

CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel-Group Randomized Trials

Kenneth F. Schulz, Douglas G. Altman, David Moher,
and the CONSORT Group

K Schulz, PhD

Vice President, Quantitative Sciences

Family Health International

P.O. Box 13950, Research Triangle Park, NC USA 27709

KSchulz@fhi.org

Ph: +1 (919) 544-7040 x542; Fx: +1 (919) 544-7261

Centre for Statistics in Medicine, University of Oxford, Wolfson College, Linton Road,
Oxford, UK (Prof D Altman, DSc) doug.altman@csm.ox.ac.uk

Ottawa Methods Centre, Ottawa Hospital Research Institute; Department of
Epidemiology and Community Medicine, Faculty of Medicine, University of Ottawa;
Ottawa, Canada (D Moher PhD) dmoher@ohri.ca

Text: 1973 words

Please note: While each journal should have exactly the same text, each journal has the flexibility to use their preferred reference or references for the CONSORT Explanation and Elaboration paper and the recently published PRISMA paper.

Introduction

Randomized controlled trials (RCTs), when appropriately designed, conducted, and reported, represent the gold standard in evaluating health care interventions. That lofty position in the medical research hierarchy does not mean, however, that readers should uncritically accept the results of all RCTs. Indeed, randomized trials can yield biased results if they lack methodological rigor. (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. (2-4)

That lack of adequate reporting fueled the development of the original CONSORT (Consolidated Standards of Reporting Trials) Statement in 1996 (5) and its revision five years later. (6-8) While those Statements positively impacted reporting quality for some RCTs, (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 organized a CONSORT Group meeting to update the 2001 Statement. (6-8) We introduce here the result of that process, CONSORT 2010.

Intent of CONSORT 2010

The CONSORT 2010 Statement (also referred to as the Statement or CONSORT 2010) is this paper including the 25-item checklist (Table) and the flow diagram (Figure). It provides guidance for reporting all RCTs, but focuses on the most common design type, individually randomized 2-group parallel trials. Other trial designs, such as cluster randomized trials and noninferiority trials, require varying amounts of additional information. CONSORT extensions for these designs, (11;12) and other CONSORT products, can be found through the CONSORT website (www.consort-statement.org). The revised CONSORT explanation and elaboration paper (E&E)[ref] supports the new Statement.

Diligent adherence by authors to the checklist items facilitates clarity, completeness, and transparency of reporting. Explicit descriptions, not ambiguity or omission, best serve the interests of all readers. Of note, the Statement does not include recommendations for designing, conducting, and analyzing trials. It solely addresses reporting – what was done and what was found.

Nevertheless, CONSORT does indirectly affect design and conduct. Transparent reporting reveals deficiencies in research, if they exist. Thus, investigators who conduct inadequate trials, but who must transparently report, should not be able to pass through the publication process without revelation of their trial's inadequacies. That emerging reality should provide impetus to improved trial design and conduct in the future, a

secondary indirect goal of our work. Moreover, CONSORT can help researchers in designing their trial.

In this paper, we present our latest revision, CONSORT 2010, and describe its development. Along with the Statement, we have updated the explanation and elaboration (E&E) article (ref) that explains the inclusion of each checklist item, provides methodological background, and illustrates published examples of transparent reporting.

CONSORT Background

Efforts to improve the reporting of RCTs accelerated in the mid 1990s, spurred partly by methodological research. While researchers had shown for many years that authors poorly report RCTs, empirical evidence began to accumulate that some poorly conducted or poorly reported aspects of trials were associated with bias. (13) Two initiatives aimed at developing reporting guidelines culminated in one of us (DM) and Drummond Rennie organizing the first CONSORT Statement in 1996. (5) Further methodological research on similar topics reinforced earlier findings (14) and fed into the revision of 2001. (6-8) Subsequently, the expanding body of methodological research informed the refinement of CONSORT 2010. More than 700 studies comprise the CONSORT Database (located on the CONSORT Website), which provides the empirical evidence to underpin the CONSORT initiative.

