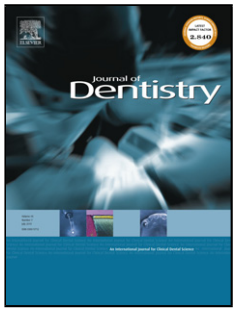
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The use of tailored subheadings was successful in enhancing compliance with CONSORT in a dental journal.

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Abstract

Objectives: Efforts to enhance the reporting of clinical trials have intensified in recent years with automated strategies and editorial involvement showing promise in improving compliance with accepted guidelines. This study aimed to evaluate the effectiveness of a concerted approach to adherence to CONSORT (CONsolidated Standards Of Reporting Trials) guidelines in a dental journal.

Materials and Methods: Following the publication of an exemplar clinical trial on the American Journal of Orthodontics and Dentofacial Orthopedics (AJO-DO) website and related changes to the author guidelines, trial submissions were required to follow a standard format incorporating subheadings mirroring the CONSORT guidelines. Compliance with CONSORT was assessed in initial submissions over a 30-month period. Reporting was compared to submissions of randomized controlled trials (RCTs) which did not include subheadings over the same period.

Results: Seventy-one RCTs were submitted to the AJO-DO from January 2014 to June 2016, 49 with subheadings and 22 without. Most CONSORT items (e.g. random sequence generation, allocation concealment and blinding) were more frequently adequately reported when RCTs were submitted with inclusion of subheadings. Overall, reporting quality of the submitted RCTs was 15.2% higher with use of the subheadings format (95%CI: 10.5, 20.0; $p<0.001$) with a mean overall score of 87.3%.

Conclusion: Enhanced compliance of submitted RCTs was found with use of a bespoke approach to trial presentation utilizing CONSORT item subheadings. The improvement in initial submissions is particularly encouraging as this arose without input either from peer reviewers or journal editors. This simple approach may have wider applicability.

Keywords: reporting guidelines; orthodontics; dentistry; adherence; RCTs; AJODO; CONSORT

Introduction

The importance of transparent reporting of research studies not least randomized controlled trials (RCTs) is well-established. The CONsolidated Standards of Reporting Trials (CONSORT) guidelines were directed at informing the reporting of RCTs[1] . CONSORT has been endorsed by most leading journals with authors encouraged to adhere to recommendations within their submissions. Moreover, numerous modifications to CONSORT have been made to account for variations in trial design, setting and outcomes[2–4].

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While CONSORT has become established and accepted, a plethora of research from biomedical specialties suggests that the published literature remains beset by poor reporting[5–8]. In particular, reporting of trials published in the medical and dental literature have been suboptimal and, while some benefit has accrued from endorsement of reporting guidelines [5], expose the ineffectiveness of existing passive approaches to CONSORT compliance with more innovative or involved systems required to optimise reporting. This has spawned a range of initiatives including more involved editorial processes and automated means of improving reporting[9], with increased editorial involvement leading to considerable improvement in reporting of clinical trials within in a dental specialty journal[9].

The American Journal of Orthodontics and Dentofacial Orthopedics (AJO-DO) has been proactive in promoting reporting in accordance with CONSORT with the approach to enhancing CONSORT compliance evolving in recent years. Initially (from June 2011), a systematic process involving the editor-in-chief (EiC), an associate editor (AE) and RCT authors was adopted whereby initial RCT submissions were first assessed by the AE to ensure all CONSORT items were reported completely following transfer from the EiC. The AE replied to the authors listing unreported items and highlighting ways to address incompletely reported items prior to resubmission. Resubmitted manuscripts were again scrutinized by the AE for CONSORT adherence and then sent for standard peer review. This initiative led to near complete reporting of most CONSORT items in published articles but did require significant input from the editorial team[9]. Similar approaches may not, however, be applicable to other journals in view of the increased onus on editorial, time, input and expertise. In order to improve reporting at the submission level, the approach changed in January, 2014 with the adoption of a publication template incorporating 20 subheadings corresponding to the 27 CONSORT items. A model clinical trial report and a specialty specific CONSORT explanation paper providing the rationale for reporting of individual items were also published[10,11].

