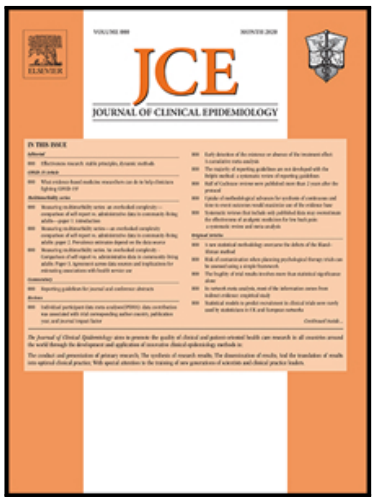

Evidence Based Social Science in China Paper 2: The quality of social science RCTs published from 2000-2020

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PII: S0895-4356(21)00294-8
DOI: https://doi.org/10.1016/j.jclinepi.2021.09.014
Reference: JCE 10624

To appear in: *Journal of Clinical Epidemiology*

Accepted date: 8 September 2021

Please cite this article as: Xiuxia Li , Yanfei Li , Kangle Guo , Nan Chen , Xudong Cui , Yaolong Chen , Kehu Yang , Evidence Based Social Science in China Paper 2: The quality of social science RCTs published from 2000-2020, *Journal of Clinical Epidemiology* (2021), doi: https://doi.org/10.1016/j.jclinepi.2021.09.014

Quality assessment of RCTs in the social sciences

Evidence Based Social Science in China Paper 2: The quality of social science RCTs published from 2000-2020

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Abstract

Objective: This study collected randomized controlled trials (RCTs) published in the social sciences in China and assessed their risk of bias and reporting quality.

Study Design and Setting: Three databases were systematically searched for publications from January 2000 to June 2020 for RCTs in the social sciences published by Chinese researchers. The risk of bias was assessed using the Cochrane Collaboration Risk of Bias Tool (CCRBT), and reporting quality was assessed using the Consolidated Standards of Reporting Trials for Social and Psychological Interventions (CONSORT-SPI).

Results: A total of 316 RCTs were identified, including 204 articles in English and 112 articles in Chinese. The most frequently researched interventions focused on education (33.9%), and the most frequently studied population were students (32.9%). Eighty-seven percent of RCTs had intermediate

reporting quality. Twenty-four of the 43 CONSORT-SPI sub-items had a compliance rate of less than 50%. Most RCTs had an unclear risk of bias for blinding outcome assessors (84.5%), blinding participants and personnel (82.9%), allocation concealment (73.1%), and random sequence generation (68.0%). A low proportion of CONSORT-SPI items were reported and, high proportion of the papers had unclear risk of bias.

Conclusion: The quality and reporting of RCTs in the social sciences needs improvement in China, especially for reporting methods and results. Most studies had an unclear risk of bias as they lacked important methodological information.

Keywords:

Randomized controlled trial; reporting quality; risk of bias; social science

What is new?

Key findings

There was an increasing number of RCTs in the social sciences in China from 2000 to 2020, and a growing number were reported in English. However, there were also differences in reporting and methodology between the Chinese and English articles, with the latter being assessed more positively on reporting quality and risk of bias.

What this adds to what was known?

This is the first study to survey the risk of bias and reporting quality of Chinese RCTs in the social sciences. This study also compared the risk of bias and reporting quality of articles published in English with those published in Chinese.

What is the implication and what should change now?

The reporting quality of RCTs in the social sciences need to be improved in China, especially in terms of reporting the trial design, relevant information about the interventions, adverse events, interruption or cessation of the trial, and stakeholder involvement.

Introduction

The ‘what works’ movement in social sciences encourages policymakers to base their decisions on scientific evidence[1]. Randomized controlled trials (RCTs), due to their advantages in eliminating bias, balancing confounding factors, and the possibilities for improving statistical power, are recognized as the most reliable method for evaluating the effects of interventions[2-4]. Ronald Fisher proposed randomization in experimental design as early as 1925 and used this method in agricultural research[5]. Subsequently, RCT study designs have been tried and implemented in education, criminal justice, social work, and other social science areas[6, 7].