Indeed, CONSORT Group members continually monitor the literature. Information gleaned from these efforts provides an evidence base on which update the Statement. We add, drop, or modify items based on that evidence and the recommendations of the CONSORT Group, an international and eclectic group of clinical trialists, statisticians, epidemiologists, and biomedical editors. The CONSORT Executive (KFS, DGA, DM) strives for a balance of established and emerging researchers. The membership of the group is dynamic. As our work expands in response to emerging projects and needed expertise, we invite new members to contribute. As such, CONSORT continually assimilates new ideas and perspectives. That process informs the continually evolving CONSORT Statement.

Over time, CONSORT has garnered much support. More than 360 journals, published around the world and in many languages, have explicitly supported the Statement. Many other healthcare journals support it without our knowledge. Moreover, thousands more have implicitly supported it with the endorsement of the Statement by the International Committee of Medical Journal Editors (www.icmje.org). Other prominent editorial groups, the Council of Science Editors and the World Association of Medical Editors, officially support CONSORT. That support appears warranted: when used by authors and journals, CONSORT seems to improve reporting. (9)

Development of CONSORT 2010

Thirty-one members of the CONSORT 2010 group met in Montebello, Canada in January 2007 to update the 2001 CONSORT Statement. In addition to the accumulating

evidence relating to existing checklist items, several new issues had come to prominence since 2001. Some participants were given primary responsibility for aggregating and synthesizing the relevant evidence on a particular checklist item of interest. Based on that evidence, the group deliberated the value of each item. As in prior CONSORT versions, we kept only those items deemed absolutely fundamental to reporting an RCT. Moreover, an item may be fundamental to a trial but not included, such as approval by an institutional ethical review board, because funding bodies strictly enforce ethical review and medical journals usually address reporting ethical review in their instructions for authors. Other items may seem desirable, such as on-site monitoring, but a lack of empirical evidence or any consensus on their value cautions against inclusion at this point. The Statement thus addresses the minimum criteria.

After the meeting, the CONSORT Executive convened teleconferences and in-person meetings to revise the checklist. After seven major iterations, a revised checklist was distributed to the larger group for feedback. With that feedback, the Executive met twice in person to consider all the comments and to produce a penultimate version. That served as the basis for writing the first draft of this paper, which was then distributed to the group for feedback. After consideration of their comments, the Executive finalized the Statement.

The CONSORT Executive then drafted an updated E&E manuscript, with assistance from other members of the larger group. The substance of the 2007 CONSORT meeting provided the material for the update. The updated E&E was distributed to the entire

group for additions, deletions, and changes. That final iterative process converged to the CONSORT 2010 E&E.[E&E ref]

Changes in CONSORT 2010

The above-described revision process resulted in evolutionary, not revolutionary, changes to the checklist (Table); the flow diagram was not modified except for one word.(Figure) Moreover, because other reporting guidelines augmenting the checklist refer to item numbers, we kept the existing items under their previous item numbers except for some renumbering of Items 2 through 5. We added additional items either as a sub-item under an existing item, an entirely new item number at the end of the checklist, or, with just Item 3, an interjected item into a renumbered segment. We summarized the noteworthy general (Panel 1) and specific changes (Panel 2). Furthermore, the website contains a side by side comparison of the 2001 and 2010 versions.

Implications and limitations

We developed CONSORT 2010 to assist authors in writing RCT reports, editors and peer reviewers in reviewing manuscripts for publication, and readers in critically appraising published articles. The CONSORT E&E provides elucidation and context to the checklist items. We strongly recommend using the E&E in conjunction with the checklist to foster complete, clear, and transparent reporting and aid appraisal of published trial reports.

CONSORT 2010 focuses predominantly on the common 2-group parallel RCT, which accounts for over half of trials in the literature. (2) Most of the items from the Statement, however, pertain to all types of randomized trials. Nevertheless, some types of trials or trial situations dictate the need for additional information in the trial report. When in question, authors, editors, and readers should consult the CONSORT website for any CONSORT extensions, expansions (amplifications), implementations, or other guidance that may be relevant.

