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Efficacy of conventional treatment with composite resin and atraumatic restorative treatment in posterior primary teeth: study protocol for a randomized controlled trial

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Abstract

Introduction: Despite the widespread acceptance of conventional treatment using composite resin in primary teeth, there is no evidence that this approach is the best option in pediatric clinics. Atraumatic restorative treatment (ART) using high-viscosity glass ionomer cement (GIC) has gradually become more popular because it performs well in clinical studies, is easy to handle and is patient friendly. Therefore, the aim of this randomized clinical trial study is to compare the efficacy of conventional treatment using composite resin with that of ART in posterior primary teeth. As secondary outcomes, cost-efficacy and patient self-reported discomfort will also be tested.

Methods and analysis: Children aged 3 to 6 years presenting with at least one occlusal and/or occlusal-proximal cavity will be randomly assigned to one of two groups according to the dental treatment: ART (experimental group) or composite resin restoration (control group). The dental treatment will be performed at a dental care trailer located in an Educational Complex in Barueri/SP, Brazil. The unit of randomization will be the child. A sample size of 240 teeth with occlusal cavities and 188 teeth with occlusal-proximal cavities has been calculated. The primary outcome will be restoration longevity, which will be clinical assessed after 6, 12, 18 and 24 months by two examiners. The duration of the dental treatment and the cost of all materials used will be considered when estimating the cost-efficacy of each treatment. Individual discomfort will be measured after each dental procedure using the Facial Scale of Wong-Baker.

Ethics and dissemination: This clinical trial was approved by the Local Ethics Committee from the Faculty of Dentistry of the University of Sao Paulo (registration

#1.556.018). Participants will be included after their legal guardians have signed an informed consent form containing detailed information about the research.

Trial registration: www.clinicaltrials.gov, NCT02562456. Registered on September 25th 2015.

Keywords: restorative dental treatment, primary teeth, composite resin, glass ionomer cement, atraumatic restorative treatment, randomized clinical trial, cost-efficacy analysis

Strengths and limitations of this study

- Considering that the success of a restorative treatment is intrinsically related to the handling of the material, it seems necessary to study these techniques under controlled conditions to extract from them the best clinical performance they can offer;
- An efficacy study can maximize the likelihood of observing an intervention effect by investigating the benefits and harms of it under highly controlled conditions;
- This is the first clinical trial comparing the longevity, cost-efficacy and self-reported discomfort assessment between conventional restoration using composite resin and ART with high-viscosity GIC in posterior primary teeth;
- Blinding of operators and patients will not be possible because of the evident differences between the techniques.

Introduction

Restorative care in primary teeth is part of the comprehensive oral health treatment of children and adolescents,[1] which should guarantee appropriate functional and aesthetic conditions until tooth exfoliation.[2] There is an ongoing search for ideal restorative materials for use in pediatric dentistry,[1] but a lack of evidence persists.[3, 4, 5]

Conventional treatment using composite resin is still one of the most common approaches used in pediatric dental clinics.[6] Despite the aesthetic quality, preservation of dental structure, and abrasion wear rate similar to that of natural primary teeth,[6] all composite resins suffer polymerization shrinkage, which can jeopardize marginal integrity[2] and restoration longevity. Additionally, to take full advantage of the properties of composite resin, absolute isolation with rubber dam is necessary,[7] making the restoration not only technique-sensitive and time-consuming,[2] but also more traumatic for the pediatric patient.[8]

An alternative to the use of composite resin is atraumatic restorative treatment (ART), a minimal intervention approach that simplifies the restorative procedure through the exclusive use of hand instruments, followed by the application of a chemical-adhesive material.[9] ART is reported to provoke less anxiety and less pain, and rarely requires local anesthesia.[10] Currently, the material of choice for ART is high-viscosity glass ionomer cement (GIC),[11] which provides biocompatibility, fluoride release, chemical adhesion to the tooth surface[12] and a coefficient of thermal expansion similar to that of natural teeth.[4] Moreover, it is easy to use because it can be placed in a single increment.[2]

The international scientific literature has already designated ART as an appropriate procedure to treat occlusal and occlusal-proximal cavities in primary teeth

when compared with amalgam.[4, 5] However, few clinical studies have compared composite resin performance in primary teeth with any other dental material.[13, 14, 15] Moreover, patient-based parameters must also be assessed in order to enable a more effective and appropriate choice of treatment for each individual. In this context, few reports have been found in the literature regarding those outcomes such as patient's acceptability[16, 17] (Novaes et al., 2012; Staman et al., 2013) and cost of restorative treatments.[18,19] (Da Mata et al., 2014; Mickenautsch et al., 2009).

Because of the need to establish the best scientific evidence about restorative treatment in primary teeth, this study aims to compare the efficacy of two types of treatment in primary molars (ART using high-viscosity GIC and composite resin restoration) using a superiority randomized clinical trial with parallel arms.

Methods/Design

The present protocol follows the guidelines of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) as detailed in Attachment A.

This clinical trial was recorded in the database for registration of clinical studies (Clinicaltrials.gov registration NCT02562456). This study will be a partnership with the city of Barueri, São Paulo, and it is nested to the Caries Detection in Children-2 study (registration NCT02473107). Each participant will be encoded by a number to guarantee information confidentiality. Any files containing identifiable data will be stored in locked filing cabinets, and only researchers will have access to participants' information.

The final trial dataset will be available for inspection with the coordinator's endorsement. Results will be fully reported in peer-reviewed journals, the patients' newsletter and on the website. If participants develop any dental treatment needs after

completion of the trial, they will be referred to the health service of the city of Barueri, São Paulo.

Sample description

Participants will be selected after screening in a dental care trailer located in the Professor Carlos Osmarinho de Lima Educational Complex (Barueri/SP). All healthy children who live in the city of Barueri seeking dental treatment are potential participants in our project. The trailer is set up as a regular dental office. The inclusion criteria are: 1) children aged 3–6 years; 2) whose parents consent their participation in the research; 3) with at least one occlusal and/or occlusal-proximal cavity in a primary molar; 4) the tooth of interest should not be associated with a fistula, abscess, pulp exposure, history of spontaneous dental pain or mobility; and 5) the cavity of interest should allow the access by the operator using hand instruments. Children who present behavior problems during the clinical examination or during dental treatment will be excluded from our study.

