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ARTICLE

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Quality analysis of randomized controlled trials reporting in the field of pediatrics by Indonesian researchers

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Abstract

Objective: To determine the quality of reports of the randomized controlled trial (RCT) in the field of pediatrics conducted by Indonesian investigators.

Methods: All pediatric RCTs conducted by Indonesian researchers were sourced from international and national (local) publications. The assessment was done using both the Consolidated Standards of Reporting Trial (CONSORT) 2010 statement and Jadad Scale. Overall scores from each assessment are reported with a comparison of overall scores between studies in international and local publications.

Results: A total of 91 pediatric randomized control trials by Indonesian authors were gathered. National publications yielded a total of 44 studies (48.4%) whilst international publications yielded 47 studies (51.6%). Using the CONSORT statement the percentage of good reports was 38.3% in international journals and 33.3% in national journals. Using Jadad scale the percentage of good reports was 43.6% (international journals) and 37.0% (national journals). Both were not statistically significant.

Conclusions: Even though Indonesian investigators still need to be familiarized with good RCT reporting, the overall quality of the reports is fairly satisfactory. There is no significant difference in quality between studies published in international or national journals.

KEYWORDS

Indonesia, pediatric, quality analysis, reporting randomized control trial

1 | INTRODUCTION

Randomized controlled trial (RCT) is the best study design to evaluate new therapies or treatment strategies in medicine.[1] It is important to make sure that RCTs are planned, conducted, analyzed, and reported appropriately to provide valid clinical evidence for medical practitioners, other investigators, or even policy makers. In the field of child health, administration of treatment and intervention is of paramount important in daily practice, thus knowledge gained from reliable RCT is very important.[2,3]

This study aimed to assess the quality of reporting clinical trials in the field of pediatrics conducted by Indonesian investigators. To determine if there are any differences between studies published in international or in national medical journals, comparisons in quality was also conducted. This assessment had never done before in Indonesia, and previous international studies indicate that the quality of RCT reports was disappointing. The assessment of quality for RCT gives us a rough estimate of whether the trial conducted is a valid representation of the actual truth.

2 | METHODS

2.1 | Selection of journals and articles

We included any randomized controlled trial (RCT) in any topics relating to child health (age of study participants from birth to 18 years old) published by Indonesian authors both in international and national medical journals. Studies published in international journals were searched through PubMed database, while studies in national journals were searched in a national database. Journals included in the national publications were Folia Medica Indonesiana, Journal of the