In China, evidence-based social sciences have gradually been developing in recent years. In 2003, Stanford University, Northwestern University and the Chinese Academy of Sciences jointly launched the Rural Education Action Project (REAP), which aims to provide the evidence basis for decision-making for education, health and nutrition in China [8]. In 2017, the first evidence-based social science research center was established at Lanzhou University. The Campbell China Network was established in 2019, and currently comprises 24 institutions. These institutions concentrate on the production, evaluation, dissemination, and transformation of evidence in the social sciences. RCTs play

a very important role in evaluating the effects of non-medical interventions and is worthy of more in-depth exploration for application in Chinese social sciences.

An important aspect of RCTs is using and reporting of appropriate methodology so that we can have confidence in study findings as a basis for decision-making [9]. Previous assessments of reporting quality and methodological quality assessments on RCTs from health and medical research fields globally identified deficiencies in the research reporting and methodological design [10, 11]. Hence, clarifying the current status of reporting of RCTs is of great value for the production and use of evidence, as it will help improve the quality of research and so promote scientific decision-making in China.

This study collected published RCTs in the social sciences in China from 2000 to 2020 to assess their risk of bias and reporting quality. Reporting quality was evaluated using the Consolidated Standards of Reporting Trials for Social and Psychological Interventions (CONSORT-SPI) and risk of bias using the Cochrane Collaboration Risk of Bias Tool (CCRBT). The CONSORT-SPI, which extends 9 of the 25 items from CONSORT 2010[12], was designed to specifically improve the reporting of Social and Psychological Intervention[6]. The CCRBT, developed by the Cochrane Collaboration, is used for assessing the risk of bias of RCTs in six domains: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias [13]. It is one of the most comprehensive approaches for assessing the potential for bias in RCTs and has frequently been used in systematic reviews [14].

2. Methods

2.1 Search strategy

A systematic search of the Chinese Social Sciences Citation Index (CSSCI) and the Social Sciences Citation Index (SSCI) was performed in June 2020. In addition, a supplementary search was conducted of the International Initiative for Impact Evaluation (3ie) Development Evidence Portal (https://developmentevidence.3ieimpact.org/). The search terms and strategies were as follows: randomized controlled trial OR randomised controlled trial OR blind* OR singleblind* OR doubleblind* OR trebleblind* OR tripleblind*. The search was refined by country/region criteria, specified as "Peoples R China".

2.2 Inclusion and exclusion criteria

An RCT was defined as a prospective study that assessed interventions in human participants who were randomly allocated to study groups [12]. Only RCTs on the social sciences with a Chinese lead author who is based at a Chinese research institution, and which were published from 2000 to 2020 were included. Social sciences are defined as the disciplines identified by the United Kingdom's Economic and Social Research Council (UK ESRC) [15]. Studies with insufficient data (e.g., protocols, conference proceedings, or abstracts, among others) were excluded.

2.3 Study selection and data extraction

Study screening and data extraction were performed independently by two reviewers. Their differences were resolved by consultation with a third reviewer. EndNote X9 software (Thomson Corporation; Stamford, CT) was used to reject duplicate articles. Following this, two reviewers screened the trials by firstly reading titles and abstracts. If both reviewers excluded a trial, it was removed from further assessment. If one reviewer included the citation or if there was insufficient information to make an informed decision, the full text was obtained for further consideration. Using a predesigned coding form, the publication details, reporting characteristics, and items about the risk of

bias were extracted from each of the included studies. Publication details included the date of publication, the language it was written in, the number of authors, the country of origin of the corresponding author, the type of journal and its impact factor (IF), and the number of participants. The reporting characteristics were extracted according to the CONSORT-SPI [6]. Items about the risk of bias were extracted according to the CCRBT[13].

2.4 Quality assessment

Two reviewers independently assessed the reporting quality and the risk of bias of the included studies. When the opinions of the two reviewers were divided, differences were resolved by consultation with a third reviewer. Reporting quality was assessed using the CONSORT-SPI, which contains 26 items (43 sub-items), covering seven aspects of research articles, including the title, abstract, introduction, methods, results, discussion, and important information[6]. Each sub-item was rated as a 'yes' if it was fully reported (Y, scored as one point) and a 'no' if it was not clearly reported or not reported at all (N, scored as zero points). As there are 43 items, a score of 43 would be considered the highest reporting quality.

The risk of bias was assessed using the CCRBT (Cochrane Collaboration; London, United Kingdom) [16], which considers random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other biases. Each item was classified as either 'yes' (low risk), 'no' (high risk), or 'unclear' (unclear risk). When all seven items were classified as low risk, the overall risk of bias of the trial was graded as low. When one or more of the items was classified as high risk, the overall risk of bias of the trial was graded as high. In other cases, the overall risk of bias of the trial was graded unclear.

