Reporting quality of randomized controlled trial abstracts: Survey of leading general dental journals

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Abstract

Background: The authors conducted a study to assess the reporting quality of randomized controlled trial (RCT) abstracts published in leading general dental journals, investigate any improvement after the release of CONSORT for Abstracts guidelines, and identify factors associated with better reporting quality.

Methods: RCTs published in ten leading general dental journals, during 2005-2007 (Pre-CONSORT period) and 2010-2012 (Post-CONSORT period), were searched via PubMed. Reporting quality of included abstracts was evaluated and scored using the original 16-item CONSORT for Abstracts checklist. Risk ratio and the *t* test were used to compare the adequate reporting rate of each item and the overall quality in two periods, respectively. Univariate and multivariate regressions were used to identify predictors of better reporting quality.

Results: 276 RCT abstracts were included and evaluated. Significantly more checklist items were reported during the Post-CONSORT (mean±SD, 4.53±1.69) period than the Pre-CONSORT period [3.87±1.10; mean difference -0.66 (95% CI: -0.99, -0.33); P<0.001]. Three items including interventions, objective and conclusions were adequately reported in most of the abstracts (>80%). In contrast, sufficient reporting of randomization, recruitment, outcome in the results section and funding were seen in none of the Pre-CONSORT abstracts and less than 2% of the Post-CONSORT abstracts. Based on the multivariate analysis, a higher impact factor (P<0.001) and a publication date in the Post-CONSORT period (P=0.003) were significantly associated with higher reporting quality.

Conclusions: The reporting quality of RCT abstracts from leading general dental journals has improved significantly, but there is still room for improvement.

Practical Implications: Joint efforts by authors, reviewers, journal editors and other stakeholders to improve the reporting of dental RCT abstracts are needed.

Key Words:

randomized controlled trials, abstracts, dentistry, CONSORT, research design, data reporting.

Introduction

In evidence-based medicine, high quality, well-designed and well-conducted randomized controlled trials (RCTs) are considered evidence of the highest grade in the hierarchy of research design, [1] gold standard to investigate benefits and harms of medical interventions, [2] and also the ideal research design in dental clinical trials. [3] Due to the significant impact of RCTs on health care, the Consolidated Standards for Reporting Clinical Trials (CONSORT) was introduced and updated to improve the reporting quality and standardize the conduct of RCTs.[4-7]

Since abstracts are the first and usually the only part of a research report that is read, good reporting of abstracts is vital. [8] Previous studies have shown that only 45% of conference abstracts will be published subsequently in full length [9], and around 50% of biomedical research is behind the paywall. [10] Thus, readers often rely on abstracts to initially assess a study, decide whether or not to retrieve more information (e.g. the full-text), or even inform their health-care decision-making. A well-written abstract should therefore contain sufficient information regarding the study, help readers to assess the validity and applicability of the findings, and aid the retrieval of research reports from databases. [6]

Considering the importance of abstracts, an extension of CONSORT Statement specifically for reporting RCT abstracts in journal and conference proceedings was developed and published in 2008.[6] However, after the release of these guidelines, reporting quality of RCT abstracts in leading medical and dental specialty journals was reported to remain suboptimal. [11-16]

RCTs from high-impact general medical journals are considered to have high potential to influence clinical practice. [17] Similarly, with their high impact factors and wide readerships, RCTs published in high-impact general dental journals are likely to impact dental practice to the same extent. However, the reporting quality of RCT abstracts from leading general dental journals has not yet been assessed. Thus, the aims of this study were to evaluate the reporting quality of RCT abstracts from leading general dental journals, to investigate any improvement in reporting quality after the release of CONSORT for Abstracts, and to identify possible predictors of better abstract reporting quality.

Materials and methods

Selection of Journals

Among general dental journals which publish papers from all dental specialties, ten journals with the highest impact factors (IF) in 2012 Journal Citation Report [18] were selected, i.e. *Journal of Dental Research* (JDR, IF=3.826), *Journal of Dentistry* (JOD, 3.2), *International Journal of Oral Science* (IJOS, 2.719), *Oral Diseases* (OD, 2.377), *Clinical Oral Investigations* (COI, 2.2), *Journal of the American Dental Association* (JADA, 1.822), *Odontology* (ODT, 1.576), *European Journal of Oral Sciences* (EJOS, 1.42), *Australian Dental Journal* (ADJ, 1.371) and *Acta Odontologica Scandinavica* (AOS, 1.358).