As such, the present study examines the impact the use of subheadings based on CONSORT items on the reporting of clinical trials submitted to a dental specialty journal. We also aimed to highlight areas where deficient reporting within initial submissions exists.

Methods

The completeness of reporting was compared between RCTs submitted to AJO-DO with or without subheadings based on the CONSORT items. Both cohorts included all RCTs

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submitted for publication between the January 2014 and June 2016. The sample was divided based on whether the submission was presented in-line with suggested subheadings (Table 1) [11]. No inclusion restrictions in terms of trial design were applied. Two experienced researchers were involved in the data extraction process. Data from 10 papers were extracted independently and consensus was reached for training and calibration purposes. Consequently, the first author extracted all data from the remaining papers.

RCT reports were assessed based on whether they reported all items completely. Items were rated as either not reported, incompletely reported, or completely reported. Furthermore, a scoring system was used based on a modified and expanded CONSORT item list for the evaluation of quality of reporting, in line with a previous analysis[12]. Scores for each item ranged from 1 to 3 with 1 indicating no description, a score of 2 representing inadequate description, and 3 indicative of adequate description. The scores for all 37 items were combined and a percentage score was derived. Non-applicable items did not receive any score. For example, the maximum for a trial with adequate description for all items was 111 corresponding to 100%. On the same basis, an RCT with 30 applicable items could receive a maximum score of 90, also equivalent to 100%. Subsequently, each item was converted to a binary variable to enable comparison of RCTs submitted with subheadings to those without subheadings for each reporting item using a dichotomous measure (i.e. adequate reporting vs no reporting/inadequate reporting.

Descriptive statistics and frequency distributions of compliance with CONSORT items were reported for both cohorts. A t-test was conducted to identify differences in reporting scores between submissions with and without subheadings. All analyses were carried out using Stata 14.1 (Stata Corp, College Station, TX, USA), with the level of statistical significance set at p=0.05.

Results

Over the 30-month period (January 2014 to June 2016), a total of 71 RCTs were submitted to the AJO-DO and assessed for completeness of reporting. Forty- nine of these initial submissions incorporated subheadings, while 22 did not. The majority of submission were from authors in Asia/Other regions (n= 41; 58%), with 23% (n= 16) from the Americas and 20% (n= 14) from Europe.

A number of pivotal items were more frequently adequately reported when RCTs were submitted with inclusion of subheadings (Table 2). In particular, sample size (subheadings:

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25/49, 51%; no subheadings: 6/22, 27%), random sequence generation (subheadings: 33/49, 67% vs no subheadings: 9/22, 41%), allocation concealment (subheadings: 21/49, 43%; no subheadings: 4/22, 18%), blinding (subheadings: 42/49, 86% vs no subheadings: 12/22, 55%), CONSORT flow diagram (subheadings: 40/49, 82% vs no subheadings: 9/22, 41%), baseline information table (subheadings: 37/49, 76%; no subheadings: 11/22, 50%), study limitations (subheadings: 42/49, 86%; no subheadings: 8/22, 36%) and generalizability (subheadings: 38/49, 78% vs no subheadings: 3/22, 14%) were more commonly adequately reported in submissions incorporating subheadings. Notwithstanding this, items such as sample size, allocation concealment or estimates/confidence intervals remain in need of a considerable improvement in reporting (Table 2).

For the evaluation of the reporting quality of the submitted RCTs, trials incorporating subheadings achieved a score of 15.2 percentage units higher compared to ones without (95%CI: 10.5, 20.0; $p<0.001$). The mean overall score for those trials was 87.3%. Reporting quality for each item is also presented in Figure 1 for submissions with or without the use of subheadings. Four items are not presented in the forest plot as these were not applicable for the majority of the examined RCTs (ie. similarity of interventions, subgroup analyses, if binary outcome/absolute numbers, ancillary analyses).

