CONSORT guidelines for reporting abstracts of randomized trials

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"I recently met a physician from southern Africa, whose primary access to information were abstracts posted on the Internet. Based on a single abstract, they altered their perinatal HIV prevention program from an effective therapy to one with lesser efficacy. Had they read the full article they would have realized 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 may have resulted in increased perinatal HIV transmission."

Arthur Amman, President of Global Strategies for HIV Prevention 2006

PLoS Med 2006:3:e252.

Importance of journal and conference abstracts

- Well-written journal and conference abstracts reporting randomized trials are important:
  - readers often base their initial assessment of a trial based on information reported in an abstract.
- They may then use this information to decide whether or not to seek more information about a trial.

Importance of journal and conference abstracts

- In some parts of the world, health practitioners often have access to the abstracts only,
  - so healthcare decisions are made on the basis of the abstract.

- Where results are reported only as a conference abstract,
  - this may provide the only permanent information about the trial and its results which is accessible to most readers.

Incomplete and inaccurate reporting

- There are concerns over the reliability and quality of trials reported in abstracts, including:
  - lack of information about the trial, in particular details of the trial methods and its results.
  - accuracy of information reported in abstracts compared with the full article.

Helping to overcome problems of poor reporting

- CONSORT for Abstracts aims to provide a list of essential items to include when reporting the main results of a randomized trial in a journal or conference abstract.
- We used a modified Delphi process to generate list of potential checklist items.
- A consensus meeting was held in January 2007, involving 26 editors, methodologists and trialists, to discuss and agree the final checklist.

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."[1]

For clinical trials, clear, transparent, and sufficiently detailed abstracts of journal articles and conference abstracts are important because readers often base their assessment of a trial on such information. Some use an abstract to decide whether to seek more information about a trial. However, in some parts of the world, health professionals often have access to the abstracts only, so health-care decisions are made on the basis of abstracts of randomised trials.[2] When a trial is reported at a conference, the abstract might provide the only permanent information accessible to most readers.[2]

The CONSORT Statement, first published in 1996[3] and updated in 2001,[4] 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[5] also provide limited guidance on the format of abstracts for journal articles.

We believe that journals and conference organisers should provide specific instructions about the key elements of a trial that authors should report, within the space limitations of an abstract (typically, 250–300 words). Our preliminary work shows that all the checklist items can be fitted within such word limits.

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.[6] When key details about a 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.

In developing this checklist we generated a list of items from existing tools for quality assessment and

Item	Description
Title	Identification of the study as randomised
Authors*	Contact details for the corresponding author
Trial design	Description of the trial design (eg, parallel, cluster, non-inferiority)
Methods	
Participants	Eligibility criteria for participants and the settings where the data were collected
Interventions	Interventions intended for each group
Objective	Specific objective or hypothesis
Outcome	Clearly defined primary outcome for this report
Randomisation	How participants were allocated to interventions
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment
Results	
Numbers randomised	Number of participants randomised to each group
Recruitment	Trial status
Numbers analysed	Number of participants analysed in each group
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision
Harms	Important adverse events or side-effects
Conclusions	General interpretation of the results
Trial registration	Registration number and name of trial register
Funding	Source of funding

* For conference abstracts.

Table: Items to include when reporting randomised trials in journal or conference abstracts[7]

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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 Wager[6], Philippa Middleton[7], Douglas G. Altman[2], Kenneth F. Schulz[8], and the CONSORT Group

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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

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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.

CONSORT for Abstracts: *PLoS Med* and *Lancet*, January 2008

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."