Search Strategy

As the CONSORT extension for Abstract was released in January 2008, we planned to retrieve RCT abstracts published before or at least 2.5 years after this date, allowing for the dissemination and endorsement of these guidelines. Therefore, all RCT abstracts published during July 2005–June 2007 (Pre-CONSORT group) or July 2010–June 2012 (Post-CONSORT group) in the ten selected journals were to be obtained. The MEDLINE database was searched via the PubMed search engine on December 25, 2012. An extended version of the Cochrane Highly Sensitive Search Strategy for retrieval of randomized studies was modified and adopted (e-Table 1). [19]

Inclusion and Exclusion Criteria

According to the Cochrane criteria for selection of RCTs, predefined inclusion criteria were: human participants, interventions associated with healthcare, experimental studies, presence of a control group, as well as randomization of participants to the study/control group.[16] Articles of the following kinds were excluded: (1) editorial/letter/case report; (2) review/systematic review/meta-analysis; (3) laboratory-based studies; (4) not a RCT (observational study/controlled clinical study); (5) not conducted on human; (6) methodology studies (studies that dealt with the design and conduct of RCTs).

All references retrieved were compiled into a reference manager software with all identifiers (journal

name, author name and address) removed to ensure blinded study selections as well as quality assessments. Two authors (FH and LD) performed the selection process independently using the specified inclusion and exclusion criteria. Any disagreement was resolved by consultation with two experts (HJ and HH) until consensus was reached. For studies whose abstracts did not enable identification as RCTs, full texts were retrieved and scrutinized.

Pilot Study

Before assessing the quality of included abstracts, a pilot study was performed to indicate necessary refinements of the checklist and calibrate reviewers. Of the original 17 items of CONSORT for Abstracts checklist, one item ("authors") specific to conference abstracts was excluded. [6] After initial calibration, two reviewers (FH and LD) evaluated independently 10 randomly selected abstracts by referring directly to the checklist and associated explanations.[6] The inter-rater agreement assessed using Cohen Kappa statistic was good (0.903).

Data Extraction and Evaluation Method

The reporting quality of included abstracts was evaluated by checking whether the criteria of the 16 items were met adequately. An individual item was scored "1" if it was reported adequately, and "0" if the reporting was inadequate. Then for each abstract, scores for all 16 items were totaled to calculate an overall CONSORT score (OCS). For the OCS, possible scores range from 0 to 16. During the quality assessment, reporting of 11 sub-items of applicable CONSORT quality items, as suggested in the explanation of CONSORT for Abstracts checklist [6], were also recorded to provide supplementary information. Additionally, the following data and descriptive information of each abstract were also extracted for reporting quality predictor analyses: number of authors, publication date, structure, word count, significance of the results, reporting of P value, and number of centers. Information on journal title and continent of origin was further obtained after the quality assessment process.

Two authors (FH and LD) evaluated the included abstracts and tabulated all extracted data independently and in duplicate. Any disagreement was resolved by consulting with two experts (HJ and

HH) until consensus was reached.

Statistical Analysis

Statistical analysis was performed with MS Excel (Microsoft Corporation, Redmond, Washington) and SPSS 19.0 software (IBM, Chicago, Illinois). Risk ratio (RR) was calculated to assess difference in the adequate reporting rate of each item between different periods (Pre- vs. Post-CONSORT). Improvements in mean OCS by characteristics were analyzed using *t* test. In addition, linear regression analysis was conducted to identify factors associated with reporting quality (OCS). We used univariate analysis to determine associations between reporting quality and potential predictors, namely impact factor, publication date, number of authors, region of the first author, word count, structure, number of centers, reporting of P value and significance of main finding. Significant predictors in the univariate analysis were then entered individually during the multivariate modeling. Assessment of residuals did not indicate significant violation of normality. Tolerance and variance inflation factor (VIF) were used to detect multicollinearity. Predictor variables with a tolerance $\leqslant$ 0.1 and/or a VIF above 10 were excluded from the final model. [20] Any two-tailed P value less than 0.05 was considered statistically significant.

