A New Reporting Guideline for Trials of Social and Psychological Interventions: CONSORT-SPI

Special Sessions on Research Priorities and Capacity Building

SSWR 2015

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Panelists

Moderator:
Joanne Yaffe, Professor, College of Social Work, University of Utah

Presenters:
Paul Montgomery, Professor of Psycho-Social Intervention, University of Oxford
Sean Grant, Associate Behavioral & Social Scientist, RAND Corporation
Joanne Yaffe, Professor, College of Social Work, University of Utah
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Respondent Panel:
Rick Barth, American Academy of Social Work and Social Welfare
Mark Fraser, Journal of the Society for Social Work and Research
Matthew Howard, British Journal of Social Work
Jeff Jenson, Prevention Science
Bruce Thyer, Research on Social Work Practice
History of Reporting Guidelines

Paul Montgomery
Professor of Psycho-Social Intervention
Centre for Evidence-Based Intervention
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http://tinyurl.com/CONSORT-study
Objectives

- Social and psychological intervention RCTs
- Reporting Guidelines & CONSORT
- Developing CONSORT-SPI
- The CONSORT-SPI Checklist

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Editorials


http://tinyurl.com/CONSORT-study
Social and Psychological Interventions

- Social/psychological mechanisms
- For various health/social issues
- Behavioural/psychological/structural techniques
- Naturalistic, “hard-to-control” settings

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Complex Interventions: MRC Framework

- Multiple intervention components
- Behaviours of providers/recipients
- Various “levels” of intervention/outcome
- Flexibility/tailoring intervention

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Example: Multisystemic Therapy

- Intensive intervention for chronic juvenile offenders
- Therapists, caseworkers, psychologists, psychiatrists
- Work with individual, family, peers, and neighbourhood
- Settings: home, school, community
- Services may focus on cognition and behaviour change, communication skills, parenting skills, family relations, peer relations, school performance, or social networks
- Tailored to the specific needs of the youth and family

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Systematic Reviews of RCTs

- Overall intervention effectiveness
- Key intervention components
- Target populations/recipients/settings
- Important implementation factors

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Good RCT Reporting Includes…

- Participant and setting characteristics
- Interventions and their implementation
- Outcome assessment
- Theories informing the study
- Trial design

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The Problem: Poor Reporting

“Sure, we can spend all day nitpicking specifics but aren't sweeping generalities so much more satisfying?”
Reporting Guidelines

- Minimum set of items on article content
- Reflect issues related to bias
- Based on evidence and consensus

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Our Case: The CONSORT Statement

CONSORT 2010 Statement: updated guidelines for reporting

| CONSORT 2010 checklist of information to include when reporting a randomised trial* |
|-----------------------------|------------------|
| **Section/Topic** | **Item No** | **Checklist item** |
| Title and abstract | 1a | Identification a: |
| | 1b | Structured sum |
| Introduction | | |
| Background and objectives | 2a | Scientific back |
| | 2b | Specific object |
| Methods | | |
| Trial design | 3a | Description of t |
| | 3b | Important chan |
| Participants | 4a | Eligibility criteri |
| | 4b | Settings and loi |
| Interventions | 5 | The intervention |
| Outcomes | 6a | Completely defi |
| | 6b | Any changes to |
| Sample size | 7a | How sample siz |
| | 7b | When applicabl |
| Randomisation: | | |
| Sequence generation | 8a | Method used to |
| | 8b | Type of random |
| Allocation concealment mechanism | 9 | Mechanism use sequence until |
| Implementation | 10 | Who generated |
| Blinding | 11a | If done, who wa |
| | 11b | If relevant, desc |
| Statistical methods | 12a | Statistical meth |
| | 12b | Methods for ad |

Flow diagram of the progress through the phases of a parallel randomised trial of two groups (that is, enrolment, intervention allocation, follow-up, and data analysis)
CONSORT for reporting randomised trials in journal and conference abstracts

In 2006, Arthur Amman, President of Global Strategies for HIV Prevention, made a disquieting remark: "I recently met a physician from southern Africa, engaged in perinatal HIV prevention, whose primary access to information was abstracts posted on the internet. Based on a single abstract, they had altered their perinatal HIV prevention program from an effective therapy to one with lesser efficacy. Had they read the full text article they would have undoubtedly realized that the study results were based on short-term follow-up, a small pivotal group, incomplete data, and unlikely to be applicable to their country situation. Their decision to alter treatment based solely on the abstract's conclusions may have resulted in increased perinatal HIV transmission." When key details about trial are lacking, it is difficult to assess the validity of the results and their applicability.

