Critical Review
Dental Materials/Dentistry

Randomized clinical trials of dental bleaching – Compliance with the CONSORT Statement: a systematic review

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Abstract: We reviewed the literature to evaluate: a) The compliance of randomized clinical trials (RCTs) on bleaching with the CONSORT; and b) the risk of bias of these studies using the Cochrane Collaboration risk of bias tool (CCRT). We searched the Cochrane Library, PubMed and other electronic databases, to find RCTs focused on bleaching (or whitening). The articles were evaluated in compliance with CONSORT in a scale: 0 = no description, 1 = poor description and 2 = adequate description. Descriptive analyses of the number of studies by journal, follow-up period, country and quality assessments were performed with CCRT for assessing risk of bias in RCTs. 185 RCTs were included for assessment. More than 30% of the studies received score 0 or 1. Protocol, flow chart, allocation concealment and sample size were more critical items, as 80% of the studies scored 0. The overall CONSORT score for the included studies was 16.7 ± 5.4 points, which represents 52.2% of the maximum CONSORT score. A significant difference among journal, country and period of time was observed ($p < 0.02$). Only 7.6% of the studies were judged at "low" risk; 62.1% were classified as "unclear"; and 30.3% as "high" risk of bias. The adherence of RCTs evaluating bleaching materials and techniques to the CONSORT is still low with unclear/high risk of bias.

Keywords: Tooth Bleaching; Dental Sensitivity

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Introduction

Dental bleaching (or whitening) has become the most sought after treatment by patients in search for esthetics. According to study of Al-Zaera,[1] which investigated the research subjects' satisfaction with dental appearance, nearly 66% of the individuals were dissatisfied with the color of their teeth. Another survey conducted in Ankara, Turkey,[2] focused on the treatment of patients who were unhappy with their smile, questioning which treatment these patients would like to receive. About half of the patients suggested dental bleaching (49.9%), followed by esthetic restorations (25.4%), orthodontic treatment (24.5%), and prosthetic restorations (16.9%).

Linked to growing demand, the effectiveness of various protocols and materials used by dental professionals has been extensively studied in the last decades, including longevity of the bleaching outcome.[3,4,5,6] Researchers have used clinical or in vitro studies to obtain data that can

predict clinical performance, as some subjective factors related to the bleaching protocol, such as postoperative sensitivity and other adverse reactions, cannot be evaluated directly.[7,8,9]

While laboratory testing is a very useful method to study the diffusion of the components of bleaching gels, such H_2O_2, into dental pulp,[10,11] clinical trials can provide reliable and direct evidence to guide clinicians in their choice of materials for in-office and at-home bleaching.[12,13,14,15]

Hence, randomized controlled trials (RCTs) are considered the standard research design for the evaluation of health interventions. In fact, RCTs and systematic reviews are at the top level of the evidence hierarchy.[16] RCTs, however, may incur risk of spurious results if their design is flawed or if the respective methodology lacks accuracy.[17] Several problems with the design and execution of RCTs raise questions regarding the validity and reliability of the respective findings. This situation may lead to an underestimation or overestimation of the true intervention effect.[18]

Therefore readers should appraise any RCT before a clinical decision is made. This evaluation depends on a good report/writing of the methods and results of RCTs. A group of experts joined efforts in 1996 and proposed several items that should be described in a RCT (CONsolidate Standard Of Randomized Trials [CONSORT] Statement), with the objective of standardizing the reporting of RCTs. The CONSORT Statement was reviewed in 2001[19] and the most recent version was published in 2010.[20,21]

Given the importance of RCTs in dental bleaching to make decisions regarding protocols, application time, and commercial brand, the aim of this study was to systematically review the literature in peer-reviewed journals to evaluate a) the compliance of RCTs with the CONSORT Statement and b) the risk of bias in these RCT studies through the Cochrane Collaboration risk of bias tool (CCRT).

Methodology

This study was not registered, as there are no currently known systematic review registries of methodologies.

Search methods

We following databases: MEDLINE via PubMed, Cochrane Library, Brazilian Library in Dentistry (BBO) and Latin American and Caribbean Literature in Health Sciences database (LILACS) and citation bases: Scopus and Web of Science were consulted (Table 1). The reference lists of all primary studies, as well as the related articles link from the PubMed database from each primary study, were manually searched. Articles in Korean, Japanese, Chinese, Arabic and related languages were not included due to difficult translation.

According to the MEDLINE database, a search strategy was defined according to a terminology for indexing biomedical information (MeSH, Medical Subject Headings, U.S. National Library of Medicine, Bethesda, MD, USA) along with free keywords. For each database, the search strategy was adapted for consultation. In order to standardize the articles evaluated, only studies published since the CONSORT Statement declaration in 1996 were included.

Eligibility criteria

We included parallel and split-mouth RCTs that evaluated the effectiveness of different types of bleaching systems and techniques on color change, toxicity, postoperative sensitivity and application technique. We did not restrict studies with patients of different age groups or populations (Table 2).

Laboratory studies were excluded, as well as those presented as conference abstracts, theses and reports published in any media other than peer-reviewed journals. Additionally, all studies that were published before 1996 were excluded (Table 2).

Three reviewers (A.P., B.M.M. and T.H.) catalogued articles that met the inclusion criteria. Article selection was carried out by first reading the titles and abstracts; then the full text of the paper was read in case of doubts.

Adherence to CONSORT statement

An evaluation tool based on the items related to the methods and results from the 2010 CONSORT Statement[20] was developed to evaluate the reporting completeness of RCTs (Table 3).[22] The items related to the title and abstract, introduction and discussion were not evaluated since the evaluation would have

Table 1. Search strategy (07/02/17).

Pubmed		
#1 ((((((((((((((((((tooth discoloration[MeSH Terms]) OR dentition, permanent[MeSH Terms]) OR color[MeSH Terms]) OR color[Title/Abstract]) OR colour[Title/Abstract]) OR "tooth discoloration"[Title/Abstract]) OR "tooth discolouration"[Title/Abstract]) OR "teeth discoloration"[Title/Abstract]) OR "teeth discolouration"[Title/Abstract]) OR "discolored tooth"[Title/Abstract]) OR "discoloured tooth"[Title/Abstract]) OR "discolored teeth"[Title/Abstract]) OR "discoloured teeth"[Title/Abstract]) OR "dental discoloration"[Title/Abstract]) OR "dental discolouration"[Title/Abstract]) OR "tooth staining"[Title/Abstract]) OR "teeth staining"[Title/Abstract]) OR "stained tooth"[Title/Abstract]) OR "stained teeth"[Title/Abstract]) OR "dental staining"[Title/Abstract]	#2 ((((((((((((((((((tooth bleaching[MeSH Terms]) OR tooth bleaching agents[MeSH Terms]) OR peroxides[MeSH Terms]) OR hydrogen peroxide[MeSH Terms]) OR carbamide peroxide[Supplementary Concept]) OR peroxides[Title/Abstract]) OR "hydrogen peroxide"[Title/Abstract]) OR "carbamide peroxide"[Title/Abstract]) OR bleaching[Title/Abstract]) OR whitening[Title/Abstract]) OR "in office"[Title/Abstract]) OR "at home"[Title/Abstract]) OR "light activation"[Title/Abstract]) OR "light activated"[Title/Abstract]) OR "laser assisted"[Title/Abstract]) OR "dentist-supervised"[Title/Abstract]) OR nightguard[Title/Abstract]) OR "tray-delivered"[Title/Abstract]) OR "jump-start"[Title/Abstract]	#3 (randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR clinical trials[mh] OR ("clinical trial"[tw]) OR ((singl*[tw] OR doubl*[tw] OR trebl*[tw] OR tripl*[tw]) AND (mask*[tw] OR blind*[tw])) OR (placebos[mh] OR placebo*[tw] OR random*[tw] OR research design[mh:noexp] OR comparative study[pt] OR evaluation studies as topic[mh] OR follow-up studies[mh] OR prospective studies[mh] OR control*[tw] OR prospective*[tw] OR volunteer*[tw]) NOT (animals[mh] NOT humans[mh]))
#1 AND #2 AND #3		
Cochrane Library		
#1 MeSH descriptor: [Tooth Discoloration] explode all trees	#8 MeSH descriptor: [Tooth Bleaching Agents] explode all trees	
#2 MeSH descriptor: [Dentition, Permanent] explode all trees	#9 MeSH descriptor: [Peroxides] explode all trees	
#3 MeSH descriptor: [Color] explode all trees	#10 MeSH descriptor: [Hydrogen Peroxide] explode all trees	
#4 color:ti,ab,kw or t*th next discoloration:ti,ab,kw or discolored next t*th:ti,ab,kw or dental next discoloration:ti,ab,kw or t*th next staining:ti,ab,kw (Word variations have been searched)	#11"carbamide peroxide":ti,ab,kw or peroxides:ti,ab,kw or "hydrogen peroxide":ti,ab,kw or bleaching:ti,ab,kw or whitening:ti,ab,kw (Word variations have been searched)	
#5 stained next t*th:ti,ab,kw or dental next staining:ti,ab,kw (Word variations have been searched)	#12 "in office":ti,ab,kw or "at home":ti,ab,kw or light next activat*:ti,ab,kw or laser next assisted:ti,ab,kw or dentist supervised:ti,ab,kw (Word variations have been searched)	
#6 #1 or #2 or #3 or #4 or #5	#13 nightguard:ti,ab,kw or tray delivered:ti,ab,kw or jump start:ti,ab,kw (Word variations have been searched)	
#7 MeSH descriptor: [Tooth Bleaching] explode all trees	#14 #7 or #8 or #9 or #10 or #11 or #12 or #13	
#15 #6 AND #14		
Lilacs and BBO		
#1 (MH: "tooth discoloration" OR MH: "permanent dentition" OR MH:color OR color OR cor OR colour OR "tooth discoloration" OR "descoloração do dente" OR "decoloración del diente" OR "descoloración del diente" OR "tooth discolouration" OR "teeth discoloration" OR "descoloração dos dentes" OR "decoloración de los dientes" OR "descoloración de los dientes" OR "teeth discolouration" OR "discolored tooth" OR "dente descolorido" OR "discoloured tooth" OR "discolored teeth" OR "dentes descoloridos" OR "diente pigmentado" OR "dientes pigmentados" OR "dentes pigmentados" OR "dente pigmentado" OR "discoloured teeth" OR "dental discoloration" OR "descoloração dental" OR "decoloración dental" OR "decoloración dentaria" OR "descoloración dental" OR "descoloración dentaria" OR "dental discolouration" OR "tooth staining" OR "manchamento dental" OR "tinción dental" OR "tinción dentaria" OR "pigmentación dental" OR "pigmentación dentaria" OR "teeth staining" OR "dentes manchados" OR "stained tooth" OR "dente manchado" OR "stained teeth" OR "mancha nos dentes" OR "mancha en los dientes" OR "dental staining" OR "mancha en lo diente" OR "mancha no dente")	#2 (MH:"tooth bleaching" OR MH:"tooth bleaching agents" OR MH:peroxides OR MH:"hydrogen peroxide" OR peroxides OR peróxidos OR "hydrogen peroxide" OR "peróxido de hidrogênio" OR "carbamide peroxide" OR "peróxido de carbamida" OR bleaching OR branqueamento OR blanqueo OR whitening OR clareamento OR blanqueamiento OR clareamiento OR "in-office" OR "em consultório" OR "en ambulatorio" OR "at home" OR caseiro OR "casero" OR "light activation" OR fotoativação OR "activación por luz" OR "light activated" OR "ativado por luz" OR "activado por luz" OR "laser assisted" OR "a laser" OR "con láser" OR "dentist-supervised" OR "superviosionado por dentista" OR "supervisado por el dentista" OR nightguard OR "tray-delivered" OR moldeira OR cubeta OR "jump-start" OR associado OR combinado)	
#1 AND #2		
Web of science		
#1Tópico: ("t*th discolo*ration") OR Tópico: ("permanent dentition") OR Tópico: (colo$r) OR Tópico: ("discolo*red t*th") OR Tópico: ("dental discolo*ration") OR Tópico: ("t*th staining") OR Tópico: ("stained t*th") OR Tópico:("dental staining")	#2 Tópico:("t*th bleaching") OR Tópico:(peroxides) OR Tópico: ("hydrogen peroxide") OR Tópico: ("carbamide peroxide") OR Tópico: (bleaching) ORTópico: (whitening) OR Tópico: ("in-office") OR Tópico: ("at home") ORTópico: ("light activat*") OR Tópico:("laser assisted") OR Tópico:("dentist-supervised") OR Tópico:(nightguard) OR Tópico: ("tray-delivered") OR Tópico: ("jump-start")	

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#1 AND #2	
Scopus	
#1 (TITLE-ABS-KEY ("t*th discoloration") OR TITLE-ABS-KEY ("permanent dentition") OR TITLE-ABS-KEY (colo*r) OR TITLE-ABS-KEY ("t*th discolouration") OR TITLE-ABS-KEY ("discolored t*th") OR TITLE-ABS-KEY ("discoloured t*th") OR TITLE-ABS-KEY ("dental discolo*ration") OR TITLE-ABS-KEY ("t*th staining") OR TITLE-ABS-KEY ("stained t*th") OR TITLE-ABS-KEY ("dental staining"))	#2 (TITLE-ABS-KEY ("t*th bleaching") OR TITLE-ABS-KEY (peroxides) OR TITLE-ABS-KEY ("hydrogen peroxide") OR TITLE-ABS-KEY ("carbamide peroxide") OR TITLE-ABS-KEY (bleaching) OR TITLE-ABS-KEY (whitening) OR TITLE-ABS-KEY ("in office") OR TITLE-ABS-KEY ("at home") OR TITLE-ABS-KEY ("light activat*") OR TITLE-ABS-KEY ("laser assisted") OR TITLE-ABS-KEY ("dentist-supervised") OR TITLE-ABS-KEY (nightguard) OR TITLE-ABS-KEY ("tray-delivered") OR TITLE-ABS-KEY ("jump-start"))
#1 AND #2	

Table 2. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Parallel and Split-mouth RCTs published in 1996 or later	Laboratory studies
	Conference abstracts
Different types of bleaching systems (in-office, at home and jump-start) (bleaching strips, gels, dentifrices, use of light) regarding.	Thesis
Studies that evaluate color change, toxicity, postoperative sensitivity and application technique	Reports published in any media other than peer-reviewed journals
The studies included patients of any age group	Reported cases

been very subjective and the adherence to these items would not weaken the quality of the study report or the risk of bias of the studies.

A total of 12 items of the CONSORT Statement were included in this CONSORT evaluation tool. As some of these items were subdivided, a total of 16 items were evaluated. The given score per item ranged from 0 to 2. In general words, 0 = no description, 1 = poor description and 2 = adequate description. More details regarding the scoring process for each score of each item are displayed in Table 3. Each item was given an equal weighting.

Prior to evaluation, the instrument was discussed between two experienced authors in clinical trials (A.D.L. and A.R.), pilot-tested in 15 articles and checked for accuracy and reproducibility by three evaluators. This process yielded modification of the instrument tool, as new possibilities for each score were observed and discussed during pilot testing.

Three reviewers (A.P., B.M.M. and T.H.) performed the round of scoring using the CONSORT evaluation tool as guide (Table 3). In case of disagreement a discussion followed and the consensus was used to determine the final score. Evaluators were not blinded to the study authors. This was not feasible, as reviewers were familiar with the studies and could easily guess the researchers' affiliation by reading the paper.

Scoring system and statistical analysis

The number of studies by journal, follow-up period and country were analyzed descriptively. Compliance with individual items of the CONSORT Statement was analyzed to identify areas in which authors could improve the description. A chart with the percentage of studies per score in each item was provided.

To achieve an overall compliance score, the scores for the 16 items were added in each article. A trial with adequate descriptions (score 2) for all CONSORT items would have received a maximum score of 32. A mean average score was calculated by period of time, journal and country. Comparison within each factor was performed with the Kruskall-Wallis and Mann-Whitney test at a level of confidence of 95%. Linear correlation analysis between 2015 ISI journal impact factor and the average CONSORT score was also performed.

These additional analyses aimed at offering information about whether improvements in the average CONSORT score occurred over the time and if these improvements were related to the journal and respective impact factor, as well as the living country of the first author.

Risk of bias in individual studies

Quality assessments were performed by two independent reviewers, using the Cochrane Collaboration's tool for assessing risk of bias in randomized trials (CCRT).[23] The assessment criteria

Table 3. Instrument tool developed from the 2010 CONSORT Statement to evaluate the compliance of the studies to the CONSORT Statement.

CONSORT item	Sub-item	Score	Adherence to the methods and results items of the consort statement
			Description
Trial design		Positive [2]	The trial design is clearly written in the text (split mouth, cross-over, factorial, cluster).
		Negative [0]	This information is not reported.
		Poor [1]	1. Information can be obtained during reading the manuscript, although this is not explicity reported by the authors. 2. There is lack of consistence between sections of the article (examples - abstract does not match the material and methods section; the presentation of the results does not match the description of the trial design; flow diagram presents different information, etc.).
Participants	Eligibility criteria	Positive [2]	The inclusion and exclusion criteria is clear, so that readers can know exactly which population the data can be extrapolated to.
		Negative [0]	The information is not reported.
		Poor [1]	1. Incomplete information of eligibility criteria compared to most of the studies on the field. 2. Presence of inconsistencies in the inclusion/exclusion criteria that prevents the readers from knowing the population at which the intervention/control groups were performed.
	Settings and location	Positive [2]	Clear description of the setting (academic, practice-based research, university, private clinics, etc.) as well as the date at which the intervention was implemented.
		Negative [0]	The setting and/or the location is not reported in the text.
		Poor [1]	1. Authors describe either the setting or the date but never both. 2. This information can be obtained indirectly in the text
Interventions		Positive [2]	The interventions for each group are described with sufficient details to allow replication, including how they were actually administered.
		Negative [0]	There is no description.
		Poor [1]	There are missing information that prevents the replication of the interventions/comparators.
Outcomes		Positive [2]	At least the primary outcomes were defined in details, including how and when they were assessed. Consider it as clear when the details are clear, but the authors did not use the term "primary outcome" or related synonyms.
		Negative [0]	There is no definition of the primary outcome and/or secondary outcomes.
		Poor [1]	1. The authors only report they have used a specific criteria without detailing the most important outcomes of such criteria. 2. The description of the primary outcome and/or secondary outcomes is very superficial and does not allow replication of the method.
Sample size		Positive [2]	Method of sample size calculation is described in a way to allow replication. It should be identified the primary outcome for each the sample size was calculated for. Elements of the sample size calculation are (1) the estimated outcomes in each group (which implies the clinically important target difference between the intervention groups); (2) the α (type I) error level; (3) the statistical power (or the β (type II) error level); and (4), for continuous outcomes, the standard deviation of the measurements should be reported. For equivalence trials, the equivalence limit, instead of the effect size should be reported.
		Negative [0]	There is no description in the article.
		Poor [1]	The sample size is described but some parameters are missing so that it prevents replication.

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Randomization	Sequence generation	Positive [2]	1. Clear description of the random sequence generation. 2. or clear description of a non-random sequence method.
		Negative [0]	There is no information in the text.
		Poor [1]	The authors only provide a very superficial description (such as the "groups were randomly allocated") or do not provide sufficient information to allow replication of the randomization process.
	Allocation concealment	Positive [2]	Clear description of the allocation concealment. See next columns for evaluation of the Risk of Bias.
		Negative [0]	There is no information in the text.
		Poor [1]	not applicable
Blinding		Positive [2]	1) The authors describe who is blinded in the study. 2. In single-blind studies (when this is clearly reported by the authors), just the description of participant or evaluator (the one blinded) is enough; however when the study is double blind or triple blind all blinded people should be described. 2) The study describes just the participant or examiner blinded but one of these people cannot be blinded by intrinsic features of the study design.
		Negative [0]	There is no description of the blinding.
		Poor [1]	Insufficient/partial information. For instance, (1) the authors describe examiners' blinding or participants' blinding, but never both. (2) The authors describe the study was blind or double-blind but does not specify who was blinded.
Statistical methods	Hypothesis testing	Positive [2]	Statistical methods are described with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. Additionally, statistical tests employed by the authors seem to be adequate for the type of trial design and nature of the data collected.
		Negative [0]	Statistical methods are not described.
		Poor [1]	1) There is not enough information to evaluate the statistical method used by the authors and/or the type of statistical tests employed by the authors are inadequate for the trial design and/or nature of the data (for instance, tests that do not take into account the paired nature of the data when this is the case). 2) The authors describe several statistical tests but does not specify for each outcome they were applied.
	Estimated effect size	Positive [2]	Authors report at least for the primary outcome the effect size and its precision (such as 95% confidence interval). Odds ratio, risk ratio, risk difference, mean difference, etc.
		Negative [0]	There is no description of the effect size and 95% confidence interval
		Poor [1]	There is incomplete information.
Participant flow	Flow diagram	Positive [2]	For each group, the numbers of participants who were randomly assigned, received intended treatment and were analyzed for the primary outcome is described in the flow chart CONSORT diagram.
		Negative [0]	The flow-chart is not presented in the article.
		Poor [1]	1. There are inconsistencies between the numbers described in the flow-chart and other parts of the manuscript. 2. Incomplete diagram with missing information
	Losses/Exclusions	Positive [2]	1. For each group, losses and exclusions after randomization are described with reasons. 2. During reading, reviewer observes that there is no loss to follow-up.
		Negative [0]	1. There is no description of losses and exclusions.
		Poor [1]	Incomplete information. For instance, 1. the authors describe the overall percentage of losses but this information is not specified per group. 2. The authors describe the losses and exclusions but does not specify the reasons

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Baseline data	Positive [2]	A table/text description containing baseline demographic and clinical characteristics of each group are presented in the article.
	Negative [0]	There is no table/text description with baseline data or description in the body of the text.
	Poor [1]	1. A table/ text description with baseline data is presented but the data is not distributed between the study groups and/or given in percentages instead of raw numbers. 2. Insufficient information about participants is provided; 3. Inconsistencies in the data presented can be observed.
Numbers analysed	Positive [2]	For each group and for each outcome, the number or participants (denominator) included in the analysis are clear.
	Negative [0]	Authors do not report the numbers analyzed.
	Poor [1]	There is no clear description of the number of participants (denominator) included in the analysis of at least one of the outcomes. 2. Instead of reporting the raw number of participants, the authors report their data in percentages. 3. The authors fail to report the baseline number of patients included in each analysis. 4. Data can be obtained indirectly in the study.
Registration and protocol	Positive [2]	The study was registered in a trial registry and the protocol number is provided.
	Negative [0]	This information is not available in the manuscript. Registration in an Ethics Committee is valid as trial registry
	Poor [1]	The authors describe that the study was registered but does not provide the registration number and/or the number provided does not link to the study.

contain six domains: sequence generation, allocation concealment, blinding of the outcome assessors, incomplete outcome data, selective outcome reporting, and other possible sources of bias. Each domain of the Cochrane risk of bias tool was evaluated at low, high or unclear risk of bias. After assessment of the domains, each study was then evaluated into low risk of bias if all domains were at low risk. The study was judged as at high risk of bias if at least one of the key domains was evaluated as high risk of bias. And finally, the study would be considered at unclear risk, if at least one domain were judged at unclear risk of bias.

Results

Characteristics of the included studies

From the 1925 articles that were originally screened, after removal of duplicates, 1756 were excluded for not complying with the inclusion criteria. The full-text of 234 papers were assessed and 49 papers were excluded for the following reasons: 1) 15 studies were not randomized clinical trials; 2) 7 studies were case reports; 3) 3 studies were duplicates; 4) 2 studies were abstracts; 5) 1 study was published in Korean language; 6) 4 studies were in vitro; 7) 2 studies were case series; 8) 1 study was a literature review; 9) 1 study was an ex-vivo study; 10) 1 study is currently in the recruitment phase and evaluation of tooth color (results not yet available); 11) 1 study evaluated the color change of the composite resin after bleaching; 12) 11 studies were not accessible. After these exclusions, 185 RCTs remained for assessment (Figure 1).

The included RCTs investigated several topics, such as the comparison of 1) at-home dental bleaching techniques; 2) in-office dental bleaching techniques; 3) patient related factors; 4) in-office vs. at home and 5) combined bleaching techniques.

Table 4 displays the 185 RCTs tabulated by their collected characteristics. The journals contributing with the most RCTs were Oper Dent (17.8%), followed by Comp Cont Educ Dent (11.4%), Am J Dent (7.6%) and Quintessence Int (7.0%). Approximately 29.2% of the publications were published in 37 different journals. The countries with most publications were USA (40.5%) and Brazil (28.1%), representing together about 70% of all publications in the field. The most frequent follow-up period (days) reported in the articles occurred between 14 (22.7%) and 28 (10.3%) days.

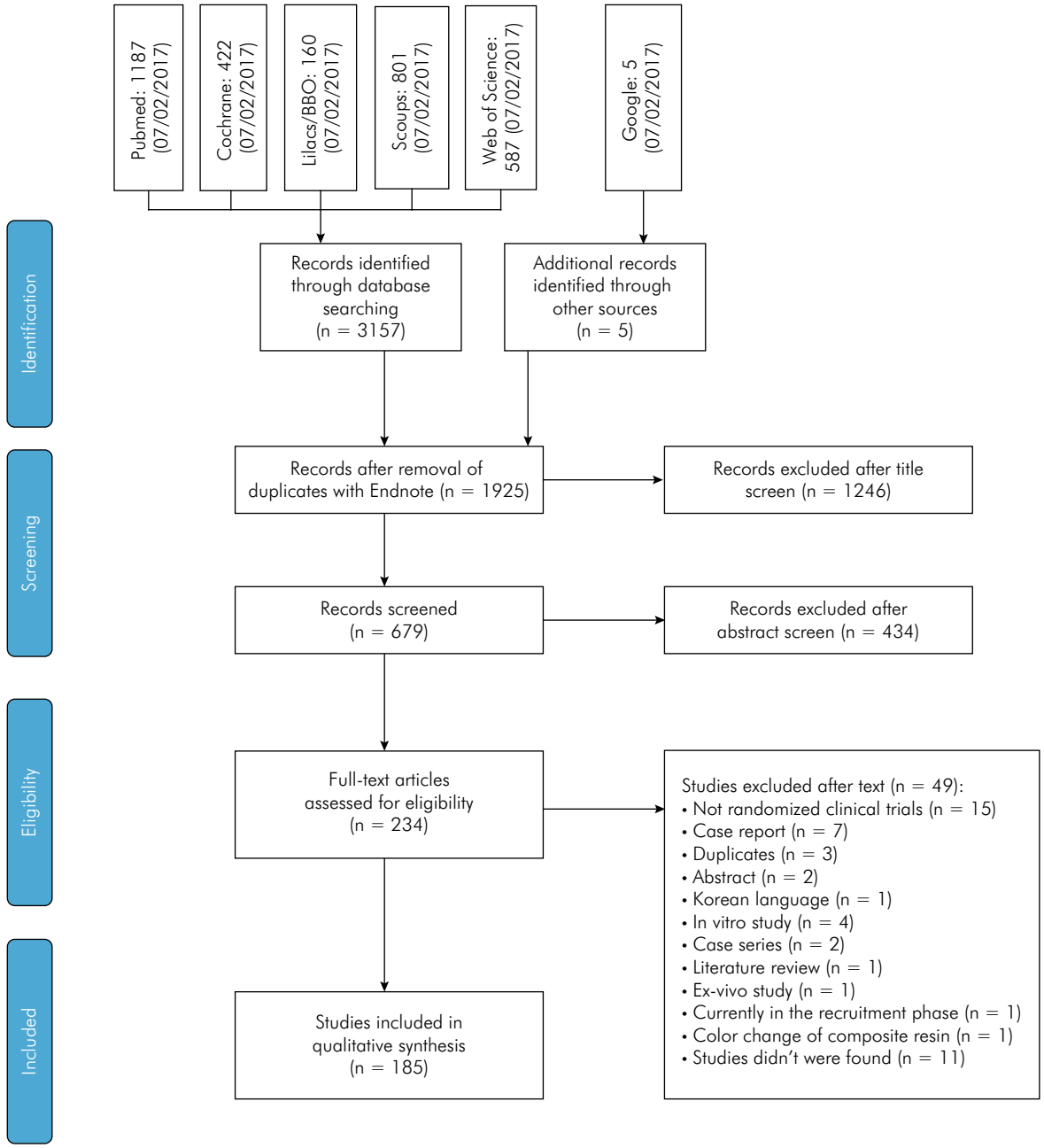

Figure 1. PRISMA Flow chart diagram.

Study compliance with each of the CONSORT instrument tool items

Figure 2 displays the percentage of studies per score for each item of the CONSORT Statement in percentage of studies. In regard to the items' intervention and outcomes, more than 80% of the studies were scored as 2, with an adequate reporting. For the items eligibility, hypothesis testing, losses/exclusion and numbers analyzed, more than 50% of the studies were scored as 2.

More than 50% of the studies received score 1 (poor reporting) or score 0 (no reporting) for all other items. This was more critical with the items protocol, flow chart, allocation concealment and sample size where more than 80% of the studies were scored as 0 (no reporting).

In order to help future randomized clinical trials of bleaching, some examples of adequate description of each item of the results, material and methods of CONSORT were added in Tables 5 to 9.

Table 4. Characteristics of the included studies by categories.

Characteristics	Categories	Number of studies	Percentage (%)
Journal	Clin Oral Investig	5	2.7
	J Clin Dent	10	5.4
	J Esthet Restor Dent	11	5.9
	J Dent	12	6.5
	JADA	12	6.5
	Quintessence Int	13	7.0
	Am J Dent	14	7.6
	Comp Cont Educ Dent	21	11.4
	Oper Dent	33	17.8
	Others*	54	29.2
Country	UK	6	3.2
	Italy	7	3.8
	Germany	14	7.6
	Brazil	52	28.1
	USA	75	40.5
	Others**	31	16.8
Period of time	1996 to 2000	17	9.2
	2001 to 2005	48	25.9
	2006 to 2010	52	28.1
	2011 to 2016	68	36.8
Follow-up period (days)	0	5	2.7
	7	12	6.5
	14	42	22.7
	21	10	5.4
	28	19	10.3
	30	6	3.2
	42	5	2.7
	168	12	6.5
	Others***	74	40.0

*Representing 37 different journals; **Representing 18 different countries; ***Representing 33 different follow-up period (days).

Average CONSORT score per study characteristics

The overall CONSORT score for the included studies in this review was 16.7 ± 5.4 points, which represents 52.2% of the maximum CONSORT score of 32 points. We observed a significant influence of journal, country, and period of time on the average CONSORT score (Table 10). Significant differences among journals were observed ($p < 0.0001$; Table 10), with the average CONSORT scores of J Dent (higher score), Oper Dent, Clin Oral Investig and JADA being higher than the remaining journals. 'Other journals' are composed of 37 different journals, which published 54 different papers (29.1% of total). A significant but weak correlation between average CONSORT score and impact journal factor was observed ($r = 0.16$; $p < 0.0001$, Figure 3).

Regarding country, a significant difference was also observed ($p = 0.02$; Table 10). Brazil showed the highest average CONSORT score, being statistically higher than those of UK, Italy and USA. On the same line, the period of time in years had a significant influence on the average CONSORT score ($p = 0.004$; Table 10). We observed an increase in the average CONSORT score in the 2011-2016 interval (19.0 ± 6.8) in comparison with the 1996-2000 period (13.4 ± 4.0). The individual CONSORT score for each one of the included studies can be seen in Table 11.

Risk of bias of the included studies

Except for the selective outcome reporting and incomplete outcome data, most of the studies were judged to be at "unclear" or "high" risk of bias in the Cochrane Collaboration tool domains (Figure 4). Table 10 reports the individual risk of bias in each domain for all included studies. This table facilitates the analysis of the risk of bias within each study. Only 14 included studies (7.6%) were judged to be at "low" risk of bias in all domains; 115 studies were classified as at "unclear" risk of bias in at least one domain, resulting in 62.2% of the studies being classified at "unclear" risk of bias at the study level. The remaining 56 studies were classified as at "high" risk of bias in at least one domain, representing 30.3% of studies judged as at "high" risk of bias.

Discussion

Study compliance with the CONSORT

Although the CONSORT Statement has been misleadingly used as an instrument to evaluate the quality of the RCTs available in the literature,[24] the aim of the CONSORT Statement is to guide authors

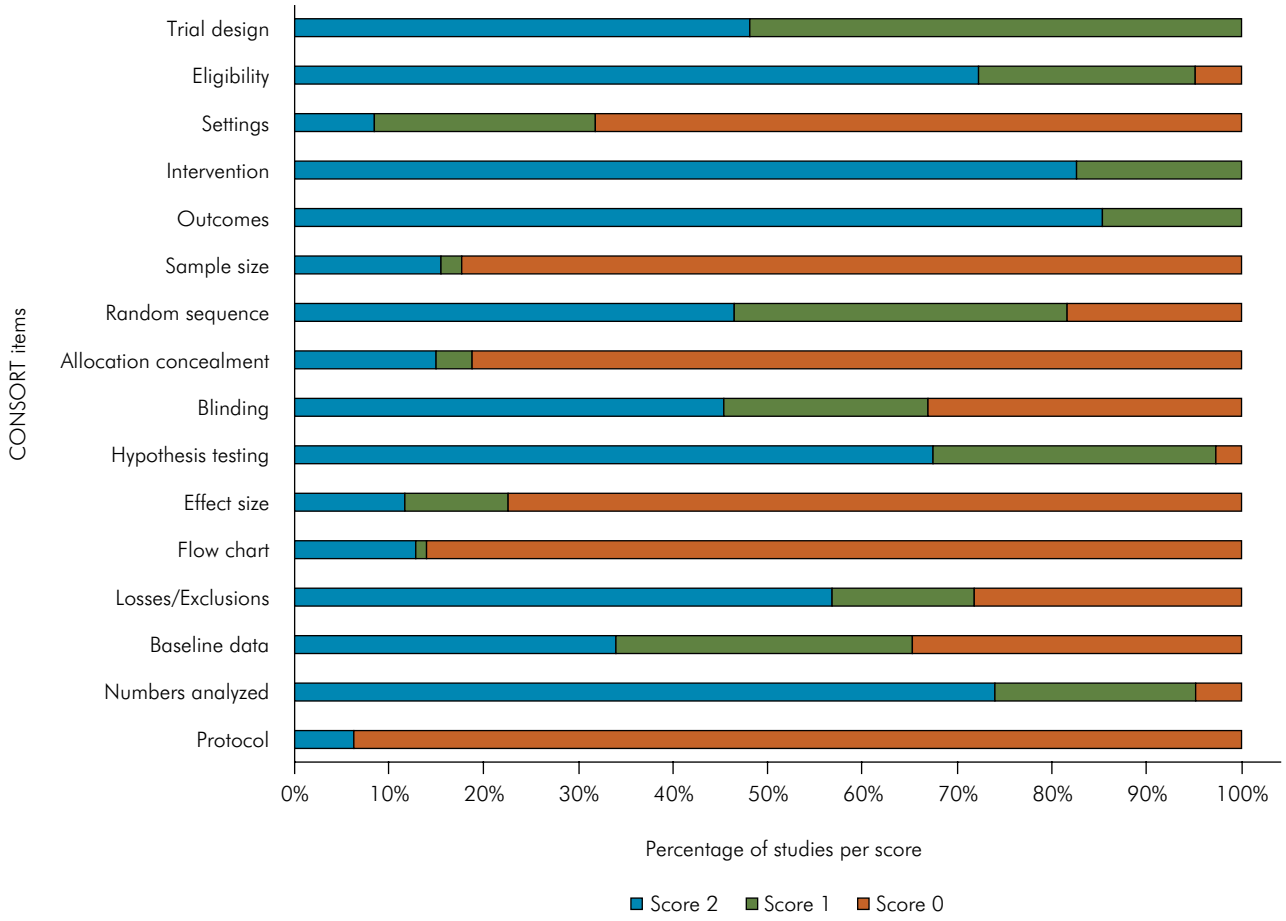

Figure 2. Percentage of studies per CONSORT score for each CONSORT item analyzed.

to describe details on their studies to enable the evaluation of the risk of bias of RCTs.[25] This is why adherence to CONSORT Statement is of ultimate importance so that readers can appraise the available literature and translate this literature into clinical knowledge pertinent to evidence-based practice. In the present study, we assessed the adherence of RCTs of bleaching materials and techniques to the CONSORT Statement. [26, 27]

In order to provide a better analysis of the compliance of the studies with each item of the CONSORT score, a 0–2 scale was developed in a way that zero means no reporting, 1 poor reporting, and 2 adequate reporting.[22] This is different from what had been done in other papers, which have reported the adherence of RCTs in other dental areas, such as orthodontics, prosthodontics, oral implants, periodontics and pediatric dentistry.[28,29,30,31,32,33] These earlier studies were more focused on the journal's compliance rather than the article's compliance with a specific subject. Subsequently, few of these earlier studies performed a comprehensive search review of the articles published in a specific research area, as we have tried to do in the present study. To the extent of the authors' knowledge this is the first study that has attempted to evaluate the adherence of RCTs of bleaching materials and techniques to the CONSORT Statement, which was one of the aims of the present study.

To evaluate the risk of bias of the RCTs it is imperative that we concentrate on the design and the results of any study report. CONSORT adherence to introduction or discussion section increases the quality of the article reporting but does not affect the risk of bias of the studies. This is the reason behind our decision to only evaluate each study's compliance

Table 5. Examples of adequate description of the evaluate parameters of the Instrument tool developed from the 2010 CONSORT Statement for bleaching studies.

Item	Examples
Trial design	
	Example 1: "This study was a randomized, single-blind, controlled trial with a parallel group and an allocation rate of 1:1."56 Example 2: "This was a randomized, parallel, placebo-controlled, triple-masked clinical trial, in which the patient, operator, and evaluator were masked to the group assignment. A third researcher, not involved in the evaluation process, was responsible for the randomization process, and delivery and guidance on the administration of the drugs."57
Participants	
Eligibility criteria	The authors judged that it was not necessary to add some examples, because this item showed an adequate reporting as seen in Figure 2.
Settings and locations	Example 1: "The study took place in the clinics of the dentistry schools at the State University of Ponta Grossa, Paraná, and the University of São Paulo, São Paulo, from June 2010 to June 2012."58 Example 2: "This study was performed from February 2011 to March 2012 in the city of Guarapuava (Paraná, Brazil)."12
Interventions	The authors judged that it was not necessary to add some examples, because this item showed an adequate reporting as seen in Figure 2.
Outcomes	The authors judged that it was not necessary to add some examples, because this item showed an adequate reporting as seen in Figure 2.
Sample size	
For Tooth sensitivity	For superiority trial: "The primary outcome of this study was the absolute risk of TS. The absolute risk of TS (that is, the number of patients [percent] who reported pain at some point during dental bleaching) was reported to be approximately 87% (4,8) for the bleaching product Whiteness HP Maxx (FGM Dental Products). Thus, a minimum sample size of 56 participants was required to have a 90% chance of detecting, as significant at the 2-sided 5% level, a decrease in the primary outcome measure from 86% in the control group to 50% in the experimental group."57 For equivalent trial: We selected the absolute risk of TS as the primary study outcome. Considering the absolute risk of TS to be approximately 90% (19, 40) participants were required to be 90% (study power) sure that the limits of a two-sided 90% confidence interval will exclude a difference between the standard and experimental group of more than 30% (equivalence limit)."59
For Color evaluation	For superiority trial: "The primary outcome of this study was color change of the participants' teeth. A previous study (34) reported that two bleaching sessions with the product Whiteness HP Maxx 35% (FGM Dental Products, Joinville, SC, Brazil) without light activation produced a whitening effect of about 7 ± 2 SGUs. To detect a difference of 2 SGUs between the means of any pair of the study groups, with a power of 80% and an alpha of 5%, a minimum sample size of 17 patients per group was required. This threshold of perceptibility was based on the fact that ''untrained'' people, such as the patients, do not detect easily changes of one shade guide unit at the lighter end of the vita classical guide."58 For equivalent trial: We based the sample size calculation on the color change measured with the spectrophotometer (DE), the primary outcome of the study. One hundred eighteen participants were required to exclude a difference of means of 2.0 units of DE at 1 week and 1 month (equivalence limit) with a power of 90 % and a of 5 %. With these calculations, we took into consideration a standard deviation of 3.3 in the DE. The equivalence limit we chose was lower than the DE threshold of 3.0, above which color differences become clinically perceptible (24-26)."60
Randomisation	
Sequence generation, allocation concealment and implementation	Example 1: "The randomization process was performed by coin toss immediately before the bleaching procedure to provide adequate allocation concealment."61 Example 2: "Participants were randomly divided into four groups according to the combination of the main factors: HP (20% or 35%) and light activation (with or without). A third person who was not involved in the research protocol performed the randomization procedure by using computer-generated tables. We used blocked randomization (block sizes of 2 and 4) with an equal allocation ratio (www.sealedenvelope.com). Opaque and sealed envelopes containing the identification of the groups were prepared by a third party not involved in the study intervention."58
Blinding	Example 1: "The participant and the operator could not be blinded to the procedure, as the application of bleaching gel for different times could not be masked. However, the examiners who evaluated the color changes were not aware of which group the participant was assigned to."62 Example 2: "Neither the participant nor the operator knew the group allocation, both being blinded to the protocol." "The two examiners, blinded to the allocation assignment, scheduled these patients for bleaching and evaluated their teeth against the shade guide at baseline and 30 days after the procedure."63

Continue

Continuation	
Statistical methods	
Hypothesis testing	The authors judged that it was not necessary to add some examples, because this item showed an adequate reporting as seen in Figure 2.
Estimated effect size	Two examples of how to report an effect size can be seen in Tables 6 and 7.
Participants	
Flow diagram	Please see the following link to have access templates of the CONSORT flow diagram available in MS Word (http://www.consort-statement.org/consort-statement/flow-diagram)
Losses and exclusions	The authors judged that it was not necessary to add some examples, because this item showed an adequate reporting as seen in Figure 2.
Baseline data	Two examples of how to report an effect size can be seen in Tables 8 and 9.
Numbers analysed	The authors judged that it was not necessary to add some examples, because this item showed an adequate reporting as seen in Figure 2.
Registration and protocol	Example 1: "The ClinicalTrials.gov identification number was NCT02017873."4 Example 2: "The clinical investigation was approved (protocol number 172.988) by the scientific review committee and by the committee for the protection of human participants of the local university. It was registered in the Brazilian clinical trials registry under the identification number RBR-6pt2n3."57

Table 6. Baseline characteristics of the participants.

Characteristics	Smokers	Non-smokers
Age (years; mean ± SD)		
Brazil	26.3 ± 6.5	24.1 ± 6.8
Chile	29.3 ± 9.4	25.5 ± 6.6
Male (%)		
Brazil	46.7	53.3
Chile	63.3	36.7
Baseline color (L*; mean ± SD)		
Brazil	82.4 ± 4.9	82.3 ± 4.3
Chile	83.2 ± 4.0	84.9 ± 3.8
Baseline color (b*; mean ± SD)		
Brazil	22.6 ± 3.6	23.2 ± 3.6
Chile	22.2 ± 3.1	21.7 ± 2.5
Baseline color (a*; mean ± SD)		
Brazil	-1.0 ± 1.0	-0.5 ± 1.0
Chile	-0.0 ± 0.7	-0.2 ± 0.6
Baseline color (SGU; mean ± SD)		
Brazil	6.8 ± 2.3	7.4 ± 2.5
Chile	7.2 ± 1.7	8.4 ± 2.9
Smoking time (years; mean ± SD)		
Brazil	8 ± 5.9	-
Chile	11.8 ± 9.1	-
Number cigarettes/day (mean ± SD)		
Brazil	13.2 ± 4.0	-
Chile	12.8 ± 3.8	-

Adapted from DeGeus et al.[64]
SD: Standard-deviation; L*: luminosity; b*: color along the yellow-blue axis; a*: Color along the red-gree axis;.

with the items related to methodology and results. Earlier studies with the same aim, conducted on different specialties of dentistry, evaluated additional items, including the subjective items of introduction and discussion sections. [28, 29, 30, 31, 32, 33]

In the present study we observed that the overall CONSORT score for the included studies was 16.6 ± 5.3 points, which represents only 52.2% of the maximum CONSORT score a study could have reached. This reduced compliance with CONSORT Statement was also observed in an earlier study from our research group evaluating the compliance of RCTs in non-carious cervical lesions with the CONSORT.[22] Similarly, other dental specialties such as periodontics and pediatric dentistry yielded similar results. For instance, a CONSORT compliance of approximately 60% was observed for RCTs in prosthodontics and implant dentistry. In orthodontics, this compliance ranged from 40 to 70%.[28,29,30,34,35] Although these variations are small, they may reflect the inclusion criteria of the RCTs, the method of compliance evaluation, the number of CONSORT items evaluated, and also the period of publication. Our previous study of RCTs in non-carious cervical lesions demonstrated that the adherence of the study increases when the study is more recent.[22]

Table 7. Demographic features of the participants of each study group.

Feature	20%	20% + light	35%	35% + light
Age (mean ± SD)	22.9 ± 4.0	22.0 ± 4.4	23.0 ± 3.4	22.0 ± 3.6
Female (n, %)	13 (68)	12 (63)	13 (68)	12 (60)
Baseline SGU (median, 25 and 75 percentil)	12 (11 – 14)	12 (11 – 12)	12 (10,5 – 15)	11 (9 – 12)

Adapted from Mena-Serrano et al.[58]
SD: Standard-deviation.

Table 8. Means (standard deviations) of the change in shade guide units obtained with the VITA Classical and VITA Bleachedguide* and the color change measured by spectrophotometer at baseline versus 1-month postbleaching.

Color evaluation tools	Groups		p-value	Mean difference (95%CI)
	Placebo	Dexamethasone		
Vita Classical	3.1 ± 2.6	3.4 ± 2.3	0.642	- 0.3 (-9.9–10.5)
Dexamethasone	2.8 ± 2.2	2.7 ± 1.6	0.775	- 0.6 (-9.4–10.6)
p-value	6.0 ± 4.7	6.6 ± 4.0	0.582	- 0.6 (-11.4–12.6)

Adapted from Rezende et al.[57]
CI: confidence interval.

Table 9. Absolute risk of tooth sensitivity, along with the risk ratio, for both groups at the different assessment points.

Periods	Group	Number of patients with TS		Absolute risk (95%CI)	Risk ratio (95%CI)	p-value*
		Yes	No			
During in-office session	HP35%	17	3	85.0 (64.0–95.0)	1.8 (1.1– 3.2)	0.02
	HP20%	7	8	47.0 (25.0–69.0)		
Up to 48 h after in-office session	HP35%	13	7	65.0 (43.2–81.9)	2.0 (0.9–4.3)	0.09
	HP20%	5	10	33.3 (15.2–58.3)		
During at-home bleaching	HP35%	5	15	25.0 (11.2–46.9)	1.3 (0.5–3.8)	0.71
	HP20%	5	10	33.3 (15.2–58.3)		

Adapted from Rezende et al.[61]
Fisher's exact test; TS: tooth sensitivity; CI: confidence interval.

The results of the present study confirmed that the journal endorsement of the CONSORT Statement might positively influence the completeness of reporting of RCTs, mainly because three out of four journals with high average CONSORT score (J Dent, Clin Oral Investig, and JADA) have adopted this policy within the last decade. The same tendency has been observed for medical journals[36] and for orthodontics journals,[28,37] but not for RCTs conducted in non-carious cervical lesions.[22] Braz Oral Res is another journal that clearly endorses the CONSORT Statement. Although there is an increasing number of journals endorsing the CONSORT Statement in medical journals as well as dental journals, the CONSORT compliance is still considered suboptimal even in these journals.[38]

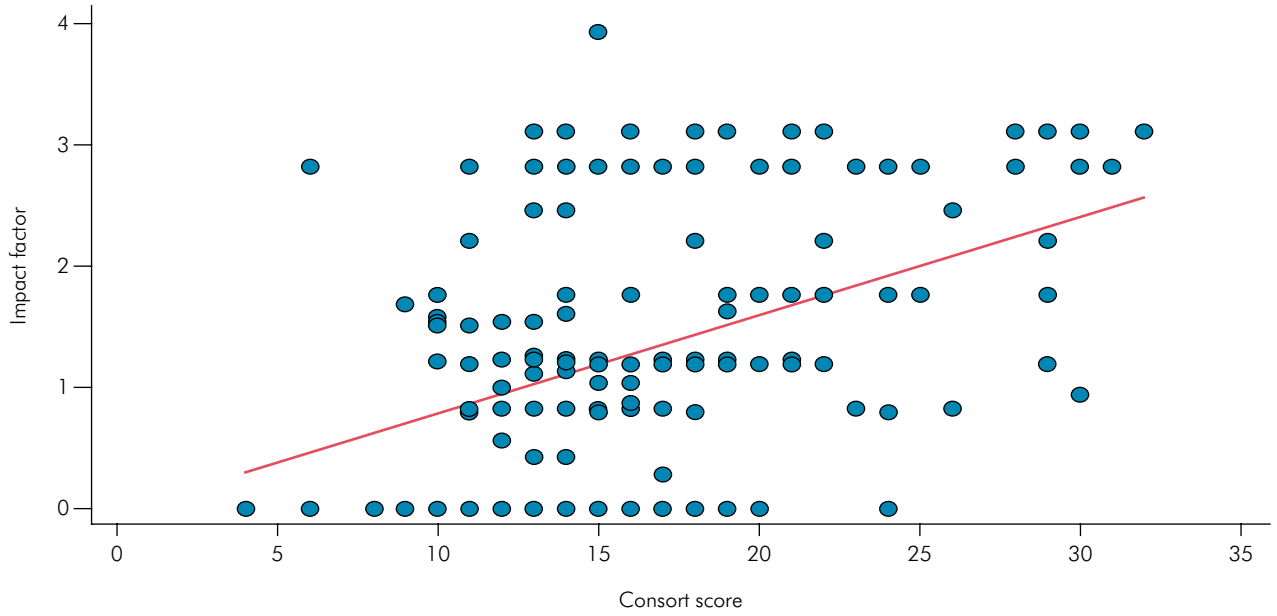

Figure 3. Linear regression between Impact Factor and Consort Score.

Table 10. Average CONSORT score per journal, country and period of time.

Characteristics	Categories	Mean ± SD	Median (interquartile range)	p-value*
Journal	Clin Oral Investig	19.60 ± 6.58 A	18 (18–22)	< 0.0001
	J Clin Dent	16.30 ± 1.42 A,B	16 (15–17)	
	J Esthet Restor Dent	15.27 ± 3.04 A,B	14 (13–17.5)	
	J Dent	21.75 ± 6.50 A	20 (17.5–28.25)	
	JADA	19.33 ± 5.28 A	19.5 (13–22.5)	
	Quintessence Int	15.54 ± 4.33 A,B	14 (13–16)	
	Am J Dent	18.36 ± 4.22 A,B	18.5 (16.25–19.75)	
	Comp Cont Educ Dent	15.24 ± 3.06 A,B	15 (13–18)	
	Oper Dent	19.94 ± 6.32 A	18 (15–25)	
	Others	13.80 ± 4.99 B	13 (11–16)	
Country	UK	14.83 ± 2.99 B	15 (12.5–17.5)	0.02
	Italy	14.29 ± 6.80 B	13 (9.5–19)	
	Germany	16.71 ± 4.05 A,B	17 (14.25–18)	
	Brazil	19.48 ± 6.93 A	20.5 (13.75–25)	
	USA	15.25 ± 3.13 B	15 (13.5–18)	
	Others	16.10 ± 4.99 A,B	14.5 (12.25–18)	
Period of time	1996 to 2000	13.47 ± 4.03 B	14 (11–16)	0.004
	2001 to 2005	15.54 ± 2.81 A,B	16 (14–18)	
	2006 to 2010	15.75 ± 4.01 A,B	15 (13–19)	
	2011 to 2016	19.03 ± 6.87 A	18 (13.75–25)	

*Kruskall Wallis and Mann-Whitney tests.

Table 11. List of the scored papers along with their average CONSORT score and evaluation of the risk of bias in each domain.

Study identification	Year	Journal	Average CONSORT score	Risk of bias tool					
				random sequence	allocation concealment	participant blinding	examiner blinding	incomplete outcome data	selective reporting
Acosta Gómez et al.[34]	1999	Univ Odontol	11	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Al Shethri et al.[65]	2003	Oper Dent	18	LOW	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Almeida et al.[66]	2012	Int J Periodontics Restorative Dent	16	UNCLEAR	UNCLEAR	HIGH	HIGH	LOW	HIGH
Alomari, El Daraa[67]	2010	J Contemp Dent Pract	13	UNCLEAR	UNCLEAR	LOW	LOW	LOW	LOW
Alonso de la Peña, Balboa Cabrita[68]	2006	Quintessence Int	14	UNCLEAR	HIGH	HIGH	HIGH	HIGH	LOW
Alonso de la Peña, Lopez Ranton[69]	2014	Oper Dent	18	LOW	UNCLEAR	HIGH	HIGH	LOW	LOW
Auschill et al.[70]	2005	Oper Dent	18	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Auschill et al.[71]	2012	Quintessence Int	26	LOW	LOW	UNCLEAR	LOW	LOW	LOW
Barlow et al.[72]	2009	Int J Dent	21	LOW	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Barnes et al.[73]	1998	Comp Cont Educ Dent	15	HIGH	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Basting et al.[74]	2012	Oper Dent	21	LOW	LOW	UNCLEAR	LOW	LOW	LOW
Berga-Caballero et al.[75]	2006	Med Oral Patol Oral Cir Bucal	13	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Bernardon et al.[76]	2010	Oper Dent	16	LOW	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Bernardon et al.[77]	2015	J Prosthet Dent	12	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	HIGH
Bernardon et al.[78]	2016	J Prosthet Dent	10	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Bizhang et al.[79]	2007	Am J Dent	20	UNCLEAR	HIGH	UNCLEAR	UNCLEAR	LOW	HIGH
Bizhang et al.[80]	2009	Oper Dent	18	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Bonafé et al.[81]	2014	Clin Oral Investig	22	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Bortolatto et al.[82]	2016	Lasers Med Sci	26	LOW	LOW	LOW	LOW	LOW	LOW
Braun et al.[83]	2007	Dent Mater	15	HIGH	UNCLEAR	LOW	LOW	LOW	LOW
Browning et al.[84]	2012	J Esthet Restor Dent	17	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Browning et al.[85]	2004	Oper Dent	13	UNCLEAR	UNCLEAR	LOW	LOW	UNCLEAR	LOW
Bruhn et al.[86]	2012	Int J Dent Hyg	16	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Callan et al.[87]	2008	Am J Dent	12	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Cardoso et al.[88]	2011	JADA	17	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Carvalho et al.[89]	2005	Rev Assoc Paul Cir Dent	6	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Cerqueira et al.[90]	2013	Rev Assoc Paul Cir Dent	19	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Cibirka et al.[91]	1999	J Esthet Dent	15	LOW	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Collins et al.[92]	2004	J Dent	19	HIGH	UNCLEAR	UNCLEAR	LOW	UNCLEAR	LOW
Corbella et al.[93]	2009	Dent Cadmos	8	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	HIGH
Cronin et al.[94]	2005	Comp Cont Educ Dent	16	UNCLEAR	UNCLEAR	UNCLEAR	LOW	UNCLEAR	HIGH
da Costa et al.[95]	2010	Oper Dent	19	LOW	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW

Continue

Continuation

da Costa et al.[96]	2011	J Esthet Restor Dent	22	LOW	LOW	UNCLEAR	LOW	LOW	LOW
Dawson et al.[97]	2011	Oper Dent	19	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
de Almeida et al.[98]	2014	Photomed Laser Surg	20	UNCLEAR	UNCLER	LOW	LOW	LOW	LOW
de Freitas et al.[99]	2016	Quintessence Int	17	LOW	UNCLEAR	UNCLEAR	LOW	UNCLEAR	LOW
de Geus et al.[100]	2015	JADA	29	LOW	LOW	UNCLEAR	LOW	LOW	LOW
de Geus et al.[4]	2015	J Dent	28	LOW	LOW	UNCLEAR	UNCLEAR	LOW	LOW
de Geus et al.[64]	2015	Oper Dent	25	LOW	LOW	LOW	LOW	LOW	LOW
de Paula et al.[63]	2013	Clin Oral Invest	29	LOW	LOW	LOW	LOW	LOW	LOW
de Paula et al.[59]	2015	J Dent	29	LOW	LOW	UNCLEAR	LOW	LOW	LOW
de Paula et al.[12]	2014	Oper Dent	30	LOW	LOW	LOW	LOW	LOW	LOW
Delgado et al.[101]	2007	P R Health Sci J	16	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR
Deliperi et al.[102]	2004	JADA	17	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Donly et al.[103]	2002	Comp Cont Educ Dent	14	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Donly et al.[104]	2005	Pediatr Dent	17	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Donly et al.[105]	2006	Gen Dent	15	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Donly et al.[106]	2007	Gen Dent	21	HIGH	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Donly et al.[107]	2010	Am J Dent	19	HIGH	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Farrel et al.[108]	2006	J Clin Dent	18	HIGH	UNCLEAR	LOW	LOW	LOW	LOW
Fernandez et al.[109]	2016	Oper Dent	30	LOW	LOW	LOW	LOW	LOW	LOW
Ferrari et al.[110]	2004	Am J Dent	17	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Gallagher et al.[111]	2002	J Clin Dent	15	UNCLEAR	UNCLEAR	HIGH	LOW	LOW	LOW
Gallo et al.[112]	2009	Quintessence Int	14	UNCLEAR	UNCLEAR	LOW	LOW	UNCLEAR	LOW
Garcia-Godoy et al.[113]	2004	Comp Cont Educ Dent	17	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Gerlach et al.[114]	2000	Comp Cont Educ Dent	20	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Gerlach et al.[115]	2001	Am J Dent	18	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Gerlach et al.[116]	2002	Comp Cont Educ Dent	16	HIGH	UNCLEAR	LOW	LOW	LOW	HIGH
Gerlach et al.[117]	2004	J Clin Dent	15	HIGH	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Gerlach et al.[118]	2005	Comp Cont Educ Dent	15	HIGH	UNCLEAR	LOW	LOW	LOW	LOW
Gerlach, Barker[119]	2003	Am J Dent	20	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Gerlach, Sagel[120]	2004	JADA	15	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Gerlach et al.[121]	2002	Am J Dent	20	HIGH	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Gerlach, Zhou[121]	2004	Comp Cont Educ Dent	20	HIGH	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Giachetti et al.[122]	2010	JADA	23	LOW	LOW	UNCLEAR	UNCLEAR	LOW	LOW
Giniger et al.[123]	2005	J Clin Dent	15	HIGH	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Giniger et al.[124]	2005	JADA	21	HIGH	UNCLEAR	LOW	LOW	LOW	LOW
Gomes et al.[13]	2008	R Dent Press Estet	10	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	HIGH

Continue

Continuation

Goodson et al.[125]	2005	J Clin Dent	11	LOW	UNCLEAR	LOW	LOW	UNCLEAR	HIGH
Grobler et al.[126]	2011	Int J Dent	13	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Guênes et al.[127]	2015	RFO UPF		UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Guerrero et al.[128]	2007	Am J Dent	20	UNCLEAR	UNCLEAR	LOW	LOW	LOW	LOW
Gurgan et al.[129]	2010	Lasers Med Sci	14	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Hanning et al.[130]	2007	Clin Oral Investig	18	UNCLEAR	UNCLEAR	LOW	LOW	LOW	HIGH
Henry et al.[131]	2013	Int J Dent Hyg	18	UNCLEAR	UNCLEAR	LOW	HIGH	LOW	LOW
Hyland et al.[132]	2015	Clin Oral Investig	11	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	HIGH
Ishikawa-Nagai et al.[133]	2004	J Esthet Restor Dent	13	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Jadad et al.[134]	2011	Am J Orthod Dentofacial Orthop	9	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Javaheri, Janis[135]	2000	Oper Dent	6	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	HIGH
Karpina et al.[136]	2002	Am J Dent	14	UNCLEAR	UNCLEAR	LOW	LOW	LOW	LOW
Karpina et al.[137]	2003	J Prosthodont	14	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	HIGH
Kihn et al.[138]	2000	JADA	17	HIGH	UNCLEAR	LOW	LOW	LOW	LOW
Kihn et al.[139]	2002	Comp Cont Educ Dent	12	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Knosel et al.[140]	2007	Angle Orthod	10	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Knosel et al.[141]	2008	Quintessence Int	12	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Kose et al.[142]	2011	Am J Dent	20	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Kose et al.[62]	2016	Oper Dent	28	LOW	LOW	LOW	LOW	LOW	LOW
Kossatz et al.[143]	2011	Oper Dent	17	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Kossatz et al.[144]	2012	JADA	25	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Kozlovsky et al.[145]	1996	Oral Health	10	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	HIGH	LOW
Krause et al.[146]	2008	Quintessence Int	13	HIGH	UNCLEAR	LOW	LOW	UNCLEAR	LOW
Kugel et al.[147]	2002	Comp Cont Educ Dent	11	HIGH	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Kugel et al.[148]	2006	Comp Cont Educ Dent	12	UNCLEAR	UNCLEAR	LOW	LOW	LOW	LOW
Kugel et al.[149]	2004	Comp Cont Educ Dent	19	UNCLEAR	UNCLEAR	LOW	LOW	LOW	LOW
Kugel et al.[150]	2009	J Esthet Restor Dent	19	HIGH	UNCLEAR	LOW	LOW	LOW	LOW
Kugel, Kastali[151]	2000	Comp Cont Educ Dent	18	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Leonard et al.[152]	1999	J Esthet Restor Dent	13	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Leonard et al.[153]	2001	J Esthet Restor Dent	18	HIGH	UNCLEAR	LOW	UNCLEAR	LOW	LOW
Leonard et al.[154]	2004	J Esthet Restor Dent	12	UNCLEAR	UNCLEAR	HIGH	LOW	UNCLEAR	LOW
Lewgoy et al.[155]	2011	Rev ABO Nac	6	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Li et al.[156]	2003	Comp Cont Educ Dent	18	HIGH	UNCLEAR	LOW	LOW	LOW	LOW

Continue

Continuation

Lo et al.[157]	2007	Am J Dent	21	UNCLEAR	UNCLEAR	LOW	LOW	LOW	HIGH
Lo Giudice et al.[158]	2016	Open Dent J	6	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Loguercio et al.[159]	2015	Braz Oral Res	30	LOW	LOW	LOW	LOW	LOW	LOW
Loyola-Rodriguez et al.[160]	2003	J Clin Pediatr Dent	12	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Luo et al.[161]	2007	J Dent	16	HIGH	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Machado et al.[162]	2013	Quintessence Int	13	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Machado et al.[163]	2016	Int J Periodontics Restorative Dent	16	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Maghaireh et al.[164]	2014	Oper Dent	16	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Marson et al.[165]	2008	Oper Dent	13	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Martín et al.[166]	2015	J Dent	30	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Martins et al.[167]	2011	Rev Assoc Paul Cir Dent	12	LOW	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Matis et al.[168]	1998	Quintessence Int	15	HIGH	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Matis et al.[169]	2000	Quintessence Int	17	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Matis et al.[170]	2002	Oper Dent	17	LOW	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Matis et al.[171]	2002	Quintessence Int	14	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Matis et al.[172]	2005	Oper Dent	15	UNCLEAR	UNCLEAR	LOW	LOW	UNCLEAR	UNCLEAR
Matis et al.[173]	2006	Oper Dent	14	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Matis et al.[174]	2007	Oper Dent	11	UNCLEAR	UNCLEAR	LOW	LOW	UNCLEAR	LOW
Matis et al.[175]	2009	Oper Dent	15	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Medeiros, de Lima[176]	2008	J Can Dent Assoc	17	LOW	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Mehta et al.[177]	2013	Eur J Oral Sci	14	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Meireles et al.[178]	2008	J Dent	22	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Meireles et al.[179]	2008	Oper Dent	21	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Meireles et al.[180]	2009	JADA	21	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Meireles et al.[181]	2010	J Dent	21	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Meireles et al.[182]	2014	J Dent	22	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Mena Serrano et al.[58]	2016	Oper Dent	30	LOW	LOW	LOW	LOW	LOW	LOW
Miller et al.[183]	2000	Pract Proced Aesthet Dent	4	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR
Moghadam et al.[184]	2013	Eur J Dent	20	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Mohan et al.[185]	2008	J Dent	19	HIGH	UNCLEAR	LOW	LOW	LOW	LOW
Mokhlis et al.[186]	2000	JADA	16	HIGH	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Mondelli et al.[187]	2012	J Appl Oral Sci	13	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW

Continue

Continuation

Montenegro-Arana et al.[188]	2016	Oper Dent	25	LOW	LOW	LOW	UN	LOW	LOW
Morgan et al.[189]	2015	Br Dent J	12	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Myers et al.[190]	2003	J Esthet Restor Dent	14	LOW	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Nathoo et al.[191]	2001	Comp Cont Educ Dent	13	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Nathoo et al.[192]	2003	J Clin Dent	17	HIGH	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	HIGH
Navarra et al.[193]	2014	Int J Dent Hyg	11	LOW	LOW	UNCLEAR	UNCLEAR	UNCLEAR	HIGH
Nutter et al.[194]	2013	J Dent	14	LOW	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Ontiveros, Paravina[195]	2009	J Dent	13	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Palé et al.[196]	2014	Odontology	14	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Paphatanasiou et al.[197]	2001	Comp Cont Educ Dent	13	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Paphatanasiou et al.[198]	2002	Comp Cont Educ Dent	17	UNCLEAR	UNCLEAR	LOW	UNCLEAR	LOW	LOW
Perry et al.[199]	2013	Comp Cont Educ Dent	9	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	HIGH	LOW
Polydorou et al.[200]	2013	Oper Dent	15	UNCLEAR	UNCLEAR	LOW	UNCLEAR	LOW	LOW
Posso Moreno et al.[201]	2010	Univ Odontol	15	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	HIGH
Reis et al.[202]	2011	Oper Dent	24	LOW	LOW	LOW	LOW	LOW	LOW
Reis et al.[203]	2011	Oper Dent	24	LOW	LOW	LOW	LOW	LOW	LOW
Reis et al.[204]	2013	Oper Dent	31	LOW	LOW	LOW	LOW	LOW	LOW
Rezende et al.[205]	2014	Rev Assoc Paul Cir Dent	13	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Rezende et al.[206]	2013	Oper Dent	23	UNCLEAR	UNCLEAR	LOW	UNCLEAR	LOW	LOW
Rezende et al.[207]	2016	Oper Dent	25	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Rezende et al.[61]	2016	Oper Dent	30	LOW	LOW	LOW	LOW	LOW	LOW
Rosenstiel et al.[208]	1996	Quintessence Int	11	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	HIGH
Santana et al.[209]	2014	Braz Dent Journal	24	UNCLEAR	UNCLEAR	LOW	LOW	LOW	LOW
Shahidi et al.[210]	2005	J Clin Dent	17	HIGH	UNCLEAR	LOW	LOW	LOW	LOW
Shanbhag et al.[211]	2013	J Contemp Dent Pract	14	HIGH	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Sielski et al.[212]	2003	Comp Cont Educ Dent	18	HIGH	UNCLEAR	LOW	LOW	LOW	HIGH
Silva et al.[213]	2012	Rev Odontol Bras Central	10	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	HIGH	HIGH
Simon et al.[214]	2014	J Clin Dent	16	HIGH	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW
Soares et al.[215]	2006	Rev Odont UNESP	8	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	HIGH	LOW
Strobl et al.[216]	2010	Lasers Med Sci	14	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Sundfeld et al.[217]	2015	Indian J Dent Res	12	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Swift et al.[218]	1997	J Esthet Restor Dent	15	UNCLEAR	UNCLEAR	LOW	UNCLEAR	LOW	LOW

Continue

Continuation

Swift et al.[219]	1999	J Esthet Restor Dent	14	UNCLEAR	UNCLEAR	LOW	UNCLEAR	LOW	LOW
Swift et al.[220]	2004	Comp Cont Educ Dent	18	UNCLEAR	UNCLEAR	LOW	UNCLEAR	LOW	LOW
Swift et al.[221]	2009	J Dent	19	UNCLEAR	UNCLEAR	LOW	LOW	LOW	LOW
Tavares et al.[222]	2003	JADA	19	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Tay et al.[6]	2009	JADA	24	LOW	LOW	LOW	LOW	LOW	LOW
Tay et al.[223]	2012	Am J Dent	29	LOW	LOW	LOW	LOW	LOW	LOW
Tsubura[224]	2010	Odontology	10	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Tsubura ,Yamaguchi[225]	2005	Odontology	12	UNCLEAR	UNCLEAR	UNCLEAR	LOW	HIGH	LOW
Türkün et al.[226]	2010	J Esthet Restor Dent	12	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	HIGH	LOW
Vano et al.[227]	2015	Int J Dent Hyg	24	UNCLEAR	LOW	UNCLEAR	LOW	LOW	LOW
Ward, Felix[228]	2012	Comp Cont Educ Dent	13	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Wetter et al.[229]	2009	Lasers Med Sci	14	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Xu et al.[230]	2007	Am J Dent	17	UNCLEAR	UNCLEAR	LOW	LOW	LOW	LOW
Yudhira et al.[231]	2007	Am J Dent	22	HIGH	LOW	LOW	LOW	LOW	LOW
Zantner et al.[232]	2006	Quintessence Int	23	LOW	UNCLEAR	LOW	LOW	LOW	LOW
Zekonis et al.[233]	2003	Oper Dent	18	LOW	UNCLEAR	UNCLEAR	LOW	LOW	LOW
Zhao et al.[234]	2013	Quintessence Int	15	LOW	LOW	UNCLEAR	UNCLEAR	LOW	LOW
Ziebolz et al.[235]	2007	Clin Oral Investig	18	HIGH	UNCLEAR	UNCLEAR	UNCLEAR	LOW	LOW
Ziemba et al.[236]	2005	J Clin Dent	19	LOW	LOW	UNCLEAR	UNCLEAR	LOW	LOW

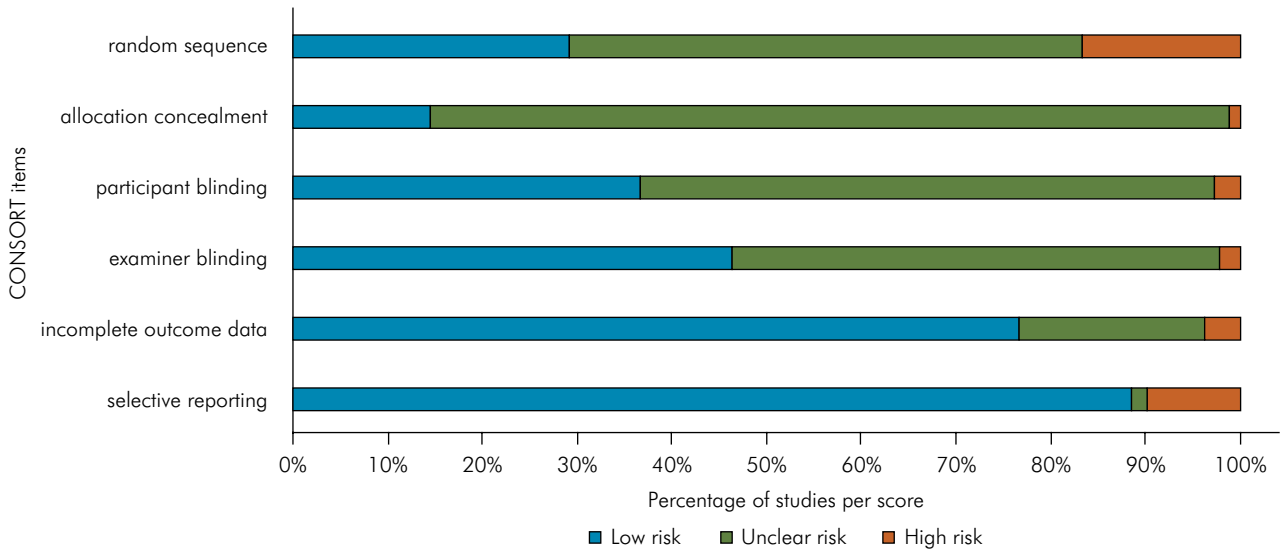

Figure 4. Methodological risk of bias chart.

Theoretically, one should expect that journals with high impact factor would publish studies with better reporting standards. Indeed, a significant correlation between journal impact factor and journal average CONSORT score was observed in the present and in earlier investigations,[39,40] but this correlation is usually weak. In the present study the correlation coefficient ($R^2 = 0.1602$) was also very weak, which means that the great variation observed in the average CONSORT score is not explained by the journal impact factor.

We hypothesize that not all members of the editorial board of these journals check the submitted articles for compliance with the CONSORT Statement, which prevents the journals from reaching an improved reporting score of RCTs. More attention to these items during the peer-review process may be required. Apart from that, the ambiguous language of what was meant by CONSORT endorsement[25,41,42] in journals may prevent a better CONSORT adherence. In fact, instructions on how CONSORT should be used by authors are inconsistent across journals and publishers. For instance, J Dent recommends the use of CONSORT and submission of the checklist and flow diagram in the instructions for authors, while Clin Oral Investig does not recommend the use of reporting guidelines in the instructions.[38] Publishers and journals should encourage authors to use CONSORT and set clear instructions for authors regarding full compliance with CONSORT. Braz Oral Res, for example, clearly indicates that authors must fully comply with the CONSORT Statement.

In regard to the period of time, better compliance was observed in more recent studies (2011–2016; mean CONSORT score of 19.0 ± 6.8) than in earlier periods (1996-2000; mean CONSORT score of 13.4 ± 4.0). This finding had been reported by other authors[28,35] and in an earlier RCT study of adhesive materials applied onto non-carious cervical lesions.[22] However, this increase is still small and substandard, as it reached slightly more than 50% of the maximum CONSORT score (32 points). Had all trials described the evaluated items correctly, the score might have been closer to 32.

Regarding the country, there is not a clear explanation why papers published by Brazilian researchers reached higher average CONSORT score than authors from more developed countries, such as USA, UK and Italy. We believe that the policies and efforts of Brazil government agencies in supporting training of specialized researchers in Science and Technology, implemented by Periódicos Capes Theses databases (www.capes.gov.br [Coordination of Personal Formation for Higher Education]) in the last 40 years, has led to an increasing number and quality of Brazilian articles in all science fields. Based on data from the SCImago database (www.scimagojr.com), the number of published papers in Dentistry is higher than those in other areas.[43]

As reported in the results section, the item sample size was reported poorly. This is also problematic in the medical field. For instance, Chan and Altman[44] reported that 73% of the 519 medical trials indexed in PubMed in December 2000 did not report sample size calculation. Although sample size does not affect the validity of the study and its risk of bias, if not done properly and based on a clinically important effect, it may result in underpowered studies, which is usually misunderstood as groups being statistically similar. However, the lack of evidence to reject the null hypothesis does not mean that the groups are similar to one another. It may also mean that the study did not have a sample size big enough to detect a smaller difference if it really existed.

Based on the same premise, by using an infinite sample size we can prove any small and non-clinical relevant difference as being statistically different which may induce readers to change equivocally the standard protocol or technique for others that may be more costly or with higher side effects.[45] This is why authors from RCTs should describe in their study the effect size rather than only the results of the hypothesis testing. Effect sizes and confidence intervals make the interpretation of the results easier. If a protocol has a fictitious relative risk for tooth sensitivity of 0.75 (95% CI 0.5 to 0.8), this means that the experimental group has a chance of 25% lower (from 50% to 20% lower) to develop tooth sensitivity. This response carries much more information than only stating that two groups were statistically

different based on a probability value of 0.1%, for instance. Unfortunately, in the present study 88.1% of the studies did not report well, or did not report at all, the effect sizes, which is also a problem in medical journals.[46]

Based on these ideas, researchers are advised to move away from significance tests and to display, instead, an estimate of effect size delimited by confidence intervals. This method incorporates all the information normally included in a hypothesis, but in a way that emphasizes what is really important (clinical significance rather than statistical significance).[46,47,48]

Another concern in the included bleaching studies is related to randomization. Ideally, such description should include details about both the methods used to generate the random sequence, as well as the method used to conceal this the random sequence. Inadequately and unclearly concealed trials have been shown to result in exaggerated effect sizes in favor of the experimental group.[49] This problem also occurs in other areas: poor reporting of allocation concealment was observed in 78% of the RCTs among dental journals[50] and 93% in the specialty of periodontology.[31] In the present study problems in random sequence generation and allocation concealment (scores 0 and 1) were seen in 53.5% and 84.8% of the trials, respectively.

These two items (random sequence and allocation concealment) allow readers to evaluate if the study is free of selection bias. A well-done random sequence generation is worthless if not well concealed. The objective of the randomization process is to balance the participants in terms of known and unknown factors so that no other variable apart from the one under investigation can account for the differences observed among participants from distinct groups.

Usually, authors refer to terms such as "random allocation" or "the groups were randomized", without further elaboration. Authors should specify the method of sequence generation (such as a random-number table or a computerized random number generator, coin toss, dice throwing, etc.) as well as restrictions to the process such as stratification, block randomization, etc.[45]

Blinding is also a key element in RCT reporting and should not be confused with allocation concealment, as blinding prevents performance and detection bias[45] instead of selection bias. In some research questions of bleaching studies, operator and patient blinding may be not possible, when for instance light activated systems are being tested. However, evaluator blinding may be always possible and it could be implemented in the study design, mainly if the primary outcome color change is being checked against a shade guide unit. In such case, lack of evaluator blindness would put the study at a higher risk of bias. However, for objective outcomes, such as color measurements with a spectrophotometer, the lack of examiner blindness is not that important. When the primary outcome is tooth sensitivity, which is a patient-centered subjective outcome, it is the lack of participants' blinding and not evaluators' that downgrade the level of confidence in the research findings.

Failures to describe who is blinded in the study are the most common problems observed in the eligible studies. Reports like "this study was single-blind", "this was a double-blind study", are useless, as they do not inform readers of who was in fact blinded. In agreement with these ideas, Pandis et al.[50] reported that inadequate description of blinding in RCTs published in leading dental journals ranged from 74 to 100%. In implant dentistry, the lack of adequate blinding reporting was informed to be 58%.[51]

The design and conduct of some RCTs may be not straightforward, particularly when there are losses to follow-up, or exclusions. This precludes the description of the numbers of participants through each phase of the study in a few sentences.[52] This can be simply described by introducing a flow chart with the number of participants in each phase of the trial. Although the CONSORT Statement recommends the inclusion of a flow chart, we observed that only 48.1% of the clinical trials followed this recommendation.

Another type of bias commonly found in RCTs is selective outcome reporting. In general, there is most enthusiasm about the publication of RCTs that show either a large effect of a new treatment

(positive trials) or equivalence of two approaches. Consequently, articles with negative findings are less submitted or accepted for publication by journals. This may even be more relevant in sponsored RCTs if the results of the trial place financial interests at risk.[53]

To manage such problems, the International Committee of Medical Journal Editors (ICMJE) has proposed comprehensive trials registration. Trials must register at or before the onset of patient enrollment.[53] For the ICMJE, this policy applies to any clinical trial that started enrollment after July 1, 2005. However, only 12 out of 120 included studies of this review published in 2005 or later performed trial registration (Table 5). Such earlier registration prevents selective reporting and reduces publication bias, two important issues that may downgrade the level of evidence of a randomized clinical trial.[54] Some dental journals as J Dent, Oper Dent, and Braz Oral Res have added this indication as mandatory in their instructions for authors.

In regard to numbers analyzed, the number of participants per group in all analyzes should be clear. Reporting summary statistics without their spread over the mean or only percentages, relative risks, odds ratios is not enough as does not allow assessment of whether or not some of the randomly assigned participants were excluded from the analysis. The same should be applied to losses and exclusions. Along with the description of these figures per group, reasons for the losses and exclusions should be given as they may be related to the intervention. For instance, when a patient quits the treatment because another disease is requiring his/her attention, this is unlikely to be related to the intervention; but if a patient does not attend the recalls because he/she wants to be withdrawn from the trial, the reason may be related to side effects or lack of efficacy of the treatments under evaluation.

Baseline information was adequately reported in only 34% of the papers and it is important to check comparability at baseline. Any differences in baseline characteristics are, however, the result of chance rather than bias; the reason of why there is no need to perform hypothesis testing for these characteristics.[55]

For any item, when reporting data, authors should be careful. They should not display percentages instead of raw figures, as it is risky. Rounded percentages may be compatible with more than one numerator and if the authors fail to provide the total number of participants, the number of participants in the event under evaluation will be unclear. For instance, 90% may represent 1 out of 10 but also 100 out of 1000 – this makes a profound influence on the precision of the data. Merging data of groups can done as long as their individual data are also reported. Finally, summary statistics for continuous variables should be presented with their measure of spread; for dichotomous variables authors should describe the number of counts vs. total number of observations.[22]

The trial design involves the description of type of the trial (parallel, cross-over, factorial, split-mouth and or multiple restorations); the conceptual framework (superiority, non-inferiority or equivalence trial) and also the allocation ratio (example 1:1 or 1:2).[20] The settings (where and when the study was performed) are also essential to place the study in historical context and to evaluate its external validity (generalization of the findings to other populations).

Risk of bias

Although incomplete outcome data and selective reporting were poorly described, this occurred in small percentage of the studies. In all other domains of the Cochrane Collaboration risk of bias tool, most the RCTs were judged to be at "unclear" or at "high" risk of bias. The implications of inadequate sequence generation, allocation concealment and examiner blinding were already discussed in details.

At the study level, only 7.57% of the studies were considered to be at low risk of bias, which means being low risk of bias in all domains. The remaining studies were at unclear or high risk of bias. This is worrying since our treatment decisions are being based on studies that do not have a rigorous methodology and therefore they may lead to biased results.

Final remarks

Although CONSORT guidelines have been included in the instructions for authors of some journals, active compliance is far from being achieved. Perhaps, the inclusion of additional subheadings, as suggested by Kloukos et al.[29] might result in better compliance with the CONSORT Statement. The results of the present study indicate that adherence of RCTs of bleaching systems to the CONSORT Statement requires improvements. Adherence to the CONSORT Statement will also make readers to rethink their methodology and ultimately reduce the high risk of bias of studies in the field.

There are some limitations in the present study. Although a very comprehensive search in terms of different databases with specific vocabulary and keywords were performed, we may have missed some articles in the search.

Nevertheless, looking at Table 4, the higher numbers of the papers were produced in USA and Brazil and the majority of them were published in English language journals. Only a few papers were published in Portuguese or Spanish (10 in total). Also, as mentioned in the results section, only one paper was excluded due to language. These details make us confident in the results herein presented. Although other studies on the field may not be cited here they are unlikely to change the results herein presented.

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