Results

Characteristics of Included Abstracts

Figure 1 shows the literature flow of this study. Our search strategy initially yielded 630 records. However, after application of inclusion and exclusion criteria, 276 trials remained. As shown in Table 1, the number of RCTs published in major general dental journals increased by 35.9% in the Post-CONSORT period, from 117 to 159. Most of the included abstracts were published in COI (29.0%), JDR (18.5%), JADA (15.2%) and JOD (14.9%). Typically, studies were carried out in a single-center (95.7%), in Europe (56.2%), and reported a statistically significant main outcome (66.3%). Only approximately half of the abstracts were structured (49.3%) and reported P values (57.2%).

Reporting of General Items

Table 2 illustrates the results of the assessment of each CONSORT checklist item/sub-item reported in the 276 included abstracts. Significantly more studies can be identified as randomized through titles in the Post-CONSORT group (44.0%; RR=2.15, 95% CI, 1.44, 3.19). Around one third of abstracts in both the Pre- (29.9%) and Post-CONSORT (35.2%) periods described the trial design. However, trial registration was only reported in 1 abstract (0.9%) and 18 abstracts (11.3%) during the Pre- and Post-CONSORT periods, respectively. Source of funding was only reported in 1 abstract (0.6%) from the Post-CONSORT sample.

Reporting of Trial Methodology

For the methods section, only objectives (Pre-CONSORT, 96.6%; Post-CONSORT, 98.1%) and details of interventions (Pre-CONSORT, 82.9%; Post-CONSORT, 81.1%) were adequately reported in most abstracts. Although eligibility criteria for participants were reported in nearly half of the included abstracts, data collection settings were rarely mentioned (Pre-CONSORT, 10.3%; Post-CONSORT, 6.3%). Primary outcome for the trial was stated significantly more frequently during the Post-CONSORT period (RR=6.26, 95% CI: 1.47, 26.54), but still this item was only adequately reported in 17 abstracts (10.7%). In addition, 13.7% of the Pre-CONSORT abstracts and 6.9% of the Post-CONSORT abstracts failed to mention random assignment. Methods of sequence generation was reported in only 3 abstracts, and the method for allocation concealment was seen in only 1 abstract from the Post-CONSORT group. Approximately 20% of the included abstracts used “single-blind” or “double-blind” to describe blinding, while only 8.5% of the Pre-CONSORT sample and 6.3% of the Post-CONSORT sample specified exactly who were blinded.

Reporting of Trial Results

33.3% of the Pre-CONSORT sample and 40.9% of the Post-CONSORT sample reported the number of participants randomized to each group. However, only 3 abstracts during Pre-CONSORT period (2.6%) and 14 during the Post-CONSORT period (8.8%; RR=3.43, 95% CI: 1.01, 11.68) stated the number of participants analyzed in each group. Only 7 of the included 276 abstracts indicated adoption of the

intention-to-treat or per-protocol analysis. Additionally, of the 19 abstracts which stated the primary outcome measure in the methods section, only 8 from the Post-CONSORT sample (5.0%) reported subsequently the primary outcome results for each intervention group, only 3 of them reported the effect size and its precision for the primary outcome. Besides, only 9 abstracts during the Pre-CONSORT period (7.7%) and 15 during the Post-CONSORT period (9.4%) reported adverse events or side effects.

Reporting of Trial Conclusions

Most abstracts (94.9% before CONSORT and 98.1% after CONSORT) reported adequately the conclusions of the trial, which were consistent with the trial results. However, only 3.4% of the Pre-CONSORT group and 2.5% of the Post-CONSORT group stated both benefits and harms of the trial in conclusions section.

Overall CONSORT Score (OCS)

Table 3 shows the mean OCS for each study period. Of the included abstracts, the mean OCS was significantly higher for studies published in the Post-CONSORT period (mean±SD, 4.53±1.69) than those published in the Pre–CONSORT period [3.87±1.10; mean difference -0.66 (95% CI: -0.99, -0.33); P<0.001].

