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Invited editorial

## Randomized controlled trials in *Contraception*: the need for “CONSORT” guidelines☆

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### 1. Introduction

When medical historians look back on the twentieth century, the development of the randomized controlled trial (RCT) will stand out as one of its scientific triumphs [1]. The RCT's unique contribution is providing unbiased comparisons between treatments, prevention strategies, or other interventions. However, this promise is often unfulfilled in family planning research. To get an unbiased comparison, performing an RCT is necessary, but insufficient: the trial must also be properly done and reported.

Regrettably, most published RCTs do not adhere to the rules of conduct for performing and reporting such research. An analysis of all the RCTs published over 2 years in four obstetrical and gynecological journals revealed that 90% of published reports violated the rules designed to avoid bias, the *raison d'être* of the RCT [2]. This alarming statistic begs the question: why the poor track record? Our hunch, supported by some indirect evidence [3], is that naiveté, not negligence, is responsible. Many investigators appear to be unaware of the rules. For example, a derivative study [3] examined the citation of methodology references in RCTs published in these four journals; reports that had no methodology citations were less likely to have described proper methods than were those that cited research methods. We inferred that authors who are aware of the rules of conduct (as evidenced by their citations) do better research and vice versa.

Fortunately, learning the rules has just gotten easier. In April 2001, the second edition of the Consolidated Standards of Reporting Trials (CONSORT) guidelines for RCTs

appeared. As a measure of the scientific importance of these guidelines, several major general medical journals, including *The Lancet* [4], *JAMA* [5], and *Annals of Internal Medicine* [6], published them simultaneously. These brief guidelines (only four pages) provide a clear, evidence-based road map for investigators, reviewers, editors, and, ultimately, readers. The authors of the CONSORT guidelines also published a lengthy companion document [7] that describes the rationale for each of the CONSORT criteria, the scientific evidence supporting the criteria, and examples from the published literature.

### 2. The evolution of CONSORT

In the 1990s, two separate initiatives by interested researchers and editors led to the first published CONSORT guidelines [8]. The guidelines included a checklist and flow chart for trial participants. Primarily directed toward simple parallel trials, the guidelines were rapidly adopted by many journals and editorial groups. These included *The Lancet*, *BMJ*, *JAMA*, *Annals of Internal Medicine*, *Obstetrics and Gynecology*, the Vancouver Group, and the Council of Science Editors.

CONSORT, like science itself, is a work in progress, and its development remains an iterative process. Examination of the use of the first proposed flow chart [9,10] led to its revision in the second edition [4-6]. As new evidence emerges, the CONSORT committee continues to revise the guidelines as needed. Suggestions and comments can be sent to the CONSORT coordinator, Leah Lepage by e-mail: llepage@uottawa.ca.

### 3. How to find CONSORT

CONSORT is now widely available to authors, editors, and readers. In addition to the journal publications [4-6],

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Table 1

	Item number	Descriptor	Reported on page number
Title and abstract	1	How participants were allocated to interventions (eg, "random allocation", "randomised", or "randomly assigned").	
Introduction			
Background	2	Scientific background and explanation of rationale.	
Methods			
Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	
Objectives	5	Specific objectives and hypotheses.	
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors, &c).	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	
Randomisation			
Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification).	
Allocation concealment	9	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were aware of group assignment. If not, how the success of masking was assessed.	
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses.	
Results			
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	
Baseline data	15	Baseline demographic and clinical characteristics of each group.	
Numbers analysed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention to treat". State the results in absolute numbers when feasible (eg, 10/20, not 50%).	
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (eg, 95% CI).	
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.	
Adverse events	19	All important adverse events or side-effects in each intervention group.	
Discussion			
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	
Generalisability	21	Generalisability (external validity) of the trial findings.	
Overall evidence	22	General interpretation of the results in the context of current evidence.	

**Checklist of items to include when reporting a randomised trial**

CONSORT guidelines also are available on the Internet ([www.consort-statement.org](http://www.consort-statement.org)). The journals [4–6] that published the revised CONSORT guidelines have waived copyright protection, so the guidelines may be reproduced and disseminated freely.