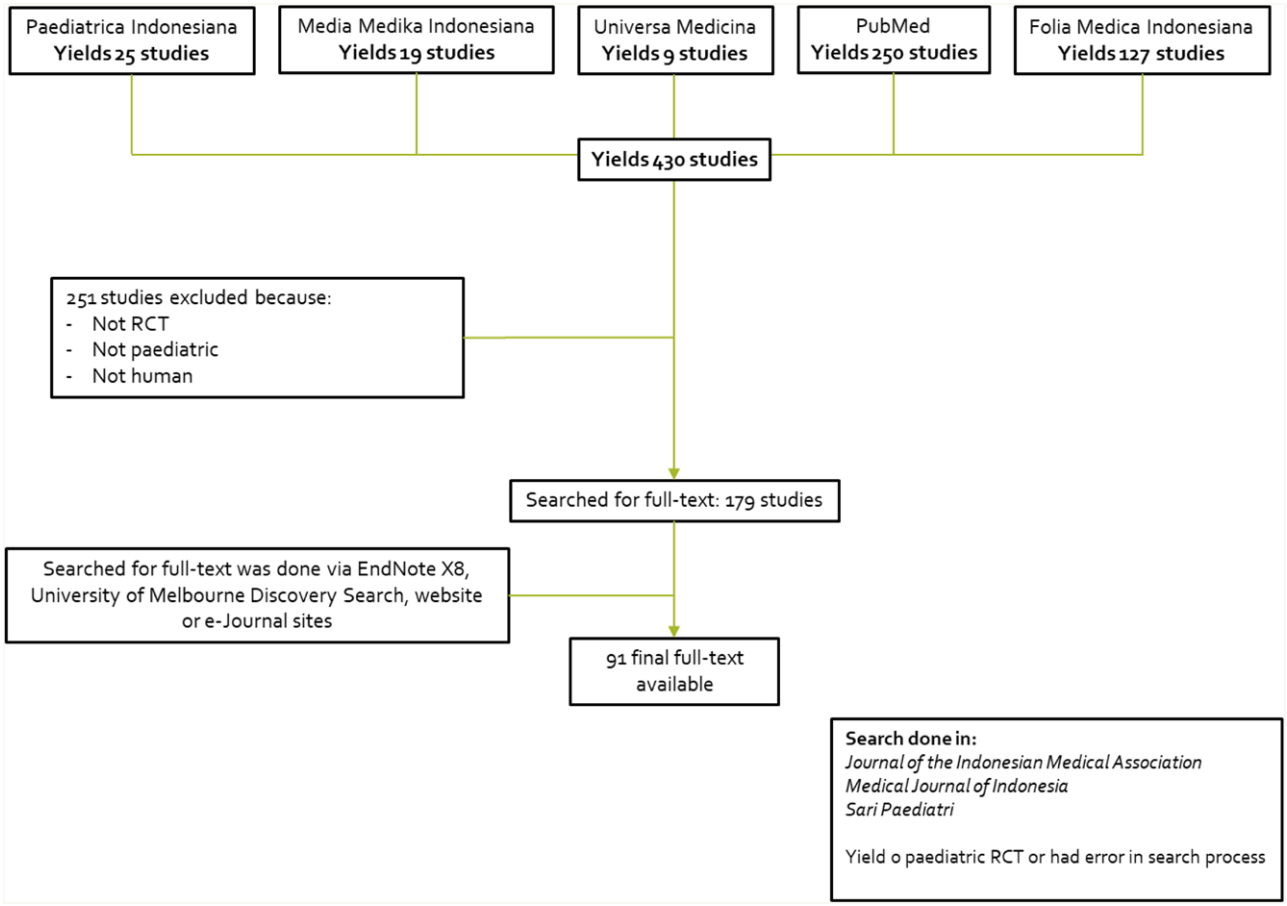

FIGURE 1 Flow diagram presenting search results and review of included studies

Indonesian Medical Association, Medical Journal of Indonesia, Media Medika Indonesiana, Paediatrica Indonesiana, Sari Paediatri, Universa Medicina, and Majalah Kedokteran Bandung. National publications included were mostly associated with state universities in Indonesia with the medical education program. The search terms used were ("indonesia"[MeSH Terms] OR "indonesia"[All Fields]) AND (Clinical Trials[ptyp] AND ("infant"[MeSH Terms] OR "child"[MeSH Terms] OR "adolescent"[MeSH Terms])). In national journal databases that don't recognize MeSH term, we used the search term "Clinical Trials" and looked upon all the hits manually.

Researcher of this study retrieved all electronic copies available (free or paid) from each publication. Studies that were done by all non-Indonesian authors consisted of all non-Indonesian participants or conducted outside Indonesia were excluded. Searching, selection, and assessment processes of each study can be seen in Figure 1.

2.2 | Assessment and appraisal of studies

We reviewed all articles by using CONSORT (Consolidated Standard of Reporting Trials) 2010 checklist and Jadad scale.

2.2.1 | CONSORT checklist

The CONSORT statement has 25 categories related to RCT's reporting (eg, sample size, statement of primary and secondary outcomes, trial registration) that is developed to improve trial's reporting. In this study, we used all 25 categories (consisting of 37 questions in total).[4]

2.2.2 | Jadad scale

Jadad Scale or Jadad scoring is a simple assessment tool consisting of 3 criteria (randomization, blinding and withdrawal or dropout descriptions) and a total score of 5.[5]

None of the authors of this study was an author or coauthor of any of the studies assessed. Journal titles and authors were hidden during the appraisal process. We determined whether adequate information was given for each of the CONSORT or Jadad checklists with a simple answer of "yes" or "no." Differences in opinion were discussed between the author and coauthors of this study. Full checklist and criteria of fulfillment for both CONSROT and Jadad were included in Appendices 1 and 2.

