Endorsement of CONSORT by Chinese Medical Journals: A Survey of "Instruction to Authors"

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ABSTRACT  Objective: To determine the extent to which Chinese medical (CM) journals incorporate Consolidated Standards for Reporting of Trials (CONSORT) into their "instruction to authors". Methods: We reviewed the latest "instruction to authors" of the CM journals in China which indexed by MEDLINE in 2010 or Excerpta Medica Database (EMBASE) in 2012 and extracted all information of CONSORT, International Committee of Medical Journal Editors (ICMJE), other reporting guidelines or clinical trial registration. By reading the instructions to authors and reviewing recent studies published in those journals, those that do not publish clinical trials were excluded. We also contacted each of journals by telephone on contributor's status to ask them whether mentioned CONSORT in their instructions and incorporated it into their editorial and peer-review process. Full-text papers of randomized controlled trials (RCTs, from January 2011 to March 2012) published in the journals which mentioned "CONSORT" in their instructions for authors were downloaded. Results: Seven CM journals were included. Three of these journals mentioned CONSORT in its instructions. By telephone survey, all journals gave responses and all respondents knew CONSORT statement. Three of 7 journals required authors to comply with the CONSORT statement and provide the CONSORT checklist and a flow chart of the trial. The rest 4 journals recommended authors of RCTs to refer to the CONSORT statement. From January 2011 to March 2012, a total of 50 RCTs were obtained from the 3 journals endorsing the CONSORT statement; 17 (17/50, 34%) contained a flow diagram in their manuscript, and none of those RCTs had mentioned the trial registration information. Conclusions: The endorsement of CONSORT by CM journals' "instruction to authors" was not satisfactory. The spread of CONSORT endorsement should be wider in instructing the performance of CM clinical trials in the future. Chinese journals should introduce CONSORT to their authors and require authors to comply with CONSORT when they submit their research.

KEYWORDS  Consolidated Standards for Reporting of Trials, randomized controlled trial, Chinese medical journal, instruction to authors, reporting quality

Randomized controlled trials (RCTs) are widely accepted as the "gold standard" for comparing different therapeutic modalities. Properly conducted and well reported RCTs provide high quality "raw materials" for conducting systematic reviews, clinical guidelines and clinical decision analysis. Unclear reporting of one RCT's methodology and results would prevent critical appraisal of the RCT and limit the effective dissemination. Therefore, in order to assess the strengths and limitations of RCTs, the authors should describe the methodology and findings of RCTs clearly and accurately.

The Consolidated Standards for Reporting of Trials (CONSORT) Group developed the CONSORT statement in 1996 to improve the reporting quality of RCTs. Since publication, it has been supported by an increasing number of medical journals and endorsed by several editorial groups, including the International Committee of Medical Journal Editors (ICMJE). The revised CONSORT Statement of 2010 was developed by 31 members of the CONSORT 2010 Group in Montebello, Canada, in January 2007. Between March 2009 and February 2010, the CONSORT website recorded an average of 13,621 visits per month, and totaling 163,461 visits for the year. CONSORT for Chinese medicine (CM) is for solicitation of comments at present.

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Evidence showed that use of CONSORT can improve the quality of reporting of RCTs. However, previous studies indicated that there were only a small part of high impact factor journals mentioned the CONSORT statement in their published "instruction to authors". For CM, this is an essential part of the healthcare system in several Asian countries, and is considered a complementary or alternative medical system in most Western countries. Majority of CM RCTs were conducted by Chinese clinical researchers and published on CM journals in China. In recent years, CONSORT statement has been well known to many Chinese clinical researchers. As CM seeks international recognition for its efficacy, more and more RCTs have been conducted and reported according to CONSORT statements. However, up to now, there is no research to assess the condition that the endorsement of the CONSORT statement by CM journals. As a result, we performed this review to determine the extent to which TCM journals in China that indexed by MEDLINE or Excerpta Medica Database (EMBASE) had incorporated CONSORT into their "instruction to authors" and if those journals endorsing the CONSORT statement adhere to the standards well.

**METHODS**

**Selection of Journals**

We included these TCM journals in China which indexed by MEDLINE in 2010 or EMBASE in 2012. If one journal was both indexed by MEDLINE and EMBASE, we included only once; we excluded these journals which published in Hong Kong or Taiwan. By reading the instructions to authors and reviewing recent studies published in those journals, which do not publish clinical trials were excluded. Two authors (XIAO Lu and HU Jing) reviewed these journals and included journals independently. A third author (ZHANG Li) was consulted and consensus was reached by discussion.

We downloaded the "instruction to authors" which published on the journals' website of each journal and contacted each of journals by telephone to ask them whether mentioned CONSORT in their instructions and incorporated it into their editorial and peer-review process.

**Data Collection Process**

Two authors (XIAO Lu and HU Jing) reviewed the instructions to authors of included journals and exacted data mentioning "CONSORT", a flow diagram and clinical trial registration independently. A third author (ZHANG Li) was consulted and consensus was reached by discussion.

As CONSORT statement was revised in 2010, full-text papers of RCTs (from January 2011 to March 2012) published in the journals which mentioned "CONSORT" in their instructions for authors were downloaded. Since the participant flow diagram is strongly recommended in the CONSORT 2010 statement and 'trial registration number and name of trial registry' is a new item added in the CONSORT 2010 checklist, we chose these two items to evaluate whether the journal had complied with CONSORT statement. Two authors (XIAO Lu and HU Jing) scanned these RCTs reports to see whether they contained flow diagrams as the CONSORT statement mentioned, and whether trial registration was provided in the full-text. A third author (ZHANG Li) was consulted and consensus was reached by discussion.

**RESULTS**

**Journal Selection**

Of 247 Chinese journals identified either in MEDLINE or in EMBASE, 236 journals were excluded including 42 duplicates, 193 non-TCM journals, and 1 from Hong Kong. Therefore, there remained 11 potential appropriate journals to be included. After reading instructions and reviewing studies published in databases in recent 2 years, 4 journals which do not publish RCT were excluded. At last, we included 7 TCM journals for further analysis.

![Figure 1. Flow of Journal Selection](image-url)

**Endorsement of the CONSORT Statement in TCM Journals Indexed by MEDLINE and EMBASE**

By checking instructions to authors and