2.5 Data analysis

Data collection and analysis was performed in Microsoft Excel 2010 (http://office.microsoft.com/zh-cn). Descriptive summary statistics (frequency, median, and interquartile range (IQR)) were calculated for each of the general and methodological items specified. Subgroup analyses were conducted to assess the differences in the CONSORT-SPI items and CCRBT domains according to the published language (Chinese vs. English). RevMan V.5.1 software was used to calculate risk ratios (RR) and 95% confidence intervals (CIs) for the pooled quality assessment.

3 Results

3.1 Search results

A flow diagram of the literature selection process is displayed in **Fig. 1**. A total of 4,986 relevant records were initially identified, 201 of which were excluded on the basis of duplication. Titles and abstracts were screened, and 4,318 were deemed to be unsuitable. The full texts of the remaining 467 articles were screened in detail, and 151 records were excluded due to an inappropriate study design or topic of research. Finally, 316 RCTs met the inclusion criteria.

3.2 Descriptive characteristics

The 316 analyzed articles were retrieved from 157 different journals and included 204 articles in English, while the other 112 were in Chinese. As shown in **Fig. 2**, the number of articles being published showed an increasing trend over time, especially for the number of articles being published in English. From 2015 onwards, the total number of English articles increased substantially, while the number of Chinese articles decreased over time. As shown in **Table 1**, only 4 (1.3%) articles were published in journals with IFs >9. Nearly half (134, 42.4%) of the studies had four to six authors, and more than one third (107, 33.9%) had a sample size per intervention group of over 100. The most

frequently applied interventions focused on education (107, 33.9%), and the most frequently studied population were students (104, 32.9%).

3.3 Reporting quality

The median (IQR) CONSORT-SPI score was 18 (16–23). Approximately 87.3% (276/316) of the included RCTs had an intermediate reporting quality score, ranging from 15 to 28. As shown in **Table 2**, the items with a compliance rate of more than 50% were reporting of the title and abstract, introduction, trial design, participants, interventions, outcomes, participant flow, baseline data, numbers analyzed, limitations, generalizability, interpretation, and declaration of interests. The sub-item with the best compliance rate was 16 (316, 100%), whereas the sub-items with the worst compliance rate were reporting of any involvement of the intervention developer in the design, conduct, analysis, or reporting of the trial, and other stakeholder involvement in trial design, conduct, or analyses (both 0, 0%). Compliance rates were also less than 10% for the items on reporting sample size, awareness of assignment, recruitment, outcomes and estimation, and ancillary analyses.

As shown in **Fig. 3**, compared with the English articles, the Chinese articles had a lower compliance rate in 24 sub-items. However, Chinese articles had a higher compliance rate in four sub-items.

3.4 Risk of bias

As shown in **Fig. 4**, 84.5% (267) of the included RCTs had an unclear risk of bias for blinding outcome assessors, 82.9% (262) for blinding participants and personnel, 73.1% (231) for allocation concealment, 68.0% (215) for random sequence generation, 22.8% (72) for other potential sources of bias, and 0.9% (3) for selective outcome reporting. Unclear risk of bias mean that the items were insufficiently reported or not reported at all. Most studies were deemed to be at low risk of bias for

incomplete outcome data (311, 98.4%), selective outcome reporting (301, 95.3%), and other potential sources of bias (244, 77.2%).

Compared with English articles, Chinese articles had a lower proportion of items at low risk of bias, and a higher proportion of items rated as having an unclear risk of bias in terms of their methods for random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, and other bias. Meanwhile, a higher proportion of Chinese RCTs were at high risk of bias due to selective reporting (**Fig. 5**).

Discussion

This study identified 316 RCTs in the social sciences in China that were published in the last twenty years. It is notable that there have been an increasing number of social science articles being published over time, and an increasing number of these were being written in English. The interventions on education and psychology, as well as populations of students, children, and older adults were featured heavily in the included RCTs.

