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Guest Editorial

Endorsement of the CONSORT guidelines, trial registration, and the quality of reporting randomised controlled trials in leading nursing journals: A cross-sectional analysis

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ABSTRACT

Objective: To establish the reporting quality of trials published in leading nursing journals and investigate associations between CONSORT Statement or trial registration endorsement and reporting of design elements.
Methods: The top 15 nursing journals were searched using Medline for randomised controlled trials published in 2012. Journals were categorised as CONSORT and trial registration promoting based on requirements of submitting authors or the journal's webpage as at January 2014. Data on sequence generation, allocation concealment, follow up, blinding, baseline equivalence and sample size calculation were extracted by one author and independently verified by the second author against source data.
Results: Seven journals were CONSORT promoting and three of these journals were also trial registration promoting. 114 citations were identified and 83 were randomised controlled trials. Eighteen trials (21.7%) were registered and those published in trial registration promoting journals were more likely to be registered (RR 2.64 95%CI 1.14–6.09). We assessed 68.7% of trials to be low risk of bias for sequence generation, 20.5% for allocation concealment, 38.6% for blinding, 55.4% for completeness of follow up and 79.5% for baseline equivalence. Trials published in CONSORT promoting journals were more likely to be at low risk of bias for blinding (RR 2.33, 95%CI 1.01–5.34) and completeness of follow up (RR 1.77, 95%CI 1.02–3.10), but journal endorsement of the CONSORT Statement or trial registration otherwise had no significant effect. Trials published in CONSORT and trial registration promoting journals were more likely to have high quality sample size calculations (RR 2.91, 95%CI 1.18–7.19 and RR 1.69, 95%CI 1.08–2.64, respectively).
Conclusion: Simple endorsement of the CONSORT Statement and trials registration is insufficient action to encourage improvement of the quality of trial reporting across the most important of trial design elements.

What is already known about the topic?

- Evaluating the quality of trials is dependent on the quality of trial reports, but trials have failed to adequately report key design elements.
- The CONSORT Statement aimed to improve the quality of randomised controlled trial reports.
- Reporting has improved, but remains variable.

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What this paper adds

- Half the leading 15 nursing journals do not promote the CONSORT Statement and most do not promote trials registration.
- The majority of trials published in nursing journals were not registered.
- Passive endorsement of the CONSORT Statement and trial registration may be insufficient to improve reporting unless managed collectively by nursing journal editors.

1. Background

Randomised controlled trials provide reliable evidence of effectiveness for interventions in clinical practice, but validity is dependent on known design elements being properly performed. A determination on trial validity cannot be obtained if the trial report does not provide sufficient information on these design elements, especially with respect to sequence generation, allocation concealment, and blinding (Guyatt et al., 1994). Modest to moderate effects are usually all that can be expected of health interventions and high quality trial methods are necessary to distinguish signal from noise (Collins and MacMahon, 2001). However, trial reports have long failed to provide sufficient information for critical appraisal to distinguish poor quality from high quality trials. For instance, a survey of trials reported in four leading medical journals in 1979–1980 found inadequacies and led to the call for editors to improve reporting standards by providing authors with a checklist of the required items (DerSimonian et al., 1982).

A widely agreed checklist, the Consolidated Standards of Reporting Trials or CONSORT statement, was first published in 1996 and most recently updated in 2010 (Schulz et al., 2010). It consists of a 25-item checklist that identifies important elements that should be reported when publishing a trial. The CONSORT Statement has been explicitly supported by leading biomedical and nursing journals worldwide. A systematic review of studies that examined the effect of journal adoption of the CONSORT statement found improvements in trial reporting, but the effects were encouraging rather than exemplary (Plint et al., 2006) and inadequacies persist even in journals that promote the CONSORT statement (Devereaux et al., 2002; Mills et al., 2005). Devereaux et al. (2002) found an average of 6.4 methodological items out of a possible 11 items were published in CONSORT promoting medical journals. Mills et al. (2005) found highly variable adherence with reporting sequence generation, allocation concealment, blinding and other design elements in the top five medical journals that promote the CONSORT Statement.

Another effort to promote information sufficiency in trials was the announcement by the International Committee of Medical Journal Editors (ICMJE) that trials would need to be prospectively registered on World Health Organization (WHO) compliant registers in order to qualify for publication in the participating journals (De Angelis et al., 2004). This requirement aimed to improve both the quality of reporting and public domain availability of trial information to reduce publication bias and selective reporting. Trial registration has consequently increased (Zarin et al., 2007) and registration has since been associated with improved reporting (Reveiz et al., 2010). However, the number of journals that require trials registration remains limited and even registered trials do not universally report the trial registration number (van de Wetering et al., 2012; Wager and Williams, 2013).

