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An Investigator-blinded, 24-month, Parallel-group, Non-inferiority Study to Compare Aesthetic restorations in primary anterior teeth: study protocol for a randomized controlled trial

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Abstract

Introduction: Children who suffer from severe caries in childhood may have negative impacts on the growth, development, nutritional problems and quality of life problems related to the oral health of the child and his family. There are no studies that have compared rehabilitative techniques of primary anterior teeth regarding patient-centered outcomes and even longevity of restoration. Thus, this project aims to evaluate the effectiveness of restorative treatment of anterior primary teeth with monochromatic composite resin in single insertion through polyvinyl crowns, after selective removal of carious tissue compared to the effectiveness of conventional restoration. **Methods and analysis**: This study proposes to conduct a randomized clinical trial (RCT), composed of a sample of 194 deciduous central and lateral incisors with active cavitated lesions, simplified ICDAS C+ score (active and extensive stage caries: ICDAS 5 & 6), with involvement of more than two surfaces. This sample will be divided into two experimental groups, both with selective removal of carious tissue: a group in which conventional restoration will be performed using opaque resins; and another group with monochrome resin with chameleon effect and polyvinyl crowns. The explanatory variables - gender, age, toothbrushing, use of fluoridated toothpaste and dental floss, and socioeconomic status - will be collected through a questionnaire with open questions. The progression of caries lesions after 24 months of follow-up will be considered as the primary outcome. Secondary outcomes will include tooth survival, longevity of restoration, quality of life, perception and satisfaction of the participants' parents/guardians.

Ethics and dissemination: This protocol has been approved by the Human Research Ethics Committee of Universidade Metropolitana de Santos - UNIMES (protocol number:

6.019.297. Approved 24 April 2023). Results will be submitted to international peer-reviewed journals and presented at international conferences.

Trial registration: www.clinicaltrials.gov, NCT05875064. Registered 15 May 2023

Keywords: Dental caries; Dental Restoration Failure; Randomized clinical trial.

Strengths and limitations of this study

- This is the first randomized clinical trial to compare the two rehabilitative techniques of primary anterior teeth affected by extensive caries lesions.
- Our study is an efficacy study in patients with strict inclusion criteria, which might limit the generalisability of the results.
- One possible limitation relates to the fact that the comparison involves two different techniques performed with two different materials, which may lead to confusion about what contributes to a potential difference between the groups: the technique itself or the material used.
- However, this potential limitation is also a strength of the study, as the compared groups are consistent with what is performed in daily clinical practice, enhancing the generalizability of the results.

INTRODUCTION

Severe childhood caries has been defined as the presence of one or more decayed, missing or filled primary teeth in children aged 71 months (5 years) or less[1] Children who suffer from severe caries in childhood may have negative impacts on the growth, development, nutritional problems and quality of life problems related to the oral health of the child and his family. In addition, the interference of oral health in school performance and school attendance was proven, with also negative impact.[2]

Probably, all these negative impacts are related to the difficulty of chewing, phonation and pain that these patients are subject to.[3,4] In addition, there is aesthetic impairment, not only by the presence of cavitation in the anterior teeth, but in many cases these teeth are found with blackened tissue. This coloration, usually associated with the expulsivity of these lesions and the difficulty of managing children at a young age, make the aesthetic-functional rehabilitation even more challenging.

There are polyvinyl crowns on the market that have been used to facilitate this type of restoration, since they return the anatomy of the teeth more quickly and without the need for the operator's ability to perform dental sculptures.[5] Likewise, the development of new restorative materials that allow the use of thicker layers and unique coloration, promoting an effect called as chameleon, because it mimics the color of the tooth.

The evidence about rehabilitation of anterior teeth is scarce and mostly comes from case reports or techniques not based on the philosophy of minimal intervention. There are no studies that have compared rehabilitative techniques of primary anterior teeth regarding patient-centered outcomes and even longevity of restoration.

METHODS

Ethical aspects

The study will be conducted in accordance with the ethical precepts stipulated in the Declaration of Helsinki (World Medical Association Declaration of Helsinki, 2008) and in accordance with the norms governing research involving human subjects stipulated in Resolution nº 466/12 and 510/2016 of the Brazilian National Board of Health and has received approval from the Human Research Ethics Committee of UNIMES University (Protocol number: 6.019.297, 24/04/2023. Approved 24 April 2023). The study was registered in ClinicalTrials.gov (NCT05875064, Registered 15 May 2023). Legal

guardians will agree to the participation of the children by signing in writing a statement of informed consent. Recruitment will be initiated after approval from the Human Research Ethics Committee.

The participants will be informed that they may withdraw from the study at any time for any reason, if they so wish. The researchers will also be able to remove participants from the study if deemed necessary.

This protocol follows the SPIRIT[6](Standard Protocol Items for Randomized Trials) recommendations, as displayed in Table 1.

Table 1. Schedule of enrolment, interventions, and assessments of the study

	STUDY PERIOD						
	Enrolment	**Allocation**	**Post-allocation**				**Close-out**
TIMEPOINT	$-t_1$	**0**	t_1	***6mo***	***12mo***	***18mo***	***24mo***
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
Conventional restoration			X				
Polyvinyl crowns			X				
ASSESSMENTS:							
Socioeconomic, habits questionnaire,	X	X					
Caries lesions progression				—	—	—	—
Tooth survival				—	—	—	—
Longevity of restorations				—	—	—	—
OHRQoL			X	—	—	—	—
Perception and Satisfaction of parents			X	X			

Abbreviations: OHRQoL - Oral Health-related Quality of Life; mo – months

Confidentiality

The confidentiality of participants will be strictly maintained through the use of identification code numbers. Participant identifiable information will be stored securely in locked filing cabinets within a restricted-access room. Medical information will only be accessible to the dental team.

Ancillary and post-trial care

Upon completion of the study, participants will continue to receive dental treatments as needed in our dental clinics, ensuring continuity of care beyond the trial period.

Objective

To evaluate the effectiveness of restorative treatment of anterior primary teeth with monochromatic composite resin in single insertion through polyvinyl crowns, after selective removal of carious tissue compared to the effectiveness of conventional restoration.

Trial Design

A randomized controlled clinical trial with two parallel arms, with an allocation ratio of 1:1 will be designed. A sample of 194 deciduous central and lateral incisors with active cavitated lesions, simplified ICDAS C+ score (active and extensive stage caries: ICDAS (5 & 6)[7], with involvement of more than two surfaces will be divided into two experimental groups: a group in which conventional restoration will be performed using opaque resins; and another group with monochrome resin with chameleon effect and polyvinyl crowns, both after selective removal of carious tissue.

Participants

The children will be randomly selected from a pool of enrolment forms of children (12 to 60 months) who seek dental care at the Pediatric Dentistry clinic of UNIMES.

Inclusion and exclusion criteria

Children ranging in age from 12 to 60 months with at least one active cavitated caries lesion involving more than 2 surfaces (C+ score; active and extensive stage caries: ICDAS (5 & 6) [7] in deciduous upper incisors will be included. Patients with special needs, with general health conditions that may affect the oral cavity, whose guardians do not

sign the written informed consent form (ICF) or that the child does not give verbal assent will be excluded. In addition, other exclusion criteria were: lack of patient collaboration, teeth with pre-operative pulp exposure or those with deep dentin caries with risk of iatrogenic pulp exposure, or subgingival marginal termination or requiring absolute isolation; teeth with signs of mobility, abscess, or fistula; less than 2/3 of root (radiographically assessed), teeth without an antagonist, teeth with previous restorations and children with bruxism and/or deep bite.[8]

Participant timeline

Each participant is enrolled in the study for about 25 months in total (1-month RCT – diagnosis and treatment, followed by a 24-months observational period). Figure 1 shows participants timeline.

Sample size

To perform the sample size calculation with independent samples, it was considered that the retention of previous restorations of primary teeth is 80[5] and that a clinically relevant difference of 10% and non-inferiority limit of 5% is expected. Thus, considering a two-tailed test, adopting a significance level of 0.05 and a power of 0.80, we reached the number of 69 teeth per group. Since each child can contribute more than one tooth, we added 20% (cluster per child) and another 20% for a possible sample loss. Thus, a final required number of 97 teeth per experimental group was obtained, totaling 194 teeth for the study (https://www.sealedenvelope.com/power/binary-noninferior/).

Recruitment

Children with ages ranging from 12 to 60 months will be selected, who seek dental care at the Pediatric Dentistry clinic of UNIMES. Potentially eligible children will be referred for clinical examination.

Allocation: Sequence generation

The participants will be selected from a pool of enrolment forms of children who looked for dental treatment in our school, using a sequence of random numbers generated by software by an external participant. The randomization procedure will be done per blocks of different sizes. The randomization will be done after the inclusion of the child.

Allocation concealment mechanism

Only at the time of the interventions will the generated sequences be known. These will be distributed in opaque envelopes and sealed to the operators. More than one tooth per patient may be included in the research, but all teeth included in the same patient will be treated with the same technique, but on different days to avoid patient fatigue and lack of cooperation.

Training and calibration of examiners and operators

There will be 1 examiner involved in the process of screening and 2 operators involved in treating patients, all specialists, PhD and professors in Pediatric Dentistry. The calibration will be carried out among the 2 operators to detect caries lesions, through the evaluation of photographs, and the decision whether or not to include the teeth in the research. The n used in this stage will be 10% of the total sample and we will calculate the Kappa statistic to evaluate the agreement between the examiners.

These will be assisted by undergraduate students, who, in addition to clinical assistants, will be responsible for opening the treatment randomization envelopes. Clinical outcomes will be evaluated by a specialist professor, MSc and PhD in Pediatric Dentistry not involved in inclusion and operative steps.

Implementation

The examiner that will perform the screening will have the initial x-ray, but will not have a part in the randomization or treatment of the patients. The assistants, undergraduate students, will be responsible for opening the opaque brown envelopes. Then, the two operators will perform the treatments.

Blinding (masking)

The examiners who will evaluate the outcomes during the follow-up will be blinded regarding the allocation group.

Interventions

Initially, a clinical examination will be performed in a dental office using reflector, mirror, tweezers and WHO probe, after prophylaxis, by the operators. For this evaluation, the diagnostic criterion used will be the International Caries Detection and Assessment System (ICDAS).[9]

Treatments for the control of caries lesions

All teeth with caries lesions will be treated according to the philosophy of selective removal of carious tissue, differing only in the restorative technique. The teeth allocated in the conventional restoration group (control) will receive restorations in resin composed by incremental technique, using opaque resin. For this, 37% phosphoric acid (Condac37, FGM) will be applied for 15 seconds in enamel and 7 seconds in dentin, and then, after washing and relative drying of the surface, application of universal adhesive (Universal Beautibond Adhesive, Shofu) with the aid of microbrush on the entire dental surface, photoactivation of the adhesive and restoration by incremental technique and photoactivation of each layer of resin for 20 seconds. The tooth will receive finishing and polishing through rotating instruments and abrasive discs (Supersnap, Shofu).

The teeth allocated in the experimental group will have the restorations carried out through monochromatic composite resin with chameleon effect in single insertion through polyvinyl crown. For this, 37% phosphoric acid (Condac37, FGM) will be applied for 15 seconds in enamel and 7 seconds in dentin, and then, after washing and relative drying of the surface, application of universal adhesive (Universal Beautibond Adhesive, Shofu) with the aid of microbrush on the entire tooth surface, photoactivation of the adhesive and adaptation of the crown matrix in acetate filled with resin in the tooth. Photoactivation will be done for 20 seconds per dental face, and the acetate matrix is then removed. The tooth will receive finishing and polishing through rotating instruments and abrasive discs (Supersnap, Shofu).

The remaining teeth identified with caries lesions that are not included in the research will be treated according to the diagnosis by the researchers involved in this study. If there is a need for more complex procedures, patients will be referred for specialized treatment.

Follow-up visits

The patients who have been selected will undergo reassessment at 6, 12, 18, and 24 months after the commencement of treatment. During the time between these consultations, various strategies will be employed to ensure strong adherence and return rates, including: (1) Scheduling consultations at the most suitable times; (2) Maintaining telephone contact with the caregivers; (3) Providing an active cell phone for unforeseen circumstances; (4) Offering gifts to children at the conclusion of each consultation.

Throughout the 24-month duration of the study, the research participants will be continuously monitored by the responsible professionals. If any additional treatment is required, the child will receive comprehensive support without any negative impact.

