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คุณภาพการรายงานวิจัยเชิงทดลองแบบสุ่มที่มีกลุ่มควบคุมในวารสารสุขภาพไทย: การทบทวนวรรณกรรมอย่างเป็นระบบ

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Quality of Reporting Randomized Controlled Trials in Thai Health Care Journals : A Systematic Review

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หลักการและวัตถุประสงค์ : การศึกษาเชิงทดลองแบบสุ่มที่มีกลุ่มควบคุม (RCTs) ที่ดีถือว่าเป็นมาตรฐานสูงสุดสำหรับการทดลองทางคลินิก โดยจะนำมาซึ่งหลักฐานเกี่ยวกับประสิทธิผลของการดูแลรักษาที่มีความน่าเชื่อถือมากที่สุด วิธีในการประเมินคุณภาพของการศึกษาเชิงทดลองแบบ RCTs คือ การพิจาณาคุณภาพรายงานวิจัยโดยมี CONSORT Statement เป็นเครื่องมือ การศึกษาครั้งนี้มีวัตถุประสงค์เพื่อศึกษาคุณภาพรายงานวิจัยเชิงทดลอง แบบ RCTs ในวารสารสุขภาพไทย

วิธีการศึกษา : สืบค้นรายงานการศึกษาเชิงทดลองแบบ RCTs ที่ตีพิมพ์เป็นภาษาไทยในวารสารสุขภาพไทย ระหว่าง พ.ศ. 2551 –2555 ในฐานข้อมูล Online Public Access Catalog (OPAC) ของมหาวิทยาลัยขอนแก่นและมหาวิทยาลัยในเครือข่าย คุณภาพรายงานวิจัยประเมินโดยการใช้แบบบันทึกข้อมูลที่ดัดแปลงมาจาก CONSORT Statement จำนวน 25 หัวข้อหลัก (37 หัวข้อย่อย) นำเสนอคุณภาพรายงานวิจัยรายหัวข้อและภาพรวมของคุณภาพรายงานวิจัย

ผลการศึกษา : จากการสืบค้นมี 757 รายงานที่เข้าข่าย พบรายงานวิจัยที่ผ่านเกณฑ์คัดเข้า 35 รายงาน ผลลัพธ์รายข้อของ CONSORT Statement มี 18/37 ข้อ (ร้อยละ 48.6) ที่มีการรายงานตั้งแต่ร้อยละ 75 ขึ้นไป ประเด็นหลักที่ควรปรับปรุงคุณภาพรายงานวิจัย ได้แก่ ขนาดตัวอย่าง (ร้อยละ 40) วิธีการสร้างการจัดสรรลำดับ (ร้อยละ 57) กระบวนการจัดการลำดับแบบสุ่ม (ร้อยละ 43) การปกปิด (ร้อยละ 57)

Background and Objective: A well designed randomized controlled trial (RCT) provides the most reliable evidence on the effectiveness of interventions, the gold standard for a clinical trial. A way to assess the quality of RCTs is to consider the reporting quality; The CONSORT Statement is a tool. The Objective of this study was to describe the quality of reporting RCTs in Thai Health Care Journals

Methods: Thai-language RCT reports published in Thai Health Care Journals between 2008 and 2012 were searched using Online Public Access Catalog (OPAC) of Khon Kaen University and Thai University Library Network of OPAC. Reporting quality of RCTs was assessed using adapted CONSORT Statement; a standard data collection form of a 25-main-item checklist (37 items). Quality of reporting is presented for each item, and also the overall.

Results: The search identified 757 RCTs. Thirty-five RCTs met the inclusion criteria. Results for each item of the CONSORT Statement; 18 of 37 (48.6%) items were reported in at least 75%. Some important items were inadequately reported; sample size determination (40%), sequence generation (57%), allocation concealment mechanism (43%), blinding (57%), participant flow (9%), reporting of estimated effect size and its precision (14%,

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แผนภูมิการไหลของผู้เข้าร่วมการทดลอง (ร้อยละ 9) การนำเสนอผลลัพธ์ด้วยค่าประมาณ Effect size และ 95% ช่วงเชื่อมั่น (ร้อยละ 14) หัวข้อที่มีการรายงานน้อยที่สุด คือ หมายเลขการลงทะเบียนและชื่อของการลงทะเบียนการทดลอง (1/35) แหล่งข้อมูลของเค้าโครงวิจัยฉบับเต็ม (1/35) และการวิเคราะห์ทางสถิติเพิ่มเติม (2/14) คุณภาพของการรายงานวิจัยเชิงทดลองแบบ RCTs โดยภาพรวมมีคุณภาพระดับปานกลาง ร้อยละ 80 โดยรายงานต่ำสุด 18 หัวข้อ สูงสุด 26 หัวข้อ