2.3 | Data analyses

Statistical calculations and data analyses were done using Microsoft Excel and IBM SPSS program. Report of results after the quality analysis was done by separating the quality of studies into 3 groups; "poor" when the study only fulfilled 0–12 criteria in CONSORT or 0–1 score in Jadad, "moderate" when the study fulfilled 13–25 criteria in CONSORT or 2–3 score in Jadad, and "good" when the study fulfilled 26–37

TABLE 1 Summary and characteristics of studies included based on publishers

Journal names	Number of articles	Articles included (%)[a]	The range of publication year	Main topics
International				
Acta Medica Indonesiana	11	1 (1.1)	2013	Surgery
Non-Indonesian publishers	239	46 (50.5)	1982–2015	Psychiatry, nutrition, ophthalmology, education, cardiology, critical care, growth and development, hematology-oncology, tropical medicine, gastroenterology
National				
Folia Medica Indonesiana	127	5 (5.5)	2007–2010	Nutrition
Media Medica Indonesia	19	11 (12.1)	–	–
Paediatrica Indonesiana	25	27 (29.7)	2001–2014	Nutrition, respirology, gastroenterology, metabolic endocrine, perinatology, neurology
Universa Medicina	9	1 (1.1)	2016	Immunology

[a]Percentage of articles included is calculated from total articles included divided by the number of articles per publisher.

TABLE 2 Summary of CONSORT and Jadad scale result from all studies included

	CONSORT score			Jadad scale		
	International (%)	National (%)	*P* value	International (%)	National (%)	*P* value
Poor	0 (0)	0 (0)	0.66	7 (14.9)	8 (18.5)	0.86
Moderate	29 (61.7)	29 (66.7)		20 (42.6)	20 (44.4)	
Good	18 (38.3)	15 (33.3)		20 (43.6)	16 (37.0)	

criteria in CONSORT or 4–5 score in Jadad. The additional statistical analysis was done to look upon the difference in proportion between studies in international and national publications. We used a chi-squared test for analyses with a P value of < 0.05 was considered as statistically significant.

3 | RESULTS

A total of 91 pediatric RCTs by Indonesian authors were gathered from numerous publications. Majority of the studies (47 or 63.5%) were published in international journals, while the rest (44 studies or 48.3%) were published in national journals. The characteristics of studies based on its publisher (international or national) and summary of studies included can be seen in Table 1. Studies with poor, moderate and good CONSORT and Jadad result is summarized in Table 2. In general, there was the only a slight difference (which are proven to be insignificant) in a number of good quality studies between international and national publications.

By using the CONSORT statement the difference in the percentage of good studies were 38.3% (international) vs 33.3% (national). The highest score in CONSORT was 35 out of 37 criteria submitted in an international publication. Using Jadad scale the difference in the percentage of good studies were 43.6% (international) and 37.0% (national). Twelve studies showed complete score in the Jadad scale, with half of the study coming from local publications and the other half from international publications. In combination, 33 (36.5%) RCTs that were done by Indonesians achieved good CONSORT score and 37 (40.6%) achieved good Jadad score (Figure 2).

The total scores for each category in both CONSORT and Jadad are summarized in Tables 3 and 4. In CONSORT, while all the studies included a scientific background, only 2.7% of all the studies attached an access toward their full trial protocols. In the Jadad scale, the mean score for the blinding process was 0.8 (maximum score of 2) and the overall mean score was 2.8 (maximum score of 5).