Outcomes

The explanatory variables, including gender, age, toothbrushing habits, fluoride toothpaste usage, and dental flossing, will be gathered using a questionnaire that consists of open-ended questions. Additionally, a socioeconomic questionnaire consisting of closed-ended questions will be administered. To ensure participant confidentiality, each individual will be assigned an identifying number. The time spent on the treatments will be timed by the auxiliary from the beginning to the end of the polishing in order to compare the durations of both techniques.

The primary outcome of this study will be the progression of caries lesions after a 24-month follow-up period. Secondary outcomes will encompass tooth survival, longevity of dental restorations, quality of life, as well as the perception and satisfaction reported by the parents or guardians of the participants.

The examination of the reported outcomes will be conducted by pediatric dentists who are not involved in the treatments performed and have received appropriate training. These examiners will evaluate the outcomes in a blinded manner.

For assessing caries progression, the modified periapical radiographic examination for preschoolers will be employed. The radiographic protocol will involve the use of E-speed children's film (E-speed, 22x35mm, Eastman Kodak, Rochester, USA), a 0.4s exposure time, and the Spectro 70X device. The bisection technique will be utilized for radiographic measurements of anterior teeth in preschool children, accompanied by the use of an apron and lead collar for radiation protection. The films will be processed either manually using the time/temperature method (with a temperature of approximately 27 degrees Celsius, developer solution for 2 minutes, fixative solution for 10 minutes, and water washing for 20 minutes) or digitally. A total of six radiographic images will be taken per patient: one before the restorative procedure, for screening, one immediately after the procedure, and subsequent follow-up images at 6, 12, 18, and 24 months. The images will be compared in pairs to determine whether there has been any progression of caries, assessed by a trained and calibrated senior researcher, without the aid of any magnification loops and while blinded regarding the chronological order of the radiographs.:

a) Absent progression: No increase in the radiolucent area of the lesion.

b) Progression present: Increase in the radiolucent area of the lesion.

Teeth demonstrating caries lesion progression with signs of pulp involvement will be treated accordingly with restorative or endodontic procedures appropriate for the observed condition.

Assessment of Restoration Longevity

During the follow-up visits at 6, 12, 18, and 24 months, a visual clinical examination will be conducted to assess the condition of caries lesions and the longevity of restorations. This examination will involve inspecting the restoration's integrity, its adaptation on all dental surfaces, and identifying any potential issues such as structural fractures, resin wear, maladaptation, or functional maintenance problems with the restored tooth.

- The clinical evaluation of restoration retention will be performed at 6, 12, 18, and 24 months, using the criteria described by Pardi et al. (2005)[10]:
- RT (total retention): Complete preservation of the restoration.
- PP1 (partial preservation 1): Presence of resin in two-thirds of the surface of each dental face.
- PP2 (partial preservation 2): Presence of resin in one-third of each face of the dental surface.
- PT (total preservation): Complete loss of resin on the surface of the dental face.

Furthermore, the degree of tooth mobility and its correlation with the normal exfoliation period will be assessed in teeth from both groups. The teeth will be clinically assessed by the examiner in accordance with the ICDAS criteria for CARS as suggested by the ICDAS Coordinating Committee[11]: (0) sound tooth surface with restoration or sealant, (1) first visual change in enamel, (2) distinct visual change in enamel/dentin adjacent to a restoration/sealant margin, (3) carious defects of <0.5mm with the signs of code 2, (4) marginal caries in enamel/dentin/cementum adjacent to a restoration/sealant with underlying dark shadow from dentin, (5) distinct cavity adjacent to a restoration/sealant, and (6) extensive distinct cavity with visible dentin.

Radiographic evaluation of dental exfoliation and tooth survival will involve examining the amount of absorbed deciduous tooth root in the radiographs taken at 6, 12, 18, and 24 months, comparing them to the initial radiograph. The association between exfoliation

and the maintenance of restorations without extensive structural failures will determine the success of restoration longevity and tooth survival in the restored tooth.

Perception of Parents/Guardians

To evaluate the parents' or guardians' perception of the treatment received, the "Child's and Parent's Questionnaire about Teeth Appearance"[12] will be administered immediately after the first treatment session and again after 6 months of treatment. The examiners will provide guidance to ensure an honest expression of their opinions.

Satisfaction of Parents/Guardians

Parents or guardians will be asked about their satisfaction with the treatment provided to their child after 6 months of treatment. The examiners will guide them to provide their genuine opinions.

Quality of Life

A questionnaire, specifically the validated Brazilian version of the Early Childhood Oral Health Impact Scale (ECOHIS)[13], will be used to assess the impact of the treatments on the oral health-related quality of life of children. The parents or guardians of the participants will complete this questionnaire during the initial consultations and at each follow-up visit.

Data collection methods

Data collection and returning assessments will be made by researchers who have experience in clinical research. They will be blinded to group allocation, and they will be the same examiners at all time-points for each participant in order to minimize inter-observer variability.

Data management

The clinic data will be directly entered into pre-designed sheets to ensure efficient data management. To maintain data quality, validation checks will be conducted, which will include identifying missing data, out-of-range values, illogical responses, and invalid entries.

Statistical Analysis

The efficacy of each treatment will be evaluated through three outcomes, which are: (1) criteria related to the control of cavitated active lesions, (2) criteria related to the longevity of restorations, (3) patient-centered outcomes.

For comparison between the two groups will be used the survival of Kaplan-Meier and the Long-Rank test. Cox regression will be performed in to enable the evaluation of the influence of some other variables on the results. To compare the two groups with respect to patient-centered outcomes, the Student's t-test or the Mann-Whitney test will be used, depending on the normality of the data. For all analyses, the significance value will be adjusted to 5%.

Data monitoring

Since adverse events related to dental treatments are unlikely, there is no Data Monitoring Committee. However, independent oversight of the collection, management, and analysis of trial data will be carried out by TG (name of person/organization responsible). TG, as the chief investigator, holds overall responsibility for the study and acts as the custodian of the data.

Harms

The procedures performed will follow the biosafety standards and will be performed by a trained professional, so no damage is foreseen. The possible risks are minimal and the same as any restorative procedure, such as discomfort during the placement of cotton and application of resin.

Auditing

The entered data will be audited on a monthly basis by the coordinator. Data queries will be raised as necessary, and any discrepancies identified will be promptly corrected and systematically recorded.

DISCUSSION

Until now no randomized clinical trial was conducted to compare conventional restorations and the use of polyvinyl crowns in primary anterior teeth with extensive caries lesions. With the expected results, we aim to provide clinical evidence for a better

treatment decision by the pediatric dentist. Currently, research has focused on testing different restorative materials but only case reports address the different possible techniques for restoring these teeth. Considering that the two techniques that will be tested start from the same assumption of selective removal of carious tissue but are conducted with different step-by-step it becomes important to verify if there is any better technique. Given that one of the techniques involves the restoration in a single increment of resin, through the polyvinyl crowns, probably its execution time will be faster, but will the quality and longevity of the restoration be similar to the conventional technique? To the best of our knowledge, this is the first randomized clinical trial to compare the two rehabilitative techniques of primary anterior teeth affected by extensive caries lesions.

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Author Contributions: Contributors Substantial contributions to the conception: TG and SKB. Design of the work: TG, APTS, MLLG and SKB Drafting the work: TG, MLLG, JMASG and SKB. Revising the work: TG, APTS, EMS, MLLG, EPF, JMASG, ARHM, LJM, JCPI and SKB. Final approval of the work: TG, EMS, ACRTH, LJM, JCPI and SKB. If stopping the trial is necessary, these authors will have.

Competing Interests: None declared. The authors have no conflicts of interest, financial or otherwise, to declare.

Availability of data and materials: This paper is a protocol description and does not contain any data at this point. Future data will be available, as described in the Data sharing statement below.

Data sharing statement: The datasets (Excel spreadsheets) generated from this protocol will be available from the corresponding author (Sandra Kalil Bussadori – sandra.skb@gmail.com) upon any reasonable request. However, reuse of this data will not be permitted for anyone who is not an author of this paper.

Patient and Public Involvement: The guardians of the patients were not involved in the design of this study. After the data analysis, the guardians will be given the opportunity to participate in a result-sharing meeting if they so desire. The consent form signed by guardians of the participants explains that the storage of data for each participant and family member is within the terms of confidentiality.

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Abstract

Introduction: Children who suffer from severe caries in childhood may have negative impacts on the growth, development, nutritional problems and quality of life problems related to the oral health of the child and his family. There are no studies that have compared rehabilitative techniques of primary anterior teeth regarding patient-centered outcomes and even longevity of restoration. Thus, this project aims to evaluate the effectiveness of restorative treatment of anterior primary teeth with monochromatic composite resin in single insertion through polyvinyl crowns, after selective removal of carious tissue compared to the effectiveness of conventional restoration. **Methods and analysis**: This study proposes to conduct a randomized clinical trial (RCT), composed of a sample of 194 deciduous central and lateral incisors with active cavitated lesions, simplified ICDAS C+ score (active and extensive stage caries: ICDAS 5 & 6), with involvement of more than two surfaces. This sample will be divided into two experimental groups, both with selective removal of carious tissue: a group in which conventional restoration will be performed using opaque resins; and another group with monochrome resin with chameleon effect and polyvinyl crowns. The explanatory variables - gender, age, toothbrushing, use of fluoridated toothpaste and dental floss, and socioeconomic status - will be collected through a questionnaire with open questions. The progression of caries lesions after 24 months of follow-up will be considered as the primary outcome. Secondary outcomes will include tooth survival, longevity of restoration, quality of life, perception and satisfaction of the participants' parents/guardians.

Ethics and dissemination: This protocol has been approved by the Human Research Ethics Committee of Universidade Metropolitana de Santos - UNIMES (protocol number:

6.019.297. Approved 24 April 2023). Results will be submitted to international peer-reviewed journals and presented at international conferences.

Trial registration: www.clinicaltrials.gov, NCT05875064. Registered 15 May 2023

Keywords: Dental caries; Dental Restoration Failure; Randomized clinical trial.

Strengths and limitations of this study

- This study employs a randomized clinical trial (RCT) design with random allocation and investigator blinding, ensuring a high level of scientific evidence and minimizing selection and detection bias.
- The trial may face challenges in maintaining participant adherence during the 24-month follow-up, potentially impacting the final sample size and the comprehensive assessment of secondary outcomes.
- Variability in participants' toothbrushing techniques and oral hygiene habits may influence results, as these factors cannot be fully controlled over time.
- The use of self-reported questionnaires to collect socioeconomic and oral hygiene data may introduce response bias, affecting the accuracy of some explanatory variables.
- One possible limitation relates to the fact that the comparison involves two different techniques performed with two different materials, which may lead to confusion about what contributes to a potential difference between the groups: the technique itself or the material used.

INTRODUCTION

Severe childhood caries has been defined as the presence of one or more decayed, missing or filled primary teeth in children aged 71 months (5 years) or less[1] Children who suffer from severe caries in childhood may have negative impacts on the growth, development, nutritional problems and quality of life problems related to the oral health of the child and his family. In addition, the interference of oral health in school performance and school attendance was proven, with also negative impact.[2]

Probably, all these negative impacts are related to the difficulty of chewing, phonation and pain that these patients are subject to.[3,4] In addition, there is aesthetic impairment, not only by the presence of cavitation in the anterior teeth, but in many cases these teeth are found with blackened tissue. This coloration, usually associated with the expulsivity of these lesions and the difficulty of managing children at a young age, make the aesthetic-functional rehabilitation even more challenging.

There are polyvinyl crowns on the market that have been used to facilitate this type of restoration, since they return the anatomy of the teeth more quickly and without the need for the operator's ability to perform dental sculptures[5,6.] Likewise, the development of new restorative materials that allow the use of thicker layers and unique coloration, promoting an effect called as chameleon, because it mimics the color of the tooth.

The evidence about rehabilitation of anterior teeth is scarce and mostly comes from case reports or techniques not based on the philosophy of minimal intervention. There are no studies that have compared rehabilitative techniques for primary anterior teeth without requiring operative preparation in terms of patient-centered outcomes or even restoration longevity. Our hypothesis is that restorations with polyvinyl crowns are not inferior to conventional restorations.

METHODS

Ethics and Dissemination

This study protocol has been reviewed and approved by the Human Research Ethics Committee of Universidade Metropolitana de Santos (UNIMES), under protocol number 6.019.297, approved on 24 April 2023. Written informed consent will be obtained from the parents or legal guardians of all participants prior to inclusion in the trial. The study adheres to the ethical principles outlined in the Declaration of Helsinki and complies with

relevant national and international guidelines for clinical trials. The participants will be informed that they may withdraw from the study at any time for any reason, if they so wish. The researchers will also be able to remove participants from the study if deemed necessary.

