Does the CONSORT checklist improve the quality of reports of randomised controlled trials? A systematic review

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ABSTRACT

Objective: To determine whether the adoption of the CONSORT checklist is associated with improvement in the quality of reporting of randomised controlled trials (RCTs).

Data sources: MEDLINE, EMBASE, Cochrane CENTRAL, and reference lists of included studies and of experts were searched to identify eligible studies published between 1996 and 2005.

Study selection: Studies were eligible if they (a) compared CONSORT-adopting and non-adopting journals after the publication of CONSORT, (b) compared CONSORT adopters before and after publication of CONSORT, or (c) a combination of (a) and (b). Outcomes examined included reports for any of the 22 items on the CONSORT checklist or overall trial quality.

Data synthesis: 1128 studies were retrieved, of which 248 were considered possibly relevant. Eight studies were included in the review. CONSORT adopters had significantly better reporting of the method of sequence generation (risk ratio [RR], 1.67; 95% CI, 1.19–2.33), allocation concealment (RR, 1.66; 95% CI, 1.37–2.00) and overall number of CONSORT items than non-adopters (standardised mean difference, 0.83; 95% CI, 0.46–1.19). CONSORT adoption had less effect on reporting of participant flow (RR, 1.14; 95% CI, 0.89–1.46) and blinding of participants (RR, 1.09; 95% CI, 0.84–1.43) or data analysts (RR, 5.44; 95% CI, 0.73–36.87). In studies examining CONSORT-adopting journals before and after the publication of CONSORT, description of the method of sequence generation (RR, 2.78; 95% CI, 1.78–4.33), participant flow (RR, 8.06; 95% CI, 4.10–15.83), and total CONSORT items (standardised mean difference, 3.67 items; 95% CI, 2.09–5.25) were improved after adoption of CONSORT by the journal.

Conclusions: Journal adoption of CONSORT is associated with improved reporting of RCTs.

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In the mid 1990s, in response to concerns about quality of reporting of randomised controlled trials (RCTs), an international group developed the Consolidated Standards of Reporting Trials (CONSORT) statement.[1,2] CONSORT is intended to improve the reporting of an RCT, enabling readers to understand its conduct and to gauge the validity of its results.

The original CONSORT statement, developed for simple two-group parallel RCTs, comprises a checklist and flow diagram.[1] Presently, CONSORT includes a 22-item checklist and four-stage flow diagram.[2] The items included in the checklist were selected, whenever possible, because empirical evidence indicates that not reporting the information is associated with biased estimates of treatment effectiveness, or because the information is essential to judge the reliability or relevance of the findings.[2-6] CONSORT has been endorsed by prominent medical journals and by editorial groups, such as the International Committee of Medical Journal Editors.

Since the publication of CONSORT, several evaluations of its effectiveness have been published.[7-10] Two articles have suggested that journal endorsement of CONSORT is associated with improved quality of reporting.[7,8] However, other study results have been equivocal.[9,10] To gain a broader global perspective of CONSORT's effectiveness, we conducted a systematic review, examining effectiveness in journals that have formally endorsed CONSORT.

METHODS

Study selection

Studies were eligible if they were comparative studies evaluating the quality of RCT reporting; one of the comparator groups included RCTs reported in CONSORT-adopting journals; and outcomes reported included any of the 22 items on the CONSORT checklist, summary scores based on the CONSORT checklist, or any measures of overall trial quality.[11] Study quality was not an exclusion criterion, and studies were not excluded based on publication status or language of publication.

Journal adoption of CONSORT was defined as a statement in the "instructions to authors" to follow CONSORT in preparing manuscripts, or a requirement for authors to submit a completed CONSORT checklist with their manuscript.

Eligible studies fell into three groups: those that (a) compared CONSORT adopters and non-adopters after the publication of CONSORT, (b) compared CONSORT-adopting journals before and after publication of CONSORT, or (c) a combination of (a) and (b). We did not specify a primary outcome for our review, but included as outcomes: (1) reporting of any of the 22 items on the CONSORT checklist, (2) summary scores based on the CONSORT checklist, or (3) any measures of overall trial quality.