In an assessment of 96 trials published in four leading nursing journals between 2002 and 2005, there was only modest adherence in the reports to the CONSORT Statement (Smith et al., 2008). On average the trials reported about half the number of required items in the CONSORT checklist with similar performance across the four journals. Performance on reporting important design elements such as sequence generation and allocation concealment was low, and lower than that found in assessments of 29 medical journals (Devereaux et al., 2002). Smith et al. (2008) found only one of the nursing journals endorsed the CONSORT Statement during the assessment period and that endorsement was associated with a small but significant increase in adherence. However, there has been no more recent assessment of the effect of CONSORT Statement on trial reporting in nursing journals or an evaluation of the impact of endorsing trial registration. We therefore sought to establish whether journal endorsement of the CONSORT Statement and trial registration had any effect on the quality of trial reports published in 2012.

2. Methods

2.1. Selection of journals and trials

This study was conducted between November 2013 and February 2014. We selected 15 leading nursing journals (Table 1) by ranked 5 year impact factor using ISI Web of Knowledge Journal Citation Reports (Science) and whether they had published any RCTs in the year of interest (2012). To determine the latter, we used Medline to search each journal title with the search restricted to publication type limitation ("randomized controlled trial") and year (2012). All the nursing journals were listed in Medline. If the journal had not published any RCTs in 2012, we selected the next ranked journal title for inclusion. Studies were included if they were described within the paper as a randomised controlled trial, an experimental study, or claimed to use random assignment for participant allocation. Quasi-experimental studies were excluded unless they otherwise met the inclusion criteria. Duplicate citations, trial protocols, and studies nested within randomised controlled trials were excluded.

2.2. Data extraction & analysis

The webpages for each journal and author guidelines were assessed to determine whether or not the journal was CONSORT-promoting and trial registration promoting. Journals were categorised as CONSORT-promoting if the journal required the author to submit a CONSORT checklist with their trial, or required the author to complete the journal's own checklist based on the CONSORT statement, or

Table 1
Journal characteristics.

Journal name	5-Year impact factor	*N* (%) of RCTs [*N* = 83]	Median sample size (min–max)	CONSORT promoting	Trial registration promoting
Birth: Iss. Peri. Care	3.161	2 (2.4)	537 (60–1013)	No	No
Oncol. Nurs. Forum	2.792	6 (7.2)	165 (84–385)	No	No
Int. J. Nurs. Stud.	2.638	17 (20.5)	153 (27–610)	Yes	Yes
Res. Nurs. Health	2.445	4 (4.8)	254 (90–504)	Yes	No
Cancer Nurs.	2.371	4 (4.8)	49 (38–62)	No	No
J. Adv. Nurs.	2.300	9 (10.8)	120 (50–337)	Yes	Yes
Nurs. Res.	2.105	6 (7.2)	80 (20–320)	Yes	No
Eur. J. Oncol. Nurs.	1.935	2 (2.4)	39 (17–60)	Yes	Yes
Am. J. Crit. Care	1.888	4 (4.8)	39 (36–300)	No	No
World. Evid.-Based Nurs.	1.845	1 (1.2)	214 (–)	No	No
J. Cardiovasc. Nurs.	1.778	3 (3.6)	40 (24–80)	No	No
J. Clin. Nurs.	1.768	16 (19.3)	70 (20–174)	Yes	No
Biol. Res. Nurs.	1.663	4 (4.8)	48 (24–140)	No	No
JOGYNN	1.624	4 (4.8)	110 (65–200)	Yes	No
J. Fam. Nurs.	1.523	1 (1.2)	76 (–)	No	No

the CONSORT statement was mentioned on the journal webpages. Journals were categorised as promoting trial registration only if trial registration was included on the web page or author guidelines as a required part of the submission. While trial registration is one of the items on the CONSORT checklist, we did not view directing authors to the checklist as a sufficiently positive approach to warrant the journal being categorised as trial registration promoting.

Journal categorisations, trial characteristics and data for risk of bias assessments were abstracted from the full text of each trial into a standardised form in Excel by the second author. The first author independently verified the extracted data against the source data; to determine whether journals were CONSORT or trial registration-promoting, the extracted data was independently compared to the journal websites and author guidelines and to determine quality of reporting, the extracted data was independently compared to the source articles. Disagreements were resolved by discussion. The quality of trial reports was assessed on five domains—sequence generation, allocation concealment, blinding, completeness of follow-up, and baseline equivalence, guided by the domain-based evaluation published in Cochrane's collaboration tools for assessing risk of bias in randomised trials (Higgins et al., 2011). Each domain was assessed as low risk, unclear risk, or high risk of bias based on the description of the relevant domain in the trial reports. Hence for sequence generation we sought evidence of random sequence generation (low risk of bias), non-random sequence generation (high risk of bias), or lack of information about sequence generation (unclear risk of bias). For example, a trial report that stated "Participants were randomized (1:1) to the intervention or control group according to a list of random permutations prepared by computer-generated blocked randomization" was assessed as low risk of bias (Tiwari et al., 2012, p. 647). By contrast a trial report that stated "The participant's names were listed in alphabetic order and each second participant was selected for interventiongroup" was assessed as high risk of bias (Jaromi et al., 2012, p. 1778). Trials that simply reported they were randomised controlled trials or used random assignment without further detail were assessed as unclear risk of bias for sequence generation.

