WEBCONSORT – active implementation of reporting guidelines

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15 September 2018

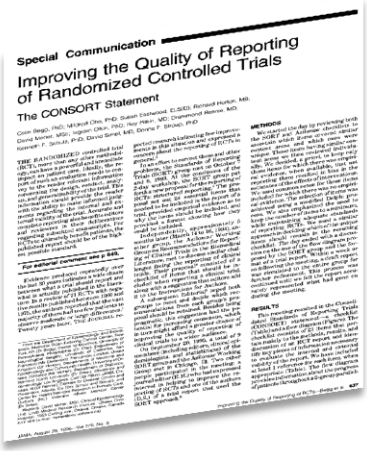

QUEST
CENTER

CONSORT

CONSORT

20th ANNIVERSARY

CONSORT



Special Communication

Improving the Quality of Reporting of Randomized Controlled Trials

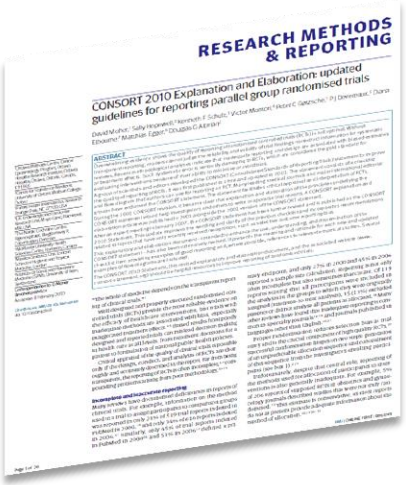
The CONSORT Statement

1996

ACADEMIA AND CLINIC

The CONSORT Statement: Revised Recommendations for Improving the Quality of Reports of Parallel-Group Randomized Trials

2001



RESEARCH METHODS & REPORTING

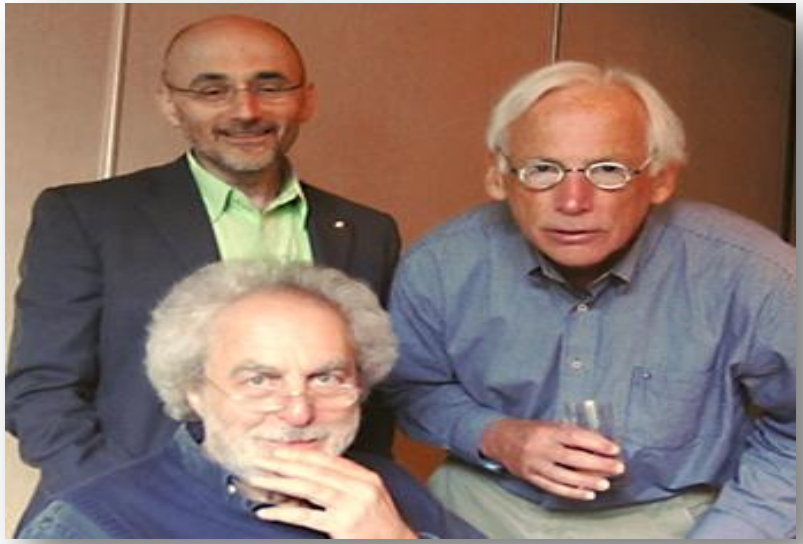
CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials

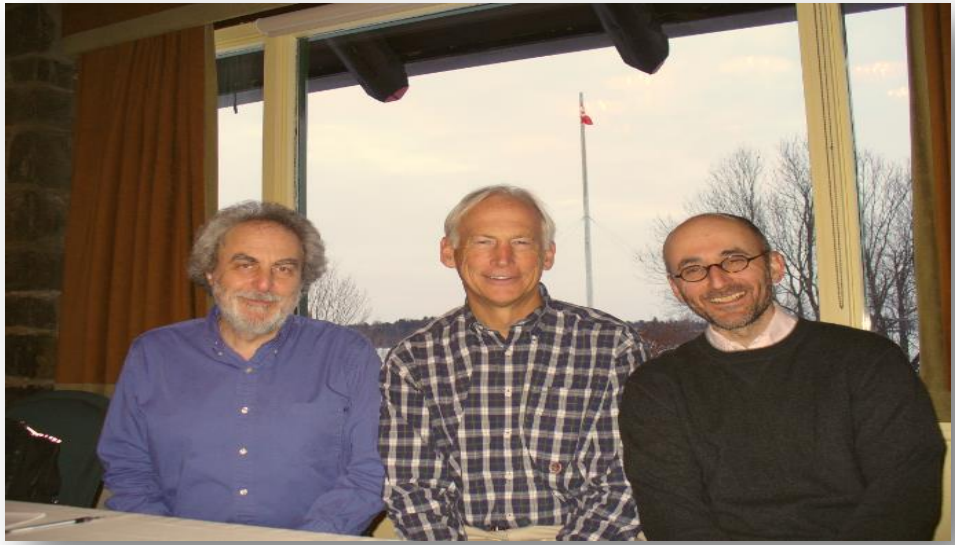
2010

BOTNAR


Academia and Clinic
Annals of Internal Medicine
CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomized Trials
Kenneth F. Schulz, PhD, MBA; Douglas G. Altman, DSc; and David Moher, PhD, for the CONSORT Group*
BMJ
RESEARCH METHODS & REPORTING
Consort 2010 statement: extension to cluster randomised trials
Reporting of Patient-Reported Outcomes in Randomized Trials
The CONSORT PRO Extension
RESEARCH METHODS & REPORTING
Improving the reporting of pragmatic trials: an extension of the CONSORT statement
RESEARCH METHODS AND REPORTING
CONSORT 2010 statement: extension to randomised pilot and feasibility trials
Reporting Randomized, Controlled Trials of Herbal Interventions: An Elaborated CONSORT Statement
Reporting of Noninferiority and Equivalence Randomized Trials
Extension of the CONSORT 2010 Statement
CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration
PLOS MEDICINE
Methods and Processes of the CONSORT Group: Example of an Extension for Trials Assessing Nonpharmacologic Treatments

CONSORT





INTERNATIONAL CONGRESS ON
PEER REVIEW
AND
BIOMEDICAL
PUBLICATION
5
September 16-18, 2005
Chicago, Illinois, USA

SUNDAY, SEPTEMBER 18

7:30 AM - 8:30 AM
Registration, Continental Breakfast, and Exhibits

8:30 AM - 9:00 AM
More Peer Review Congresses? Why?
Drummond Rennie (United States)

9:00 AM - 10:00 AM
Reporting of Studies: Abstracts and Publication After Meeting Presentations
Moderator: David Moher (Canada)

Trials Reported in Abstracts: The Need for a Mini-CONSORT
Sally Hopewell and Mike Clarke (United Kingdom)
Abstract | Article **published in *J Clin Epidemiol*. 2006;59(7):681-684.**

Are Relative Risks and Odds Ratios in Abstracts Believable?
Peter C. Gøtzsche (Denmark)
Abstract | Article **published in *BMJ*. 2006;333(7561):231-234.**

Do Clinical Trials Get Published After Presentation at Biomedical Meetings? A Systematic Review of Follow-up Studies
Erik von Elm, and Roberta Scherer (Switzerland, United States)
Abstract | Article **published in *Cochrane Database Syst Rev*. 2007 Apr 18;(2):MR000005.**

INTERNATIONAL CONGRESS ON
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September 16-18, 2005
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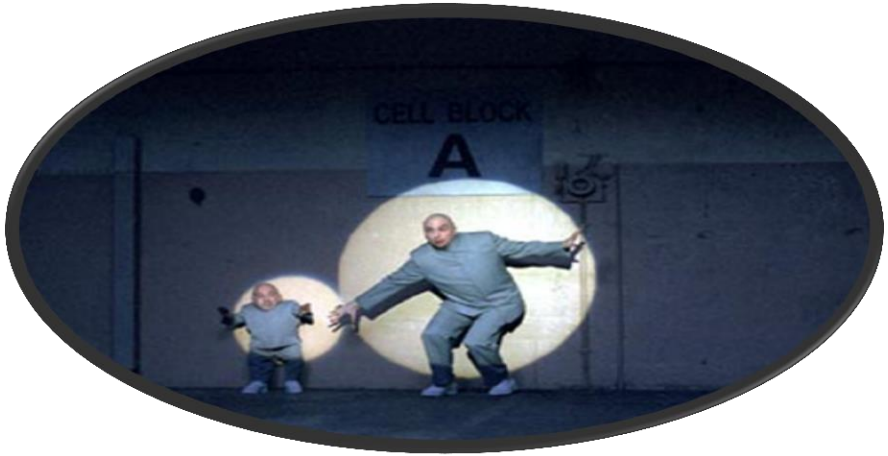
Trials reported as abstracts: the need for a mini-CONSORT

