



WEBCONSORT – active implementation of reporting guidelines

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Oxford Clinical Trials Research Unit, Centre for Statistics in Medicine, University of Oxford.

15 September 2018











CONSORT

Improving the Quality of Reporting of Randomized Controlled Trials

The CONSORT Statement

CONSORT



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Annals of Internal Medicine

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

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Jane Blazeby, MD

David Moher, PhD

Michael D. Brundage

Kenneth F. Schulz, PhD. MBA: Douglas G. Altman. DSc; and David Moher, PhD, for the CONSORT Group The CONSORT (Consolidated Standards of Reporting Trials) statement is used worldwide to improve the reporting of randomized, controlled trials. Schulz and colleagues describe the latest version, For author affliations, see end of text. * For the CONSORT Group contributors to CONSORT 2010, see the Appen

CONSORT 2010, which updates the reporting new methodological evidence and accumulatir BM

Editor's Note: In order to encourage di. CONSORT 2010 Statement, this article is www.annals.org and will also be publis. Lancet, Obstetrics & Gynecology, PLos Medicine, Journal of Clinical Epidemio cine, and Trials. The authors jointly hold a article. For details on further use, see the CO vie.consort-statement.org)

Randomized, controlled trials, when signed, conducted, and reported, r standard in evaluating health care interv odological rigor (1). To assess a trial acc a published report need complete, clea information on its methodology and nately, attempted assessments frequently of many trial reports neglect to provide 1 descriptions of that critical information (2 That lack of adequate reporting fi

ment of the original CONSORT (Cons of Reporting Trials) statement in 1996 (5 years later (6-8). While those stateme oorting quality for some randomized, c 10), many trial reports still remain inades more, new methodological evidence and ence has accumulated since the last revisi sequently, we organized a CONSORT undate the 2001 statement (6-8). We result of that process, CONSORT 2010

INTENT OF CONSORT 2010 The CONSORT 2010 State

cluding the 25-item checklist (Table) and

See also:	
Web-Only	
Appendix	
Conversion c	of graphics into slide

June 2010 Annah of Imernal Medicine Volume

RESEARCH METHODS & REPORTING

Consort 2010 statement: extension to cluster randomised trials

The Consolidated Standards of Reporting Trials (CONSORT) statement was developed to improve the reporting o

reporting of pa **Reporting of Patient-Reported Outcomes** further update in 2008. In ear in Randomized Trials statement for th quidance bas for the reportin The CONSORT PRO Extension

The CONSORT (Consolidated Standards of Reporting Trials) Statement aims to improve the reporting of randomized controlled trials (RCTs); however, i lacks guidance on the reporting of patient-reported outcomes (PROs), which are often inadequately reported in trials, thus limiting the value of these data. In this article, we describe the development of the CONSORT PRO extension based on the methodological framework for guideline development profor the CONSORT PRO Groun posed by the Enhancing the Quality and Transparency of Health Research

Page 1 of 2

RESEARCH METHODS & REPORTING

D P OPEN ACCESS

Improving the reporting of pragmatic trials: an extension of the CONSORT statement

Merrick Zwarenstein, 123 Shaun Treweek, 45 Joel J Gagnier 54 Douglas G Altman, 7 Sean Tunis, 8910 Brian Haynes, 7 Andrew D Oxman.5 David Moher.12 To for the CONSORT and Pragmatic Titals in Healthcare (Practinc) groups Pragmatic trials are designed to inform decisions about practice, but poor reporting can reduce

their usefulness. The CONSORT and Practific groups describe modifications to the CONSORT guidelines to help readers assess the applicability of th

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Methods At two, two-day meetings held in Toronto in 2005 and 2008, we reviev Benature on pragmatic trials and applicability, and our experiences in

