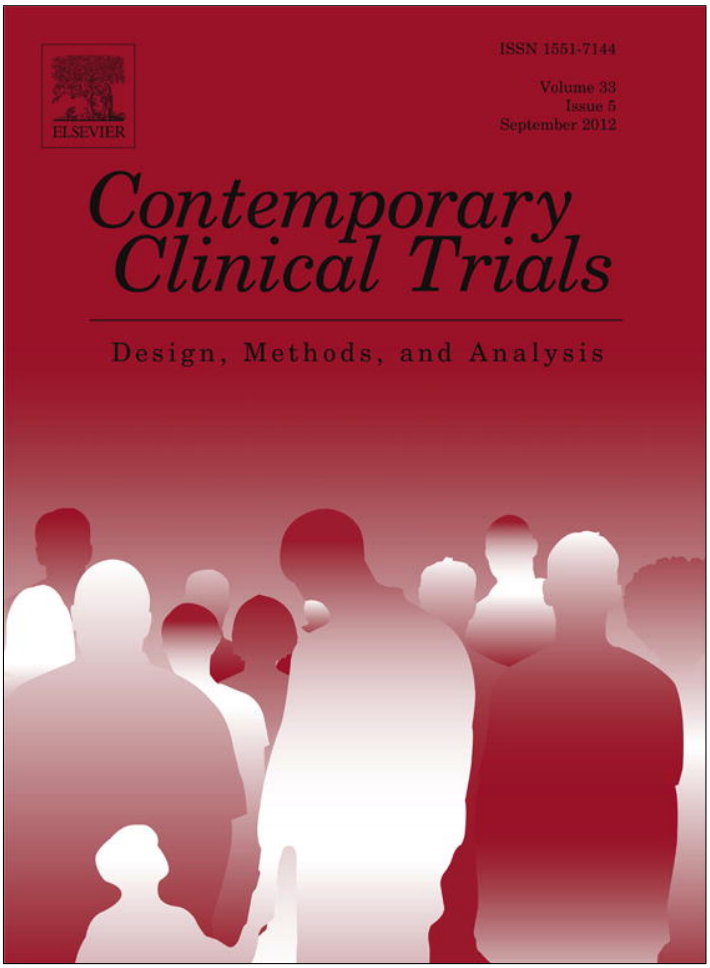

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Review

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),

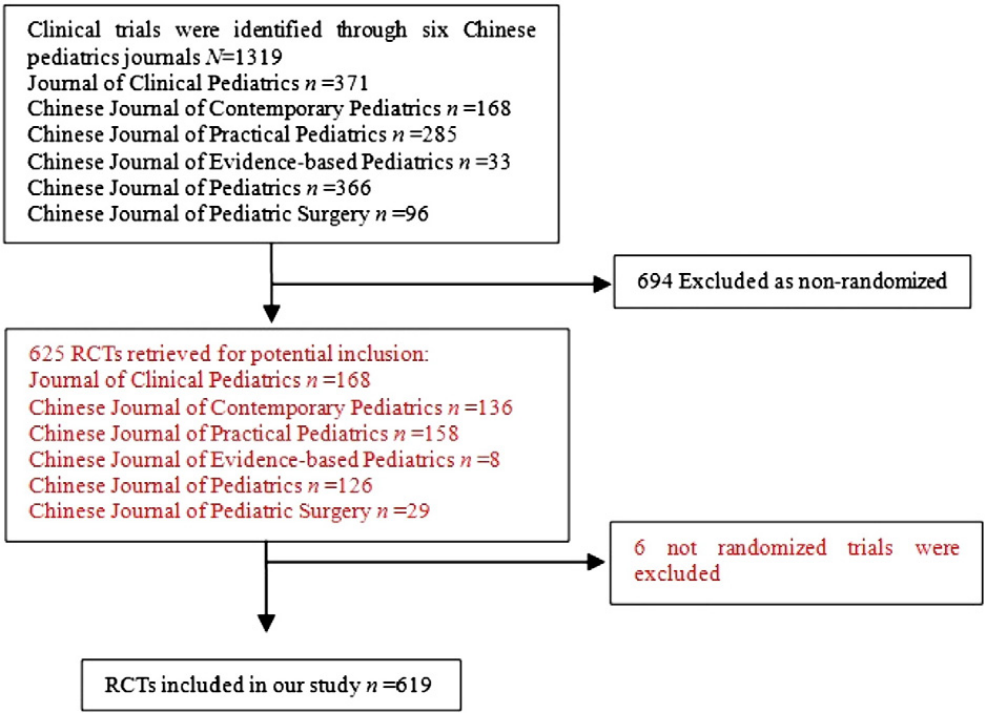

Fig. 1. Flow chart of studies considered for inclusion.