Study identification

The main search strategy was developed in MEDLINE (1996 to 2005 week 28) and customised for EMBASE (1996 to 2005 week 32); both were executed through the Ovid interface. In addition, the Cochrane Methodology Register (up to 2nd Quarter 2005) and the Cochrane Database of Methodology Reviews (up to 2nd Quarter 2005) were initially searched via Update Software in 2004 and then via Wiley InterScience for the 2005 update. The Science Citation Index, Social Sciences Citation Index and Arts & Humanities Citation Index (June 2005) were searched through the ISI Web of Knowledge interface.

We searched for grey literature, checked the bibliographic references of relevant articles, and consulted with CONSORT experts.

The search was designed to retrieve citations published since 1996, when CONSORT was first published. Keywords included *randomised controlled trial*, *publication bias*, *CONSORT*, and *epidemiological methods*. The full search strategy is available from the authors.

Study inclusion

Two reviewers (A C P and A M) independently reviewed titles and abstracts using

broad screening criteria (comparative study, and outcomes included some measure of trial reporting quality). Articles of potential relevance were further assessed (by A C P and D M) for eligibility. Disagreements were resolved by consensus. The reviewers were not blinded to authors or journals.

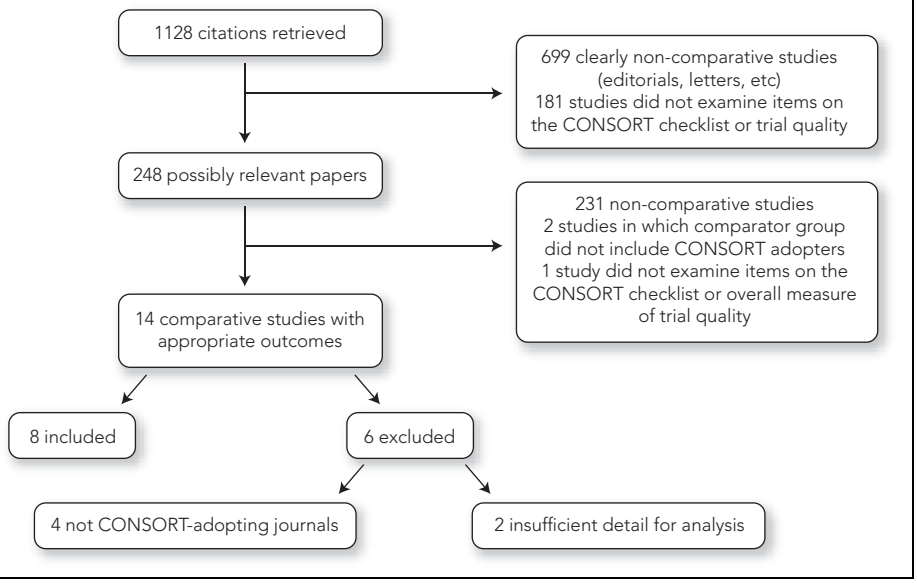
Detailed determination of study eligibility

When a comparative study with appropriate outcomes was identified, a detailed assessment was undertaken to determine eligibility. First, the study was reviewed to determine the journals and time frame in which the individual RCTs forming the basis for the comparison were published.

Second, the journals for these individual RCTs were examined to determine whether they met our definition of CONSORT adopter. We reviewed the most recent "instructions to authors" to determine if the journal was currently a CONSORT adopter (as indicated by a statement to use CONSORT in preparing the manuscript or by requiring submission of a completed checklist). We then reviewed previous issues to determine the journal's CONSORT adoption date, and compared this with the date of RCT publication. The journal had to have adopted the CONSORT statement at least 6 months before the RCT publication to be considered a CONSORT adopter.

If CONSORT use was not currently required by a journal, we assumed the journal had never adopted the CONSORT statement.

