

## Chinese authors do need CONSORT: Reporting quality assessment for five leading Chinese medical journals

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### ABSTRACT

**Objective:** Only a few Chinese medical journals have recommended CONSORT in their "Instruction for authors or Guide for authors". This study aims to evaluate the reporting quality of randomized controlled trials (RCTs) published in the five leading Chinese medical journals indexed by MEDLINE.

**Methods:** We identified RCTs published from 2004 to January 2007 in five leading Chinese medical journals by searching three important Chinese databases systematically, namely CNKI (China National Knowledge Infrastructure/Chinese Academic Journals full text Database), VIP (a full text database of China) and CBM disc (China Biomedicine Database Disc) and assessed the quality of each RCT by using the Consolidated Standards for Reporting of Trials (CONSORT) and the 5-point Jadad scale.

**Results:** One hundred and forty two RCTs were included. Based on the items in the revised CONSORT statement, 130 (91.55%) of the 142 RCTs mentioned "randomization" in the title or abstract, but only 38 (26.76%) RCTs described the method to generate the random sequence; only 6 RCTs had adequate allocation concealment; 24 (17.61%) RCTs mentioned "masking", but only 7 described the process of masking. Three out of 40 items were reported clearly in all included trials, while five items were not mentioned at all. The quality of RCTs was low as assessed by the Jadad scale and 22 RCTs were high-quality research ( $\geq 3$  points).

**Conclusions:** The reporting quality of RCTs published in the five leading Chinese medical journals is low. Chinese journals should adopt the CONSORT statement to improve the reporting quality of Chinese randomized controlled trials.

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### 1. Introduction

Randomized controlled trial (RCT) is generally regarded as the "gold standard" design to assess the effectiveness of

medical interventions. Well-designed and properly conducted RCT provides high-quality "raw materials" for conducting systematic reviews, health technology assessment and decision analysis reports. Poorly designed and reported trials usually exaggerate the treatment effects which will mislead clinical decision making [1–4]. The critical appraisal of the validity of clinical trials is possible only if the design, conduction and analysis of published trials are described thoroughly and accurately.

The Consolidated Standards for Reporting Trials (CONSORT) were developed to improve the reporting quality of RCTs [5]. Many studies have showed that reporting quality of trials can be improved following CONSORT [6–11]. However,

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only a few Chinese medical journals have recommended CONSORT in their “Instruction for authors or Guide for authors” and little is known about the quality of reporting in China. This study aims to determine the reporting quality of RCTs published in five Medline-indexed leading Chinese medical journals in an effort to identify problems and make recommendations for Chinese medical journals and authors.

## 2. Methods

This study is a descriptive study.

### 2.1. Selection of journals and RCTs

We used the total cites and impact factors in the “Chinese Journal Citation Reprints-2006” [12] to select five Medline-indexed, leading Chinese medical journals with top ranking in disciplines of Pediatrics, Gynaecology and Obstetrics, Internal Medicine and Surgery: Chinese Journal of Pediatrics, Chinese Journal of Obstetrics and Gynecology, Chinese Journal of Internal Medicine, Chinese Journal of Surgery, and Chinese Journal of Cardiology. We included all articles published between January 2004 and January 2007 that reported to be RCTs (i.e., a trial in which the allocation of participants to interventions was described by the words random, randomly, randomized, or randomization).

All articles were searched from three databases including CNKI (China National Knowledge Infrastructure/Chinese Academic Journals full text Database), VIP (a full text database of China) and CBM disc (China Biomedicine Database Disc). We did a pilot study to identify the RCTs published in the Chinese Journal of Cardiology by handsearching and electronic searching from the three databases. No RCT was missed comparing the retrieved results from full text Database CNKI with handsearching results. So we decided to

electronically search the three databases with following search strategies:

CNKI:	1 “random\$” in fulltext 2 “case” in fulltext 3 1 AND 2
VIP:	“randomize” in title, abstract and keywords
CBM disc:	1 random\$ 2 randomized controlled trial/ 3 randomized controlled trial\$.pt. 4 double blind 5 double blind method/ 6 single blind 7 single blind method/ 8 triple blind 9 blind\$ 10 or/1-9 11 10/limit:animal 12 10 not 11

### 2.2. Assessment of RCTs

We assessed the reporting quality of each RCT based on the CONSORT statement [13]. The revised CONSORT statement checklist was modified to 40 items. We assigned a ‘yes or no’ answer for each item according to whether the author had reported it or not.

We also assessed the quality of each RCT using Jadad scale [14] which is the most widely used scale and present the best validity and reliability evidence [15,16]. There are three items: random allocation, double blind and dropouts/withdrawals. Each item was presented as a question to elicit ‘yes or no’ answer. Points awarded for items 1 and 2 depended on whether the study was described as randomized or double blind and the appropriateness of the method to generate the sequence of randomization or to produce double blind. Scale scores can range from 0 to 5 points, with higher scores indicating better quality.

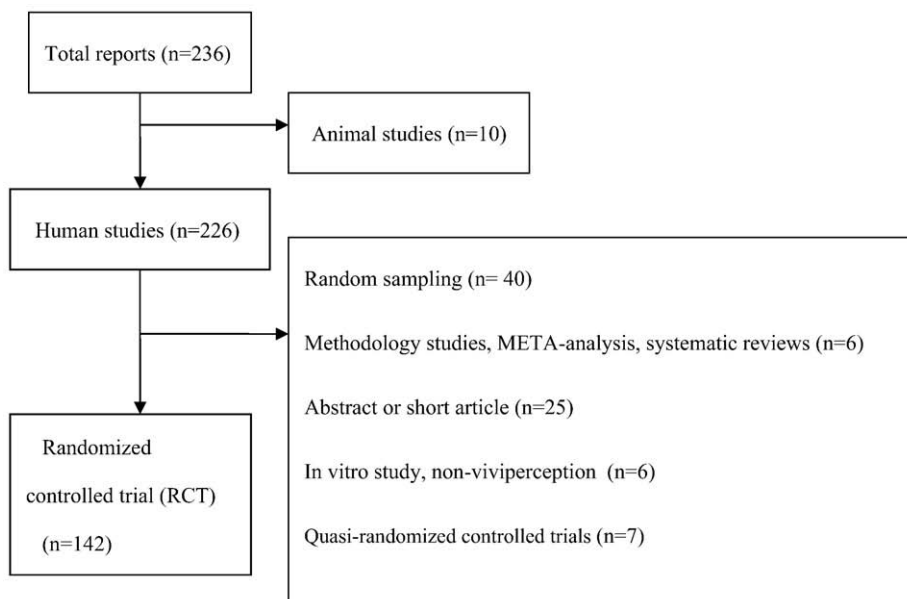


Fig. 1. Flow chart of studies considered for inclusion.

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