In collaboration with members of the CONSORT Group, we have extended the current CONSORT Statement to develop a checklist of essential items which authors should include when reporting the main results of a randomised trial in a journal or conference abstract. We recognise that many journals have developed their own structure for reporting abstracts. Our intention is not to suggest changes to these formats, but to recommend what information should be reported within them when describing randomised trials.

Yet a study that examined 35 journals' instructions for authors found that only 4% of the text was devoted to the content or format of the abstract. When key details about trial are lacking, it is difficult to assess the validity of the results and their applicability.

The CONSORT Statement, first published in 1996 and updated in 2001, provides recommendations for reporting randomised trials in health-care journals and updated in 2001, provides recommendations for reporting randomised trials in health-care journals and elsewhere. CONSORT has been endorsed by the World Association of Medical Editors, the International Committee of Medical Journal Editors (ICMJE), and the Council of Science Editors. Currently, the CONSORT Statement provides limited guidance about preparing abstracts and, while it encourages the use of a structured format, this is not a formal requirement. The ICMJE Uniform Requirements for the reporting of parallel group randomised trials as a further update in 2010. A separate statement for the reporting of abstracts was published in 2008. In earlier papers we introduced a brief statement for the reporting of abstracts, based on the 2010 CONSORT statement for the reporting of abstracts.

Marion K Campbell director healthcare evaluation, Dou

Annals of Internal Medicine

Extending the CONSORT Statement to Randomized Trials of Nonpharmacologic Treatment: Explanation and Elaboration

Isabelle Boutron, MD, PhD; David Moher, PhD; Douglas G. Altman, DSc; Kenneth F. Schulz, PhD, MBA; and Philippe Ravaud, MD, PhD, for the CONSORT Group* A

Adequate reporting of randomized, controlled trials (RCTs) is necessary to allow accurate critical appraisal of the validity and applicability of the results. The CONSORT (Consolidated Standards of Reporting Trials) Statement, a 22-item checklist and flow diagram, is intended to address this problem by improving the reporting of RCTs. However, some specific issues that apply to trials of nonpharmacologic treatments (for example, surgery, technical interventions, devices, rehabilitation, psychotherapy, and behavioral intervention) are not specifically addressed in the CONSORT Statement. Furthermore, considerable evidence suggests that the reporting of nonpharmacologic trials still needs improvement. Therefore, the CONSORT group developed an extension of the CONSORT Statement for trials assessing nonpharmacologic treatments. A consensus meeting of 33 experts was organized in Paris, France, in February 2006, to develop an extension of the CONSORT Statement for trials of nonpharmacologic treatments. The participants extended 11 items from the CONSORT Statement, added 1 item, and developed a modified flow diagram.

To allow adequate understanding and implementation of the CONSORT extension, the CONSORT group developed this elaboration and explanation document from a review of the literature to provide examples of adequate reporting. This extension, in conjunction with the main CONSORT Statement and other CONSORT extensions, should help to improve the reporting of RCTs performed in this field.


*For contributors to the CONSORT Extension for Nonpharmacologic Treatment Interventions, see the Appendix (available at www.annals.org).
Development of CONSORT-SPI

Sean Grant
Associate Behavioral & Social Scientist
RAND Corporation

http://tinyurl.com/CONSORT-study
CONSORT-SPI Project

- Official CONSORT Extension
- Rigorous consensus development
- Multi-pronged dissemination strategy

Phase 1: Lit Reviews
Phase 2: Delphi Process
Phase 3: Consensus Meeting
Phase 4: Write-up
Phase 5: Disseminate and Implement

