

Ottawa Hospital Research Institute

OHRI



IRHO

Institut de recherche de l'Hôpital d'Ottawa



The influence of CONSORT on the quality of reports of RCTs: An updated review

AN INSTITUTE OF • UN INSTITUT DE



Thanks to MRC (UK), and CIHR (Canada) for funding support

Background

- In 1996 in response to concerns about the quality of reporting of randomized controlled trials (RCTs) the Consolidated Standards of Reporting Trials (CONSORT) statement was developed
- CONSORT is a 25-item checklist and flow diagram asking authors to describe their methods and findings when reporting their randomised trial
- In 2006 Plint et. al. published a systematic review including 8 studies which assessed the influence of CONSORT on the quality of reporting of RCTs, concluding that “*journal adoption of CONSORT is associated with improved reporting of RCTs*”.
- Over five years have passed since the Plint publication and several new evaluations have been published
- Our objective was to update the Plint review

Methods

- 5 databases were searched
- Title and abstract screening was followed by full text screening and general data abstraction
- The studies were then reviewed and should more information be needed contact authors were e-mailed up to three times
- Readily available data across any of the 22 items was abstracted, 22 study authors provided information which was used to create and verify comparison groups
- Independent data abstraction and internal validity assessment was completed
- A 10% random sample of data was verified
- Random effects model
 - **risk ratio**
- For more details please see published protocol published in CDSR March, 2010

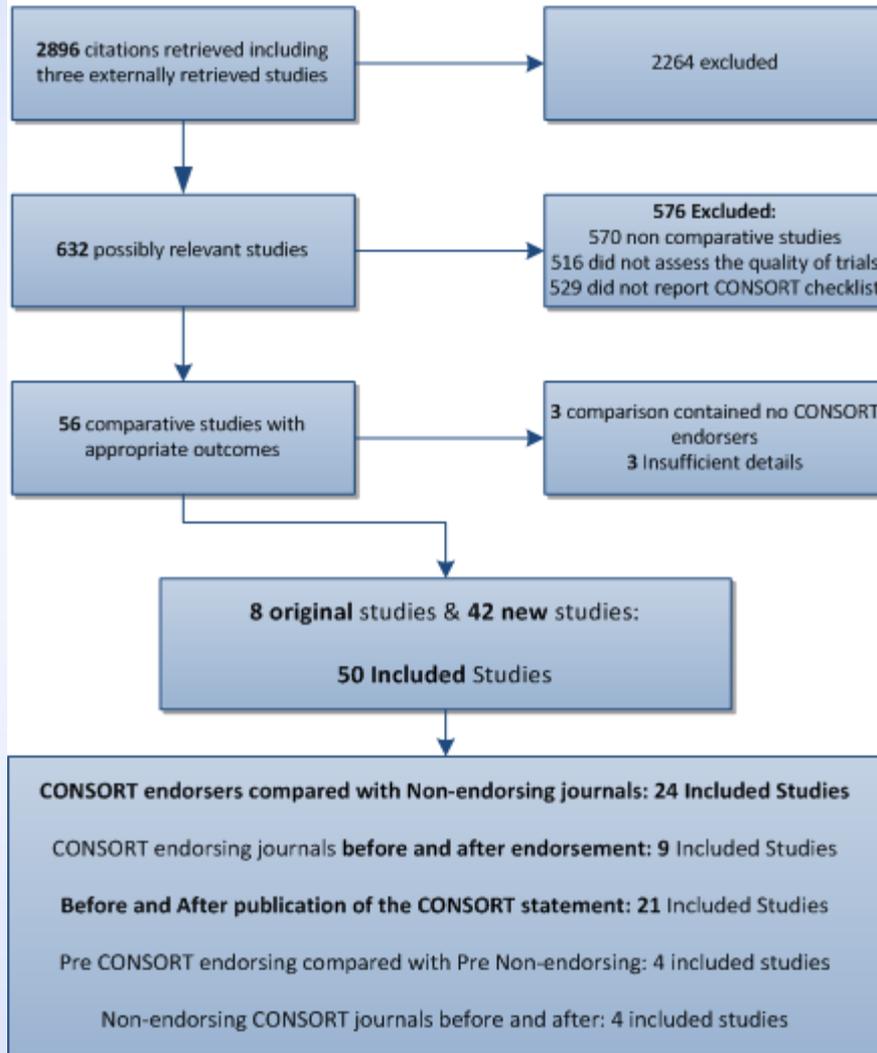
Comparison groups

- CONSORT endorsing journals versus non-endorsing journals
- CONSORT endorsing journals before and after endorsing CONSORT
- CONSORT endorsing journals pre CONSORT endorsement compared with Pre non-endorsement (Control)
 - *considering the difference in quality of reporting of endorsers and non-endorsers*
- Non-endorsing CONSORT journals before and after (Control)
 - *Considering the quality of reporting over time*