The results of this trial will be disseminated through several channels. Findings will be submitted for publication in peer-reviewed international journals and shared at relevant national and international conferences. Furthermore, the data generated from this study may be made available upon reasonable request to promote transparency and allow further research in the field.

This protocol follows the SPIRIT[8](Standard Protocol Items for Randomized Trials) recommendations, as displayed in Table 1.

Table 1. Schedule of enrolment, interventions, and assessments of the study

	STUDY PERIOD						
	Enrolment	**Allocation**	**Post-allocation**				**Close-out**
TIMEPOINT	$-t_1$	**0**	t_1	***6mo***	***12mo***	***18mo***	***24mo***
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
Conventional restoration			X				
Polyvinyl crowns			X				
ASSESSMENTS:							
Socioeconomic, habits questionnaire,	X	X					
Caries lesions progression				◆—	—	—	—◆
Tooth survival				◆—	—	—	—◆

Longevity of restorations				←	—	—	→
OHRQoL			X	←	—	—	→
Perception and Satisfaction of parents			X	X			

Abbreviations: OHRQoL - Oral Health-related Quality of Life; mo – months

Confidentiality

The confidentiality of participants will be strictly maintained through the use of identification code numbers. Participant identifiable information will be stored securely in locked filing cabinets within a restricted-access room. Medical information will only be accessible to the dental team.

Ancillary and post-trial care

Upon completion of the study, participants will continue to receive dental treatments as needed in our dental clinics, ensuring continuity of care beyond the trial period.

Objective

To evaluate the effectiveness of restorative treatment of anterior primary teeth with monochromatic composite resin in single insertion through polyvinyl crowns, after selective removal of carious tissue compared to the effectiveness of conventional restoration.

Trial Design

A randomized controlled clinical trial with two parallel arms, with an allocation ratio of 1:1 will be designed. A sample of 194 deciduous central and lateral incisors with active cavitated lesions, simplified ICDAS C+ score (active and extensive stage caries: ICDAS (5 & 6)[9], with involvement of more than two surfaces will be divided into two experimental groups: a group in which conventional restoration will be performed using opaque resins; and another group with monochrome resin with chameleon effect and polyvinyl crowns, both after selective removal of carious tissue.

Participants

The children will be randomly selected from a pool of enrolment forms of children (12 to 60 months) who seek dental care at the Pediatric Dentistry clinic of UNIMES.

Inclusion and exclusion criteria

Inclusion Criteria:

- Children ranging in age from 12 to 60 months with at least one active cavitated caries lesion involving more than 2 surfaces (C+ score)[9] in deciduous upper incisors will be included.

Exclusion Criteria:

- Patients with special needs, with general health conditions that may affect the oral cavity, whose guardians do not sign the Inform Consent Form will be excluded. In addition, teeth with pulp exposure, spontaneous pain, mobility, presence of swelling or fistula near the tooth and teeth with previous restorations; less than 2/3 of root (radiographically assessed), teeth without an antagonist, teeth with previous restorations and children with bruxism and/or deep bite.[10]

Participant timeline

Each participant is enrolled in the study for about 25 months in total (1-month RCT – diagnosis and treatment, followed by a 24-months observational period). Table 1 shows participants timeline. The planned start date will be November 2024 and end date will be November 2026.

Sample size

To perform the sample size calculation with independent samples, it was considered that the retention of previous restorations of primary teeth is 80%[5] and that a clinically relevant difference of 10% and non-inferiority limit of 5% is expected. Thus, considering a two-tailed test, adopting a significance level of 0.05 and a power of 0.80, we reached the number of 69 teeth per group. Since each child can contribute more than one tooth, we added 20% (cluster per child) and another 20% for a possible sample loss. Thus, a final required number of 97 teeth per experimental group was obtained, totaling 194 teeth for the study (https://www.sealedenvelope.com/power/binary-noninferior/).

Recruitment

Children with ages ranging from 12 to 60 months will be selected, who seek dental care at the Pediatric Dentistry clinic of UNIMES. Potentially eligible children will be referred for clinical examination.

Allocation: Sequence generation

The participants will be selected from a pool of enrolment forms of children who looked for dental treatment in our school, using a sequence of random numbers generated by software by an external participant. The randomization procedure will be done per blocks of different sizes. The randomization will be done after the inclusion of the child.

Allocation concealment mechanism

Only at the time of the interventions will the generated sequences be known. These will be distributed in opaque envelopes and sealed to the operators. More than one tooth per patient may be included in the research, but all teeth included in the same patient will be treated with the same technique, but on different days to avoid patient fatigue and lack of cooperation.

Training and calibration of examiners and operators

There will be 1 examiner involved in the process of screening and 2 operators involved in treating patients, all specialists, PhD and professors in Pediatric Dentistry. The calibration will be carried out among the 2 operators to detect caries lesions, through the evaluation of photographs, and the decision whether or not to include the teeth in the research. The n used in this stage will be 10% of the total sample and we will calculate the Kappa statistic to evaluate the agreement between the examiners.

These will be assisted by undergraduate students, who, in addition to clinical assistants, will be responsible for opening the treatment randomization envelopes. Clinical outcomes will be evaluated by a specialist professor, MSc and PhD in Pediatric Dentistry not involved in inclusion and operative steps.

Implementation

The examiner that will perform the screening will have the initial x-ray, but will not have a part in the randomization or treatment of the patients. The assistants, undergraduate

students, will be responsible for opening the opaque brown envelopes. Then, the two operators will perform the treatments.

Blinding (masking)

The examiners who will evaluate the outcomes during the follow-up will be blinded regarding the allocation group.

Interventions

Initially, a clinical examination will be performed in a dental office using reflector, mirror, tweezers and WHO probe, after prophylaxis, by the operators. For this evaluation, the diagnostic criterion used will be the International Caries Detection and Assessment System (ICDAS).[9]

Treatments for the control of caries lesions

All teeth with caries lesions will be treated according to the philosophy of selective removal of carious tissue, differing only in the restorative technique. The teeth allocated in the conventional restoration group (control) will receive restorations in resin composed by incremental technique, using opaque resin. For this, 37% phosphoric acid (Condac37, FGM) will be applied for 15 seconds in enamel and 7 seconds in dentin, and then, after washing and relative drying of the surface, with a etch and rinse approach, followed by the application of universal adhesive (Universal Beautibond Adhesive, Shofu) with the aid of microbrush on the entire dental surface, photoactivation of the adhesive and restoration by incremental technique and photoactivation of each layer of resin for 20 seconds (Radii Xpert, SDI, peak 1500 mW/cm2) . We have added this information. We have added this information. The tooth will receive finishing and polishing through rotating instruments and abrasive discs (Supersnap, Shofu).

The teeth allocated in the experimental group will have the restorations carried out through monochromatic composite resin with chameleon effect in single insertion through polyvinyl crown. For this, 37% phosphoric acid (Condac37, FGM) will be applied for 15 seconds in enamel and 7 seconds in dentin, and then, after washing and relative drying of the surface, application of universal adhesive (Universal Beautibond Adhesive, Shofu) with the aid of microbrush on the entire tooth surface, photoactivation of the adhesive and adaptation of the crown matrix in acetate filled with resin in the tooth. Photoactivation will be done for 20 seconds per dental face, and the acetate matrix is then

removed. The tooth will receive finishing and polishing through rotating instruments and abrasive discs (Supersnap, Shofu).

The remaining teeth identified with caries lesions that are not included in the research will be treated according to the diagnosis by the researchers involved in this study. If there is a need for more complex procedures, patients will be referred for specialized treatment.

Follow-up visits

The patients who have been selected will undergo reassessment at 6, 12, 18, and 24 months after the commencement of treatment. During the time between these consultations, various strategies will be employed to ensure strong adherence and return rates, including: (1) Scheduling consultations at the most suitable times; (2) Maintaining telephone contact with the caregivers; (3) Providing an active cell phone for unforeseen circumstances; (4) Offering gifts to children at the conclusion of each consultation.

Throughout the 24-month duration of the study, the research participants will be continuously monitored by the responsible professionals. If any additional treatment is required, the child will receive comprehensive support without any negative impact.

Outcomes

The explanatory variables, including gender, age, toothbrushing habits, fluoride toothpaste usage, and dental flossing, will be gathered using a questionnaire that consists of open-ended questions. Additionally, a socioeconomic questionnaire consisting of closed-ended questions will be administered. To ensure participant confidentiality, each individual will be assigned an identifying number. The time spent on the treatments will be timed by the auxiliary from the beginning to the end of the polishing in order to compare the durations of both techniques.

The primary outcome of this study will be the progression of caries lesions after a 24-month follow-up period. Secondary outcomes will encompass tooth survival, longevity of dental restorations, quality of life, as well as the perception and satisfaction reported by the parents or guardians of the participants.

The examination of the reported outcomes will be conducted by pediatric dentists who are not involved in the treatments performed and have received appropriate training. These examiners will evaluate the outcomes in a blinded manner.

For assessing caries progression, the modified periapical radiographic examination for preschoolers will be employed. The radiographic protocol will involve the use of E-speed

children's film (E-speed, 22x35mm, Eastman Kodak, Rochester, USA), a 0.4s exposure time, and the Spectro 70X device. The bisection technique will be utilized for radiographic measurements of anterior teeth in preschool children, accompanied by the use of an apron and lead collar for radiation protection. The films will be processed either manually using the time/temperature method (with a temperature of approximately 27 degrees Celsius, developer solution for 2 minutes, fixative solution for 10 minutes, and water washing for 20 minutes) or digitally. A total of six radiographic images will be taken per patient: one before the restorative procedure, for screening, one immediately after the procedure, and subsequent follow-up images at 6, 12, 18, and 24 months. The images will be compared in pairs to determine whether there has been any progression of caries, assessed by a trained and calibrated senior researcher, without the aid of any magnification loops and while blinded regarding the chronological order of the radiographs.:

a) Absent progression: No increase in the radiolucent area of the lesion.

b) Progression present: Increase in the radiolucent area of the lesion.

Teeth demonstrating caries lesion progression with signs of pulp involvement will be treated accordingly with restorative or endodontic procedures appropriate for the observed condition.

Assessment of Restoration Longevity

During the follow-up visits at 6, 12, 18, and 24 months, a visual clinical examination will be conducted to assess the condition of caries lesions and the longevity of restorations. This examination will involve inspecting the restoration's integrity, its adaptation on all dental surfaces, and identifying any potential issues such as structural fractures, resin wear, maladaptation, or functional maintenance problems with the restored tooth.

- The clinical evaluation of restoration retention will be performed at 6, 12, 18, and 24 months, using the criteria described by Pardi et al. (2005)[11]:
- RT (total retention): Complete preservation of the restoration.
- PP1 (partial preservation 1): Presence of resin in two-thirds of the surface of each dental face.
- PP2 (partial preservation 2): Presence of resin in one-third of each face of the dental surface.
- PT (total preservation): Complete loss of resin on the surface of the dental face.

Furthermore, the degree of tooth mobility and its correlation with the normal exfoliation period will be assessed in teeth from both groups. The teeth will be clinically assessed by the examiner in accordance with the ICDAS criteria for CARS as suggested by the ICDAS Coordinating Committee[12]: (0) sound tooth surface with restoration or sealant, (1) first visual change in enamel, (2) distinct visual change in enamel/dentin adjacent to a restoration/sealant margin, (3) carious defects of <0.5mm with the signs of code 2, (4) marginal caries in enamel/dentin/cementum adjacent to a restoration/sealant with underlying dark shadow from dentin, (5) distinct cavity adjacent to a restoration/sealant, and (6) extensive distinct cavity with visible dentin.

Radiographic evaluation of dental exfoliation and tooth survival will involve examining the amount of absorbed deciduous tooth root in the radiographs taken at 6, 12, 18, and 24 months, comparing them to the initial radiograph. The association between exfoliation and the maintenance of restorations without extensive structural failures will determine the success of restoration longevity and tooth survival in the restored tooth.

Perception of Parents/Guardians

To evaluate the parents' or guardians' perception of the treatment received, the "Child's and Parent's Questionnaire about Teeth Appearance"[13] will be administered immediately after the first treatment session and again after 6 months of treatment. The examiners will provide guidance to ensure an honest expression of their opinions.