Information sufficiency for a risk of bias assessment meant the report contained enough information to be certain a trial was at low or high risk of bias on each domain. Thus information sufficiency was a measure of reporting clarity. The quality of an *a priori* sample size calculation was assessed on four elements—level of alpha reported, level of beta or power reported, delta or size of anticipated effect reported, and primary outcome identified (Machin et al., 2009; Schulz and Grimes, 2005).

Chi-square tests or Fisher's exact tests (where cell size was less than 5) were used to determine the associations between journal promoting status and adherence to each element for risk of bias and sample size calculation. The threshold for significance was set at $p < 0.05$ (two tailed). The estimations of effects were described with risk ratios (RR) and 95% confidence intervals (95%CI). Data analyses were done using SPSS version 22.

3. Results

One hundred and fourteen citations were identified from the database search (Fig. 1). Sixteen reports were screened out and 98 citations were obtained. Eighty three reports met the inclusion criteria. Nearly two-thirds of the trials (51) were published in five journals, being the *International Journal of Nursing Studies, Journal of Clinical Nursing, Journal of Advanced Nursing, Nursing Research, and Oncology Nursing Forum*. The sample sizes of the trials were small with an overall median of 85 participants (range 17 to 1013). Eighty two of the trials (98.8%) were described as randomised controlled trials or claimed to use random allocation. One trial was described as a quasi-experimental trial, but used a random allocation strategy and five trials described as randomised controlled trials (6.0%) did not use random allocation, but employed a non-random strategy.

Among the 15 journals, seven journals (46.7%) promoted the CONSORT statement, three of which (20.0%) also promoted trial registration (Table 1). One journal had announced it would only publish reports of trials from January 1, 2015 if the trial had been prospectively registered (Nursing Research) but was not considered to be trial registration promoting for 2012 publications. Fifty

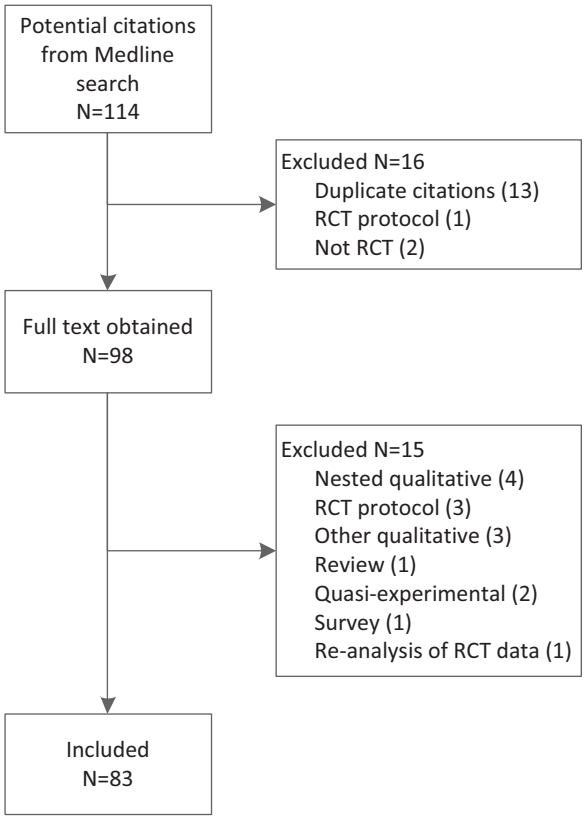

Fig. 1. Flow diagram.

eight trials (69.9%) were published in CONSORT promoting journals and 28 trials (33.7%) were published in trial registration promoting journals (Table 2). However, only 18 trials (21.7%) presented the trial registration numbers in the reports and thus could be considered registered. Eight trials were registered on *ClinicalTrials.gov*, five on the Australia New Zealand Clinical Trials Register, four on ISRCTN and one on the Hong Kong Clinical Trials Register. Eleven of the 28 trials (39.2%) published in trial registration promoting journals and 16 of the 58 trials (27.6%) published in CONSORT promoting journals were registered. Trials published in trial registration promoting journals were three times as likely to be registered (RR 3.09 95%CI 1.34–7.09, $p = 0.006$), but publication in a CONSORT promoting journal did not significantly increase the likelihood of registration (RR 3.45, 95%CI 0.86–13.89, $p = 0.08$).

