* (102, 56%) published the most acupuncture clinical research protocol, followed by *BMC Complementary and Alternative Medicine* (24, 13.2%), *BMJ Open* (13, 7.1%), *Evidence-based Complementary and Alternative Medicine* (8, 4.4%), *Journal of Alternative and Complementary Medicine* (5, 2.7%), and *Contemporary Clinical Trials* (3, 1.6%).

Table 5 Top ten institutes that published acupuncture clinical research protocols

Institutes	Records	%
Kyung Hee Univ	25	13.7
Korea Inst Oriental Med	18	10
China Acad Chinese Med Sci	16	8.8
Capital Med Univ	14	7.7
Chengdu Univ Tradit Chinese Med	13	7.1
Beijing Univ Chinese Med	11	6
Shanghai Univ Tradit Chinese Med	7	3.8
Univ Hong Kong	7	3.8
Daejeon Univ	6	3.3
Heilongjiang Univ Chinese Med	6	3.3

Institutes

Table 5 demonstrates the list of top ten institutes where published acupuncture clinical research protocols. Kyung Hee University published the most acupuncture protocols (25, 13.7%), followed by Korea Institute of Oriental Medicine (18, 10%), the China Academy of Chinese Medical Sciences (16, 8.8%), Capital Medical University (14, 7.7%), and Chengdu University of Chinese Medicine (13, 7.1%).

Discussion

In the early of 2017, Kung *et al.* published an article and summarized acupuncture publication trends from 1988 to 2015 based on searching WoS database (11). It is valuable to objectively characterize acupuncture publication trends, which listed the ranking of prolific country/areas, authors, organizations, research fields, and related journals. China, USA, and South Korea were the countries responsible for the most published acupuncture article according to Kung's study. This result was generally consistent with our findings, in which the South Korea was ranked first, followed by China and USA. This result may be linked to an increased demand of academic papers from institutes and universities, on the other hand, increasing open access academic journals give positions for publishing research protocols. Because of acupuncture analgesia, acupuncture was firstly recognized by the worldwide. Until now, regarding to research fields, pain was consistently the most common

focus of acupuncture research. However, we found that with the exception of pain and pain related symptoms such as osteoarthritis and inflammation, other less commonly research fields but effect health significantly such as urinary retention, hyperlipidemia, heart failure, sjogren syndrome, colic, cognitive impairment has been studied in last 3 years.

Our results showed that all included protocols were identified as type of RCT, indicating that other types of clinical research such as cohort study has not been reported yet. However, in addition to RCTs, observational research also plays important roles in clinical research, which could be a supplementary for RCTs, especially for generating the hypothesis (12-14). In recent years, the development of guidelines such as the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) and the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) helped to develop standards for protocol writing in acupuncture clinical research (15,16). In turn, the methodology and quality of acupuncture clinical research has been improved significantly.

Among 182 records, multi-center randomized controlled trials account for a small part of available randomized controlled trial protocols. Most included clinical protocols calculated small sample size with single center design. As the golden standard evidence in clinical research, the results that RCTs generated were considered to be the most valued data in evidence-based medicine. However, several limitations of acupuncture RCTs should be mentioned. First, conducting small sample size RCT to explore the effectiveness and safety of acupuncture might fail to minimize bias because of the insufficient power. Otherwise, it is hard to conduct blinding to acupuncturist during the acupuncture treatment, considering the characteristics of acupuncture, which also have influence on the precision of research results. Third, different from medicine RCTs that comparing western drugs with placebo, sham acupuncture used in acupuncture RCTs is still controversial (17). Depending on the variety of depth, location, and whether electricity stimulation will be used, there are 17 kinds of sham control groups in acupuncture RCTs could be utilized (18). In addition, it is inefficiency and lavish to explore the effectiveness and safety of acupuncture for diseases through conducting small sample size RCTs.

Observational research could be used to generate hypotheses to be answered in front of large-scale RCTs and replace the exploration role of RCTs with small sample size. The selection of optimal acupuncture point protocol is complex and tough to acupuncturists, and large-scale cohort

study or registry study might be able to solve this problem according to big data collected from hospital information system. The relationship between internal validity and external validity of acupuncture related RCTs should also be valued by clinical researchers. Although acupuncture related RCTs are able to provide high-level clinical evidence, considering the tough inclusion/exclusion criteria and standard intervention protocols, the external validity might be limited. To achieving acupuncture clinical research evidence, observational research such as cohort study and registry study based on large sample size and multi-center are needed in the future. To avoid selected reporting of partial results between exposure (acupuncture) and outcomes, protocols of these studies should be recommended to report on the platforms or peer-review journal.

The limitations of this study should be noted. First, we only searched WoS database, making it impossible to trace all sources that might be included by other databases. Another limitation is that we did not assess the quality of included protocols or designs, such as whether the included protocols or designs has followed SPIRIT or STRICTA statements, and whether they appropriately described the details of trials such as randomization, concealment, blinding, and statistics.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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