Satisfaction of Parents/Guardians

Parents or guardians will be asked about their satisfaction with the treatment provided to their child after 6 months of treatment. The examiners will guide them to provide their genuine opinions.

Quality of Life

A questionnaire, specifically the validated Brazilian version of the Early Childhood Oral Health Impact Scale (ECOHIS)[14], will be used to assess the impact of the treatments on the oral health-related quality of life of children. The parents or guardians of the participants will complete this questionnaire during the initial consultations and at each follow-up visit.

Data collection methods

Data collection and returning assessments will be made by researchers who have experience in clinical research. They will be blinded to group allocation, and they will be the same examiners at all time-points for each participant in order to minimize inter-observer variability.

Data management

The clinic data will be directly entered into pre-designed sheets to ensure efficient data management. To maintain data quality, validation checks will be conducted, which will include identifying missing data, out-of-range values, illogical responses, and invalid entries.

Statistical Analysis

The efficacy of each treatment will be evaluated through three primary outcomes:

1) Control of Cavitated Active Lesions: Kaplan-Meier survival analysis will be used to estimate the probability of lesion control over time, with the Log-Rank test employed to compare survival curves between the two groups. The absolute risk difference will be calculated to quantify the difference in lesion control rates, with a 95% confidence interval reported.
2) Longevity of Restorations: Kaplan-Meier survival analysis will also be used to evaluate restoration longevity, with comparisons made using the Log-Rank test. Cox regression analysis will be performed to assess the influence of additional variables on restoration longevity. The absolute risk difference and its 95% confidence interval will be provided to highlight the comparative effectiveness of the treatments.
3) Patient-Centered Outcomes: For comparing patient-centered outcomes between the two groups, the Student's t-test will be used for normally distributed data, while the Mann-Whitney U test will be applied for non-normally distributed data. The absolute risk difference for patient-centered outcomes will also be calculated, and a 95% confidence interval will be reported.

For all statistical analyses, the significance level will be set at 5%.

Data monitoring

Since adverse events related to dental treatments are unlikely, there is no Data Monitoring Committee. However, independent oversight of the collection, management, and analysis of trial data will be carried out by TG (name of person/organization responsible). TG, as the chief investigator, holds overall responsibility for the study and acts as the custodian of the data.

Harms

The procedures performed will follow the biosafety standards and will be performed by a trained professional, so no damage is foreseen. The possible risks are minimal and the same as any restorative procedure, such as discomfort during the placement of cotton and application of resin.

Auditing

The entered data will be audited on a monthly basis by the coordinator. Data queries will be raised as necessary, and any discrepancies identified will be promptly corrected and systematically recorded.

DISCUSSION

Until now no randomized clinical trial was conducted to compare conventional restorations and the use of polyvinyl crowns in primary anterior teeth with extensive caries lesions. With the expected results, we aim to provide clinical evidence for a better treatment decision by the pediatric dentist. Currently, research has focused on testing different restorative materials but only case reports address the different possible techniques for restoring these teeth. Considering that the two techniques that will be tested start from the same assumption of selective removal of carious tissue but are conducted with different step-by-step it becomes important to verify if there is any better technique. Given that one of the techniques involves the restoration in a single increment of resin, through the polyvinyl crowns, probably its execution time will be faster, but will the quality and longevity of the restoration be similar to the conventional technique? To the

best of our knowledge, this is the first randomized clinical trial to compare the two rehabilitative techniques of primary anterior teeth affected by extensive caries lesions.

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Funding: The study will be funded by the researchers themselves.

Author Contributions: As the study guarantor, SKB is responsible for the overall content. Contributors Substantial contributions to the conception: TG and SKB. Design of the work: TG, APTS, MLLG and SKB Drafting the work: TG, MLLG, JMASG and SKB. Revising the work: TG, APTS, EMS, MLLG, EPF, JMASG, ARHM, LJM, JCPI and SKB. Final approval of the work: TG, EMS, ACRTH, LJM, JCPI and SKB. All authors critically reviewed and approved the final manuscript as submitted.

Competing Interests: None declared. The authors have no conflicts of interest, financial or otherwise, to declare.

Availability of data and materials: This paper is a protocol description and does not contain any data at this point. Future data will be available, as described in the Data sharing statement below.

Data sharing statement: Data generated from this clinical trial will be made available to other researchers upon reasonable request. The data will be shared in accordance with BMJ's Tier 2 data policy, ensuring legal and ethical considerations are upheld.

- Description of Data: The dataset includes anonymized patient records, clinical outcome measures, and intervention details.
- Availability: Data will be accessible within 6 months of publication of the final study results.
- Access: Requests for data access can be submitted through OSF.
- Protection: Personal identifiers will be removed to protect participant confidentiality and comply with data protection regulations.

Patient and Public Involvement: Patients or the public were not involved in the design, recruitment, or conduct of this study. The research question and outcome measures were developed by the research team based on clinical experience and existing scientific literature. However, the burden of the intervention and the time required to participate were carefully considered to minimize any inconvenience to participants and their families. Moving forward, we plan to engage participants and their families in the dissemination of the study results. Feedback will be sought on how best to communicate the findings, and results will be shared in an accessible format through public presentations and relevant patient networks.

Ethics and Dissemination:

This study protocol has been reviewed and approved by the Human Research Ethics Committee of Universidade Metropolitana de Santos (UNIMES), under protocol number 6.019.297, approved on 24 April 2023. Written informed consent will be obtained from the parents or legal guardians of all participants prior to inclusion in the trial. The study adheres to the ethical principles outlined in the Declaration of Helsinki and complies with relevant national and international guidelines for clinical trials.

The results of this trial will be disseminated through several channels. Findings will be submitted for publication in peer-reviewed international journals and shared at relevant national and international conferences. Furthermore, the data generated from this study may be made available upon reasonable request to promote transparency and allow further research in the field.

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PARTICIPANT CONSENT FORM

Aesthetic restorations in deciduous anterior teeth: a randomized clinical study
CAAE Number:

You are being invited to participate as a volunteer in a survey whose title and "Restorations aesthetics in teeth previous deciduous: study clinical randomized".
This document, called the Free and Informed Consent Form, aims to ensure your rights as a participant and is prepared in two copies, one of which must be kept with youand other with the researcher.

Put please, read with attention and calm. If there is questions before or same after of sign it, you may clarify them with the researcher. No there will be none type of penalty or prejudice if you no to accept to participate or to remove your authorization in anymoment.

Justification and objectives:

There are no studies that have compared tooth rehabilitation techniques previous deciduous (teeth of milk from the front) as the longevity from the restoration and to the what the patients feel the respect of these restorations.
Thus, this project aims to evaluate the effectiveness of restorative treatment of anterior deciduous teeth with single-color composite resin in single insertion through of crowns of acetate, after removal selective of tissue decayed compared the effectiveness from the restoration conventional.

Procedures:

All teeth with caries lesions will be treated according to the philosophy of selective removal of decayed tissue, differing only in the restorative technique. The teeth allocated node group of restoration conventional (control) will receive restorations in resincomposed by incremental technique, using opaque resin. The teeth allocated in the group experimental will have restorations made using monochromatic composite resin with effect chameleon in insertion unique through of crown of polyvinyl.

Discomforts and risks:

You procedures carried out will follow to the standards of biosafety and will be carried out by a qualified professional, therefore no damages are expected. Possible risks are minimal and the same as any restorative procedure, such as discomfort during the placing of cotton and application from the resin. In addition from that, there is risk minimum of breakof data confidentiality, but ways will be provided to ensure such confidentiality, such as: patient coding and access to complete data only to the principal investigator. We will understand if you wish to stop participating in the research at any time without none prejudice or coercion.

Benefits:

You benefits to the patient voluntary involve the apprenticeship of the factors responsible for the illness caries; conditions buccal health analyzed put guys trained and capable to that purpose; treatment of the teeth involved in the search, with

possible reduction and/or cessation of caries disease and contribution to the study of approaches that are effective for the treatment of cavitated carious lesions in teeth deciduous previous.

Follow-up and assistance:
At any time, before, during or until the end from the research, we put ourselves to disposition to the clarification of any doubt on the search.

Secrecy and privacy:
You are assured that your identity will be kept confidential. The data collected will be used exclusively to ends from the search, and what may to be presented at scientific events and/or published, without revealing the identity of the participants.

Compensation and Indemnity:
If this research demonstrably causes any cost or damage, please contact researcher responsible the end of reimbursement or possible indemnity.

Contact:
If you have any questions about the research, if you need to consult this consent recordor any others questions, you may to enter in contact with you researchers:

Name of the researcher in charge: Professor Dr. Thais
GimenezAddress: Avenue Counselor Nebias, 536 - Saints-
SP.
E-mail: thais.gimenez@alumni.usp.br

Name of the student
researcherAddress:
Telephone:
E-mail:

In case of complaints or claims about your participation and about ethical issues of the study, you can contact the secretariat of the Research Ethics Committee of University Metropolitan of Saints (from 08:30 to the 11:30 am and of the 1:00 p.m. to the 17h) in the AvenueCounselor Nebias, 536 - 2. to walk. Saints- SP. E-mail: cpq@unimes.br

Consent Free and Clarified:
After to have received clarifications on the nature from the search, your objectives, procedures, expected benefits, potential risks and the discomfort that this study may to entail, accepted to participate:

Name of participant: _____

_____ Date: ____/_____/ _____.
(Signature of participant or name and signature of your RESPONSIBLE LEGAL)

RUBRICA DO PARTICIPANTE DA PESQUISA

RUBRICA DO PESQUISADOR

Responsibility of Researcher:

I assure that I have explained and provided a copy of this document to the participant. I inform that the study was approved by the CEP to which the project was presented. I undertake to use the material and data obtained in this research exclusively for the purposes expected in this document or according to the consent given for the participant.

_____. Date: ____/_____/_____.

(Signature of researched

RUBRICA DO PARTICIPANTE DA PESQUISA

RUBRICA DO PESQUISADOR

BMJ Open

An Investigator-blinded, 24-month, Parallel-group, Non-inferiority Study to Compare Aesthetic Restorations in Primary Anterior Teeth in a Pediatric Dental Clinic: Study Protocol for a Randomized Controlled Trial

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An Investigator-blinded, 24-month, Parallel-group, Non-inferiority Study to Compare Aesthetic Restorations in Primary Anterior Teeth in a Pediatric Dental Clinic: Study Protocol for a Randomized Controlled Trial

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Abstract

Introduction: Children who suffer from severe caries in childhood may have negative impacts on the growth, development, nutritional problems and quality of life problems related to the oral health of the child and his family. There are no studies that have compared rehabilitative techniques of primary anterior teeth regarding patient-centered outcomes and even longevity of restoration. Thus, this project aims to evaluate the effectiveness of restorative treatment of anterior primary teeth with monochromatic composite resin in single insertion through polyvinyl crowns, after selective removal of carious tissue compared to the effectiveness of conventional restoration. **Methods and analysis**: This study proposes to conduct a randomized clinical trial (RCT), composed of a sample of 194 deciduous central and lateral incisors with active cavitated lesions, simplified ICDAS C+ score (active and extensive stage caries: ICDAS 5 & 6), with involvement of more than two surfaces. This sample will be divided into two experimental groups, both with selective removal of carious tissue: a group in which conventional restoration will be performed using opaque resins; and another group with monochrome resin with chameleon effect and polyvinyl crowns. The explanatory variables - gender, age, toothbrushing, use of fluoridated toothpaste and dental floss, and socioeconomic status - will be collected through a questionnaire with open questions. The progression of caries lesions after 24 months of follow-up will be considered as the primary outcome. Secondary outcomes will include tooth survival, longevity of restoration, quality of life, perception and satisfaction of the participants' parents/guardians.

Ethics and dissemination: This protocol has been approved by the Human Research Ethics Committee of Universidade Metropolitana de Santos - UNIMES (protocol number:

6.019.297. Approved 24 April 2023). Results will be submitted to international peer-reviewed journals and presented at international conferences.

Trial registration: www.clinicaltrials.gov, NCT05875064. Registered 15 May 2023

Keywords: Dental caries; Dental Restoration Failure; Randomized clinical trial.

Strengths and limitations of this study

- This study employs a randomized clinical trial (RCT) design with random allocation and investigator blinding, ensuring a high level of scientific evidence and minimizing selection and detection bias.
- The trial may face challenges in maintaining participant adherence during the 24-month follow-up, potentially impacting the final sample size and the comprehensive assessment of secondary outcomes.
- The use of self-reported questionnaires to collect socioeconomic and oral hygiene data may introduce response bias, affecting the accuracy of some explanatory variables.
- The reliance on a single examiner for radiographic assessments is a potential limitation. Standardized radiographic criteria and periodic intra-rater reliability will be performed to minimize bias.
- One possible limitation relates to the fact that the comparison involves two different techniques performed with two different materials, which may lead to confusion about what contributes to a potential difference between the groups: the technique itself or the material used.