Recommendations We recommend extending wight CONS ORT checklist transformation -Centre for Primary Care and Public Health, Queen Mary University of London, London We recommend extending eight CONS. Off checklist terms for reporting interventions, cutomenes, sample arb, silonding, participant flow, and criteria will make testing to checklist and the constraint of the heid and conditions. In principal studies are needed to ascertain the us checklist term extensions, is the meantime we recommend that those should use this terms on other CONSDIT statement to facilitate the whold use the terms on other CONSDIT statement to facilitate the should use the terms on other CONSDIT statement to facilitate the used of the terms of the terms of the terms of the terms of the statement of the constraint terms of the terms of the terms of the statement of the terms of the terms of the terms of the terms of the statement of the terms of the terms of the terms of the terms of the statement of the terms of the terms of the terms of the terms of the statement of the terms of the statement of the terms of the statement of the terms of the statement of terms of the statement of the terms of terms of the terms of terms

Randomised controlled trials are used to assess the benefits and harms of interventions in health care. If consetti ducted properly, they minimise the risk of bias (threats to internal validity), particularly selection bias.¹³ There is, however, considerable evidence that trials are not always cabi ity) | setti well reported.34 and this can be associated with bias. extr. such as selective reporting of outcomes? Se The usefulness of a trial report also depends on the clarity with which it details the relevance of its intervenopti desi ple, tions, participants, outcomes, and design to the clinical, health service, or policy question it examines. Further-

Table 11 Key differences between trials with explanatory and progmatic att for Clinical Trials meeting by Marlon Campbell, University of Abendeen

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Reporting Randomized, Controlled Trials of Herbal Interventions: An Elaborated CONSORT Statement

Joel J. Gagnier, ND, MSc: Heather Boon, PhD; Paula Rochon, MD, MPH; David Moher, PhD; Joanne Barnes, PhD, MRPharmS FLS; and Claire Bombardier, MD, for the CONSORT Group*

Herbal medicinal products are widely used, vary greatly in a and quality, and are actively tested in randomized, controlled trial (RCTs). The authors' objective was to develop recommendation for reporting RCTs of herbal medicine interventions, based on the

RCTs of herbal medicines. Item 4, concerning the herbal medicin intervention, required the most extensive elaboration. These recom-mendations have been developed to improve the reporting of RCTs using herbal medicine interventions

Reporting of Noninferiority and Equivalence Randomized Trials Extension of the CONSORT 2010 Statement

Gilda Piaggio, PhD	The CONSORT (Consolidated Standards of Reporting T	iale) Statement which	en no empir-
Diana R. Elbourne, PhD	 Includes a checklist and a flow diagram, is a guideline developed to 		easoning was
Stuart J. Pocock, PhD	authors improve the reporting of the findings from r		ated them by
Stephen J. W. Evans, MSc	trials. It was updated most recently in 2010. Its prin		nsus meeting.
Douglas G. Altman, DSc	vidually randomized trials with 2 parallel groups that assess the possible superiority of one treatment compared with another. The CONSORT State-		eeting check-
for the CONSORT Group			imizing item
HE ORIGINAL CONSORT (CON-	ment has been extended to other trial designs such		tions on evi-
solidated Standards of Report-	tion, and recommendations for noninferiority and equiva		a, deletion, or
ing Trials) Statement was de-	in 2006. In this article, we present an updated extens		ntil all items
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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 Wager⁶, Phi**l**ippa Middleton⁷, Douglas G. Altman², Kenneth F. Schulz⁸, and the CONSORT Group 1 UK Cochane Center, Oxford, United Kinadom, 3 Centre for Statistics in Medicine, Wolford, College, Oxford University, Oxford, United Kingdom, 8 School of Naming and

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Methods and Processes of the CONSORT Group: Example of an

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s-Bains, France (Dr Plaggio) rtment, London School of Hy-dicine, London, United King me and Pocock and Mr Evans) in Medicine, University of Ox nd empirical evidence. A II, 109 participants were Ingdom (Dr Altman).
 Cilda Plaggio, PhD, Statis
 Ae de l'Etraz, 01220 Devone ation. All rights rese

equent to the meeting. ave a structured format tension to the CONSORT Statement should improve the quality d of allocation, blinding reporting randomized, controlled trials assessing nonpharmacoand number analyzed act on primary efficacy www.amait.org number; and source of n Intern Med. 2008 148 W-60 W-66 s explanatory document, when available, for the