Overall, the reporting quality of most trials was at an intermediate level. Only a few trials reported details of stakeholder involvement, analytical methods, adverse events, trial registration, protocol publication, and trial design (e.g., random sequence generation, allocation concealment, and blinding) adequately or at all. This lack of information on study design may affect the validity and credibility of the results [13, 17]. We do not know if the trials are poorly done or simply poorly reported. Therefore, the reporting of future RCTs in the social sciences in China needs to be improved. Furthermore, the risk of bias in most trials was unclear also because the methodological details were not clearly reported.

Of the included RCTs, the English publications performed better in terms of both the number and reporting quality. Qianan Cao and Shibing Liang evaluated the reporting quality of Chinese RCTs in

acupuncture and children's fields respectively, with similar findings to this study [18, 19]. However, the disparity in the number of English articles found compared to Chinese articles might be related to the databases used to search the literature. The English articles were from the SSCI database, which included more than 3200 academic journals in the social sciences, while the Chinese articles were from the CSSCI database, which currently has more than 500 journals [20-22]. The difference in reporting quality between English and Chinese articles found in the current analysis may be a result of the stricter reporting requirements and clearer author instructions for publication international journals, including requests for detail from referees [23, 24]. Specifically, reporting of Chinese social science RCTs needs to be improved for stakeholder involvement, analytical methods, harms, trial registration, protocol publication, and trial design (e.g., random sequence generation, allocation concealment, and blinding). Chinese journals should be in line with the standards of high-impact international journals, and Chinese authors need to refer to international norms when reporting RCTs in the social sciences. In this study, it can be seen that Chinese articles seem better than English articles in terms of the normative reporting of titles and abstracts, which might be due to the reason that Chinese journals often have clear requirements on titles and abstracts of study.

Regarding the risk of bias of included RCTs, in both Chinese and English articles, most of the articles were assessed as unclear risk of bias because of the lack of information about random sequence generation, allocation concealment, blinding of participants and personnel, and blinding of outcome assessment. Thus future reports need to be strengthened with respect to these items. In particular, Chinese articles seem to have a higher percentage of selective reporting bias than English articles, and in some RCTs, not all of the studies' pre-specified primary outcomes have been reported, which needs

to attract the attention of future researchers. Meanwhile, in order to reduce the risk of selective reporting bias, Chinese researches also needs to adopt trial registration as standard practice.

Compared with RCTs in medical research, RCTs designed for the social sciences might have greater difficulty controlling for confounding factors[9, 25]. Therefore, the CCRBT, which was originally developed and for use in medical research, might not adequately assess the methodological issues of RCTs in the social sciences. Meanwhile, the CONSORT-SPI is a reporting guideline for trials of social and psychological interventions[6], so it is worthy of further exploration for use in other fields of the social sciences. Therefore, with the increasing number of RCTs in different fields of the social sciences, it is necessary to develop or further validate the reporting guidelines and risk of bias assessment tools.

Aside from reporting quality of the present trials, trial registration and protocol publication are also worthy of attention. It is believed that prospective registration of RCTs can limit publication bias[26] and prevent research misconduct[27], thereby improving scientific quality[28]. Learning from medical research interventions, we can see that trial registration increases awareness of study quality and internal validity before the conduct of a trial[12]. However, few Chinese articles in the social sciences provide details of trial registration, nor are the study protocols published. Currently, there is no dedicated platform for trial registration, and there is a lack of channels for publishing RCT protocols for social science research in China, although they could use global platforms such as 3ie's RIDIE. Development of these practices needs to be prioritized to improve the quality of social science research in China.

Several limitations of this study should be acknowledged. Firstly, the CSSCI and SSCI databases, which are representative of the indexed and high-level social science journals in China and from

around the world respectively[29], were searched. Therefore, the findings might be biased toward better quality papers. However, CSSCI and SSCI are considered to be the most important sources of social science research. Therefore, our findings are likely to capture the bulk of the relevant research. Secondly, the reporting and risk of bias assessment was based solely on reporting of the included trials. It is possible that investigators may have used proper methods but failed to report them, so studies are poorly reported rather than poorly done. Finally, it is important to note that CONSORT-SPI and CCRBT are all regularly updated. Thus, the findings of our study may change over time as new items are added or older items are revised. Our findings are also likely to change with additional RCTs published in the future – hopefully with better reporting standards.