สรุป : รายงานวิจัยเชิงทดลองแบบสุ่มที่มีกลุ่มควบคุม (RCTs) ในวารสารสุขภาพไทยควรมีการปรับปรุงคุณภาพการรายงานให้ดีขึ้น

13%). The least reported items were registration number and name of trial registry (1/35), where the full trial protocol can be accessed (1/35) and statistical methods for additional analyses (2/14). The overall quality was moderate; 28 RCTs were reported in 18 to 26 items.

Conclusions : The quality of reporting RCTs published in Thai Health Care Journals needs to be improved.

Keywords: CONSORT, Clinical Trials, RCTs, Endorsement, Reporting Quality.

ศรีนครินทร์เวชสาร 2559; 31 (3):320-327. ♦ Srinagarind Med J 2016; 31 (3): 320-327.

Introduction

A well-designed randomized controlled trial (RCT) provides the most reliable evidence on the effectiveness of interventions[1], and also can reduce bias in selection and confounding biases. Because of this, the RCT is considered as the "gold standard" for a clinical trial[2].

Currently the number of RCTs published continues to rise. The literature search on November 24th, 2013 using a keyword of "Randomized controlled trial" for the number of RCT articles published in the database PUBMED (MEDLINE) found 39 reports of RCTs in 1965 and increased to 33,129 reported in 2012[3]. As there are many RCTs published each year, some of them may contain either trivial or serious flaws. Some flaws are so serious that they then lead to misleading conclusions, or research that fails to provide important information to guide clinical decisions making[4-6]. In 1994 Altman observed research papers and summary of empirical evidence of prevalence of methodological problems in published reports of randomized trials; 68% of 206 reports not reporting an adequate method for generating random numbers; 89% of 196 report not reporting the mechanism used to allocated intervention, and inadequate information on harmful consequence of intervention[7].

Quality of RCT is a multidimensional concept, which could relate to the design, conduct, and analysis of a trial, its clinical relevance, or quality of reporting[8]. Alternative way to assess the quality of RCTs is to consider the reporting quality. The Consolidated Standards of Reporting Trials (CONSORT) Statement is a tool to improve the quality of reporting of RCTs. The CONSORT Statement has been published since 1996, and was revised to CONSORT 2010 which is comprised of a 25-main-item checklist and a flow diagram[9]. This tool provides guidance on reporting RCTs and recommendations for authors regarding how to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding in their critical appraisal and interpretation[10, 11].

More than 400 journals worldwide are supporting the CONSORT Statement with endorsement and have required authors to comply with the CONSORT Statement[12, 13]. The results from Cochrane systematic review showed the benefit of CONSORT endorsing journals; 25/27 outcomes are improved with CONSORT endorsement [14]. Recent regional studies evaluated the endorsement of Japanese and Chinese RCT reports to the CONSORT Statement. These studies revealed the need for improvement of reporting quality and

encourage journals adhering to CONSORT Statement[15, 16].

In Thailand, based on literature reviews by the first review author (AP), there were just about 10% (5/52) of Thai Health Care Journals that provided the CONSORT Statement for authors in "Instructions for authors". In addition, there is no research that evaluates the reporting quality of RCTs published in Thai Health Care Journals. The objectives of this study was to describe the quality of published randomized controlled trials (RCTs) in Thai Health Care Journals.

Methods

Inclusions:

All Thai language full-texts of RCTs involving human subjects, of parallel designs that investigated the effectiveness of interventions, published during 2008 to 2012 listed in the Thai-Journal Citation Index (TCI) Group I in the fields of science technology were included.

Searching of RCT reports and study selection:

Thai-language RCT reports published between January 2008 to December 2012 in Thai Health Care Journals (TCI Group I) were searched using the Online Public Access Catalog (OPAC) of Khon Kaen University and the Thai University Library Network of OPAC. The keywords or phrases used were "randomized controlled trial", "random", "trial", "clinical trial", "placebo", and "blind".

The first review author (AP) combined all search results, removed duplicates records, and selected potentially relevant studies according to the pre-defined inclusion criteria by screening titles and abstracts, then the full-text were retrieved and examined.