Factors Associated with Reporting Quality

Table 4 demonstrates the results of linear regression analysis. In the univariate analysis, we found 7 potential factors significantly associated with reporting quality of RCT abstracts. A greater OCS was associated with a higher impact factor, more authors, reporting of P values, first author from Asia, publication date after CONSORT, being published in JDR, and being carried out in multiple centers. In the multivariate analysis, journal of publication was excluded due to significant multicollinearity bias (tolerance<0.001). And among the 6 entered factors, only impact factor (B=0.44; 95% CI: 0.24, 0.65; P<0.001) and publication date (B=0.53; 95% CI: 0.18, 0.89; P=0.003) remained significant predictors of greater OCS. The R^2 of the final model was relatively low (R^2 16.8%; adjusted R^2 13.7%), indicating other factors not included in this model are likely to influence the OCS.

Discussion

In this study, 276 RCT abstracts from ten leading general dental journals were identified and assessed. The results suggest that reporting quality improved significantly after the release of CONSORT for Abstracts guidelines, but further improvement is still needed. Only three checklist items including interventions, objective and conclusions were reported adequately in most abstracts, while all other items were reported adequately in less than half of the abstracts. Although four CONSORT items (title, outcome in the methods section, numbers analyzed and trial registration) were reported significantly better during the Post-CONSORT period, they were under reported in both periods. No abstract in the Pre-CONSORT sample adequately reported the details of randomization, outcome in the results section and source of funding, while only very slight improvements in these domains were found in the Post-CONSORT group. The pattern of inadequate reporting found in this study is generally in line with recent studies concerning reporting quality of abstracts in dental specialty journals. [13, 14, 16]

The CONSORT for Abstracts guidelines [6] placed huge emphasis on the transparent and detailed reporting of key elements in methodology and results domains, such as allocation concealment, undesired effects, and source of funding etc. Previous research had revealed that trials with inadequate allocation concealment tend to generate exaggerated treatment effects [21]; insufficient reporting of undesirable effects hampers readers in making balanced decisions [6]; and that studies funded by industry tend to have higher odds of outcomes favoring the sponsors [22]. Adequate information in these aspects is therefore crucial for both readers and reviewers. But unfortunately, these items were typically under reported in dental RCT abstracts. [13, 14] However, better reporting were noticed in top-tier medical journals.[15, 23] According to Ghimire *et al* [15], of the RCT abstracts published in four high-impact general medical journals in 2010, 11.8% described allocation concealment, 42.8% mentioned harms, 47.6% stated the source of funding, and 99.3% reported trial registration. This highlights the potential influence of impact factor on reporting quality of abstracts.

In the present study, after multivariate modeling only impact factor and publication date remained significant predictors of abstract reporting quality, indicating that higher impact factor and publication after CONSORT were significantly associated with higher OCS. This finding is in keeping with several recent similar studies. [24, 25] The correlation between impact factor and quality of a journal has been under debate. [26, 27] Possible explanations for the positive association between reporting quality of RCT abstracts and IF include stricter peer review [24], higher rate of CONSORT adoption [25], as well as more active editorial policy to implement CONSORT guidelines [28]. Actually, previous research has shown that mentioning of the CONSORT for Abstracts guidelines in the instructions for authors and an active policy to implement them can lead to improvements in RCT abstracts reporting. [28] Thus, further improvement in general dental journals can be expected if relevant editors adopt these guidelines in the same manner. However, another possible reason is that some quality items are missing in the full publication, and therefore unreported in trial abstracts. A former study has indicated that RCTs from higher impact journals tend to report more details than those from lower impact journals [29], and this may lead to better reporting of abstracts in high impact dental journals.

