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Use of computerized anesthesia in children's anxiety and pain perception during dental care: protocol for a randomized clinical trial

Uso da anestesia computadorizada na ansiedade e percepção da dor em crianças durante o atendimento odontológico: protocolo para um ensaio clínico randomizado

Uso de anestesia computarizada en la percepción del dolor y la ansiedad de los niños durante la atención odontológica: protocolo para un ensayo clínico aleatorizado

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Abstract
This study was designed to evaluate the use of computerized anesthesia during dental care in children. The randomized controlled trial will be carried with 92 children aged 5-11 years. Children will be randomly assigned to receive conventional anesthesia - control group, or computerized anesthesia - intervention group. To measure the child's anxiety, the Dental Subscale of the Children's Fear Survey Schedule - CFSS-DS and the VENHAM Picture Test Modified – VPTM will be used, as well as verification of heart rate. Coping style will be evaluated with The Monitor-Blunter Dental Scale - MBDS. The child's behavior will be assessed using the Brazilian version of the VENHAM Scale and pain will be assessed using the Faces Pain Scale – Revised (FPS-R) and the Face, Legs, Activity, Cry and Consolability (FLACC). Cortisol level will be evaluated before and after the procedure, through unstimulated saliva. Dentist's stress will be evaluated using the visual analogue scale (VAS). Given the conflicting results regarding the benefits of computerized anesthesia in the literature, it is believed that the results will help define the best strategy to reduce perception of pain, anxiety and behavior during the pediatric dentistry consultation.
Keywords: Anxiety; Behavior; Computerized anesthesia; Pain perception; Pediatric dentistry.

Resumo
Este estudo foi desenhado para avaliar o uso de anestesia computadorizada durante o atendimento odontológico em crianças. Este ensaio clínico randomizado será realizado com 92 crianças de 5 a 11 anos. As crianças serão aleatoriamente designadas para receber anestesia convencional - grupo controle, ou anestesia computadorizada - grupo intervenção. Para mensurar a ansiedade da criança, serão utilizadas a Escala Odontológica do Children's Fear Survey Schedule - CFSS-DS e a VENHAM Picture Test Modified – VPTM, bem como a verificação da frequência cardíaca. O estilo de enfrentamento será avaliado com o The Monitor-Blunter Dental Scale - MBDS. O comportamento da criança será avaliado pela versão brasileira da Escala VENHAM e a dor pela Face Pain Scale – Revised (FPS-R) e Face, Legs, Activity, Cry and Consolability (FLACC). O nível de cortisol será avaliado antes e

após o procedimento, por meio de saliva não estimulada. O estresse do dentista será avaliado por meio da escala visual analógica (VAS). Dados os resultados conflitantes sobre os benefícios da anestesia computadorizada na literatura, acredita-se que os resultados ajudarão a definir a melhor estratégia para reduzir a percepção de dor, ansiedade e comportamento.
Palavras-chave: Anestesia; Ansiedade; Comportamento; Percepção da dor; Odontopediatria.

Resumen
Este estudio fue diseñado para evaluar el uso de anestesia computarizada durante el cuidado dental en niños. Este ensayo controlado aleatorio se llevará a cabo con 92 niños de 5 a 11 años. Los niños serán asignados al azar para recibir anestesia convencional - grupo de control, a anestesia computarizada - grupo de intervención. Para medir la ansiedad del niño se utilizará la Subescala Dental del Children's Fear Survey Schedule - CFSS-DS y el VENHAM Picture Test Modified - VPTM, así como la verificación de la frecuencia cardíaca. Se evaluará el estilo de afrontamiento con la Escala Dental Monitor-Blunter - MBDS. La conducta del niño será evaluada mediante la versión brasileña de la escala VENHAM y el dolor será evaluado mediante la Faces Pain Scale – Revised (FPS-R) y la Face, Legs, Activity, Cry and Consolability (FLACC). El nivel de cortisol se evaluará antes y después del procedimiento, a través de saliva no estimulada. El estrés del odontólogo se evaluará mediante la escala analógica visual (EVA). Dados los resultados contradictorios sobre los beneficios de la anestesia computarizada en la literatura, se cree que los resultados ayudarán a definir la mejor estrategia para reducir la percepción del dolor, la ansiedad y el comportamiento.
Palabras clave: Anestesia; Ansiedad; Comportamiento; Percepción del dolor; Odontopediatría.