Data extraction:

Data abstraction was done by the first review author (AP) using a standard data extraction form (pre-prepared and piloted forms) which was designed and developed based on the revised version of the CONSORT Statement (25–main items checklist consists of 37 items)[13]. The second review author (PP) randomly selected 10% of 35 included studies, and independently extracted the data in order to verify the accuracy of data extraction. There was 8.9% of disagreement. Discrepancies were resolved by discussion between the two reviewers. Data entry was done by the first review author (AP). The same reviewer double-checked for accuracy information between data extraction forms and the electronic files.

Data extraction items included the characteristics of RCT reports (e.g. title, journal's name, year of publication, number of objectives, number of participants, follow-up time), and reporting quality depending on items from the CONSORT Statement. For the quality of reporting; we assigned an answer "yes", "no", or "not applicable" for each item based on whether it was reported or was not. In addition, there were 5 items (7b, 11b, 12b, 14b, and 18) which were not possible to assign as a "not applicable" category.

Outcomes and outcome measures

1) Reporting quality of RCT reports for each item:

The percentage of reporting quality for each item of the 35 included studies was calculated; e.g. there were 35 included studies that reported item 1a =35/35=100%. Then considered each item as a good grade if that item was reported at least 75%.

2) Overall reporting quality of RCT reports:

For each RCT report, the percentage of reported items (e.g. reported 37 items/37 items=100%) was calculated and then classified into a grade of good (reported at least 75%), moderate (reported 50% to 74.9%), or low (reported less than 50%).

Statistical analysis

We canducted a descriptive statistics with STATA 10.0 for general characteristics of RCT reports; the numbers and percentages were calculated. The numbers of objectives, number of participants, and time to follow-up in each RCT were presented as median, and maximum : minimum. The quality of RCT reports for each item, and the overall quality were determined by

the numbers and percentages of reporting.

Results

The search strategies identified 757 records. After 202 duplicates were removed, the first review author (AP) applied the inclusion criteria to examine all 555 records of RCTs by screening titles and abstracts to remove obviously irrelevant reports. For 61 remaining records, full-text RCTs were screened by the first review author. Finally, there were 35 RCTs included in this study, the reason for exclusion were noted (Fig. 1).

Of all 35 included RCTs, most of them were published in 2008 (28.5%), with single research objective (85.7%), recruited participants from 20 to 60 persons, and the follow-up period less than a month (57.2%), (Table 1).

For the reporting quality of RCT reports for each item of the 35 included studies, there were 18 of 37 items (48.6%) reported in at least 75%; four items (2a, 2b, 6a, 21) were reported with 100%. Fourteen items (7a, 7b, 8b, 9, 10, 12b, 13a, 17a, 17b, 20, 21, 23, 24, 25) were reported less than 50%. The least reported items were item 23 (registration number and name of trial registry) and item 24 (where the full trial protocol can be accessed, if available) with the percentage of 2.9%. As a consequence of no included studies reported (item 3b) method changes, (item 6b) outcome change, and (item 14b) that the trial was ended or stopped, these 3 items were not applicable for calculation of any percentage, (Table 2).

The overall quality of reporting was moderate – there were 28 RCTs that reported 18 to 26 items (28/35=80%). Of 37 items, the median of reported items was 19 items (min. = 13, max. = 25), (Table 3).

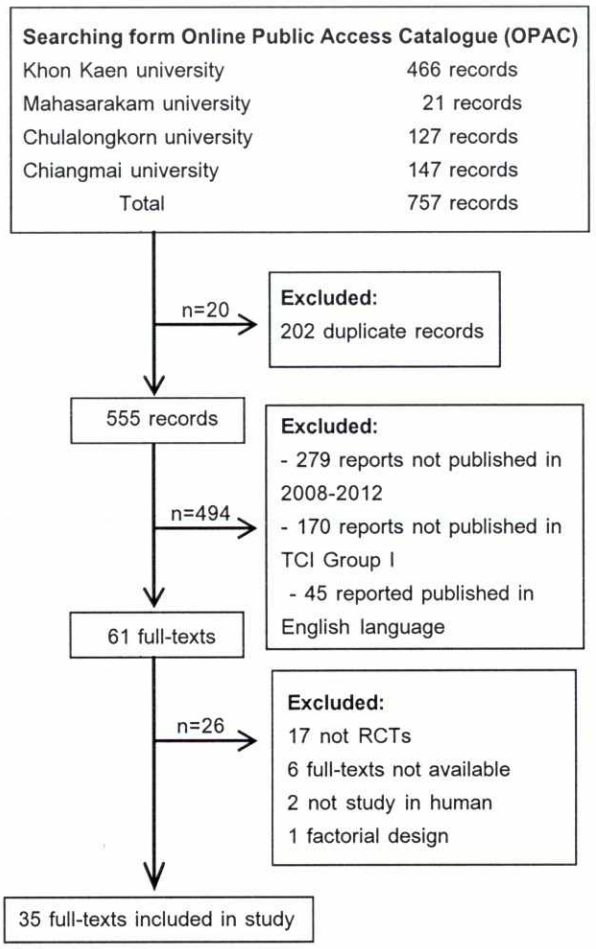

Figure 1 Flow diagram of included RCT reports.