4 | DISCUSSION

The aim of this study was to assess the quality of reporting pediatric randomized controlled trials conducted by Indonesian investigators in both local and international publications. We found that 36.5% of all study reports showed good CONSORT scores, while 40.6% achieved good Jadad scores. These results are relatively satisfactory considering the results of a study by Shah et al, which showed that good CONSORT scores (>80% adherence to all the criteria) were only achieved in 13.6% of RCTs in Asia-Pacific region.[6] Sjögren et al assessed 100 RCTs and found only 6.7% of studies had good Jadad score[4,5] with the median score of 2.[7] It should be kept in mind that Sjögren et al did not specifically assess RCT reports in developing countries nor did it assess RCTs in the field of pediatrics. Moher et al who assessed specifically 251 pediatric RCT reports at a global scale found that the mean scores for quality of study using CONSORT was 12.7 out of 32 CONSORT checklists included.[8] When appraising the same study with Jadad scale, Moher et al found a mean score of 1.9 out of 5. Even though studies published in the international publication have slightly higher CONSORT and JADAD score, there were no significant differences in quality (from both CONSORT and Jadad) between RCTs published in international or national publications.

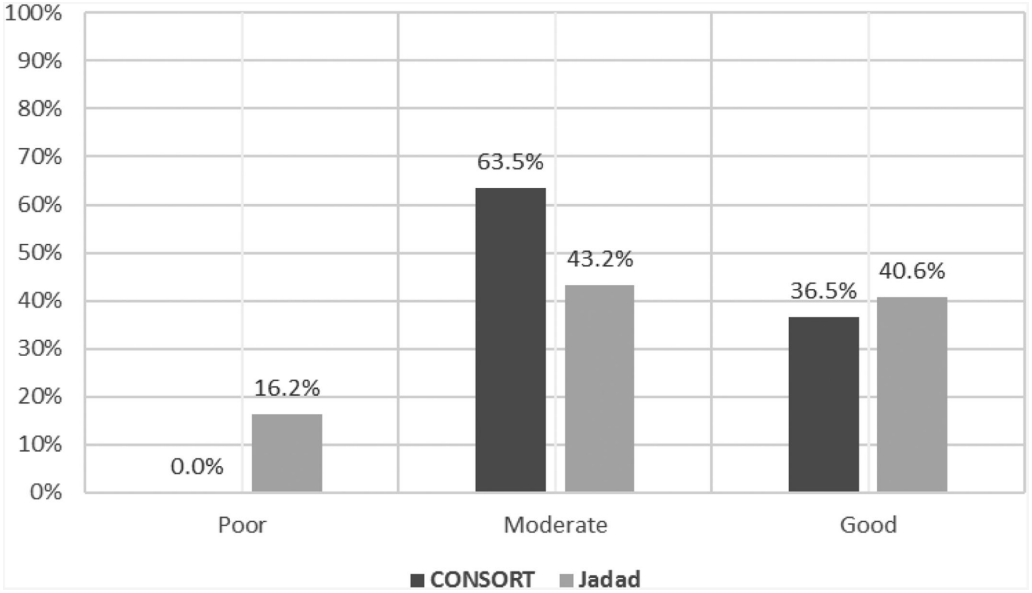

FIGURE 2 Summary of scores from all Indonesian pediatric RCTs included

4.1 | Jadad scale

What is worth noting from Moher's study is that the lowest mean score in Jadad scale was in the report on blinding (mean of 0.6) which somewhat similar to our results, in which mean score for blinding in Jadad scale was only 0.8. Most of the RCTs included in our study mentioned that blinding process was conducted, yet the authors failed to elaborate the whole blinding protocol, how it was done, and whether single, double or triple blinding was used. Another study by Deveraux et al looked upon investigators' understanding about blinding and found that most had a different interpretation as to what is a single, double or triple blinding.[9] With different understanding among the investigators (and undoubtedly clinicians), elaboration of blinding would be important to allow judgment of trial's validity by readers.

