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THE REPORTING QUALITY OF ABSTRACTS OF RANDOMISED CONTROLLED TRIALS SUBMITTED TO THE ICS MEETING IN HEIDELBERG

Aims of Study

The quality of randomised controlled trials(RCTs) is associated with bias(1,2). Thus reports of RCTs must have enough detail of key elements of quality to enable them to be interpreted properly. A group of editors of major medical journals sponsored a group to come up with guidelines for the reporting of RCTs, called the CONSORT statement(3). Details of this and other reporting quality guidelines are on the internet at http://www.consort-statement.org/. This study examines the quality of abstracts of RCTs reported at the ICS meeting in Heidelberg in 2002.

Methods

All of the abstracts accepted for the meeting at Heidelberg were read to identify reports of RCTs. Copies of these were then printed and examined to see whether they complied with the 22 items in the CONSORT statement. As these were all abstracts the first item was changed so that to comply the title had to say it was a randomised trial. Each item was scored as not met, partially met, met.

Results

Fifty-three reports of randomised controlled trials were found. 5 of these were podium presentations, 14 discussion posters, and 34 non-discusion posters.

Compliance with the CONSORT items is given in the table.

CONSORT ITEM		Not met	Partially met	Met
No.	Description			
1	How participants were allocated to interventions (eg. "random allocation" or "randomly assigned")	30 (57%)	3 (5.7%)	19 (38%)
2	Scientific background and explanation of rationale	9 (17%)	17 (32%)	27 (51%)
3	Eligibility criteria for participants and the settings and locations where the data were collected	5 (9%)	28 (53%)	20 (38%)
4	Precise details of the interventions intended for each group and how and when they were actually administered	2 (4%)	18 (34%)	33 (62%)
5	Specific objectives and hypotheses	5 (9%)	21 (40%)	27 (51%)
6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurement (eg. multiple observations, training of assessor, &c)	6 (11%)	24 (45%)	23 (43%)
7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	50 (94%)	1 (2%)	2 (4%)
8	Method used to generate the random allocation sequences, including details of any restriction (eg. blocking, stratification)	47 (89%)	5 (9%)	1 (2%)
9	Method used to implement the random allocation sequence (eg. numbered containers or central telephone), clarifying whether the sequence was concealed until investigations were assigned	50 (94%)	2 (4%)	1 (2%)
10	Who generated the allocation sequence, who enrolled participants, and who assigned the participants to their groups	52 (98%)	0 (0%)	1 (2%)
11	Whether or not the participants, those administering	23 (43%)	9 (17%)	21 (40%)

	the interventions, and those assessing the… outcomes were aware of group assignment. If not, how the success of masking was assessed.			
12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	30 (57%)	7 (13%)	16 (30%)
13	Flow of participants through each stage (a diagram is strongly recommended). Specifically for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome. Describe protocol deviations from study as planned together with the reasons	12 (23%)	17 (32%)	23 (45%)
14	Dates defining the periods of recruitment and follow-up	48 (91%)	0 (0%)	5 (9%)
15	Baseline demographic and clinical characteristics of each group	39 (74%)	9 (17%)	5 (9%)
16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention to treat". State the results in absolute numbers when feasible (eg. 10/20, not 50%)	14 (26%)	27 (51%)	2 (4%)
17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (eg, 95% CI)	24 (45%)	27 (51%)	2 (4%)
18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory	13 (25%)	25 (47%)	15 (28%)
19	All important adverse events or side-effects in each intervention group	17 (32%)	10 (19%)	26 (49%)
20	Interpretation of results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes	0 (0%)	16 (30%)	37 (70%)
21	Generalisability (external validity) of the trial findings	38 (72%)	9 (17%)	6 (11%)
22	General interpretation of the results in the context of current evidence	26 (49%)	22 (42%)	5 (9%)

Only 2/53 (4%) of the abstracts complied fully with more than 10 of the items, and 30/53 (57%) did not comply at all with 10 or more.

Conclusions

The quality of reporting of studies at ICS is so poor that it is difficult to interpret the results. Reporting was particularly poor on the details of the randomisation and the numeric results.

1. Egger M, Ebrahim S, Davey Smith G. Where now for meta-analysis? *International Journal of Epidemiology* 2002;31:1–5.
2. Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA* 1995;273:408–412.
3. Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D, et al. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Annals of Internal Medicine* 2001;132:663-94.