1. Introduction

Use Anxiety and fear can act as a barrier to dental treatment, especially when local anesthesia is required (Garret-Bernardin et al., 2017). These feelings probably originate from previous experiences, whether objective, when the child has already previously experienced it, or even subjective, when has seen or heard someone report a negative experience with the dentist. Therefore, when the child faces these negative feelings such as pain, fear and/or anxiety, there is a greater manifestation of non-collaborative behavior during this procedure (Cademartori & Martins, et al., 2017).

This demonstrates the importance that pain control procedures have during the dental treatment (Feda et al., 2010). Pain control through the administration of dental anesthesia is necessary and essential for clinical care. However, this usual and effective method can represent a challenge to the dentist's skills in the management of pain and anxiety, especially in children (Baghdadi, 1999). Local anesthesia is a relatively common procedure during the dental treatment, but it is also one of the factors that can cause fear and anxiety, triggering difficulties in managing children's behavior during dental care (Smaïl-Faugeron et al., 2015). The pain due to this procedure can be related to a combination of factors, such as, damage to soft tissues in needle penetration, pressure in the dissemination of the solution, distention of the tissues or a rapid liberation of the anesthetic (Meechan et al., 2005).

Considering that anxiety and fear can increase the perception of pain (Garret-Bernardin et al., 2017), it is essential to explore the approaches currently available with the potential to reduce these feelings and discomforts associated with local anesthesia. Amongst the available strategies to mitigate this negative sensation and increase patient satisfaction, there is the use of topic anesthesia (Malamed SF. Handbook of Local Anesthesia-Sixth Edition. Elsevier. 2013. 314 p., 2013), heating of the anesthetic solution (Ram et al., 2002), use of vibrating devices and jet injectors (Deepak et al., 2017) and prolonged injection time (Allen et al., 2002). Despite the technique of prolonged injection, that reduces pression and volume, being considered as one of the most effective strategies, the manual control of the velocity of injection is hard, since it depends on operator individual characteristics (Asarch et al., 1999).

In this matter, computer controlled local anesthesia delivery (CCLAD) systems has been developed with the aim of reducing pain, fear and anxiety as it provides a constant flow rate of local anesthetic regardless of location, density and soft tissue resilience at the injection site (Hochman et al., 1997). In the literature, studies that have used different CCLAD can be observed. Among them are The Wand® system (Milestone Scientific) (Allen et al., 2002; Muzumdar et al., 2021), the Quicksleeper™ device (Dental HiTec, Cholet, France) (Smaïl-Faugeron et al., 2019), the Sleeper One™ device (Dental Hi

Tec, Cholet, France) (Elbay et al., 2016), Comfort Control Syringe™ (Dentsply International, York, PA, USA) (Deepak et al., 2017), Computer controlled Intraligamentary anesthesia (CC-ILA) (Helmy et al., 2022) and Morpheus™ (Meibach Tech) (Smolarek et al., 2020).

Then, with the emergence of this technique, studies were developed with different systems, with the objective of comparatively evaluating this technology with the conventional method, with the presence of controversial results, some favorable to the use of this technique (Allen et al., 2002; Baghlaf et al., 2015; Berrendero et al., 2021; Deepak et al., 2017; Feda et al., 2010; Garret-Bernardin et al., 2017; Langthasa et al., 2012; Palm et al., 2004; Shetty et al., 2022) and others that do not present a significant difference between the two techniques (Amoudi et al., 2008; Asarch et al., 1999; Kandiah & Tahmassebi, 2012; Queiroz et al., 2015; Tahmassebi et al., 2009).

In the scientific literature, only one systematic review was found (França et al., 2022) that evaluated the effectiveness of the Morpheus® device in pediatric dental procedures. There was no significant difference between the two methods regarding pain perception, behavior during anesthesia and anxiety. However, other anesthetic injection systems have been studied by other researchers. Some studies found in the literature demonstrate the relationship between cortisol and anxiety levels in children during dental care (Lin et al., 2017; Nabwera et al., 2018) however; none of the studies assess the influence of techniques and devices that involve anesthesia on these measures. When the body is stressed, reactive cortisol levels increase in the individual's body (Queiroz et al., 2015; Salameh et al., 2015).