Sally Hopewell and Mike Clarke

UK Cochrane Centre, Oxford, UK
University of Oxford, UK

Recommendations

- Develop a key reporting standard (mini-CONSORT) for abstracts reporting **randomized trials**.
- This would serve two purposes:
  - help users of abstracts (conference and journal) to appraise their quality, especially if this is all someone has access to.
  - help raise the professional profile of the scientific conference and medical journal.



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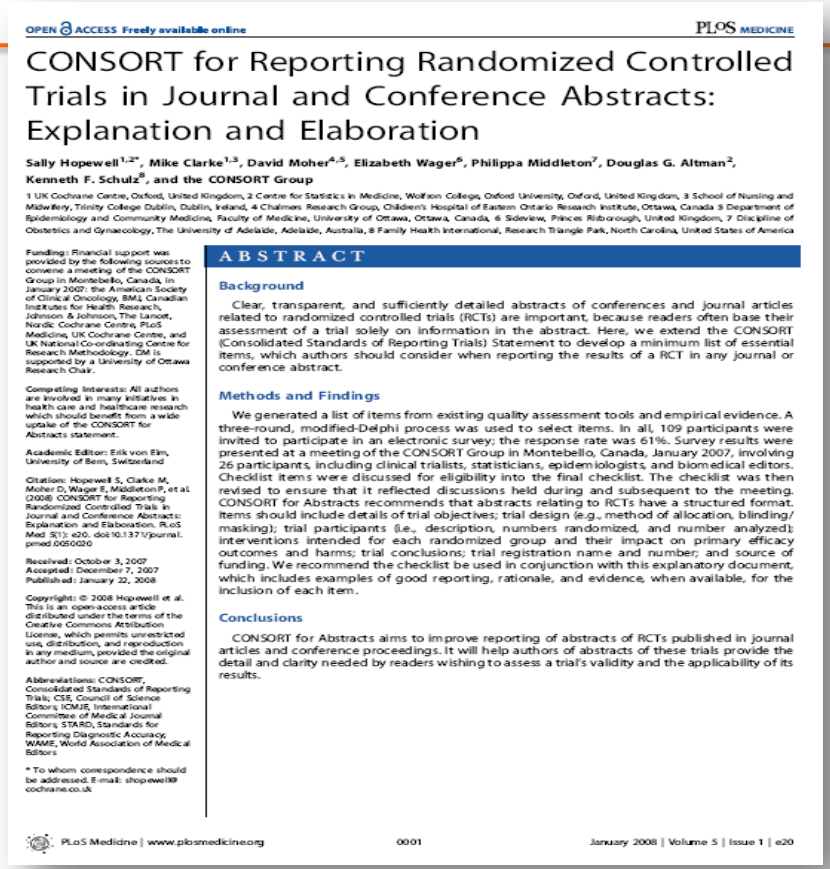

OPEN ACCESS Freely available online PLoS MEDICINE

CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration

Sally Hopewell[1,2*], Mike Clarke[1,3], David Moher[4,5], Elizabeth Wager[6], Philippa Middleton[7], Douglas G. Altman[2], Kenneth F. Schulz[8], and the CONSORT Group

1 UK Cochrane Centre, Oxford, United Kingdom, 2 Centre for Statistics in Medicine, Wolfson College, Oxford University, Oxford, United Kingdom, 3 School of Nursing and Midwifery, Trinity College Dublin, Dublin, Ireland, 4 Chalmers Research Group, Children's Hospital of Eastern Ontario Research Institute, Ottawa, Canada 5 Department of Epidemiology and Community Medicine, Faculty of Medicine, University of Ottawa, Ottawa, Canada, 6 Sideview, Princes Risborough, United Kingdom, 7 Discipline of Obstetrics and Gynaecology, The University of Adelaide, Adelaide, Australia, 8 Family Health International, Research Triangle Park, North Carolina, United States of America