1 Selection of studies for review



Assessment of methodological quality

A single non-blinded reviewer (A C P) assessed reporting quality using a five-item checklist based on principles of internal and external validity.[12] Quality assessment included the use of a control group, RCT

2 Characteristics and quality of included studies

First author, year, country	Number of RCTs	Number of journals	Number of CONSORT adopters*	Clinical content	Study design	More than one outcome reviewer	Interobserver reliability or consensus method	Blinded reviewer	Source of funding†
Hewitt,[13] 2005, UK	234	4	3 (2 follow; 1 checklist)	Multiple areas	Post-intervention	Yes	No	Not reported	University of York
Halpern,[14] 2004, Canada	99‡	15‡	1 (1 checklist)	Obstetrical anaesthesia	Before/after	Not reported	Yes	Not reported	Not reported
Faunce,[15] 2003, Australia	13	7	2 (2 checklist)	Overdoses in health volunteers	Before/after; post-intervention	Yes	Not reported	Not reported	Not reported
Montori,[16] 2002, Canada	200	5	4 (2 follow; 2 checklist)	Multiple areas	Post-intervention	Yes	Yes	Not reported	Not reported
Hill,[17] 2002, US/Australia	240§	68§	2 (2 follow)	Adult rheumatological diseases	Before/after; post-intervention	Yes	Yes	Yes¶	Arthritis Foundation of Australia
Devereaux,[7] 2002, Canada	105	7	6 (4 follow; 2 checklist)	Internal medicine	Post-intervention	Yes	Yes	Not reported	Heart and Stroke Foundation of Canada; Canadian Institutes of Health Research (CIHR); Alberta Heritage Foundation; Canada Research Chair
Sanchez-Thorin,[18] 2001, Colombia	75**	1**	1 (1 checklist)	Ophthalmology	Before/after	Yes	Yes	Not reported	Not reported
Moher,[8] 2001, Canada	211	4	3 (2 follow; 1 checklist)	Multiple areas	Before/after with control group	Yes	Yes	No	Jefferson Smurfit Foundation, Ireland; US National Library of Medicine; Merck; Glaxo Wellcome; CIHR

* "Follow" means journal instructions to authors include a statement to follow CONSORT; "checklist" means authors must submit a CONSORT checklist with the article. † "Source of funding" means salary support to the investigators. ‡ The study reported the results of 99 articles from 15 journals. Separate results were reported for journals with more than five articles, for a total of 83 articles from 7 journals — these results were considered for the systematic review. § This study reported the results of 240 papers published in 68 journals. The author provided unpublished data for 133 papers in 66 journals for inclusion in the systematic review. ¶ A random selection of articles was reviewed in a blinded manner. ** This study used results from a previously published paper by Scherer and Crawley[23] as the comparison group. Sanchez-Thorin et al examined 24 RCTs from one ophthalmology journal and included as a comparison the results of 51 trials published in the same journal and reported by Scherer et al, who examined 125 trials published in three ophthalmology journals. RCT = randomised controlled trial. ◆

3 CONSORT items investigated in the included studies

Study	Methods	Results	Other
Hewitt[13]	Allocation concealment		
Halpern*[14]			Total number of CONSORT items (out of 30)
Faunce[15]	Eligibility criteria; stopping rules	Protocol deviation	
Montori[16]	Blinding of participants, data analysts, and outcome assessors		
Hill[17]	Sequence generation; allocation concealment; blinding	Participant flow	
Devereaux[7]	Sequence generation; allocation concealment; blinding of participants, data analysts, intervention administrators, and outcome assessors; method of analysis	Baseline characteristics; participant flow	
Sanchez-Thorin[18]	Eligibility criteria; interventions; objectives; outcomes; sample size determination; sequence generation; allocation concealment; randomisation implementation; blinding of participants, intervention administrators, and outcome assessors; method of analysis	Participant flow diagram; numbers analysed; results for outcome	Description of allocation method in title and abstract
Moher*[8]	Total score (22 items); allocation concealment	Total score (10 items)	Total number of CONSORT items (out of 40); total number of CONSORT items for title/abstract, introduction, discussion

* Both these papers developed a checklist of items based on the CONSORT checklist and gave an overall score to the trials reviewed using this score. Moher et al also reported the results as a total per section of the RCT, and reported the Jadad score as a quality indicator. ◆

cohort ascertainment, how the authors reached agreement on whether a checklist item was included, and whether the reviewers were blinded when assessing outcomes.