Conclusion

Overall, in recent years there has been an increasing number of RCTs in the social sciences being published in China, with a growing share of papers being written in English. However, there were several differences both in the reporting quality and risk of bias between Chinese and English articles, especially for items relating to trial design and outcomes. In the future, journal editors in China should request more thorough reporting and researchers need to improve the reporting quality of their RCTs. Special reporting guidelines and risk of bias assessment tools should also be developed and utilized for social sciences. Furthermore, with the increasing number of RCTs in the social sciences, China needs to develop dedicated platforms for trial registration and channels for protocol publication for trials conducted in Chinese. Trials conducted in English should register on global platforms such as the International Initiative for Impact Evaluation's Registry for International Development Impact Evaluations (RIDIE).[1]

[1] https://www.3ieimpact.org/evidence-hub/ridie

Declarations

Ethics approval and consent to participate Not applicable.

Consent for publication All authors read and approved the final manuscript.

Availability of data and material http://lzucms.lzu.edu.cn-/xunzhengyixue/index.html

Funding

This research was supported by the Major Project of the National Social Science Fund of China: "Research on the Theoretical System, International Experience and Chinese Path of Evidence-based Social Science" (Project No. 19ZDA142).

Author contributions

KHY, YLC and XXL initiated and designed the study, with contributions from XXL, YFL, KLG, and NC contributed to the design of the search strategy. KLG, NC, and XDC reviewed search results with support from YFL and XXL. YFL did data extraction, with contributions from KLG, NC, XDC, and YLC. XXL, YFL, KLG and XDC analyzed the data and interpreted the results. XXL, YFL, KLG, NC and XDC wrote the first draft of the manuscript. XXL, YFL, YLC and KHY revised the final manuscript and all authors approved the final version for submission.

Declaration of interest for all authors

None.

Acknowledgments

We would like to thank Professor Howard White who is the Chief Executive Officer of Campbell Collaboration for his guidance and full text revision.

Reference

[1] Boruch R, Rui N. From randomized controlled trials to evidence grading schemes: current state of evidence-based practice in social sciences. Journal of Evidence-Based Medicine 2010;1(1):41-9.

[2] Bhide A, Shah PS, Acharya G. A simplified guide to randomized controlled trials. Acta obstetricia et gynecologica Scandinavica 2018;97(4):380-7.

[3] Brocklehurst P, Hoare Z. How to design a randomised controlled trial. British dental journal 2017;222(9):721-6.

[4] Byar DP, Simon RM, Friedewald WT, Schlesselman JJ, Demets DL, Ellenberg JH, et al. Randomized clinical trials. Perspectives on some recent ideas. N Engl J Med 1976;295(2):74-80.

[5] Hall NS. R. A. Fisher and his advocacy of randomization. Journal of the history of biology 2007;40(2):295-325.

[6] Grant S, Mayo-Wilson E, Montgomery P, Macdonald G, Michie S, Hopewell S, et al. CONSORT-SPI 2018 Explanation and Elaboration: guidance for reporting social and psychological intervention trials. Trials 2018;19(1):406.

[7] Turner L, Shamseer L, Altman DG, Weeks L, Peters J, Kober T, et al. Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals. The Cochrane database of systematic reviews 2012;11(11):Mr000030.

[8] Boswell M, Rozelle S, Zhang L, Liu C, Luo R, Shi Y. Conducting influential impact evaluations in China: the experience of the Rural Education Action Project. Journal of Development Effectiveness 2011;3:420-30.

[9] Yang K, Li X, Bai Z. Research methods of Evidence-based social science: Systematic review and meta-analysis. Lanzhou: Lanzhou University Press; 2018.

[10] Alvarez G, Solà I, Sitjà-Rabert M, Fort-Vanmeerhaeghe A, Gich I, Fernández C, et al. A methodological review revealed that reporting of trials in manual therapy has not improved over time. Journal of clinical epidemiology 2020;121:32-44.

[11] Falagas ME, Grigori T, Ioannidou E. A systematic review of trends in the methodological quality of randomized controlled trials in various research fields. Journal of clinical epidemiology 2009;62(3):227-31.e9.

[12] Li X, Wang R, Shi X, Chen Z, Pan Y, Li X, et al. Reporting characteristics and risk of bias in randomised controlled trials of acupuncture analgesia published in PubMed-listed journals. Acupuncture in medicine : journal of the British Medical Acupuncture Society 2017;35(4):259-67.

[13] Higgins JP, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ (Clinical research ed) 2011;343:d5928.

