WEBCONSORT – active implementation of reporting guidelines

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**RESEARCH METHODS & REPORTING**

**CONSORT 2010 statement: extension to cluster randomised trials**

The CONSORT (Consolidated Standards of Reporting Trials) statement was developed to improve the reporting of trials in biomedical journals. The CONSORT 2010 statement extends this to cluster randomised trials, which are trials in which participants are clustered into groups that receive different interventions. The CONSORT 2010 statement includes a checklist and a flow diagram to guide the reporting of cluster randomised trials.

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

Pragmatic trials are designed to test questions about practice, but poor reporting can compromise their validity. The CONSORT and Pragmatic groups have developed guidelines to ensure the applicability of these trials.

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**CONSORT Statement: Reporting of Randomized Controlled Trials in Journal and Conference Abstracts**

The CONSORT statement is designed to improve the reporting of randomized controlled trials in journal articles and conference abstracts. It includes a checklist and a flow diagram to guide the reporting of these trials.

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**Consort 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomized Trials**

The CONSORT (Consolidated Standards of Reporting Trials) statement is currently undergoing updates to improve the reporting of randomized trials. The updated guidelines are expected to be published soon.

**Reporting of Noninferiority and Equivalence Randomized Trials**

These categories refer to trials where the goal is to show that one intervention is not worse than another (noninferiority) or that the difference between two interventions is negligible (equivalence). Reporting guidelines are crucial to ensure these trials are reported accurately.

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**Consort 2010 Statement**

The CONSORT (Consolidated Standards of Reporting Trials) statement is a guideline designed to improve the reporting of randomized controlled trials (RCTs). This is important for assessing the effectiveness of interventions and for comparing such interventions. The CONSORT statement includes a checklist and a flow diagram to guide the reporting of these trials.
CONSORT
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)

Are Relative Risks and Odds Ratios in Abstracts Believable?
Peter C. Gotzsche (Denmark)

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

Sally Hoewel1,2, Mike Clarke1,3, David Moher1,2, Elizabeth Wager1, Philippa Midden3, Douglas G. Altman4, Kenneth F. Schulz1, and the CONSORT Group

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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 Statement of Reporting Trials (CONSORT) 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 Montreal, Canada, January 2007, involving 23 participants, including clinical trialists, statisticians, epistemologists, and biostatisticians. Checklist items were discussed for eligibility into the final checklist. The checklist was then updated 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. The checklist should include details of trial objectives, trial design (e.g., method of allocation, blinding, masking), trial participants (e.g., description, number 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 where 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 who wish to assess a trial's validity and the applicability of its results.

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

Sally Hopewell¹,²,³∗, Isabelle Boutron³,⁴, Douglas G. Altman², Ginny Barbour⁵, David Moher⁶, Victor Montori⁷, David Schriger⁸, Jonathan Cook², Stephen Gery², Omar Omar², Peter Dutton², Corran Roberts², Eleni Frangou², Lei Clifton², Virginia Chiocchia², Ines Rombach², Karolina Wartolowska², and Philippe Ravaud³,⁴
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.
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).
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”.

Trial design
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)

Manuscripts randomised (n=324)

Excluded (n=33)
- Two journals declined to participate (n=33)

Allocated to WebCONSORT (n=166)
Received allocated intervention (n=166)
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)

Allocated to Control (n=158)
Received allocated intervention (n=158)
Did not receive allocated intervention (n=0)

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)

<table>
<thead>
<tr>
<th>Type of extension selected by author:</th>
<th>Intervention (n=94)</th>
<th>Control (n=103)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonpharmacological extension</td>
<td>43</td>
<td>50</td>
</tr>
<tr>
<td>Cluster extension</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Non inferiority extension</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>Pragmatic extension</td>
<td>20</td>
<td>16</td>
</tr>
<tr>
<td>Herbal extension</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>Acupuncture extension</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Extension correctly matched</th>
<th>Intervention (n=94)</th>
<th>Control (n=103)</th>
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</thead>
<tbody>
<tr>
<td>Yes</td>
<td>72 (77%)</td>
<td>82 (80%)</td>
</tr>
<tr>
<td>No</td>
<td>22 (23%)</td>
<td>21 (20%)</td>
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</tbody>
</table>
Comparison in mean percentage score between WebCONSORT and Control (n=197 manuscripts)

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>WebCONSORT</th>
<th>Control</th>
<th>Mean Difference 4, Fixed, 95% CI</th>
<th>Mean Difference 4, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall score</td>
<td>0.51 0.2</td>
<td>0.47 0.2</td>
<td>0.04 [-0.02, 0.10]</td>
<td></td>
</tr>
<tr>
<td>1.1.1 Primary outcome</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONSORT</td>
<td>0.59 0.22</td>
<td>0.56 0.23</td>
<td>0.03 [-0.03, 0.09]</td>
<td></td>
</tr>
<tr>
<td>Cluster extension</td>
<td>0.24 0.32</td>
<td>0.18 0.27</td>
<td>0.06 [-0.21, 0.33]</td>
<td></td>
</tr>
<tr>
<td>Non-inferiority extension</td>
<td>0.4 0.32</td>
<td>0.23 0.23</td>
<td>0.17 [-0.09, 0.43]</td>
<td></td>
</tr>
<tr>
<td>Pragmatic extension</td>
<td>0.28 0.21</td>
<td>0.23 0.23</td>
<td>0.00 [-0.07, 0.23]</td>
<td></td>
</tr>
<tr>
<td>Non-pharmacologic extension</td>
<td>0.17 0.25</td>
<td>0.14 0.22</td>
<td>0.03 [-0.07, 0.13]</td>
<td></td>
</tr>
<tr>
<td>Acupuncture extension</td>
<td>0.8 0.28</td>
<td>0     0</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>Herbal extension</td>
<td>0.1 0.14</td>
<td>0.12 0.13</td>
<td>-0.02 [-0.23, 0.19]</td>
<td></td>
</tr>
</tbody>
</table>

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
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 too long for authors to comply.
  • implementation at the revision stage may be too 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; Neuourology 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!