Data collection and analysis

Data were extracted by one reviewer (A C P) using a standardised data form, and then checked for accuracy by a second reviewer (D M). Only "consensus" data were used in the review. All data were entered in Review Manager 4.2 (Nordic Cochrane Centre, Copenhagen, Denmark). Dichotomous data were expressed as risk ratios (RR) with 95% confidence intervals. Continuous data were expressed as standardised mean differences with 95% confidence intervals. Consistency across the studies was examined using the I-squared test. Data were pooled using fixed effect models. A priori subgroup analyses included a comparison of RCTs published in journals that specifically require submission of a completed CONSORT checklist with journals that are not CONSORT adopters.

Authors of several possibly relevant studies were contacted for clarification of eligibility and invited to contribute unpublished data. We did not contact the authors of all included studies for additional unpublished data.

RESULTS

Description of studies

Our search strategy identified 1128 studies; 248 were potentially relevant and eight of them[7,8,13-18] met our inclusion criteria (Box 1). One study was included after the author provided unpublished data.[17] Six studies that examined changes in the quality of trial reporting over time or compared quality of trial reporting between journals were excluded, either because they did not include a comparator group or were not published in CONSORT-adopting journals,[9,19-21] or because insufficient detail was available to determine eligibility.[10,22]

The number of RCTs in individual studies ranged from 13 to 240, and the number of journals in individual studies ranged from 1 to 68 (Box 2). All studies were published in English. One study used a different definition of CONSORT adoption (journals in which the editor applied the CONSORT checklist were considered CONSORT adopters),[7] but 88% of RCTs in the study met our definition of CONSORT adoption. For all other included studies, the definition of CONSORT adopters matched our definition.

Overall, 37 different outcomes were reported (range, 1–16 per study) (Box 3). This variability resulted in most outcomes being reported in only one study. Outcomes used in more than one study were reporting of allocation concealment (five studies), sequence generation (three studies), blinding (four studies), participant flow (two studies) and overall number of CONSORT checklist items (two studies, one using a total of 30 items, the other 40 items). Blinding as an outcome was assessed as reported or not in one study,[17] and blinding of participants and data analysts in three studies.[7,17,18]

Box 2 summarises the methodological quality of the studies. All studies were quasi-experimental, with only one study having an a priori defined control group.[8]

CONSORT adopters and non-adopters

CONSORT-adopting journals had better reporting of the method of sequence generation and allocation concealment (Box 4A). For the two studies that reported total number of CONSORT items, the standardised mean difference was 0.83 (95% CI, 0.46–1.19). CONSORT adoption appeared to have less effect on reporting of participant flow and reporting of blinding of participants or data analysts.

Although we planned a priori to determine the influence of journals requiring submission of a completed CONSORT checklist when manuscripts are submitted, this comparison was impossible as very few journals actually require checklist submission. The paucity of data also precluded meaningful examination of publication bias. Tests for heterogeneity were all non-significant.