RESEARCH METHODS & REPORTING

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

David Moher,[1] Sally Hopewell,[2] Kenneth F Schulz,[3] Victor Montori,[4] Peter C Gøtzsche,[5] P J Devereaux,[6] Diana Elbourne,[7] Matthias Egger,[8] Douglas G Altman[2]

Table 1 | CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item
Title and abstract		
	1a	Identification as a randomised trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts[45 65])
Introduction		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

CONSORT for Abstracts checklist

Item	Description
Title	Identification of the study as randomised
Authors*	Contact details for the corresponding author
Trial design	Description of the trial design (eg, parallel, cluster, non-inferiority)
Methods	
Participants	Eligibility criteria for participants and the settings where the data were collected
Interventions	Interventions intended for each group
Objective	Specific objective or hypothesis
Outcome	Clearly defined primary outcome for this report
Randomisation	How participants were allocated to interventions
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment
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*For conference abstracts.

***Table:* Items to include when reporting randomised trials in journal or conference abstracts**[7]

Item	Description
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***Table*: Items to include when reporting randomised trials in journal or conference abstracts**[7]

A typical abstract

Effectiveness of early switch from intravenous to oral antibiotics in severe community acquired pneumonia: multicentre randomised trial

BMJ 2006;333(7580):1193.

BEFORE

Objectives **To compare the effectiveness of an early switch to oral antibiotics with the standard 7 day course of intravenous antibiotics in severe community acquired pneumonia.**
Design **Multicentre randomised controlled trial.**
Setting **Five teaching hospitals and 2 university medical centres in the Netherlands.**
Participants **302 patients in non-intensive care wards with severe community acquired pneumonia. 265 patients fulfilled the study requirements.**
Intervention **Three days of treatment with intravenous antibiotics followed, when clinically stable, by oral antibiotics or by 7 days of intravenous antibiotics.**
Main outcome measures **Clinical cure and length of hospital stay.**
Results **302 patients were randomised** **(mean age 69.5 (standard deviation 14.0), mean pneumonia severity score 112.7 (26.0)). 37 patients were excluded from analysis because of early dropout before day 3, leaving 265 patients for intention to treat analysis. Mortality at day 28 was 4% in the intervention group and 6% in the control group (mean difference 2%, 95% confidence interval 3% to 8%). Clinical cure was 83% in the intervention group and 85% in the control group (2%, 7% to 10%). Duration of intravenous treatment and length of hospital stay were reduced in the intervention group, with mean differences of 3.4 days (3.6 (1.5) *v* 7.0 (2.0) days; 2.8 to 3.9) and 1.9 days (9.6 (5.0) *v* 11.5 (4.9) days; 0.6 to 3.2), respectively.**
Conclusions **Early switch from intravenous to oral antibiotics in patients with severe community acquired pneumonia is safe and decreases length of hospital stay by 2 days.**
Trial registration Clinical Trials NCT00273676.

Item	Reported
Title	√
Trial design	
Methods	
Participants	√
Intervention	√
Objective	√
Outcomes	√
Randomization	
Blinding	
Results	
Number randomized	
Recruitment	
Number analysed	
Outcome	√
Harms	
Conclusions	√
Trial registration	√
Funding	

Word count: 248

Effectiveness of early switch from intravenous to oral antibiotics in severe community acquired pneumonia: multicentre randomised trial

BMJ 2006;333(7580):1193.

AFTER

Objectives Effectiveness of early switch to oral antibiotics compared with standard 7 day course of intravenous antibiotics in severe community acquired pneumonia.

Design **Multicentre parallel randomised controlled open label trial. A central randomisation centre used computer generated tables to allocate treatments.**

Setting **Five teaching hospitals and 2 university medical centres in the Netherlands.**

Participants 302 patients in non-intensive care wards with severe community acquired pneumonia. 265 patients fulfilled the study requirements.

Intervention Three days of treatment with intravenous antibiotics followed, when clinically stable, by oral antibiotics or by 7 days of intravenous antibiotics. Follow-up 28 days.

Main outcome measures Clinical cure and length of hospital stay.