[14] Zeng X, Zhang Y, Kwong JS, Zhang C, Li S, Sun F, et al. The methodological quality assessment tools for preclinical and clinical studies, systematic review and meta-analysis, and clinical practice guideline: a systematic review. J Evid Based Med 2015;8(1):2-10.

[15] ESRC. What is social science? UK: Economic and Social Research Council 2019. https://esrc.ukri.org/about-us/what-is-social-science/social-science-disciplines/. accessed 30 Aug 2020.

[16] Tao WW, Jiang H, Tao XM, Jiang P, Sha LY, Sun XC. Effects of Acupuncture, Tuina, Tai Chi, Qigong, and Traditional Chinese Medicine Five-Element Music Therapy on Symptom Management and Quality of Life for Cancer Patients: A Meta-Analysis. Journal of pain and symptom management 2016;51(4):728-47.

[17] Guyatt GH, Oxman AD, Vist G, Kunz R, Brozek J, Alonso-Coello P, et al. GRADE guidelines: 4. Rating the quality of evidence--study limitations (risk of bias). Journal of clinical epidemiology 2011;64(4):407-15.

[18] Cao Q. Study on Evaluation of heat-sensitiveMoxibustion Randomized ControlledTrial Methodology and Report Quality. Jiangxi University Of Traditional Chinese Medicine; 2020.

[19] Liang S, Sun Y, Li Y, Qiao S, Lai B, Robinson N, et al. Randomized Controlled Trials of Pediatric Tuina for Anorexia: Quality Assessment of Methodological and Intervention Reports. Chinese Archives of Traditional Chinese Medicine 2020;38(06):94-8.

[20] Xue K, li YF, Xu FW. Digital communication research: how far is the distance between China and the world? -- A comparative study based on CSSCI and SSCI databases. News and Writing 2020(3):32-9.

[21] Wang Q. Comparison of the Research Status of Humanities and Social Sciences in Sports at Home and Alive -- Based on Knowledge Graph Analysis of CSSCI, SSCI and A&HCI literatures from 2000 to 2017. Journal of Chengdu Sport University 2020;v.46;No.260(01):42-8.

[22] Ma ZQ, Kun LL, Zeng N. Analysis on the Hotspots and Trends of Blended Learning Research at Home and Abroad -- Based on the Comparison of SSCI and CSSCI Journals from 2005 to 2015. MODERN DISTANCE EDUCATION RESEARCH 2016(4):49-57.

[23] Kaper NM, Swart KMA, Grolman W, Van Der Heijden G. Quality of reporting and risk of bias in therapeutic otolaryngology publications. The Journal of laryngology and otology 2018;132(1):22-8.

[24] Chen YP, Chen L, Li WF, Lee AWM, Vermorken JB, Wee J, et al. Reporting Quality of Randomized, Controlled Trials Evaluating Combined Chemoradiotherapy in Nasopharyngeal Carcinoma. International journal of radiation oncology, biology, physics 2017;98(1):170-6.

[25] Yang K. Evidence-based social science: the origin, development and prospects. Library and Information 2018(03):1-10.

[26] Melander H, Ahlqvist-Rastad J, Meijer G, Beermann B. Evidence b(i)ased medicine--selective reporting from studies sponsored by pharmaceutical industry: review of studies in new drug applications. BMJ (Clinical research ed) 2003;326(7400):1171-3.

[27] Mathieu S, Boutron I, Moher D, Altman DG, Ravaud P. Comparison of registered and published primary outcomes in randomized controlled trials. Jama 2009;302(9):977-84.

[28] Carr D. Raising the bar on the ethical standards of acupuncture research. Acupuncture in medicine : journal of the British Medical Acupuncture Society 2015;33(3):178-9.

[29] CAO S, WU Y, WEI J, MA C. History, schools and trend in knowledge map: Investigation and visualization based on SSCI and CSSCI. Journal of Library Science in China 2015;7(00):250-1.