3.1. Information sufficiency for risk of bias assessment

Fifty seven trials (68.7%) used random sequence generation while six trials (7.2%) did not report random sequence generation (Table 2). Thus 63 (75.9%) trials had information sufficiency for a risk of bias assessment on sequence generation. Thirty two trials (38.6%) reported allocation concealment, but only 17 of the trials (20.5%) provided sufficient information for a risk of bias assessment on allocation concealment. Eleven trials (13.2%) did not report allocation concealment. Thus 28 (33.7%) trials had information sufficiency for a risk of bias assessment on allocation concealment. Thirty five trials (42.1%) reported blinding in one or more groups, but in three trials (3.6%) the blinding would not have addressed bias in outcome collection, otherwise known as information bias (Last, 2001). Twenty five trials (30.1%) did not report blinding. Thus 57 (68.7%) trials had information sufficiency for a risk of bias assessment on blinding. Fifty-nine trials (71.1%) provided a participant flow diagram, and had sufficient information to determine whether there was complete follow up, intention-to-treat analysis had been used, or there had been greater than 90% follow up with equal loss in both groups for reasons unlikely to affect the outcome. In those trials without a participant flow diagram, either

Table 2
Number of trials that provided sufficient information for clear risk of bias assessment (low and high) by journal.

Journal	Trials	Sequence generation *N* (%)	Allocation concealment *N* (%)	Blinding *N* (%)	Completeness of follow-up *N* (%)	CONSORT diagram *N* (%)	Baseline equivalence *N* (%)
Birth Iss. Peri. Nat. Care	2	1 (50.0)	0 (0.0)	2 (100)	2 (100)	1 (50.0)	2 (100)
Oncol. Nurs. Forum	6	6 (100)	2 (33.3)	3 (50.0)	5 (83.3)	3 (50.0)	5 (83.1)
Int. J. Nurs. Stud.^§	17	14 (82.4)	6 (35.3)	12 (70.6)	17 (100)	17 (100)	13 (76.5)
Res. Nurs. Health^	4	2 (50.0)	0 (0.0)	3 (75.0)	4 (100)	3 (75.0)	4 (100)
Cancer Nurs.	4	3 (75.0)	1 (25.0)	0 (0.0)	3 (75.0)	3 (75.0)	3 (75.0)
J. Adv. Nurs.^§	9	9 (100)	4 (44.4)	8 (88.9)	9 (100)	9 (100)	8 (88.9)
Nurs. Res.^	6	5 (83.3)	2 (33.3)	4 (66.7)	5 (83.3)	5 (83.3)	4 (66.7)
Eur. J. Oncol. Nurs.^§	2	1 (50.0)	0 (0.0)	1 (50.0)	2 (100)	1 (50.0)	2 (100)
Am. J. Crit. Care	4	2 (50.0)	2 (50.0)	2 (50.0)	4 (100)	3 (25.0)	3 (75.0)
World Evid. Based Nurs.	1	1 (100)	1 (100)	1 (100)	1 (100)	0 (0.0)	1 (100)
J. Cardiovasc. Nurs.	3	2 (66.7)	0 (0.0)	3 (100)	3 (100)	0 (0.0)	3 (100)
J. Clin. Nurs.^	16	12 (75.0)	6 (37.5)	11 (68.8)	14 (87.5)	11 (68.8)	15 (93.8)
Biol. Res. Nurs.	4	3 (75.0)	2 (50.0)	4 (100)	4 (100)	3 (75.0)	4 (100)
JOGYNN^	4	2 (50.0)	2 (50.0)	2 (50.0)	3 (75.0)	2 (50.0)	4 (100)
J. Fam. Nurs.	1	0 (0.0)	0 (0.0)	1 (100)	1 (100)	0 (0.0)	1 (100)
Total	83	63 (75.9)	28 (33.7)	57 (68.7)	77 (92.7)	59 (71.1)	75 (90.3)

^ CONSORT promoting.
§ Trial registration promoting.

there had been complete follow up (7 trials, 8.4%), intention to treat analysis (2 trials, 2.4%) or it was clear whether or not there was greater 90% follow up with equal loss (9 trials, 10.8%). Thus 77 trials (92.7%) had information sufficiency for a risk of bias assessment about completeness of follow up. Sixty six trials (79.5%) provided a table with group equivalence at baseline (or adjustment of imbalance in the analysis), while 9 trials (10.8%) did not. Thus, 75 (90.3%) trials had information sufficiency for a risk of bias assessment on baseline equivalence.

3.2. Risk of bias assessment

The proportion of trials at low, unclear and high risk of bias varied across the risk of bias domains (Fig. 2). Randomisation and baseline equivalence were the domains most frequently reported in sufficient detail to be assessed as low risk of bias (68.7% and 79.5%, respectively). Allocation concealment was the domain least frequently reported in sufficient detail to be assessed as low risk of bias (20.5%). This pattern was reflected in the trial reports in published in each journal (Table 3).