Elaboration of the randomization process by Indonesian authors was satisfactory (mean score of 1.2) compared to other global pediatric RCTs assessed by Moher et al (mean score of 0.8). Though all study always mentioned that randomization was done, many of them did not elaborate the exact procedures. It should be noted that randomization is the basis of a good clinical trial; it minimizes confounding bias and allows all participants (with their unique initial conditions) to have similar chance to be allocated into treatment or control group.[10] Without elaboration of randomization process, readers of RCT reports would not be able to judge or comprehend the degree of bias and validity that each trial may have. Echoing on the previous paragraph, understanding upon randomization and blinding processes can be different between investigators, thus elaboration of each process is essential.

Withdrawal report was somewhat sufficient in all of the studies included (75.7% of studies included a number of withdrawal with sufficient explanations). This result is better when compared to Moher et al study in which only 41.8% of the studies included gave sufficient explanations toward participants withdrawal. Knowing reasons for withdrawal is essential as it allows the reader to glimpse into whether there is any adverse reaction from the intervention assigned (or lack of it). It also allows readers to critically judge whether all participants in their original arm were included in the analysis, or only those who completed the study were analyzed (intention to treat analysis vs per protocol analysis).

Though criticized as an oversimplification of RCT report assessment, Jadad scale is pragmatic and easy to use especially by readers without prior advanced knowledge on research methods. Indonesian investigators should be reminded that mentioning blinding or randomization process is not sufficient if not accompanied by the procedures of the processes.

4.2 | Consolidated standards of reporting trial statement (CONSORT)

Highest score for CONSORT is achieved in the introduction category; it shows how Indonesian researcher put special emphasize upon the reasoning behind their studies. Yet there is still relatively low understanding upon writing a proper RCT title. There is still no consensus upon proper writing of RCT titles, some publication recommended that title should include the phrase "Randomised Controlled Trial," while other preferred shorter title without the inclusion of the aforementioned phrase.[11] CONSORT specifically recommends the addition of the word "randomized" in the title as to help ease journal indexing andidentification.

In Methods section, CONSORT asked for explanation whether any changes had been done to the method (3b) or outcome (6b) after trial commencement as they assume that study must have slight modifications to account for real conditions on the field. Only 4.1% (3b) and 9.5% (6b) of the studies included an explanation or mentioned any changes in their protocols (mostly regarding changes of sample size due to lack of participants). Researchers should be reminded that there is an importance in reporting any modification (or lack thereof) in their study; it helped others to be aware of any possible obstacles that the researchers might face while conducting the study. Contrary to

TABLE 3 Total CONSORT score for each item

Categories		Studies (n (%))
Title and abstract	1a	27 (29.7)
	1b	76 (83.8)
Introduction	2a	91 (100)
	2b	87 (95.9)
Method	3a	71 (78.4)
	3b	4 (4.1)
	4a	90 (98.6)
	4b	88 (97.3)
	5	86 (94.6)
	6a	88 (97.3)
	6b	9 (9.5)
	7a	36 (39.2)
	7b	25 (27.0)
	8a	42 (45.9)
	8b	36 (39.2)
	9	37 (40.5)
	10	44 (48.6)
	11a	33 (36.5)
	11b	77 (85.1)
	12a	81 (89.2)
	12b	75 (82.4)
Results	13a	70 (77)
	13b	59 (64.9)
	14a	87 (95.9)
	14b	87 (95.9)
	15	79 (86.5)
	16	61 (67.6)
	17a	36 (39.2)
	17b	36 (39.2)
	18	67 (75.7)
	19	53 (58.1)
Discussion	20	31 (33.8)
	21	87 (95.9)
	22	88 (97.3)
Other information	23	7 (8.1)
	24	2 (2.7)
	25	85 (93.2)

popular belief, to acknowledge and explain changes happening due to realistic boundaries on the field actually shows the researcher's integrity thus validity and reliability.[12]

Less than half of the studies (39.2%) reported how to estimate sample size (7a). Studies did mention the number of participants included, but that is not sufficient. Cohen et al have shown that due to insufficient sample size over half of the studies assessed resulted in not enough power to achieve statistical significance.[13]

In the Results section, CONSORT recommends that effect size and precision should be reported for primary and secondary outcomes (17a and 17b) in the form of 95% confidence interval (CI). However, only less than half of the studies (39.2%) included 95% CI of the clinical results. Including 95% CI of the clinical results is important as it may show important clinical results even if it did not give statistical significance.[14]

Only 33.8% of the studies reported limitations in their trials (20), quite probably because the investigators do not want their study to look weak. Reporting study limitations are important not only to judge its validity by readers but also to inform other researches who want to replicate the study so that they are able to make an improvement.