Results **302 patients (early switch=152; standard care=150) were randomised (mean age 69.5 (standard deviation 14.0), mean pneumonia severity score 112.7 (26.0)). 37 patients were excluded from analysis because of early dropout before day 3, leaving 265 (n=132; n=133) patients for intention to treat analysis. Clinical cure was 83% in the intervention group and 85% in the control group (2%, 7% to 10%). Duration of intravenous treatment and length of hospital stay were reduced in the intervention group, with mean differences of 3.4 days (3.6 (1.5) *v* 7.0 (2.0) days; 2.8 to 3.9) and 1.9 days (9.6 (5.0) *v* 11.5 (4.9) days; 0.6 to 3.2), respectively.**

Conclusions Early switch from intravenous to oral antibiotics in patients with severe community acquired pneumonia is safe and decreases length of hospital stay by 2 days. Mobility and other side effects were comparable across groups.

Trial registration Clinical Trials NCT00273676.

Funding: Dutch Health Insurance Council, OG 99-64.

Item	Reported
Title	√
Trial design	√
Methods	
Participants	√
Intervention	√
Objective	√
Outcomes	√
Randomization	√
Blinding	√
Results	
Number randomized	√
Recruitment	√
Number analysed	√
Outcome	√
Harms	√
Conclusions	√
Trial registration	√
Funding	√

Word count: 260

C S M

COMPARISON

Objectives Effectiveness of early switching to oral antibiotics compared with the standard 7 day course of intravenous antibiotics in severe community acquired pneumonia.
Design Multicentre parallel randomised controlled, open label, trial. A central randomisation centre used computer generated tables to allocate treatments. **Setting** Five teaching hospitals and 2 university medical centres in the Netherlands.
Participants 302 patients in non-intensive care wards with severe community acquired pneumonia. 265 patients fulfilled the study requirements.
Intervention Three days of treatment with intravenous antibiotics followed, when clinically stable, by oral antibiotics or by 7 days of intravenous antibiotics. Follow-up 28 days.
Main outcome measures Clinical cure and length of hospital stay.
Results 302 patients (early switch n=152: standard care n=150) were randomised (mean age 69.5 (standard deviation 14.0), mean pneumonia severity score 112.7 (26.0)). 37 patients were excluded from analysis because of early dropout before day 3, leaving 265 patients (n=132; n=133) for intention to treat analysis. Clinical cure was 83% in the intervention group and 85% in the control group (2%, 7% to 10%). Duration of intravenous treatment and length of hospital stay were reduced in the intervention group, with mean differences of 3.4 days (3.6 (1.5) v 7.0 (2.0) days; 2.8 to 3.9) and 1.9 days (9.6 (5.0) v11.5 (4.9) days; 0.6 to 3.2), respectively. Adverse events were comparable across groups.
Conclusions Early switch from intravenous to oral antibiotics in patients with severe community acquired pneumonia is safe and decreases length of hospital stay by 2 days.
Trial registration Clinical Trials NCT00273676.
Funding: Dutch Health Insurance Council, OG 99-64.

Deleted: To compare the effectiveness

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Deleted: switch

Deleted: Mortality at day 28 was 4% in the intervention group and 6% in the control group (mean difference 2%, 95% confidence interval 3% to 8%).