Funding: Financial support was provided by the following sources to convene a meeting of the CONSORT Group in Montebello, Canada, in January 2007: the American Society of Clinical Oncology, BMJ, Canadian Institutes for Health Research, Johnson & Johnson, The Lancet, Nordic Cochrane Centre, PLoS Medicine, UK Cochrane Centre, and UK National Co-ordinating Centre for Research Methodology. DM is supported by a University of Ottawa Research Chair.

Competing Interests: All authors are involved in many initiatives in health care and healthcare research which should benefit from a wide uptake of the CONSORT for Abstracts statement.

Academic Editor: Erik von Elm, University of Bern, Switzerland

Citation: Hopewell S, Clarke M, Moher D, Wager E, Middleton P, et al. (2008) CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration. PLoS Med 5(1): e20. doi:10.1371/journal.pmed.0050020

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Abbreviations: CONSORT, Consolidated Standards of Reporting Trials; CSE, Council of Science Editors; ICMJE, International Committee of Medical Journal Editors; STARD, Standards for Reporting Diagnostic Accuracy; WAME, World Association of Medical Editors

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ABSTRACT

Background

Clear, transparent, and sufficiently detailed abstracts of conferences and journal articles related to randomized controlled trials (RCTs) are important, because readers often base their assessment of a trial solely on information in the abstract. Here, we extend the CONSORT (Consolidated Standards of Reporting Trials) Statement to develop a minimum list of essential items, which authors should consider when reporting the results of a RCT in any journal or conference abstract.

Methods and Findings

We generated a list of items from existing quality assessment tools and empirical evidence. A three-round, modified-Delphi process was used to select items. In all, 109 participants were invited to participate in an electronic survey; the response rate was 61%. Survey results were presented at a meeting of the CONSORT Group in Montebello, Canada, January 2007, involving 26 participants, including clinical trialists, statisticians, epidemiologists, and biomedical editors. Checklist items were discussed for eligibility into the final checklist. The checklist was then revised to ensure that it reflected discussions held during and subsequent to the meeting. CONSORT for Abstracts recommends that abstracts relating to RCTs have a structured format. Items should include details of trial objectives; trial design (e.g., method of allocation, blinding/masking); trial participants (i.e., description, numbers randomized, and number analyzed); interventions intended for each randomized group and their impact on primary efficacy outcomes and harms; trial conclusions; trial registration name and number; and source of funding. We recommend the checklist be used in conjunction with this explanatory document, which includes examples of good reporting, rationale, and evidence, when available, for the inclusion of each item.

Conclusions

CONSORT for Abstracts aims to improve reporting of abstracts of RCTs published in journal articles and conference proceedings. It will help authors of abstracts of these trials provide the detail and clarity needed by readers wishing to assess a trial's validity and the applicability of its results.

International Committee of Medical Journal Editors

Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication

Updated October 2008

"Articles on clinical trials should contain abstracts that include the items that the CONSORT group has identified as essential."

Implementation of CONSORT

Hopewell *et al. BMC Medicine* (2016) 14:199
DOI 10.1186/s12916-016-0736-x

BMC Medicine

RESEARCH ARTICLE Open Access

Impact of a web-based tool (WebCONSORT) to improve the reporting of randomised trials: results of a randomised controlled trial

Sally Hopewell[1,2,3*], Isabelle Boutron[3,4], Douglas G. Altman[2], Ginny Barbour[5], David Moher[6], Victor Montori[7], David Schriger[8], Jonathan Cook[2], Stephen Gerry[2], Omar Omar[2], Peter Dutton[2], Corran Roberts[2], Eleni Frangou[2], Lei Clifton[2], Virginia Chiocchia[2], Ines Rombach[2], Karolina Wartolowska[2], and Philippe Ravaud[3,4]

Background

- Evidence suggests that use of CONSORT improves reporting.
- In addition to CONSORT there are different extensions specifying additional information for more complex trials:
  - cluster trials, non-inferiority trials, pragmatic trials, non-pharmacologic interventions.
- However, any specific trial may require several different extensions
  - which can make their application difficult for authors and journal editors to implement.