ample, angioplasts), implanted devices (for grample, CTs published in journal ample, angiopauty, implanted nevices (tor example, scenakers), nonimplantable devices, rehabilitation, phys-therapy, behavioral therapy, psychotherapy, and comple-entary and alternative medicine. Although the CON-XRT Statement can be applied to reports of these trials, rtain issues, such as the complexity of the interventior pertise of the care provider, and difficulties with blinding), present specific challenges that the revised CONSORT in product of the second paying explanation and elabora in document do not address in depth (3, 4, 9–13). Because these important study aspects are often inad

id processes used by the CONSORT Group to develop

acologic treatments, we used general guideline develop-ent principles (18) and drew on the experience gained and developing previous CONSORT extensions (19). eering Committee

A steering committee was ultimately responsible for



CONSORT 2010 statement: extension to randomised pilot and feasibility trials Sandra M Eldridge,³ Claire L Chan,³ Michael J Campbell,² Christine M Bond,³ Sally Hopewell,⁴

for the CONSORT Group

Lehana Thabane,5 Gillian A Lancaster® on behalf of the PAFS consensus group

Reporting Trials (CONSORT) statement is a guideline designed to improve the transparency and quality of the reporting of randomised controlled reference number

The development of the extension was motivated by the growing number of studies described as feasibility or pilot studies and by research that has identified weaknesses in their reporting explanation of the changes made and and conduct. We followed recommended good practice to develop the extension. Including

Consequently, although much of the Information to be reported in these trials is similar to those in randomised controlled trials (RCTs) assessing effectiveness and efficacy, there are some key differences in the type of Information and in the appropriate Interpretation of standard CONSORT reporting items. We have retained some of the original CONSORT statement Items, but most have been adapted some removed, and new

participants were identified and consent obtained: If applicable, the prespecified criteria used to judge whether or how to proceed with a future definitive RCT- if relevant, other Important unintended consequences Implications for progression from pilot to future definitive RCT, including any proposed amendments; and ethical approval or approval by a research review committee confirmed with a

This article includes the 26 item checklist, a separate checklist for the abstract, a template for a CONSORT flowchart for these studies, and an supporting examples. We believe that routine use of this proposed extension to the CONSORT statement will result in

Background: The conduct of randomized, controlled trials of non-pharmacologic treatments presents specific challenges that are not adequately addressed in trial reports. Results: The consensus was that 11 items on the CONSORT Results: The consensus was that 11 items on the CONSORT checklat needed some modifications for nonpharmacologic task-tem. The scale of the scale of the scale of the scale interval of the scale of the scale of the scale of the scale ing), item 12 (datatiscal methods), item 31 (aparts), about 10 even immedizability). In addition, the meeting participant added 11 item mendizability. In addition, the meeting participant added 11 item Objective: To develop an extension of the CONSORT (Consoliid Standards of Reporting Trials) Statement for trials of non macologic treatments. RESEARCH METHODS AND REPORTING

31%. Survey results were ated to implementation of the intervention. Lanuary 2007, involving , and biomedical editors. The checklist was then nitation: Evidence was not always available to support the in-sion of each checklist item. inclusion: The methods and processes used to develop this ex-ssion could be used for other reporting guidelines. The use of this

ditional methodological issues related to nonpharmacologic research were identified.

author affiliations, see and of text. er contributors to the CONSORT Extension for Norpharmacologic Treatment erventors, see the Appendix.

uately reported (3), we developed an extension of the ONSORT Statement for trials of nonpharmacologic in-rventions (14-17). This article describes the methods

To develop the CONSORT extension for nonphar

e development of this reporting guide. They secured

items added. The new items cover how

Extension for Trials Assessing Nonpharmacologic Treatments

Isabelle Boutron, MD. PhD: David Moher, PhD: Douglas G. Altman, DSc: Kenneth F. Schulz, PhD, MBA: and Philippe Rayaud, MD, PhD.