3.3. Information sufficiency on sample size calculations

Eight of the trials were pilot studies where a sample size calculation might be considered unnecessary. In the remaining 75 trials, 62 trials (82.7%) reported a sample size calculation (Table 4), but it was only calculated *a priori* in 54 trials (72.0%). Thus 21 qualifying trials (28.0%) either did not include a sample size calculation or only included a *post hoc* sample size calculation. The majority of trials reported levels of alpha, beta (or power), and delta (respectively 50 trials, 53 trials, and 52 trials). However, only 38 trials (50.6%) identified the primary outcome for the sample size calculation. Thus 36 trials (48.0%) specified all four elements for a high quality sample size calculation. Thirty two of the 55 trials (58.2%) published in CONSORT promoting journals had a high quality sample size calculation. Seventeen of the 26 trials (65.4%) published in trials registration promoting journals had a high quality sample size calculation.

3.4. Association of low risk of bias and quality of sample size calculation with publication in CONSORT promoting and trial registration promoting journals

Publication in CONSORT and trials registration promoting journals was not generally associated with increased likelihood of low risk of bias assessments on important design elements (Table 5). However, publication in CONSORT promoting journals was associated with an increased likelihood of low risk of bias assessments on blinding (RR 2.33, 95%CI 1.01–5.34, $p = 0.03$ and completeness of follow up (RR 1.77, 95%CI 1.02–3.09 $p = 0.02$). Publication in trials registration promoting journals was not associated with any significantly increased likelihood of low risk of bias assessments. Adherence with the elements of a high quality sample size calculation was significantly associated with publication in CONSORT promoting and trials registration promoting journals, although the association appears stronger in CONSORT promoting journals (RR 2.91 compared with 1.69).

4. Discussion

Half the leading 15 nursing journals did not support the CONSORT statement and 80% did not support trials registration as at January 2014, despite the CONSORT Statement being published since 1996 (Begg et al., 1996)

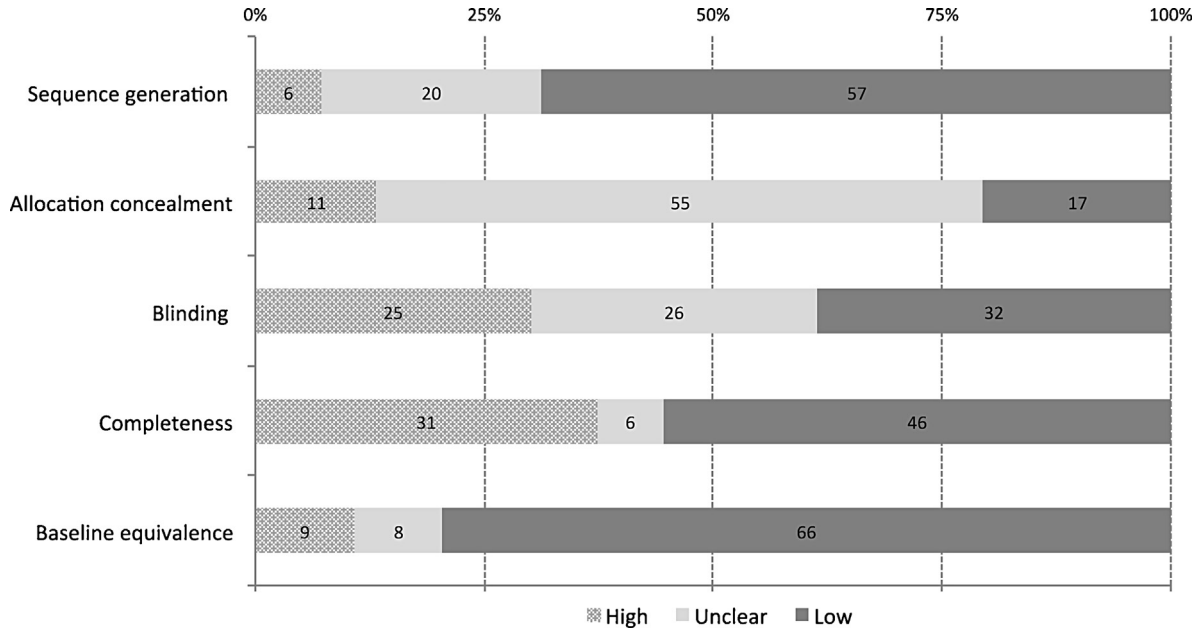

Fig. 2. Risk of bias assessment (values in bars are numbers of trials in each series).

Table 3
Number of trial reports at low risk of bias by quality domain and journal.