The child will be set as the unit of randomization, which means that all eligible teeth of a child included in our research will be treated according to the same treatment independently of the number of cavities. For sample calculation, data on the longevity of 2 years of occlusal and occlusal-proximal composite resin restorations[15] were extracted from the literature as 86% and 60%, respectively. A minimum difference of 10% between treatment longevities was set as the superiority limit. Taking the significance level as 5%, a power of 80% and the addition of 40% owing to study design (cluster per children), the minimum number of teeth per group was calculated using a two-tailed test. Additionally, a sample loss of 20% was

estimated, resulting in 204 teeth for the occlusal group and 240 teeth for the occlusal-proximal group (Table 1).

Table 1 – Sample distribution.

Groups	Type of cavity	
	Occlusal	Occlusal-proximal
Control (Composite resin)	102	120
Experimental (ART)	102	120
Total	204	240

Recruitment will take place from December 2015 to June 2017. Each participant will be enrolled in the study for about 25 months: 1 month for the Randomized Clinical Trial (RCT) diagnosis and treatment, followed by a 24-month observation period. Details are illustrated in Figure 1. Participants' enrolment will be facilitated by locating the trailer inside an Educational Complex.

After screening, participants who have met the eligibility criteria will have their registration data collected and will be clinically examined by one operator. Radiographic examination will be performed if any doubts about the pulp involvement of the tooth of interest persist. As the child will receive complete dental treatment during the study, radiographic examination will also be used if any other treatment need demand it.

The same operator will also determine the dental caries experience of the child which will be assessed based on the World Health Organization (WHO) criteria that only considers evident carious cavities, and restored and/or missing teeth as a result of

carious progression.[20] Thus, the following indices will be calculated for each child: def-t and DMFT; children in whom (def-t) + (DMFT) is lower than or equal to three will be classified as having low dental caries experience. Children with higher scores will be classified as having high dental caries experience.[21]

The randomization process will be designed in blocks of different sizes generated by software. Opaque, sealed and sequentially numbered envelopes will be used to randomize the participants into the treatment groups.

The restorative treatment will be performed by four trained and calibrated operators who will disclose which treatment they are performing at the commencement of the restorative procedure. However, blinding participants and operators will not be possible due to the evident differences between both techniques.

Study groups

Participants will be randomly assigned into two different groups:

(a) Group I (control): composite resin restoration, using 37% phosphoric acid, Adper Scotchbond Multipurpose adhesive system (3M/ESPE) and Filtek Z350 resin-composite (3M/ESPE).

(b) Group II (experimental): ART using high-viscosity GIC Fuji IX (Gold Label – GC Corp) with manual dosage and hand-mixed powder and liquid.

Treatment protocol

(a) Composite resin restoration

All children from Group I will be treated according to conventional techniques using composite resin:

- Use local anesthesia;
- Maintain absolute isolation of the operatory field with rubber dam and clamp;
- Remove caries: use hand excavators to remove caries in dentin. Both infected and affected dentin should be removed from the dentin–enamel junction, maintaining the affected dentin in the remaining dental walls. If necessary, round bur at high speed under water cooling will be used to remove the unsupported enamel;
- Etch enamel for 15 s and dentin for 7 s using 37% phosphoric acid, followed by rinsing for the same amount of time and drying with compressed air;
- Apply the Adper Scotchbond Multipurpose adhesive system (3M/ESPE) according to the manufacturer's guidelines: primer application followed by gentle drying for 5 s; then polymerization of the adhesive for 10 s with the XL 3000 curing light (3M/ESPE);
- Apply light-cured Filtek Z350 resin (3M/ESPE) using the oblique incremental placement technique. Each increment should be polymerized for 20 s. In occlusal-proximal cavities, an adapted matrix strip should be used with a wooden wedge to maintain it in place, providing appropriate contour to the restoration;
- Remove the rubber dam and check the occlusion with articulating paper. If necessary, finishing burs (F and FF) should be used under a cooling spray.

(b) Atraumatic restorative treatment (ART) using glass ionomer cement (GIC)

All children from Group II will be treated according to the ART philosophy as described by Frencken:[22]

- Maintain relative isolation of the operatory field with cotton rolls;
- Remove caries: using only hand excavators compatible with the size of the carious cavity. Both infected and affected dentin should be removed from the dentin–enamel junction. Thus, as described for Group I, the affected dentin will be maintained in the remaining walls;
- Clean the cavity: cavity walls should be cleaned with cotton balls moistened with water;
- Condition the dentin: apply a drop of 11.5% polyacrylic acid on a cotton ball for 15 s. Then, wash the cavity with three cotton balls moistened with water and dry using three more cotton balls;
- Use correct dosage (one spoon measure of the powder to one drop of polyacrylic acid): place the polyacrylic acid flask vertically and upside down, wait a few seconds until the bubbles rise and then drip two drops. Use the first drop to condition the cavity, because this initial drop may contain bubbles;
- Hand mix: spread the second drop of polyacrylic acid over the paper pad. Then, mix the powder in with the acid in two stages—manipulate the first part for 10 s and the second part for 15–20 s, applying moderate pressure. Use the material only while it remains glossy;
- Apply GIC: insert the GIC with a #1 spatula followed by finger pressure using petroleum jelly. For occlusal-proximal cavities, use an adapted matrix strip with a wooden wedge to maintain it in place, providing appropriate contour to the restoration. Protecting the restoration with petroleum jelly is necessary to inhibit syneresis and imbibition;

- Check the occlusion: after the initial set (approximately 5 min), check the occlusion with articulating paper. If necessary, sharp hand instruments should be used for adjustments. A new layer of petroleum jelly should be applied to the surface of the restoration;
- Instruct the patient not to eat solid food for 1 h.

Dental care other than restorative treatment related to this project will also be provided in the dental care trailer by three operators trained in the same philosophy regarding non-cavitated carious lesions[23] and pulp treatment[24]. Moreover, all participants and their respective legal guardians will receive verbal instructions about the use of toothpaste with a minimum concentration of 1000 ppm fluoride to prevent dental caries.[25]

The risks related to the present research are similar to those found during conventional clinical dental treatment. Thus, there is no Data Monitoring Committee. Independent surveillance of trial data collection, management and analysis will be undertaken by the principal investigator who has overall responsibility for the study and is in charge of the data.