Discussion

Summary of main findings:

This is the first study evaluated the adherence to the CONSORT Statement checklist of reporting published in Thai Health Care Journals; restricted to Thai language. A total of 35 included RCT studies were identified through the Online Public Access Catalog (OPAC) of Khon Kaen University and Thai University Library Network of OPAC from 2008 to 2012. The overall quality of reporting was moderate; of 37 items, 18 to 26 items were reported in 28 RCTs. The quality of reporting by each item; of those 35 included RCTs, 18 of 37 items were reported in at least 75%. In addition, several important items were poorly reported; (i) item 7a, Sample size determination (40%), (ii) item 8a, Method used to generate the random allocation sequence (57%), (iii) item 9, Allocation concealment mechanism (43%), (iv) item 13a, Participant flows (9%), (v) item 11a, Blinding (57%), and (vi) item 17a, Reporting confidence interval of estimated effect size (14%).

The explanation for inadequate reporting of RCTs published in Thai Health Care Journals could be due to that most of Thai Health Care journals do not require

Table 1 Characteristics of RCT reports in Thai Health Care Journal (n=35).

Characteristics	n (%)
1. Years of publication	
2008	10 (28.5)
2009	6 (17.1)
2010	3 (8.6)
2011	8 (22.9)
2012	8 (22.9)
2. Number of Objective (s)	
1	30 (85.7)
2	4 (11.4)
4	1 (2.9)
4. Participants (Persons)	
Fewer than 20	3 (8.6)
Between 20 - 60	18 (51.4)
Between 61 - 100	7 (20)
More than 100	7 (20)
(Median 60 : min 7, max 748)	
5. Follow-up (Days)	
Less than 30	20 (57.2)
Between 30 - 60	6 (17.1)
Between 60 - 90	3 (8.6)
More than 90	6 (17.1)
(Median 24: min 1, max 365)	

authors to comply with the CONSORT Statement for manuscript submission. It was found that only 5 out of 52 Thai Health Care Journals mentioned the CONSORT Statement in their Instruction to Authors.

Agreements/Disagreements with other studies

One recent systematic review[17] which included 27 RCTs evaluated Traditional Chinese Medicine treatment in diabetes mellitus published in 2011 was consistent with the current study; (i) very few journals recommended the CONSORT Statement in their Instruction for authors, (ii) inappropriate reporting of item 7a sample size calculation; they found none but the current study found some (40%); In addition, the percentages of reporting the following items were high which were similar to the current study; item 3a, trial design (100%), item 4a, eligibility criteria for participants (88.9%), item 5, intervention for each group (100%), and item 9, method used to generate the random allocation sequence (57%).

Another study evaluated a compliance to the CONSORT Statement on the participant flow diagrams of infectious diseases published in the top general medical and infectious disease journals in 2010[18]. Of 67 included RCTs, 77.6% presented the CONSORT participant flow diagram (item 13a). Findings of this study were opposed to the current study that found only 8.6%. This could be explained by the significant difference in number of the CONSORT Statement endorsements by the journal. They found 46.3% of the included journals endorsed the CONSORT guidelines in their instruction to the authors; conversely, there were very few for the current study (9.6%).