INTRODUCTION

Severe early childhood caries (sECC) has been defined as the presence of one or more decayed, missing or filled primary teeth in children aged 71 months (5 years) or less[1]. Children who suffer from severe caries in childhood may affect their growth and development as a result of nutritional problems. Subsequently, this may negatively affect their quality of life related to the oral health of the child and his family[2,3]. In addition, the interference of oral health in school performance and school attendance was proven, with also negative impact[4].

Probably, all these negative impacts are related to the difficulty of chewing, phonation and pain that these patients are subject to[2,3]. In addition, there is aesthetic impairment, not only by the presence of cavitation in the anterior teeth, but in many cases these teeth are found with blackened tissue. This coloration, usually associated with the expulsivity of these lesions and the difficulty of managing children at a young age, make the aesthetic-functional rehabilitation even more challenging. Furthermore, child behavior poses a significant challenge when restoring anterior teeth in pediatric patients. Infants and preschool children often exhibit fear and limited cooperation during dental procedures, which can complicate treatment and require careful behavior management strategies to ensure success.

There are polyvinyl crowns on the market that have been used to facilitate this type of restoration, since they return the anatomy of the teeth more quickly and without the need for the operator's ability to perform dental sculptures[5,6]. Likewise, the development of new restorative materials that allow the use of thicker layers and unique coloration, promoting an effect called as chameleon, because it mimics the color of the tooth[7].

The evidence about rehabilitation of anterior teeth is scarce and mostly comes from case reports or techniques not based on the philosophy of minimal intervention. Recent studies have explored the application of minimally invasive techniques for the restoration of anterior primary teeth, highlighting their potential for aesthetic and functional success. For instance, Zulekha et al.[5] demonstrated that composite resin restorations in primary maxillary incisors provide satisfactory retention rates and aesthetics over 12 months. Similarly, Ozdemir et al.[8] reported comparable performance between composite resin and preformed zirconia crowns in terms of clinical outcomes and parental satisfaction. Although long-term evidence in pediatric patients remains limited, these studies establish a foundation for the use of composite resin as a viable control group. This technique aligns

with the philosophy of minimally invasive dentistry, focusing on preserving healthy dental structures while achieving functional and aesthetic rehabilitation. However, there are no studies that have compared two minimally invasive rehabilitative techniques for primary anterior teeth in terms of patient-centered outcomes or even restoration longevity.

METHODS

This protocol follows the SPIRIT[9](Standard Protocol Items for Randomized Trials) recommendations, as displayed in Table 1.

Table 1. Schedule of enrolment, interventions, and assessments of the study

	STUDY PERIOD						
	Enrolment	Allocation	Post-allocation				Close-out
TIMEPOINT	$-t_1$	0	t_1	6mo	12mo	18mo	24mo
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
Conventional restoration			X				
Polyvinyl crowns			X				
ASSESSMENTS:							
Socioeconomic, habits questionnaire,	X	X					
Caries lesions progression				←	—	—	→
Tooth survival				←	—	—	→
Longevity of restorations				←	—	—	→
OHRQoL			X	←	—	—	→
Perception and Satisfaction of parents			X	X			

Abbreviations: OHRQoL - Oral Health-related Quality of Life; mo – months

Hypothesis

The null hypothesis (H_0) for each primary and secondary outcome independently are:

H_0 for caries lesion progression (primary outcome): There is no difference in the progression of caries lesions between polyvinyl crowns and conventional restorations after 24 months.

H_0 for restoration longevity (secondary outcome): There is no difference in the survival rates of restorations between polyvinyl crowns and conventional restorations after 24 months.

H_0 for patient-centered outcomes (secondary outcome): There is no difference in parental perception, satisfaction, or quality of life impact between polyvinyl crowns and conventional restorations.

Confidentiality

The confidentiality of participants will be strictly maintained through the use of identification code numbers. Participant identifiable information will be stored securely in locked filing cabinets within a restricted-access room. Medical information will only be accessible to the dental team.

Ancillary and post-trial care

Upon completion of the study, participants will continue to receive dental treatments as needed in our dental clinics, ensuring continuity of care beyond the trial period.

Objective

To evaluate the effectiveness of restorative treatment of anterior primary teeth with monochromatic composite resin in single insertion through polyvinyl crowns, after selective removal of carious tissue compared to the effectiveness of conventional restoration.

Trial Design

A randomized controlled clinical trial with two parallel arms, with an allocation ratio of 1:1 will be designed. A sample of 194 deciduous central and lateral incisors with active cavitated lesions, simplified ICDAS C+ score (active and extensive stage caries: ICDAS (5 & 6)[10], with involvement of more than two surfaces will be divided into two experimental groups: a group in which conventional restoration will be performed using

opaque resins; and another group with monochrome resin with chameleon effect and polyvinyl crowns, both after selective removal of carious tissue.

Participants

The children will be randomly selected from a pool of enrolment forms of children (12 to 60 months) who seek dental care at the Pediatric Dentistry clinic of UNIMES.

Inclusion and exclusion criteria

Inclusion Criteria:

- Children ranging in age from 12 to 60 months with at least one active cavitated caries lesion involving more than 2 surfaces (C+ score)[10] in deciduous upper incisors will be included.

Exclusion Criteria:

- Patients with special needs, with general health conditions that may affect the oral cavity, whose guardians do not sign the Inform Consent Form will be excluded. In addition, teeth with pulp exposure, spontaneous pain, mobility, presence of swelling or fistula near the tooth and teeth with previous restorations; less than 2/3 of root (radiographically assessed), teeth without an antagonist, teeth with previous restorations and children with bruxism and/or deep bite.[8]

Participant timeline

Each participant is enrolled in the study for about 25 months in total (1-month RCT – diagnosis and treatment, followed by a 24-months observational period). Table 1 shows participants timeline. The planned start date will be November 2024 and end date will be November 2026.

Sample size

To perform the sample size calculation with independent samples, it was considered that the retention of previous restorations of primary teeth is 80%[5] and that a clinically relevant difference of 10% (based on previous studies evaluating restorative longevity and caries progression in primary teeth[5,11]) and non-inferiority limit of 5% is expected.

Thus, considering a two-tailed test, adopting a significance level of 0.05 and a power of 0.80, we reached the number of 69 teeth per group. Since each child can contribute more than one tooth, we added 20% (cluster per child) and another 20% for a possible sample loss. Thus, a final required number of 97 teeth per experimental group was obtained, totaling 194 teeth for the study (https://www.sealedenvelope.com/power/binary-noninferior/).

Recruitment

Children with ages ranging from 12 to 60 months will be selected, who seek dental care at the Pediatric Dentistry clinic of UNIMES. Potentially eligible children will be referred for clinical examination.

Allocation: Sequence generation

The participants will be selected from a pool of enrolment forms of children who looked for dental treatment in our school, using a sequence of random numbers generated by software by an external participant. The randomization procedure will be done per blocks of different sizes. The randomization will be done after the inclusion of the child.

Allocation concealment mechanism

Only at the time of the interventions will the generated sequences be known. These will be distributed in opaque envelopes and sealed to the operators. More than one tooth per patient may be included in the research, but all teeth included in the same patient will be treated with the same technique, but on different days to avoid patient fatigue and lack of cooperation.

Training and calibration of examiners and operators

There will be 1 examiner involved in the process of screening and 2 operators involved in treating patients, all specialists, PhD and professors in Pediatric Dentistry. The calibration will be carried out among the 2 operators to detect caries lesions, through the evaluation of photographs, and the decision whether or not to include the teeth in the research. The n used in this stage will be 10% of the total sample and we will calculate the Kappa statistic to evaluate the agreement between the examiners.

These will be assisted by undergraduate students, who, in addition to clinical assistants, will be responsible for opening the treatment randomization envelopes. Clinical outcomes

will be evaluated by a specialist professor, MSc and PhD in Pediatric Dentistry not involved in inclusion and operative steps.

Implementation

The examiner that will perform the screening will have the initial x-ray, but will not have a part in the randomization or treatment of the patients. The assistants, undergraduate students, will be responsible for opening the opaque brown envelopes. Then, the two operators will perform the treatments.

Blinding (masking)

The examiners who will evaluate the outcomes during the follow-up will be blinded regarding the allocation group.

Behavioral Evaluation and Management

Children's behavior will be assessed using the Frankl Behavioral Rating Scale (FBRS) both before and after the dental procedures. The FBRS is widely recognized for its ability to categorize child behavior into four levels: definitely negative, negative, positive, and definitely positive, allowing for a standardized assessment of cooperation during treatment[12]. This evaluation will provide a baseline for behavioral tendencies and a measure of improvement or deterioration following treatment.

Behavior Management Strategies

Considering that the study involves infants and preschool children—who may exhibit limited cooperation due to fear or unfamiliarity with dental settings—specific behavior management strategies will be employed to ensure effective and minimally stressful treatment. These strategies include:

Tell-Show-Do Technique: A step-by-step explanation of the procedure, demonstration using non-threatening instruments, and gradual introduction of the actual procedure to build trust and reduce anxiety[13].

Positive Reinforcement: Use of verbal praise or small rewards (e.g., stickers or toys) to encourage cooperative behavior during the session[14].

Parental Presence: In cases where additional comfort is needed, caregivers will be allowed to stay in the operatory room to provide reassurance, minimizing the child's distress[13].

Behavioral management strategies will be adapted to the individual needs of each child, considering their developmental stage and initial behavior as determined by the FBRS assessment.

These measures align with recommendations from the AAPD, emphasizing the importance of creating a positive dental experience for young children while facilitating successful completion of dental procedures.

Interventions

Initially, a clinical examination will be performed in a dental office using reflector, mirror, tweezers and WHO probe, after prophylaxis, by the operators. For this evaluation, the diagnostic criterion used will be the International Caries Detection and Assessment System (ICDAS).[15]

Treatments for the control of caries lesions

All teeth with caries lesions will be treated according to the philosophy of selective removal of carious tissue, differing only in the restorative technique. The teeth allocated in the conventional restoration group (control) will receive restorations in resin composed by incremental technique, using opaque resin. For this, 37% phosphoric acid (Condac37, FGM) will be applied for 15 seconds in enamel and 7 seconds in dentin, and then, after washing and relative drying of the surface, with a etch and rinse approach, followed by the application of universal adhesive (Universal Beautibond Adhesive, Shofu) with the aid of microbrush on the entire dental surface, photoactivation of the adhesive and restoration by incremental technique and photoactivation of each layer of resin for 20 seconds (Radii Xpert, SDI, peak 1500 mW/cm2) . We have added this information. We have added this information. The tooth will receive finishing and polishing through rotating instruments and abrasive discs (Supersnap, Shofu).

The teeth allocated in the experimental group will have the restorations carried out through monochromatic composite resin with chameleon effect in single insertion through polyvinyl crown. For this, 37% phosphoric acid (Condac37, FGM) will be applied for 15 seconds in enamel and 7 seconds in dentin, and then, after washing and relative drying of the surface, application of universal adhesive (Universal Beautibond Adhesive, Shofu) with the aid of microbrush on the entire tooth surface, photoactivation of the adhesive and adaptation of the crown matrix in acetate filled with resin in the tooth.

Photoactivation will be done for 20 seconds per dental face, and the acetate matrix is then removed. The tooth will receive finishing and polishing through rotating instruments and abrasive discs (Supersnap, Shofu).

The remaining teeth identified with caries lesions that are not included in the research will be treated according to the diagnosis by the researchers involved in this study. If there is a need for more complex procedures, patients will be referred for specialized treatment.

Follow-up visits

The patients who have been selected will undergo reassessment at 6, 12, 18, and 24 months after the commencement of treatment. During the time between these consultations, various strategies will be employed to ensure strong adherence and return rates, including: (1) Scheduling consultations at the most suitable times; (2) Maintaining telephone contact with the caregivers; (3) Providing an active cell phone for unforeseen circumstances; (4) Offering gifts to children at the conclusion of each consultation.

Throughout the 24-month duration of the study, the research participants will be continuously monitored by the responsible professionals. If any additional treatment is required, the child will receive comprehensive support without any negative impact.

