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Review

Does the reporting of randomized clinical trials published in Chinese pediatrics journals improve after the CONSORT Statement is adopted?

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ABSTRACT

Background: There is no systematic assessment whether the quality of reporting has been improved since the CONSORT Statement was introduced into China in 1997. The aim of this study is to determine whether the use of the CONSORT Statement is associated with improved quality of reporting of RCTs published in Chinese pediatrics journals.

Methods: Six core Chinese pediatrics journals that included *Journal of Clinical Pediatrics*, *Chinese Journal of Contemporary Pediatrics*, *Chinese Journal of Practical Pediatrics*, *Chinese Journal of Evidence-based Pediatrics*, *Chinese Journal of Pediatrics*, and *Chinese Journal of Pediatric Surgery* were searched from inception through Dec. 2010. The CONSORT checklists were used to assess the quality of reporting. Data was collected using a standardized form. Analyses were performed using SPSS 15.0 software.

Results: A total of 619 RCTs were included. The quality of reporting has improved significantly in aspects such as introduction, recruitment, baseline data, and ancillary analyses ($p<0.05$), but not in several important methodological components, including sample size calculation (0.63% vs.1.08%), randomization sequence generation (3.18% vs. 7.58%), allocation concealment (0% vs. 1.08%), and blinding (0% vs. 0.87%).

Conclusions: The quality of reporting of RCTs has not significantly improved since the CONSORT Statement was introduced into China. The reporting remains poor, and often inadequate for assessment of the rigor of studies. Chinese pediatrics journals should reinforce the use of the CONSORT Statement in the reporting of trials.

Contents

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1. Introduction

Randomized controlled trials (RCTs) are recognized as the "gold standard" for assessing effectiveness of health interventions [1,2], and represent a critical base for evidence-based medicine. Nonetheless, only high-quality RCTs can inform appropriate practice. Studies have suggested that low quality RCTs overestimate the effects of interventions by about 30% across a varieties of conditions than those with higher quality [3,4]. RCTs have been increasingly conducted over the past two decades; the number of RCT publications is enormous.

The Consolidated Standards of Reporting Trials (CONSORT) Statement, first published in 1996, aimed to improve the reporting of RCTs, and consequently enhance the readers' comprehension of trial design, conduct, analysis, and interpretation. Furthermore, it was hoped the Statement may improve the assessment of the validity of study findings [5,6]. While the CONSORT Statement was introduced into China in 1997 [7], no study exists to examine the extent to which RCTs published in Chinese pediatrics journals adhere to the Statement.

The aim of our study was to determine the overall quality of reporting of RCTs published in Chinese pediatrics journals, and to examine if there is any improvement in the reporting. We also aimed to identify deficiencies of reporting of the current Chinese pediatrics trials to inform future research.

2. Methods

2.1. Selection of journals and RCTs

We selected all Chinese pediatrics journals indexed in the Chinese Science Citation Database (CSCD) including *Journal of Clinical Pediatrics*, *Chinese Journal of Contemporary Pediatrics*, *Chinese Journal of Practical Pediatrics*, *Chinese Journal of Evidence-based Pediatrics*, *Chinese Journal of Pediatrics*, and *Chinese Journal of Pediatric Surgery*. Indexed journals are believed to have higher quality than non-indexed journals.

Reports were included only if they involved human subjects, and were described as a randomized controlled trial using terms such as "random", "randomly", "randomized", and "randomization".

Two reviewers (HM Li & GQ-Qi) independently hand-searched the six journals from their inception through Dec. 2010. They independently screened titles and abstracts of identified reports. One reviewer subsequently screened full text articles of potentially included studies (GQ-Qi) and a second reviewer independently screened a 20% random sample (HM Li). Eleven disagreements of articles were resolved by consensus with a third reviewer (B Ma).

2.2. Data collection and analysis

Variables extracted included publication and reporting characteristics as well as items from the CONSORT checklists. The disease conditions under investigation were classified using the International Classification of Diseases (ICD-10).

Study reports were grouped according to the year that the CONSORT Statement was introduced to China: 1996 and earlier (pre-CONSORT) and 1997–2010 (post-CONSORT). We also collected the information regarding the reporting of ethics review and informed consent [8], source of funding [9], clinical trials registry [10], and the number of patients enrolled.

Data were collected using a standardized form, and summarized using descriptive statistics. Analyses were performed using Excel (version Microsoft Excel 2003; http://office.microsoft.com/zh-cn/) and SPSS (version 15.0; http://www.spss.com).

3. Results

Of 1319 clinical trials published in six core Chinese pediatrics journals, we identified 700 RCTs, resulting in 619 included RCTs (see Fig. 1).

3.1. Epidemiological characteristics (Table 1)

A total of 619 publications, in which 157 studies published before in 1996, published in six Chinese pediatrics journals indexed in the Chinese Science Citation Database met the inclusion criteria. Frequency of citation of each RCTs ranged from 0 to 54, nearly one-third (26.2%) trials had not been cited and only 6.0% had been cited more than 15 times. Almost all (98.7%) the trials were written by clinicians. The most common conditions studied were diseases of the respiratory system (27.5%) and digestive system (16.3%).

3.2. Descriptive characteristics (Table 2)

The RCTs included a median of three authors (IQR: 2.0–5.0). Mostly studies (72.4%) were performed in single research center and the median sample size was only 52 (IQR:18.0–125.0). Few RCTs (1.8%) mentioned ethical approval, and only 4.0% adequately discussed informed consent which again varied significantly between these RCTs published before in 1996 and 1997–2010 [0% versus 2.4%, respectively ($p<0.05$)]. Of the 619 papers, only 20.5% RCTs reported their sources of funding although this differed significantly between RCTs published before and after 1996 ($p<0.05$). None of any RCTs reported registration number or if was registered.

3.3. PRISMA Checklist Assessment (Table 3)

Compared with the RCTs published before 1996, there was an increase in some items of CONSORT checklist in the reports of RCTs published after 1996. This increase was statistically significant in title and abstract (item 1a, 1b), introduction (item 2a, 2b), trial design (item 3a), participants (item 4a), outcomes (item 6a), statistical methods (item 12a, 12b), recruitment (item 14a,14b), baseline data (item 15),