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Project Executive

- Paul Montgomery, University of Oxford
- Evan Mayo-Wilson, Johns Hopkins University
- Sean Grant, University of Oxford
- Geraldine Macdonald, Queen’s University Belfast
- Sally Hopewell, University of Oxford
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- Laurence Moore
- Mark Petticrew
- Steve Pilling
- Lawrence Sherman
- James Thomas
- Elizabeth Waters
- David Weisburd
- Jo Yaffe

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Phase 1: Lit Reviews

- Social/behavioural science guidelines developed/disseminated with less rigour
- 89 new/modified reporting standards compared to CONSORT guidelines
- 239 RCTs report <50% of standards on average


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CONSORT-SCI

CONSORT: Transparent Reporting of Trials
Average compliance of RCTs with key reporting standards


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CONSORT-SPI

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Phase 2: Delphi Process

- N = 384 (32 countries total)
- 58 items recommended for inclusion
- All but 1 of CONSORT 2010 checklist items (registration)
- Substantive qualitative feedback for consensus meeting and E&E

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Phase 3: Consensus Meeting

• 31 participants from Delphi process
• 9 extended CONSORT 2010 items
  • 14 “sub-items” in total
• Other “Delphi” items discussed in E&E
## Consensus Meeting Participants

- Doug Altman
- Kamaldeep Bhui
- Andrew Booth
- Peter Craig
- Manuel Eisner
- Mark Fraser
- Larry Hedges
- Robert Kaplan
- Peter Kaufmann
- Spyros Konstantopoulos
- Kenneth McLeroy
- Brian Mittman
- Arthur Nezu
- Edmund Sonuga-Barke
- Gary VandenBos
- Robert West

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Phase 3: Consensus Meeting

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Phase 4: Write-Up

• Draft official guideline extension
• Tailored E&E documents to disciplines
  • Rationale for each item
  • Examples of good reporting

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Phase 5: Dissemination

• Simultaneous co-publication
• Journal endorsement and adherence
• Presentations at conferences/meetings
• Editorials and newsletters
• Training and education

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CONSORT-SPI Checklist

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Applying CONSORT-SPI

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University of Pennsylvania

*Acknowledgement to Nancy Hanrahan, Ph.D., University of Pennsylvania
Co-author of example used in next section

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1a. Identification of Randomized Trial in Title

• Article Title - A Pilot Randomized Control Trial: Testing a Transitional Care Model for Acute Psychiatric Conditions

• Page 1 (page 315)
1B. Structured Summary

• Abstract
  – Objective
  – Method
  – Results
  – Conclusions

• Page 1 (page 315)
2a. Scientific Background & Rationale

• Background
• Pages 1 & 2 (pages 315 & 316)
2b. Specific Objectives or Hypothesis

• The article reports findings from research that examined the feasibility and effectiveness of the Naylor TCM for individuals with SMI and comorbid health conditions with the aim of reducing hospital readmissions, reducing emergency department (ED) use, improving continuity of care, and improving health quality of life following a hospitalization for an acute psychiatric condition.

• Page 1 (p. 315)
3a. Description of Trial Design

- Such as parallel, factorial, including allocation ratio
- Page 3 (p. 317)
3b. Important Changes to Methods After Trial Commencement

- Such as eligibility criteria – with reasons
- None noted
4a. Eligibility Criteria

• Hospital patients were eligible if they were:
  – a. aged 18 to 64
  – b. had a diagnosis of an SMI such as schizophrenia, bipolar & major depression
  – c. had a diagnosis of major medical condition such as diabetes, asthma, or cancer
  – d. were English speaking
  – e. resided in the city of Philadelphia

• Page 4 (page 317)
4b. Settings & Locations Where Data Collected

- From an inpatient unit of a 515 bed acute care general hospital in a large northeastern urban city
- Baseline in hospital and follow up in community
- Page 4 (page 317)
5. Interventions for Each Group

• Intervention Procedure & Protocol described
• Usual care meant that a case manager was assigned & psychiatrist provided medication management
• Pages 3, 4, & 5 (Table 1) (pages 317-319)
6 a. Outcomes

• Completely specified
  – Health related quality of life
  – Continuity of care
  – Service utilization
• No changes in outcomes
• Page 6 (page 320)
7a & b. Sample Size