outcomes and estimation (item 17a), ancillary analyses (item 18) between these RCTs published before 1996 and published after 1996.

Nonetheless, as for randomization, there were still over time few trials that report the sequence generation (item 8a, 8b), allocation concealment mechanism (item 8), implementation (item 10) and blinding (item 11a, 11b). Besides, few trials reported how sample size was determined (item 7a), participant flow (item 13a, 13b) and where the full trial protocol can be accessed (item 24). Moreover, none of any RCTs published in Chinese pediatrics journals reported some items, such as trial design (item 3b), outcomes (item 6b), sample size (item 7b), outcomes and estimation (item 17b) and registration (item 23).

4. Discussion

This is the first survey of the extent to which Chinese clinical pediatrics randomized controlled trials adhere to important items of the CONSORT Statement. Overall, the quality of reports of RCTs published in Chinese pediatrics journals has not been improved since the CONSORT Statement was first introduced into China in 1997.

Many deficits in reporting were evident in these RCTs published in Chinese pediatrics journal, we identified areas of particular concern. Our review revealed that these RCTs were not highly referenced by other researchers working in the same field. This may be due, in part, to the overall poor quality of this body of work, which may also be a reason that most RCTs published in Chinese pediatrics journals are performed in single research center and sample size is small.

In addition, the reporting of ethical issues was inadequate in the Chinese RCTs. Fewer than 2% of the RCTs reported having ethical committee approval, although the latter was a legal requirement in China [11]. Also, only 4% RCTs gave details about informed consent procedures, a few mentioned that participants attended of "their own free will" but the remainder made no mention of consent. However, this level appears better than in a review of traditional Chinese medicine trials [12]. Likewise, no any RCTs was registered or reported a registration number, although the International Committee of Medical Journal Editors (ICMJE) have required all clinical trials to be registered in an effort to increase transparency and accountability [13,14]. This may be due to lack of compulsory policies that only having been registered trials can be published in journals in China. Now, Chinese periodicals association only just recommended that priority be published clinical trial has been registered [15].

Our study also provided some disappointing results. For example, as for randomization, few trials reported detailed information on their method used to generate the random allocation sequence (<8%), allocation concealment mechanism (<2%) and implementation (<1%). It was well known that only unpredictable and unknown allocation schedule could minimize selection and confounding biases. So, CONSORT Statement deemed that use of the term 'randomized' is not sufficient, the trial report should also specify the exact method used in generating the sequence, e.g. computer-generated random number, which will allow readers to check if researchers use an appropriate random method. A description of adequate allocation concealment is also important, as selection bias may arise from researchers consciously or subconsciously exerting influence on the enrolment process. Some researchers have found exaggerated treatment effects in studies which have inadequate or unclear allocation concealment [4,16]. Our findings appeared same as a review of traditional Chinese medicine trials [12]. Although the adequate randomization methods accounted for a larger proportion (12%) than allocation concealment, there are also some investigations which showed that only 6.8% of the RCTs published in Chinese journals were deemed authentic randomized trials [17]. So we deemed that

Table 1
Epidemiology of RCTs published in Chinese pediatrics journals.