Outcomes

The primary outcome will be the longevity of both restorative treatments after follow-up for 2 years. Secondary outcomes will include the cost-efficacy of both types of restorative treatment and self-reported discomfort.

(I) Longevity

Treatment longevity will be evaluated after 6, 12, 18 and 24 months by two trained examiners. The intra-examiner and inter-examiner concordances will be calculated using Cohen's Kappa test. Only scores above 0.7 will be accepted. After prophylaxis, the occlusal restorations will be clinically evaluated according to the Frencken and Holmgren[26] criteria (Attachment B).

For occlusal-proximal restorations, the adopted criteria are those proposed by Roeleveld et al.[27] (Attachment C). The width and depth of marginal defects, the surface wear and the excess or lack of material will be measured using the WHO CPI periodontal probe, which has a ball-shaped tip 0.5 mm in diameter.

If any treatment need is noted at the return visits, the procedure will be performed by one of the three trained operators until the case is resolved. Oral hygiene and fluoride use instructions will be repeated at each return visit for all children.

Data from each participant will be registered in clinical records for future statistical analysis. Data quality will be ensured by validation checks that include missing data, out of range values, and illogical and invalid responses. All data entered will be audited by the coordinator, and data queries will be raised as necessary.

(II) Cost-efficacy

The direct cost analysis will be based on previous publications[28, 29] adjusted to the Brazilian reality[30]. Both the professional cost and the procedure cost will be considered.

To calculate the professional cost, we will use the previous calculation of Floriano et al.[31], such that the time spent in each session will be converted to hours and multiplied by the average income of a dentist per hour ($13.89) and a dental

assistant per hour ($7.06) as ruled by the Brazilian federal law n^{o} 3999/61.[30, 31] To estimate the procedure cost, we will consider both the variable cost, which includes electricity and the depreciation of instruments and equipment, and the materials cost.[28, 32] To calculate the instruments and equipment depreciation (peripherals and dental chair), we will use the previous calculation of Da Mata et al.[18] and Floriano et al.[29] that considers their cost, a lifespan of 3 years for instruments[18] and 5 years for equipment[30] and a monthly use of 160 h.

A researcher other than the operator will time each restorative treatment session, including the return visits, and will register in predetermined sheets the specifications and quantity of all materials used. Prices will be inferred from the market value converted to US dollars and obtained by averaging the values from different places that have commercialized the products used. The prices will also be updated during the course of the study.

In order to estimate the cost-efficacy, the incremental cost-efficacy ration (ICER) will be estimated by dividing the average total cost by the survival after 2 years of each treatment:

$$ICER = (cost_{ART}\text{-}efficacy_{ART}) / (cost_{TC}\text{-}efficacy_{TC})$$

(III) Child self-reported discomfort

The self-reported discomfort of each child will be evaluated using the Wong-Baker Facial Scale.[33] This scale indicates the discomfort of an individual who has to choose among six faces, each one expressing different facial expressions. The first image is a smiling happy face, followed by gradually less cheerful expressions up to the last one, which is a very sad face covered in tears. The scale will be applied immediately after each restorative treatment session by the operator who is timing the procedure.

The participant will be asked to choose the face that best match how he or she felt during the treatment. This answer should be given solely by the child, with no parental or professional interference.[34]

Data analysis

To compare the longevity of the restorations, both Kaplan–Meier survival analysis and Cox regression with shared frailty will be applied. The association between restoration longevity and caries experience or the type of cavity will also be evaluated using Cox's Regression with shared frailty. To determine the data normality, the Kolmogorov–Smirnov test will be used. In relation to the secondary outcomes, the comparison between groups in relation to the time spent in each procedure as well as the average cost of a restoration will be done through the use of linear regression adjusted to the cluster effect. Multilevel Poisson regression will be used to compare both groups and the other independent variables to the self-reported discomfort. The significance level will be adjusted to 5%.

Ethics and dissemination

This clinical trial was approved by the Ethics Committee of Research in Humans from the Faculty of Dentistry of the University of Sao Paulo (registration #1.556.018). Participants will be included after their parents or legal guardians have signed an informed consent form containing detailed information about the research.

This study will involve the publication of grouped data collected from participants' individual information. This statement will be described in the consent form of each participant.

Funding

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Authors' contributions

DPR, MMB, FMM and IF contributed to the conception of this trial. DPR was responsible for its design. DPR is the trial coordinator and NML is the principal investigator. DPR, NML and IO drafted the protocol. IF is in charge of the recruitment of participants. NML is responsible for the patients' treatment. CSS and LY are responsible for timekeeping, recording materials and organizing treatment. TKT is responsible for patient evaluations over time. All authors critically reviewed and approved the final manuscript as submitted.

Competing interests

We declare that there are no conflicts of interest regarding the performance of this trial.

Acknowledgments

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	01
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	04
	2b	All items from the World Health Organization Trial Registration Data Set	_____
Protocol version	3	Date and version identifier	04
Funding	4	Sources and types of financial, material, and other support	15
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	01, 02
	5b	Name and contact information for the trial sponsor	02
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	16
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_____

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	05
	6b	Explanation for choice of comparators	05
Objectives	7	Specific objectives or hypotheses	06
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	06
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	07
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	07
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	09, 10, 11, 12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12, 13, 14
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	08

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	07
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	08
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	09
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	09
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	08 e 09
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	09
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_____
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_____

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	06
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	12
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	06, 12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	12
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	15
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	07, 15
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	06
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	06
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	06
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	06
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Attachment B – Assessment criteria by Frencken and Holmgren (2001)