Given the importance of the subject, the conflicting results observed in the available literature on this technique and the need to consider articles published in the last two years also evaluating computerized anesthesia and cortisol, it is considered important to develop a protocol for a randomized clinical trial with the objective of to evaluate how the degree of anxiety, stress and fear of children acts, through cortisol, in the face of clinical procedures that use computerized anesthesia in dentistry.

2. Methodology

Trial design

This is a randomized, controlled, parallel-group clinical trial, based on the methodology of Severino, A. J. (2018). Two groups will be compared: patients who will receive conventional anesthesia (control group) and patients who will receive computerized anesthesia (intervention group). The study - Use of Computerized Anesthesia in Children's Anxiety and Pain Perception During Dental Care: Randomized Clinical Trial Protocol - was registered at REBec (www.ensaiosclinicos.gov.br) (RBR-7dqyscg) and is currently in the active phase. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. The Standard Protocol Items for Clinical Trials (SPIRIT) was used to guide the present protocol.

Participants, interventions, and outcomes setting

The study will be carried out at the Pediatric Dentistry Clinic of the Faculty of Dentistry of the Federal University of Pelotas (UFPel), reference to public service in the Southern region. Patients already treated in the Children's Clinic subjects, referred by the Basic Health Units (from 5 to 11 years old), will be randomly selected in order of arrival.

Eligibility: inclusion/exclusion criteria

The inclusion criteria will consider the following items: a – children with ages between 5 and 11 years; b - good general health; c - need for dental treatment under local anesthesia (restoration, endodontics or extractions).

The exclusion criteria will consider the following: a - children with physical disabilities; b - mental deficiency.

Interventions

The intervention group, which will receive computerized anesthesia, will use anesthetic techniques performed with the Morpheus device. In Brazil, electronically controlled anesthetic injection technology began to be marketed in 2005, with this device.

First, patients who meet the inclusion criteria will be randomized into intervention and control groups. Random allocation will be done through the sealed envelopes site (www.sealedenvelopes.com). The generated numbers will be organized in sealed envelopes, with 46 envelopes containing (G1) the control group, which will receive only the conventionally used anesthesia techniques and 46 containing the (G2) who will receive computerized anesthesia. On the day of the dental appointment, children will be invited on a first-come, first-served basis. If they do not meet the criteria, the next child will be invited.

The selected children will be assisted by graduate students from the Postgraduate Program in Dentistry at UFPEL and an assistant at the Children's Clinic of the Faculty of Dentistry at the Federal University of Pelotas (FO/UFPEL).

During the consultation, a questionnaire will be applied to parents and demographic (sex and age) and socioeconomic information (family income and maternal education) will be collected, as well as information regarding their anxiety and fear and that of their children in relation to dental care.

The child's assessments will be performed before (VENHAM measurement, cortisol level and Brazilian version of the VENHAM) during (heart rate, Brazilian version of the VENHAM and FLACC scale) and after (trait and state anxiety, monitoring and blunting, FPS-R, Brazilian version of the VENHAM and cortisol level) dental care, regardless of the presence of parents.

Prior to data collection, the training and calibration of the interviewers will be carried out at the FO/UFPEL. There will be theoretical training for the interviewers where the inclusion and exclusion criteria used in the study will be presented, as well as the instruments used; and practical training with interviewers for the placement of the oximeter and with graduate students in the use of the Morpheus® device. Theoretical training was carried out online, with the post-graduate student and the advisor on norms and techniques of the Morpheus device.

Dental treatment protocols

The treatment will be provided by post-graduate students during the Children's Clinic of the Faculty of Dentistry of the Federal University of Pelotas. Operators will be trained on the Morpheus device with a consultant specializing in the product and replicating their learning on dental mannequins. The procedures, therefore, will be performed under local anesthesia. These treatments will be performed according to predefined protocols by operators to the criteria used to arrive at the treatment decision. In addition to the proposed treatment under anesthesia, other treatments necessary for the patient will also be performed. Additional treatments will be planned/defined by the responsible operator.