#### 4. CONSORT: the nuts and bolts

CONSORT features a 22-point checklist and a flow diagram (Table 1 and Fig. 1). Each item is numbered and described in narrative, and authors specify on which page of their manuscript each criterion is met. The revised flow chart encompasses the four stages of a trial: enrollment, intervention allocation, follow-up, and analysis. The chart enables the tracking of every participant and determining whether an intention-to-treat analysis was done. Because the flow chart may not be applicable for all trials, flexibility in its use is allowed.

CONSORT guidelines are evidence-based to the extent possible. For example, literature searches for RCTs commonly miss reports because they are not clearly identified as RCTs [11]. Hence, Item #1 on the CONSORT checklist [4–6] specifies using key descriptors ("random allocation," "randomized," or "randomly assigned") in the title and abstract of an RCT report. Simply using the phrase "a

randomized controlled trial" as a subtitle (e.g., "Wishful thinking vs. postcoital douching for contraception: a randomized controlled trial") will help to signal RCTs.

Item #9 of the CONSORT guidelines describes the process and reporting of allocation concealment. Randomization involves two separate and important components: generation of a truly random, unpredictable sequence and concealment of the upcoming assignments from those involved with the trial. The latter component, termed allocation concealment (as distinguished from blinding), is necessary to avoid selection bias. Empiric evidence indicates that trials with inadequate or unclear allocation concealment yield larger treatment effects than do trials with adequate concealment (odds ratios exaggerated by 30%–40%) [12]. Other studies have corroborated this finding [13].

#### 5. Relevance to this journal

Could RCTs published in *Contraception* benefit from adoption of the CONSORT guidelines? Consideration of the two CONSORT items (#1 and #9) mentioned above is illustrative. As pointed out to us by Dr. Paul O'Brien of London (written communication, May 29, 2001), the March 2001 issue of *Contraception* contained four reports of RCTs. This is a laudable proportion (44%) of the nine

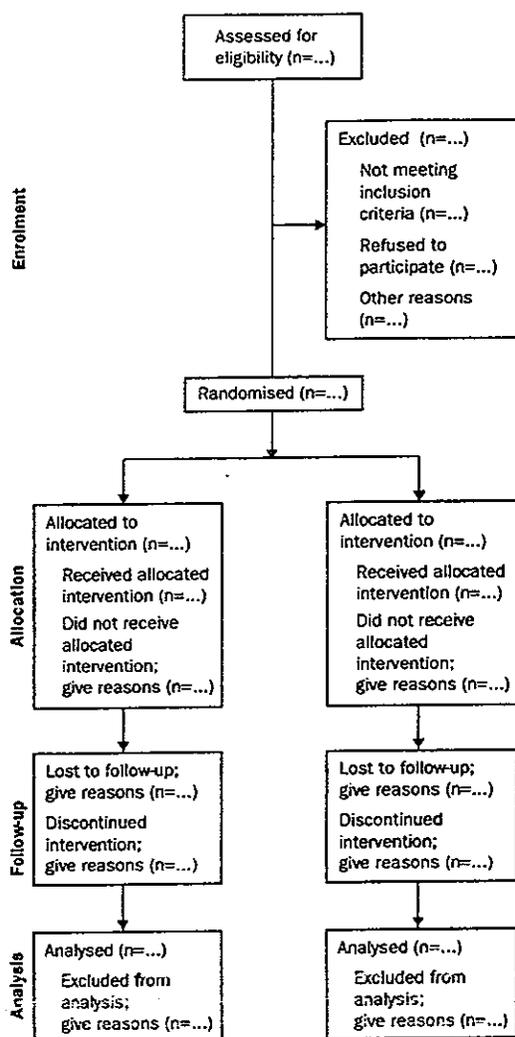


Fig. 1. Flow diagram of the progress through the phases of a randomised trial.

articles published in the March issue. However, three of the four RCT reports [14–16] did not identify themselves as RCTs in either the title or abstract (although one [15] used the word “factorial” in the abstract). The fourth report [17] mentioned the RCT design in the abstract but not in the title. These omissions make finding trials for inclusion in systematic reviews, such as the Cochrane Library, unnecessarily difficult [11]. Regarding allocation concealment [12], none of these four RCT reports [14–17] mentioned it, leaving readers unable to judge whether the trials were properly done.