Significant improvement of OCS during Post-CONSORT period was confirmed in the linear regression analyses. This is consistent with recent studies on reporting quality of RCT abstracts in general medical journals [23] and oncology research [24]. Comparisons of adequate reporting rates of each quality item between periods indicated that this significant change could mainly be attributed to significant improvements in four domains, including title, outcome in the methods section, numbers analyzed and trial registration. However, unlike our findings, several similar studies found no or only slight improvement in RCT abstract reporting over time. [13, 30] One possible reason for this difference is the starting date (July 2010) we designed for the Post-CONSORT group, which was much later than the abovementioned studies. Considering the time needed for dissemination and endorsement of relevant guidelines, and the time usually spent from paper drafting to final publication, a time frame of more than 30 months should be more capable of revealing the true difference between periods. [15, 24]

Inadequate reporting of information in abstracts has been attributed to lack of structure. [31, 32] The CONSORT for Abstracts guidelines strongly recommended the use of structured abstracts. [6] However, in this study, no significant difference between structured and unstructured formats was detected. Similar findings were reported in studies concerning RCT abstracts in general medical [15] and orthodontic journals [14]. This is in support of the notion that abstract format may not be a definitive factor predicting reporting quality [25], and that other factors may have a greater impact on reporting quality of RCT abstracts [14].

Word limit was another commonly considered key constraint for detailed reporting. [13, 15, 17] A recent study [25] found significant associations between word count and reporting quality of abstracts in cancer nursing research. However, this association was not confirmed in our analysis. Our finding is in keeping with several similar studies [14, 16], and in support of the notion that a higher word count does not guarantee a good reporting quality [25]. Nevertheless, the CONSORT group stated that a length of 250-300 words would be adequate to address all items in the checklist. [6] Although since the year of 2000 MEDLINE has increased its word limit for abstract to almost 1,000 [13], at present leading general dental journals are still using a word limit of 250 (JOD, COI, JADA, ODT, AOS) or 200 (JDR, EJOS, OD, ADJ). Considering the relatively poor abstract reporting quality found in the included journals, an upward adjustment of their word limits would be advisable.

Another interesting finding is that as much as 13.7% of the Pre-CONSORT abstracts and 6.9% of the Post-CONSORT abstracts did not mention randomization at all. Only after scrutiny of the full-texts were these trials identified as RCTs. Similar finding was also reported in a study on RCT abstracts in periodontology. [13] Importance of reporting RCT abstracts according to the CONSORT guidelines is further highlighted by this phenomenon. Previous data has shown that researchers and healthcare decision makers relying on using the search term “RCT [publication type]” in Medline have been missing important evidence due to inappropriate indexing.[33] Trials that fail to “label” themselves “RCTs” are at risk of being not properly indexed, and are likely to be overlooked by readers, reviewers and other relevant stakeholders.

Our study has several limitations. Firstly, a random sample of RCTs published in general dental journals was not taken, and thus our findings may not be representative of all general dental journals. However, selecting abstracts based on the impact factor has been widely used in similar studies [12-16, 23], and we have included half of the 20 general dental journals listed under the "Dentistry, Oral Surgery & Medicine" category of 2012 Journal Citation Reports [18]. Secondly, by using linear regression we found a significant positive association between impact factor, publication date and abstract reporting quality. But judging by the R^2 value, our final model can only explain about 15% of the variation of OCS. Other potential factors, such as journal endorsement, awareness of editors and involvement of statisticians, might also have influence on OCS [24, 34]. However, these are beyond the scope of this study and could be investigated in further research. Lastly, a comparison of the included abstracts and their corresponding full articles was beyond our scope, thus our study cannot indicate whether the relatively poor abstract reporting quality was due to inadequate reporting only, or also poor methodological quality of the trial. Reporting quality and methodological quality of trials are two different dimensions [35], and are evaluated in different ways [13, 36, 37]. Interestingly however, a previous study evaluating RCT articles in dental specialty journals, as compared to our findings, has shown better reporting in most items such as description of settings (adequate reporting rate, 65%) and allocation concealment (22%) [34]. This suggests that at least a certain proportion of poor abstract reporting results from reporting behavior itself, not methodological quality of the study.

Despite these, our study has several strengths. It is the first evaluation of the reporting quality of RCT abstracts published in general dental journals. A validated highly sensitive search strategy for the retrieval of RCTs using PubMed was utilized, with a large number of recent RCT abstracts identified and included from ten leading general dental journals. In addition, quality assessment was conducted using the original CONSORT for Abstracts checklist.