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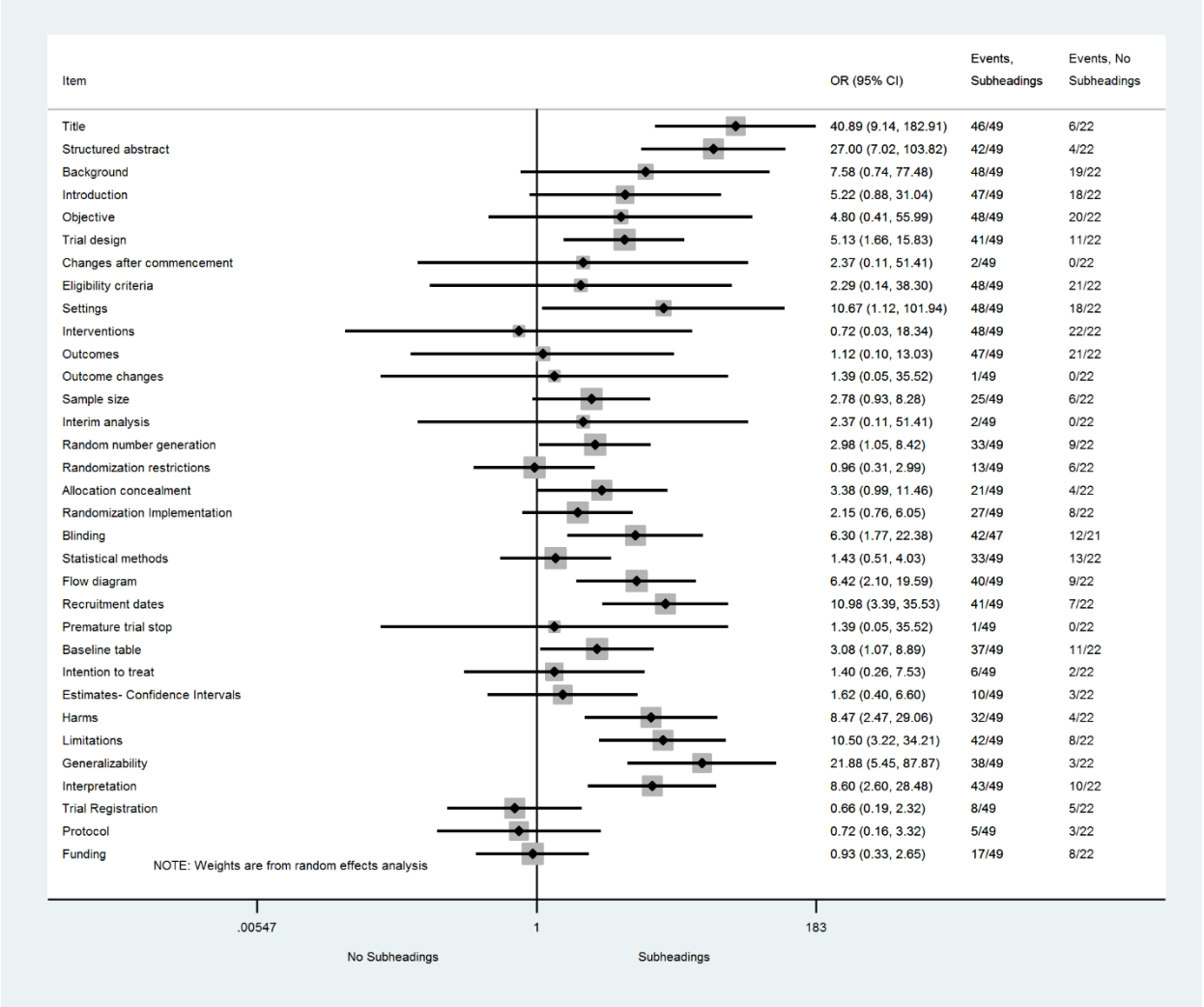


Figure 1. Forest plot presenting reporting items for RCTs submitted using subheadings compared to RCTs not using subheadings.