Endorsement

- “Endorsement” of CONSORT by a journal is defined as any of the following situations, which imply the CONSORT statement is at least in principle incorporated into the editorial process for a particular journal:
 - journal editorial statement endorsing the CONSORT statement, the checklist or both;
 - requirement or recommendation in journal's “Instructions to Authors” to follow CONSORT when preparing their manuscript;
 - requirement for authors to submit a CONSORT checklist with their manuscript
- Reporting quality was assessed by comparing the proportion of RCTs adhering to individual CONSORT items or a total sum score across comparison groups.

Full Search PRISMA Flow



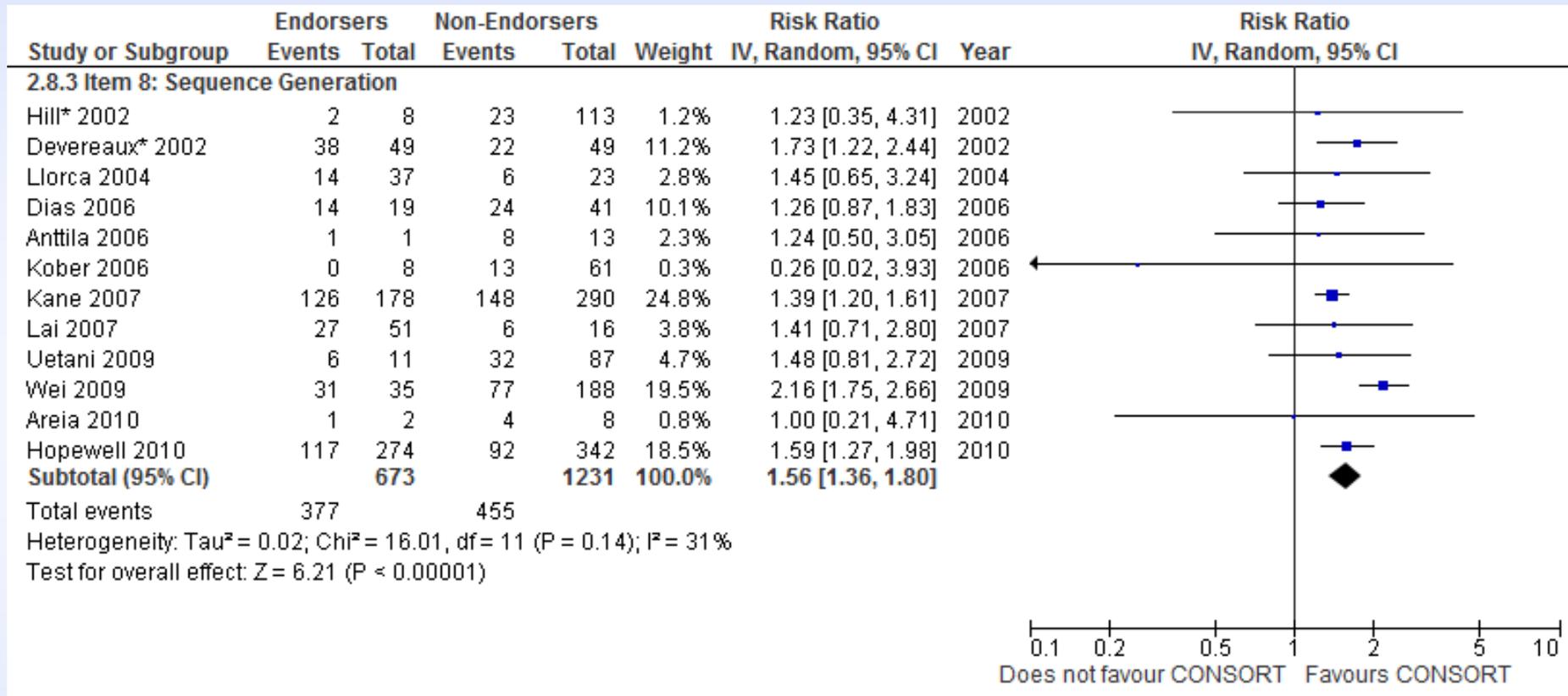
Descriptive characteristics of included studies