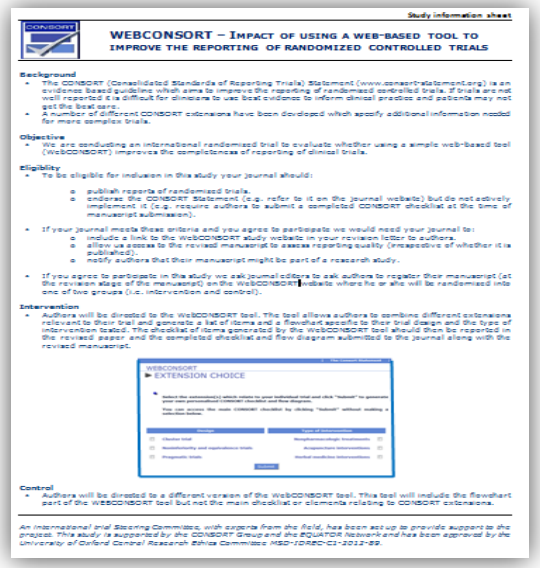
Objective

- To evaluate the impact of using a simple web based tool (WebCONSORT) to improve the completeness of reporting of randomised trials published in biomedical publications.

Eligibility criteria

- We conducted a multicentre randomised trial to evaluate the impact of the web-based tool on reporting:
  - planned sample size n=302 manuscripts.

- To be eligible for inclusion in the trial journals must:
  - publish reports randomised trials.
  - endorse the CONSORT Statement but not actively implement it (i.e. require authors to submit completed CONSORT checklist).



Study information sheet

WEBCONSORT – IMPACT OF USING A WEB-BASED TOOL TO IMPROVE THE REPORTING OF RANDOMIZED CONTROLLED TRIALS

Background

- The CONSORT (Consolidated Standards of Reporting Trials) Statement (www.consort-statement.org) is an evidence based guideline which aims to improve the reporting of randomised controlled trials. If trials are not well reported it is difficult for clinicians to use best evidence to inform clinical practice and patients may not get the best care.
- A number of different CONSORT extensions have been developed which specify additional information needed for more complex trials.

Objective

- We are conducting an international randomised trial to evaluate whether using a simple web-based tool (WebCONSORT) improves the completeness of reporting of clinical trials.

Eligibility

- To be eligible for inclusion in this study your journal should:
  - publish reports of randomised trials.
  - endorse the CONSORT Statement (e.g. refer to it on the journal website) but do not actively implement it (e.g. require authors to submit a completed CONSORT checklist at the time of manuscript submission).
- If your journal meets these criteria and you agree to participate we would need your journal to:
  - include a link to the WebCONSORT study website in your revision letter to authors.
  - allow us access to the revised manuscript to assess reporting quality (irrespective of whether it is published).
  - notify authors that their manuscript might be part of a research study.
- If you agree to participate in the study we ask journal editors to ask authors to register their manuscript (at the revision stage of the manuscript) on the WebCONSORT website where he or she will be randomised into one of two groups (i.e. intervention and control).

Intervention

- Authors will be directed to the WebCONSORT tool. The tool allows authors to combine different extensions relevant to their trial and generate a list of items and a flowchart specific to their trial design and the type of intervention tested. The checklist of items generated by the WebCONSORT tool should then be reported in the revised paper and the completed checklist and flow diagram submitted to the journal along with the revised manuscript.

Control

- Authors will be directed to a different version of the WebCONSORT tool. This tool will include the flowchart part of the WEBCONSORT tool but not the main checklist or elements relating to CONSORT extensions.

An international trial Steering Committee, with experts from the field, has been set up to provide support to the project. This study is supported by the CONSORT Group and the EQUATOR Network and has been approved by the University of Oxford Central Research Ethics Committee MSD-IDREC-C1-2012-89.