Discussion

Main Findings

The impact of CONSORT on trial reporting is established with a previous review alluding to improved reporting within 25 of 27 items in CONSORT-endorsing journals[5]. Nevertheless, reports documenting inadequate compliance are pervasive throughout the biomedical literature, with statistically significant differences between endorsers and non-endorsers found in relation to just 4 of 27 items in the afore-mentioned systematic review[5]. It is therefore important that the research and operational focus shifts to developing and

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refining approaches to improving adherence with these established guidelines[13]. Ensuring compliance with key reporting guidelines is fraught with difficulties including lack of awareness among authors, time and resource implications for editorial staff and peer reviewers, and lack of knowledge and expertise in relation to guideline implementation among editors. The present study outlines a user friendly and simple approach, which appears to have been effective in improving the CONSORT compliance of initial submissions to a dental specialty journal.

Limitations and strengths

This relatively simple approach complements previous efforts within this specialty journal involving stepwise editorial involvement and feedback to authors which was previously shown to improve CONSORT compliance [9]. The CONSORT checklist remains accessible through the journal website and it is possible for authors to use this list. However, access to or passive recommendation of use of the checklist alone is not sufficient to ensure optimal reporting [9] and its effect will be negated by the requirement for all accepted manuscripts to conform to the use of CONSORT-based subheadings. The updated approach is a more passive process that requires relatively little editorial input. Specifically, baseline interventions included publication of an exemplar trial report on the journal website and a specialty-specific CONSORT explanatory document within the journal[11,12]. Thereafter, less editorial input is required, however the quality of reporting of CONSORT sub-items is still assessed by the editorial team. A potential pitfall of this approach is that adherence to templates can result in “filling the blanks” to satisfy formatting requirements. The extent of this type of bias is hard to assess; however, it does not appear to be significant.

The present study involved a relatively small sample of trials; however, the improvement in reporting among initial submissions was convincing. Moreover, analysis involved all trial submissions over a defined period and we were able to scrutinize initial submissions both for trials that went on to be accepted for publication and rejected. A similar approach has been used within specific medical journals[14]. As such, it is reasonable to assume that this is a representative cross-section of orthodontic clinical trials and to infer that the present approach has had a significant positive impact on clinical trial submissions to this specialty journal.

Findings in context

The overall CONSORT compliance rates among submissions conforming to and not using the

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subheading system in the present cross-sectional survey were 87.3% and 72.1%, respectively. These figures compare favourably with previous reports based on passive promotion of CONSORT guidance within the biomedical literature with a survey of 105 trials published in 29 journals alluding to adequate reporting in over 50% of trials for just 5 of 11 key methodological factors[8]. Significantly better compliance was found in CONSORT promoting journals but reporting was still limited even among these journals with, for example, allocation concealment and blinding of the assessor adequately reported in just 57% and 47%, respectively, of trials published in CONSORT endorsers[8]. A caveat to these figures, however, is the inconsistency among endorsing journals in relation to specific expectations of clinical trial submissions, with Shamseer *et al*. (2016) [15] highlighting that 42% of CONSORT endorsing journals explicitly stating use of CONSORT to be obligatory, while 38% require a completed checklist, and 39% also outline explicitly the need for inclusion of a flow diagram. When compared to previously published reports of RCTs within the same orthodontic journal, the quality of reporting of initial submissions without subheadings was similar to published reports after peer review from 2007 to 2009 (overall percentage score 62.9%) [16] as well as from 2010 to 2013 (overall percentage score 73.1%) [7], while initial submissions complying with the subheading system outstripped these published articles in terms of CONSORT compliance (87.3%; Figure 2). It is not unreasonable to assume that following peer-review CONSORT compliance would likely improve further[14].

The present approach was augmented by the use of an exemplar clinical trial published on the journal website, which was integral to the process. It was, however, complemented by the publication of a specialty specific, orthodontic CONSORT explanatory document, which was published in the print journal[9]. The intention of the tailored CONSORT guidance was to develop a document which might resonate more with researchers within the specialty as, while the original CONSORT document incorporates a range of examples, these may be less well understood by researchers from divergent research areas. The effect of this undertaking is unclear, although we do believe to have had much less impact than the introduction of subheadings. As such, if attempts are made to mimic the present system in other journals, the use of a specialty-specific CONSORT is likely dispensable.