The Consolidated Standards of

trials (PCTs). In this article we present an extension to that statement for randomised pilot and feasibility trials conducted in advance of a future definitive RCT. The checklist applies to any randomised study in which a future definitive RCT, or part of it, is conducted

describe the study (eg. pilot, feasibility, trial, study). The extension does not directly apply to internal pilot studies non-randomised pilot and feasibility studies, or phase II studies, but these studies all have some similarities to randomised pilot and feasibility studies and so many of the principles might

on a smaller scale, regardless of its design (eg, cluster, factorial, crossover) or the terms used by authors to One this ar: DMF 2016:355-15239 http://dx.doi.org/10.1136/bmj. built into the design of a main trial ccepted: 18 September 2016

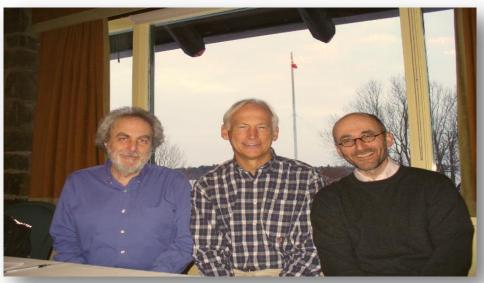
also apply

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CONSORT











PEER REVIEW AND BIOMEDICAL PUBLICATION



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 PEER REVIEW AND BIOMEDICAL PUBLICATION

September 16-18, 2005 Chicago, Illinois, USA

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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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 Wager⁶, Philippa Middleton⁷, Douglas G. Altman², Kenneth F. Schulz⁸, and the CONSORT Group

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Funding: Rearclai up port was provided by the following occurs to convene a meeting of the CONSOFT Group in Montebles, Canada, in January 2007: the American Society Institutes for Hamilton Rearch, Johnson & Johnson, The Lancet, Nordis Cohrane Centre, Ruis Maddine, UK Cohrane Centre, Ruis Maddine, UK Cohrane Centre, Ruis Maddine, UK Cohrane Centre, Ruis Rearch Mathodiky, DM Is supported by a University of Otawa Rearch Charle.

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) CONSOFT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts Explanation and Elaboration. R.oS Med S(1): e20. doi:10.1371/journal. pmed.055020

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Abbreviations: CONSORT, Consolidated Standards of Reporting Trials (SE, Council of Science Editors) (CME) International Committee of Medical Journal Biltors, STARD, Standards for Reporting Diagnostic Accuracy; WAME, World Association of Medical Biltors

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ABSTRACT

Background

Clear, transparent, and sufficiently detailed abstracts of conferences and journal articles related to randomized controlled trails (RCIs) are important, because readers often base their assessment of a trail solely on information in the abstract. Here, we extend the CONSORT (Consolidated Standards of Reporting Trails) 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-Deiphi process was used to select items. In all, 109 participants 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 thems 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. (CNSORT for Abstracts recommends that abstracts relating to RCTs have a structured format. 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 used in conjunction with this explanatory document, which includes examples of good reporting, rationale, and evidence, when available, for the inclusion of each trans.

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.

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January 2008 | Volume 5 | Issue 1 | e20

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. Altman², Ginny Barbour⁵, David Moher⁶, Victor Montori⁷, David Schriger⁸, Jonathan Cook², Stephen Gerry², Omar Omar², Peter Dutton², Corran Roberts², Eleni Frangou², Lei Clifton², Virginia Chiocchia², Ines Rombach², Karolina Wartolowska², and Philippe Ravaud^{3,4}







- 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.







 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).

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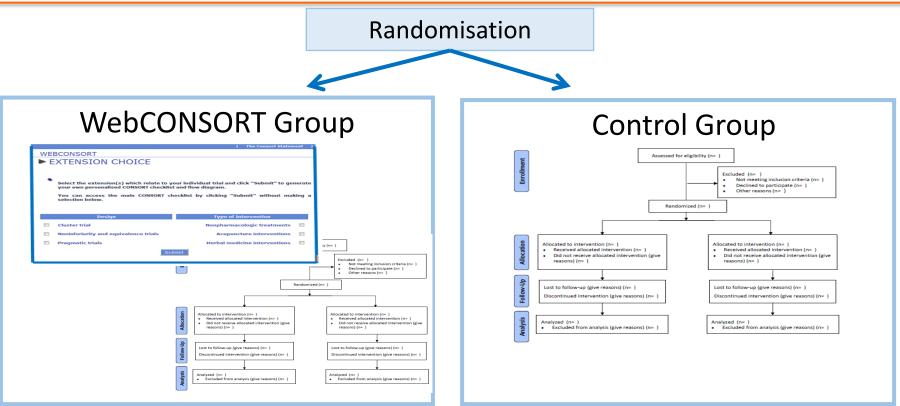