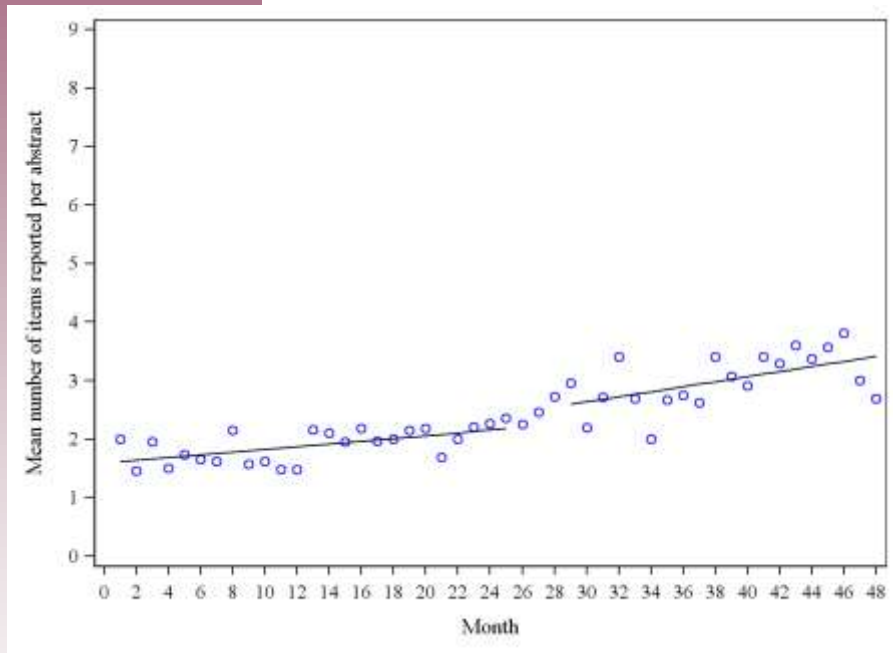
Does active implementation of CONSORT for Abstracts guidelines improve reporting of abstracts of randomized trials: an interrupted time-series analysis

Sally Hopewell, Philippe Ravaud, Gabriel Baron and Isabelle Boutron

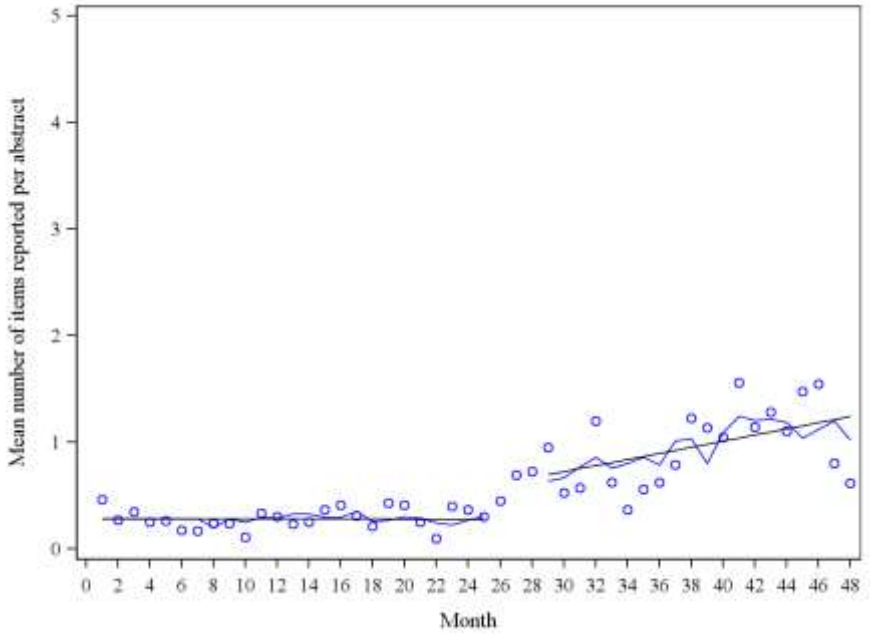
Focused on poorly reported items in 2006

- Trial design (20%)
- Sequence generation (0%)
- Allocation concealment (0%)
- Who was blinded (6%)
- Number participants randomized in each group (43%)
- Number of participants analysed in each group (19%)
- Primary outcome - result for each group and effect size (43%)
- Harms (35%)
- Funding source (0%)

Change in mean number of items reported per abstract for the primary outcome (0-9) and secondary outcome (0-5) over time (Jan 2006 - Dec 2009) before and after CONSORT for Abstracts (Jan 2008) – all journals