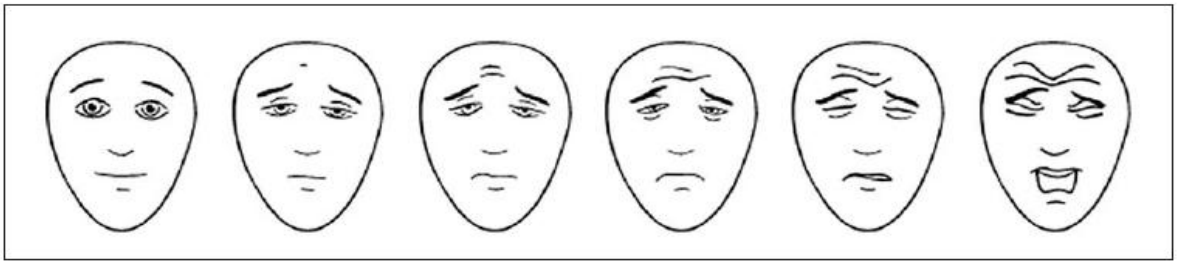
Outcomes

The primary outcome will be pain perception. Secondary outcomes will be anxiety, behavior, operator and child stress and perception of computerized anesthesia.

The FPS-R, showed in Figure 1, is indicated for children from 5 years old, and its application is accompanied by the following explanation: “These faces show how much something causes you pain can. This one (pointing to the leftmost face) shows no pain. The faces show more and more pain (pointing to each which shows a lot of pain. Now, point to the face that would represent what hurts you the most right now.” The chosen face is equivalent to the values 0, 2, 4, 6, 8 or 10, counting from left to right, so that “0” is equivalent to the absence of pain while “10” to a lot of pain. Words such as “joyful” and “sad”

should not be used during the assessment (Da Silva & Thuler, 2008). This scale will be applied by a previously trained and calibrated interviewer after the consultation.

Figure 1 - Faces Pain Scale – Revised used to measure pain perception.



Instruções: "Essas faces mostram o quanto algo pode provocar dor. Esta face (aponte para a face mais à esquerda) não expressa dor alguma. As faces mostram cada vez mais dor (aponte para cada uma da esquerda para a direita) até esta (face mais à direita) – esta expressa muita dor. Aponte para a face que expressa quanta dor você sente (neste momento)".

The FLACC, showed in Table 1, scale will be used during the procedure in order to cognitively assess the child's pain. Each category can be scored on a scale of 0-2, with a total score ranging from 0-10. "0" is considered relaxed or comfortable, "1-3" is mild discomfort, "4-6" is moderate pain, and "7-10" is severe discomfort or pain or even both. The higher the score, the greater the intensity of pain behavior shown by the child (Merkel et al., 1997).

Table 1 - Face, Legs, Activity, Cry and Consolability Scale (FLACC) used to assess pain behavior.

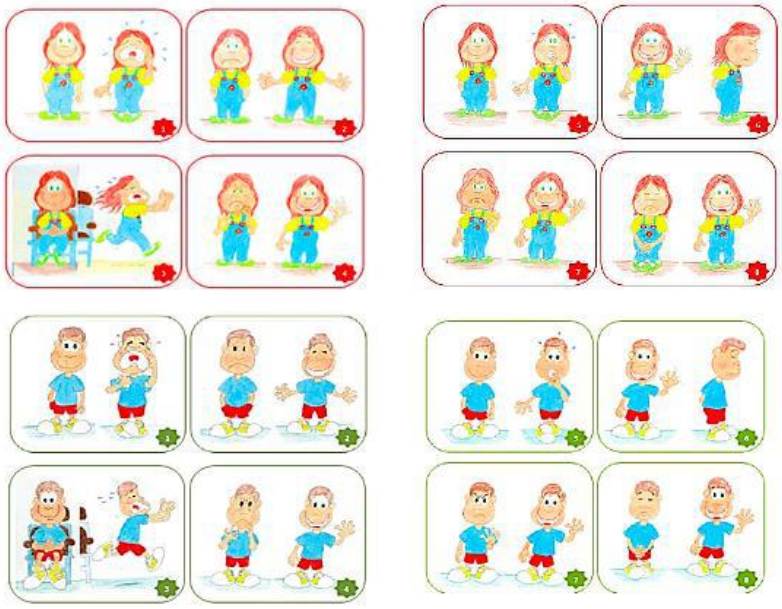
		Punctuation	
Categories	**0**	**1**	**2**
Face	No special expression or smile	Grimacing or frowning from time to time, introversion, disinterest	Frequent quivering of the chin, clenched jaws
Legs	Normal or relaxed	Restless, agitated, tense	Kicking or stretching
Activity	Quiet, in normal position, moving easily	Squirming, moving back and forth, tense	Curved, stiff or with sudden movements
Cry	No crying (awake or asleep)	Groans or whimpers; occasional complaint	Continued crying, screaming or sobbing; complain frequently
Consolability	Satisfied, relaxed	Reassured by occasional touching, hugging, or talking; can be distracted	Hard to console or comfort

Source: Authors.

