The Revised CONSORT Statement for Reporting Randomized Trials: Explanation and Elaboration

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Overwhelming evidence now indicates that the quality of reporting of randomized, controlled trials (RCTs) is less than optimal. Recent methodologic analyses indicate that inadequate reporting and design are associated with biased estimates of treatment effects. Such systematic error is seriously damaging to RCTs, which boast the elimination of systematic error as their primary hallmark. Systematic error in RCTs reflects poor science, and poor science threatens proper ethical standards.

A group of scientists and editors developed the CONSORT (*Con*solidated *S*tandards *o*f *R*eporting *T*rials) statement to improve the quality of reporting of RCTs. The statement consists of a checklist and flow diagram that authors can use for reporting an RCT. Many leading medical journals and major international editorial groups have adopted the CONSORT statement. The CONSORT statement facilitates critical appraisal and interpretation of RCTs by providing guidance to authors about how to improve the reporting of their trials.

This explanatory and elaboration document is intended to enhance the use, understanding, and dissemination of the CONSORT statement. The meaning and rationale for each checklist item are presented. For most items, at least one published example of good reporting and, where possible, references to relevant empirical studies are provided. Several examples of flow diagrams are included.

The CONSORT statement, this explanatory and elaboration document, and the associated Web site (http://www.consort-statement.org) should be helpful resources to improve reporting of randomized trials.

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For author affiliations and current addresses, see end of text.

> The RCT is a very beautiful technique, of wide applicability, but as with everything else there are snags. When humans have to make observations there is always the possibility of bias (1).

Well-designed and properly executed randomized, controlled trials (RCTs) provide the best evidence on the efficacy of health care interventions*, but trials with inadequate methodologic approaches are associated with exaggerated treatment effects (2–5). Biased* results from poorly designed and reported trials can mislead decision making in health care at all levels, from treatment decisions for the individual patient to formulation of national public health policies.

Critical appraisal of the quality of clinical trials is possible only if the design, conduct, and analysis of RCTs are thoroughly and accurately described in published articles. Far from being transparent, the reporting of RCTs is often incomplete (6–9), compounding problems arising from poor methodology (10–15).

Incomplete and Inaccurate Reporting

Many reviews have documented deficiencies in reports of clinical trials. For example, information on whether assessment of outcomes* was blinded was reported in only 30% of 67 trial reports in four leading journals in 1979 and 1980 (16). Similarly, only 27% of 45 reports published in 1985 defined a primary end point* (14), and only 43% of 37 trials with negative findings published in 1990 reported a sample size* calculation (17). Reporting is not only frequently incomplete but also sometimes inaccurate. Of 119 reports stating that all participants* were included in the analysis in the groups to which they were originally assigned (intention-to-treat* analysis), 15 (13%) excluded patients or did not analyze all patients as allocated (18). Many other reviews have found that inadequate reporting was common in specialty journals (19–29) and journals published in languages other than English (30, 31).

Proper randomization* eliminates selection bias* and is the crucial component of high-quality RCTs (32) Successful randomization hinges on two steps: generation* of an unpredictable allocation sequence and concealment* of this sequence from the investigators enrolling participants (**Table 1**) (2, 21). Unfortunately, reporting of the methods used for allocation of participants to interventions is also generally inadequate. For

Throughout the text, terms marked with an asterisk are defined at end of text.

Table 1. **Treatment Allocation. What's So Special about Randomization?**

The method used to assign treatments or other interventions to trial participants is a crucial aspect of clinical trial design. Random assignment* is the preferred method; it has been successfully used in trials for more than 50 years (33). Randomization has three major advantages (34). First, it eliminates bias in the assignment of treatments. Without randomization, treatment comparisons may be prejudiced, whether consciously or not, by selection of participants of a particular kind to receive a particular treatment. Second, random allocation facilitates blinding* the identity of treatments to the investigators, participants, and evaluators, possibly by use of a placebo, which reduces bias after assignment of treatments (35). Third, random assignment permits the use of probability theory to express the likelihood that any difference in outcome* between intervention groups merely reflects chance (36). Preventing selection and confounding* biases is the most important advantage of randomization (37).

