Randomised controlled trials

CONSORT

(Consolidated Standards of Reporting Trials)

CONSORT

- Initiated (1994) by an international group of triallists statisticians, epidemiologists and biomedical journal editors
- Strong impetus from concerns arising from EBM movement e.g. Cochrane
- Supported by
  - International Committee of Medical Journal Editors (Vancouver Group/ ICJME)
  - World Association of Medical Editors
- Revised 2001 and 2010
- Focus on parallel group trials.
- Other trial designs included in 2010

Dodgy reporting

- Review of 122 RCTs of SSRI treatment of depression (Hotopf et al 1997)
  - Only one (0.8%) had reported randomisation adequately!
- Pre-/ post- CONSORT
  - improvement in reporting of allocation concealment from 61% to 39% not adequately reported (Moher et al 2001)
- This is important – bias from:
  - Unclear randomisation procedures
  - Lack of allocation concealment
  - Failure to mask outcome assessment

CONSORT

- Main aim was to encourage (enforce?) correct reporting of RCTs
- Implicit within this is a semi-covert agenda to improve the design and conduct of trials
- If you have not designed and conducted your RCT appropriately
  - Deficiencies will be apparent in your publication
  - You may not be able to report some of the required information
  - Your trial may not be published, or at least not published in a good journal

CONSORT

- Consolidated Standards of Reporting Trials
- Readers should understand..
  - Design
  - Conduct
  - Analysis
  - Interpretation

- Aims for
  - Standardisation
  - Transparency
- Facilitates
  - Comprehension
  - Inference
  - Systematic review and meta-analysis

Moher et al, BMC Medical Research Methodology, 2001

CONSORT

CONSORT

TRANSPARENT REPORTING of TRIALS

Support CONSORT

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Home | CONSORT Statement | Extensions | About CONSORT | Library of Examples | Resources | News

+AllTrials

Please join CONSORT in supporting the All Trials campaign to get all clinical trial results reported.

Reporting Examples

Submit Example

If you find an example of good reporting, login here to submit it to our Library.

EQUATOR Network

equator network

Resources for reporting health research studies

Welcome to the CONSORT Statement Website

CONSORT, which stands for Consolidated Standards of Reporting Trials, encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising from inadequate reporting of randomized controlled trials (RCTs).

The main product of CONSORT is the CONSORT Statement, which is an evidence-based, minimum set of recommendations for reporting RCTs. It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation.

The CONSORT Statement comprises a 25-item checklist and a flow diagram, along with some brief descriptive text. The checklist items focus on reporting how the trial was designed, analyzed, and interpreted; the flow diagram displays the progress of all participants through the trial.

Considered an evolving document, the CONSORT Statement is subject to periodic changes as new evidence emerges. This website contains the current definitive version of the CONSORT Statement and up-to-date information on extensions.

The recent publication of CONSORT 2010 Statement now makes the previous version, CONSORT 2001 Statement, out-dated. Users of the guideline are strongly recommended to refer to this most up-to-date version while writing or interpreting reports of clinical trials. In conjunction, the content of the CONSORT website has also been changed to reflect CONSORT 2010.

News

In Memoriam

Dr. Vincent Kokich, Editor-in-Chief of the American Journal of Orthodontics and Dentofacial Orthopedics (AJODO) and strong promoter of CONSORT and PRISMA passes away

Read more

Peer Review Congress in Chicago in September 2013

Two new EQUATOR events at the upcoming Peer Review Congress in Chicago in September 2013 - Workshop Registration is now open.

Read more

CONSORT PRO Extension

A new extension to the CONSORT Statement for reporting trials including Patient-Reported Outcomes (CONSORT-PRO) is now available.

Read more

www.equator-network.org

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Enhancing the QUAlity and Transparency Of health Research

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The resource centre for good reporting of health research studies

Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.