CONSORT-adopting journals before and after CONSORT publication

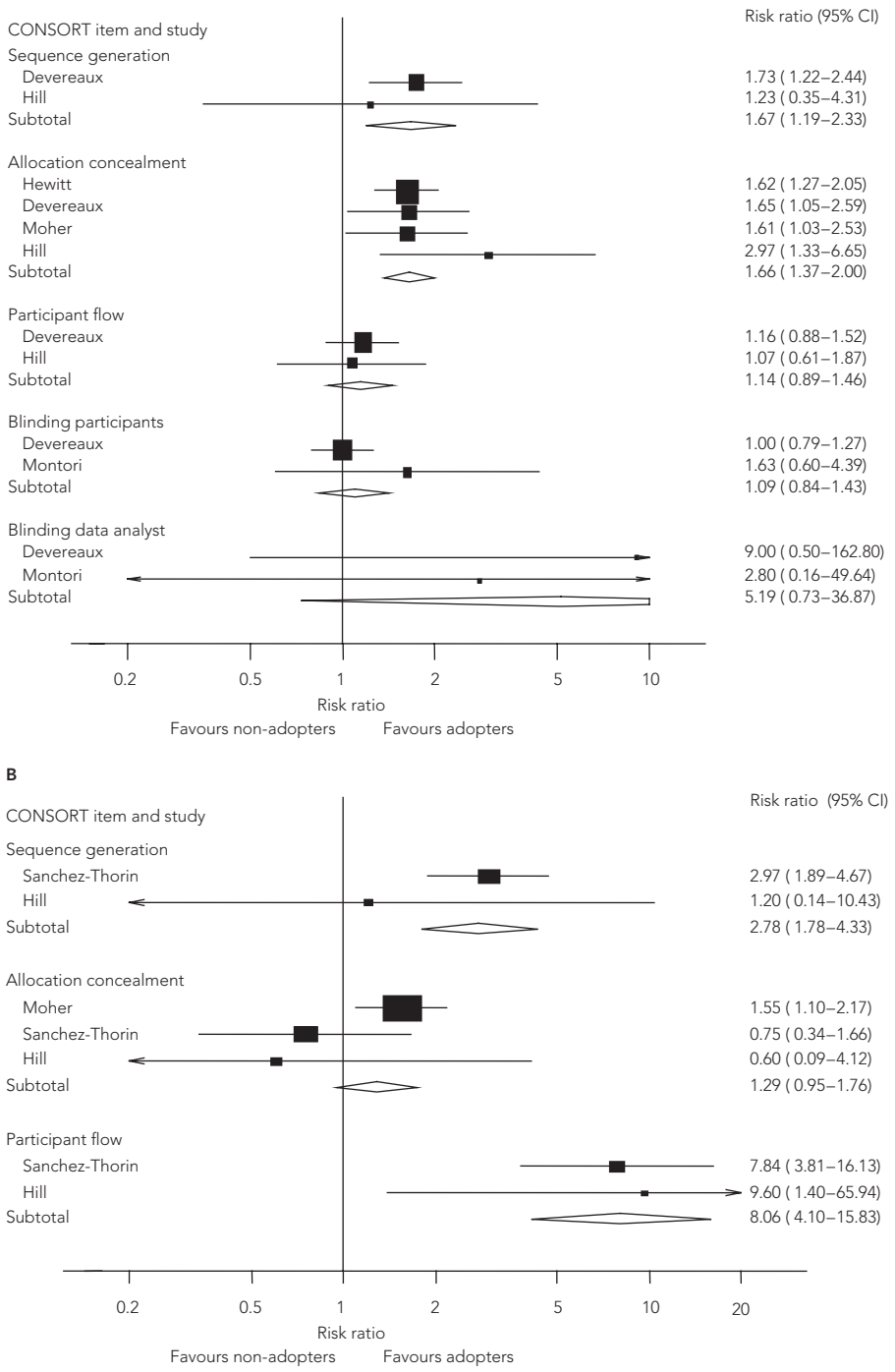
The descriptions of the method of sequence generation, participant flow and total CONSORT items (standardised mean difference, 3.67 items; 95% CI, 2.09–5.25) were better after adoption of CONSORT (Box 4B). CONSORT adoption appeared to have less effect on allocation concealment. The paucity of data precluded meaningful examination of publication bias. There was no evidence of heterogeneity.