Implications of results

Based on the present analysis, it is reasonable to assume that the use of subheadings resulted in improved CONSORT compliance within initial submissions to a specialty journal

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(AJO-DO). Moreover, the AJO-DO has the highest impact factor of any orthodontic journal and it is known that potential authors often target journals based on impact factor hierarchy[17,18]. It is possible that articles which are not accepted for publication in this journal may subsequently be accepted elsewhere while benefiting from the enhanced CONSORT compliance induced by the subheadings format. The benefit of the present approach may conceivably, therefore, permeate into other journals within the specialty. While the use of CONSORT and other guidelines including PRISMA and to a lesser extent STROBE are encouraged by most journals [19,20], this does not necessarily translate into enhanced adherence and reporting completeness. Indeed, specifically within the area of restorative dentistry, CONSORT was also found to have limited impact, leading to a call for more innovative approaches to improving adherence [21].

The use of subheadings according to CONSORT may be mimicked in other dental journals and indeed more widely in medical journals. As such, the present approach has the potential for widespread utility. This is particularly important and timely as a realization has emerged that adherence to reporting guidelines based on passive approaches is suboptimal almost universally[22,23]. Moreover, analogous approaches can be adopted for other study designs with AJO-DO, for example, also adopting a similar approach to presentation of systematic reviews (SRs) according to PRISMA sub-items.

The implications of improved trial reporting which may stem from the present or similar approaches are clear with the financial and ethical implications of waste in clinical research being especially stark[24]. Moreover, the yield from systematic reviews may also be hampered by inadequate primary study design and reporting with a recent meta-epidemiological study within orthodontic SRs highlighting that meta-analysis was possible in just 27% of 157 systematic reviews over a 14-year period with a median of just 4 studies contributing to those reviews including meta-analyses[25]. However, this problem is not confined to the dental literature with 13.5% of all Cochrane SRs which incorporated a GRADE assessment shown to have a high level of evidence with the quality of evidence most often rated down due to methodological limitations or due to imprecision[26]. Design imitations typically related to problems due to inadequate randomization procedures including allocation concealment, lack of blinding and large losses to follow-up[26,27]. The pressing need to produce high-quality primary research studies throughout the biomedical literature and therefore for robust guideline implementation persists.

CONCLUSIONS

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The adoption of a relatively simple and low cost approach was successful in enhancing CONSORT compliance in a specialty dental journal. This method may have wider utility in view of the need to supersede passive approaches to implementation of accepted reporting guidelines.

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Conflict of Interest: None

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Reviews: a cross-sectional, descriptive analysis, BMC Med. Res. Methodol. 11 (2011) 160. doi:10.1186/1471-2288-11-160.

Figure 2. Mean percentage CONSORT compliance score in the AJO-DO based on the present and previous analyses. [7, 15]