Outcomes

The explanatory variables, including gender, age, toothbrushing habits, fluoride toothpaste usage, and dental flossing, will be gathered using a questionnaire that consists of open-ended questions. Additionally, a socioeconomic questionnaire consisting of closed-ended questions will be administered. To ensure participant confidentiality, each individual will be assigned an identifying number. The time spent on the treatments will be timed by the auxiliary from the beginning to the end of the polishing in order to compare the durations of both techniques.

The primary outcome of this study will be the progression of caries lesions through clinical criteria and longevity of restorations after a 24-month follow-up period. Secondary outcomes will encompass progression of caries lesions by radiographic criteria, change in the perception of parents/guardians, change in the satisfaction of parents/guardians and change in the impact of treatments in children´s oral health-related quality of life.

The examination of the reported outcomes will be conducted by pediatric dentists who are not involved in the treatments performed and have received appropriate training. These examiners will evaluate the outcomes in a blinded manner.

Assessment of progression of caries lesion by radiographic criteria

For assessing caries progression, the modified periapical radiographic examination for preschoolers will be employed. The radiographic protocol will involve the use of E-speed children's film (E-speed, 22x35mm, Eastman Kodak, Rochester, USA), a 0.4s exposure time, and the Spectro 70X device. The bisection technique will be utilized for radiographic measurements of anterior teeth in preschool children, accompanied by the use of an apron and lead collar for radiation protection. The films will be processed either manually using the time/temperature method (with a temperature of approximately 27 degrees Celsius, developer solution for 2 minutes, fixative solution for 10 minutes, and water washing for 20 minutes) or digitally. A total of six radiographic images will be taken per patient: one before the restorative procedure, for screening, one immediately after the procedure, and subsequent follow-up images at 6, 12, 18, and 24 months. The images will be compared in pairs to determine whether there has been any progression of caries, assessed by a trained and calibrated senior researcher, without the aid of any magnification loops and while blinded regarding the chronological order of the radiographs.:

a) Absent progression: No increase in the radiolucent area of the lesion.

b) Progression present: Increase in the radiolucent area of the lesion.

Teeth demonstrating caries lesion progression with signs of pulp involvement will be treated accordingly with restorative or endodontic procedures appropriate for the observed condition.

Radiographic outcomes: Presence or absence of radiolucency in the periapical region, progression of caries, and assessment of root resorption associated with physiological exfoliation. These outcomes will be assessed at 6, 12, 18, and 24 months, ensuring comprehensive follow-up data.

Assessment of progression of caries lesion through clinical criteria and longevity of restorations

During the follow-up visits at 6, 12, 18, and 24 months, a visual clinical examination will be conducted to assess the condition of caries lesions and the longevity of restorations.

This examination will involve inspecting the restoration's integrity, its adaptation on all dental surfaces, and identifying any potential issues such as structural fractures, resin wear, maladaptation, or functional maintenance problems with the restored tooth.

The clinical evaluation of restoration retention will be performed at 6, 12, 18, and 24 months, using the criteria described by Pardi et al. (2005)[11]:

- RT (total retention): Complete preservation of the restoration.
- PP1 (partial preservation 1): Presence of resin in two-thirds of the surface of each dental face.
- PP2 (partial preservation 2): Presence of resin in one-third of each face of the dental surface.
- PT (total preservation): Complete loss of resin on the surface of the dental face.

Furthermore, the degree of tooth mobility and its correlation with the normal exfoliation period will be assessed in teeth from both groups. The teeth will be clinically assessed by the examiner in accordance with the ICDAS criteria for CARS as suggested by the ICDAS Coordinating Committee[15]: (0) sound tooth surface with restoration or sealant, (1) first visual change in enamel, (2) distinct visual change in enamel/dentin adjacent to a restoration/sealant margin, (3) carious defects of <0.5mm with the signs of code 2, (4) marginal caries in enamel/dentin/cementum adjacent to a restoration/sealant with underlying dark shadow from dentin, (5) distinct cavity adjacent to a restoration/sealant, and (6) extensive distinct cavity with visible dentin.

Radiographic evaluation of dental exfoliation and tooth survival will involve examining the amount of absorbed deciduous tooth root in the radiographs taken at 6, 12, 18, and 24 months, comparing them to the initial radiograph. Clinical outcomes: The association between exfoliation and/or the maintenance of restorations without extensive structural failures, such as marginal integrity, absence of recurrent caries, and restoration retention, will determine the success, or absence of caries progression, of restoration longevity and tooth survival in the restored tooth. These outcomes will be assessed at 6, 12, 18, and 24 months, ensuring comprehensive follow-up data.

Perception of Parents/Guardians

To evaluate the parents' or guardians' perception of the treatment received, the "Child's and Parent's Questionnaire about Teeth Appearance"[16] will be administered immediately

after the first treatment session and again after 6 months of treatment. The examiners will provide guidance to ensure an honest expression of their opinions.

Satisfaction of Parents/Guardians

Parents or guardians will be asked about their satisfaction with the treatment provided to their child after 6 months of treatment. The examiners will guide them to provide their genuine opinions.

As parental satisfaction and perception are prone to bias, the parents/guardians will be blinded to the intervention performed. They will not be informed whether their child received a conventional composite restoration or a polyvinyl crown. Additionally, satisfaction and perception will be evaluated using validated questionnaires with structured Likert-scale questions to standardize responses and minimize reporting bias.

Quality of Life

A questionnaire, specifically the validated Brazilian version of the Early Childhood Oral Health Impact Scale (ECOHIS)[17], will be used to assess the impact of the treatments on the oral health-related quality of life of children. The parents or guardians of the participants will complete this questionnaire during the initial consultations and at each follow-up visit.

Data collection methods

Data collection and returning assessments will be made by researchers who have experience in clinical research. They will be blinded to group allocation, and they will be the same examiners at all time-points for each participant in order to minimize inter-observer variability.

Data management

The clinic data will be directly entered into pre-designed sheets to ensure efficient data management. To maintain data quality, validation checks will be conducted, which will include identifying missing data, out-of-range values, illogical responses, and invalid entries.

Statistical Analysis

The efficacy of each treatment will be evaluated through three primary outcomes:

1) Control of Cavitated Active Lesions: Kaplan-Meier survival analysis will be used to estimate the probability of lesion control over time, with the Log-Rank test employed to compare survival curves between the two groups. The absolute risk difference will be calculated to quantify the difference in lesion control rates, with a 95% confidence interval reported.
2) Longevity of Restorations: Kaplan-Meier survival analysis will also be used to evaluate restoration longevity, with comparisons made using the Log-Rank test. Cox regression analysis will be performed to assess the influence of additional variables on restoration longevity. The absolute risk difference and its 95% confidence interval will be provided to highlight the comparative effectiveness of the treatments.
3) Patient-Centered Outcomes: For comparing patient-centered outcomes between the two groups, the Student's t-test will be used for normally distributed data, while the Mann-Whitney U test will be applied for non-normally distributed data. The absolute risk difference for patient-centered outcomes will also be calculated, and a 95% confidence interval will be reported.

For all statistical analyses, the significance level will be set at 5%.

Data monitoring

Since adverse events related to dental treatments are unlikely, there is no Data Monitoring Committee. However, independent oversight of the collection, management, and analysis of trial data will be carried out by TG (name of person/organization responsible). TG, as the chief investigator, holds overall responsibility for the study and acts as the custodian of the data.

Harms

The procedures performed will follow the biosafety standards and will be performed by a trained professional, so no damage is foreseen. The possible risks are minimal and the same as any restorative procedure, such as discomfort during the placement of cotton and application of resin.

Auditing

The entered data will be audited on a monthly basis by the coordinator. Data queries will be raised as necessary, and any discrepancies identified will be promptly corrected and systematically recorded.

DISCUSSION

Until now no randomized clinical trial was conducted to compare conventional restorations and the use of polyvinyl crowns in primary anterior teeth with extensive caries lesions. Symmetry plays a pivotal role in the aesthetic success of anterior teeth restorations, particularly in central incisors. Restorations must achieve harmonious proportions and balance to mimic the natural dentition. Techniques that simplify this process, such as polyvinyl crowns, aim to enhance symmetry while reducing operator variability[18]. With the expected results, we aim to provide clinical evidence for a better treatment decision by the pediatric dentist. Currently, research has focused on testing different restorative materials but only case reports address the different possible techniques for restoring these teeth. Considering that the two techniques that will be tested start from the same assumption of selective removal of carious tissue but are conducted with different step-by-step it becomes important to verify if there is any better technique. Given that one of the techniques involves the restoration in a single increment of resin, through the polyvinyl crowns, probably its execution time will be faster, but will the quality and longevity of the restoration be similar to the conventional technique? To the best of our knowledge, this is the first randomized clinical trial to compare the two rehabilitative techniques of primary anterior teeth affected by extensive caries lesions.

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Author Contributions: As the study guarantor, SKB is responsible for the overall content. Contributors Substantial contributions to the conception: TG and SKB. Design of the work: TG, APTS, MLLG and SKB Drafting the work: TG, MLLG, JMASG and SKB. Revising the work: TG, APTS, EMS, MLLG, EPF, JMASG, ARHM, LJM, JCPI and SKB. Final approval of the work: TG, EMS, ACRTH, LJM, JCPI and SKB. All authors critically reviewed and approved the final manuscript as submitted.

Competing Interests: None declared. The authors have no conflicts of interest, financial or otherwise, to declare.

Availability of data and materials: This paper is a protocol description and does not contain any data at this point. Future data will be available, as described in the Data sharing statement below.

Data sharing statement: Data generated from this clinical trial will be made available to other researchers upon reasonable request. The data will be shared in accordance with BMJ's Tier 2 data policy, ensuring legal and ethical considerations are upheld.

- Description of Data: The dataset includes anonymized patient records, clinical outcome measures, and intervention details.
- Availability: Data will be accessible within 6 months of publication of the final study results.
- Access: Requests for data access can be submitted through OSF.
- Protection: Personal identifiers will be removed to protect participant confidentiality and comply with data protection regulations.

Patient and Public Involvement: Patients or the public were not involved in the design, recruitment, or conduct of this study. The research question and outcome measures were developed by the research team based on clinical experience and existing scientific literature. However, the burden of the intervention and the time required to participate were carefully considered to minimize any inconvenience to participants and their families. Moving forward, we plan to engage participants and their families in the

dissemination of the study results. Feedback will be sought on how best to communicate the findings, and results will be shared in an accessible format through public presentations and relevant patient networks.

Ethics and Dissemination:

This study protocol has been reviewed and approved by the Human Research Ethics Committee of Universidade Metropolitana de Santos (UNIMES), under protocol number 6.019.297, approved on 24 April 2023. Written informed consent will be obtained from the parents or legal guardians of all participants prior to inclusion in the trial. The study adheres to the ethical principles outlined in the Declaration of Helsinki and complies with relevant national and international guidelines for clinical trials.

The results of this trial will be disseminated through several channels. Findings will be submitted for publication in peer-reviewed international journals and shared at relevant national and international conferences. Furthermore, the data generated from this study may be made available upon reasonable request to promote transparency and allow further research in the field.

Supporting information

S1 File. SPIRIT checklist.
S2 File. Feedback from the Ethics Committee in original language.
S3 File. Feedback from the Ethics Committee in English.
S4 File. Clinical Trials.
S5 File. Statement Consent in original language.
S6 File. Statement Consent in English.

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An Investigator-blinded, 24-month, Parallel-group, Non-inferiority Study to Compare Aesthetic Restorations in Primary Anterior Teeth in a Pediatric Dental Clinic: Study Protocol for a Randomized Controlled Trial

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An Investigator-blinded, 24-month, Parallel-group, Non-inferiority Study to Compare Aesthetic Restorations in Primary Anterior Teeth in a Pediatric Dental Clinic: Study Protocol for a Randomized Controlled Trial

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Abstract

Introduction: Children who suffer from severe caries in childhood may have negative impacts on the growth, development, nutritional problems and quality of life problems related to the oral health of the child and his family. There are no studies that have compared rehabilitative techniques of primary anterior teeth regarding patient-centered outcomes and even longevity of restoration. Thus, this project aims to evaluate the effectiveness of restorative treatment of anterior primary teeth with monochromatic composite resin in single insertion through polyvinyl crowns, after selective removal of carious tissue compared to the effectiveness of conventional restoration. **Methods and analysis**: This study proposes to conduct a randomized clinical trial (RCT), composed of a sample of 194 deciduous central and lateral incisors with active cavitated lesions, simplified ICDAS C+ score (active and extensive stage caries: ICDAS 5 & 6), with involvement of more than two surfaces. This sample will be divided into two experimental groups, both with selective removal of carious tissue: a group in which conventional restoration will be performed using opaque resins; and another group with monochrome resin with chameleon effect and polyvinyl crowns. The explanatory variables - gender, age, toothbrushing, use of fluoridated toothpaste and dental floss, and socioeconomic status - will be collected through a questionnaire with open questions. The progression of caries lesions after 24 months of follow-up will be considered as the primary outcome. Secondary outcomes will include tooth survival, longevity of restoration, quality of life, perception and satisfaction of the participants' parents/guardians.

