ORIGINAL ARTICLE REPORTING QUALITY OF RANDOMIZED Check for updates CONTROLLED TRIALS OF PERIODONTAL DISEASES IN JOURNAL ABSTRACTS—A CROSS-SECTIONAL SURVEY AND BIBLIOMETRIC ANALYSIS

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KEY WORDS

Periodontal diseases, Randomized Controlled Trials, Abstracts, Consolidated Standards of Reporting Trials (CONSORT), Bibliometrics, Journal Impact Factor

Source of Funding: No research funding was obtained for this study. Conflict of Interest: The authors have no actual or potential conflicts of interest.

Received 26 November 2016; revised 14 August 2017; accepted 28 August 2017

J Evid Base Dent Pract 2018: [130-141] 1532-3382/\$36.00

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ABSTRACT

Objective

Randomized controlled trials (RCTs) by proper design, conduct, analysis, and reporting provide reliable information in clinical care. Reporting of RCT abstracts is of equal importance as there is evidence that many clinicians will change their clinical decisions based on RCT abstracts. The reporting quality of RCT abstracts has been suboptimal. It is not clear whether the reporting quality is related to the journal metrics. The main objective of this study is to conduct a cross-sectional survey to evaluate the reporting quality of RCTs of periodontal diseases in journal abstracts and to perform a bibliometric analysis. The null hypothesis was that there is no association between the journal metrics (5-year impact factor, Eigenfactor score, and Article Influence Score), abstract metrics (word count, and number of authors), journal endorsement of Consolidated Standards of Reporting Trials (CONSORT), and the overall quality of reporting of CONSORT RCT abstract—modified checklist questions.

Materials

CONSORT RCT abstract extension checklist with explanation and elaboration was used and modified to assess the quality of reporting of RCT abstracts of periodontal diseases in the journal abstracts in the year 2012. Bibliometric analysis of journal metrics (5-year impact factor, Eigenfactor score, and Article Influence Score) and abstract metrics (number of authors and abstract word count), the geographic distribution, and the CONSORT-endorsing journal abstracts was compared with the reporting quality of RCT abstracts in periodontal diseases. Calibration and intrarater agreement were done before the data collection and analysis. A second reviewer was consulted for independent evaluation and clarification as needed. For descriptive analysis, the values of continuous variables were expressed as median and interquartile ranges (IQRs) and as proportion percent for binary categorical variables. For association analysis between the binary (yes/no) response variable and the continuous variable, the Mann–Whitney test (for independent samples) was used. For examining the

association between 2 categorical variables, Fisher's exact test was used. The chi-square test was performed to examine the association between 2 sets of binary response variables (yes/no). A P value of < .05 was considered statistically significant. All analyses were conducted using SAS, version 9.4.

Results

A total of 198 RCT abstracts of periodontal diseases in the year 2012 from 57 journals were included in the study. Fifteen journals, listed as endorsers of CONSORT, contributed 108 RCT abstracts. Four journals (Journal of Periodontology, Journal of Clinical Periodontology, Clinical Oral Implants Research, and European Journal of Oral Implantology) contributed 84 of 198 RCT abstracts in 2012. European countries contributed the majority (n = 81, 40.91%) of RCT abstracts. Among 31 countries in this study, United States contributed the most RCTs (n = 28, 14.14%) followed by India (24, 12.12%), Italy (n = 22, 11.11%), and Brazil (n = 20, 10.1%). The frequency of journal metrics were 5-year impact factor (median 2.316; IQR: 1.439-2.970); Eigenfactor score (0.00474; 0.00202-0.01395); and Article Influence Score (0.553; 0.382-0.755). The number of authors in 198 RCT abstracts ranged between 2 and 20 (median n = 5, IQR: 4-6), whereas the word count ranged between 48 and 569 (median 235, IQR: 205-269). All RCT abstracts reported the experimental interventions (checklist question #5, frequency 100%). Some items were almost always reported-participant eligibility criteria (#3, 99%); comparison interventions (#6, 99.5%); specific objective or hypothesis (#7, 99.5%); primary outcome (#8, 99.5%); and reporting trial results as a summary (#16, 98.5%). All RCT abstracts never reported how the allocations were concealed (#11, 0) and the source of funding for the trials (#23, 0). Some items were almost always never reported-the number of participants included in the analysis for each intervention (#15, 2%); trial registration number (#21, 2.5%); name of trial register (#22, 2.5%); and how the randomization or sequence generation was done (#22). Dismal reporting was noted in many checklist questions including the identification of the study as randomized in the title #1, 51%; design of the trial #2, 32.8%; trial setting #4, 3.5%; randomization #10, 3.5%; blinding #12, 21.7%; details about blinding #13, 8.1%; number of participants randomized to each intervention #14, 26.3%; effect size #17, 13.6%; precision of the estimate of the effect #18, 6.1%; and adverse effects #19, 14.1%. Strikingly, there was a very high reporting of statistical significance #25, 92.4%. European countries, in particular, reported relatively better than other countries in essential questions such as #17 effect size reporting, and #18 precision (uncertainty), which have been largely unreported by rest of the countries. Finally, despite the majority of RCTs published in 2012 were by CONSORT-endorsing journals, there was no difference in the quality of reporting in majority

of checklist items when compared with journals not listed as CONSORT endorsers. With few exceptions, there was no statistically significant association between the majority of the CONSORT RCT abstract checklist questions and the journal metrics and abstract metrics analyzed in this study. Unexpectedly, lower ranking journals in journal metrics reported certain essential checklist questions relatively better.

Conclusion

The reporting quality of RCT of periodontal diseases in the journal abstracts published in 2012 needs substantial improvement. These items have been laid out in this study to help all stakeholders–authors, clinicians, researchers, peer reviewers, journal editors, and publishers to take note and help with the improvement of the same. Despite few significant associations in the bibliometric factors analyzed with better reporting, the results overall led to the failure to reject the null hypothesis that there is no association between the journal metrics, word count, and number of authors and the quality of reporting of CONSORT RCT abstract–modified checklist questions.

INTRODUCTION

Randomized controlled trials (RCTs) provide the highest experimental evidence in clinical care. It forms the basis of sound systematic reviews and meta-analyses which are considered the highest levels of evidence to provide highest quality of clinical care. The research design includes randomization which eliminates bias to a great degree when conducted properly preventing other sources of bias such as allocation, attrition, performance, and assessment.¹ In addition, the cause and effect can be demonstrated effectively in an RCT.²

There is plethora of evidence that a majority of clinical trials have not been conducted appropriately due to various reasons including poor study design.^{3,4} Reporting of RCT has been suboptimal as well which led to the formation of an expert group toward developing standards in reporting. This group now well known as the Consolidated Standards of Reporting Trials (CONSORT) comprises of experts in research methodology, epidemiologists, and journal editors among others.⁵ Since 1993, several CONSORT statements and their revisions and extensions have been published to improve the quality of reporting of RCT.^{6,7} A recent systematic review concluded that the quality of reporting RCT has remained suboptimal⁸ and dental journals have been documented to have suboptimal reporting.⁹ The reporting of essential items crucial for the clinicians' decision-making such as randomization, blinding, and effect size are suboptimal. Transparent and clear reporting of trials has been called

for consistently and all stakeholders to share responsibility for such good quality reporting.^{10,11}

Abstracts of clinical research have long been considered to be important as it conveys the essence of a study in a short manner, and authors have been urged to submit an abstract of the research along with the full manuscript.^{12–14} There is evidence to show that abstracts are accessed more than the full-text articles¹⁵ and that abstracts are critical as clinical decisions can be made by clinicians without referring to the full text of the study due to various factors such as time constraints, lack of availability of full-text articles, and so forth.^{16–18} There have been some calls in the literature to improve the quality of reporting RCT abstracts in particular as the data contained in the abstract had deficiencies.^{19,20}

The CONSORT group recently introduced an extension to the CONSORT statement exclusively for journal and conference abstracts.^{21,22} This extension has been used to assess the reporting quality of journal abstracts in many health care fields, and the results have been suboptimal in general while there is some evidence that adherence to CONSORT statement may improve the situation.^{23–34}

Periodontal disease is a broad term referring to the many diseases affecting the periodontium—gingiva, periodontal ligament, cementum, and alveolar bone. The etiology can range from accumulation of bacterial biofilms causing plaque-induced gingivitis to autoimmune conditions such as mucus membrane pemphigoid.³⁵ Several 100 RCTs are published every year in periodontal diseases which will have an impact in clinical care of these diseases. The quality of reporting of RCT in dental journals in general has been suboptimal as mentioned previously⁹ which will in turn affect the interpretation of these important studies. Similarly, the reporting of RCT abstracts has been suboptimal as well.^{26,27,33,36}

Much of the literature on assessing the quality of reporting of clinical studies has focused on high-impact journals as they tend to reach a wider audience.^{4,26,28,37} However, bibliometric trends have revealed that studies originate in various parts of the world, and they are likely to be published in lesser known journals.^{38,39} Hence, it is important to assess the quality of reporting of RCT in all journals irrespective of their impact. There are several metrics in journals that are used to assess the quality of the journals. The most commonly used are impact factor and 5-year impact factor which rely on the number of citations of the article. The other 2 metrics are Eigenfactor score and Article Influence Score which take into consideration the impact of cited journals and also discount journal self-citation to be fair for new journals.^{40,41}

In dentistry, few studies^{26,27,33,36} have reported on the reporting quality of RCT abstracts. Overall, the quality of RCT abstract reporting has been suboptimal. However, all of them

were focused on certain subgroup of journals based on the specialty or journal metrics. Given the fact that RCT publications are increasing exponentially in the last few years and are being published by several journals,⁴⁰ it is imperative to assess the quality of reporting of RCT abstracts across all journals that publish in dentistry. There is a need for detailed documentation on the reporting quality of RCT abstracts on a wide range of Medline-indexed journals irrespective of their journal metric publishing on a specific topic in dentistry. In addition, there is a need to understand the association between various journal metrics (5-year impact factor, Eigenfactor score, and Article Influence score) and abstract metrics such as abstract word count to the reporting quality of RCT abstracts in periodontology. This information may help the researchers, clinicians, and journal editors and publishers to devise practical ways to improve the quality of reporting of RCT abstracts.