A study of Guo et al. in 2014[19] assessed quality of reporting RCTs published in cancer nursing research from 1984 to 2010. The investigators included 227 RCTs (220 published between 1997 and 2010, 7 published between 1984 and 1996). There were 89 included RCTs published during 2006 to 2010 which seems comparable to the current sample. Comparing selected items between this study's results to the present study, some items did not show big differences; item 7a, sample size calculation (59.6% vs. 40%), item 8a, the method used to generate the random allocation sequence (50.6% vs. 57%), and item 9, allocation concealment mechanism (40.4% vs. 43%), whereas, some items were obviously different; item 13a, participant flows (84.3% vs. 9%), item, 11a blinding (29.2% vs. 57%), and item 17a, reporting confidence interval of estimated effect size (51.7% vs. 14%). The lower rate for reporting of the flow diagram in the present study could be caused by journal restrictions on the number of allowable figures, and no requirement for authors to comply with the CONSORT Statement. For the lower proportion of reporting of the blinding in this study maybe due to the fact that generally nursing interventions are non-pharmacologic treatments that are not feasible to blind. For a lack of reporting confidence interval of the effect size in the present study, this is probably due to the fact that authors do not realize the importance of reporting a range of plausible values for the effect size which is valuable for quantifying the effectiveness of a

Table 2 Quality of reporting of RCTs in which item was clearly reported (n=35).

Section/Topic	Item no.	CONSORT Item	n (%)
Title and	1a	Identification as a randomized trial in the title	30 (85.7)
abstract	1b	Structured summary of trial design, methods, results, and conclusions	32 (91.4)
Background	2a	Scientific background and explanation of rationale	35 (100)
and objectives	2b	Specific objectives or hypotheses	35 (100)
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	33 (94.3)
	3b	Important changes to methods after trial commencement(such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	34 (97.1)
	4b	Settings and locations where the data were collected	30 (85.7)
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	33 (94.3)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when theywere assessed	35(100)
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	14 (40)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	3/8 (37.5)*
Sequence	8a	Method used to generate the random allocation sequence	20 (57.2)
generation	8b	Type of randomization; details of any restriction (such as blocking and block size)	6 (17.1)
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	15 (42.8)
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7 (20)
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	20 (57.1)
	11b	If relevant, description of the similarity of interventions	24/32 (75)*
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	32 (91.4)
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	1/8 (12.5)*
Participant flow	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	3 (8.6)
	13b	For each group, losses and exclusions after randomization, together with reasons	19/21 (90.5)*
Recruitment	14a	Dates defining the periods of recruitment and follow-up	32 (91.4)
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	27 (77.1)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	28 (80)
Outcomes andestimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	5 (14.3)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	2/14(12.5)*
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	3/5 (60)*
Harms	19	All important harms or unintended effects in each group	28 (80)
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14 (40)
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	35 (100)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	29 (82.9)
Registration	23	Registration number and name of trial registry	1 (2.9)
Protocol	24	Where the full trial protocol can be accessed, if available	1 (2.9)
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	8 (22.9)

N/A = Not Applicable

* = Excluded one or more RCT reports with not applicable circumstance

Table 3 Overall quality of reporting of RCTs.

Overall quality of RCT reports (37 items)	n (%)
Good: (reported 27-37 items)	0
Moderate (reported 18-26 items)	28 (80)
Low (reported 0-17 items)	7 (20)
(Median 19 : min 13, max 25)	

particular intervention, and that very few of Thai Health Care Journals adopt the CONSORT Statement.

Peters et al, 2015[20] investigated the quality of 18 RCTs on otorhinolaryngologic topics published between January 2010 to June 2014 in the PUBMED database. There were 3 items with a lower rate of reporting than the present study: item 7a, Sample size (28%). Item 8a, Method used to generate the random allocation sequence (44%), item 9, Allocation concealment mechanism (11%). These might be the result that none of the top 5 otorhinolaryngologic journals endorse the CONSORT Statement in the Instructions to Authors.

Strengths and Limitations

This was the first systematic review that explored the quality of RCT reports in Thai health care journals. It was conducted under the rigorous methodology, transparency, and used comprehensive searches through the databases and related journals together with the verification of the accuracy of information retrieval by consultation with librarians in order to retrieve all relevant RCT reports.

There are some limitations. Firstly, a limitation of keywords used for searching RCTs through OPAC; lack of ability to do advanced searches. Secondly, this study only included RCTs published in the Thai language between 2008 and 2012 which may not be representative of the Thai Health Care journals reporting in general.

Conclusions

Implications for practice

Our finding showed the quality of reporting RCTs need to be improved as some important items remained poorly reported. The evidences from other studies suggested that the use of CONSORT checklists is beneficial for the completeness of RCT reports, therefore Thai Health Care Journals should encourage authors to apply the CONSORT Statement as a guide for preparing manuscripts.

Implications for research

In the future, it is advisable for investigators to explore the quality of reporting of RCTs in Thai health care journals by recruiting RCT reports published in both Thai and English languages, expanding the years of publication, comparing the reporting quality of before and after publication of the CONSORT, as well as addressing the reasons for items not being reported.