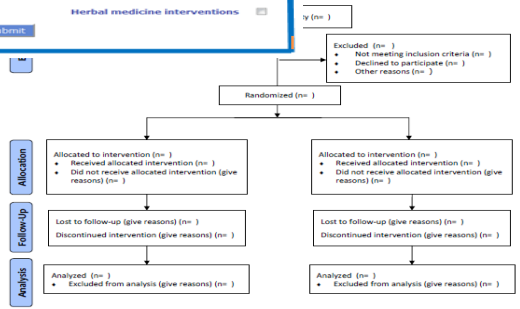
Trial design

- To participate in the study, journal's needed to include a link to the WebCONSORT study website in their revision letter to authors:
  - *"As part of the process of revising your manuscript we would like to use the WebCONSORT tool which is designed to help you improve the reporting of your randomised trial. You can access the tool by clicking on the following link: www.webconsort.fr/registration" .*
  - *"Please be aware that by submitting your manuscript to our journal it may be part of research study, any participation will not impact on any future acceptance or rejection of your manuscript".*

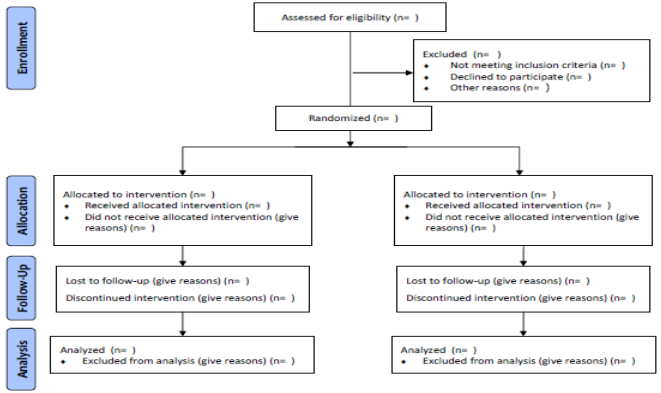
Intervention

Randomisation

WebCONSORT Group

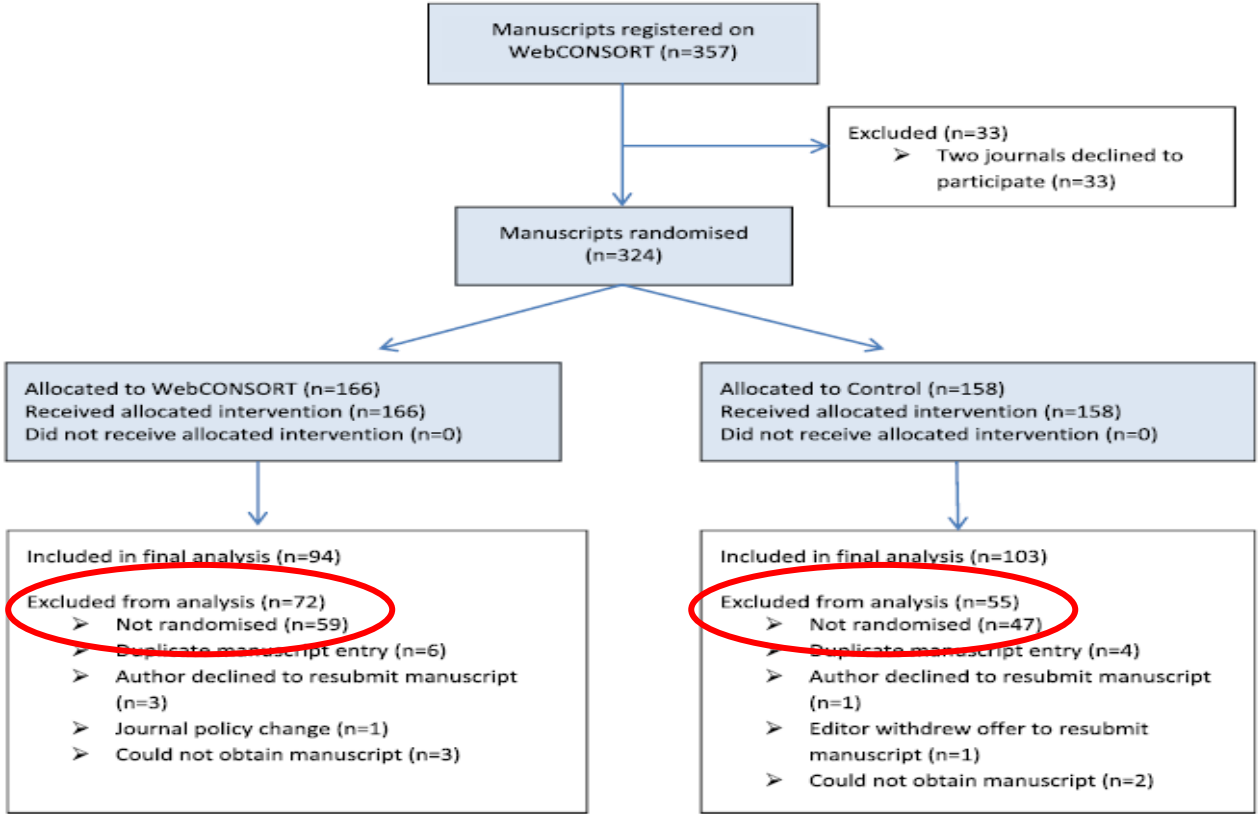


Control Group



Primary outcome

- The proportion of CONSORT items (initial and extensions) reported in revised manuscript.
  - CONSORT Statement : 10 most important and poorly reported checklist items.
  - CONSORT extensions: 5 most important and poorly reported modified items (per extension).

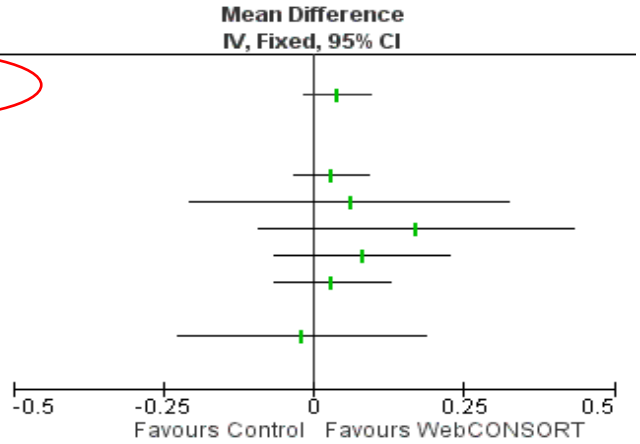

Manuscripts registered on WebCONSORT (n=357)
Excluded (n=33)