Journal	Trials	Sequence generation *N* (%)	Allocation concealment *N* (%)	Blinding *N* (%)	Completeness of follow-up *N* (%)	Baseline equivalence *N* (%)	Trial registered *N* (%)
Birth Iss. Peri. Nat. Care	2	1 (50.0)	0 (0.0)	0 (0.0)	2 (100)	2 (100)	0 (0.0)
Oncol. Nurs. Forum	6	6 (100)	2 (33.3)	2 (33.3)	5 (83.3)	5 (83.1)	0 (0.0)
Int. J. Nurs. Stud.^§	17	14 (82.4)	5 (29.4)	6 (35.3)	13 (76.5)	13 (76.5)	8 (47.1)
Res. Nurs. Health^	4	2 (50.0)	0 (0.0)	2 (50.0)	2 (50.0)	4 (100)	0 (0.0)
Cancer Nurs.	4	2 (50.0)	0 (0.0)	0 (0.0)	3 (75.0)	2 (50.0)	0 (0.0)
J. Adv. Nurs.^§	9	8 (88.9)	3 (33.3)	7 (77.8)	5 (55.6)	8 (88.9)	3 (33.3)
Nurs. Res.^	6	4 (66.7)	1 (16.7)	3 (50.0)	4 (66.7)	4 (66.7)	1 (16.7)
Eur. J. Oncol. Nurs.^§	2	1 (50.0)	0 (0.0)	1 (50.0)	1 (50.0)	1 (50.0)	0 (0.0)
Am. J. Crit. Care	4	2 (50.0)	1 (25.0)	0 (0.0)	2 (50.0)	3 (75.0)	2 (50.0)
World Evid. Based. Nurs.	1	1 (100)	1 (100)	0 (0.0)	1 (100)	1 (100)	0 (0.0)
J. Cardiovasc. Nurs.	3	2 (66.7)	0 (0.0)	1 (33.3)	3 (100)	3 (100)	0 (0.0)
J. Clin. Nurs.^	16	10 (62.5)	6 (37.5)	6 (37.5)	9 (56.3)	14 (87.5)	3 (18.8)
Biol. Res. Nurs.	4	2 (50.0)	1 (25.0)	2 (50.0)	1 (25.0)	2 (50.0)	0 (0.0)
JOGYNN^	4	2 (50.0)	2 (50.0)	2 (50.0)	3 (75.0)	4 (100)	1 (25.0)
J. Fam. Nurs.	1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100)	0 (0.0)
Total	83	57 (68.7)	17 (20.5)	32 (38.6)	46 (55.4)	66 (79.5)	18 (21.7)

^ CONSORT promoting.
§ Trial registration promoting.

and the ICMJE announcement a decade ago that leading medical journals would not publish trials unless they were prospectively registered (De Angelis et al., 2004). Trial registration was low even in journals that promoted registration. Reporting was inadequate with allocation concealment the domain least reported. Publication in a CONSORT promoting journal did not significantly increase the likelihood of low risk of bias, except on blinding and follow up, and publication in a trial registration promoting journal did not significantly increase the likelihood of low risk of bias on any domain. Publication in either a CONSORT promoting or trial registration promoting journal did increase the likelihood of a high quality sample size calculation being reported.

Adequate information is crucial to determining the quality of trials (Cullum et al., 2008) and reporting quality is a useful proxy for trial quality. In an assessment of 250 trials, unclear allocation concealment was associated with a 33% over-estimation of treatment effect, which was almost as strong as the 41% over-estimation of effect associated with inadequate allocation concealment (Schulz et al., 1995). In our study there was inadequate information to assess the quality of the trials in all domains, with allocation concealment being the domain with greatest insufficiency (66.4% rated unclear). This pattern is similar to that observed in leading medical journals where allocation concealment was less frequently reported than sequence generation, blinding, and baseline

Table 4
Number of qualifying trials reports (excluding reports of pilot studies) that adhere to elements necessary for high quality sample size calculation by journals.

Journal	Trials	*a priori* Sample size calculation *N* (%)	Alpha *N* (%)	Beta *N* (%)	Delta *N* (%)	Primary outcome *N* (%)	High quality sample size calculation *N* (%)
Birth Iss. Peri. Nat. Care	2	2 (100.0)	1 (50.0)	2 (100)	2 (100)	1 (50.0)	1 (50.0)
Oncol. Nurs. Forum	5	4 (80.0)	2 (40.0)	3 (60.0)	2 (40.0)	2 (40.0)	0 (0.0)
Int. J. Nurs. Stud.^§	17	13 (76.5)	13 (76.5)	13 (76.5)	13 (76.5)	11 (64.7)	11 (64.7)
Res. Nurs. Health^	4	3 (75.0)	3 (75.0)	3 (75.0)	3 (75.0)	1 (25.0)	1 (25.0)
Cancer Nurs.	2	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
J. Adv. Nurs.^§	8	8 (100)	8 (100)	8 (100)	8 (100)	6 (75.0)	6 (75.0)
Nurs. Res.^	5	5 (100)	4 (80.0)	4 (80.0)	4 (80.0)	4 (80.0)	4 (80.0)
Eur. J. Oncol. Nurs.^§	1	1 (100.0)	0 (0.0)	1 (100.0)	1 (100.0)	1 (100.0)	0 (0.0)
Am. J. Crit. Care	3	1 (33.3)	1 (33.3)	1 (33.3)	1 (33.3)	1 (33.3)	1 (33.3)
World Evid. Based Nurs.	1	1 (100)	1 (100)	0 (0.0)	1 (100)	1 (100)	1 (100)
J. Cardiovasc. Nurs.	2	1 (50.0)	1 (50.0)	1 (50.0)	1 (50.0)	0 (0.0)	0 (0.0)
J. Clin. Nurs.^	16	11 (68.8)	10 (62.5)	11 (68.8)	11 (68.8)	7 (43.8)	7 (43.8)
Biol. Res. Nurs.	4	2 (50.0)	2 (50.0)	2 (50.0)	2 (50.0)	1 (25.0)	1 (25.0)
JOGYNN^	4	3 (75.0)	4 (100.0)	4 (100.0)	4 (100.0)	3 (75.0)	3 (75.0)
J. Fam. Nurs.	1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100)	0 (0.0)
Total	75	54 (72.0)	50 (66.7)	53 (70.7)	52 (69.3)	38 (50.6)	36 (48.0)