The evidence-based approach we have used for CONSORT was not only used for the augmentations of CONSORT mentioned above, but also served as a model for development of other reporting guidelines, such as for reporting systematic reviews and meta-analyses of studies evaluating interventions [PRISMA], diagnostic studies(15), and observational studies. (16) The explicit goal of all these initiatives is to improve reporting. The Enhancing the Quality and Transparency of Health Research (EQUATOR) Network will facilitate reporting guideline development and help disseminate guidelines: www.equator-network.org provides information on all reporting guidelines in health research.

With CONSORT 2010 we once again intentionally declined to produce a rigid structure for the reporting of RCTs. Indeed, SORT(17) tried a rigid format; it failed in a pilot run with an editor and authors. (18) Consequently, the format of articles should abide by journal style, editorial directions, the traditions of the research field addressed, and, where possible, author preferences. We do not wish to standardize the structure of

reporting. Authors should simply address checklist items somewhere in the article, with ample detail and lucidity. That stated, we think that manuscripts benefit from frequent subheadings within the major sections, especially the methods and results sections.

CONSORT urges completeness, clarity, and transparency of reporting, which simply reflects the actual trial design and conduct. However, as a potential drawback, a reporting guideline might encourage some authors to report fictitiously the information suggested by the guidance rather than what was actually done. Authors, peer reviewers, and editors should vigilantly guard against that potential drawback and refer, for example, to trial protocols, to information on trial registers, and to regulatory agency websites. Moreover, the Statement does not include recommendations for designing and conducting RCTs. The items should elicit clear pronouncements of how and what the authors did, but do not contain any judgments on how and what the authors should have done. Thus, CONSORT 2010 is not intended as an instrument to evaluate the quality of an RCT. Nor is it appropriate to use the checklist to construct a “quality score”.

Nevertheless, we suggest that researchers begin trials with their end publication in mind. Poor reporting allows authors, intentionally or inadvertently, to escape scrutiny of any weak aspects of their trials. However, with wide adoption of CONSORT by journals and editorial groups, most authors should have to report transparently all important aspects of their trial. The ensuing scrutiny rewards well-done trials and penalizes poorly-done trials. Thus, investigators should understand the CONSORT 2010 reporting

guidelines prior to beginning a trial as a further incentive to design and conduct their trials according to rigorous standards.

CONSORT 2010 supplants the prior version published in 2001. Any support for the earlier version accumulated from journals or editorial groups will automatically extend to this newer version, unless specifically requested otherwise. Journals that do not currently support CONSORT may do so by registering on the CONSORT Website. If a journal supports or endorses CONSORT 2010, it should cite one of the original versions of CONSORT 2010, the E&E, and the CONSORT Website in their “Instructions to Authors.” We suggest that authors who wish to cite CONSORT should cite this or another of the original journal versions of CONSORT 2010, and, if appropriate, the E&E [ref]. All CONSORT material can be accessed through the original publishing journals or the CONSORT website. Groups or individuals who desire to translate the Statement into other languages should first consult the CONSORT policy statement on the website.

We emphasize that CONSORT 2010 represents an evolving guideline. It requires perpetual reappraisal and, if necessary, modifications. In the future we will further revise the CONSORT material considering comments, criticisms, experiences, and accumulating new evidence. We invite readers to submit recommendations via the CONSORT website.

Author Contributions

Dr. Schulz, Dr. Moher, and Professor Altman participated in meetings and regular conference calls, planned the CONSORT 2007 meeting at Montebello, developed the agenda, prepared background research, identified and invited participants, contributed to the CONSORT meeting, drafted the manuscript, and, after critical review by the CONSORT Group, finalized the text of the manuscript. Members of the CONSORT Group attended the meeting, except for those noted below, and provided input on and review of the revised checklist and text of this article. Some members also prepared background material.