OBJECTIVE

The objective of this study is to conduct a cross-sectional survey to evaluate the reporting quality of RCTs of periodontal diseases in journal abstracts and to perform a bibliometric analysis.

Specific Aims

- To evaluate the reporting quality of RCTs of periodontal diseases in journal abstracts in the year 2012 using a modified checklist questions of CONSORT RCT abstract extension.
- 2) To compare the reporting quality of RCTs of periodontal diseases in journal abstracts and the
 - a) journal metrics as defined by the 5-year impact factor score, Eigenfactor score, and Article Influence Score;
 - b) number of words in the abstract;
 - c) number of authors; and
 - d) geographic region (countries and their respective continents) of corresponding author;
- To conduct subgroup analyses as described previously in 1 and 2 restricted to frequent journals and countries which publish the most number of RCTs.
- 4) To compare the reporting quality of RCTs of periodontal diseases in journal abstracts between CONSORT-endorsing journals and those who do not endorse CONSORT per CONSORT published list of journals in May 2015.

Null Hypothesis

There is no association between the journal metrics (5-year impact factor, Eigenfactor score, and Article Influence

Score), abstract metrics (word count and number of authors), journal endorsement of CONSORT, and the overall quality of reporting of CONSORT RCT abstract–modified checklist questions.

MATERIALS AND METHODS

Development of CONSORT RCT Abstract–Modified Checklist Questions

The original CONSORT for reporting randomized controlled trials in journal and conference abstracts has 17 items with description.²² This checklist is meant to be used for both journal and conference abstracts. A couple of items are required mainly for conference abstracts (author information and trial status). The rest of the 15 items are considered essential for any RCT abstract.

The CONSORT authors have recommended that this checklist be used with the explanation and elaboration document to extract the details that are necessary for optimal reporting.²¹ Many authors who have used this checklist have modified this checklist to aid in their assessment and also to get multiple information that may be embedded within 1 checklist item.^{24,42} It is very useful to obtain information on effect size which is only one of the criteria in evaluation of outcomes in the Results section of abstract, the other 2 being primary results and measure of the precision (confidence interval). In addition, many authors focus on the presentation of "P" value but more often do not present the effect size.⁴³⁻⁴⁵ Although the abstracts in general today follow a structured format, it is still common to see occasionally unstructured abstracts. Structured abstracts have been shown to improve understanding of the studies better.46,47

With the goal of being able to use the CONSORT RCT Abstract checklist effectively, a simple, modified checklist with focused 25 questions (Table 1, Available at www.jebdp. com) was prepared with the statements in the CONSORT RCT explanation document as the template for the questions.²¹

The expanded checklist allowed the authors to be very specific in quality assessment of individual abstracts. For example, in the primary outcome of the study, all 3 of the following measures were checked for reporting:

- for the primary outcome, report trial results as a summary of the outcome in each group (eg, the number of participants with or without the event or the mean and standard deviation of measurements)
 - this item ascertains the overall results in each group of the RCT.
- for the primary outcome, report the contrast between groups known as the effect size. For binary outcomes,

the effect size could be the relative risk, relative risk reduction, odds ratio, or risk difference. For survival time data, the measurement could be the hazard ratio or difference in median survival time. For continuous data, the effect measure is usually the difference in means.

- this item ascertains that the actual difference between the groups in the RCT is clearly mentioned.
- for the primary outcome, present the confidence intervals for the contrast between groups and as a measure of the precision (uncertainty) of the estimate of the effect. This item goes one step further to understand the confidence underlying the difference between the groups in the RCT.

RCT Abstract Search Process

National Library of Medicine database PubMed was searched to retrieve all the RCTs published under the Medline Subject Heading (MeSH) term "Periodontal Diseases." Filters applied were Languages: English; Species: Humans; Article Types: Randomized Controlled Trial; and Publication Dates–Custom Range: 2012/01/01-2012/12/31. The goal behind this specific search was to focus on search reproducibility rather than to capture as many RCTs as possible through multiple databases and using unrestricted search terms. A similar search was also conducted with the filter of Publication Dates–Custom Range: 2011/01/01-2011/12/31 to retrieve RCT from 2011. The journal and abstract metrics were collected from these RCT abstracts.

Calibration Phase-2011 RCT Abstracts

All the RCT citations and abstracts were retrieved for the year 2011 and were imported to EndNote X6 software (Thomson Reuters, Philadelphia, PA). The citations were sorted in the software to ensure only the 2011 citations were included (n = 193). For instance, 2012 RCT citations were included in the search that were published online early in 2011. A randomization online Web site (www.randomizer. org) was used to randomly produce 10 numbers between 1 and 193. The corresponding randomly chosen RCT abstracts were then evaluated with the CONSORT RCT abstract-modified checklist questions twice at 2 different time points (23 questions based on the original CONSORT RCT Abstract checklist were tested for calibration; questions 24 and 25 were not part of the original checklist and hence not included). The intrarater assessment was calculated using Cohen's kappa (κ) statistics. Excellent agreement was considered when $\kappa \geq 0.75$, fair when $\kappa = 0.40$ -0.74, and poor when $\kappa \leq 0.39$.

2012 RCT Abstract Data Collection Phase

All the RCT citations and abstracts retrieved for the year 2012 were imported to EndNote X6 software (Thomson

Reuters) as mentioned previously. The citations were sorted in the software to ensure only the 2012 citations and abstracts were included. For instance, 2013 RCT citations that were included in the search (published online early in 2012) was discarded.

INCLUSION CRITERIA

The inclusion criteria included only RCT abstracts in humans published in English in the year 2012 under the MeSH term "Periodontal Diseases" with clearly defined periodontal interventions and outcomes.

EXCLUSION CRITERIA

The exclusion criteria included RCT with no periodontal outcomes mentioned such as studies done in endodontics, prosthodontics, third molar surgery, and radicular cyst enucleation. Studies that are not RCTs such as observational study, animal studies, in vitro studies, ex vivo studies and secondary research such as cost-effectiveness study based on RCT were also excluded. Gray literature, theses, dissertations, and conference abstracts were not included. When in doubt, full-text articles were obtained to read the Materials and Methods section only to confirm eligibility.

Evaluation Using CONSORT RCT Abstract–Modified Checklist Questions

The final eligible abstracts were evaluated using the CON-SORT RCT abstract-modified checklist (25 questions). Bibliometric information was gathered simultaneously from Journal Citation Reports database during the evaluation and entered into an MS Excel data spreadsheet.

Second Reviewer

A periodontology senior graduate resident who is the second author (H.M., now a practicing periodontist) familiar with the CONSORT RCT abstract checklist evaluation was consulted as a second reviewer for selected checklist questions for a second independent evaluation and assessment.

Statistical Analysis

For descriptive analysis, the values of continuous variables were expressed as median and interquartile ranges and as proportion percent for binary categorical variables. For association analysis between the binary (yes/no) response variable and the continuous variable, the Mann–Whitney test (for independent samples) was used. For examining the association, that is, the association between 2 categorical variables, Fisher's exact test was used. The chi-square test was performed to examine the association between 2 sets of binary response variables (yes/no). A P value of < .05 was considered statistically significant. All analyses were conducted using SAS, version 9.4.

RESULTS

Calibration Phase-2011 RCT Abstracts

The modified checklist questions with details aided in easy assessment of the RCT abstract with a kappa mean score of 0.93 ± 0.08 indicating high intrarater agreement during calibration phase.

2012 RCT Abstract Data Collection Phase

The study flow diagram (Figure 1) illustrates clearly the search process and the excluded abstracts. The initial search yielded a total of 300 citations of which 227 abstracts were included for abstract eligibility analysis. A total of 198 abstracts were considered eligible for final analysis using the RCT abstract–modified checklist questions.

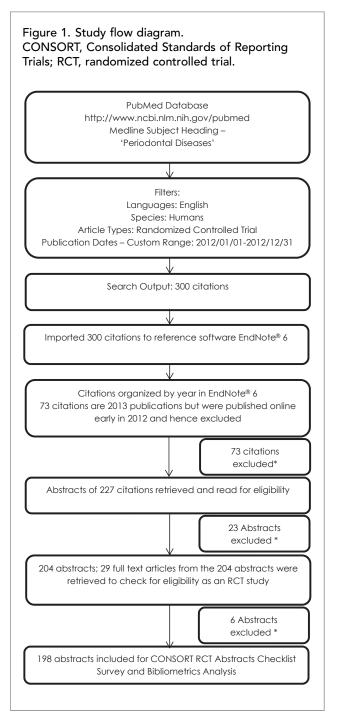
Second Reviewer

The second reviewer was consulted for 23 abstracts for further independent evaluation. The second reviewer was in agreement for majority (> 90%) of the responses of the first evaluation by the primary author (S.K.). The rare conflicts were solved with simple discussion, and the consensus was taken for final evaluation.