Two journals declined to participate (n=33)
Manuscripts randomised (n=324)
Allocated to WebCONSORT (n=166)
Received allocated intervention (n=166)
Did not receive allocated intervention (n=0)
Allocated to Control (n=158)
Received allocated intervention (n=158)
Did not receive allocated intervention (n=0)
Included in final analysis (n=94)
Excluded from analysis (n=72)
Not randomised (n=59)
Duplicate manuscript entry (n=6)
Author declined to resubmit manuscript (n=3)
Journal policy change (n=1)
Could not obtain manuscript (n=3)
Included in final analysis (n=103)
Excluded from analysis (n=55)
Not randomised (n=47)
Duplicate manuscript entry (n=4)
Author declined to resubmit manuscript (n=1)
Editor withdrew offer to resubmit manuscript (n=1)
Could not obtain manuscript (n=2)

Number and type of extension(s)

	Intervention (n=94)	Control (n=103)
Type of extension selected by author:		
Nonpharmacological extension	43	50
Cluster extension	10	9
Non inferiority extension	9	8
Pragmatic extension	20	16
Herbal extension	2	13
Acupuncture extension	2	0
Extension correctly matched		
Yes	72 (77%)	82 (80%)
No	22 (23%)	21 (20%)

Comparison in mean percentage score between WebCONSORT and Control (n=197 manuscripts)