- Power not done as pilot study
- Sample size of 40
- No interim analyses
- Page 3 (page 317)
8a & b. Randomization

- Sequence generation
- A computerized randomization schedule was based on a double parallel method using a sample size of 60 (assuming a single group size of 30 with attrition to 20 participants) with block sizes of 6 participants. This means that for every block 3 were assigned to the intervention and 3 assigned to control. There were a total of 10 blocks in this design. This design chosen to keep the psychiatric NP caseload manageable as we only had one nursing providing intervention.
- Page 3 (page 317)
9. Allocation Concealment Mechanism

• Once experimental participants were consented by the research assistant the NP was notified of the patient participant
• Page 3 (page 317)
10. Implementation

- Randomization done by computer
- Research Assistants enrolled participants
- Research assistants then contacted PI for next allocation assignment
- Page 3 (Not all aspects reported)(page 317)
11a. & b. Awareness of Assignment

- NP aware of experimental intervention participants
- Research Assistants – not blinded as often need assistance in locating participants for follow up interviews
- Noted that experimental intervention also received usual care
- Page 3 (page 317)
12  a. & b. Analytical Interventions

• Statistical methods to compare groups
• Chi-square or t test of differences between groups conducted
• Page 6 (page 320)
13 a. & b. Participants Flow

- CONSORT flow chart included
- Losses & exclusions after randomization all noted in flow chart
- Reasons for losses noted
- Figure 1, Page 4 (page 318)
14 a & b. Recruitment

- Dates – March 2011 to August 2011
- Follow ups – at 6 & 12 weeks from baseline
- Page 3 (page 317)
15. Baseline Data

- Table 2 – characteristics of participants by groups
- Table 3 – health related quality of life by group at baseline (and at 12 week follow up)
- Pages 7 & 8 (Tables 2 & 3) (pages 321-322)
16. Numbers Analyzed

- Participants analyzed by assigned group
  - Analyzed outcomes of intervention group = 18 and control = 17 (baseline both groups 20)
- Page 6 (page 320)
17 a. & b. Outcomes & Estimation

• Each outcome for each group – Tables 3, 4, & 5

• Effect sizes not noted – outcomes not statistically significant – no difference from zero – except one in wrong direction

• Pages 8 & 9 Tables 3,4, & 5 (pages 322-323)
18. Ancillary Analyses

• Other analyses conducted, e.g., subgroup - none conducted
19. Harms

• No harms noted
20. Limitations

• Last paragraph indicates limitations – titled limitations
• Page 11 (page 325)
21. Generalizability

• Applicability of trial findings – noted in conclusion of article
• Page 12 (page 326)
22. Interpretation

• Discussion section
• Pages 9-11 (pages 323-325)
23. Registration

• None noted – not registered
24. Protocol

• Where protocol could be accessed
  – Not noted
  – Basically articles covers protocol of study
  – Referenced to another article from the same study

• Pages 3-6, 8-9 Methods section (pages 317-320, 322-323)
25. Declaration of Interests

• End of article
  – Declaration of conflicting Interests – Authors declared no potential conflicts of interest with respect to research, authorship, and/or publication of this article.

• Funding – from Robert Wood Johnson Foundation Interdisciplinary Nursing Quality Research Initiative

• Page 12 (page 326)
Respondent Panel

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Matthew Howard, British Journal of Social Work, Frank A. Daniels Distinguished Professor for Human Services Policy Information, School of Social Work, University of North Carolina

Jeff Jenson, Prevention Science, Philip D. and Eleanor G. Winn Professor for Children and Youth at Risk, Graduate School of Social Work, University of Denver

Bruce Thyer, Research on Social Work Practice, Professor, Florida State University College of Social Work
Questions

• How might implementation of the CONSORT-SPI guidelines benefit consumers of social work research?

• What limits, if any, do you see to implementation of these guidelines?

• What might we do to make uptake of these guidelines easier?
Thank you!

• Please email with questions/comments: CONSORT.study@spi.ox.ac.uk
• Visit our website: http://tinyurl.com/CONSORT-study