Ethics and dissemination: This protocol has been approved by the Human Research Ethics Committee of Universidade Metropolitana de Santos - UNIMES (protocol number:

6.019.297. Approved 24 April 2023). Results will be submitted to international peer-reviewed journals and presented at international conferences.

Trial registration: www.clinicaltrials.gov, NCT05875064. Registered 15 May 2023

Keywords: Dental caries; Dental Restoration Failure; Randomized clinical trial.

Strengths and limitations of this study

- This study employs a randomized clinical trial (RCT) design with random allocation and investigator blinding, ensuring a high level of scientific evidence and minimizing selection and detection bias.
- The trial may face challenges in maintaining participant adherence during the 24-month follow-up, potentially impacting the final sample size and the comprehensive assessment of secondary outcomes.
- The use of self-reported questionnaires to collect socioeconomic and oral hygiene data may introduce response bias, affecting the accuracy of some explanatory variables.
- The reliance on a single examiner for radiographic assessments is a potential limitation. Standardized radiographic criteria and periodic intra-rater reliability will be performed to minimize bias.
- One possible limitation relates to the fact that the comparison involves two different techniques performed with two different materials, which may lead to confusion about what contributes to a potential difference between the groups: the technique itself or the material used.

INTRODUCTION

Severe early childhood caries (sECC) has been defined as the presence of one or more decayed, missing or filled primary teeth in children aged 71 months (5 years) or less[1]. Children who suffer from severe caries in childhood may affect their growth and development as a result of nutritional problems. Subsequently, this may negatively affect their quality of life related to the oral health of the child and his family[2,3]. In addition, the interference of oral health in school performance and school attendance was proven, with also negative impact[4].

Probably, all these negative impacts are related to the difficulty of chewing, phonation and pain that these patients are subject to[2,3]. In addition, there is aesthetic impairment, not only by the presence of cavitation in the anterior teeth, but in many cases these teeth are found with blackened tissue. This coloration, usually associated with the expulsivity of these lesions and the difficulty of managing children at a young age, make the aesthetic-functional rehabilitation even more challenging. Furthermore, child behavior poses a significant challenge when restoring anterior teeth in pediatric patients. Infants and preschool children often exhibit fear and limited cooperation during dental procedures, which can complicate treatment and require careful behavior management strategies to ensure success.

There are polyvinyl crowns on the market that have been used to facilitate this type of restoration, since they return the anatomy of the teeth more quickly and without the need for the operator's ability to perform dental sculptures[5,6]. Likewise, the development of new restorative materials that allow the use of thicker layers and unique coloration, promoting an effect called as chameleon, because it mimics the color of the tooth[7].

The evidence about rehabilitation of anterior teeth is scarce and mostly comes from case reports or techniques not based on the philosophy of minimal intervention. Recent studies have explored the application of minimally invasive techniques for the restoration of anterior primary teeth, highlighting their potential for aesthetic and functional success. For instance, Zulekha et al.[5] demonstrated that composite resin restorations in primary maxillary incisors provide satisfactory retention rates and aesthetics over 12 months. Similarly, Ozdemir et al.[8] reported comparable performance between composite resin and preformed zirconia crowns in terms of clinical outcomes and parental satisfaction. Also, recent studies have examined the success rates and longevity of zirconia crowns in treating anterior primary teeth, demonstrating promising results[9],[10]. Although long-term

evidence in pediatric patients remains limited, these studies establish a foundation for the use of composite resin as a viable control group. This technique aligns with the philosophy of minimally invasive dentistry, focusing on preserving healthy dental structures while achieving functional and aesthetic rehabilitation. However, there are no studies that have compared two minimally invasive rehabilitative techniques for primary anterior teeth in terms of patient-centered outcomes or even restoration longevity.

METHODS

This protocol follows the SPIRIT[11](Standard Protocol Items for Randomized Trials) recommendations, as displayed in Table 1.

Table 1. Schedule of enrolment, interventions, and assessments of the study

	STUDY PERIOD						
	Enrolment	**Allocation**	**Post-allocation**				**Close-out**
TIMEPOINT	$-t_1$	**0**	t_1	***6mo***	***12mo***	***18mo***	***24mo***
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
Conventional restoration			X				
Polyvinyl crowns			X				
ASSESSMENTS:							
Socioeconomic, habits questionnaire,	X	X					
Caries lesions progression				—	—	—	—
Tooth survival				—	—	—	—
Longevity of restorations				—	—	—	—
OHRQoL			X	—	—	—	—
Perception and Satisfaction of parents			X	X			

Abbreviations: OHRQoL - Oral Health-related Quality of Life; mo – months

Hypothesis

The null hypothesis (H_0) for each primary and secondary outcome independently are:

H_0 for caries lesion progression (primary outcome): Polyvinyl crowns are inferior to conventional restorations in preventing the progression of caries lesions after 24 months.
H_0 for restoration longevity (secondary outcome): Polyvinyl crowns are inferior to conventional restorations in the survival rates of restorations after 24 months.
H_0 for patient-centered outcomes (secondary outcome): Polyvinyl crowns are inferior to conventional restorations in terms of parental perception, satisfaction, or quality of life impact.

Confidentiality

The confidentiality of participants will be strictly maintained through the use of identification code numbers. Participant identifiable information will be stored securely in locked filing cabinets within a restricted-access room. Medical information will only be accessible to the dental team.

Ancillary and post-trial care

Upon completion of the study, participants will continue to receive dental treatments as needed in our dental clinics, ensuring continuity of care beyond the trial period.

Objective

To evaluate the effectiveness of restorative treatment of anterior primary teeth with monochromatic composite resin in single insertion through polyvinyl crowns, after selective removal of carious tissue compared to the effectiveness of conventional restoration.

Trial Design

A randomized controlled clinical trial with two parallel arms, with an allocation ratio of 1:1 will be designed. A sample of 194 deciduous central and lateral incisors with active cavitated lesions, simplified ICDAS C+ score (active and extensive stage caries: ICDAS (5 & 6)[12], with involvement of more than two surfaces will be divided into two experimental groups: a group in which conventional restoration will be performed using

opaque resins; and another group with monochrome resin with chameleon effect and polyvinyl crowns, both after selective removal of carious tissue.

Participants

The children will be randomly selected from a pool of enrolment forms of children (12 to 60 months) who seek dental care at the Pediatric Dentistry clinic of UNIMES.

Inclusion and exclusion criteria

Inclusion Criteria:

- Children ranging in age from 12 to 60 months with at least one active cavitated caries lesion involving more than 2 surfaces (C+ score)[12] in deciduous upper incisors will be included.

Exclusion Criteria:

- Patients with special needs, with general health conditions that may affect the oral cavity, whose guardians do not sign the Inform Consent Form will be excluded. In addition, teeth with pulp exposure, spontaneous pain, mobility, presence of swelling or fistula near the tooth and teeth with previous restorations; less than 2/3 of root (radiographically assessed), teeth without an antagonist, teeth with previous restorations and children with bruxism and/or deep bite.[8]

Participant timeline

Each participant is enrolled in the study for about 25 months in total (1-month RCT – diagnosis and treatment, followed by a 24-months observational period). Table 1 shows participants timeline. The planned start date will be November 2024 and end date will be November 2026.

Sample size

To perform the sample size calculation with independent samples, it was considered that the retention of previous restorations of primary teeth is 80%[5] and that a clinically relevant difference of 10% (based on previous studies evaluating restorative longevity and caries progression in primary teeth[5,13]) and non-inferiority limit of 5% is expected. Thus, considering a two-tailed test, adopting a significance level of 0.05 and a power of 0.80, we reached the number of 69 teeth per group. Since each child can contribute more

than one tooth, we added 20% (cluster per child) and another 20% for a possible sample loss. Thus, a final required number of 97 teeth per experimental group was obtained, totaling 194 teeth for the study (https://www.sealedenvelope.com/power/binary-noninferior/).

Recruitment

Children with ages ranging from 12 to 60 months will be selected, who seek dental care at the Pediatric Dentistry clinic of UNIMES. Potentially eligible children will be referred for clinical examination.

Allocation: Sequence generation

The participants will be selected from a pool of enrolment forms of children who looked for dental treatment in our school, using a sequence of random numbers generated by software by an external participant. The randomization procedure will be done per blocks of different sizes. The randomization will be done after the inclusion of the child.

Allocation concealment mechanism

Only at the time of the interventions will the generated sequences be known. These will be distributed in opaque envelopes and sealed to the operators. More than one tooth per patient may be included in the research, but all teeth included in the same patient will be treated with the same technique, but on different days to avoid patient fatigue and lack of cooperation.

Training and calibration of examiners and operators

There will be 1 examiner involved in the process of screening and 2 operators involved in treating patients, all specialists, PhD and professors in Pediatric Dentistry. The calibration will be carried out among the 2 operators to detect caries lesions, through the evaluation of photographs, and the decision whether or not to include the teeth in the research. The n used in this stage will be 10% of the total sample and we will calculate the Kappa statistic to evaluate the agreement between the examiners.

These will be assisted by undergraduate students, who, in addition to clinical assistants, will be responsible for opening the treatment randomization envelopes. Clinical outcomes

will be evaluated by a specialist professor, MSc and PhD in Pediatric Dentistry not involved in inclusion and operative steps.

Implementation

The examiner that will perform the screening will have the initial x-ray, but will not have a part in the randomization or treatment of the patients. The assistants, undergraduate students, will be responsible for opening the opaque brown envelopes. Then, the two operators will perform the treatments.

Blinding (masking)

The examiners who will evaluate the outcomes during the follow-up will be blinded regarding the allocation group.

Behavioral Evaluation and Management

Children's behavior will be assessed using the Frankl Behavioral Rating Scale (FBRS) both before and after the dental procedures. The FBRS is widely recognized for its ability to categorize child behavior into four levels: definitely negative, negative, positive, and definitely positive, allowing for a standardized assessment of cooperation during treatment[14]. This evaluation will provide a baseline for behavioral tendencies and a measure of improvement or deterioration following treatment.

Behavior Management Strategies

Considering that the study involves infants and preschool children—who may exhibit limited cooperation due to fear or unfamiliarity with dental settings—specific behavior management strategies will be employed to ensure effective and minimally stressful treatment. These strategies include:

Tell-Show-Do Technique: A step-by-step explanation of the procedure, demonstration using non-threatening instruments, and gradual introduction of the actual procedure to build trust and reduce anxiety[15].

Positive Reinforcement: Use of verbal praise or small rewards (e.g., stickers or toys) to encourage cooperative behavior during the session[16].

Parental Presence: In cases where additional comfort is needed, caregivers will be allowed to stay in the operatory room to provide reassurance, minimizing the child's distress[15].

Behavioral management strategies will be adapted to the individual needs of each child, considering their developmental stage and initial behavior as determined by the FBRS assessment.

These measures align with recommendations from the AAPD, emphasizing the importance of creating a positive dental experience for young children while facilitating successful completion of dental procedures.

Interventions

Initially, a clinical examination will be performed in a dental office using reflector, mirror, tweezers and WHO probe, after prophylaxis, by the operators. For this evaluation, the diagnostic criterion used will be the International Caries Detection and Assessment System (ICDAS)[17].

Treatments for the control of caries lesions

All teeth with caries lesions will be treated according to the philosophy of selective removal of carious tissue, differing only in the restorative technique. The teeth allocated in the conventional restoration group (control) will receive restorations in resin composed by incremental technique, using opaque resin. For this, 37% phosphoric acid (Condac37, FGM) will be applied for 15 seconds in enamel and 7 seconds in dentin, and then, after washing and relative drying of the surface, with a etch and rinse approach, followed by the application of universal adhesive (Universal Beautibond Adhesive, Shofu) with the aid of microbrush on the entire dental surface, photoactivation of the adhesive and restoration by incremental technique and photoactivation of each layer of resin for 20 seconds (Radii Xpert, SDI, peak 1500 mW/cm2) . We have added this information. We have added this information. The tooth will receive finishing and polishing through rotating instruments and abrasive discs (Supersnap, Shofu).