Successful randomization in practice depends on two interrelated aspects: adequate generation of an unpredictable allocation sequence and concealment of that sequence until assignment occurs (2, 21). A key issue is whether the schedule is known or predictable by the people involved in allocating participants to the comparison groups* (38). The treatment allocation system should thus be set up so that the person enrolling participants does not know in advance which treatment the next person will get, a process termed *allocation concealment** (2, 21). Proper allocation concealment shields knowledge of forthcoming assignments, whereas proper random sequences prevent correct anticipation of future assignments based on knowledge of past assignments.

Terms marked with an asterisk are defined in the glossary at the end of the text.

example, at least 5% of 206 reports of supposed RCTs in obstetrics and gynecology journals described studies that were not truly randomized (21). This estimate is conservative, as most reports do not at present provide adequate information about the method of allocation (19, 21, 23, 25, 30, 39).

Improving the Reporting of RCTs: The CONSORT Statement

DerSimonian and colleagues (16) suggested that "editors could greatly improve the reporting of clinical trials by providing authors with a list of items that they expected to be strictly reported." Early in the 1990s, two groups of journal editors, trialists, and methodologists independently published recommendations on the reporting of trials (40, 41). In a subsequent editorial, Rennie (42) urged the two groups to meet and develop a common set of recommendations; the outcome was the CONSORT statement (*Con*solidated *S*tandards *of Re*porting *T*rials) (43).

The CONSORT statement (or simply CONSORT) comprises a checklist of essential items that should be included in reports of RCTs and a diagram for documenting the flow of participants through a trial. Most of CONSORT is also relevant to a wider class of trial designs, such as equivalence, factorial, cluster, and crossover trials. Modifications to the CONSORT checklist for reporting trials with these and other designs are in preparation.

The objective of CONSORT is to facilitate critical appraisal and interpretation of RCTs by providing guidance to authors about how to improve the reporting of their trials. Peer reviewers and editors can also use CONSORT to help them identify reports that are difficult to interpret and those with potentially biased results. However, CONSORT was not meant to be used as a quality assessment instrument. Rather, the content of CONSORT focuses on items related to the internal and external validity* of trials. Many items not explicitly mentioned in CONSORT should also be included in a report, such as information about approval by an ethics committee, obtaining of informed consent from participants, existence of a data safety and monitoring committee, and sources of funding. In addition, other aspects of a trial should be properly reported, such as information pertinent to cost-effectiveness analysis (44–46) and quality-of-life assessments (47).

The Revised CONSORT Statement: Explanation and Elaboration

Since its publication in 1996, CONSORT has been supported by an increasing number of journals (48–51) and several editorial groups, including the International Committee of Medical Journal Editors (the Vancouver Group) (52). Evidence is accumulating that the introduction of CONSORT has improved the quality of reports of RCTs (53, 54). However, CONSORT is an ongoing initiative, and the statement is revised periodically (3). The 1996 version of the statement (43) received much comment and some criticism. For example, Meinert (55) pointed out that the terminology used lacked clarity and that the information presented in the flow diagram was incomplete. Work on a revised statement started in 1999; the revised checklist is shown in **Table 2** and the revised flow diagram in **Figure 1** (56–58).

During revision, it became clear that explanation and elaboration of the principles underlying the CONSORT statement would help investigators and others to write or appraise trial reports. In this article, we discuss