Table 1. Descriptive characteristics of the included RCTs

Category	Characteristic	Number (%) n=316
Language of publication	English	204 (64.6%)
	Chinese	112 (35.4%)
Journal impact factor	≤1.0	48 (15.2%)
	1.1-3.0	183 (57.9%)
	3.1–6.0	69 (21.8%)
	6.1–9.0	8 (2.5%)
	>9.0	4 (1.3%)
	None	4 (1.3%)
Number of authors	1	27 (8.5%)
	2–3	85 (26.9%)
	4–6	134 (42.4%)
	7–10	54 (17.1%)
	>10	16 (5.1%)
Sample size per intervention group	⩽20	43 (13.6%)
	21–50	90 (28.5%)
	51–100	76 (24.1%)
	>100	107 (33.9%)
Type of interventions	Educational intervention	107 (33.9%)
	Psychological intervention	100 (31.6%)
	Physical intervention	51 (16.1%)
	Economic intervention	9 (2.8%)
	Nutrition intervention	3 (0.9%)
	Others	46 (14.6%)
Research populations	Students	104 (32.9%)
	Children	49 (15.5%)
	Older adults	25 (7.9%)
	Women	21 (6.6%)
	Adolescents	15 (4.7%)
	Smokers	11 (3.5%)
	Immigrants	2 (0.6%)
	Professional athlete	10 (3.2%)
	Others	79 (25%)

Table 2. Reporting quality of 316 included trials based on the CONSORT-SPI checklist

Section	Item	Number	% (n=316)
Title and abstract			
	1a. Identification as a randomized trial in the title	262	82.9
	1b. Structured summary	173	54.7
Introduction			
Background and objectives	2a. Scientific background and explanation of rationale	304	96.2
	2b. How the intervention was hypothesized to work	301	95.3
Methods			
Trial design	3a. Description of trial design	313	99.1
	3b. Important changes to methods	1	0.3
Participants	4a. Eligibility criteria for settings and those delivering the interventions	309	97.8
	4b. Settings and locations where the data were collected	235	74.4
Interventions	5. The interventions for each group to allow replication	284	89.9
	5a. Which interventions were actually delivered	201	63.6
	5b. Other informational materials	7	2.2
	5c. How intervention providers were assigned to each group	98	31.0
Outcomes	6a. Completely defined pre-specified outcomes	304	96.2
	6b. Any changes to trial outcomes	44	13.9
Sample size	7a. How sample size was determined	106	33.5
	7b. Interim analyses and stopping guidelines	3	0.9
Sequence generation	8a. Method used to generate the random allocation sequence	96	30.4
	8b. Type of randomization and details of any restriction	92	29.1
Allocation concealment mechanism	9. Mechanism used to implement the random allocation sequence	83	26.3
Implementation	10. Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	51	16.1
Awareness of assignment	11a. Who was aware of intervention assignment after allocation, and how any masking was done	31	9.8
	11b. The similarity of interventions	110	34.8
Analytical methods	12a. How missing data were handled	58	18.4
	12b. Methods for additional analyses	34	10.8
Results			
Participant flow	13a. The number approached, screened, and eligible prior to random assignment, with reasons for non-enrolment	283	89.6
	13b. Losses and exclusions after randomization	283	89.6
Recruitment	14a. Dates defining the periods	138	43.7
	14b. Why the trial ended or was stopped	1	0.3
Baseline data	15. Include socioeconomic variables where applicable	184	58.2
Numbers analysed	16. Number included in each analysis	316	100
Outcomes and estimation	17a. Indicate availability of trial data	315	99.7
	17b. Presentation of both absolute and relative effect sizes	28	8.9
Ancillary analyses	18. Results of any other analyses performed	35	11.1
Harms	19. All important harms or unintended effects in each group	1	0.3

Discussion			
Limitations	20. Trial limitations, addressing sources of potential bias, imprecision	206	65.2
Generalisability	21. Generalisability of the trial findings	289	91.5
Interpretation	22. Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	307	97.2
Registration	23. Registration number and name of trial registry	52	16.5
Protocol	24. Where the full trial protocol can be accessed	22	7.0
Declaration of interests	25. Declaration of any other potential interests	244	77.2
Stakeholder involvement	26a. Any involvement of the intervention developer in the design, conduct, analysis, or reporting of the trial	0	0
	26b. Other stakeholder involvement in trial design, conduct, or analyses	0	0
	26c. Incentives offered as part of the trial	19	6.0

Figure legends:

Fig. 1 Flow diagram of the literature screening

Fig. 2 Publication years of RCTs in the social sciences in China

Fig. 3 Forest plots comparing the number of RCTs complied with CONSORT-SPI items between Chinese and English articles

Fig. 4 Risk of bias assessment of the included RCTs (n=316)

Fig. 5 Forest plots comparing the number of RCTs with low, high, and unclear risk of bias for CCRBT domains between Chinese and English articles