- To participate in the study, journal's needed to include a link to the WebCONSORT study website in their revision letter to authors:
 - "As part of the process of revising your manuscript we would like to use the WebCONSORT tool which is designed to help you improve the reporting of your randomised trial. You can access the tool by clicking on the following link: <u>www.webconsort.fr/registration</u>".
 - "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





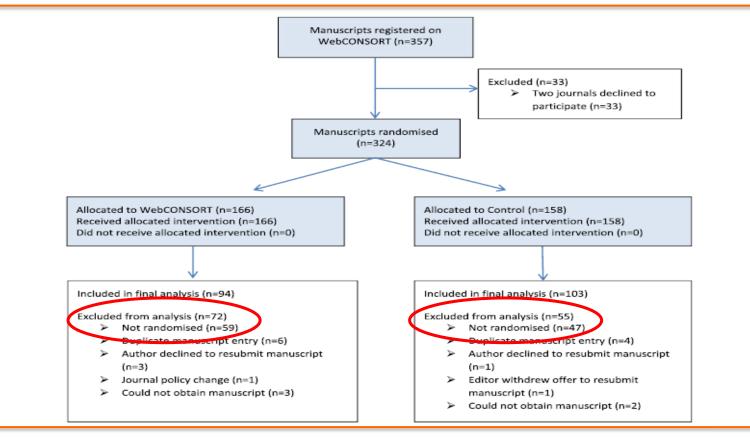




- The proportion of CONSORT items (initial and extensions) reported in revised manuscript.
 - CONSORT Statement : 10 most important and poorly reported checklist items.
 - CONSORT extensions: 5 most important and poorly reported modified items (per extension).









Number and type of extension(s)

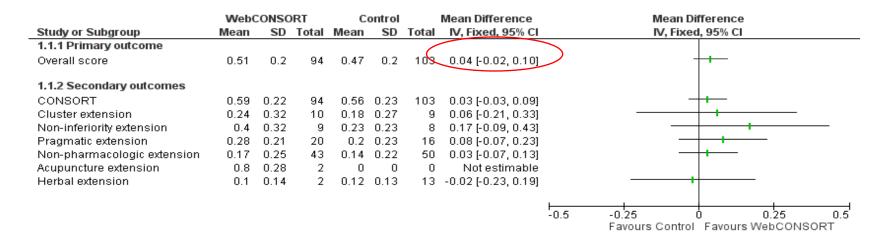


	Intervention (n=94)	Control (n=103)
Type of extension selected by author:		
Nonpharmacological extension	43	50
Cluster extension	10	9
Non inferiority extension	9	8
Pragmatic extension	20	16
Herbal extension	2	13
Acupuncture extension	2	0
Extension correctly matched		
Yes	72 (77%)	82 (80%)
No	22 (23%)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





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

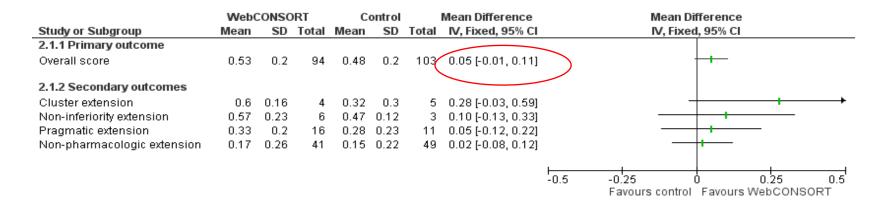


Mean difference 0.04; 95% CI -0.02 to 0.10





Sensitivity analysis: excluding manuscript if extension wrongly selected by author



Mean difference 0.05; 95% CI -0.01 to 0.11







- 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 !





