

**Bristol Seminar 3<sup>rd</sup> October 2011**

# **Other CONSORT extensions: an update**

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# What are CONSORT extensions?

- **Main CONSORT is based on a standard two group parallel trial design**
- **CONSORT extensions are modifications to this guidance that have been developed by/with the CONSORT group to respond to a need for reporting specific details for trials with particular **DESIGNS, INTERVENTIONS** or types of **DATA****
- **Modifications to checklist and flow diagram are highlighted and examples of good reporting given**

# Current CONSORT extensions

<b>DESIGNS</b>	<b>Cluster</b>	<b>Non-inferiority/ equivalence</b>	<b>Pragmatic</b>
<b>INTERVENTIONS</b>	<b>Herbal</b>	<b>Non- pharmacological (Isabelle)</b>	<b>Acupuncture (STRICTA)</b>
<b>DATA</b>	<b>Harms</b>	<b>Abstracts (Sally)</b>	

Full details (pdfs and checklists) on CONSORT website:

<http://www.consort-statement.org/>

# Trial design extensions

## Cluster trials:

- **Sometimes randomising groups rather than individuals is preferred eg, if threat of contamination of an intervention or if it's the only feasible method of conducting the trial**
- **Reporting needs to address two levels of inference:**
  - Cluster level: eg, families, medical practices, schools
  - Individual level eg, participant

NB, a single person may be a cluster with individual teeth/lesions etc.. the units within the cluster
- **Campbell MK, Elbourne DR, Altman DG. CONSORT statement: extension to cluster randomised trials. BMJ 2004; 328(7441):702-8.**
- **Now also in Chinese and Spanish**
- **UPDATE: CONSORT group have completed update in line with CONSORT 2010 checklist – publication imminent**

# Cluster extension: example of checklist

Item \*= addition to CONSORT 2001 *Modifications to checklist in italics*

## TITLE & ABSTRACT

- 1\* How participants were allocated to interventions (e.g., “random allocation”, “randomised”, or “randomly assigned”), *specifying that allocation was based on clusters*

## INTRODUCTION

### Background

- 2\* Scientific background and explanation of rationale, *including the rationale for using a cluster design.*

## METHODS

### Participants

- 3\* Eligibility criteria for participants *and clusters* and the settings and locations where data collected.

### Interventions

- 4\* Precise details of the interventions intended for each group, *whether they pertain to the individual level, the cluster level or both*, and how and when they were actually administered.

### Objectives

- 5\* Specific objectives and hypotheses, *whether they pertain to the individual level, cluster level or both.*

# Cluster extension: Impact on reporting?

**Ivers et al (2011). Impact of CONSORT extension for cluster randomised trials on quality of reporting and study methodology: review of random sample of 300 trials, 2000-8. *BMJ* 2011;343:d5886**

- **Pre- to post- 2004: Significant improvements in five of 14 reporting criteria:**
  - identification as cluster randomised
  - justification for cluster randomisation
  - reporting whether outcome assessments were blind
  - reporting the number of clusters randomised
  - reporting the number of clusters lost to follow-up
- **No significant improvements were found in adherence to methodological criteria. (eg, sample size calculation accounted for clustering)**
- **NB Adherence to recommendations more likely in RCTs conducted in clinical settings, higher impact factor journals and general medical journals**

**Conclusion: quality of reporting improved in only a few aspects since the publication of the extension...., no improvements at all were observed in essential methodological features.**

**Overall, adherence to reporting/methodological guidelines for cluster trials remains suboptimal, and further efforts are needed to improve both reporting and methodology.**

# Trial design extensions

- **Non-inferiority/equivalence trials:**
  - To determine whether a new treatment has at least as much efficacy as standard treatment because it has another advantage eg, lower cost, easier administration
  - Particular methodological features need reporting eg, are participants similar to those in trials that established efficacy of the reference treatment? Similarly for outcome measures
  - **Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJW. Reporting of noninferiority and equivalence randomized trials: An extension of the CONSORT statement. JAMA. 2006; 295:1152-1160.**
  - **UPDATE:** updating in line with CONSORT 2010 is currently in development

# Trial design extensions

- **Pragmatic trials:**
  - **Designed to measure effectiveness of an intervention in real world populations within usual care settings in response to need of purchasers/providers of health care to use evidence from trials in policy decisions.**
  - **Developed during 2 meetings in Toronto (24 people in 2005 & 42 in 2008) including members of CONSORT and Pragmatic Trials in Healthcare (Practihc) groups.**
  - **Additional specific guidance for 8 of the 22 checklist items**
  - **No modification to flow diagram**
  - **Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, Oxman AD, Moher D for the CONSORT and Pragmatic Trials in Healthcare (Practihc) group. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ 2008; 37;a2390. UPDATE: planned to align with CONSORT 2010**