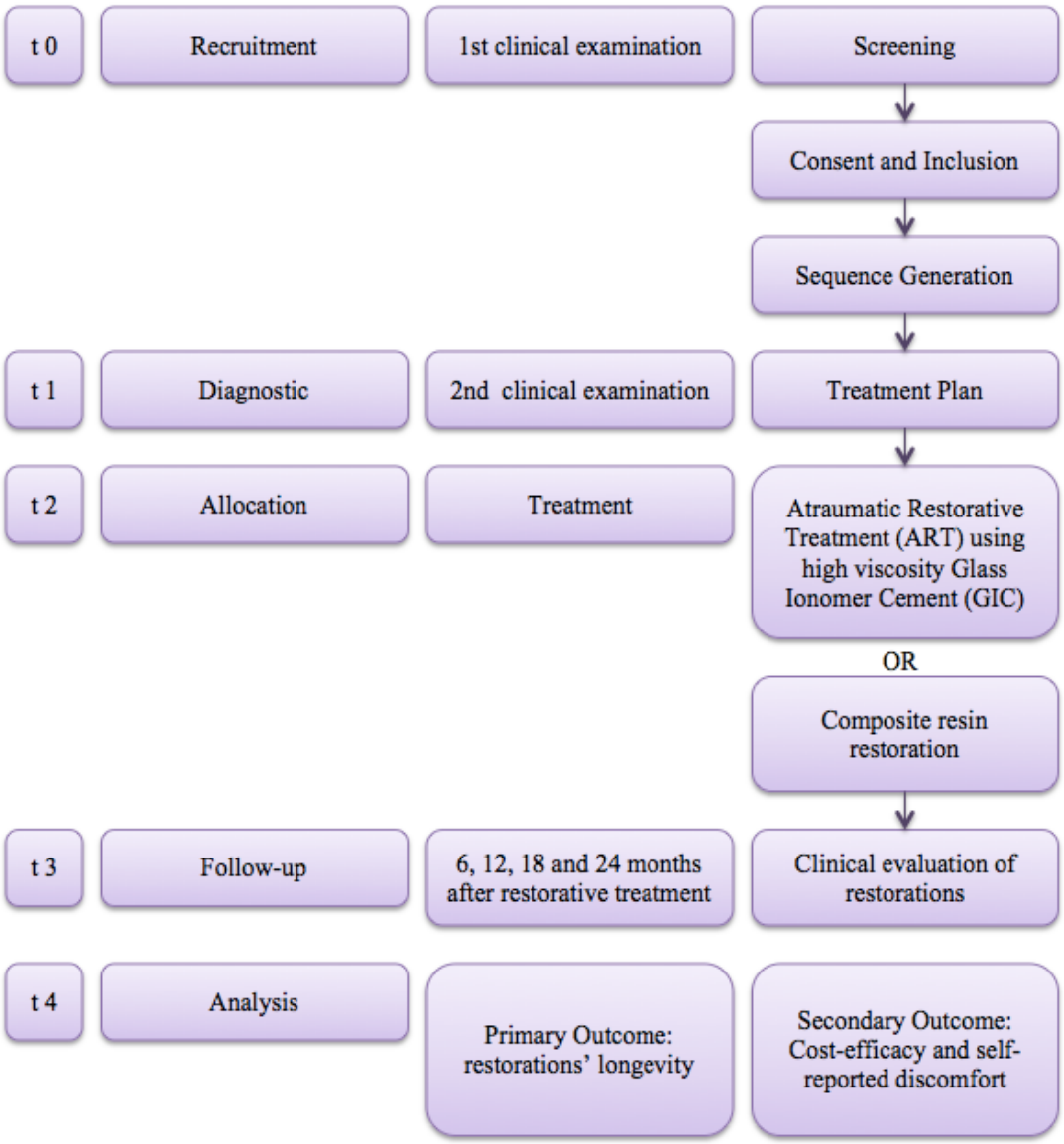
Score	Criteria
0	Present, good
1	Present, slight marginal defect for whatever reason, at any one place, which is less than 0.5 mm in depth. No repair is needed
2	Present, marginal defect for whatever reason, at any one place which is deeper than 0.5 mm but less than 1.0 mm. Repair is needed
3	Present, gross defect of more than 1.0 mm in depth. Repair is needed
4	Not present, restoration has (almost) completely disappeared. Treatment is needed
5	Not present, other restorative treatment has been performed
6	Not present, tooth has been extracted
7	Present, wear and tear gradually over larger parts of the restoration but are less than 0.5 mm at the deepest point. No repair is needed
8	Present, wear and tear gradually over larger parts of the restoration which are deeper than 0.5 mm. Repair is needed
9	Unable to diagnose

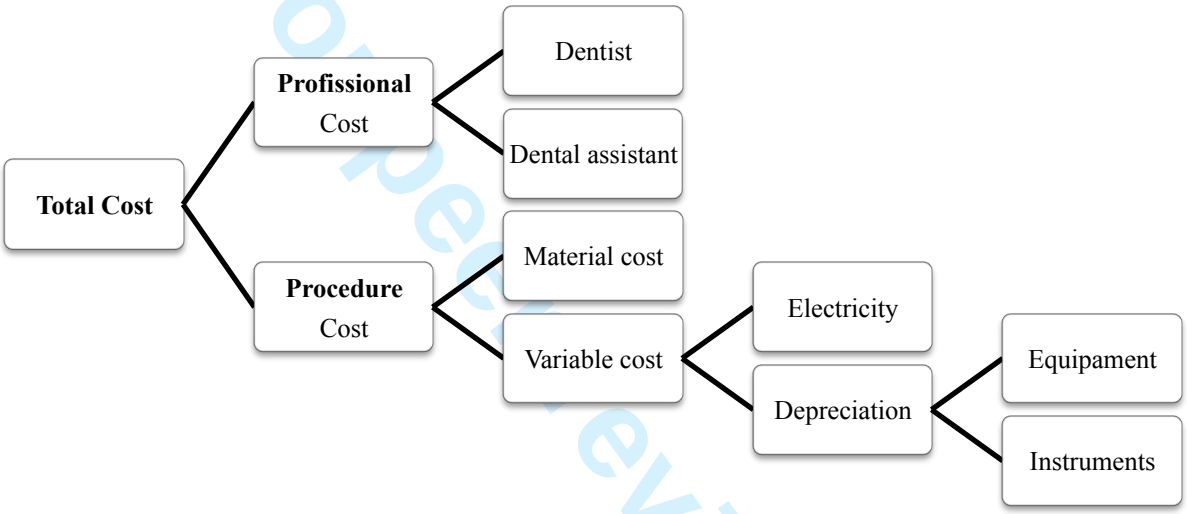
Note: Restorations considered to have survived are scored by codes: 0, 1 and 7; those considered to have failed by codes: 2, 3, 4 and 8; while those that are considered to be unrelated to success and failure are coded: 5 and 6.