CONSORT RCT in Journal Abstract–Modified Checklist (25 Questions) Frequency

Table 2, Available at www.jebdp.com summarizes the main results of the 198 RCT abstracts evaluated on the CONSORT RCT abstract-modified checklist questions. All RCT abstracts reported the experimental interventions (checklist question #5, frequency 100%). Some items were almost always reported-participant eligibility criteria (#3, 99%); comparison interventions (#6, 99.5%); specific objective or hypothesis (#7, 99.5%); primary outcome (#8, 99.5%); and reporting trial results as a summary (#16, 98.5%). All RCT abstracts never reported how the allocations were concealed (#11, 0) and the source of funding for the trials (#23, 0). Some items were almost always never reportedthe number of participants included in the analysis for each intervention (#15, 2%); trial registration number (#21, 2.5%); name of trial register (#22, 2.5%); and how the randomization or sequence generation was done (#22). Dismal reporting was noted in many checklist questions including the identification of the study as randomized in the title (#1, 51%), design of the trial (#2, 32.8%), trial setting (#4, 3.5%), randomization (#10, 3.5%), blinding (#12, 21.7%), details about blinding (#13, 8.1%), number of participants randomized to each intervention (#14, 26.3%), effect size (#17, 13.6%), precision of the estimate of the effect (#18, 6.1%), and adverse effects (#19, 14.1%). Strikingly, there was a very high reporting of statistical significance (#25, 92.4%).

Although not part of the essential checklist item in CON-SORT, it was interesting to note that 92.4% of RCT abstracts reported "statistical significance," but only 13.6% and 6.1%



reported on the effect size and precision of the estimate of the effect, respectively.

Checklist questions (3, 5-8, 10, 11, 15, 16, and 21-23) that had total responses ranging between \leq 5 and \geq 189 out of 198 abstracts surveyed were excluded from all comparisons with journal and abstract metrics. There was discrepancy between the remaining 13 checklist questions (#1, #2, #4, #9, #12, #13, #14, #17, #18, #19, #20, #24, and #25) and were subjected to further analyses with the corresponding bibliometric data. In addition, journal subset and country subset analyses were performed to check if these factors had any association with reporting quality of RCT abstracts.

Comparison of Journal Metrics (5-Year Impact Factor, Eigenfactor Score, and Article Influence Score) and Abstract Metrics (Word Count and Number of Authors) with Selected CONSORT for RCT Abstract–Modified Checklist Questions

The Wilcoxon rank-sum test (Mann–Whitney *U* test) and 2-sample test were performed. Two-sided probability, P < .05, was considered statistically significant. The statistically significant results with salient notes are shown in Table 3, Available at www.jebdp.com.

Journal Frequency

Fifty-seven journals published 198 RCTs involving periodontal diseases in 2012. About half of the RCTs (49.49%) published in 2012 were from a total of 6 journals (*Journal of Periodontology, Journal of Clinical Periodontology, Clinical Oral Implants Research, European Journal of Oral Implantology, American Journal of Dentistry,* and *Clinical Implant Dentistry and Related Research*), whereas the remaining 50% were contributed in 51 journals (Table 4, Available at www.jebdp.com). This underscores the importance of evaluating reporting quality in all journals not only the major journals in periodontology. About one-third of the trials (30.81%) were published in the *Journal of Periodontology* (publication of the American Academy of Periodontology) and *Journal of Clinical Periodontology* (publication of the European Academy of Periodontology).

Journal Categories and Frequency

Journals were divided into 3 categories to study the distribution better. Only 4 journals contributed 10 or more RCTs in 2012—Journal of Periodontology, Journal of Clinical Periodontology, Clinical Oral Implants Research, and European Journal of Oral Implantology. Altogether, these 4 journals contributed 84 RCTs out of 198 included in this study.

Continents Frequency

The majority of RCTs were published by authors (corresponding author) in Europe with the least reported from Africa and Oceania. It is striking to note the paucity of RCT from Africa given that Africa has a total of 54 countries (Table 5, Available at www.jebdp.com).

Countries Frequency

United States tops the list with 24 RCT published in this sample followed by India, Italy, Brazil, and Turkey. It is interesting to note the increasing body of RCT literature arising from Asia and South America in the topic of periodontal diseases (Table 6, Available at www.jebdp.com).

Country Categories and Frequency

Countries were divided into 3 categories to study the distribution better. A total of 7 countries contributed 10 or more RCTs in 2012—USA, India, Italy, Brazil, Turkey, Germany, and Sweden. Altogether, these 7 countries contributed 129 RCT out of 198 included in this study. The remaining RCT were published by 14 countries (1 RCT each) and 17 countries (2-10 RCT).

Journal Metric Frequency

RCTs in periodontal diseases were published in journals with a wide impact metric. Only 37 journals were found to have an impact factor score and article influence score, and 41 journals had the Eigenfactor score. Some studies were published in medical journals that had higher impact than the top ranking dental journals (Table 7, Available at www.jebdp.com).

Correlation Between Journal Metrics

When the journal metrics were correlated removing the outliers of high-impact medical journals, a very high correlation was noted between 5-year impact factor and Article Influence Score. The other metrics had a reasonably good correlation as well.

Abstract Metric–Number of Authors and Word Count

The majority of RCTs were published by 4-6 authors with some studies being reported by as few as 2 authors and some as high as 20 authors. Eight RCTs had ≥10 authors published in the Journal of Dental Research, European Journal of Oral Implantology, Journal of Clinical Periodontology, Antimicrobial Agents and Chemotherapy, and Clinical Oral Investigations. The majority of abstracts had a word count of 205-269 with 1 abstract as low as 48 words and some as high as 569.

Comparison of Continents with Selected CONSORT for RCT Abstract–Modified Checklist Questions

The Fisher's exact test was performed for this comparison. P value < .05 was considered statistically significant. European countries clearly demonstrated superior reporting in the checklist questions (#1, #12, #13, #17, #18, and #20). North America reported questions about blinding better similar to Europe. It is interesting to note the stark difference in better reporting of effect size and precision among European countries compared to other countries (Table 8, Available at www. jebdp.com).

Comparison of Top 4 Frequent Journal Metrics (5-Year Impact Factor, Eigenfactor Score, and Article Influence Score) and Abstract Metrics (Word Count and Number of Authors) with Selected CONSORT for RCT Abstract–Modified Checklist Questions

The top 4 frequent journals in this study were the Journal of Periodontology (J Periodontol); Journal of Clinical

Periodontology (J Clin Periodontol); Clinical Oral Implants Research (Clin Oral Implants Res); and European Journal of Oral Implantology (Eur J Oral Implantol). The Wilcoxon rank-sum test (Mann–Whitney U test) and 2-sample test were performed. Two-sided probability, P < .05, was considered statistically significant. The statistically significant results with salient notes are shown in Table 9, Available at www.jebdp.com.

Comparison of Top 7 Frequent Country Journal Metrics (5-Year Impact Factor, Eigenfactor Score, and Article Influence Score) and Abstract Metrics (Word Count and Number of Authors) with Selected CONSORT for RCT Abstract–Modified Checklist Questions

The top 7 frequent countries in this study that published >10 RCTs in 2012 in "Periodontal Diseases": USA, India, Italy, Brazil, Turkey, Germany, and Sweden. Wilcoxon ranksum test (Mann–Whitney *U* test) and 2-sample test were performed. Two-sided probability, P < .05, was considered statistically significant. The statistically significant results with salient notes are shown in Table 10, Available at www. jebdp.com.

Comparison of RCT Abstracts Published in CONSORT Endorsing Journals (N = 108) with Selected CONSORT for RCT Abstract–Modified Checklist Questions

Information about CONSORT endorsement by the journals was obtained from the CONSORT Web site only which lists all the 585 journals currently endorsing CONSORT guidelines. Accessed on May 20, 2015, 15 journals in this study contributing a total of 108 RCTs are listed in CONSORT Web site as CONSORT endorsers (http://www.consortstatement.org/about-consort/endorsers). The chi-square test was performed; *P* value < .05 was considered statistically significant. The results suggest that there is no statistically significant difference between CONSORT endorsing and CONSORT nonendorsing journals per the CONSORT Web site list in the items of reporting except title (mention randomization in the title) and structured abstract (Table 11, Available at www.jebdp.com).

DISCUSSION

A cross-sectional survey was designed and executed to understand in detail the quality of reporting of RCT of periodontal diseases in journal abstracts. CONSORT RCT abstract extension was used as a template, and a modified checklist with 25 questions was used to assess the same in 198 RCT abstracts published in the year 2012 in journals indexed in PubMed. To understand if there is any association with the bibliometric of the journals, bibliometric analysis was conducted.

CONSORT RCT in journal abstract-modified checklist (25 questions)

During the conception of this survey, it was noted that the original checklist items²² had few words to describe each item, whereas the accompanying explanation and elaboration article²¹ gave much more detailed information that made assessment of RCT abstracts much easier. Previous authors have modified the checklist, but they reported some difficulty in certain checklist items mainly due to misinterpretation of definitions.^{26,36} Hence, having a detailed checklist question may improve this situation, and the CONSORT RCT explanation and elaboration document was used as a template to create a checklist of questions. The main hope behind this approach is that any individual would be able to evaluate an RCT abstract with a simple check 'yes' or 'no' without much ambiguity.