Category	Characteristic	Number (%) of N = 619
Number of times cited	0	162 (26.2)
	1–5	278 (44.9)
	5–10	83 (13.4)
	10–15	59(9.5)
	>15	37(6.0)
Role of first author	Clinician	611(98.7)
	Graduate student	5 (0.8)
	Other	3(0.5)
Condition focused on in review (common ICD-10[a])	Diseases of the respiratory system	170(27.5)
	Diseases of the digestive system	101(16.3)
	Diseases of the blood and blood-forming organs and immune mechanism	67(10.8)
	Diseases of the nervous system	62(10.0)
	Diseases of the genitourinary system	44(7.1)
	Diseases of the circulatory system	41(6.6)
	Symptoms, signs and abnormal clinical and laboratory findings, not classified elsewhere	29(4.7)
	Endocrine, nutritional and metabolic diseases	26(4.2)
	Infectious and parasitic diseases	21(3.4)
	Diseases of the skin and subcutaneous tissue	15(2.4)
	Diseases of the musculoskeletal system and connective tissue	14(2.3)
	Neoplasms	10(1.6)
	Mental and behavioral disorders	9(1.5)
	Pregnancy, childbirth and the puerperium	8(1.3)
	Diseases of the eye and adnexa	2(0.3)
	Diseases of the ear and mastoid process	0(0.0)

[a] International Classification of Diseases 10.

the quality of the RCTs included in our study may be overstated. Likewise, almost all the trials (<1%) did not provide detailed information about blinding of either participants or investigators. Without blinding the groups may have been treated differently by the investigator and the outcomes not measured objectively, thus creating further assessment bias. Participants aware of their treatment may behave differently or have particular expectations [18], thus affecting the results.

Even though the CONSORT Statement was first introduced into China in 1997, compliance with CONSORT reporting guidelines was still very low. Such as few studies described the following items, such as settings and locations where the data were collected, were there any changes to trial outcomes after the trials commenced and reasons, how sample size was determined, participant flow, trial limitations and so on. This may be due, in part, to only one Chinese pediatrics journal (Chinese Journal of Evidence-based Pediatrics) that has been registered as requiring authors to conform with CONSORT and did not include CONSORT Statement in "Instruction to Authors". The intention of the CONSORT Statement was to improve the quality of reporting of RCTs. Some studies on the quality of reports of RCTs before and after the publication of CONSORT have suggested that the adoption of this statement was associated with improved reporting of RCTs [19–21]. But based on the results as well as on experiences and impressions collected during our analysis, we did not see the same tendency in China. This may be due, in part, to the CONSORT Statement that is not mandated by the editors of journals, even many medical editors of journals and authors did not know the statement very well in China. Hu J et al's study assessed the application of the CONSORT Statement in "Instruction to Authors" of 84 Chinese medical journals shown that more than 50% (39/69) of journals indicated that they do not know CONSORT Statement, approximately 40%(8/21) of journals thought it does not need to include CONSORT Statement in "Instruction to Authors" of Chinese medical journals [22]. So, we strongly recommend the use of CONSORT Statement by authors. We also recommend that Chinese editors of medical journals recognize and promote use of CONSORT Statement in their publications.

Table 2
Descriptive characteristics of RCTs published in Chinese pediatrics journals.

Category		All N = 619	≤1996 n = 157	1997–2010 n = 462
Author number median (IQR)		3(2–5)	3(2–4)	4(3–5)
Smple size median (IQR)		52(18–125)	46(12–89)	58(22–138)
Involving research centers	Single center n(%)	448(72.4)	120(76.4)	328(71.0)
	Multi-center n(%)	171(27.6)	37(23.6)	134(29.0)
Informed consent[a] yes n(%)		25(4.0)	0(0)	25(5.4)
Ethnic review yes n(%)		11(1.8)	0(0)	11(2.4)
Funding[a] yes n(%)		127(20.5)	2(1.27)	125(27.1)
Clinical trials registry yes n(%)		0(0)	0(0)	0(0)

[a] Indicates $p<0.05$.

There are some limitations to our study. We focused on our assessment to the extent to which trials reported CONSORT items. Thus, we can not make inferences about the relationship between CONSORT adherence and trial quality or the validity of trial results. We selected RCTs published in Chinese pediatrics journals indexed in the Chinese Science Citation Database, therefore, our findings may not represent the quality of reporting of clinical pediatrics RCTs published in other Chinese or foreign journals. The quality of the current RCTs published in Chinese pediatrics journal as just judged by authors' description in articles and did not try to contact the authors to check the detailed randomization method and allocation concealment etc, so the quality of these RCTs included in our study may be exaggerated.