The teeth allocated in the experimental group will have the restorations carried out through monochromatic composite resin with chameleon effect in single insertion through polyvinyl crown. For this, 37% phosphoric acid (Condac37, FGM) will be applied for 15 seconds in enamel and 7 seconds in dentin, and then, after washing and relative drying of the surface, application of universal adhesive (Universal Beautibond Adhesive, Shofu) with the aid of microbrush on the entire tooth surface, photoactivation of the adhesive and adaptation of the crown matrix in acetate filled with resin in the tooth.

Photoactivation will be done for 20 seconds per dental face, and the acetate matrix is then removed. The tooth will receive finishing and polishing through rotating instruments and abrasive discs (Supersnap, Shofu).

The remaining teeth identified with caries lesions that are not included in the research will be treated according to the diagnosis by the researchers involved in this study. If there is a need for more complex procedures, patients will be referred for specialized treatment.

Follow-up visits

The patients who have been selected will undergo reassessment at 6, 12, 18, and 24 months after the commencement of treatment. During the time between these consultations, various strategies will be employed to ensure strong adherence and return rates, including: (1) Scheduling consultations at the most suitable times; (2) Maintaining telephone contact with the caregivers; (3) Providing an active cell phone for unforeseen circumstances; (4) Offering gifts to children at the conclusion of each consultation.

Throughout the 24-month duration of the study, the research participants will be continuously monitored by the responsible professionals. If any additional treatment is required, the child will receive comprehensive support without any negative impact.

Outcomes

The explanatory variables, including gender, age, toothbrushing habits, fluoride toothpaste usage, and dental flossing, will be gathered using a questionnaire that consists of open-ended questions. Additionally, a socioeconomic questionnaire consisting of closed-ended questions will be administered. To ensure participant confidentiality, each individual will be assigned an identifying number. The time spent on the treatments will be timed by the auxiliary from the beginning to the end of the polishing in order to compare the durations of both techniques.

The primary outcome of this study will be the progression of caries lesions through clinical criteria and longevity of restorations after a 24-month follow-up period. Secondary outcomes will encompass progression of caries lesions by radiographic criteria, change in the perception of parents/guardians, change in the satisfaction of parents/guardians and change in the impact of treatments in children´s oral health-related quality of life.

The examination of the reported outcomes will be conducted by pediatric dentists who are not involved in the treatments performed and have received appropriate training. These examiners will evaluate the outcomes in a blinded manner.

Assessment of progression of caries lesion by radiographic criteria

For assessing caries progression, the modified periapical radiographic examination for preschoolers will be employed. The radiographic protocol will involve the use of E-speed children's film (E-speed, 22x35mm, Eastman Kodak, Rochester, USA), a 0.4s exposure time, and the Spectro 70X device. The bisection technique will be utilized for radiographic measurements of anterior teeth in preschool children, accompanied by the use of an apron and lead collar for radiation protection. The films will be processed either manually using the time/temperature method (with a temperature of approximately 27 degrees Celsius, developer solution for 2 minutes, fixative solution for 10 minutes, and water washing for 20 minutes) or digitally. A total of six radiographic images will be taken per patient: one before the restorative procedure, for screening, one immediately after the procedure, and subsequent follow-up images at 6, 12, 18, and 24 months. The images will be compared in pairs to determine whether there has been any progression of caries, assessed by a trained and calibrated senior researcher, without the aid of any magnification loops and while blinded regarding the chronological order of the radiographs.:

a) Absent progression: No increase in the radiolucent area of the lesion.

b) Progression present: Increase in the radiolucent area of the lesion.

Teeth demonstrating caries lesion progression with signs of pulp involvement will be treated accordingly with restorative or endodontic procedures appropriate for the observed condition.

Radiographic outcomes: Presence or absence of radiolucency in the periapical region, progression of caries, and assessment of root resorption associated with physiological exfoliation. These outcomes will be assessed at 6, 12, 18, and 24 months, ensuring comprehensive follow-up data.

Assessment of progression of caries lesion through clinical criteria and longevity of restorations

During the follow-up visits at 6, 12, 18, and 24 months, a visual clinical examination will be conducted to assess the condition of caries lesions and the longevity of restorations.

This examination will involve inspecting the restoration's integrity, its adaptation on all dental surfaces, and identifying any potential issues such as structural fractures, resin wear, maladaptation, or functional maintenance problems with the restored tooth.

The clinical evaluation of restoration retention will be performed at 6, 12, 18, and 24 months, using the criteria described by Pardi et al. (2005)[13]:

- RT (total retention): Complete preservation of the restoration.
- PP1 (partial preservation 1): Presence of resin in two-thirds of the surface of each dental face.
- PP2 (partial preservation 2): Presence of resin in one-third of each face of the dental surface.
- PT (total preservation): Complete loss of resin on the surface of the dental face.

Furthermore, the degree of tooth mobility and its correlation with the normal exfoliation period will be assessed in teeth from both groups. The teeth will be clinically assessed by the examiner in accordance with the ICDAS criteria for CARS as suggested by the ICDAS Coordinating Committee[17]: (0) sound tooth surface with restoration or sealant, (1) first visual change in enamel, (2) distinct visual change in enamel/dentin adjacent to a restoration/sealant margin, (3) carious defects of <0.5mm with the signs of code 2, (4) marginal caries in enamel/dentin/cementum adjacent to a restoration/sealant with underlying dark shadow from dentin, (5) distinct cavity adjacent to a restoration/sealant, and (6) extensive distinct cavity with visible dentin.

Radiographic evaluation of dental exfoliation and tooth survival will involve examining the amount of absorbed deciduous tooth root in the radiographs taken at 6, 12, 18, and 24 months, comparing them to the initial radiograph. Clinical outcomes: The association between exfoliation and/or the maintenance of restorations without extensive structural failures, such as marginal integrity, absence of recurrent caries, and restoration retention, will determine the success, or absence of caries progression, of restoration longevity and tooth survival in the restored tooth. These outcomes will be assessed at 6, 12, 18, and 24 months, ensuring comprehensive follow-up data.

Perception of Parents/Guardians

To evaluate the parents' or guardians' perception of the treatment received, the "Child's and Parent's Questionnaire about Teeth Appearance"[18] will be administered immediately

after the first treatment session and again after 6 months of treatment. The examiners will provide guidance to ensure an honest expression of their opinions.

Satisfaction of Parents/Guardians

Parents or guardians will be asked about their satisfaction with the treatment provided to their child after 6 months of treatment. The examiners will guide them to provide their genuine opinions.

As parental satisfaction and perception are prone to bias, the parents/guardians will be blinded to the intervention performed. They will not be informed whether their child received a conventional composite restoration or a polyvinyl crown. Additionally, satisfaction and perception will be evaluated using validated questionnaires with structured Likert-scale questions to standardize responses and minimize reporting bias.

Quality of Life

A questionnaire, specifically the validated Brazilian version of the Early Childhood Oral Health Impact Scale (ECOHIS)[19], will be used to assess the impact of the treatments on the oral health-related quality of life of children. The parents or guardians of the participants will complete this questionnaire during the initial consultations and at each follow-up visit.

Data collection methods

Data collection and returning assessments will be made by researchers who have experience in clinical research. They will be blinded to group allocation, and they will be the same examiners at all time-points for each participant in order to minimize inter-observer variability.

Data management

The clinic data will be directly entered into pre-designed sheets to ensure efficient data management. To maintain data quality, validation checks will be conducted, which will include identifying missing data, out-of-range values, illogical responses, and invalid entries.

Statistical Analysis

The efficacy of each treatment will be evaluated through three primary outcomes:

1) Control of Cavitated Active Lesions: Kaplan-Meier survival analysis will be used to estimate the probability of lesion control over time, with the Log-Rank test employed to compare survival curves between the two groups. The absolute risk difference will be calculated to quantify the difference in lesion control rates, with a 95% confidence interval reported.
2) Longevity of Restorations: Kaplan-Meier survival analysis will also be used to evaluate restoration longevity, with comparisons made using the Log-Rank test. Cox regression analysis will be performed to assess the influence of additional variables on restoration longevity. The absolute risk difference and its 95% confidence interval will be provided to highlight the comparative effectiveness of the treatments.
3) Patient-Centered Outcomes: For comparing patient-centered outcomes between the two groups, the Student's t-test will be used for normally distributed data, while the Mann-Whitney U test will be applied for non-normally distributed data. The absolute risk difference for patient-centered outcomes will also be calculated, and a 95% confidence interval will be reported.

For all statistical analyses, the significance level will be set at 5%.

Data monitoring

Since adverse events related to dental treatments are unlikely, there is no Data Monitoring Committee. However, independent oversight of the collection, management, and analysis of trial data will be carried out by TG (name of person/organization responsible). TG, as the chief investigator, holds overall responsibility for the study and acts as the custodian of the data.

Harms

The procedures performed will follow the biosafety standards and will be performed by a trained professional, so no damage is foreseen. The possible risks are minimal and the same as any restorative procedure, such as discomfort during the placement of cotton and application of resin.

Auditing

The entered data will be audited on a monthly basis by the coordinator. Data queries will be raised as necessary, and any discrepancies identified will be promptly corrected and systematically recorded.

DISCUSSION

Until now no randomized clinical trial was conducted to compare conventional restorations and the use of polyvinyl crowns in primary anterior teeth with extensive caries lesions. Symmetry plays a pivotal role in the aesthetic success of anterior teeth restorations, particularly in central incisors. Restorations must achieve harmonious proportions and balance to mimic the natural dentition. Techniques that simplify this process, such as polyvinyl crowns, aim to enhance symmetry while reducing operator variability[20]. With the expected results, we aim to provide clinical evidence for a better treatment decision by the pediatric dentist. Currently, research has focused on testing different restorative materials but only case reports address the different possible techniques for restoring these teeth. Considering that the two techniques that will be tested start from the same assumption of selective removal of carious tissue but are conducted with different step-by-step it becomes important to verify if there is any better technique. Given that one of the techniques involves the restoration in a single increment of resin, through the polyvinyl crowns, probably its execution time will be faster, but will the quality and longevity of the restoration be similar to the conventional technique? To the best of our knowledge, this is the first randomized clinical trial to compare the two rehabilitative techniques of primary anterior teeth affected by extensive caries lesions.

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Competing Interests: None declared. The authors have no conflicts of interest, financial or otherwise, to declare.

Availability of data and materials: This paper is a protocol description and does not contain any data at this point. Future data will be available, as described in the Data sharing statement below.

Data sharing statement: Data generated from this clinical trial will be made available to other researchers upon reasonable request. The data will be shared in accordance with BMJ's Tier 2 data policy, ensuring legal and ethical considerations are upheld.

- Description of Data: The dataset includes anonymized patient records, clinical outcome measures, and intervention details.
- Availability: Data will be accessible within 6 months of publication of the final study results.
- Access: Requests for data access can be submitted through OSF.
- Protection: Personal identifiers will be removed to protect participant confidentiality and comply with data protection regulations.

Patient and Public Involvement: Patients or the public were not involved in the design, recruitment, or conduct of this study. The research question and outcome measures were developed by the research team based on clinical experience and existing scientific

literature. However, the burden of the intervention and the time required to participate were carefully considered to minimize any inconvenience to participants and their families. Moving forward, we plan to engage participants and their families in the dissemination of the study results. Feedback will be sought on how best to communicate the findings, and results will be shared in an accessible format through public presentations and relevant patient networks.

Ethics and Dissemination:

This study protocol has been reviewed and approved by the Human Research Ethics Committee of Universidade Metropolitana de Santos (UNIMES), under protocol number 6.019.297, approved on 24 April 2023. Written informed consent will be obtained from the parents or legal guardians of all participants prior to inclusion in the trial. The study adheres to the ethical principles outlined in the Declaration of Helsinki and complies with relevant national and international guidelines for clinical trials.

The results of this trial will be disseminated through several channels. Findings will be submitted for publication in peer-reviewed international journals and shared at relevant national and international conferences. Furthermore, the data generated from this study may be made available upon reasonable request to promote transparency and allow further research in the field.

Supporting information

S1 File. SPIRIT checklist.
S2 File. Feedback from the Ethics Committee in original language.
S3 File. Feedback from the Ethics Committee in English.
S4 File. Clinical Trials.
S5 File. Statement Consent in original language.
S6 File. Statement Consent in English.

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