The CONSORT Group contributors to CONSORT 2010

Douglas G. Altman, Centre for Statistics in Medicine, University of Oxford, United Kingdom; Virginia Barbour, PLoS Medicine, United Kingdom; Jesse A. Berlin, Johnson & Johnson Pharmaceutical Research and Development, United States; Isabelle Boutron, University Paris 7 Denis Diderot, Assistance Publique des Hôpitaux de Paris, INSERM, France; P.J. Devereaux, McMaster University, Canada; Kay Dickersin, Johns Hopkins Bloomberg School of Public Health, United States; Diana Elbourne, London School of Hygiene & Tropical Medicine, United Kingdom; Susan Ellenberg, University of Pennsylvania School of Medicine, United States; Val Gebski, University of Sydney, Australia; Steven Goodman, Journal of the Society for Clinical Trials, United States; Peter C. Gøtzsche, Nordic Cochrane Centre, Denmark; Trish Groves, BMJ, United Kingdom; Steven Grunberg, American Society of Clinical Oncology, United States; Brian Haynes, McMaster University, Canada; Sally Hopewell, Centre for Statistics in Medicine,

University of Oxford, United Kingdom; Astrid James, The Lancet, United Kingdom; Peter Juhn, Johnson & Johnson, United States; Philippa Middleton, The University of Adelaide, Australia; Don Minckler, University of California Irvine, United States; David Moher, Ottawa Methods Centre, Ottawa Hospital Research Institute, Canada; Victor M. Montori, Knowledge and Encounter Research Unit, Mayo Clinic College of Medicine, United States; Cynthia Mulrow, Annals of Internal Medicine, United States; Stuart Pocock, London School of Hygiene & Tropical Medicine, United Kingdom; Drummond Rennie, JAMA, United States; David L. Schriger, Annals of Emergency Medicine, United States; Kenneth F. Schulz, Family Health International, United States; Iveta Simera, EQUATOR Network, United Kingdom; and Elizabeth Wager, Sideview, United Kingdom.

1Contributed to CONSORT 2010, but did not attend the Montebello meeting

Mike Clarke, UK Cochrane Centre, UK; and Gordon Guyatt, McMaster University, Canada.

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Panel 1: Noteworthy general changes in CONSORT 2010

- We simplified and clarified the wording, such as in items 1, 8, 10, 13, 15, 16, 18, 19, and 21.
- We improved consistency of style across the items by removing the imperative verbs from the 2001 version.
- We enhanced specificity of appraisal by breaking some items into sub-items. Many journals expect authors to complete a CONSORT checklist indicating where in the manuscript the items have been addressed. Experience with the checklist noted pragmatic difficulties when an item comprised multiple elements. For example, item 4 addresses eligibility of participants and the settings and locations of data collection. With the 2001 version, an author could provide a page number for that item on the checklist, but only have reported eligibility in the paper, for example, and not reported the settings and locations. CONSORT 2010 relieves obfuscations and forces the author to provide page numbers in the checklist for both eligibility and settings.

Panel 2: Noteworthy specific changes in CONSORT 2010

- Item 1.b, “Title and Abstract,” we added a sub-item on providing a structured summary of trial design, methods, results, and conclusions and referenced the CONSORT for Abstracts article. (19)
- Item 2.b, “Introduction,” we added a new sub-item (formerly item 5 from CONSORT 2001) on “Specific objectives or hypotheses.”
- Item 3.a, “Trial design,” we added a new item including this sub-item to clarify the basic trial design (e.g, parallel group, crossover, cluster) and the allocation ratio.
- Item 3.b, “Trial design,” we added a new sub-item that addresses any important changes to methods after trial commencement, with a discussion of reasons.
- Item 4, “Participants” was formerly Item 3 from CONSORT 2001.
- Item 5, “Interventions” (formerly Item 4 from CONSORT 2001), we encouraged greater specificity by stating that descriptions of interventions should include “sufficient details to allow replication.” (3)
- Item 6, “Outcomes,” we added a sub-item on identifying any changes to the primary and secondary outcome (endpoint) measures after the trial commenced. This followed from empirical evidence that authors frequently provide analyses of outcomes in their published papers that were not the prespecified primary and secondary outcomes in their protocols, while ignoring their prespecified outcomes (i.e., selective outcome reporting). (4;20) We eliminated text on any methods used to enhance the quality of measurements.