- 50 Included Studies
 - 8995 RCTs
- Studies conducted in 16 countries
- Median (IQR) no. of included Journals, 8 (4 - 33)
- 17 assessed 1996 Checklist, 26 assessed 2001 Checklist, 7 Modified version
- 42 studies were specific to medical field
- 22 contact authors (of 49) provided study data

Validity assessment: Questions and Summary

Question	Low	High	Unclear
The RCTs included in the study represent a large cohort (i.e. an entire year), or were randomly chosen from a large cohort.	28/50	8/49	14/50
The reviewer(s) who assessed CONSORT criteria was blinded to study authors, institutions, sponsorship and/or journal name.	1/50	2/50	47/50
Was consideration of potential clustering reported? (If potential for clustering does not exist, answer 'low' risk)	14/50	6/50	30/50
There is no evidence of selective outcome reporting.	41/50	4/50	5/50
More than one reviewer assessed CONSORT criteria.	36/50	1/50	13/50
If applicable, (i.e. more than one reviewer assessed CONSORT criteria), whether inter-reviewer agreement was greater than or equal to 90% agreement or a kappa statistic of 0.8.	18/50	9/50	23/50
If quality of included RCTs was assessed, the reviewer(s) conducted a blinded assessment.	41/50	0/50	9/50

CONSORT endorsing journals versus non-endorsing journals

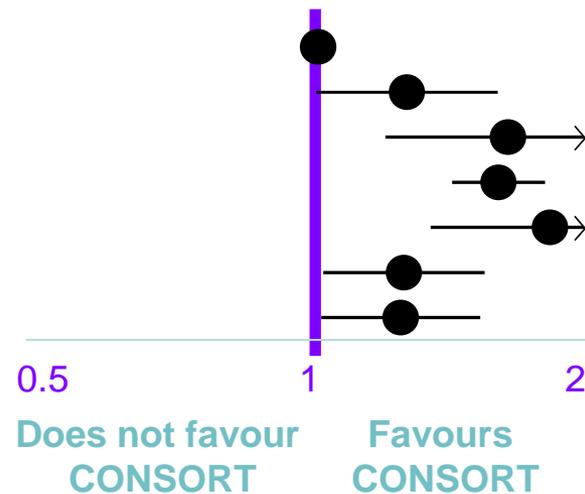


Sequence generation is approximately 56% better reported in the 673 trial reports in endorsing journals compared to the 1231 trials published in non-endorsing journals (RR = 1.56; 95%CI: 1.36, 1.80).