^ CONSORT promoting.
§ Trial registration promoting.

Table 5
Association of low risk of bias and high quality sample size calculation with publication in CONSORT promoting and trial registration promoting nursing journals.

Elements for quality assessment	CONSORT promoting				Trial registration promoting			
	CONSORT promoting RCTs ($n = 58$)	CONSORT non-promoting RCTs ($n = 25$)	Effect estimates RR (95%CI)	p-Value	Trial registration promoting RCTs ($n = 28$)	Trial registration non-promoting RCTs ($n = 55$)	Relative risk (95%CI)	p-Value
Low ROB for sequence generation	41 (70.7)	16 (64.0)	1.11 (0.79–1.55)	0.55	25 (82.1)	32 (61.8)	1.33 (0.99–1.74)	0.08
Low ROB for allocation concealment	12 (20.7)	5 (29.4)	1.03 (0.41–2.63)	1.00*	8 (28.6)	9 (16.4)	1.76 (0.76–4.03)	0.19
Low ROB for blinding	27 (46.6)	5 (20.0)	2.33 (1.01–5.34)	0.03*	14 (50.0)	18 (32.7)	1.53 (0.90–2.60)	0.13
Low ROB for follow-up	37 (63.8)	9 (36.0)	1.77 (1.02–3.09)	0.02	19 (67.9)	27 (49.1)	1.38 (0.95–2.00)	0.08
Low ROB for baseline equivalence	47 (81.0)	19 (76.0)	1.07 (0.83–1.37)	0.60	22 (78.6)	44 (80.0)	0.98 (0.78–1.24)	0.88
High quality sample size calculation	32 (58.2)^	4 (20.0)^	2.91 (1.18–7.19)	0.004*	17 (65.3)§	19 (38.8)§	1.69 (1.08–2.64)	0.03

* Fisher's exact test.
^ Pilot studies removed from analysis, $n = 55$ and 20, respectively.
§ Pilot studies removed from analysis, $n = 26$ and 49, respectively.

characteristics (Devereaux et al., 2002). The 20.5% of the trials in our study that reported sufficient information for allocation concealment to be assessed at low risk of bias was an improvement over an earlier study of 96 trials published in nursing journals (Smith et al., 2008) where only 14% of trials reported allocation concealment. This improvement, if a change from 14% to 20.5% may be read as such, has been slow and inadequate. Stronger editorial vigilance is needed to ensure clear reporting on this important domain.

The other domain critical to quality in randomised trials is sequence generation, which allocation concealment is designed to protect. Schulz et al. (1995) found trials with inadequate sequence generation over-estimated treatment effects by 31% in comparison to those with adequate sequence generation. About a quarter of the trials in our study did not report sufficient information on sequence generation to assess risk of bias. Insufficient information on sequence generation may reflect the poor understanding on the part of editors and reviewers, or tolerance for accepting a trial is randomised if it is described as such without offering evidence to support that description (Wager and Williams, 2013). While the 68.7% of trials that provided sufficient information to be assessed at low risk of bias was an improvement on the 49% reported by Smith et al. (2008), improvement is needed as unclear sequence generation can over-estimate effects by 11% (Savović et al., 2012). If insufficient information reflects a willingness to tolerate lower quality reports from small trials, that view must be changed as there is no reason small trials cannot be conducted to the highest standard (Sackett and Cook, 1993). Effects derived from small trials with adequate sequence generation do not over-estimate treatment effects in comparison to large trials, but small trials without adequate sequence generation can over-estimate effects by as much as 54% (Kjaergard et al., 2001). Journals also need to guide their reviewers as to what constitutes random sequence generation. We found five trials described as randomised, but which used non-random sequences (patients' birthdays, identification numbers, timing of clinical visits, name order) and one trial described as quasi-experimental that used a random sequence generation technique (random permuted blocks).