Acknowledgements

This study was conducted as a part of the master degree dissertation of AP in Public Health (Biostatistics) at Khon Kaen University, Khon Kaen, Thailand.

We would like to gratefully acknowledge Prof. Dr. Malinee Laopaiboon for her idea to explore the quality of RCTs reporting. We would like to thanks the librarians from the Faculty of Public Health, and Medicine, Khon Kaen University, for providing the useful information on searching approaches of OPAC, and their assistances for accessing the full-text articles. The authors wish to thank Professor. James A. Will, University of Wisconsin, Madison, Wisconsin, for his valuable comments and critical review of the manuscript.

References

1. Portney LG, Watkins MP. Foundations of clinical research: applications to practice. 3rd ed: Prentice Hall Upper Saddle River, NJ; 2008.
2. Grimes DA, Schulz KF. An overview of clinical research: the lay of the land. Lancet 2002; 359(9300): 57-61.
3. Corlan AD. Medline trend: automated yearly statistics of PubMed results for any query 2004 [updated 2012 Feb 14;cited 2013 Nov 24]. Available from: http://dan.corlan.net/medline-trend.html.
4. Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias: dimensions of methodological quality associated with estimates of treatment effects in controlled trials. JAMA 1995; 273: 408-12.

5. Moher D, Jones A, Cook DJ, Jadad AR, Moher M, Tugwell P, et al. Does quality of reports of randomised trials affect estimates of intervention efficacy reported in meta-analyses? Lancet 1998; 352 (9128): 609-13.
6. Wood L, Egger M, Gluud LL, Schulz KF, Juni P, Altman DG, et al. Empirical evidence of bias in treatment effect estimates in controlled trials with different interventions and outcomes: meta-epidemiological study. BMJ 2008; 336 (7644): 601-5.
7. Altman DG. Poor-quality medical research: What can journals do? JAMA 2002; 287: 2765-7.
8. Juni P, Altman DG, Egger M. Assessing the quality of controlled clinical trials. BMJ 2001; 323(7303): 42-6.
9. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux P, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. J Clin Epidemiol 2010; 63: e1-e37.
10. Jadad AR, Enkin MW. Randomized Controlled Trials: Questions, Answers and Musings. 2nd ed. Malden, Mass: Wiley-Blackwell; 2007.
11. Hopewell S, Altman DG, Moher D, Schulz KF. Endorsement of the CONSORT Statement by high impact factor medical journals: a survey of journal editors and journal 'Instructions to Authors'. Trials 2008; 9: 20.
12. Altman DG. Endorsement of the CONSORT statement by high impact medical journals: survey of instructions for authors. BMJ 2005; 330 (7499): 1056-7.
13. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010; 340: c332.
14. Turner L, Shamseer L, Altman DG, Wee ks L, Peters J, Kober T, Dias S, Schulz KF, Plint AC, Mohe r D. Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals. Cochrane Database of Systematic Reviews 2012, Issue 11. Art. No.: MR000030. DOI: 10.1002/14651858.MR000030.pub2.
15. Xu L, Li J, Zhang M, Ai C, Wang L. Chinese authors do need CONSORT: reporting quality assessment for five leading Chinese medical journals. Contemp Clin Trials 2008; 29: 727-31.
16. Uetani K, Nakayama T, Ikai H, Yonemoto N, Moher D. Quality of reports on randomized controlled trials conducted in Japan: evaluation of adherence to the CONSORT statement. Internal Medicine 2009; 48: 307-13.
17. Wang P, Xu Q, Sun Q, Fan F-f, Guo X-r, Guo F. Assessment of the Reporting Quality of Randomized Controlled Trials on the Treatment of Diabetes Mellitus with Traditional Chinese Medicine: A Systematic Review. PloS one 2013; 8: e70585.
18. Godwin OP, Dyson B, Lee PS, Park S, Lee E. Compliance to the CONSORT Statement on Participant Flow Diagrams in Infectious Disease Randomized Clinical Trials. J Pharma Care Health Sys 2. 2015;129. doi: 10.4172/2376-0419.1000130.
19. Guo JW, Sward KA, Beck SL, Staggers N. Quality of reporting randomized controlled trials in cancer nursing research. Nurs Res 2014; 63: 26-35.
20. Peters JP, Hooft L, Grolman W, Stegeman I. Assessment of the Quality of Reporting of Randomised Controlled Trials in Otorhinolaryngologic Literature – Adherence to the CONSORT Statement. PloS one 2015; 10 : e0122328.