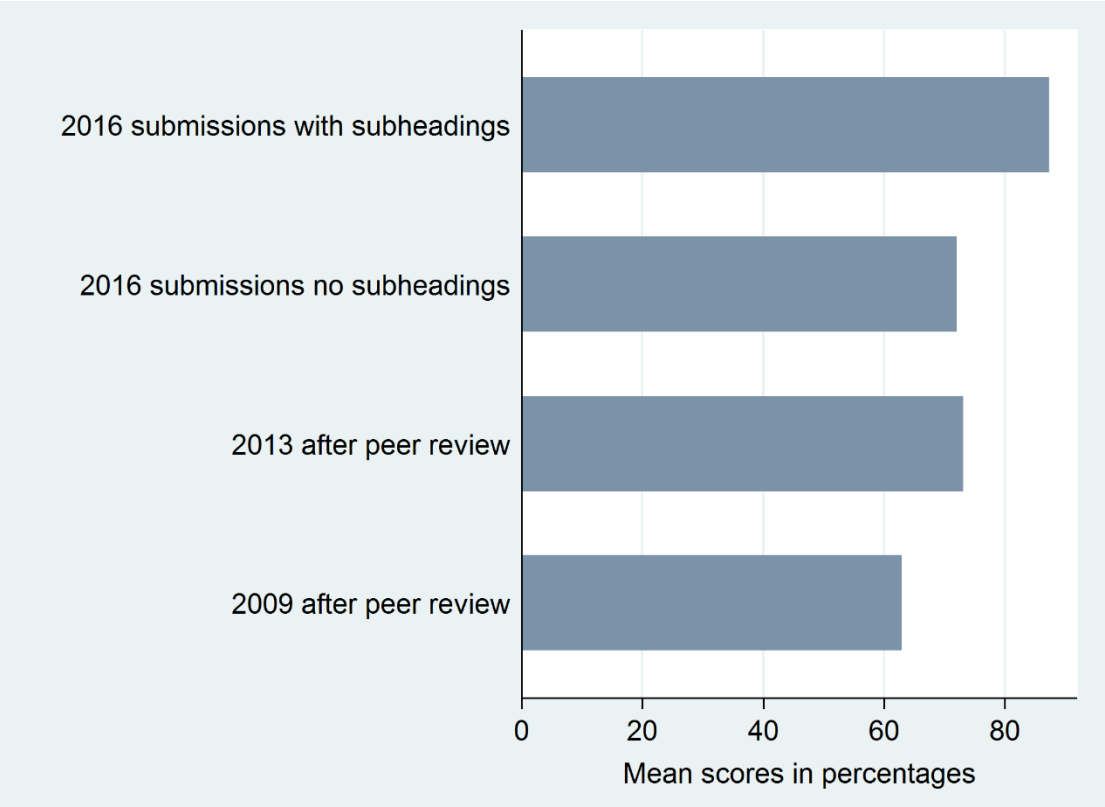


Table 1. List of recommended subheadings based on CONSORT diagrams.

1	Title
2	Structured abstract
	Introduction
3	Background
4	Specific objectives or hypotheses
	Methods
5	Trial design and any changes after trial commencement
6	Participants, eligibility criteria, and settings
7	Interventions
8	Outcomes (primary and secondary) and any changes after trial commencement
9	Sample size calculation
10	Interim analysis and stopping guidelines
11	Randomization (random number generation, allocation concealment, implementation)

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12	Blinding
13	Statistical analysis (primary and secondary outcomes, subgroup analysis)
	Results
14	Participant flow (include flow diagram, early stopping and time periods)
15	Baseline data (include baseline table)
16	Numbers analyzed for each outcome, estimation and precision, subgroup analyses
17	Harms
	Discussion
18	Main findings in the context of the existing evidence, interpretation
19	**Limitations**
20	**Generalizability**
	Registration
	Protocol
	Funding

Table 2. Frequency distributions on reporting of items based on the CONSORT checklist and included in the subheadings, according to the structure of the manuscript at initial submission.

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	Presence of subheadings at submission stage					
	No		**Yes**		**Total**	
	No.	%	No.	%	No.	%
Title						
Adequate	6	27	46	94	52	73
Inadequate	16	73	3	6	19	27
Structured Abstract						
Adequate	4	18	42	86	46	65
Inadequate	18	82	7	14	25	35
Background						
Adequate	19	86	48	98	67	94
Inadequate	3	14	1	2	4	6
Introduction						
Adequate	18	82	47	96	65	92
Inadequate	4	18	2	4	6	8
Objective						
Adequate	20	91	48	98	68	96
Inadequate	2	9	1	2	3	4
Trial Design						
Adequate	11	50	41	84	52	73
Inadequate	8	36	8	16	16	23
No description	3	14	0	0	3	4
Changes after trial commencement						
Adequate	0	0	2	4	2	3
Non-applicable	21	95	47	96	68	96
No description	1	5	0	0	1	1