The present study provides empirical evidence of suboptimal reporting quality of RCTs in pediatrics and highlights the need for endorsement of the CONSORT Statement by Chinese journals in the field of pediatrics, as well as the need for increased vigilance of authors and editors regarding compliance of manuscripts to the CONSORT Statement.

5. Conclusion

Overall, the quality of reporting of RCTs published in Chinese pediatrics journals has not substantially improved since the publication of CONSORT Statement. The quality of the current RCTs as judged by their publications is still generally poor and often not adequate to allow readers to assess trial validity. In the future, Chinese journals should enhance to adopt the CONSORT Statement to improve the reporting quality of Chinese RCTs and ensure truth and reliability of conclusions.

Table 3
CONSORT assessment of reporting characteristics of RCTs published in Chinese pediatrics journals.

Section/topic	Item no.	Checklist item	≤1996 n = 157 (%)	1997–2010 n = 462 (%)
Title and abstract				
	1a[a]	Identification as a randomized trial in the title	20(12.74)	261(56.49)
	1b[a]	Structured summary of trial design, methods, results, and conclusions	2(1.57)	276(59.74)
Introduction				
Background and objectives	2a[a]	Scientific background and explanation of rationale	55(35.03)	299(64.72)
	2b[a]	Specific objectives or hypotheses	2(1.57)	276(59.74)
Methods				
Trial design	3a[a]	Description of trial design (such as parallel, factorial) including allocation ratio	21(13.38)	185(40.04)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	0(0)	0(0)
Participants	4a[a]	Eligibility criteria for participants	14(8.92)	156(33.77)
	4b	Settings and locations where the data were collected	12(7.64)	57(12.34)
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	151(96.82)	451(97.40)
Outcomes	6a[a]	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	31(19.75)	172(37.23)
	6b	Any changes to trials outcomes after the trials commenced, with reasons	0(0)	0(0)
Sample size	7a	How sample size was determined	1(0.63)	5(1.08)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	0	0
Randomization				
Sequence generation	8a	Method used to generate the random allocation sequence	5(3.18)	35(7.58)
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4(2.55)	30(6.50)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	0 (0)	5(1.08)
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	0(0)	4(0.87)
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	0(0)	4(0.87)
	11b	If relevant, description of the similarity of interventions	0(0)	2(0.43)
Statistical methods	12a[a]	Statistical methods used to compare groups for primary and secondary outcomes	12(7.64)	285(55.84)
	12b[a]	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8(5.10)	176(38.10)
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	0(0)	1(0.22)
	13b	For each group, losses and exclusions after randomisation, together with reasons	14(8.92)	44(9.52)
Recruitment	14a[a]	Dates defining the periods of recruitment and follow-up	86(54.78)	361(78.14)
	14b[a]	Why the trial ended or was stopped	24(15.29)	266(57.58)
Baseline data	15[a]	A table showing baseline demographic and clinical characteristics for each group	61(38.85)	281(60.82)
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	41(26.11)	135(29.22)
Outcomes and estimation	17a[a]	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	98(62.42)	369(79.87)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	0	0
Ancillary analyses	18[a]	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	1(0.64)	43(9.31)
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	21(13.38)	80(17.32)
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	3(1.91)	27(5.84)
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	55(35.03)	164(35.50)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	41(26.11)	157(33.98)
Other information				
Registration	23	Registration number and name of trial registry	0(0)	0(0)
Protocol	24	Where the full trial protocol can be accessed, if available	0(0)	10(2.16)
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2(1.27)	125(27.1)

[a] Indicates $p<0.05$.

Author contributions

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Acquisition of data: Bin Ma, Guo-qing QI, Haimin Li.
Analysis and interpretation of data: Bin Ma, Wen-jie Liu, Yuan Zhang, Haimin Li.
Drafting of the manuscript: Bin Ma, Kehu Yang.
Final approval of manuscript: Bin Ma, Kehu Yang, Guo-qing QI, Haimin Li, Qing Hu, Wen-jie Liu, Yuan Zhang.

Financial disclosure

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Conflict of interest declarations

All the authors declared that none any conflict of interests.

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