## 6. Will CONSORT make a difference?

Early evidence suggests that adoption of the CONSORT guidelines benefits the quality of RCT reports. Although trial quality overall appears to be improving, the pace appears to be faster for journals that adopted the initial CONSORT guidelines than in another journal that did not [18].

RCTs offer the best chance for unbiased comparisons in clinical research [7]. However, this benefit can only be realized if trials are well-designed, carefully performed, and clearly reported. The revised CONSORT guidelines [4–6] represent yet another important step in that direction. If authors follow CONSORT, readers have a road map to judge accurately the validity of the results. The scientific process demands that transparency. Without transparency, authors blind readers. We value blinding participants, investigators, and outcome assessors in RCTs, but blinding readers debases scientific inquiry. Moreover, we hope that journals requiring transparency through CONSORT will stimulate investigators to upgrade the methodological quality of their trials. Following proper methods [7] and incorporating the CONSORT guidelines represent an investigator's (and journal's) best insurance against bias; this is a premium well worth paying because everyone is the beneficiary [19,20].

## References

- [1] Randal J. Randomized controlled trials mark a golden anniversary. *J Natl Cancer Inst* 1999;91:10–2.
- [2] Schulz KF, Chalmers I, Grimes DA, Altman DG. Assessing the quality of randomization from reports of controlled trials published in obstetrics and gynecology journals. *JAMA* 1994;272:125–8.
- [3] Grimes DA, Schulz KF. Methodology citations and the quality of randomized controlled trials in obstetrics and gynecology. *Am J Obstet Gynecol* 1996;174:1312–5.
- [4] Moher D, Schulz KF, Altman DG, Lepage L. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001;357:1191–4.
- [5] Moher D, Schulz KF, Altman D. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA* 2001;285:1987–91.
- [6] Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *Ann Intern Med* 2001;134:657–62.
- [7] Altman DG, Schulz KF, Moher D, et al. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med* 2001;134:663–94.
- [8] Begg C, Cho M, Eastwood S, et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA* 1996;276:637–9.
- [9] Meinert CL. Beyond CONSORT: need for improved reporting standards for clinical trials. *Consolidated standards of reporting trials. JAMA* 1998;279:1487–9.
- [10] Egger M, Juni P, Bartlett C. Value of flow diagrams in reports of randomized controlled trials. *JAMA* 2001;285:1996–9.
- [11] Dickersin K, Hewitt P, Mutch L, Chalmers I, Chalmers TC. Perusing the literature: comparison of MEDLINE searching with a perinatal trials database. *Control Clin Trials* 1985;6:306–17.
- [12] 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.
- [13] Moher D, Pham B, Jones A, et al. Does quality of reports of randomised trials affect estimates of intervention efficacy reported in meta-analyses? *Lancet* 1998;352:609–13.
- [14] Hapangama D, Glasier AF, Baird DT. The effects of peri-ovulatory administration of levonorgestrel on the menstrual cycle. *Contraception* 2001;63:123–9.

- [15] Hays MA, Irsula B, McMullen SL, Feldblum PJ. A comparison of three daily coital diary designs and a phone-in regimen. *Contraception* 2001;63:159–66.
- [16] Canto De Cetina TE, Canto P, Ordonez Luna M. Effect of counseling to improve compliance in Mexican women receiving depot-medroxyprogesterone acetate. *Contraception* 2001;63:143–6.
- [17] Biswas A, Viegas OAC, Coeling Bennink HJT, Korver T, Ratnam SS. Implanon<sup>R</sup> contraceptive implants: effects on carbohydrate metabolism. *Contraception* 2001;63:137–41.
- [18] Moher D, Jones A, Lepage L. Use of the CONSORT statement, and quality of reports of randomized trials: a comparative before-and-after evaluation. *JAMA* 2001;285:1992–5.
- [19] Bossuyt PMM. Better standards for better reporting of RCTs. A revised CONSORT statement should further improve standards of reporting. *BMJ* 2001;322:1317–8.
- [20] Grimes DA. Randomized controlled trials: “it ain’t necessarily so.” *Obstet Gynecol* 1991;78:703–4.

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