Differences and Similarities in Methodology From Previous Studies

This study differs from the previous studies^{26,27,33,36} reporting on the quality of RCT abstracts in dentistry as follows:

- All journals irrespective of their metric or ranking was included that reported RCT on periodontal diseases unlike the previous reports which focused mainly on high-impact specialty journals.
- This study focused the assessment of all studies on the clinical entity "periodontal diseases." The MeSH search term was used for this purpose. This approach allows evaluating a reasonable number of RCT from all Medline-indexed journals in a specific topic thereby preventing selection bias restricted to a small group of journals.
- Comparison of selected checklist questions that showed discrepancy between the RCT abstracts with relevant journal metrics (5-year impact factor, Eigenfactor score, and Article Influence score) was performed.
- Subgroup analyses of most frequent journals and countries publishing the most number of RCT in the selected time frame of 2012.

This study is similar in some manner to the previous studies^{26,27,33,36} reporting on the quality of RCT abstracts in dentistry as follows:

- A modified checklist with detailed, focused questions with additional "notes" using the CONSORT RCT abstract extension with explanation and elaboration document as the template was used to assess reporting. Although the modification is similar in general to previous studies, detailed focused question-based assessment was made. The goal was to decrease ambiguity as much as possible so that the entire assessment can be made by 1 person and reduce the need to get a second opinion. This can be tested for reliability and validity with 2 or more evaluators in the future studies. In addition, "split-mouth" design was added and scored "yes" in trial design as it is a common study design in dental research although it has its own limitations as described elsewhere.⁴⁸ Additional useful data gathered included whether the abstract was written in a structured format and whether the abstract reported statistical significance with or without a "*P*" value.^{27,33,36}

- Comparison of selected checklist questions that showed discrepancy between the RCT abstracts with relevant abstract metrics (number of authors and word count) was performed.^{27,33,36}
- Comparison of selected checklist questions that showed discrepancy between the journals with the geographic distribution of RCT publications was studied.^{27,33,36}

CONSORT RCT Abstract Reporting

Overall, the results of this study are in agreement with the previous studies^{26,27,33,36} with good reporting of experimental interventions (checklist question #5), participant eligibility criteria (#3); comparison interventions (#6); specific objective or hypothesis (#7); primary outcome (#8); reporting trial results as a summary (#16) and poor reporting on how the allocations were concealed (#11), source of funding for the trials (#23), number of participants included in the analysis for each intervention (#10); trial registration number (#15); name of trial register (#21); and how the randomization or sequence generation was done (#22). Dismal reporting was noted in many checklist questions including the identification of the study as randomized in the title, design of the trial, trial setting, randomization, blinding, number of participants actually receiving the intervention and those who were eventually analyzed, effect size, precision of the estimate of the effect, and adverse effects. Direct comparison with these studies was not possible as three studies^{27,33,36} used a "scoring" system of "no description," "inadequate," and "adequate," whereas a simple dichotomous "yes" or "no" was used in this study. Nevertheless, the findings are similar, and the overall conclusions on suboptimal reporting remain unchanged. Another study²⁶ exclusively done in periodontology and implant dentistry used a shortened version of 15-item checklist with dichotomous approach, and the results were similar again. The authors also compared pre- and post-CONSORT samples to see whether there is any improvement in RCT abstract reporting. It is encouraging to note that there was some improvement in certain items post-CONSORT sample. This has also been noted by other studies to underscore the fact that the compliance to CONSORT guidelines improves better reporting and hence better clarity for the consumers of this

body of research,³⁰ but there is still room for improvement.^{29,31,37,49}

Bibliometrics–Journal and Abstract Metrics

This study evaluated in detail 3 major journal metrics (5-year impact factor, Eigenfactor score, and Article Influence score) and compared with the RCT abstract reporting. It was interesting to note that in the majority of the checklist questions analyzed, there was no statistically significant association between the journals' metrics and the compliance with essential reporting. Interestingly, lower ranked journals in terms of these metrics reported certain items relatively better than higher ranked journals. This is important because the previous studies focused mainly on the specialty journals. The findings from this study underscores the fact that higher impact scores do not necessarily mean better reporting of RCT abstracts across the board. There is room for improvement for all journals irrespective of their metrics.

Similar conclusion can be drawn in terms of word count and number of authors as well. Relatively, better reporting was noted within the recommended 250-300 words by CON-SORT almost always. A consistently good reporting in compliance to include all essential RCT abstract items should be feasible between 250 and 300 words.²¹ This observation on word count has been well documented in previous studies as well.^{27,33,36} Hence, authors and editors should make an effort to include all the items and not point to the word limit restriction as the cause for poor reporting.

Medline Search Process–Lessons Learned

This study underscored the importance of filters built in literature databases. Despite using strict filters within PubMed search (Languages, Species, Randomized Controlled Trials, and Publication Dates), several articles that did not meet the filter were obtained during the initial search. Only the filter language was 100% accurate with no foreign language citations was obtained. However, animal study, in vitro studies, observational studies, and studies outside the publication dates specified were all obtained using these filters. Rather than pointing at the database filters for such inaccuracies, the first approach would be to have authors, editors take responsibility in identifying the relevant fields such as accurate study design, species, and whether it is a clinical study using keywords for accurate indexing. For instance, in this study, about 50% of RCT did not report in the title as a randomized study when in fact they were. Such omissions may lead to inaccurate indexing and may never get retrieved for future secondary research such as systematic reviews.

Medline Subject Heading (MeSH) "Periodontal Diseases"

The rationale for using the MeSH term "Periodontal Diseases" is mainly for the search reproducibility. PubMed

defines each MeSH term in detail, and the researcher exactly knows what is included in the search filter.⁵⁰ However, this filter also has a drawback of excluding studies that are not indexed accurately due to various factors including those of the authors, journal editors, publishers, and the database software. The main aim of this study is not to be comprehensive in procuring as many RCT abstracts as possible but to get a broad sense of what the quality of RCT abstract reporting in all the PubMed-indexed journals in a specific topic. Hence, reproducibility and focused search with clear definitions were made priorities. MeSH includes "apical periodontitis" under "Periodontal Diseases" which led to search output with few RCT in endodontics. They were eliminated from this study during the initial eligibility screening. PubMed has introduced several clinical filters⁵⁰ including those specific for clinical trials. The filter of "RCTs" was used in this study. The fact that about 50% of RCT abstracts evaluated in this study did not mention that their study is "randomized" and that PubMed was still able to filter them is noteworthy. On the other hand, the authors and editors need to be wary that it is also likely that PubMed can exclude these trials from a simple filter-based search. Hence, impact of these studies may not reach the audience (clinicians, researchers, and exclusion in systematic reviews) at all levels effectively.

Geographic Distribution

While Europe clearly dominated this sample of RCT abstracts with 81 trials, Asian countries have contributed 51 trials to literature. India in Asia and Brazil in South America are 2 of the top 4 countries contributing to this study besides USA and Italy. This shows the growing influence of developing nations in conducting RCT as was also noted in a recent bibliometric study.³⁸ The relatively better reporting by European nations was also noted in previous studies.^{27,33}

CONSORT Endorsement

Despite majority of RCTs (108/198) were published in journals which were listed as CONSORT-endorsing journals (15/57) as of May 2015,⁵ it was surprising to note that there was no statistically significant difference in most of the checklist questions of the quality of reporting when compared with journals that were not listed in the CONSORT /Web site. The only exception in the recommended items was that the CONSORT-endorsing journals reported the title as randomized study relatively better. In addition, the abstracts tended to be structured in CONSORT-endorsing journals. Besides these 2 observations, the quality of reporting on the actual study design, conduct, analyses, funding, among others were all similar to those RCT abstracts published in the remaining journals not listed as CONSORT endorsers. The previous studies reported in dentistry did not include a wide gamut of journals such as this study, and hence, a direct comparison

is not feasible.^{26,27,33,36} This finding is important to alert the journal editors, especially those who have already listed as CONSORT-endorsing journals, to be more vigilant and implement adherence in the quality of reporting per CONSORT standards.^{8,51,52}

Statistical Significance, Effect Size and Uncertainty

Although not part of the essential checklist item in CON-SORT, it was interesting to note that 92.4% of RCT abstracts reported "statistical significance," but only 13.6% and 6.1% reported on the effect size and precision of the estimate of the effect, respectively. This is of concern because overemphasis on statistical significance has been shown to be associated with misinterpretation of research studies.⁴³ This finding is consistent in most of the studies published previously.^{27,33,36} Research has shown that "spin" which is the special emphasis on beneficial effect of experimental treatment such as the statistical significance⁵³ in an RCT abstract can cause misrepresentation of the research and can have profound negative impact by spreading in the news media and press releases.^{54,55}

Structured Abstracts

Thirty-three RCT abstracts of 198 did not have a structured abstract in this study. Structured abstracts are essential for better reporting and easy understanding.^{46,47,56} During the analysis of this study, it was clear that abstracts that had no structure reported the abstract of the study poorly in general.

Strengths and Limitations

This study provides in depth analysis of the reporting quality of RCT abstracts in 57 journals across 38 countries. This reporting was associated with salient journal metrics and abstract metrics. This is a cross-sectional survey and was conducted primarily by 1 examiner (S.K.). However, the evaluation was done after calibration exercise with high intrarater agreement of k = 0.91. The premise of this decision is to be able to use such a checklist of questions for an objective evaluation of an abstract by an individual health care provider rather than multiple examiners. However, this has to be substantiated by future studies by comparing calibrated and noncalibrated intrarater and inter-rater assessments. In addition, a second reviewer (H.M.) familiar with the study concept, design, and analyses of the modified checklist of questions was consulted who independently evaluated the checklist questions and provided input on selected items where the primary examiner had equivocal interpretations. The majority of the responses of secondary examiner were identical to the primary examiner.

Recommendations for Future Research

Novel and simple ways to improve the reporting of RCT abstract should be devised and tested. For example, an electronic checklist while uploading the manuscript for publication can be tested for compliance and improved reporting. Published abstracts indexed in PubMed can be rewritten with the appropriate permissions and tested for understanding, dissemination, and application in clinical care. Authors should resort to transparent reporting, and journal editors should only accept RCT abstracts with all essential items reported. Adherence to established reporting standards can be studied in detail over a period of time to encourage better reporting.

CONCLUSION

The reporting quality of RCT of periodontal diseases in the journal abstracts published in 2012 is poor in many essential CONSORT RCT abstract-modified checklist questions. These items have been identified clearly to help all stakeholders—authors, clinicians, researchers, peer reviewers, journal editors, and publishers to take note and help with the improvement of the same. Despite some significant differences in the bibliometric factors analyzed with better reporting, the results overall failed to reject the null hypothesis that there is no association between the journal metrics, word count, number of authors, CONSORT endorsement, and the quality of reporting of CONSORT RCT abstract-modified checklist questions.

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ltem		Description	Q#	In the RCT abstract being assessed, c	lid the autho	ors
Title		Identification of the study as randomized	1.	State explicitly in the title that the participants were randomly assigned to their comparison groups?	Yes	No
Trial design		Description of the trial design (eg, parallel, cluster, noninferiority)	2.	Describe the design of the trial (eg, parallel group, cluster randomized, crossover, factorial, superiority, equivalence or noninferiority, or some other combination of these designs)? Note: Select "yes" if split-mouth design is mentioned.	Yes	No
Methods	Participants	Eligibility criteria for participants and the settings where the data were collected	3.	Describe the participant eligibility criteria that may relate to demographics, clinical diagnosis, and comorbid conditions?	Yes	No
			4.	Provide a clear description of the trial setting in which they were studied, so that readers may assess the external validity (generalizability) of the trial and determine its applicability to their own setting? Note: Please note that this is the location(s) of the trial such as the university or private clinic, not where the participants come from.	Yes	No
	Interventions	Interventions intended for each group	5.	Describe the essential features of the experimental interventions?	Yes	No
			6.	Describe the essential features of comparison interventions?	Yes	No
	Objective	Specific objective or hypothesis	7.	Provide a clear statement of the specific objective or hypothesis addressed in the trial?	Yes	No
	Outcome	Clearly defined primary outcome for this report	8.	Explicitly state the primary outcome for the trial?	Yes	No

Table 1. Consolidated Standards of Reporting Trials (CONSORT) for reporting randomized controlled trials in journal abstract-modified checklist (25 questions).

			9.	Explicitly state when the primary outcome was assessed (eg, the time frame over which it was measured)?	Yes	No
	Randomization	How participants were allocated to interventions	10.	Report how the randomization or sequence generation was done (eg, use of computer or random number table)?	Yes	No
			11.	Describe how the allocations were concealed (eg, sequentially numbered, opaque sealed envelopes)?	Yes	No
	Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	12.	Report about blinding? Note: Select "yes" if the authors mention about blinding with less well-understood terms such as "single" or "double" blind that CONSORT recommends that authors should avoid.	Yes	No
			13.	Describe whether or not participants, those administering the intervention (usually health care providers), and those assessing the outcome (the data collectors and analysts) were blinded to the group allocation?	Yes	No
Results	Numbers randomized	Number of participants randomized to each group	14.	Report the number of participants randomized to each intervention? Note: Overall randomized number of participants is not adequate. The number of participants randomized to each intervention should be provided.	Yes	No
	Numbers analyzed	Number of participants analyzed in each group	15.	Report the number of participants included in the analysis for each intervention? Note: Overall analyzed number of participants is not adequate. The number of participants analyzed in each intervention should be provided.	Yes	No
	Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	16.	For the primary outcome, report trial results as a summary of the outcome in each group (eg, the number of participants with or without the event, or the mean and standard deviation of measurements)?	Yes	No
					(cor	ntinued)

Table 1. (continued)					
ltem		Description	Q#	In the RCT abstract being assessed, d	id the authc	ors
			17.	For the primary outcome, report the contrast between groups known as the effect size? For binary outcomes, the effect size could be the relative risk, relative risk reduction, odds ratio, or risk difference. For survival time data, the measurement could be the hazard ratio or difference in median survival time. For continuous data, the effect measure is usually the difference in means.	Yes	No
			18.	For the primary outcome, present the confidence intervals for the contrast between groups and as a measure of the precision (uncertainty) of the estimate of the effect?	Yes	No
	Harms	Important adverse events or side effects	19.	Describe any important adverse (or unexpected) effects of an intervention in the abstract? If no important adverse events have occurred, did the authors state this explicitly?	Yes	No
Conclusions		General interpretation of the results	20.	Clearly state the conclusions of the trial, consistent with the results reported in the abstract, along with their clinical application (avoiding overgeneralization) balancing the benefits and harms in their conclusions.? Where applicable, authors should also note whether additional studies are required before the results are used in clinical settings.	Yes	No
Trial registration		Registration number and name of trial register	21.	Provide details of the trial registration number?	Yes	No

Source of funding

22.

23.

Provide details of the name of trial register?

Report the source of funding for the trial?

Yes

Yes

No

No

The Journal of EVIDENCE-BASED DENTAL PRACTICE

Funding

141.e3

Additional useful data	Structured abstract	24.	Reports the abstract in traditional structure with subtitles (introduction/ background, materials/methods, results, and conclusion)	Yes	No
	Statistical significance	25.	Report "statistical" significance with or without a " <i>P</i> " value	Yes	No
RCT, randomized controlled trial. Adapted from: Hopewell S et al; CONSORT Gro	oup. CONSORT for reporting randomized controlled trials	in journal and con	ference abstracts: explanation and elaboration. PLoS Mee	d. 2008 Jan 22;	; 5(1):e20.

ltem		Description	Q#	In the RCT abstract being assessed, did the authors	Yes	Percent
Title		Identification of the study as randomized	1.	State explicitly in the title that the participants were randomly assigned to their comparison groups?	101	51.0
Trial design		Description of the trial design (eg, parallel, cluster, noninferiority)	2.	Describe the design of the trial (eg, parallel group, cluster randomized, crossover, factorial, superiority, equivalence or noninferiority, or some other combination of these designs)? Note: Select "yes" if split-mouth design is mentioned.	65	32.8
Methods	Participants	Eligibility criteria for participants and the settings where the data were collected	3.	Describe the participant eligibility criteria that may relate to demographics, clinical diagnosis, and comorbid conditions?	196	99.0
			4.	Provide a clear description of the trial setting in which they were studied, so that readers may assess the external validity (generalizability) of the trial and determine its applicability to their own setting? Note: Please note that this is the location(s) of the trial such as the university or private clinic, not where the participants come from.	7	3.5
	Interventions	Interventions intended for each group	5.	Describe the essential features of the experimental interventions?	198	100.0
			6.	Describe the essential features of comparison interventions?	197	99.5
	Objective	Specific objective or hypothesis	7.	Provide a clear statement of the specific objective or hypothesis addressed in the trial?	197	99.5
	Outcome	Clearly defined primary outcome for this report	8.	Explicitly state the primary outcome for the trial?	197	99.5

Table 2. Consolidated Standards of Reporting Trials (CONSORT) for reporting randomized controlled trials in journal abstract-modified checklist (25 questions) frequency.

141.e5

			9.	Explicitly state when the primary outcome was assessed (eg, the time frame over which it was measured)?	188	94.9
	Randomization	How participants were allocated to interventions	10.	Report how the randomization or sequence generation was done (eg, use of computer or random number table)?	3	1.5
			11.	Describe how the allocations were concealed (eg, sequentially numbered and opaque sealed envelopes)?	0	—
	Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	12.	Report about blinding? Note: Select "yes" if the authors mention about blinding with less well-understood terms such as "single" or "double" blind that CONSORT recommends that authors should avoid.	43	21.7
			13.	Describe whether or not participants, those administering the intervention (usually health care providers), and those assessing the outcome (the data collectors and analysts) were blinded to the group allocation?	16	8.1
Results	Numbers randomized	Number of participants randomized to each group	14.	Report the number of participants randomized to each intervention? Note: Overall randomized number of participants is not adequate. The number of participants randomized to each intervention should be provided.	52	26.3
	Numbers analyzed	Number of participants analyzed in each group	15.	Report the number of participants included in the analysis for each intervention? Note: Overall analyzed number of participants is not adequate. The number of participants analyzed in each intervention should be provided.	4	2.0
	Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	16.	For the primary outcome, report trial results as a summary of the outcome in each group (eg, the number of participants with or without the event, or the mean and standard deviation of measurements)?	195	98.5
						(continued)

Table 2. (co	ontinued)
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ltem		Description	Q#	In the RCT abstract being assessed, did the authors	Yes	Percent
			17.	For the primary outcome, report the contrast between groups known as the effect size? For binary outcomes, the effect size could be the relative risk, relative risk reduction, odds ratio, or risk difference. For survival time data, the measurement could be the hazard ratio or difference in median survival time. For continuous data, the effect measure is usually the difference in means.	27	13.6
			18.	For the primary outcome, present the confidence intervals for the contrast between groups and as a measure of the precision (uncertainty) of the estimate of the effect?	12	6.1
	Harms	Important adverse events or side effects	19.	Describe any important adverse (or unexpected) effects of an intervention in the abstract? If no important adverse events have occurred, did the authors state this explicitly?	28	14.1
Conclusions		General interpretation of the results	20.	Clearly state the conclusions of the trial, consistent with the results reported in the abstract, along with their clinical application (avoiding overgeneralization) balancing the benefits and harms in their conclusions? Where applicable, authors should also note whether additional studies are required before the results are used in clinical settings.	183	92.4
Trial registration		Registration number and name of trial register	21.	Provide details of the trial registration number?	5	2.5
			22.	Provide details of the name of trial register?	5	2.5
Funding		Source of funding	23.	Report the source of funding for the trial?	0	_

Additional useful data	Structured abstract	24.	Reports the abstract in traditional structure with subtitles (introduction/ background, materials/methods, results, and conclusion)	165	83.3
	Statistical significance	25.	Report "statistical" significance with or without a "P" value	183	92.4
RCT, randomized controlled trial. Checklist questions 3, 5-8, 10, 11, 15, comparisons with journal and abstrac	16, 21-23 (highlighted in bold) had total responses ranging betw t metrics.	veen \leq 5 and \geq 18	39 (values in bold) out of 198 abstracts surveyed. These	items were excl	uded from all
Adapted from: Hopewell S et al; CON	SORT Group. CONSORT for reporting randomized controlled tria	als in journal and	conference abstracts: explanation and elaboration. PLo	S Med. 2008 Jar	1 22; 5(1):e20.

Table 3. Comparison of journal metrics (5-year impact factor, Eigenfactor score, and Article Influence Score) and abstract metrics (word count and number of authors) with selected consort for RCT abstract–modified checklist questions.

Comparison of journal metric (5-year impact factor) with selected CONSORT for RCT abstract^a-modified checklist questions

		Yes	5-Year impact factor ^b	No	5-Year impact factor	
Q#	Keywords of the checklist questions	n	Median (IQR)	n	Median (IQR)	P value ^c
1.	Title–participants randomly assigned	93	3.083 (2.694-4.506)	71	2.557 (1.548-3.083)	<.0001
17.	Effect size	24	4.206 (2.694-4.506)	140	3.083 (1.714-3.864)	.0119
20.	Conclusions	154	3.083 (2.316-4.206)	10	1.504 (1.504-1.714)	.0002
24.	Structured abstract	139	3.083 (1.833-4.206)	25	2.597 (1.714-2.602)	.0171

The results suggest that there is a statistically significant difference between the underlying distributions of the ranked 5-year impact factor scores in the categories of: reporting of randomization in the title, number of participants randomized to each intervention, conclusions, and structured abstract.

Comparison of journal metric (Eigenfactor score) with selected CONSORT for RCT abstract-modified checklist questions

		Yes	Eigenfactor score ^d	No	Eigenfactor score	
Q#	Keywords of the checklist questions	n	Median (IQR)	n	Median (IQR)	P value
2.	Design of the trial	56	0.00547 (0.00239-0.01478)	115	0.01478 (0.00369-0.01492)	.0035
13.	Details about blinding	15	0.00241 (0.00236-0.01478)	156	0.01478 (0.00369-0.01492)	.0184
20.	Conclusions	160	0.01478 (0.00346-0.01492)	11	0.00241 (0.00241-0.00586)	.0308

The results suggest that there is a statistically significant difference between the underlying distributions of the ranked Eigenfactor scores in the categories of: design of the trial, details about blinding, and conclusions. Note that the journals with low rank Eigenfactor scores reported trial design and details about blinding better.

Comparison of journal metric (Article Influence Score) with selected CONSORT for RCT abstract-modified checklist questions

		Yes	Article Influence Score ^e	No	Article Influence Score	
Q#	Keywords of the checklist questions	n	Median (IQR)	n	Median (IQR)	P value
1.	Title–participants randomly assigned	93	0.802 (0.631-1.184)	71	0.606 (0.407-0.802)	<.0001
2.	Design of the trial	51	0.631 (0.407-1.016)	113	0.802 (0.553-1.047)	.0418
17.	Effect size	24	1.016 (0.631-1.184)	140	0.802 (0.481-1.016)	.0379
20.	Conclusions	154	0.802 (0.553-1.047)	10	0.407 (0.407-0.481)	.0004

The results suggest that there is a statistically significant difference between the underlying distributions of the ranked Article Influence Score in the categories of: reporting randomization in the title, trial design, effect size, and conclusions. Note that the low ranks of Article Influence Score reported trial design better.

(continued)

Table 3. (continued)

Comparison of abstract metric (word count) with selected CONSORT for RCT abstract-modified checklist questions

		Yes	Word count ^f	No	Word count	
Q#	Keywords of the checklist questions	n	Median (IQR)	n	Median (IQR)	P value
19.	Adverse (or unexpected) effects	28	265 (224-296)	170	231 (203-265)	.0095
24.	Structured abstract	165	236 (206-274)	33	231 (184-256)	.0262
25.	Statistical significance	183	239 (205-270)	15	212 (114-235)	.0165

The results suggest that there is a statistically significant difference between the underlying distributions of the ranked word count scores in the categories of: reporting of adverse effects, structured abstract, and statistical significance.

Comparison of abstract metric (number of authors) with selected CONSORT for RCT abstract-modified checklist questions

		Yes	Number of authors ^f	No	Number of authors	
Q#	Keywords of the checklist questions	n	Median (IQR)	n	Median (IQR)	P value
9.	When the primary outcome was assessed	188	5 (4-7)	10	4 (3-5)	.0357

The results suggest that there is a statistically significant difference between the underlying distributions of the ranked number of authors' scores in the categories of: reporting of when the primary outcome was assessed.

CONSORT, Consolidated Standards of Reporting Trials; RCT, randomized controlled trial.

^a Checklist questions (3, 5-8, 10, 11, 15, 16, and 21-23) that had total responses ranging between \leq 5 and \geq 189 out of 198 abstracts surveyed were excluded from all comparisons with journal and abstract metrics. These items were consistently either always reported (3, 5-8, and 16) or never reported (10, 11, 15, and 21-23).

^b Five-year impact factor maintained at 3 decimals as reported in Journal Citation Reports.

^c The Wilcoxon rank-sum test (Mann–Whitney U test) and 2-sample test were performed. Two-sided probability, P < .05, was considered statistically significant.

^d Eigenfactor score maintained at 5 decimals as reported in Journal Citation Reports.

^e Article Influence Score maintained at 3 decimals as reported in Journal Citation Reports.

^fWord count and the number of authors rounded off to nearest full number.

Table 4. Journal frequency and CONSORT endorsement^a.

Journal title	Journal abbreviation	CONSORT endorsement ^a (yes/no)	Frequency	Percent	Cumulative frequency	Cumulative percent
Journal of Periodontology	J Periodontol	Yes	31	15.66	31	15.66
Journal of Clinical Periodontology	J Clin Periodontol	Yes	30	15.15	61	30.81
Clinical Oral Implants Research	Clin Oral Implants Res	Yes	12	6.06	73	36.87
European Journal of Oral Implantology	Eur J Oral Implantol	No	11	5.56	84	42.42
American Journal of Dentistry	Am J Dent	Yes	8	4.04	92	46.46
Clinical Implant Dentistry and Related Research	Clin Implant Dent Relat Res	No	6	3.03	98	49.49
The Journal of Clinical Dentistry	J Clin Dent	No	6	3.03	104	52.53
Photomedicine and Laser Surgery	Photomed Laser Surg	No	6	3.03	110	55.56
Clinical Oral Investigations	Clin Oral Investig	Yes	5	2.53	115	58.08
The International Journal of Oral & Maxillofacial Implants	Int J Oral Maxillofac Implants	No	5	2.53	120	60.61
Lasers in Medical Science	Lasers Med Sci	No	5	2.53	125	63.13
Quintessence International	Quintessence Int	Yes	5	2.53	130	65.66
International Journal of Dental Hygiene	Int J Dent Hyg	No	4	2.02	134	67.68
The International Journal of Periodontics & Restorative Dentistry	Int J Periodontics Restorative Dent	No	4	2.02	138	69.7
Journal of Oral and Maxillofacial Surgery	J Oral Maxillofac Surg	Yes	4	2.02	142	71.72
Compendium of Continuing Education in Dentistry	Compend Contin Educ Dent	No	3	1.52	145	73.23
Implant dentistry	Implant Dent	No	3	1.52	148	74.75
Journal of the International Academy of Periodontology	J Int Acad Periodontol	No	3	1.52	151	76.26
Journal of Periodontal Research	J Periodontal Res	Yes	3	1.52	154	77.78
Australian Dental Journal	Aust Dent J	Yes	2	1.01	156	78.79
						(continued)

Journal title	Journal abbreviation	CONSORT endorsement ^a (yes/no)	Frequency	Percent	Cumulative frequency	Cumulative percent
Indian Journal of Dental Research	Indian J Dent Res	No	2	1.01	158	79.8
Journal of Dental Research	J Dent Res	Yes	2	1.01	160	80.81
Journal of Investigative and Clinical Dentistry	J Investig Clin Dent	No	2	1.01	162	81.82
PLoS one	PLoS One	Yes	2	1.01	164	82.83
Swedish Dental journal	Swed Dent J	No	2	1.01	166	83.84
Acta Cytologica	Acta Cytol	No	1	0.51	167	84.34
Acta Odontológica Latinoamericana	Acta Odontol Latinoam	No	1	0.51	168	84.85
American Journal of Perinatology	Am J Perinatol	No	1	0.51	169	85.35
Antimicrobial Agents and Chemotherapy	Antimicrob Agents Chemother	No	1	0.51	170	85.86
Brazilian Dental Journal	Braz Dent J	No	1	0.51	171	86.36
Brazilian Oral Research	Braz Oral Res	No	1	0.51	172	86.87
The British Journal of Oral & Maxillofacial Surgery	Br J Oral Maxillofac Surg	Yes	1	0.51	173	87.37
The Chinese Journal of Dental Research	Chin J Dent Res	No	1	0.51	174	87.88
European Journal of Clinical Microbiology & Infectious Diseases	Eur J Clin Microbiol Infect Dis	No	1	0.51	175	88.38
European Journal of Paediatric Dentistry	Eur J Paediatr Dent	No	1	0.51	176	88.89
General Dentistry	Gen Dent	No	1	0.51	177	89.39
Gerodontology	Gerodontology	No	1	0.51	178	89.9
Health Psychology	Health Psychol	Yes	1	0.51	179	90.4
International Dental Journal	Int Dent J	No	1	0.51	180	90.91
Journal of Biomedical Materials Research. Part B, Applied Biomaterials	J Biomed Mater Res B Appl Biomater	No	1	0.51	181	91.41
						(continued)

Table 4. (continued) CONSORT Cumulative endorsement^a Cumulative Journal title Journal abbreviation (yes/no) Frequency Percent frequency percent Journal of Breath Research J Breath Res No 1 0.51 182 91.92 Journal of the California J Calif Dent Assoc 1 0.51 183 92.42 No Dental Association The journal of Contemporary 0.51 92.93 J Contemp Dent Pract 1 184 No Dental Practice 0.51 93.43 Journal of Dentistry 1 185 J Dent Yes Journal of Dental Hygiene J Dent Hyg No 1 0.51 186 93.94 94.44 Journal of the Indian Society of J Indian Soc Pedod Prev Dent 0.51 Yes 1 187 Pedodontics and Preventive Dentistry 94.95 The Journal of Oral J Oral Implantol No 1 0.51 188 Implantology Journal of Oral Rehabilitation J Oral Rehabil No 1 0.51 189 95.45 Kathmandu Univ Med J 1 0.51 95.96 Kathmandu University Medical No 190 Journal 96.46 Lasers in Surgery and Lasers Surg Med No 1 0.51 191 Medicine Medicina Oral, Patología Oral Med Oral Patol Oral Cir Bucal No 1 0.51 192 96.97 y Cirugía Bucal Minerva Stomatologica Minerva Stomatol No 1 0.51 193 97.47 Oral Diseases Oral Dis 1 0.51 194 97.98 No Oral Health and Dental Oral Health Dent Manag 98.48 No 1 0.51 195 Management Oral Health & Preventive Oral Health Prev Dent 98.99 No 1 0.51 196 Dentistry 99.49 Oral Surgery, Oral Medicine, Oral Surg Oral Med Oral 0.51 197 No 1 Oral Pathology and Oral Pathol Oral Radiol Radiology The Southeast Asian Journal of Southeast Asian J Trop Med 0.51 198 100 No 1 Tropical Medicine and Public Public Health Health

CONSORT, Consolidated Standards of Reporting Trials; RCT, randomized controlled trial.

^a Information about CONSORT endorsement by the journals was obtained from the CONSORT Web site only which lists all the 585 journals currently endorsing CONSORT guidelines. Accessed on May 20, 2015, 15 journals in this study contributing a total of 108 RCTs are listed in CONSORT Web site as CONSORT endorsers. http://www.consort-statement.org/about-consort/endorsers.

Table 5. Continents frequency.									
Continent	Frequency	Percent	Cumulative frequency	Cumulative percent					
Country not reported, unknown	2	1.01	2	1.01					
Africa	7	3.54	9	4.55					
Asia	51	25.76	60	30.30					
Europe	81	40.91	141	71.21					
North America	33	16.67	174	87.88					
Oceania	1	0.51	175	88.38					
South America	23	11.62	198	100.0					

Country	Frequency	Percent	Cumulative frequency	Cumulative percent
USA	28	14.14	28	14.14
India	24	12.12	52	26.26
Italy	22	11.11	74	37.37
Brazil	20	10.1	94	47.47
Turkey	13	6.57	107	54.04
Germany	11	5.56	118	59.6
Sweden	11	5.56	129	65.15
Egypt	7	3.54	136	68.69
Canada	5	2.53	141	71.21
Spain	5	2.53	146	73.74
The Netherlands	5	2.53	151	76.26
Iran	4	2.02	155	78.28
Switzerland	4	2.02	159	80.3
Belgium	3	1.52	162	81.82
Norway	3	1.52	165	83.33
Poland	3	1.52	168	84.85
Not reported	2	1.01	170	85.86
Argentina	2	1.01	172	86.87
Denmark	2	1.01	174	87.88
Greece	2	1.01	176	88.89
Hungary	2	1.01	178	89.9
Israel	2	1.01	180	90.91
Japan	2	1.01	182	91.92
UK	2	1.01	184	92.93
Austria	1	0.51	185	93.43
Chile	1	0.51	186	93.94

Table 6. (continued)									
Country	Frequency	Percent	Cumulative frequency	Cumulative percent					
China	1	0.51	187	94.44					
France	1	0.51	188	94.95					
Ireland	1	0.51	189	95.45					
Korea	1	0.51	190	95.96					
Macedonia	1	0.51	191	96.46					
New Zealand	1	0.51	192	96.97					
Pakistan	1	0.51	193	97.47					
Republic of Serbia	1	0.51	194	97.98					
Saudi Arabia	1	0.51	195	98.48					
Serbia	1	0.51	196	98.99					
Taiwan	1	0.51	197	99.49					
Thailand	1	0.51	198	100					

Table 7. Journal metric frequency.										
Journal metric	Number of abstracts	Median	Minimum	Maximum	Interquartile range (IQR)					
Five-year impact factor	37	2.316	0.575	5.224	1.439-2.970					
Eigenfactor Score	41	0.00474	0.00061	1.16582	0.00202-0.01395					
Article Influence Score	37	0.553	0.160	1.896	0.382-0.755					

							Continer	nt		
Q#	Keywords of the checklist questions			Africa	Asia	Europe	North America	South America	Total	P value ^b
1.	Title–participants randomly assigned	Yes	Frequency	3	24	55	7	10	99	.0001
			Percent	1.54	12.31	28.21	3.59	5.13	50.77	
		No	Frequency	4	27	26	26	13	96	
			Percent	2.05	13.85	13.33	13.33	6.67	49.23	
12.	Report about blinding	Yes	Frequency	1	9	12	15	6	43	.0106
			Percent	0.51	4.62	6.15	7.69	3.08	22.05	
		No	Frequency	6	42	69	18	17	152	
			Percent	3.08	21.54	35.38	9.23	8.72	77.95	
13.	Details about blinding	Yes	Frequency	0	0	8	6	2	16	.0208
			Percent	0.00	0.00	4.10	3.08	1.03	8.21	
		No	Frequency	7	51	73	27	21	179	
			Percent	3.59	26.15	37.44	13.85	10.77	91.79	
17.	Effect size	Yes	Frequency	0	2	17	7	1	27	.0149
			Percent	0.00	1.03	8.72	3.59	0.51	13.85	
		No	Frequency	7	49	64	26	22	168	
			Percent	3.59	25.13	32.82	13.33	11.28	86.15	

Table 8. Comparison of continents with selected CONSORT for RCT abstract^a-modified checklist questions.

18.	Confidence intervals-precision (uncertainty)	Yes	Frequency	0	0	10	1	1	12	.0424
			Percent	0.00	0.00	5.13	0.51	0.51	6.15	
		No	Frequency	7	51	71	32	22	183	
			Percent	3.59	26.15	36.41	16.41	11.28	93.85	
20.	Conclusions	Yes	Frequency	7	48	78	25	22	180	.0132
20.	Conclusions	Yes	Frequency Percent	7 3.59	48 24.62	78 40.00	25 12.82	22 11.28	180 92.31	.0132
20.	Conclusions	Yes	•							.0132

CONSORT, Consolidated Standards of Reporting Trials; RCT, randomized controlled trial. ^a Checklist questions (3, 5-8, 10, 11, 15, 16, and 21-23) that had total responses ranging between \leq 5 and \geq 189 out of 198 abstracts surveyed were excluded from all comparisons with journal and abstract metrics. These items were consistently either always reported (3, 5-8, and 16) or never reported (10, 11, 15, and 21-23). ^b Fisher's exact test was performed. *P* < .05 was considered statistically significant.

Table 9. Comparison of journal (top 4 frequent)^a metric (5-year impact factor) with selected CONSORT for RCT abstract-modified checklist questions.

		Yes	5-Year impact factor ^b	No	5-Year impact factor	P value ^c
Q#	Keywords of the checklist questions	n	Median (IQR)	n	Median (IQR)	
13.	Details about blinding	4	4.506 (4.506-4.506)	80	3.083 (3.083-4.506)	.0173
19.	Adverse (or unexpected) effects	13	3.083 (2.694-4.206)	71	4.206 (3.083-4.506)	.0412

The results suggest that there is a statistically significant difference between the underlying distributions of the ranked 5-year impact factor scores among top 4 frequent journals in the categories of: reporting of details about blinding and adverse effects. Note that low rank of 5-year impact factor reported adverse events better.

Comparison of journal (top 4 frequent) metric (Eigenfactor score) with selected CONSORT for RCT abstract-modified checklist questions

		Yes	Eigenfactor score ^d	No	Eigenfactor score	
Q#	Keywords of the checklist questions	n	Median (IQR)	n	Median (IQR)	P value
1.	Title–participants randomly assigned	62	0.01478 (0.01478-0.01492)	22	0.01492 (0.01478-0.01492)	.0175
2.	Design of the trial	26	0.01478 (0.00130-0.01492)	58	0.01492 (0.01478-0.01492)	.0248
17.	Effect size	19	0.01478 (0.00130-0.01478)	65	0.01492 (0.01478-0.01492)	.0010
18.	Confidence intervals-precision (uncertainty)	12	0.00804 (0.00130-0.01478)	72	0.01492 (0.01478-0.01492)	.0018
19.	Adverse (or unexpected) effects	13	0.01478 (0.00130-0.01492)	71	0.01492 (0.01478-0.01492)	.0309

The results suggest that there is a statistically significant difference between the underlying distributions of the ranked Eigenfactor scores in the categories of: reporting of title, trial design, effect size, confidence interval (precision and uncertainty), adverse effects. Note that in the significant differences, the better reporting were done in low ranking Eigenfactor scores.

Comparison of journal (top 4 frequent) metric (Article Influence Score) with selected CONSORT for RCT abstract-modified checklist questions

		Yes	Article Influence Score ^e	No	Article Influence Score	
Q#	Keywords of the checklist questions	n	Median (IQR)	n	Median (IQR)	P value
13.	Details about blinding	4	1.184 (1.184-1.184)	80	0.802 (0.802-1.184)	.0173
19.	Adverse (or unexpected) effects	13	0.802 (0.631-1.016)	71	1.016 (0.802-1.184)	.0412

The results suggest that there is a statistically significant difference between the underlying distributions of the ranked Article Influence Score in the categories of: reporting details about blinding and adverse effects. Note that the lower ranks of Article Influence Score reported adverse effects better.

Comparison of abstract (top 4 frequent journals) metric (word count) with selected CONSORT for RCT abstract-modified checklist questions

The results suggest that there is no statistically significant difference between the underlying distributions of the ranked word count scores in any of the questionnaire items.

(continued)

Table 9. (continued)

Comparison of abstract (top 4 frequent journals) metric (number of authors) with selected CONSORT for RCT abstract-modified checklist questions

		Yes <u>Number of authors</u> ^f <u>No</u> <u>Number of autho</u>		Number of authors	S	
Q#	Keywords of the checklist questions	n	Median (IQR)	n	Median (IQR)	P value
12.	Report about blinding	13	6 (5-8)	71	5 (4-7)	.0311

The results suggest that there is a statistically significant difference between the underlying distributions of the ranked number of authors' scores in the item of reporting about blinding.

CONSORT, Consolidated Standards of Reporting Trials; IQR, interquartile range; RCT, randomized controlled trials. ^a Top 4 frequent journals in this study: Journal of Periodontology (J Periodontol); Journal of Clinical Periodontology (J Clin Periodontol); Clinical Oral Implants Research (Clin Oral Implants Res); European Journal of Oral Implantology (Eur J Oral Implantol).

^b Five-year impact factor maintained at 3 decimals as reported in Journal Citation Reports.

 $^{\circ}$ The Wilcoxon rank-sum test (Mann–Whitney U test), 2-sample test were performed. Two-sided probability, P < .05, was considered statistically significant.

^dEigenfactor score maintained at 5 decimals as reported in Journal Citation Reports.

^e Article Influence Score maintained at 3 decimals as reported in Journal Citation Reports.

^fNumber of authors rounded off to nearest full number.

Table 10. Comparison of Top 7 Frequent Country Journal Metrics (5-year impact factor, Eigenfactor score, Article Influence Score), and Abstract Metrics (word count and number of authors) with Selected CONSORT for RCT Abstract–Modified Checklist Questions.

Comparison of country (top 7 frequent)^a metric (5-year impact factor) with selected CONSORT for RCT abstract-modified checklist questions

		Yes	5-Year impact factor ^b No 5-Year impact factor			
Q#	Keywords of the checklist questions	n	Median (IQR)	n	Median (IQR)	P value ^c
20.	Conclusions	100	3.083 (2.362-4.015)	5	1.504 (1.504-1.504)	.0067

The results suggest that there is a statistically significant difference between the underlying distributions of the ranked 5-year impact factor scores among top 4 frequent journals in the item of reporting randomization in the title, conclusions.

Comparison of country (top 7 frequent) metric (Eigenfactor score) with selected CONSORT for RCT abstract-modified checklist questions

		Yes	Eigenfactor score ^d	No	Eigenfactor score	
Q#	Keywords of the checklist questions	n	Median (IQR)	n	Median (IQR)	P value
2.	Design of the trial	34	0.00363 (0.00130-0.01478)	75	0.01478 (0.00369-0.01492)	.0003
18.	Confidence intervals-precision (uncertainty)	11	0.00130 (0.00130-0.01478)	98	0.01437 (0.00270-0.01492)	.0449
19.	Adverse (or unexpected) effects	18	0.00256 (0.00130-0.01478)	91	0.01478 (0.00369-0.01492)	.0191

The results suggest that there is a statistically significant difference between the underlying distributions of the ranked *Eigenfactor* scores in the categories of: reporting of trial design, confidence intervals (precision-uncertainty), and adverse effects. Note that in the significant differences, the better reporting were done in low ranking *Eigenfactor* scores.

Comparison of country (top 7 frequent) metric (Article Influence Score) with selected CONSORT for RCT abstract–modified checklist questions

		Yes	Article Influence Score ^e	No	Article Influence Score	
Q#	Keywords of the checklist questions	n	Median (IQR)	n	Median (IQR)	P value
1.	Title–participants randomly assigned	58	0.802 (0.631-1.184)	47	1.184 (0.407-0.820)	.0123
2.	Design of the trial	32	0.631 (0.499-0.802)	73	0.802 (0.553-1.047)	.0325
20.	Conclusions	100	0.802 (0.580-1.047)	5	0.407 (0.407-0.407)	.0109

The results suggest that there is a statistically significant difference between the underlying distributions of the ranked Article Influence Score in the categories of: reporting title, trial design, and conclusions. Note that the lower ranks of Article Influence Score reported title and trial design better.

Comparison of country (top 7 frequent) metric (word count) with selected CONSORT for RCT abstract-modified checklist questions

		Yes	Word count ^f	No	Word count	
Q#	Keywords of the checklist questions	n	Median (IQR)	n	Median (IQR)	P value
19.	Adverse (or unexpected) effects	21	286 (230-303)	108	230 (200-264)	.0033

The results suggest that there is statistically significant difference between the underlying distributions of the ranked word count scores in the reporting of adverse effects.

(continued)

Table 10. (continued)

Comparison of country (top 7 frequent) metric (number of authors) with selected CONSORT for RCT abstract-modified checklist questions

The results suggest that there is no statistically significant difference between the underlying distributions of the ranked number of authors in the items of reporting.

CONSORT, Consolidated Standards of Reporting Trials; IQR, interquartile range; RCT, randomized controlled trial.

^a Top 7 frequent countries in this study that published >10 RCTs in 2012 in "Periodontal Diseases": USA, India, Italy, Brazil, Turkey, Germany, and Sweden. ^b Five-year impact factor maintained at 3 decimals as reported in Journal Citation Reports.

^c The Wilcoxon rank-sum test (Mann–Whitney U test) and 2-sample test were performed. Two-sided probability, P < .05, was considered statistically significant.

^d Eigenfactor score maintained at 5 decimals as reported in Journal Citation Reports.

- ^e Article Influence Score maintained at 3 decimals as reported in Journal Citation Reports.
- ^fWord count rounded off to nearest full number.

Table 11. Comparison of RCT Abstracts published in CONSORT-endorsing journals^a (n = 108) with selected CONSORT for RCT Abstract^a-modified checklist questions.

<u>Q</u> #	Keywords of the checklist questions	<u>Yes</u> n (%)	<u>No</u> n (%)	P value ^b
1.	Title–participants randomly assigned	64	44	.0110
_	Structured abstract	98	10	.0022

CONSORT, Consolidated Standards of Reporting Trials; RCT, randomized controlled trial.

^a Information about CONSORT endorsement by the journals was obtained from the CONSORT Web site only which lists all the 585 journals currently endorsing CONSORT guidelines. Accessed on May 20, 2015, 15 journals in this study contributing a total of 108 RCTs are listed in CONSORT Web site as CONSORT endorsers. http://www.consortstatement.org/about-consort/endorsers.

 $^{\rm b}$ The chi-square test was performed; P < .05 was considered statistically significant.