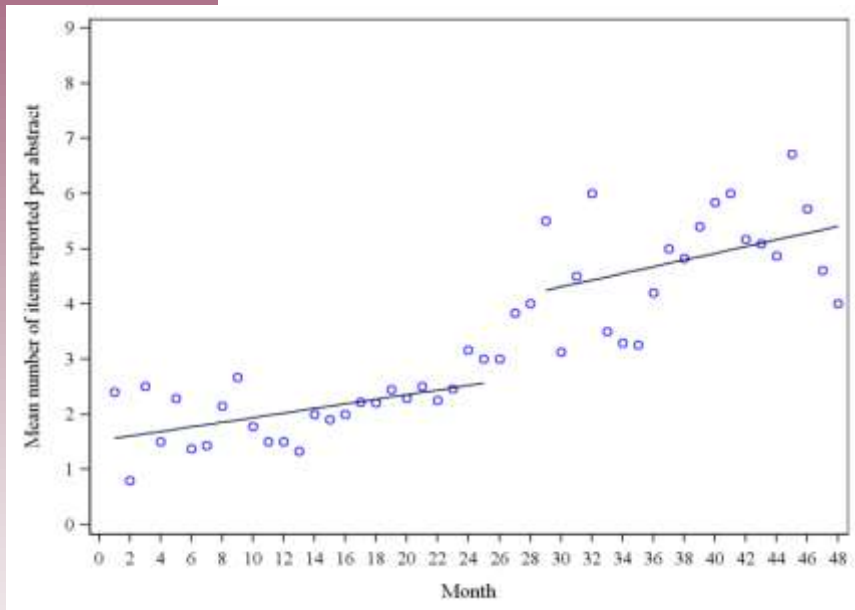


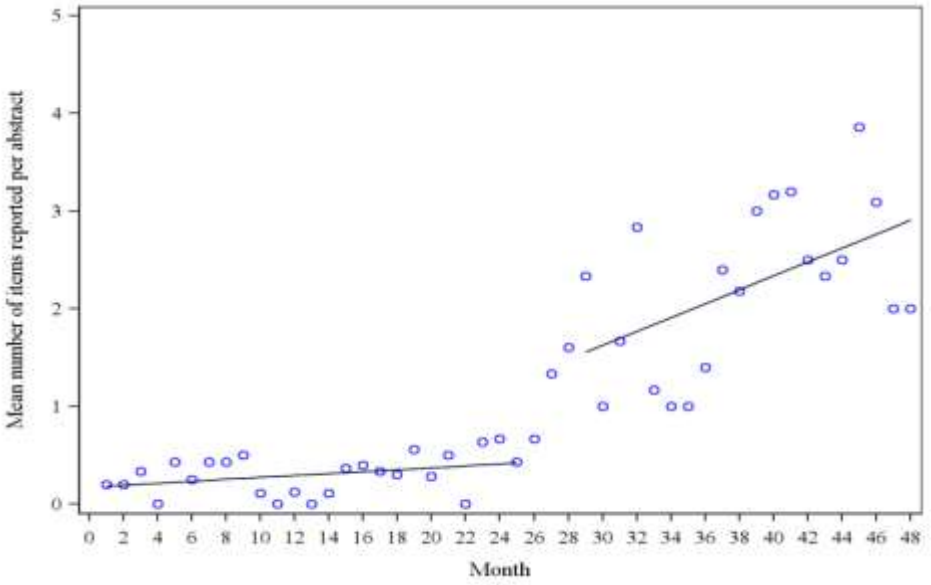
Primary outcome 0-9
Items reported <50% abstracts



Secondary outcome 0-5
Items reported <20% abstracts

Instructions to Authors' with a policy to implement the guidelines (Annals and Lancet)