- Item 9, “Allocation concealment mechanism,” we reworded to include mechanism in both the report topic and the descriptor to reinforce that authors should report the actual steps taken to ensure allocation concealment rather than simply report imprecise, perhaps banal, assurances of concealment.
- Item 11, “Blinding,” we added the specification of how blinding was done and also, if relevant, a description of the similarity of interventions and procedures. We also eliminated text on “how the success of blinding (masking) was assessed” because of a lack of empirical evidence supporting the practice as well as theoretical concerns about the validity of any such assessment. (21;22)
- Item 12.a, “Statistical methods,” we added that statistical methods should also be provided for analysis of secondary outcomes.
- Sub-item 14.b, “Recruitment,” based on empirical research, we added a sub-item “Why the trial ended or was stopped.” (23)
- Item 15, “Baseline data,” we added “A table” to clarify that baseline and clinical characteristics of each group are most clearly expressed in a table.
- Item 16, “Numbers analyzed,” we replaced mention of “intention to treat” analysis, a widely misused term, by a more explicit request for information about retaining participants in their original assigned groups. (24)
- Sub-item 17.b, “Outcomes and estimation,” for appropriate clinical interpretability, prevailing experience suggested adding “For binary outcomes, presentation of both relative and absolute effect sizes is recommended”. (25)

- Item 19, “Harms,” we included a reference to the CONSORT paper on harms. (26)
- Item 20, “Limitations,” we changed the Topic from “Interpretation” and supplanted the prior text with a sentence focusing on the reporting of sources of potential bias and imprecision.
- Item 22, “Interpretation,” we changed the Topic from “Overall evidence.” Indeed, we understand that authors should be allowed leeway for interpretation under this nebulous heading. However, concerns in the CONSORT Group emerged that too frequently conclusions in papers misrepresented the actual analytical results and that harms were ignored or marginalized. Therefore, we changed the checklist item to include the concepts of results matching interpretations and of benefits being balanced with harms.
- Item 23, “Registration,” we added a new item. Empirical evidence supports the need for trial registration and recent requirements by journal editors have fostered compliance. (27)
- Item 24, “Protocol,” we added a new item on availability of the trial protocol. Empirical evidence suggests that authors often ignore, in the conduct and reporting of their trial, what they stated in the protocol. (4;20) Hence, availability of the protocol can instigate adherence to the protocol before publication and facilitate assessment of adherence after publication.
- Item 25, “Funding,” we added a new item. Empirical evidence points toward funding source being associated with estimated treatment effects. (28)