Attachment C – Assessment criteria by Roeleveld et al. (2006)

Score	Criteria
00	Restoration still present, correct
10	Restoration present, slight defect at the margin and/or wear of the surface; < 0.5 mm in depth, repair needed
11	Restoration present, defect at the margin and/or wear of the surface; > 0.5 mm in depth, repair needed
12	Restoration present; underfilled > 0.5 mm, no gap, repair needed
13	Restoration overfilled > 0.5 mm, repair needed
20	Secondary caries, discoloration in depth, surface hard and intact, caries within dentin; repair needed
21	Secondary caries. Surface defect, caries within dentin; repair needed
30	Restoration not present, bulk fracture, loose, (partly) lost; repair needed (if still possible without exposing the pulp)
40	Inflammation of the pulp (restoration still in situ, not categorized in the former categories); fistula or severe pain complaints; extraction needed
50	Tooth not present because of extraction
60	Tooth not present because of shedding
70	Tooth not present because of extraction
90	Patient not present

Note: Restorations considered to have survived are scored by codes: 00 and 10; those considered to have by code: 11, 12, 13, 20, 21, 30 or 40; while those considered to be unrelated to success and failure are coded: 50, 60, 70 or 90


t 0
Recruitment
1st clinical examination
Screening
Consent and Inclusion
Sequence Generation
t 1
Diagnostic
2nd clinical examination
Treatment Plan
t 2
Allocation
Treatment
Atraumatic Restorative Treatment (ART) using high viscosity Glass Ionomer Cement (GIC)
OR
Composite resin restoration
t 3
Follow-up
6, 12, 18 and 24 months after restorative treatment
Clinical evaluation of restorations
t 4
Analysis
Primary Outcome: restorations' longevity
Secondary Outcome: Cost-efficacy and self-reported discomfort



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Efficacy of conventional treatment with composite resin and atraumatic restorative treatment in posterior primary teeth: study protocol for a randomized controlled trial

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Efficacy of conventional treatment with composite resin and atraumatic restorative treatment in posterior primary teeth: study protocol for a randomized controlled trial

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Abstract

Introduction: Despite the widespread acceptance of conventional treatment using composite resin in primary teeth, there is limited evidence that this approach is the best option in pediatric clinics. Atraumatic restorative treatment (ART) using high-viscosity glass ionomer cement (GIC) has gradually become more popular because it performs well in clinical studies, is easy to handle and is patient friendly. Therefore, the aim of this randomized clinical trial study is to compare the restoration longevity of conventional treatment using composite resin with that of ART in posterior primary teeth. As secondary outcomes, cost-efficacy and patient self-reported discomfort will also be tested.

Methods and analysis: Children aged 3 to 6 years presenting with at least one occlusal and/or occlusal-proximal cavity will be randomly assigned to one of two groups according to the dental treatment: ART (experimental group) or composite resin restoration (control group). The dental treatment will be performed at a dental care trailer located in an Educational Complex in Barueri/SP, Brazil. The unit of randomization will be the child. A sample size of 240 teeth with occlusal cavities and 188 teeth with occlusal-proximal cavities has been calculated. The primary outcome will be restoration longevity, which will be clinical assessed after 6, 12, 18 and 24 months by two examiners. The duration of the dental treatment and the cost of all materials used will be considered when estimating the cost-efficacy of each treatment. Individual discomfort will be measured after each dental procedure using the Facial Scale of Wong-Baker.

Ethics and dissemination: This clinical trial was approved by the Local Ethics Committee from the Faculty of Dentistry of the University of Sao Paulo (registration

#1.556.018). Participants will be included after their legal guardians have signed an informed consent form containing detailed information about the research.

Trial registration: www.clinicaltrials.gov, NCT02562456. Registered on September 25th 2015.

Keywords: restorative dental treatment, primary teeth, composite resin, glass ionomer cement, atraumatic restorative treatment, randomized clinical trial, cost-efficacy analysis

Strengths and limitations of this study

- Considering that the success of a restorative treatment is intrinsically related to the handling of the material, it seems necessary to study these techniques under controlled conditions to extract from them the best clinical performance they can offer;
- An efficacy study can maximize the likelihood of observing an intervention effect by investigating the benefits and harms of it under highly controlled conditions;
- This is the first clinical trial comparing the longevity, cost-efficacy and self-reported discomfort assessment between conventional restoration using composite resin and ART with high-viscosity GIC in posterior primary teeth;
- Blinding of operators and patients will not be possible because of the evident differences between the techniques.

Introduction

Restorative care in primary teeth is part of the comprehensive oral health treatment of children and adolescents,[1] which should guarantee appropriate functional and aesthetic conditions until tooth exfoliation.[2] There is an ongoing search for ideal restorative materials for use in pediatric dentistry,[1] but a lack of evidence persists.[3, 4, 5]

Conventional treatment using composite resin is still one of the most common approaches used in pediatric dental clinics.[6] Despite the aesthetic quality, preservation of dental structure, and abrasion wear rate similar to that of natural primary teeth,[6] all composite resins suffer polymerization shrinkage, which can jeopardize marginal integrity[2] and restoration longevity. Additionally, to take full advantage of the properties of composite resin, absolute isolation with rubber dam is necessary,[7] making the restoration not only technique-sensitive and time-consuming,[2] but also more traumatic for the pediatric patient.[8]

An alternative to the use of composite resin is atraumatic restorative treatment (ART), a minimal intervention approach that simplifies the restorative procedure through the exclusive use of hand instruments, followed by the application of a chemical-adhesive material.[9] ART is reported to provoke less anxiety and less pain, and rarely requires local anesthesia.[10] Currently, the material of choice for ART is high-viscosity glass ionomer cement (GIC),[11] which provides biocompatibility, fluoride release, chemical adhesion to the tooth surface[12] and a coefficient of thermal expansion similar to that of natural teeth.[4] Moreover, it is easy to use because it can be placed in a single increment.[2]

The international scientific literature has already designated ART as an appropriate procedure to treat occlusal and occlusal-proximal cavities in primary teeth

when compared with amalgam.[4, 5] However, few clinical studies have compared composite resin performance in primary teeth with any other dental material.[13, 14, 15] Moreover, patient-based parameters must also be assessed in order to enable a more effective and appropriate choice of treatment for each individual. In this context, few reports have been found in the literature regarding those outcomes such as patient's acceptability [16, 17] (Novaes et al., 2012; Staman et al., 2013) and cost of restorative treatments.[18,19] (Da Mata et al., 2014; Mickenautsch et al., 2009).