Search for reporting guidelines

Visit the library for more resources

Key reporting guidelines

CONSORT	Full Record | Checklist | Flow Diagram
STROBE	Full Record | Checklist
PRISMA	Full Record | Checklist | Flow Diagram
STARD	Full Record | Checklist | Flow Diagram
COREQ	Full Record
ENTREQ	Full Record
SQUIRE	Full Record | Checklist
CHEERS	Full Record | Checklist
CARE	Full Record | Checklist
SAMPL	Full Record

Toolkits

The EQUATOR Network works to

EQUATOR highlights

23/10/2013 - Updated Declaration of Helsinki

News

EQUATOR workshop for WHO staff in Geneva

Enhancing the Quality and Transparency of Health Research

- CONSORT — RCTs
- STROBE — Observational epidemiology
- PRISMA — Systematic reviews
- STARD — Diagnostic accuracy
- COREQ — Qualitative research
- ENTREQ — Qualitative research synthesis
- SQUIRE — Quality improvement
- CHEERS — Health economic evaluation
- CARE — Clinical case reporting
- SAMPL — Statistical analysis and methods

OPEN ACCESS Freely available online

PLoS MEDICINE

Guidelines and Guidance

CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomised Trials

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Introduction

Randomised controlled trials, when appropriately designed, conducted, and reported, represent the gold standard in evaluating healthcare interventions. However, randomised trials can yield biased results if they lack methodological rigour [1]. To assess a trial accurately, readers of a published report need complete, clear, and transparent information on its methodology and findings. Unfortunately, attempted assessments frequently fail because authors of many trial reports neglect to provide lucid and complete descriptions of that critical information [2,3,4].

That lack of adequate reporting fuelled the development of the original CONSORT (Consolidated Standards of Reporting Trials) statement in 1996 [5] and its revision five years later [6,7,8]. While those statements improved the reporting quality for some randomised controlled trials [9,10], many trial reports still remain inadequate [2]. Furthermore, new methodological evidence and additional experience has accumulated since the last revision in 2001. Consequently, we organised a CONSORT Group meeting to update the 2001 statement [6,7,8]. We introduce here the result of that process, CONSORT 2010.

Intent of CONSORT 2010

The CONSORT 2010 Statement is this paper including the 25 item checklist in the table (Table 1) and the flow diagram indirect goal of our work. Moreover, CONSORT can help researchers in designing their trial.

Background to CONSORT

Efforts to improve the reporting of randomised controlled trials accelerated in the mid-1990s, spurred partly by methodological research. Researchers had shown for many years that authors reported such trials poorly, and empirical evidence began to accumulate that some poorly conducted or poorly reported aspects of trials were associated with bias [14] Two initiatives aimed at developing reporting guidelines culminated in one of us (DM) and Drummond Rennie organising the first CONSORT statement in

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CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials

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ABSTRACT

Overwhelming evidence shows the quality of reporting of randomised controlled trials (RCTs) is not optimal. Without transparent reporting, readers cannot judge the reliability and validity of trial findings nor extract information for systematic reviews. Recent methodological analyses indicate that inadequate reporting and design are associated with biased estimates of treatment effects. Such systematic error is seriously damaging to RCTs, which are considered the gold standard for evaluating interventions because of their ability to minimise or avoid bias.

A group of scientists and editors developed the CONSORT (Consolidated Standards of Reporting Trials) statement to improve the quality of reporting of RCTs. It was first published in 1996 and updated in 2001. 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 endorsed the CONSORT statement. The statement facilitates critical appraisal and interpretation of RCTs.

During the 2001 CONSORT 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. A CONSORT explanation and elaboration article was published in 2001 alongside the 2001 version of the CONSORT statement.

After an expert meeting in January 2007, the CONSORT statement has been further revised and is published as the CONSORT 2010 Statement. This update improves the wording and clarity of the previous checklist and incorporates recommendations related to topics that have only recently received recognition, such as selective outcome reporting bias.

This explanatory and elaboration document—intended to enhance the use, understanding, and dissemination of the CONSORT statement—has also been extensively revised. It presents the meaning and rationale for each new and updated checklist item providing examples of good reporting and, where possible, references to relevant empirical studies. Several examples of flow diagrams are included.

The CONSORT 2010 Statement, this revised explanatory and elaboration document, and the associated website (www.consort-statement.org) should be helpful resources to improve reporting of randomised trials.