Conclusions

- There has been an improvement in the overall reporting quality of RCT abstracts published in leading general dental journals after the release of CONSORT for Abstracts guidelines, but there is still room for further improvement.
- A significant positive association between abstract reporting quality and journal impact factor was found.
- Reporting of results and some methodological domains was particularly inadequate.
- Journal endorsement and active implementation of the CONSORT for Abstracts guidelines are recommended.

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Tables

e-Table 1. The search strategy used in this study (as of December 25, 2012)

Electronic Database	Search Strategy	No. of Hits
PubMed	(randomized controlled trial[Publication Type] OR randomized controlled trials[MeSH Terms] OR random allocation[MeSH Terms] OR double-blind method[MeSH Terms] OR single-blind method[MeSH Terms]) OR ((single*[Text Word] OR doubl*[Text Word] OR trebl*[Text Word] OR tripl*[Text Word]) AND (mask*[Text Word] OR blind*[Text Word])) OR random*[Text Word] NOT (animal[MeSH Terms] NOT human[MeSH Terms]) NOT (review[Publication Type] OR "meta analysis"[Publication Type]) AND ("Journal of dental research"[Journal] OR "Journal of dentistry"[Journal] OR "International Journal of Oral Science"[Journal] OR "Oral diseases"[Journal] OR "Clinical oral investigations"[Journal] OR "Journal of the American Dental Association (1939)"[Journal] OR "Odontology"[Journal] OR "European journal of oral sciences"[Journal] OR "Australian dental journal"[Journal] OR "ACTA ODONTOL SCAND"[Journal]) AND (("2005/07/01"[Date - Publication] : "2007/06/30"[Date - Publication]) OR ("2010/07/01"[Date - Publication] : "2012/06/30"[Date - Publication]))	630

Table 1. Characteristics of included abstracts

Characteristic	Category	Pre-CONSORT (N=117), n (%)	Post-CONSORT (N=159), n (%)	Overall (N=276), n (%)
Journal	JDR	23 (19.7)	28 (17.6)	51 (18.5)
	JOD	18 (15.4)	23 (14.5)	41 (14.9)
	OD	5 (4.3)	4 (2.5)	9 (3.3)
	COI	23 (19.7)	57 (35.8)	80 (29.0)
	JADA	24 (20.5)	18 (11.3)	42 (15.2)
	ODT	1 (0.9)	1 (0.6)	2 (0.7)
	EJOS	13 (11.1)	8 (5.0)	21 (7.6)
	ADJ	1 (0.9)	10 (6.3)	11 (4.0)
	AOS	9 (7.7)	10 (6.3)	19 (6.9)
Continent	Africa	0 (0.0)	3 (1.9)	3 (1.1)
	Asia	8 (6.8)	28 (17.6)	36 (13.0)
	Europe	72 (61.5)	83 (52.2)	155 (56.2)
	North America	26 (22.2)	16 (10.1)	42 (15.2)
	Oceania	1 (0.9)	4 (2.5)	5 (1.8)
	South America	10 (8.5)	25 (15.7)	35 (12.7)
Number of authors	<4	23 (19.7)	25 (15.7)	48 (17.4)
	4~7	87 (74.4)	108 (67.9)	195 (70.7)
	>7	7 (6.0)	26 (16.4)	33 (12.0)
Word count	<200	40 (34.2)	41 (25.8)	81 (29.3)
	200~250	59 (50.4)	62 (39.0)	121 (43.8)
	250~300	17 (14.5)	46 (28.9)	63 (22.8)
	>300	1 (0.9)	10 (6.3)	11 (4.0)
Structured format	Yes	56 (47.9)	80 (50.3)	136 (49.3)
	No	61 (52.1)	79 (49.7)	140 (50.7)
P value	Yes	60 (51.3)	98 (61.6)	158 (57.2)
	No	57 (48.7)	61 (38.4)	118 (42.8)
Trial outcome	Positive	77 (65.8)	106 (66.7)	183 (66.3)
	Negative	40 (34.2)	53 (33.3)	93 (33.7)
Centers	Single center	115 (98.3)	149 (93.7)	264 (95.7)
	Multi-center	2 (1.7)	10 (6.3)	12 (4.3)

Table 2. Reporting of each CONSORT checklist item and sub-item by publication period