DISCUSSION

Studies evaluating the effectiveness of the CONSORT checklist are methodologically weak. The eight studies we identified used

different quasi-experimental designs, which (with one exception) did not include a control group, addressed different questions, and used a large number of discrete outcomes, negating the possibility of combining them — a strength of the systematic review process. Further, analysis of studies that sample journals should take account of the clustering effect in the analysis, which would widen the confidence intervals. Only one study included in the review considered this effect. Nevertheless, our review suggests some improvement in the quality of reporting RCTs when the CONSORT checklist is used. Although the degree of improvement in quality of reporting of particular trial items differs somewhat between our comparison groups (CONSORT adopters v non-adopters after CONSORT publication, and CONSORT adopters before and after CONSORT publication), the direction of the effect remains the same. The difference in magnitude may be related to the small number of studies.

4 Effects of adopting CONSORT



A: Analysis of CONSORT-adopters compared with non-adopters. **B:** Analysis of CONSORT-adopters before and after adopting CONSORT. ◆

Our results are encouraging, but provide no definitive answer as to whether the CONSORT checklist improves reporting of RCTs. Perhaps unique to our review is ascertaining whether the RCTs were published in journals that adhered to CONSORT. If journals do not enforce the use of the checklist, it is likely that the effects we observed underestimate the possible benefits with proper enforcement of CONSORT. A review of 167 high-impact journals found that only 22% mentioned CONSORT in their instructions to authors, and 25% of these referred to the obsolete 1996 version.[24] In another study involving 15 high-impact journals (five of which were not included in the previously mentioned review) that have reported endorsing CONSORT, only eight referred to the statement in their instructions to authors.[25] CONSORT-adopting journals should be more proactive in enforcing adherence to CONSORT.

Although we did not find a strong influence of CONSORT on the quality of reporting of blinding, a recent study has suggested that the CONSORT checklist may have had a positive influence. In a study of RCTs in journals that adopted the original and then the revised CONSORT checklist, the authors found that the quality of reporting of blinding improved by 23%–55% between publication of the two checklists.[26] This is particularly important in light of emerging data suggesting investigators, educators and readers vary greatly in their interpretations and definitions of types of blinding.[27]

Many of the evaluations included in our review were conducted shortly after the introduction of CONSORT. The benefits from CONSORT might take longer to materialise. It might be prudent to conduct further evaluations of the checklist after a longer adoption period, such as 5 years.

The trials reported a large number of discrete outcomes, and it is possible that individual studies selectively reported their outcomes. As we did not contact all authors of included studies for unpublished outcome data, we cannot address this issue.

In summary, it appears that use of the CONSORT checklist is associated with some improvement in reporting of RCTs. With endorsement by more journals, and greater editorial efforts to ensure that authors comply, CONSORT could begin to yield the full benefits for which it was intended.

COMPETING INTERESTS

None identified.