Assessing completeness of follow up can be difficult, especially if it is unclear how loss to follow up was treated in the analysis or to what degree the researchers undertook an intention to treat analysis as opposed to a modification of intention to treat (Hollis and Campbell, 1999). While only 7.2% of trials were assessed as unclear, a further 37.3% were assessed as being at high risk of bias. Much of the high risk of bias or information insufficiency could be ameliorated by the inclusion of a participant or CONSORT flow diagram. All of the trials assessed as unclear and about a third of the trials assessed as being at high risk of bias did not have such a diagram and there is varied compliance with the diagram even among the journals that are CONSORT promoting. Adherence with publishing the diagram ranged from 50% to 100% in these journals.

We found 82.7% of qualifying trials mentioned a sample size calculation, but only 36 (48%) reported *a priori* the calculation in sufficient detail to expose all the assumptions. Our findings are similar to those of another report that found only 43% of trials published between 2005 and 2006 in six high impact medical journals had all the necessary parameters reported (Charles et al., 2009). The detail most frequently missed in our study was exposing the primary outcome. It appears to be assumed that identifying the effect size is sufficient, but in the cases where the delta is Cohen's *d*, or a similar index, failing to expose the intended primary outcome allows the authors to conduct multiple tests without adjusting for multiplicity. Multiple testing increases the likelihood of obtaining a positive result, but at the very real risk of Type I error (Schulz and Grimes, 2005). In addition, eight trials in our study reported a *post hoc* sample size calculation, which has very little value given it is based on the observed delta rather than an expected delta inferred from other sources. *Post-hoc* calculations may also be the product of data dredging with *post hoc* outcome selection, and is considered deceptive (Schulz and Grimes, 2005).

A possible explanation for the lack of significant associations in our study is a cohort effect with all submitting authors being influenced by the CONSORT Statement, thus diluting the effect of journal endorsement. Variability across journals on information sufficiency would suggest otherwise. A second possible explanation was the small number of trials published in the nursing journals in 2012. If the direction of effect is considered, the point estimates almost all suggest journal endorsement may have a positive effect and including more than one year in our study might have redressed a lack of power. Unfortunately, we were limited by resource constraints and including other years was not possible. However, a systematic review of eight studies reporting on 1111 papers published in medical journals up to 2005 found associations between CONSORT endorsement and quality of trial reporting on some domains but not others (Plint et al., 2006).

Our findings, like those of Plint et al. (2006), suggest simple endorsement of trial reporting and registration is not sufficiently effective across all domains, as authors have no strong reason to change behaviour. Indeed there is anecdote that authors remain unaware of reporting standards (Wager, 2014). The solution to inadequate reporting may lie with a more robust editorial position on adherence to the CONSORT Statement and trial registration, as well as ensuring reviewers and all involved in the editorial process understand and adhere to the necessity of adequate reporting. Interviews with editors have suggested that the competitive nature of publishing and more tolerance of poor reporting in small trials or those conducted in developing nations influence editorial adherence to the CONSORT Statement (Wager and Williams, 2013). Overcoming these barriers to improved reporting will likely require nursing journal editors to act in concert, undertaking to promote adherence as a collective, to not publish a trial until the authors adequately report the necessary domains and the trial is registered on a WHO compliant trials register. An approach such as that initiated by the ICMJE in 2004 would be a useful starting point.

Our study is subject to one further limitation. We did not adjust for cluster effects in the analyses that examined for an association between journal promotion status and the risk of bias or sample size calculation quality. The number of journals promoting either or both the CONSORT Statement and trials registration means that any significant finding may be driven by an aggregation (or cluster) of reports in a journal. However, adjustment for clustering would move any p values towards the null and most associations in our study were non-significant. Those associations that were significant were considered relatively minor and did not drive our summative conclusions.

5. Conclusions and implications

Randomised controlled trials published in nursing journals still provide insufficient information to support critical appraisal and risk of bias assessments, especially on sequence generation and allocation concealment. Readers are poorly served by continued non-adherence to the CONSORT Statement and trial registration, and passive promotion of the CONSORT checklist has not delivered the necessary improvements. Active engagement during the editorial process, training for editors and reviewers, and the requirement for prospective trial registration on a WHO-compliant register may deliver improvements. These actions will require nursing journal editors to act cooperatively, rather than competitively. Without such efforts, critical appraisal of trials published in nursing journals will continue to be an exercise in frustration.

Conflict of interest

Andrew Jull was Handling Editor for the International Journal of Nursing Studies until 31 March 2014 and remains a member of the Editorial Advisory Board. Papers he handled as part of the editorial process may have been included in the trials published by the International Journal of Nursing Studies in 2012.

Contribution of the paper

AJ conceived the idea, both authors contributed to the data collection and analysis, PS drafted the paper, which AJ revised with additional analyses, and redrafted. Both authors have approved the final draft.

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