Items	Criteria and sub-items	Pre-CONSORT (N=117), n (%)	Post-CONSORT (N=159), n (%)	Risk Ratio (95% CI)
1. Title	Identification of the study as randomized	24 (20.5)	70 (44.0)	2.15 (1.44, 3.19)
2. Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	35 (29.9)	56 (35.2)	1.18 (0.83 1.67)
3. Participant	Eligibility criteria for participants and the settings where the data were collected	9 (7.7)	7 (4.4)	0.57 (0.22, 1.49)
	3a. Eligibility criteria for participants	58 (49.6)	84 (52.8)	1.07 (0.84, 1.35)
	3b. Settings of data collection	12 (10.3)	10 (6.3)	0.61 (0.27, 1.37)
4. Interventions	Interventions intended for each group	97 (82.9)	129 (81.1)	0.98 (0.88, 1.09)
5. Objective	Specific objective or hypothesis	113 (96.6)	156 (98.1)	1.02 (0.98, 1.06)
6. Outcome 1 [a]	Clearly defined primary outcome for this report	2 (1.7)	17 (10.7)	6.26 (1.47, 26.54)
7. Randomization	How participants were allocated to interventions	0 (0.0)	1 (0.6)	NE
	7a. Random assignment	101 (86.3)	148 (93.1)	1.08 (0.99, 1.17)
	7b. Sequence generation	2 (1.7)	1 (0.6)	0.37 (0.03, 4.01)
	7c. Allocation concealment	0 (0.0)	1 (0.6)	NE
8. Blinding (Masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded	10 (8.5)	10 (6.3)	0.74 (0.32, 1.71)
	8a. Generic description only (e.g., single-blind, double-blind)	23 (19.7)	36 (22.6)	1.15 (0.72, 1.84)
9. Numbers randomized	Number of participants randomized to each group	39 (33.3)	65 (40.9)	1.23 (0.89, 1.68)
10. Recruitment	Trial status (e.g. whether it is still ongoing, closed to recruitment, or closed to follow-up)	0 (0.0)	2 (1.3)	NE
11. Numbers analyzed	Number of participants analyzed in each group	3 (2.6)	14 (8.8)	3.43 (1.01, 11.68)
	11a. Intention-to-treat analysis or per-protocol analysis	3 (2.6)	4 (2.5)	0.98 (0.22, 4.30)
12. Outcome 2 [b]	For the primary outcome, a result for each group and the estimated effect size and its precision	0 (0.0)	3 (1.9)	NE
	12a. Primary outcome result for each group	0 (0.0)	8 (5.0)	NE
	12b. Estimated effect size	0 (0.0)	3 (1.9)	NE
	12c. Precision of the estimate (e.g., CI 95%)	0 (0.0)	3 (1.9)	NE
13. Harms	Important adverse events or side effects	9 (7.7)	15 (9.4)	1.23 (0.56, 2.71)
14. Conclusions	General interpretation of the results	111 (94.9)	156 (98.1)	1.03 (0.99, 1.08)
	14a. Benefits and harms balanced	4 (3.4)	4 (2.5)	0.74 (0.19, 2.88)
15. Trial registration	Registration number and name of trial register	1 (0.9)	18 (11.3)	13.25 (1.79, 97.81)
16. Funding	Source of funding	0 (0.0)	1 (0.6)	NE

[a] Outcome reported in Materials and Methods section.

[b] Outcome reported in Results section.

NE: not estimable due to zero cell counts.