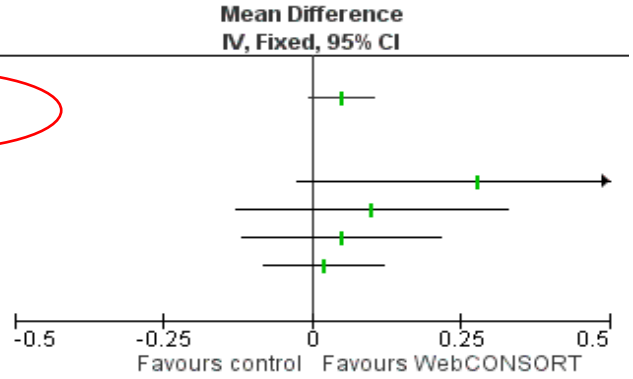
Study or Subgroup	WebCONSORT Mean	SD	Total	Control Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
1.1.1 Primary outcome							
Overall score	0.51	0.2	94	0.47	0.2	103	0.04 [-0.02, 0.10]
1.1.2 Secondary outcomes							
CONSORT	0.59	0.22	94	0.56	0.23	103	0.03 [-0.03, 0.09]
Cluster extension	0.24	0.32	10	0.18	0.27	9	0.06 [-0.21, 0.33]
Non-inferiority extension	0.4	0.32	9	0.23	0.23	8	0.17 [-0.09, 0.43]
Pragmatic extension	0.28	0.21	20	0.2	0.23	16	0.08 [-0.07, 0.23]
Non-pharmacologic extension	0.17	0.25	43	0.14	0.22	50	0.03 [-0.07, 0.13]
Acupuncture extension	0.8	0.28	2	0	0	0	Not estimable
Herbal extension	0.1	0.14	2	0.12	0.13	13	-0.02 [-0.23, 0.19]



Mean difference 0.04; 95% CI -0.02 to 0.10

Sensitivity analysis: excluding manuscript if extension wrongly selected by author

Study or Subgroup	WebCONSORT Mean	SD	Total	Control Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
2.1.1 Primary outcome							
Overall score	0.53	0.2	94	0.48	0.2	103	0.05 [-0.01, 0.11]
2.1.2 Secondary outcomes							
Cluster extension	0.6	0.16	4	0.32	0.3	5	0.28 [-0.03, 0.59]
Non-inferiority extension	0.57	0.23	6	0.47	0.12	3	0.10 [-0.13, 0.33]
Pragmatic extension	0.33	0.2	16	0.28	0.23	11	0.05 [-0.12, 0.22]
Non-pharmacologic extension	0.17	0.26	41	0.15	0.22	49	0.02 [-0.08, 0.12]



Mean difference 0.05; 95% CI -0.01 to 0.11

Conclusion

- Overall there was no difference between WebCONSORT and control in completeness of reporting of revised manuscripts.
- Creating a customised CONSORT checklist specific to an individual trial, for use at the revision stage of manuscript submission, does not optimize use of CONSORT and its extensions.
- These findings have important implications for future implementation of CONSORT and reporting guidelines more generally:
  - combined customised checklist to long for authors to comply.
  - implementation at the revision stage may be to late.

Participating journals

- American Journal of Kidney Diseases; Annals of Surgery; Arquivos Brasileiros; BMC Anesthesiology; BMC Cancer; BMC Endocrine Disorders; BMC Family Practice; BMC Gastroenterology; BMC Health Services Research; BMC Infectious Diseases; BMC Medicine; BMC Nursing; BMC Oral Health; BMC Public Health; BMC Surgery; British Journal of Geriatrics; British Journal of Obstetrics and Gynaecology; British Journal of Surgery; Canadian Medical Association Journal; Child and Adolescent Psychiatry and Mental Health; Chinese Medicine; Conflict and Health; Critical Care; Indian Journal of Dermatology; International Journal of Nursing Studies; International Journal of Paediatric Dentistry; Journal of Advanced Nursing; Journal of Cardiothoracic Surgery; Journal of Genetic Counseling; Journal of Gynecologic Oncology; Journal of Hand Surgery; Journal of Hepatology; Journal of the American Podiatric Medical Association; NIHR HTA monograph; Neurourology and Urodynamics; Nordic Journal of Music Therapy; Orphanet Journal of Rare Diseases; Pediatric Pulmonology; Peritoneal Dialysis International; Physiotherapy; Public Health Nutrition; Thrombosis and Haemostasis.

The road is long !