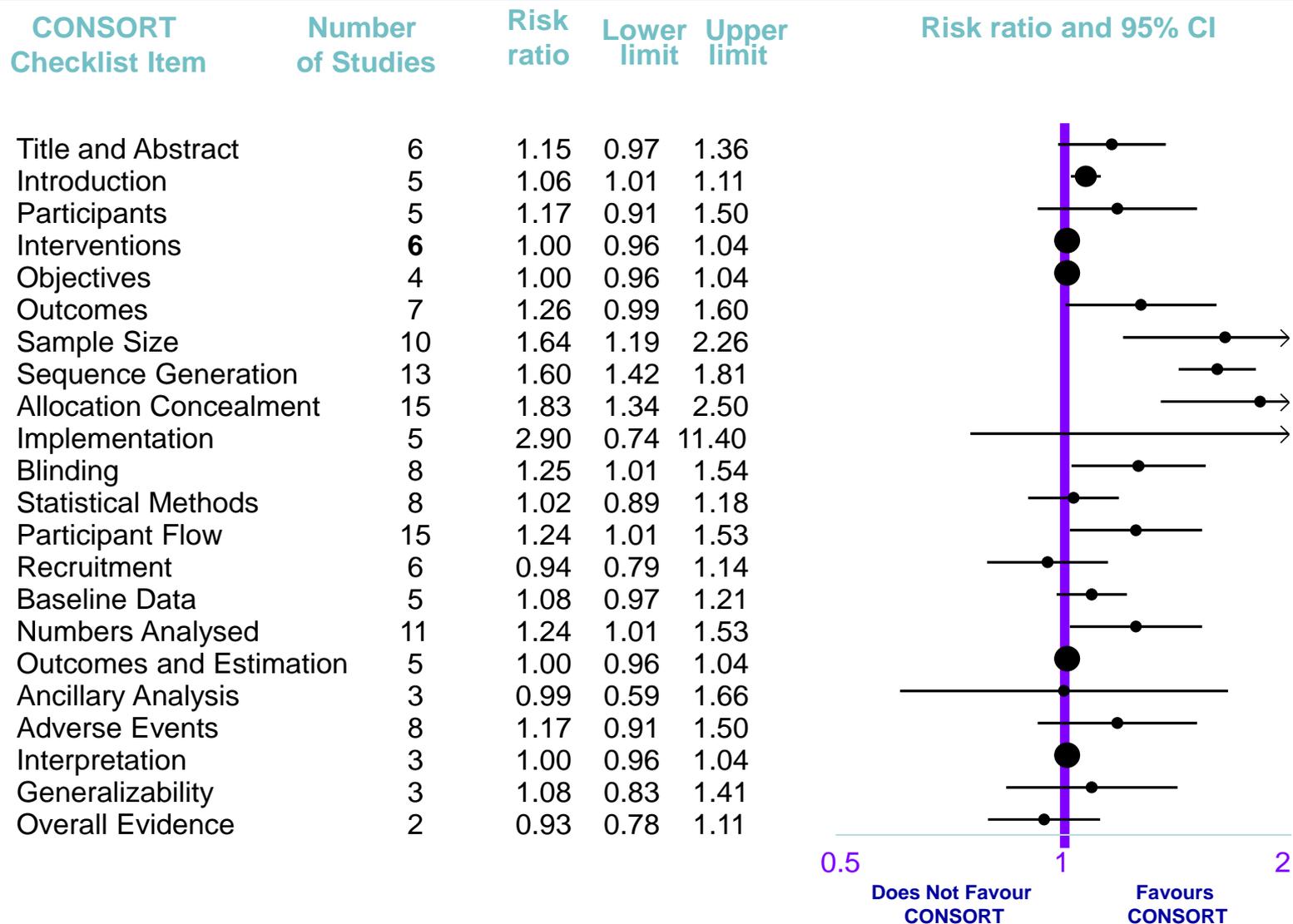
CONSORT endorsing journals versus non-endorsing journals

CONSORT Checklist Items	Number of Studies	Risk ratio	Lower limit	Upper limit
Interventions	5	1.00	0.96	1.04
Outcomes	7	1.26	0.99	1.60
Sample Size	10	1.64	1.19	2.26
Sequence Generation	12	1.60	1.42	1.81
Allocation Concealment	14	1.83	1.34	2.50
Blinding	8	1.25	1.01	1.54
Participant Flow	15	1.24	1.01	1.53

Risk ratio and 95% CI



CONSORT endorsing journals versus non-endorsing journals



Conclusions

- Large number of studies examining effectiveness of CONSORT checklist
- Wide variety of methods for evaluating effectiveness of CONSORT checklist
- Internal validity of the included studies is not optimal
- Improvement in the quality of reporting of RCTs is associated with endorsement of the CONSORT checklist

- We need to get better at reporting of RCTs
- Improve endorsement of CONSORT in journals

Acknowledgements

- Research team
 - Lucy Turner, Larissa Shamseer, Amy Plint, Doug Altman, Ken Schulz, Jodi Peters, and Laura Weeks
- The 22 corresponding authors who clarified data and/or provided additional data

Ottawa Hospital Research Institute

OHRI



IRHO

Institut de recherche de l'Hôpital d'Ottawa

Thank you!

More information about CONSORT:

www.consort-statement.org

twitter @CONSORTing: www.twitter.com/consorting

David Moher: dmoher@ohri.ca

AN INSTITUTE OF • UN INSTITUT DE