"The whole of medicine depends on the transparent reporting of clinical trials."[1]

Well designed and properly executed randomised con-

mary end point, and only 27% in 2000 and 45% in 2006 reported a sample size calculation. Reporting is not only often incomplete but also sometimes inaccurate. Of 119

CONSORT

- 22 item checklist
  - Evidence of bias
  - Essential information to judge reliability or relevance of findings

- Title and abstract (1)
- Background (1)
- Methods (10)
- Results (7)
- Discussion (3)

Moher et al, BMC Medical Research Methodology, 2001

Elements of an RCT

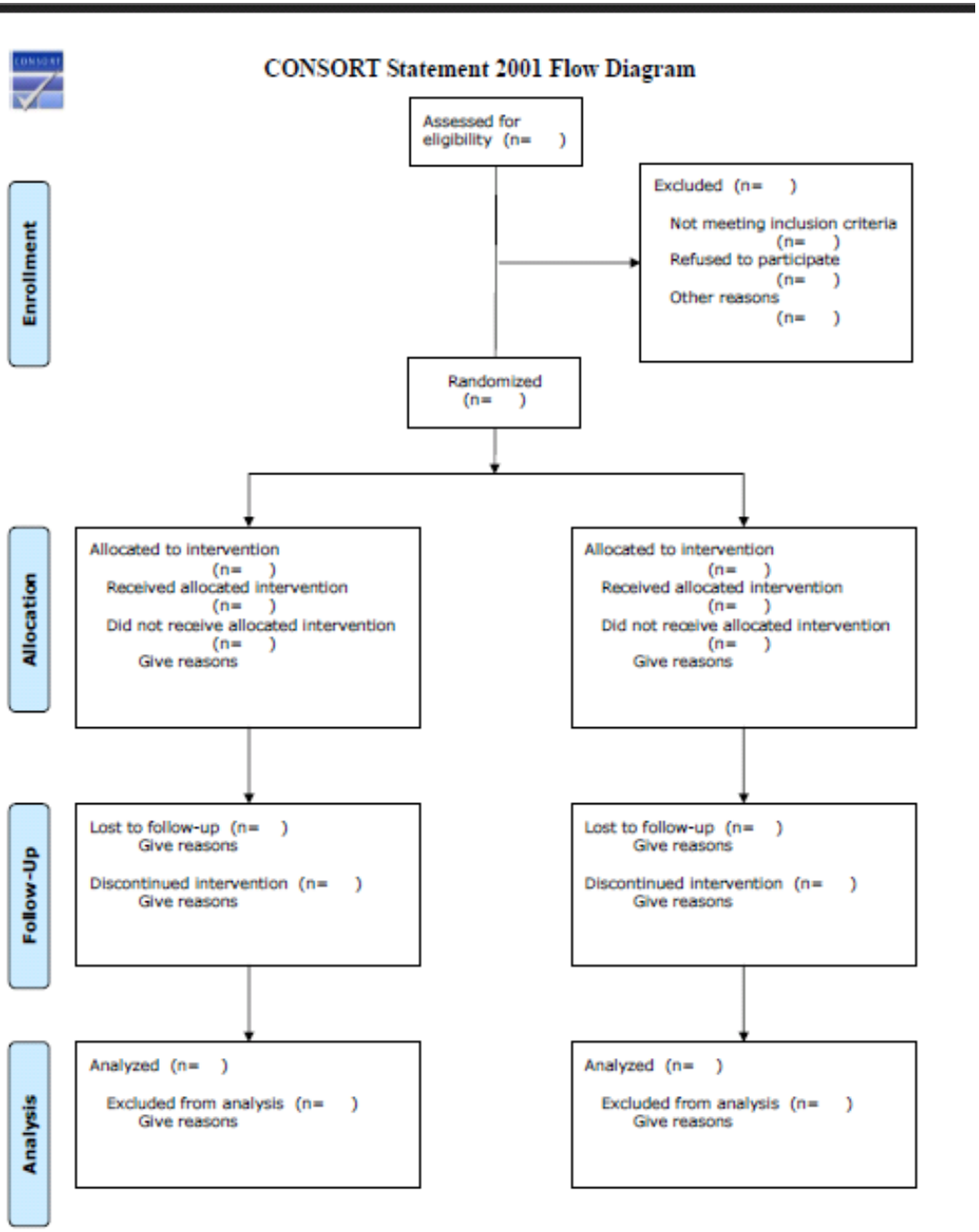
1. Review the literature
2. Formulate a single primary hypothesis
3. Specify the objectives of the trial
4. Define the reference population

5. Select study population
6. Subject identification and recruitment
7. Informed consent
8. Baseline measurements
9. Randomisation

10. Management of intervention and control groups (placebos or best established treatment)

11. Blind follow-up and reassessment
12. Analysis on an ‘intention to treat’ basis
13. Interpretation of data
14. Publication, communication and dissemination

- Flow chart on
  - recruitment
  - Randomisation/ allocation
  - follow up
  - analysis



From Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet 2001; 357(9263):1191-1194.

For more information, visit www.consort-statement.org.