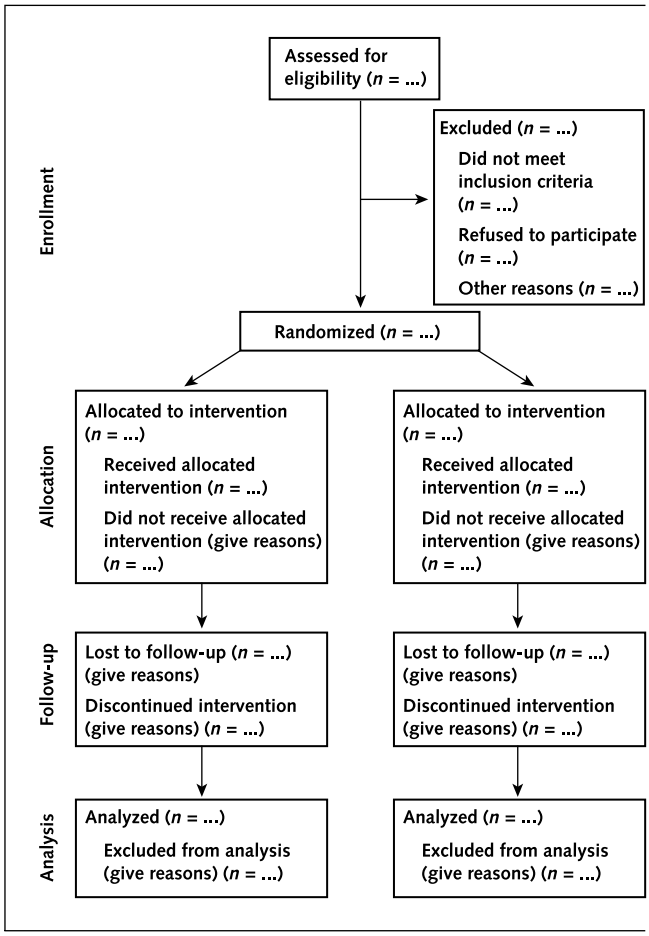
Table 2. **Checklist of Items To Include When Reporting a Randomized Trial†**

Paper Section and Topic	Item Number	Descriptor	Reported on Page Number
Title and abstract	1	How participants were allocated to interventions (e.g., "random allocation," "randomized," 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 (e.g., multiple observations, training of assessors).	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	
Randomization			
Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification).	
Allocation concealment	9	Method used to implement the random allocation sequence (e.g., 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 blinded to group assignment. If done, how the success of blinding was evaluated.	
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 analyzed 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 analyzed	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 (e.g., 10 of 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 (e.g., 95% confidence interval).	
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.	
Generalizability	21	Generalizability (external validity) of the trial findings.	
Overall evidence	22	General interpretation of the results in the context of current evidence.	

† From references 56–58.

(**Table 2**) and provide published examples of good reporting. (For further examples, see www.consort-statement.org). In these examples, we have removed authors' however, relevant references should always be cited where needed, such as to support unfamiliar methodologic approaches. Where possible, we describe the find-

Figure 1. **Revised template of the CONSORT (*Con*solidated *S*tandards *o*f *R*eporting *T*rials) diagram showing the flow of participants through each stage of a randomized trial (56–58).**



on clinical trials offer fuller discussion of methodologic issues (59–61).

For convenience, we sometimes refer to "treatments" and "patients," although we recognize that not all interventions evaluated in RCTs are technically treatments and the participants in trials are not always patients.

Checklist Items

Title and Abstract

Item 1. How participants were allocated to interventions (e.g., "random allocation," "randomized," or

Examples

Title: "Smoking reduction with oral nicotine inhalers: double blind, randomised clinical trial of efficacy and safety" (62).

Abstract: "Design: Randomized, double-blind, placebo-controlled trial" (63).

Explanation

The ability to identify a relevant report in an electronic database depends to a large extent on how it was indexed. Indexers for the National Library of Medicine's MEDLINE database may not classify a report as an RCT if the authors do not explicitly report this information. To help ensure that a study is appropriately indexed as an RCT, authors should state explicitly in the abstract of their report that the participants were randomly assigned to the comparison groups. Possible wordings include "participants were randomly assigned to . . . ," "treatment was randomized," or "participants were assigned to interventions by using random allocation." We also strongly encourage the use of the word "randomized" in the title of the report to permit instant identification.

In the mid-1990s, electronic searching of MEDLINE yielded only about half of all RCTs relevant to a topic (64). This deficiency has been remedied in part by the work of the Cochrane Collaboration, which by 1999 had identified almost 100 000 RCTs that had not been indexed as such in MEDLINE. These reports have been reindexed (65). Adherence to this recommendation should improve the accuracy of indexing in the future.