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Eligibility criteria						
Adequate	22	100	49	100	71	100
Settings						
Adequate	18	82	48	98	66	93
Inadequate	2	9	1	2	3	4
No description	2	9	0	0	2	3
Interventions						
Adequate	22	100	48	98	70	99
Inadequate	0	0	1	2	1	1
Outcomes						
Adequate	21	95	47	96	68	96
Inadequate	1	5	1	2	2	3
No description	0	0	1	2	1	1
Outcome changes						
Adequate	0	0	1	2	1	1
Non-applicable	22	100	48	98	70	99
Sample Size						
Adequate	6	27	25	51	31	44
Inadequate	14	64	23	47	37	52
No description	2	9	1	2	3	4
Interim analysis						
Adequate	0	0	2	4	2	3
Non-applicable	22	100	47	96	69	97
Random number generation						
Adequate	9	41	33	67	42	59
Inadequate	10	45	16	33	26	37
No description	3	14	0	0	3	4
Restrictions in randomization						
Adequate	6	27	13	27	19	27
Inadequate	0	0	4	8	4	6

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No description	16	73	32	65	48	68
Allocation Concealment						
Adequate	4	18	21	43	25	35
Inadequate	6	27	15	31	21	30
No description	12	55	13	27	25	35
Implementation of Randomization						
Adequate	8	36	27	55	35	49
Inadequate	1	5	14	29	15	21
No description	13	59	8	16	21	30
Blinding						
Adequate	12	55	42	86	54	76
Inadequate	2	9	3	6	5	7
Non-applicable	1	5	2	4	3	4
No description	7	32	2	4	9	13
Similarity of Interventions						
Adequate	3	14	6	12	9	13
Inadequate	1	5	1	2	2	3
Non-applicable	16	73	40	82	56	79
No description	2	9	2	4	4	6
Statistical Methods						
Adequate	13	59	33	67	46	65
Inadequate	9	41	16	33	25	35
Subgroup analysis						
Adequate	2	9	2	4	4	6
Inadequate	1	5	2	4	3	4
Non-applicable	19	86	44	90	63	89
No description	0	0	1	2	1	1
Flow Diagram with reasons						
Adequate	9	41	40	82	49	69
Inadequate	2	9	9	18	11	15

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No description	11	50	0	0	11	15
Recruitment Dates						
Adequate	7	32	41	84	48	68
No description	15	68	8	16	23	32
Premature trial stop						
Adequate	0	0	1	2	1	1
Non-applicable	22	100	48	98	70	99
Baseline Table						
Adequate	11	50	37	76	48	68
Inadequate	4	18	8	16	12	17
No description	7	32	4	8	11	15
Intention-to-treat						
Adequate	2	9	6	12	8	11
Inadequate	2	9	5	10	7	10
No description	18	82	38	78	56	79
Estimates/Confidence Intervals						
Adequate	3	14	10	20	13	18
Inadequate	0	0	8	16	8	11
No description	19	86	31	63	50	70
If Binary Outcome/absolute numbers						
Adequate	1	5	6	12	7	10
Non-applicable	21	95	43	88	64	90
Ancillary analysis						
Adequate	0	0	1	2	1	1
Inadequate	1	5	1	2	2	3
Non-applicable	21	95	47	96	68	96
Harms						
Adequate	4	18	32	65	36	51
Inadequate	3	14	2	4	5	7
Non-applicable	3	14	12	24	15	21

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No description	12	55	3	6	15	21
Limitations						
Adequate	8	36	42	86	50	70
Inadequate	3	14	1	2	4	6
No description	11	50	6	12	17	24
Generalizability						
Adequate	3	14	38	78	41	58
Inadequate	3	14	3	6	6	8
No description	16	73	8	16	24	34
Interpretation						
Adequate	10	45	43	88	53	75
Inadequate	11	50	6	12	17	24
No description	1	5	0	0	1	1
Registration						
Adequate	5	23	8	16	13	18
Inadequate	0	0	2	4	2	3
Non-applicable	5	23	33	67	38	54
No description	12	55	6	12	18	25
Protocol						
Adequate	3	14	5	10	8	11
Inadequate	1	5	2	4	3	4
Non-applicable	6	27	37	76	43	61
No description	12	55	5	10	17	24
Funding						
Adequate	8	36	17	35	25	35
Non-applicable	5	23	28	57	33	46
No description	9	41	4	8	13	18
Total	**22**	**100**	**49**	**100**	**71**	**100**