Because of the need to establish the best scientific evidence about restorative treatment in primary teeth, this study aims to compare the efficacy of two types of treatment in primary molars (ART using high-viscosity GIC and composite resin restoration) using a superiority randomized clinical trial with parallel arms.

Our hypothesis is that the longevity of restorations using the conventional treatment with resin composite under rubber dam for occlusal and occlusal-proximal cavities in primary molars differs from the longevity of atraumatic restorations using high viscosity glass ionomer. Regarding the secondary outcomes, we expect that ART has a better cost-efficacy and it is the only treatment highly accepted among children in this study.

Methods/Design

The present protocol follows the guidelines of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) as detailed in Attachment A.

This clinical trial was recorded in the database for registration of clinical studies (Clinicaltrials.gov registration NCT02562456). This study is part of a partnership with the city of Barueri, São Paulo, and it is nested to the Caries Detection in Children-2 study (registration NCT02473107). Each participant will be encoded by

a number to guarantee information confidentiality. Any files containing identifiable data will be stored in locked filing cabinets, and only researchers will have access to participants' information.

The final trial dataset will be available for inspection with the coordinator's endorsement. Results will be fully reported in peer-reviewed journals, the patients' newsletter and on the website. If participants develop any dental treatment needs after completion of the trial, they will be referred to the health service of the city of Barueri, São Paulo.

Sample description

Participants will be selected after screening in a dental care trailer located in the Professor Carlos Osmarinho de Lima Educational Complex (Barueri/SP). All healthy children who live in the city of Barueri seeking dental treatment are potential participants in our project. The trailer is set up as a regular dental office. The inclusion criteria are: 1) children aged 3–6 years; 2) whose parents consent their participation in the research; 3) with at least one occlusal and/or occlusal-proximal cavity in a primary molar; 4) the carious lesion should be in dentin, clinically classified as a shallow or a medium cavity; 5) the tooth of interest should not be associated with a fistula, abscess, pulp exposure, history of spontaneous dental pain or mobility; and 6) the cavity of interest should allow the access by the operator using hand instruments (ICDAS 5 or 6). Children who present behavior problems during the clinical examination or during dental treatment will be excluded from our study.

The child will be set as the unit of randomization, which means that all eligible teeth of a child included in our research will be treated according to the same treatment independently of the number of cavities. For sample size calculation, data

on the longevity of 2 years of occlusal and occlusal-proximal composite resin restorations[15] were extracted from the literature as 86% and 60%, respectively. A minimum difference of 10% between treatment longevities was set as the superiority limit. Taking the significance level as 5%, a power of 80% and the addition of 40% owing to study design (cluster per children), the minimum number of teeth per group was calculated using a two-tailed test. Additionally, a sample loss of 20% was estimated, resulting in 204 teeth for the occlusal group and 240 teeth for the occlusal-proximal group (Table 1).

Table 1 – Sample distribution.

Groups	Type of cavity	
	Occlusal	Occlusal-proximal
Control (Composite resin)	102	120
Experimental (ART)	102	120
Total	204	240

Recruitment will take place from December 2015 to June 2017. Each participant will be enrolled in the study for about 25 months: 1 month for the Randomized Clinical Trial (RCT) diagnosis and treatment, followed by a 24-month observation period. Details are illustrated in Figure 1. Participants' enrolment will be facilitated by locating the trailer inside an Educational Complex.

After screening, participants who have met the eligibility criteria will have their registration data collected and will be clinically examined by one operator. Radiographic examination will be performed if any doubts about the pulp

involvement of the tooth of interest persist. As the child will receive complete dental treatment during the study, radiographic examination will also be used if any other treatment need demand it.

The same operator will also determine the dental caries experience of the child which will be assessed based on the World Health Organization (WHO) criteria that only considers evident carious cavities, and restored and/or missing teeth as a result of carious progression.[20] Thus, the following indices will be calculated for each child: def-t and DMFT; children in whom (def-t) + (DMFT) is lower than or equal to three will be classified as having low dental caries experience. Children with higher scores will be classified as having high dental caries experience.[21]

The randomization process will be designed in blocks of different sizes generated by software. Opaque, sealed and sequentially numbered envelopes will be used to randomize the participants into the treatment groups.

The restorative treatment will be performed by four trained and calibrated operators who will disclose which treatment they are performing at the commencement of the restorative procedure. However, blinding participants and operators will not be possible due to the evident differences between both techniques.

Study groups

Participants will be randomly assigned into two different groups:

(a) Group I (control): composite resin restoration, using 37% phosphoric acid, Adper Scotchbond Multipurpose adhesive system (3M/ESPE) and Filtek Z350 resin-composite (3M/ESPE).

(b) Group II (experimental): ART using high-viscosity GIC Fuji IX (Gold Label – GC Corp) with manual dosage and hand-mixed powder and liquid.

Treatment protocol

(a) Composite resin restoration

All children from Group I will be treated according to conventional techniques using composite resin:

- Use local anesthesia;
- Maintain absolute isolation of the operatory field with rubber dam and clamp;
- Remove caries: use hand excavators to remove caries in dentin. Both infected and affected dentin should be removed from the dentin–enamel junction, maintaining the affected dentin in the remaining dental walls. If necessary, round bur at high speed under water cooling will be used to remove the unsupported enamel;
- Etch enamel for 15 s and dentin for 7 s using 37% phosphoric acid, followed by rinsing for the same amount of time and drying with compressed air;
- Apply the Adper Scotchbond Multipurpose adhesive system (3M/ESPE) according to the manufacturer's guidelines: primer application followed by gentle drying for 5 s; then polymerization of the adhesive for 10 s with the XL 3000 curing light (3M/ESPE);
- Apply light-cured Filtek Z350 resin (3M/ESPE) using the oblique incremental placement technique. Each increment should be polymerized for 20 s. In occlusal-proximal cavities, an adapted matrix strip should be used with a wooden wedge to maintain it in place, providing appropriate contour to the restoration;

- Remove the rubber dam and check the occlusion with articulating paper. If necessary, finishing burs (F and FF) should be used under a cooling spray.