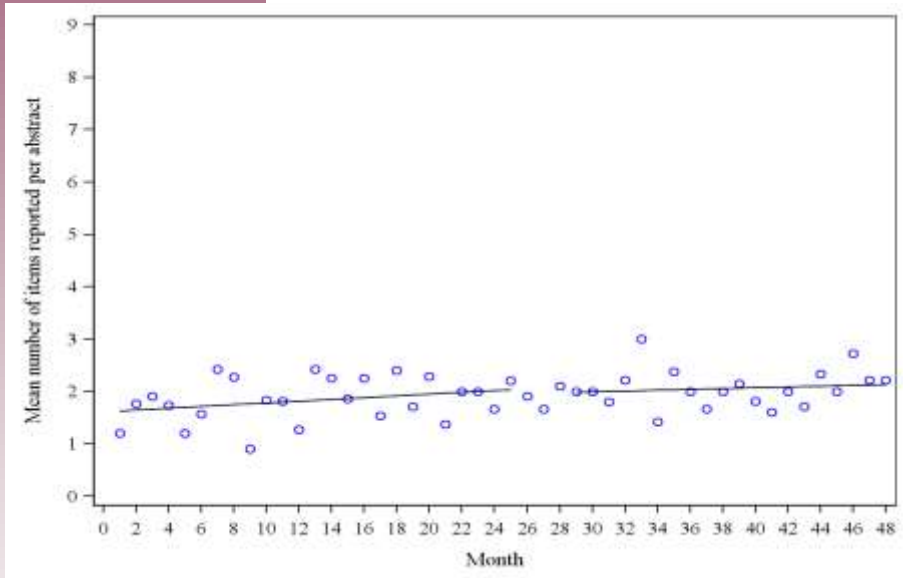


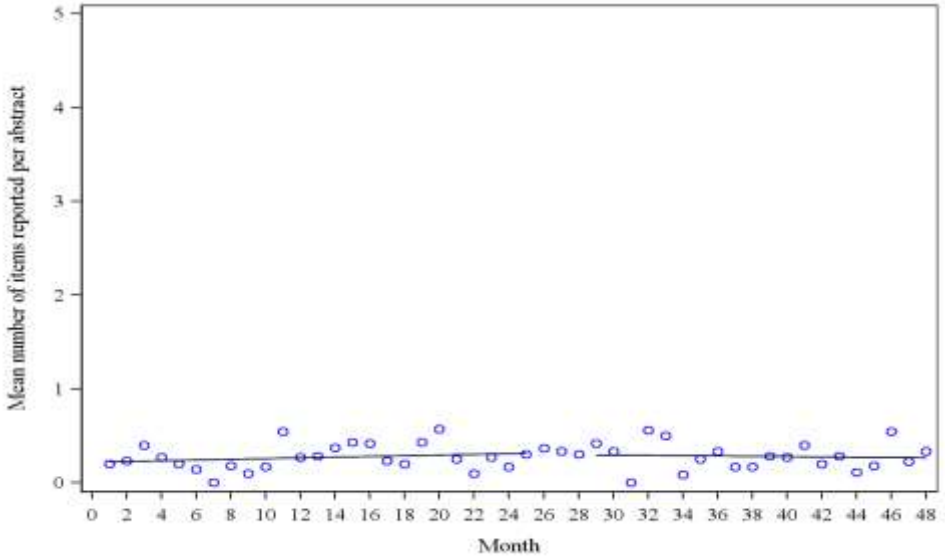


Primary outcome 0-9
Items reported <50% abstracts

Secondary outcome 0-5
Items reported <20% abstracts

No mention of CONSORT for Abstracts (JAMA and NEJM)

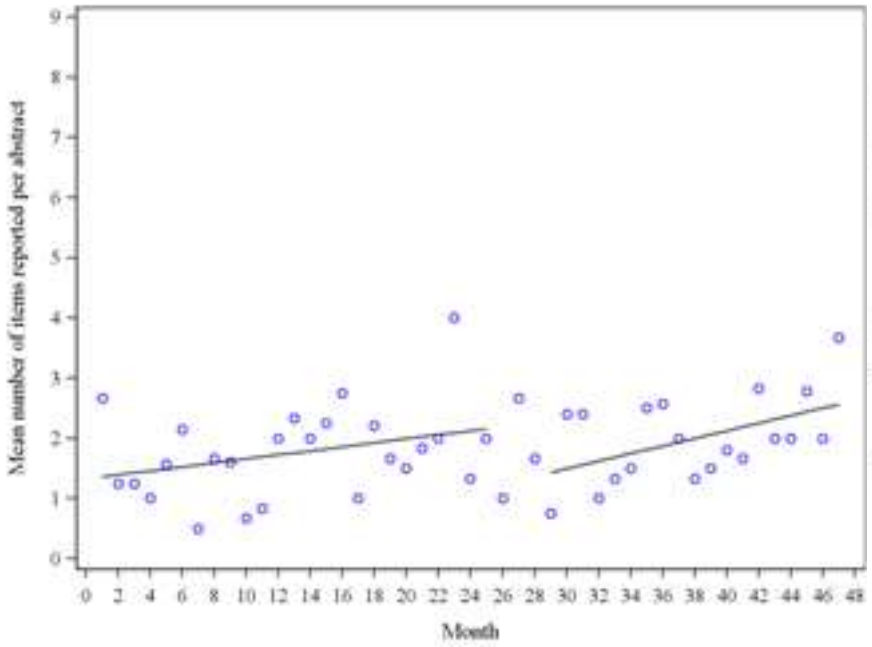




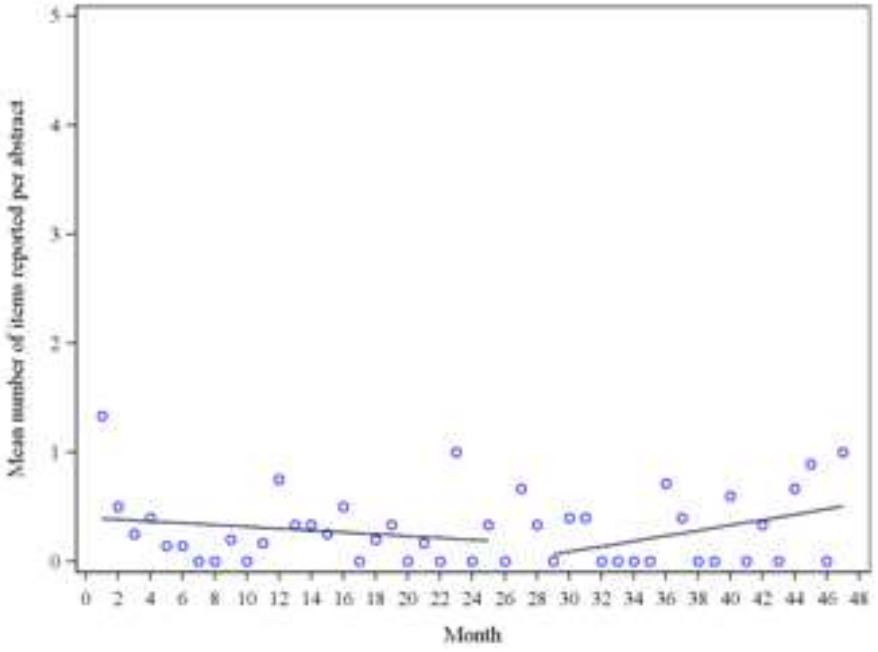
Primary outcome 0-9
Items reported <50% abstracts

Secondary outcome 0-5
Items reported <20% abstracts

Instructions to Authors' only (BMJ)



Primary outcome 0-9
Items reported <50% abstracts



Secondary outcome 0-5
Items reported <20% abstracts

What about CONSORT for Abstracts extensions for other study designs?

- Cluster randomized trials
- Non-inferiority and equivalence trials

- PRISMA for Abstracts extension
- STROBE for Abstracts extension

Implementation

- Trialists should use of CONSORT for Abstracts when writing for publication.
- Journals should endorse the guidance by:
  - modifying their 'Instructions to Authors'.
  - making it a requirement of publication.
- In the case of conference abstracts:
  - require trialists to submit abstracts according to these recommendations.
- Improving the reporting of randomized trials will enable readers to use abstracts more effectively and assess the validity of the research more effectively.

For more information see:

www.consort-statement.org