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REFERENCES

1 Begg C, Cho M, Eastwood S, et al. Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *JAMA* 1996; 276: 637-639.
2 Moher D, Schulz KF, Altman D for the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA* 2001; 285: 1987-1991.
3 Hollis S, Campbell F. What is meant by intention-to-treat analysis? Survey of published randomized controlled trials. *BMJ* 1999; 319: 670-674.
4 Ruiz-Canela M, Martinez-Gonzalez MA, de Irala-Estevez J. Intention to treat analysis is related to methodological quality [letter]. *BMJ* 2000; 320: 1007-1008.
5 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: 408-412.
6 Moher D, Pham B, Jones A, et al. Does the quality of reports of randomised trials affect estimates of intervention efficacy reported in meta-analyses? *Lancet* 1998; 352: 609-613.
7 Devereaux PJ, Manns BJ, Ghali WA, et al. The reporting of methodological factors in randomized controlled trials and the association with a journal policy to promote adherence to the Consolidated Standards of Reporting Trials (CONSORT) checklist. *Control Clin Trials* 2002; 23: 380-388.
8 Moher D, Jones A, Lepage L for the CONSORT Group. Use of the CONSORT statement and quality of reports of randomized trials: a comparative before-and-after evaluation. *JAMA* 2001; 285: 1992-1995.
9 Piggot M, McGee H, Feuer D. Has CONSORT improved the reporting of randomized controlled trials in the palliative care literature? A systematic review. *Palliat Med* 2004; 18: 32-38.
10 Bhandari M, Guyaa G, Lochner H, et al. Application of the Consolidated Standards of Reporting Trials (CONSORT) in the fracture care literature. *J Bone Joint Surg Am* 2002; 84: 485-489.
11 Jadad AR, Moore RA, Carroll D, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? *Control Clin Trials* 1996; 17: 1-12.
12 Campbell DC, Stanley JT. Experimental and quasi-experimental design for research. Boston: Houghton Mifflin Company, 1966.
13 Hewitt C, Hahn S, Torgerson DJ, et al. Adequacy and reporting of allocation concealment: a review of recent trials published in four general medical journals. *BMJ* 2005; 330: 1057-1058.
14 Halpern SH, Darani R, Douglas MJ, et al. Compliance with the CONSORT checklist in obstetric anaesthesia randomised controlled trials. *Int J Obstet Anesth* 2004; 13: 207-214.
15 Faunce TA, Buckley NA. Of consents and CONSORTS: reporting ethics, law, and human rights in RCTs involving monitored overdose of healthy volunteers pre and post the "CONSORT" guidelines. *J Toxicol Clin Toxicol* 2003; 41: 93-99.
16 Montori VM, Bhandari M, Devereaux PJ, et al. In the dark: the reporting of blinding status in randomized controlled trials. *J Clin Epidemiol* 2002; 55: 787-790.
17 Hill CL, LaValley MP, Felson DT. Secular changes in the quality of published randomized clinical trials in rheumatology. *Arthritis Rheum* 2002; 46: 779-784.
18 Sanchez-Thorin JC, Cortes MC, Montenegro M, Villate N. The quality of reporting of randomized clinical trials published in *Ophthalmology*. *Ophthalmology* 2001; 108: 410-415.
19 Latronico N, Botteri M, Minelli C, et al. Quality of reporting of randomised controlled trials in the intensive care literature: a systematic analysis of papers published in *Intensive Care Medicine* over 26 years. *Intensive Care Med* 2002; 28: 1316-1323.
20 Doig GS, Simpson F, Delaney A. A review of the true methodological quality of nutritional support trials conducted in the critically ill: time for improvement. *Anesth Analg* 2005; 100: 527-533.
21 Torgerson CJ, Torgerson DJ, Birks YF, Porthouse J. A comparison of randomised trials in health and education. *Br Educ Res J* 2005; 31: 761-785.
22 Stinson JN, McGrath PJ, Yamada JT. Clinical trials in the *Journal of Pediatric Psychology*: applying the CONSORT statement. *J Pediatr Psychol* 2003; 28: 159-167.
23 Scherer RW, Crawley B. Reporting of randomized clinical trial descriptors and use of structured abstracts. *JAMA* 1998; 280: 269-272. Correction in *JAMA* 1998; 280: 1054.
24 Altman DG. Endorsement of the CONSORT statement by high impact medical journals: a survey of instructions for authors. *BMJ* 2005; 330: 1056-1057.
25 Mills E, Wu P, Gagnier J, et al. An analysis of general medical and specialist journals that endorse CONSORT found that reporting was not enforced consistently. *J Clin Epidemiol* 2005; 58: 662-667.
26 Mills EJ, Wu P, Gagnier J, et al. The quality of randomized trial reporting in leading medical journals since the revised CONSORT statement. *Contemp Clin Trials* 2005; 26: 480-487.
27 Devereaux PJ, Manns BJ, Ghali WA, et al. Physician interpretations and textbook definitions of blinding terminology in randomized controlled trials. *JAMA* 2001; 285: 2000-2003.

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