We encourage the use of structured abstracts when a summary of the report is required. Structured abstracts provide readers with a series of headings pertaining to the design, conduct, and analysis of a trial; standardized information appears under each heading (66). Some studies have found that structured abstracts are of higher quality than the more traditional descriptive abstracts (67) and that they allow readers to find information more easily (68).

Introduction

Item 2. Scientific background and explanation of

Example

> The carpal tunnel syndrome is caused by compression of the median nerve at the wrist and is a common cause of pain in the arm, particularly in women. Injection with corticosteroids is one of the many recommended treatments.
>
> One of the techniques for such injection entails injection just proximal to (not into) the carpal tunnel. The rationale for this injection site is that there is often a swelling at the volar side of the forearm, close to the carpal tunnel, which might contribute to compression of the median nerve. Moreover, the risk of damaging the median nerve by injection at this site is lower than by injection into the narrow carpal tunnel. The rationale for using lignocaine (lidocaine) together with corticosteroids is twofold: the injection is painless, and diminished sensation afterwards shows that the injection was properly carried out.
>
> We investigated in a double blind randomised trial, firstly, whether symptoms disappeared after injection with corticosteroids proximal to the carpal tunnel and, secondly, how many patients remained free of symptoms at follow up after this treatment (69).

Explanation

Typically, the introduction consists of free-flowing text, without a structured format, in which authors explain the scientific background or context and the scientific rationale for their trial. The rationale may be explanatory (for example, to compare the bioavailability of two formulations of a drug or assess the possible influence of a drug on renal function) or pragmatic (for example, to guide practice by comparing the clinical effects of two alternative treatments). Authors should report the evidence of the benefits of any active intervention included in a trial. They should also suggest a plausible explanation for how the intervention under investigation might work, especially if there is little or no previous experience with the intervention (70).

The Helsinki Declaration states that biomedical research involving people should be based on a thorough knowledge of the scientific literature (71). That is, it is unethical to expose human subjects unnecessarily to the risks of research. Some clinical trials have been shown to have been unnecessary because the question they addressed had been or could have been answered by a systematic review of the existing literature (72). Thus, duction. Ideally, the introduction should include a reference to a systematic review of previous similar trials or a note of the absence of such trials (73).

In the first part of the introduction, authors should describe the problem that necessitated the work. The nature, scope, and severity of the problem should provide the background and a compelling rationale for the study. This information is often missing from reports. Authors should then describe briefly the broad approach taken to studying the problem. It may also be appropriate to include here the objectives* of the trial (item 5).

Methods

Item 3a. Eligibility criteria for participants.

Example

> . . . all women requesting an IUCD [intrauterine contraceptive device] at the Family Welfare Centre, Kenyatta National Hospital, who were menstruating regularly and who were between 20 and 44 years of age, were candidates for inclusion in the study. They were not admitted to the study if any of the following criteria were present: (1) a history of ectopic pregnancy, (2) pregnancy within the past 42 days, (3) leiomyomata of the uterus, (4) active PID [pelvic inflammatory disease], (5) a cervical or endometrial malignancy, (6) a known hypersensitivity to tetracyclines, (7) use of any antibiotics within the past 14 days or long-acting injectable penicillin, (8) an impaired response to infection, or (9) residence outside the city of Nairobi, insufficient address for follow-up, or unwillingness to return for follow-up (74).

Explanation

Every RCT addresses an issue relevant to some population with the condition of interest. Trialists usually restrict this population by using eligibility criteria* and by performing the trial in one or a few centers. Typical selection criteria may relate to age, sex, clinical diagnosis, and comorbid conditions; exclusion criteria are often used to ensure patient safety. Eligibility criteria should be explicitly defined. If relevant, any known inaccuracy in patients' diagnoses should be discussed because it can affect the power* of the trial (75). The common distinction between inclusion and exclusion criteria is unnecessary (76).

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