(b) Atraumatic Restorative Treatment (ART) using glass ionomer cement (GIC)

All children from Group II will be treated according to the ART philosophy as described by Frencken et al. (1996):[22]

- Maintain relative isolation of the operatory field with cotton rolls;
- Remove caries: using only hand excavators compatible with the size of the carious cavity. Both infected and affected dentin should be removed from the dentin–enamel junction. Thus, as described for Group I, the affected dentin will be maintained in the remaining walls;
- Clean the cavity: cavity walls should be cleaned with cotton balls moistened with water;
- Condition the dentin: apply a drop of 11.5% polyacrylic acid on a cotton ball for 15 s. Then, wash the cavity with three cotton balls moistened with water and dry using three more cotton balls;
- Use correct dosage (one spoon measure of the powder to one drop of polyacrylic acid): place the polyacrylic acid flask vertically and upside down, wait a few seconds until the bubbles rise and then drip two drops. Use the first drop to condition the cavity, because this initial drop may contain bubbles;
- Hand mix: spread the second drop of polyacrylic acid over the paper pad. Then, mix the powder in with the acid in two stages—manipulate the first part for 10 s and the second part for 15–20 s, applying moderate pressure. Use the material only while it remains glossy;

- Apply GIC: insert the GIC with a #1 spatula followed by finger pressure using petroleum jelly for a few seconds. For occlusal-proximal cavities, use an adapted matrix strip with a wooden wedge to maintain it in place, providing appropriate contour to the restoration. Protecting the restoration with petroleum jelly is necessary to inhibit syneresis and imbibition;
- Check the occlusion: after the initial set (approximately 5 min), check the occlusion with articulating paper. If necessary, sharp hand instruments should be used for adjustments. A new layer of petroleum jelly should be applied to the surface of the restoration;
- Instruct the patient not to eat solid food for 1 h.

Dental care other than restorative treatment related to this project will also be provided in the dental care trailer by three operators trained in the same philosophy regarding non-cavitated carious lesions [23] and pulp treatment [24]. Moreover, all participants and their respective legal guardians will receive verbal instructions about the use of toothpaste with a minimum concentration of 1000 ppm fluoride to prevent dental caries.[25]

The risks related to the present research are similar to those found during conventional clinical dental treatment. Thus, there is no Data Monitoring Committee. Independent surveillance of trial data collection, management and analysis will be undertaken by the principal investigator who has overall responsibility for the study and is in charge of the data.

Outcomes

The primary outcome will be the longevity of both restorative treatments after follow-up for 2 years. Secondary outcomes will include the cost-efficacy of both types of restorative treatment and self-reported discomfort.

(I) Longevity

Treatment longevity will be evaluated after 6, 12, 18 and 24 months by two trained examiners. The intra-examiner and inter-examiner concordances will be calculated using Cohen's Kappa test. Only scores above 0.7 will be accepted. After prophylaxis, the occlusal restorations will be clinically evaluated according to the Frencken and Holmgren[26] criteria (Attachment B).

For occlusal-proximal restorations, the adopted criteria are those proposed by Roeleveld et al.[27] (Attachment C). The width and depth of marginal defects, the surface wear and the excess or lack of material will be measured using the WHO CPI periodontal probe, which has a ball-shaped tip 0.5 mm in diameter.

If any treatment need is noted at the return visits, the procedure will be performed by one of the three trained operators until the case is resolved. Oral hygiene and fluoride use instructions will be repeated at each return visit for all children.

Data from each participant will be registered in clinical records for future statistical analysis. Data quality will be ensured by validation checks that include missing data, out of range values, and illogical and invalid responses. All data entered will be audited by the coordinator, and data queries will be raised as necessary.

(II) Cost-efficacy

The direct cost analysis will be based on previous publications[28, 29] adjusted to the Brazilian reality[30]. Both the professional cost and the procedure cost will be considered (Figure 2).

To calculate the professional cost, we will use the previous calculation of Floriano et al.[31], such that the time spent in each session will be converted to hours and multiplied by the average income of a dentist per hour ($13.89) and a dental assistant per hour ($7.06) as ruled by the Brazilian federal law nº 3999/61.[30, 31] To estimate the procedure cost, we will consider both the variable cost, which includes electricity and the depreciation of instruments and equipment, and the materials cost.[28, 32] To calculate the instruments and equipment depreciation (peripherals and dental chair), we will use the previous calculation of Da Mata et al.[18] and Floriano et al.[29] that considers their cost, a lifespan of 3 years for instruments[18] and 5 years for equipment[30] and a monthly use of 160 h.

A researcher other than the operator will time each restorative treatment session, including the return visits, and will register in predetermined sheets the specifications and quantity of all materials used. Prices will be inferred from the market value converted to US dollars and obtained by averaging the values from different places that have commercialized the products used. The prices will also be updated during the course of the study.

In order to estimate the cost-efficacy, the incremental cost-efficacy ratio (ICER) will be estimated by dividing the average total cost by the survival after 2 years of each treatment:

$$ICER = (cost_{ART}\text{-}efficacy_{ART}) / (cost_{CT}\text{-}efficacy_{CT})$$

(III) Child self-reported discomfort

The self-reported discomfort of each child will be evaluated using the Wong-Baker Facial Scale.[33] This scale indicates the discomfort of an individual who has to choose among six faces, each one expressing different facial expressions. The first image is a smiling happy face, followed by gradually less cheerful expressions up to the last one, which is a very sad face covered in tears. The scale will be applied immediately after each restorative treatment session by the operator who is timing the procedure.

The participant will be asked to choose the face that best match how he or she felt during the treatment. This answer should be given solely by the child, with no parental or professional interference.[34]

Data analysis

To compare the longevity of the restorations, both Kaplan–Meier survival analysis and Cox regression with shared frailty will be applied. The association between restoration longevity and caries experience or the type of cavity will also be evaluated using Cox's Regression with shared frailty. To determine the data normality, the Kolmogorov–Smirnov test will be used. In relation to the secondary outcomes, the comparison between groups in relation to the time spent in each procedure as well as the average cost of a restoration will be done through the use of linear regression adjusted to the cluster effect. Multilevel Poisson regression will be used to compare both groups and the other independent variables to the self-reported discomfort. The significance level will be adjusted to 5%.

Ethics and dissemination

This clinical trial was approved by the Ethics Committee of Research in Humans from the Faculty of Dentistry of the University of Sao Paulo (registration #1.556.018). Participants will be included after their parents or legal guardians have signed an informed consent form containing detailed information about the research.