Trial registration number and access to the full protocol were only available in 8.1% and 2.7% of the international and national reports, respectively. As of recently, many publications require RCT to submit their study to a clinical registrar and attach their clinical trial registry number upon submission. This allows the investigator to at least share a minimum amount of data with other people and prevent the reader from conducting a redundant assessment of the same trial that might be submitted to more than one journal (by having a unique trial registry number). Availability of full trial protocols is also very limited among Indonesian pediatric RCTs due to the fact that most journals do not have access to the full protocol as a requirement when submitting an RCT report.

It is recommended for investigators conducting RCT to have a glimpse upon CONSORT's statement to see what compromises in a good trial report. Many of the checklist presents may be familiar; yet others, while very much necessary for the sake of validity and reliability, are often forgotten or overlooked.[15]

To the best of our knowledge, this study is the first of its kind and holds immense novelty value. This study will become a cornerstone in improving future RCTs conducted by researchers (in and outside of Indonesia). The weakness of this study is the fact that the scoring systems are still not fair as some points that supposedly holds more value than the others are treated as the same (for example, randomization and loss to follow-up hold the same values to one another). We have tried and use 2 different scoring system to negate this effect but the development of a future scoring system that would address this problem would be beneficial for future quality analysis.

There had been a common belief amongst Indonesian researchers that articles inn international publications would be of higher quality compared to the one in local publications. Some believe that international publications put higher scrutiny in the reviewing process. Through this study, we had shown that there is no real difference in the quality of studies published inside or outside of Indonesia. The researcher should strive to create good and reliable studies regardless of where they are going to publish those studies.

We conclude that even though there are several problems concerning topics in the conduct of pediatric RCTs by Indonesian investigators, the overall quality of the reports is fairly satisfactory. There is no significant difference in quality between studies published in international or local publications. Familiarizing investigators toward good conduct and reporting of RCT can improve the studies overall quality.

TABLE 4 Breakdown of Jadad score in each category for all studies included

		Randomization (out of 2)	Blinding (out of 2)	Withdrawal (out of 1)	Total
Mean (SD)		1.2 (0.6)	0.8 (0.8)	0.8*	2.8 (1.4)
Score n (%)	0	8 (8.1)	44 (48.6)	22 (24.3)	5 (5.4)
	1	50 (55.4)	22 (24.3)	69 (75.7)	10 (10.8)
	2	33 (36.5)	25 (27)	–	32 (35.1)
	3	–	–	–	7 (8.1)
	4	–	–	–	22 (24.3)
	5	–	–	–	15 (16.2)

*Standard deviation is not applicable.

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Appendix 1: CONSORT score

Section/topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomized trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
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 prespecified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomization			
Sequence	8a	Method used to generate the random allocation sequence	
Generation	8b	Type of randomization; details of any restriction (such as blocking and block size)	
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	
Concealment		describing any steps taken to conceal the sequence until interventions were assigned	
Mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	
	13b	For each group, losses and exclusions after randomization, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	

(Continues)

Section/topic	Item No	Checklist item	Reported on page No
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials, noninferiority and equivalence trials, nonpharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix 2: JADAD scale

Item	Maximum points	Descriptions
Randomization	2	1 point if randomization is mentioned 1 additional point if the method of randomization is appropriate Deduct 1 point if the method of randomization is inappropriate
Blinding	2	1 point if blinding is mentioned 1 additional point if the method of blinding is appropriate Deduct 1 point if the method of blinding is inappropriate
Withdrawals	1	1 point if the number and the reason for withdrawal in each group are stated