Table 3. Mean overall CONSORT score (OCS) by characteristics

Characteristic	Category	Mean OCS (SD)	
		Pre-CONSORT	Post-CONSORT
Journal	JDR	4.35 (1.23)	5.68 (2.41) *
	JOD	4.22 (0.94)	4.57 (1.27)
	OD	4.60 (0.89)	3.50 (1.29)
	COI	3.61 (0.99)	4.53 (1.44) **
	JADA	3.25 (1.03)	3.83 (1.25)
	ODT	4.00 (NA)	4.00 (NA)
	EJOS	3.54 (0.66)	3.38 (1.30)
	ADJ	3.00 (NA)	3.50 (1.27)
	AOS	4.44 (1.13)	4.90 (1.10)
Continent	Africa	NA	4.33 (1.53)
	Asia	4.25 (1.49)	4.61 (1.79)
	Europe	3.99 (1.03)	4.63 (1.64) **
	North America	3.42 (1.17)	4.25 (1.57)
	Oceania	4.00 (NA)	4.25 (1.71)
	South America	3.90 (0.88)	4.36 (1.93)
Number of authors	<4	3.70 (1.15)	4.20 (1.63)
	4~7	3.95 (1.09)	4.44 (1.61) *
	>7	3.43 (0.98)	5.23 (1.93) *
Word count	<200	3.98 (1.35)	4.85 (1.96) *
	200~250	3.78 (0.97)	4.37 (1.76) *
	250~300	4.00 (0.87)	4.54 (1.44)
	>300	3.00 (NA)	4.10 (0.88)
Structured format	Yes	3.84 (1.13)	4.28 (1.39)
	No	3.90 (1.08)	4.78 (1.92) **
P value	Yes	4.05 (1.08)	4.69 (1.68) **
	No	3.68 (1.09)	4.26 (1.67) *
Trial outcome	Positive	3.79 (1.09)	4.69 (1.73) ***
	Negative	4.03 (1.10)	4.21 (1.57)
Centers	Single center	3.86 (1.08)	4.46 (1.65) ***
	Multi-center	4.50 (2.12)	5.50 (2.07)
Overall		3.87 (1.10)	4.53 (1.69) ***

NA: not applicable.

* P<0.05; ** P<0.01; *** P<0.001.

Table 4. Univariate and multivariate linear regression derived coefficients and 95% confidence intervals, with overall CONSORT score (OCS) as the dependent variable for the included 276 abstracts.

		Univariate		Multivariate [a]			
Predictor	Category/unit	B	95% CI	B	95% CI	Tolerance	VIF
Journal	JDR	Reference					
	JOD	-0.66	(-1.25, -0.08) *				
	OD	-0.97	(-1.98, 0.04)				
	COI	-0.82	(-1.32, -0.32) ***				
	JADA	-1.58	(-2.16, -1.00) ***				
	ODT	-1.08	(-3.09, 0.93)				
	EJOS	-1.60	(-2.33, -0.88) ***				
	ADJ	-1.62	(-2.55, -0.70) **				
	AOS	-0.39	(-1.14, 0.36)				
Impact factor	Per unit	0.50	(0.30, 0.70) ***	0.44	(0.24, 0.65) ***	0.93	1.08
Continent	Asia	Reference		Reference			
	Africa	-0.19	(-1.96, 1.57)	0.08	(-1.59, 1.76)	0.91	1.10
	Europe	-0.20	(-0.74, 0.35)	0.10	(-0.42, 0.62)	0.41	2.44
	North America	-0.79	(-1.46, -0.12) *	-0.40	(-1.05, 0.24)	0.51	1.96
	Oceania	-0.33	(-1.73, 1.08)	-0.16	(-1.49, 1.17)	0.87	1.15
	South America	-0.30	(-1.00, 0.40)	-0.16	(-0.82, 0.49)	0.58	1.74
Publication date	Pre-CONSORT	Reference		Reference			
	Post-CONSORT	0.66	(0.31, 1.01) ***	0.53	(0.18, 0.89) **	0.89	1.12
Number of authors	1 Person	0.07	(0.02, 0.13) *	0.02	(-0.04, 0.08)	0.83	1.21
Word count	1 word	0.00	(-0.01, 0.00)				
Structured format	No	Reference					
	Yes	-0.30	(-0.66, 0.05)				
P value	No	Reference		Reference			
	Yes	0.47	(0.11, 0.82) *	0.32	(-0.03, 0.66)	0.93	1.08
Trial outcome	Negative	Reference					
	Positive	0.18	(-0.19, 0.56)				
Centers	Single center	Reference		Reference			
	Multi-center	1.13	(0.27, 2.00) *	0.87	(0.00, 1.74)	0.86	1.16

[a] For multivariate analysis, constant=2.543, R^2=0.168, adjusted R^2=0.137, P<0.001.

* P<0.05; ** P<0.01; *** P<0.001.

Figure Legend

Fig. 1: Flow chart of the included abstracts.