This study will involve the publication of grouped data collected from participants' individual information. This statement will be described in the consent form of each participant.

Funding

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Authors' contributions

DPR, MMB, FMM and IF contributed to the conception of this trial. DPR was responsible for its design. DPR is the principal investigator and NML is trial coordinator. DPR, NML and IO drafted the protocol. IF is in charge of the recruitment of participants. NML is responsible for the patients' treatment. CSS and LY are responsible for timekeeping, recording materials and organizing treatment. TKT is responsible for patient evaluations over time. All authors critically reviewed and approved the final manuscript as submitted.

Competing interests

We declare that there are no conflicts of interest regarding the performance of this trial.

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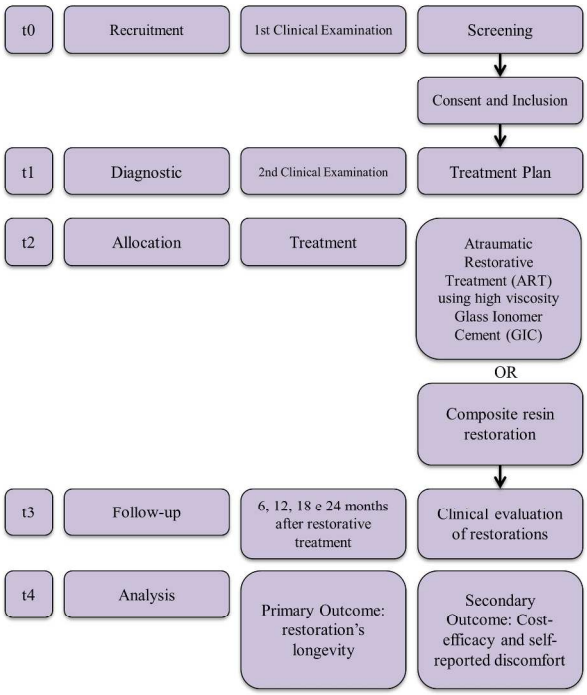

Figure 1: Clinical trial's timeline

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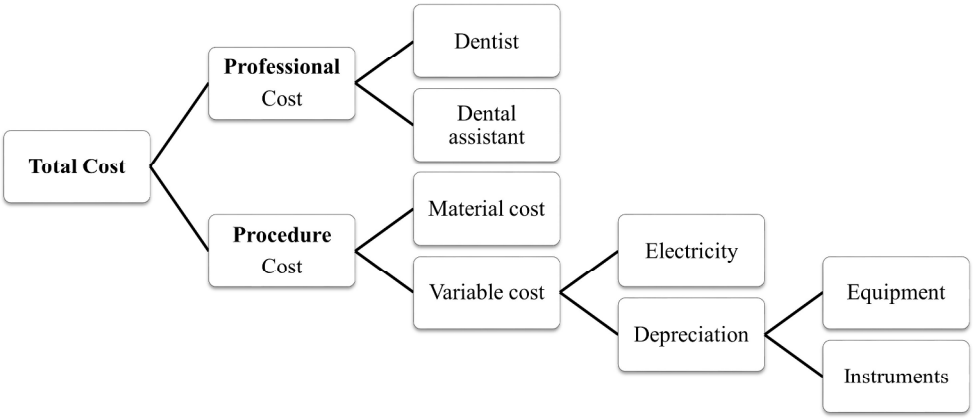

Figure 2: Diagram of total cost calculation

254x190mm (300 x 300 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	01
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	04
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	04
Funding	4	Sources and types of financial, material, and other support	15
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	01, 02
	5b	Name and contact information for the trial sponsor	02
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	16
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	05
	6b	Explanation for choice of comparators	05
Objectives	7	Specific objectives or hypotheses	06
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	06
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	07
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	07
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	09, 10, 11, 12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12, 13, 14
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	08

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	07
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	08
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	09
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	09
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	08 e 09
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	09
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_____
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_____

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	06
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	12
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	06, 12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	12
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	15
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	07, 15
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	06
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	06
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	06
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	06
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

Attachment B – Assessment criteria by Frencken and Holmgren (2001)

Score	Criteria
0	Present, good
1	Present, slight marginal defect for whatever reason, at any one place, which is less than 0.5 mm in depth. No repair is needed
2	Present, marginal defect for whatever reason, at any one place which is deeper than 0.5 mm but less than 1.0 mm. Repair is needed
3	Present, gross defect of more than 1.0 mm in depth. Repair is needed
4	Not present, restoration has (almost) completely disappeared. Treatment is needed
5	Not present, other restorative treatment has been performed
6	Not present, tooth has been extracted
7	Present, wear and tear gradually over larger parts of the restoration but are less than 0.5 mm at the deepest point. No repair is needed
8	Present, wear and tear gradually over larger parts of the restoration which are deeper than 0.5 mm. Repair is needed
9	Unable to diagnose

Note: Restorations considered to have survived are scored by codes: 0, 1 and 7; those considered to have failed by codes: 2, 3, 4 and 8; while those that are considered to be unrelated to success and failure are coded: 5 and 6.

Attachment C – Assessment criteria by Roeleveld et al. (2006)

Score	Criteria
00	Restoration still present, correct
10	Restoration present, slight defect at the margin and/or wear of the surface; < 0.5 mm in depth, repair needed
11	Restoration present, defect at the margin and/or wear of the surface; > 0.5 mm in depth, repair needed
12	Restoration present; underfilled > 0.5 mm, no gap, repair needed
13	Restoration overfilled > 0.5 mm, repair needed
20	Secondary caries, discoloration in depth, surface hard and intact, caries within dentin; repair needed
21	Secondary caries. Surface defect, caries within dentin; repair needed
30	Restoration not present, bulk fracture, loose, (partly) lost; repair needed (if still possible without exposing the pulp)
40	Inflammation of the pulp (restoration still in situ, not categorized in the former categories); fistula or severe pain complaints; extraction needed
50	Tooth not present because of extraction
60	Tooth not present because of shedding
70	Tooth not present because of extraction
90	Patient not present

Note: Restorations considered to have survived are scored by codes: 00 and 10; those considered to have by code: 11, 12, 13, 20, 21, 30 or 40; while those considered to be unrelated to success and failure are coded: 50, 60, 70 or 90