# Intervention extensions

- **Trials of herbal interventions:**
  - Herbal medicinal products are widely used, vary greatly in content and quality, and are actively tested in RCTs.
  - Developed through a consensus meeting with 16 participants in Toronto. Participants included a group of experts in clinical trial methodology and reporting, herbal medicinal products, medical statistics and/or herbal product manufacturing.
  - Context-specific elaborations of 9 CONSORT checklist items. **Item 4 concerning the intervention itself required the most extensive elaboration. No modification to flow diagram.**
  - **Gagnier JJ, Boon H, Rochon P, Moher D, Barnes J, Bombardier C. Reporting randomized, controlled trials of herbal interventions: an elaborated CONSORT statement. Ann Intern Med 2006; 144(5):364-7**  
**UPDATE: planned**

# Intervention extensions

- **Acupuncture trials: STRICTA**

- **Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines, first published in 2001.**
- **Developed by the STRICTA Group, CONSORT Group and Chinese Cochrane Centre. In 2008 21 participants met in Freiburg, Germany.**
- **STRICTA aims to ensure that acupuncture trials are more accurately interpreted and more easily replicated. Endorsed by eight leading acupuncture journals (<http://www.stricta.info>).**
- **Available in Chinese and Korean, Russian and Japanese to follow**

**NOW UPDATED to align with CONSORT 2010**

- **MacPherson H, Altman DG, Hammerschlag R, Youping L, Taixiang W, White A, Moher D; STRICTA Revision Group. Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement. PLoS Med. 2010 Jun 8;7(6):e1000261.**
- **STRICTA 2010 checklist consists of six items split into 17 sub-items. Includes details of the rationale for acupuncture, details of needling, treatment regimen, other components of treatment, the practitioner background and the control or comparator intervention.**

# Data extensions

- **Harms:** considerable evidence that reporting of harms-related data from RCTs needs improvement.

### **Table 3. Common Poor Reporting Practices for Harms-Related Data**

1. Using generic or vague statements, such as “the drug was generally well tolerated”
2. Failing to provide separate data for each study arm.
3. Providing summed numbers for all adverse events for each study arm, without separate data for each type of adverse event.
4. Providing summed numbers for a specific type of adverse event, regardless of severity
5. Reporting only AEs observed at a certain frequency/rate threshold (eg, 10%)
6. Reporting only the adverse events that reach a *P value threshold* in the comparison of the randomized arms (eg,  $P < 0.05$ ).
7. Reporting measures of central tendency (for example, means or medians) for continuous variables without any information on extreme values.
8. Improperly handling or disregarding the relative timing of the events, when timing is an important determinant of the adverse event in question.
9. Not distinguishing between patients with 1 AE and participants with multiple AEs
10. Providing statements about whether data were statistically significant without giving the exact counts of events.
11. Not providing data on harms for all randomly assigned participants.

# Data extensions

- **Harms:**

- **Members of the CONSORT Group met in Montebello, Canada, in May 2003 to address this problem.**
- **10 new recommendations about reporting harms-related issues added to the main CONSORT checklist**
- **Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. Ann Intern Med 2004; 141(10):781-788**

**UPDATE:** planned

# CONSORT extensions in draft

- **Trial designs:**
  - **Multi-arm parallel group trials**
  - **Crossover trials**
  - **Factorial trials**
  - **Within-person randomized trials**

# New CONSORT extensions in development/planned

- **N of 1 trials**
- **QOL**
  - A collaboration between the International Society for Quality of Life Research (ISOQOL), the CONSORT Executive, the Midland and COnDuCT Medical Research Council Hubs for Trials Methodology Research (MRC MHTMR), journal editors, policy makers and patient representatives.
  - A Delphi exercise is currently in progress and the Consensus Meeting will be held in London, UK in Jan 2012.
  - For further information contact [consortqol@contacts.bham.ac.uk](mailto:consortqol@contacts.bham.ac.uk).
- **Paediatric trials (CONSORT C)**

# “Unofficial” CONSORT extensions

- Various groups have independently developed particular CONSORT-style guidelines in diverse fields without collaboration with the CONSORT Group

**NB, for your own assessment**

## **Include:**

- Homeopathy (REDHOT)
  - Behavioural interventions
  - Trials on livestock (REFLECT)
  - Trials in allergen-specific immunotherapy (GA<sup>2</sup>LEN)
  - Trials in E-health (<http://www.jmir.org/announcement/view/48> )
  - CONSORT Extensions for Development Effectiveness: guidelines for reporting RCTs of social and economic policy interventions in developing countries. J Devel Effect 2010;2(1):173-86
- Many listed on EQUATOR website**
- <http://www.equator-network.org/resource-centre/library-of-health-research-reporting/reporting-guidelines/experimental-studies/>



**[www.equator-network.org](http://www.equator-network.org)**

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The EQUATOR Network is funded by:

