Randomized Clinical Trials in Pediatric Dentistry: Application of Evidence-Based Dentistry through the CONSORT Statement

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In order to include appropriate informed decisions on dental therapeutic or preventive procedures in children, Pediatric Dentists should apply the fundamentals of "Evidence-Based Dentistry" (EBD). This oral health approach assists clinicians in understanding and applying the most relevant research published on evidence in the clinical setting when treating their patients. One of the crucial steps of EBD is to critically appraise and use the primary articles about therapy or prevention, namely, Randomized Clinical Trials (RCT), the study design that best addresses the questions related with these clinical areas. The aim of the present paper was to provide the basic concepts and an example of how to critically read and understand articles on RCT studies in Pediatric Dentistry employing the CONSORT statement, a process that involves assessing the reliability of results, risk of bias (internal validity), and applicability of reported clinical findings (external validity).

Keywords: *Randomized Clinical Trials, Pediatric Dentistry, Evidence-Based Dentistry, CONSORT.*

INTRODUCTION

During recent decades, oral care professionals have been greatly encouraged to carry out their daily clinical practice based on current and valid research knowledge, in order to improve the quality of treatments delivered, increase the success of the intervention, maximize benefits to the patient, and minimize personal and financial risk.[1–3] This is precisely the main purpose of the management approach known as "Evidence-Based Dentistry" (EBD), developed during the last two decades of the XX century, which intends to assist Dentists in understanding and applying findings (or evidence) from the most relevant dental literature directly to their patients in the clinical setting.[4,5] When making clinical decisions, the best research evidence should be properly integrated with other components of EBD, such as professional clinical capabilities and patient/parental interests and preferences (e.g., economic constraints).[2,6–8]

The American Dental Association (ADA) summarizes the concept of EBD as "A*n approach to oral healthcare that requires the judicious integration of systematic assessment of clinically relevant scientific evidence, relating to the patient's oral and medical condition and history, with the dentist's clinical expertise and the patient's treatment need and references*".[9] As one can note, one of the main steps in practicing EBD is systematic assessment of the relevant literature, which implies conducting a critical reading or evaluation of published articles possessing sufficient scientific value and determining the relevance of their results in clinical practice.[7] EBD in Pediatric Dentistry (or *Evidence-Based Pediatric Dentistry*) "increases the opportunities for children to

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benefit from clinical research, protects and promotes their oral health priorities in the present and in the future, and contributes to a more trustworthy science", for both the patient's and the society's best interests.[2,10,11]

Randomized Clinical Trials (RCT)

RCT are the best study design or the "gold standard" in clinical research to provide the most reliable evidence on the effects -both beneficial and adverse- of health care interventions (other adequate designs for the same purpose comprise systematic reviews with meta-analyses, and high-quality clinical-practice guidelines).[12,13] Examples of well-conducted RCT that reach valid conclusions in the Pediatric Dentistry area, including the most fundamental clinical issues, such as preventive methods, restorative dentistry, pulp treatment, oral surgery, early orthodontics/orthopedics, and new materials/techniques, have been published in the leading specialized and general dental journals.[14–27]

RCT are comparative in nature: some patients receive the treatment-under-investigation (the *experimental* group), which is compared with that of another group of patients with similar characteristics (the *control* group), receiving the best currently available treatment or a placebo; the allocation of participants to study groups is carried out by randomization.[28] The structure of this design can be observed in Figure 1. The RCT is considered the most rigorous method of hypothesis testing -with the least risk of the occurrence of bias (Table 1), for assessing new therapies, provided that there are sufficient participating subjects and that randomization guarantees fair baseline parity between the treatment and the control groups regarding known and unknown prognostic factors.[6,12] Other important procedural issues should be considered, such as blinding to participant assignment, justification of sample size, quality measurement of outcomes, and suitability of the statistical methods.[29–31]

Table 1. Principal bias that risks the result validity of an RCT. The first four occur during the trial performance, prior to the reporting of its results (adapted from *Kiriakou et al* [28]).

Type of bias	Prevention method
• Selection bias	- Proper randomly assignment
• Performance bias	- Blinding to assignment of researchers and participants
• Attrition bias	- Blinding of participants, Intention-to-treat analysis
• Detection bias	- Blinding of outcome evaluators/analyzers
• Publication bias	- Trial registration, no selective reporting
• Other	- Careful trial design, no selective reporting

However, if methodological flaws are present during the design, performance, analyses, and reporting of a RCT, then the data regarding the treatment's effects can be biased, that is, underestimated or overestimated; thus, they are not reliable in the clinical decision-making process.[31,32] It is well-known that health care RCT papers vary in terms of quality, comprehensibility, and relevance to practice, and as surprising as it may seem, it is a sad but true fact that not all published research is of good quality, or it may be incomplete and/or inaccurately skim a paper with little consideration of how the study was developed or whether it meets the criteria for scientific validity, blindly trusting the information presented and applying the research findings in their patients, with no hesitation. However, on other occasions, the reader wants to know whether the conclusions from a paper are valid; therefore, he/she will evaluate it with a critical eye to detect poorly conducted studies with unreliable conclusions.[12,28,34] In this context, the process of the critical appraisal of a paper has been defined as the "... *application of rules of evidence in a study to assess the validity of the data, completeness of reporting, methods and procedures, conclusions, and compliance with ethical standards*".[30] In addition, when properly performed, this evaluating process allows researchers to identify the articles suitable for inclusion in systematic reviews and meta-analysis in the Pediatric Dentistry area.[35]

Fundamentals of critical reading of Pediatric Dentistry RCT

Critical reading should comprise a crucial skill of EBD of Pediatric Dentists who routinely prescribe drugs, perform dental treatments on primary teeth, or provide hygienic/preventive counsel, and for those who wish to apply valid evidence. This process consists of the systematic assessment and interpretation of any study results.[5,12,36] When reading a RCT related with the Pediatric Dentistry field, the clinician should first evaluate its *internal validity*; in other words, whether the study is sufficiently free of biases -errors that systematically deviate from the underlying truth-, mainly deficient randomization, no double-blinding, duplicate information, small sample size, inadequate statistical tests, unconcealed allocation, poor data-collection methods, or exclusion of dropouts.[6,29] On the other hand, *external validity* refers to whether the study results properly reflect what may be expected in the population-of-interest, namely, in children with the same characteristics as those of the investigated sample, which represents that population.[28,29,37] By means of the critical appraisal, Pediatric Dentists may inform their clinical decisions regarding therapy or prevention based on individual, valid RCT papers.[35]

In order to assist Pediatric Dentists and other oral health care providers to critically review a journal paper, diverse structured checklists and scales have been designed and developed for the purpose of identifying and then assessing the quality of some of key methodological and reporting features that a well-written paper should have, in terms of usefulness, validity (risk of bias), and applicability of results.[33,36,38] One of the most popular RTC guidelines among editors, peer reviewers, and authors is CONSORT.

What is CONSORT?

The *Consolidated Standards of Reporting Trials* statement or CONSORT (http://www.consort-statement.org/) comprises a checklist of essential items that was developed in 1996 by two independent groups of expert clinical researchers, epidemiologists, biostatisticians, peer-review authors, and journal editors, in order to enhance the quality of the reporting of RCT.[35] This comprehensive tool is revised periodically and, since its last upgrade, in 2010, the checklist is constituted of 37 items concerning the indispensable information that must be reported by a well-designed and conducted RCT with a two-group parallel design and random assignment of participants to these study groups. The evaluation process consists of a series of checkmarks for the items. CONSORT focuses particularly on issues related with internal and external validity, as previously mentioned, and other methodological concerns. In the CONSORT checklist,

the items are evaluated separately and do not have numerical scores related with them, and the quality of the final decision involves some degree of subjectivity or the preferences of each reviewer.[37] All of this information should be additionally taken into account during the standard appraisal process and the interpretation of results.[4] In addition, CONSORT provides a functional diagram constituted of several key points, documenting the flow of participants throughout the following phases of the clinical study: enrollment; participant allocation; follow-up, and analysis (Figure 3).[30,35,37] The efficacy of this guide has been greatly accepted worldwide: more than 600 leading general and specialty medical and dental journals, and biomedical editorial groups, have progressively adopted the statement into their "guidelines to authors" since its inception.[6,35,39]

Figure 1. Methodological structure of a parallel two-arm RCT.

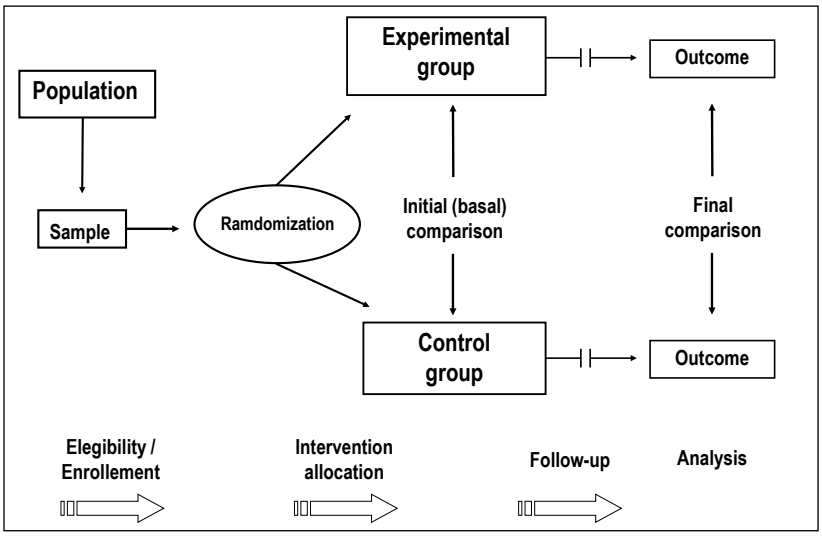


Figure 2. Four biases that should be prevented during an RCT prior to reporting results (adapted from *Greenhalgh*.[57]

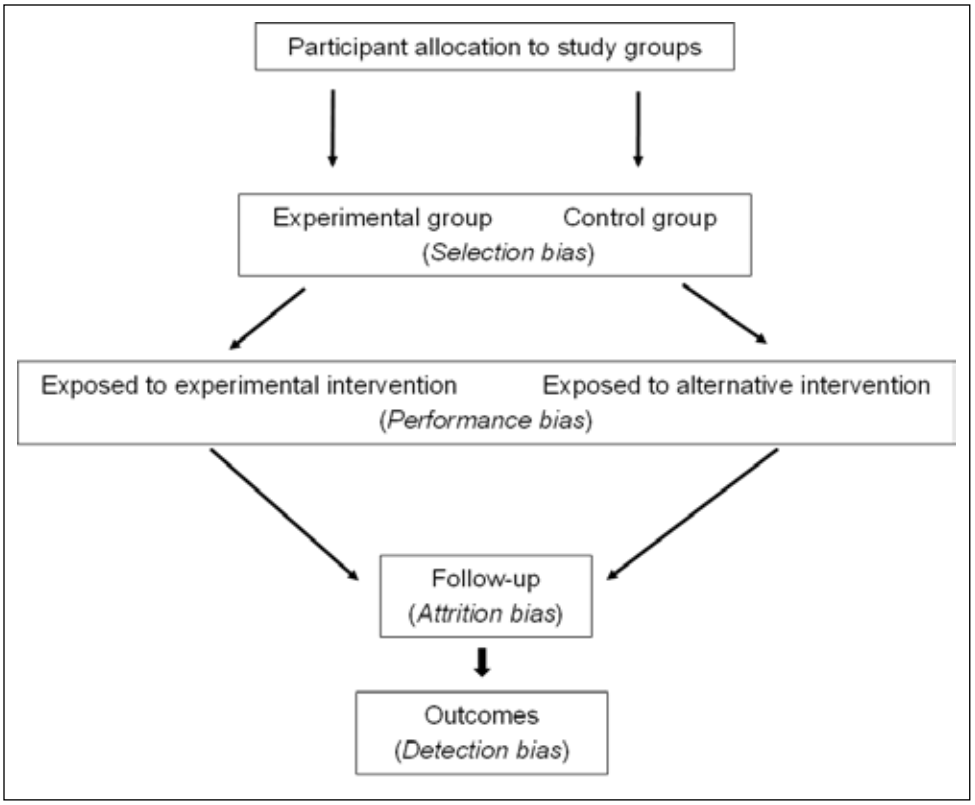
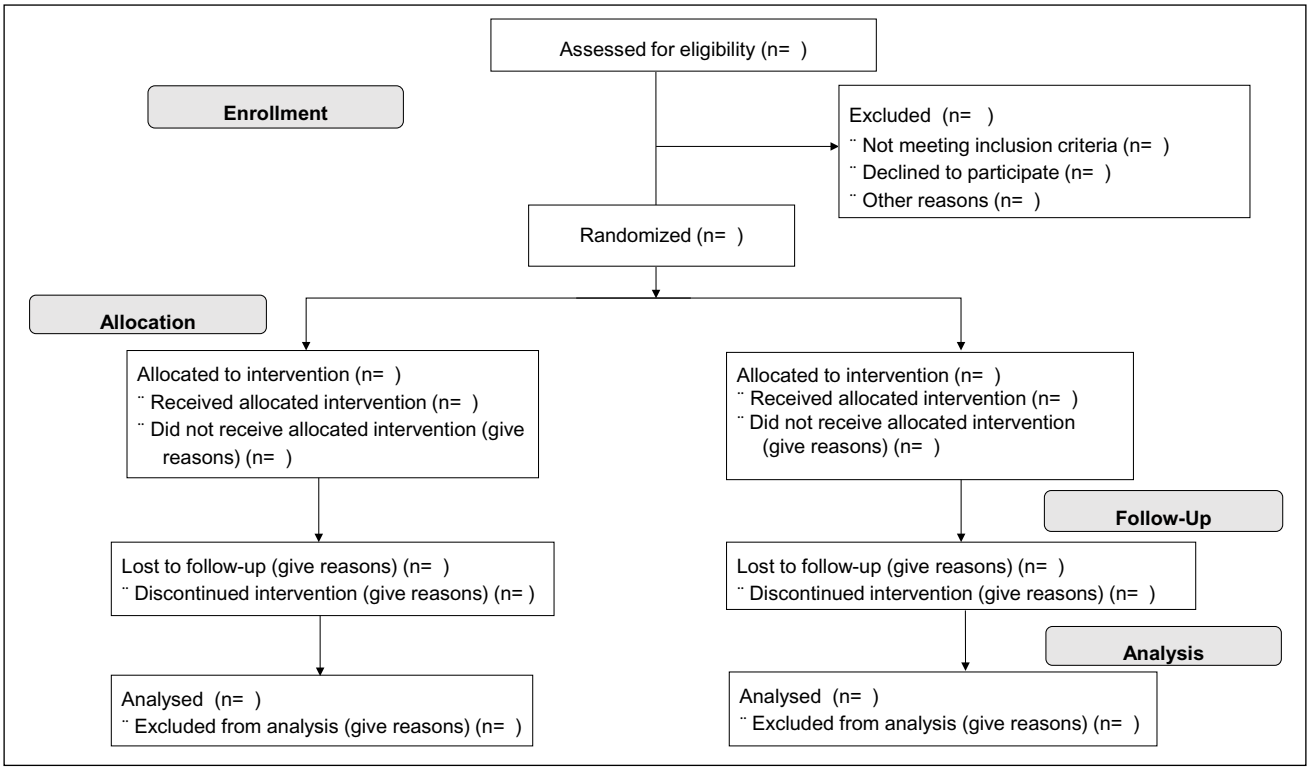


Figure 3. CONSORT 2010 Participant flow Diagram (obtained and adapted from http://www.consort-statement.org/).



Application of EBD through the CONSORT statement:

Critical evaluation of an RCT in Pediatric Dentistry

The main purpose of the present paper was to describe how to critically read a published RCT article in the Pediatric Dentistry field using the CONSORT statement. Briefly: first, the paper will describe a hypothetical clinical scenario, as an illustrative example, relating to a child exhibiting generalized dental caries, with some primary molars requiring pulpectomy procedures. Then, the Dentist, interested in useful and valid information on primary pulp-canal debridement, decides to search for reliable evidence from a clinical study in order to find any faster instrumentation procedure, for example, the *rotatory* technique, for employment in the Dentist's current and future patients; the professional finds a potential published article (*it is real*). Finally, the authors will read a CONSORT evaluation on the retrieved article by means of the previously mentioned specific items and will give his/her own pertinent comments and conclusions regarding the reported results. However, the CONSORT item checklist does not specifically consider the ethical issues of RCT. For this reason, Henschel et al.[10] developed, in 2010, the "Scottish Intercollegiate Guidelines Network (SIGN) Methodology Checklist" concerning ethical issues items for articles in RCT in children. Thus, our investigation team decided to choose, from this checklist, the items "Informed Consent" and "Ethical Review Board Approval", and added them to CONSORT, for a total of 39 items in the final scoring.

Clinical scenario

A general practitioner from a small town has referred, to a Pediatric Dentist's office, a 7 year-old male patient exhibiting multiple, deep carious cavities in his primary teeth, to receive routine treatment. After a detailed clinical and radiographic examination, the Pediatric Dentist decides to perform three pulpectomy procedures. The Dentist knows that, although traditional manual instrumentation has proven effective in primary root canals, some authors have assessed rotary instrumentation as an alternative and faster procedure for pulpectomy in primary molars, reporting promising results.[40–42]

Interested in these findings, the Pediatric Dentist undertakes a search of the published literature in three databases -PubMed, Embase, and Google Scholar-, looking for a recent clinical study to answer the Dentist's concerns. Then, the Dentist finds an RCT article that appears to meet his/her expectations [*Comparison between rotatory and manual techniques on duration of instrumentation and obturation times in primary teeth*]. In this RCT,[43] published in 2011, the authors compared rotary and manual debridement techniques for root canals as part of pulpectomy treatment in primary molars. Initially, the Dentist only reads both the title and the abstract; there, the researchers recruited 40, 5–9-year-old patients assigned to two intervention groups (manual vs. rotatory) and measured and compared time for instrumentation and for canal obturation as result variables. The authors concluded that the rotatory technique is significantly shorter in time for either debridement or obturation procedures; therefore, they suggest the use of this method when treating primary molars indicated for pulpectomy treatment. Given these findings, the professional then decides to critically read the entire article before considering whether to apply the results in his/her patient.

CONSORT critical evaluation

The following exercise is based on the CONSORT 2010 item checklist requirements for reporting parallel-group randomized trials, and it has been adapted to the consultants of any Pediatric Dentistry journal. The exercise was adapted from a previous similar paper by Pandis *et al*.[35] It is also useful for making informed clinical decisions on similar child patients. The selected article was independently evaluated in depth according to the items selected by two of the authors (JAG-R and MSR-R) in a blinded manner,[32] scoring each item either as "No" or "Yes" (some items do not apply for all trials). Any discrepancy between the two evaluators was resolved by the third observer (AJP-G):

TITLE and ABSTRACT:

Item	Explanation	Evaluators' comments
1a: "Identification as a randomized trial in the title".	Authors should include in the title the terms "randomized", "clinical", "trial", "controlled" or "comparative", in order to facilitate its appropriate indexing and identification.[28]	Yes. The terms "Comparison between..." appear in the title. This serves as a clue for considering the study as an RCT design.
1b: "Structured summary of trial design, methods, results, and conclusions".	The structured abstract facilitates the initial assessment of the article and aids in its inclusion in systematic reviews and meta-analyses.[28]	Yes. The abstract is structured, and clearly details each of the sections mentioned in the item.

INTRODUCTION

Item	Explanation	Evaluators' comments
2a: "Scientific background and explanation of rationale".	It is important to identify available information on the topic-of-interest: what is known and what is not clearly defined regarding the efficacy or safety of the studied interventions.[33,44]	Yes. The *Introduction* section describes the general aspects of mechanical instrumentation in the pulpectomy treatment in primary teeth. It emphasizes previous reports on both manual and rotatory techniques.
2b: "Specific objectives or hypothesis".	Objectives are questions to be answered by the study. A hypothesis is a predictive declaration about the possible results of a study, and must be tested by statistical methods in order to establish whether the objectives were met.[33]	Yes. The purpose of the study is described at the end of the Introduction (... the aim of this study was to compare the instrumentation time and quality of...). However, the null hypothesis was not specifically stated.

METHODS

Item	Explanation	Evaluators' comments
	Trial design	
3a: "Description of trial design (e.g., parallel, factorial, crossover, split-mouth, etc.), including allocation ratio".	The study design should be mentioned in detail. Remember that the CONSORT statement was developed specifically for two parallel groups randomized trials, the most common type.[44]	Yes. The trial design appears clearly specified at the beginning of the section ("The investigation consisted of a double-blinded, randomized, clinical trial.").
3b: "Important changes to methods after trial commencement (such as eligibility criteria), with reasons".	Any methodological adjustment from the study plan made once the trial is initiated. For example, the sample size or follow-up duration must be written down and plainly explained and justified. Some reasons for these changes include newly published, important evidence, the inability to recruit the original sample size intended, or financial constraints.[28]	Authors do not report any important changes after the commencement of the investigation.
	Participants	
4a: "Eligibility criteria for participants".	The information concerning to inclusion and exclusion criteria must be outlined in detail to establish the generalization of the study results (or external validity) to other clinical settings.[31]	Yes. First, researchers describe the demographic and clinical (systemic and bucodental) characteristics necessary to integrate the trial sample; additionally, they took every affected molar as the unit of experimentation and provided four clinical/radiographic selection criteria, corresponding to the treatment indications for the pulpectomy procedure in primary molars.

	Participants	
4b: “Setting and locations where the data were collected”.	For purposes of external validity, readers need to know all of the information about the geographic location or the site (university clinic, private office, investigation center, etc.) where the data were obtained. In some cases, the expertise level of the care providers should be mentioned.[38]	No. The authors do not provide this information. An example could be as follows: “The sample was selected among patients attending the clinic of the Pediatric Dentistry Department of the University’s Faculty of Dentistry, between January and May 2011”.
	Interventions	
5: “The interventions for each group with sufficient details to allow replication, including how and when they were actually administered”.	Each procedure or intervention must be clearly described step-by-step in order to allow its replication by other clinicians; this requirement also includes the characteristics of the materials/reagents employed, the drug dose, administration route, and frequency, duration, and timing of the intervention, etc. Standardization of the interventions of should be included.[28]	Yes. The pulpectomy procedure in both study groups is very well described in an extensive paragraph. Regarding standardization of the treatment, we consider that the phrase “All treatments were performed at a single visit by the same operator” is sufficient to meet the item’s requirement.
	Outcomes	
6a: “Completely defined pre-specified primary and secondary outcomes measures, including how and when they were assessed”.	All outcomes must be defined as *primary* (or main) or *secondary*, according to the pre-specified study objectives, and the methods used, including on how and where they were evaluated. Adverse events should be also reported.[44]	Yes, but partially. Some of these requirements are documented in the final lines of the “pulpectomy procedure” paragraph. Authors specify, as primary outcomes, the “time taken for instrumentation and for obturation..., and the quality of the root canal filling...” No secondary outcomes are proposed. However, potential adverse events are not pre-specified in this section.
6b: “Any changes to trial outcomes after the trial commenced, with reasons”.	Sometimes, outcomes planned as primary ones at the beginning of the trial may be later depicted as secondary outcomes, or vice versa, which is considered a form of selective outcome reporting. Thus, any outcome must be explicitly mentioned in order to enhance reporting transparency.[5,38]	No outcome changes are mentioned after the study’s commencement.
	Sample size	
7a: “How sample size was determined”.	RCT need to have sufficient statistical power to detect a significant difference between the study groups if such a difference truly exists, or contrariwise, to detect no difference where there is none. The higher the sample size, the higher the statistical power will be. Therefore, the sample-size calculation process must be plainly justified and presented, including any compensation due to possible losses to follow-up.[45,46]	No. The sample-size calculation is not outlined. They only mention: “Sample size was 20 subjects per group”.
7b: “When applicable, explanation of any interim analysis and stopping guidelines”.	In many clinical trials, follow-up periods are prolonged; thus, during this time, obvious differences between groups or frequent adverse effects can be evident, so that the study may be stopped prematurely for ethical reasons. If necessary, a careful interim result analysis is carried out to address and confirm this decision.[33]	Not specified by the authors.
	Randomization	
8a: “Method used to generate the random allocation sequence”.	Different methods are used to generate random number sequences, such as random tables or special computer or on- line software. Researchers must explain how they assigned the participants to the study groups.[47,48]	No. This process is not described; the authors simply state: “Patients were randomized into 2 groups of treatment”. However, in the next *Evaluators’ comments*, this issue is better described.
8b: “Type of randomization; details of any restriction (such as blocking and block size)”.	There are diverse randomization methods available in clinical research: simple; in blocks, or stratified. Authors should report the on those employed in trial and whether any restrictions were applied (and the reasons).[47,48]	Yes, according to the brief paragraph: “...and the instrumentation technique selected for each case was made from a list of random numbers”. No restriction is mentioned.

Allocation		
9: "Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned".	Treatment allocation concealment avoids any conjecture from researchers on patient assignment to study groups, in order to obtain unbiased assessments of the study's effects; for this purpose, the use is recommended of an independent assignment protocol, preferably by someone external to the trial. The most common technique is that of the sealed opaque envelope containing the treatment cards. The method used should be reported.[47–49]	No. In the present trial, they do not specify any allocation concealment method.
Implementation		
10: "Who generated the random allocation sequence, who enrolled participants, who assigned participants to interventions".	Similar to the previous item, this requirement avoids introducing unbiased assessments. All of the components of the randomization process must be fully explained.[47,48]	No. There is no mention of these details regarding the allocation sequence method.
Blinding		
11a: "If done, who was blinded after assignment to interventions (e.g., participants, care providers, those assessing outcomes) and how".	Authors must mention who was blinded: patient; operator; outcome evaluator, statistician (single- or double-blind) to measure the treatment effects and results with less risk of bias.[48]	Yes. They refer that only the "participants, assessing observer, and analyst were blinded in regard to the group assignation technique," but blinding of the operator was not possible "because the rotary and manual techniques each have recognizable characteristics..."
11b: "If relevant, description of the similarity of the interventions".	When applicable, authors should describe any similarities between interventions that improve blinding, because this may prevent any assumptions about the treatment efficacy by the outcome evaluators.[33]	No. This is not specified. But, as mentioned previously, there are obvious differences between the two instrumentation methods compared. Perhaps it is due to this reason that the authors did not consider it necessary to explain this issue.
Statistical methods		
12a: "Statistical methods used to compare groups for primary or secondary outcomes".	Researchers must provide sufficient details, including the justification of chosen statistical techniques applied on the collected data, in order to make a decision on rejecting or not the null hypothesis (e.g., Intention-to-treat analysis).[47,48]	Yes. The pertinent statistical information emerges in the last paragraph of the *Materials and Method* section. We think that the authors might specify why they used the non-parametric Mann–Whitney *U* test instead of the Student *t* test for continuous result data.
12b: "Methods for additional analyses, such as subgroup analyses and secondary outcomes".	Although the number of statistical tests should be limited in an RCT, unnecessary or inappropriate additional tests remain common in dental research, for example, in cases of missing data, subgroup comparisons, or follow-up losses. This practice may render false-positive results and incorrect interpretations.[49,50]	Yes. Authors only outline the previously mentioned statistical methods. No additional tests are mentioned.

RESULTS:

Item	Explanation	Evaluators' comments
Participant flow		
13a: "For each group, the number of participants who were randomly assigned, received intended treatment and were analyzed for the primary outcome".	Researchers must show in a diagram the flow of participants through the trial phases: Enrollment; Allocation; Follow-up, and Analysis. This should also contain the number and reasons for dropouts and treatment failures.[33]	Yes. The flow diagram is included and is well-structured.
13b: "For each group, losses and exclusions after randomization, together with reasons".	Authors must report the numbers of lost and excluded participants during the trial phases, and the corresponding explanatory reasons. Thus, the reader can assess whether the withdrawals and exclusions were reasonable.[28,38]	Yes. These data are clearly annotated in the participant flow diagram. There were no losses during the follow-up period; thus, all selected patients were included in the analysis process.
Recruitment		
14a: "Dates defining periods of recruitment and follow-up".	It is important to know how long these phases lasted, so that the reader can situate the trial's historic background. This information is also relevant for planning future, similar studies.[5]	No. This information is not included.

Recruitment		
14b: "Why the trial ended or was stopped".	As explained in Item 7b, a trial can be prematurely stopped due to clinical (patent benefit or harm) or ethical reasons, after a halfway data examination. In this case, this should be described (e.g., the precise date) and justified in detail.[44]	The present trial was not ended or stopped early.
Baseline data		
15: "A table showing baseline demographic and clinical characteristics for each group".	Baseline sample demographic and clinical data allow the reader to assess whether the two study group participants were fairy similar after the randomization process and before providing the interventions. This comprises a crucial condition for enhancing internal validity.[51]	Yes. The authors present a specific table in which they exhibit information on age (median, range), gender, and treated teeth.
Numbers analyzed		
16: "For each group, number of participants (denominator) included in each analysis and whether analysis was for originally assigned groups".	It is important to know whether the study groups finished with an equal number of participants during the analysis process. The term "denominator" or event rate applies for categorical data (in fractions) when the results are expressed as percentages (very common for assessing drug adverse effects). Analysis of intention-to-treat is widely recommended for RTC, and consists of evaluating and comparing participants according their original assignment to the study groups after randomization.[52]	Yes. The authors mention, in the participant flow diagram, how many patients were analyzed per study group.
Outcomes and estimation		
17a: "For each primary and secondary outcome, results for each group and the estimated effect size and its precision (such as 95% confidence interval)".	Researchers should first report the summary results and the effect size for each study group, for example, in cases of continuous data: number of participants with or without the outcome-of-interest (mean ± standard deviations), and differences in means. For binary results, frequencies and percentages, and the effect size may be expressed as the relative risk, odds ratio, or risk difference.[31,51,53]	In the present article, authors used binary results; thus, this item does not apply.
17b: "For binary outcomes, presentation of both absolute and relative effect size is recommended".	As mentioned previously, for binary results, it is recommended to report the effect size through risk measurements, with their corresponding confidence intervals. These measurements are not difficult to calculate and interpret.[49]	This does not apply, because only continuous data were collected. The authors present tables describing clearly the results from each dependent-variable comparison.
Ancillary analyzes		
18: "Results of any other analyzes performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory".	Some crucial participant characteristics may not be well- balanced between the study groups after randomization, e.g., gender; age; bucodental hygiene; child cooperation level; among others, and researchers may be tempted to perform additional statistical testing, such as subgroup analyses or variable adjustments; however, this increases the risk of obtain false-positive results (see item 12b). Such comparisons should be stated in the *Results* section when detecting obvious differences in the groups.[47,48]	No applicable. There was no need for additional statistical tests.
Harms		
19: "All important harms or unintended effects in each group".	Researchers must clearly report any expected or unexpected adverse effects in order to undertake an unbiased benefit-harm analysis of the experimental intervention efficacy.[44]	No. They do not consider this issue.

DISCUSSION:

Item	Explanation	Evaluator' comments
	Limitations	
20: "Trial limitations, addressing sources of potential bias, imprecision and, if relevant, multiplicity of analyses".	Authors must outline inevitable biases (Figure 2) that could occur during the study and the methods for controlling these; in addition, it is relevant to discuss the imprecision observed of the results obtained and their clinical significance.[5]	No. The authors do not describe whether there was any type of limitation during the performance of their study.
	Generalizability	
21: "Generalizability (external validity, applicability) of the trial findings".	To decide whether the article's results may be clinically applied in other patients or settings, the reader should carefully assess the external validity, including inclusion and exclusion criteria (e.g., demographic and clinical characteristics), and the feasibility of the tested intervention (e.g., costs, personal training, patient's interests).[33]	Not specified, perhaps unnecessary. It is accepted that selection criteria, such as clinical/radiographic features for pulpectomy treatment in primary teeth, are "universal" and applicable in nearly all children.
	Interpretation	
22: "Interpretation consistent with results, balancing benefits and harms, and considering other, relevant evidence".	Authors should discuss the reported evidence in a wider context, beyond their own trial, with the aim of corroborating or not the results provided with other, similar published studies. Also, it is recommended that they include, in the *Discussion* section, a brief exposition about the benefit/harm balance from the tested interventions.[54]	Yes. They take an extensive paragraph to state the similarities and differences between the current trial's results and those from other, previous studies, and attempt to explain the possible reasons (for example, due to methodological differences).

OTHER INFORMATION

Item	Explanation	Evaluators' comments
	Registration	
23: "Registration number and name of trial registry".	Trial registration of every dentistry RTC is strongly recommended and fostered prior to administering any intervention, in order to decrease mistreatment of data or results; for example, no publication, withholding, selective reporting, and duplicate information; registration is also useful when designing or planning a systematic review with meta-analysis.[13] Thus, in its case, researchers should provide the pertinent details of this process.[33]	No. No related information provided.
	Protocol	
24: "Where the full trial protocol can be assessed, if available".	Sometimes, other clinicians are interested in having access to the original protocol of a study, in order to learn how to structure a dentistry investigation plan or how to apply its information for future, related trials and for assessing whether researchers only reported positive results, namely, selective reporting. Therefore, trial protocols should be available for anyone, in a transparent manner.[5,44]	No. Not mentioned.
	Funding	
25: "Sources of funding and other support (such as supply of drugs), role of funders".	Authors should emphatically declare any form of external or internal scholarship, financial support, or sponsorship during the study's performance. If so, they should also mention all pertinent information under the *Acknowledgments* heading, before the references.[33]	No. No conflict of interest statement was noted. They only thank the person who edited the manuscript, in the *Acknowledgments* section.

Additional items: Ethical issues (Scottish Intercollegiate Guidelines Network [SIGN] Methodology Checklist):[10]

Item	Explanation	Evaluators' comments
26a: "Informed consent procedure".	Ethical considerations are crucial when conducting an RCT in children. Principles such as respect, autonomy of children, and their assent to participate must be taken into consideration. Minors (and parents or legal guardians) need to be informed in detail about the trial and about anything that will happen to the children, and must include the consideration of their own (parents' and legal guardians') potential worries and fears. This process must be expressed in written form, namely, signed informed consent.[10,55]	Yes, by means of the next declaration: "The clinical procedure was explained to either the parents or legal guardians, and written informed consent was obtained", in the *Materials and Method* section.
26b: "Ethical Review Board approval".	It is very important for the study protocol (including financial concepts) and the informed consent form ton be carefully reviewed and, in its case, approved by an authorized Ethical Review Board, at a university, hospital or investigation center.[10]	Yes, but briefly: "The study obtained the study was approved by the University Ethics Committee".

FINAL COMMENTS

In their daily practice with respect to child oral care, Pediatric Dentists face some situations that merit research to rationalize treatments. RCT are essential components of the modern dental investigation and greatly aid in ensuring that patients, particularly children, receive efficacious therapies, validated by requirements regarding methodological and ethical issues.[7,10] When making clinical decisions, Pediatric Dentistry practitioners should base their appraisals on the best available published evidence, a key step in EBD practice; likewise, and as in any health science, Pediatric Dentists need to continually remain up-dated on new therapy options.[7] Therefore, it is essential to promote among researchers the aim for achieve both methodological quality and reporting quality (complete and transparent trial reporting) in order to facilitate the recognition of well-constructed and proper RCT and to apply their findings in our patients with greater confidence.[28,29,35,56]

Each published Pediatric Dentistry article should include important characteristics to take into account when evaluating its quality ("Will this article help my patients?"), and this is a daunting task to carry out without a guide.[7,57] Approaches such as the CONSORT checklist may facilitate this process; in addition, it is very appropriate to improve the quality of reporting in clinical research (diminishing the possibility of, for example, incomplete, selective, and misleading information), thus increasing the evidence level deriving from RCT in Dentistry.[33] CONSORT also guides editors and peer reviewers in the paper evaluation task, authors to assess their own manuscript reporting, and researchers to identify suitable trials for inclusion in a systematic review with or without meta-analysis ("Does this new research add to the literature in any way?").[35,57] Designing and conducting a meaningful RCT require methodological and clinical expertise and should be written, as an article, in a sufficiently clear manner to avoid readers having to speculate when interpreting the study results; during this appraisal process, Pediatric Dentistry practitioners should identify not only the trial's potential benefits, but also its flaws and limitations, in order to obtain the best reliable and applicable clinical information on their child patients.[29,33]

On the other hand, some limitations to the CONSORT approach have been mentioned. First, the checklist assigns an equivalent weight to all evaluative items, although influence on the validity of the study results is not similar from item-to-item.[56,58] Second, the rating of a number of CONSORT items involves some degree of subjectivity and is dependent on the evaluator's perceptions and knowledge.[37] As mentioned previously, there are two instruments for assessing the methodological and reporting quality of dental clinical trials: checklists and scales. The main difference between these is that, in a checklist, the items are evaluated separately and do not have numerical scores attached to them, while in a scale, each item is scored numerically and then all items are added together to create an overall quality score. Scales are easier to interpret than checklists, but they may provide a false impression in terms of meaningfulness;[12,29] there are >25 RCT scales for the evaluation of quality and reporting (e.g., the Jadad, the PEDro, or the Delphi scale).[37] And third, the fact that lack of pertinent information on the article does not necessarily imply that the trial methodological procedures were not executed.[56]

According to Pandis *et al*,[56] the quality scores of RCT in major dental journals with the highest impact factor in their corresponding clinical field are considered suboptimal in key CONSORT issues, ranging from 56.1–69% (the *Journal of Pediatric Dentistry* attained 60.4%). Thus, it is very important those well-conducted and clearly reported children RCT are carried out, in order to improve the overall quality research in the Pediatric Dentistry field, and additionally for necessary practitioner professional updating and clinical performance improvement, through proper therapy decision-making.

CONCLUSIONS

The results and findings derived from well-conducted RCTs provide the highest clinical care evidence for new interventions in the pediatric dentistry field. Thus, it is strongly suggested, during the development of an RTC paper, the reporting of crucial methodological information that is essential for the practitioner decision-making task, and also for the peer-review and editorial review processes. Some issues that must be included are randomization methods, blinding, effect size, statistical management of the follow-up losses, among others.[58–60] Therefore, reporting of any RTC in pediatric dentistry research should adhere to the CONSORT 2010 statement in order to improve and optimize the overall quality, in terms of validity and generalizability, of the submitted manuscript.[61] Due to its widely recognized usefulness, this tool has been officially endorsed by over 600 health science journals –in their instructions to authors– and also by prominent editorial groups worldwide.[62,63]

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