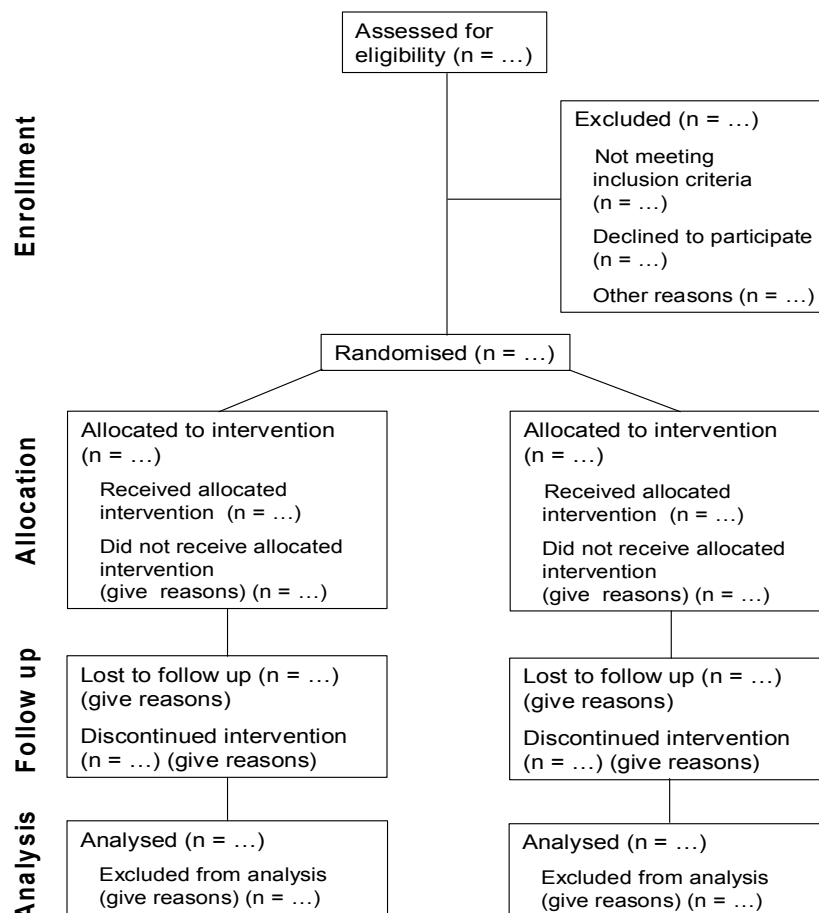
Table: CONSORT 2010 Checklist of Information to Include When Reporting a Randomized Trial*

Section/Topic	Item #	Checklist Item	Report ed on Page #
TITLE AND ABSTRACT	1.a 1.b	Identification as a randomized trial in the title Structured summary of trial design, methods, results, and conclusions; for specific guidance see CONSORT for Abstracts (19;29))	
INTRODUCTION			
Background and objectives	2.a 2.b	Scientific background and explanation of rationale Specific objectives or hypotheses	
METHODS			
Trial design	3a 3b	Description of trial design (e.g., parallel, factorial) including allocation ratio Important changes to methods after trial commencement (e.g. eligibility criteria), with reasons	
Participants	4a 4b	Eligibility criteria for participants Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6.a 6.b	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed Any changes to trial outcomes after the trial commenced with reasons	
Sample size	7.a 7.b	How sample size was determined When applicable, explanation of any interim analyses and stopping guidelines	
Randomization: Sequence generation	8.a 8.b	Method used to generate the random allocation sequence Type of randomization; details of any restriction (e.g., blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (e.g., sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11.a 11.b	If done, who was blinded after assignment to interventions (e.g. participants, care providers, those assessing outcomes) and how If relevant, description of the similarity of interventions	
Statistical methods	12.a 12.b	Statistical methods used to compare groups for primary and secondary outcomes Methods for additional analyses, such as subgroup analyses and adjusted analyses	
RESULTS			
Participant flow (A diagram is strongly recommended)	13.a 13.b	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome For each group, losses and exclusions after randomization, together with reasons	
Recruitment	14.a 14.b	Dates defining the periods of recruitment and follow-up Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	

Section/Topic	Item #	Checklist Item	Report ed on Page #
Outcomes and estimation	17.a 17.b	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval) For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group; for specific guidance see CONSORT for Harms(26)	
DISCUSSION			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
OTHER INFORMATION			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (e.g., supply of drugs); role of funders	

* We strongly recommend reading this Statement in conjunction with the CONSORT 2010 explanation and elaboration [ref] for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials, (11) noninferiority and equivalence trials(12), nonpharmacologic treatments(30), herbal interventions(31), and pragmatic trials. (32) Moreover, additional extensions are forthcoming. For those and also for up-to-date references relevant to this checklist, see www.consort-statement.org.

Figure: Flow Diagram of the progress through the phases of a 2-group parallel randomized trial (i.e., enrollment, intervention allocation, follow-up, and data analysis)



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