To measure the child's anxiety, an anxiety scale will be applied according to the VENHAM Picture Test Modified - VPTM and heart rate verification will be verified by the oximeter. The VPTM, showed in Figure 2, are figures of human drawings that will be presented to children. The following question will be asked by an evaluator: "I would like you to point to the boy who is feeling the same way you are feeling right now. Look carefully at the faces of the figures and see how they feel". Each one of the four pairs of the eight figures will be shown separately to the child. The figure that, in each pair, reveals the negative sentiment that the child is feeling will be assigned a point in the evaluation. The sum of the assessment of all pairs of figures can vary from zero to eight, with zero representing anxiety-free children, one to three represent low anxiety level,

four to six represent medium anxiety level and seven to eight represent highly anxious children (Ramos-Jorge et al., 2006).

Figure 2 - VENHAM Picture Test Modified used to measure anxiety.



Source: Authors.

In addition, they will be evaluated in trait-anxiety/state-anxiety and as monitors/blunters by Brazilian Version of The Monitor-Blunter Dental Scale (Supplementary File 3). Trait anxiety describes individual differences in anxiety/fear propensity (DFA) (Barlow, 2002). For example, compared to state anxiety, which considers the child's immediate emotional response, as is the case with VPTM scale, trait anxiety is the most constant level of anxiety in relation to dental treatment.

Furthermore, children will be assessed according to their coping style, that is, how they like to be treated during dental care, using The Monitor-Blunter Dental Scale (MBDS). By researching and attending to information, monitors reduce their insecurities and are able to focus on what is known and safe. “Blunters”, on the other hand, apply the avoidance coping style and prefer to be distracted. In essence, there are two types – those who prefer to know what is going to happen before and during an anxiety-provoking procedure and those who prefer to have their attention focused elsewhere (Miller, 1987).

The evaluation of behavior through the Brazilian Version of the VENHAM Scale (Cademartori, Da Rosa, et al., 2017), will be done through filming and pain measurement by the FPS -R (Faces Pain Scale) and FLACC (Face, Legs, Activity, Cry, Consolability).

According to the Brazilian version of the VENHAM the entire service will be recorded on video for later evaluation, in order to minimize the interference of the evaluator. On this scale, at each evaluated moment, the child will receive a value for her behavior according to the reactions presented. Three moments will be evaluated: initial moment of consultation, during the procedure and final moment of care. The corresponding scores, categories and criteria are:

a) Score 0: Total cooperation (dichotomized into yes and no): Best possible working condition. The child does not show physical protest, such as crying or body movements.

b) Score 1: Mild protest: The child protests in a low voice (mumbling) or restrained crying, as a sign of discomfort. However, it does not prevent the continuity of treatment.

c) Score 2: Moderate protest: The child expresses his discomfort verbally, with loud crying and/or body movements (hands, arms, head, etc), which make treatment difficult. However, it still responds to requests to cooperate, even if with some

resistance.

d) Score 3: Intense protest: Comply with demands reluctantly, requiring extra effort by dentist, body movement. May require initial restraint of hands in view of more prominent body movement.

e) Score 4: More intense protest: The child performs greater body movements, including trunks and legs. It can interrupt the procedure, representing a real problem for the dentist, demanding physical and mental effort from him. Physical restraint of some body organ (hands and/or head) is required. Still, the child partially and reluctantly cooperates with the directions.

f) Score 5: Widespread protest: No adherence or cooperation from the child. The situation results in physical and mental exhaustion for both the child and the dentist. Physical restraint is necessary (holding hands, arms, legs, head, tool...), the child may try to run away from the chair, cover the mouth and, sometimes, care becomes impossible in the same session.

Each moment will be evaluated considering the most negative score observed. The peak score and the overall sum will be considered in the evaluation. In the first, the most negative score of the four evaluated moments will be considered. In the second, the sum of the values will be performed and the average of these scores will be calculated.

The cortisol level will be evaluated in the morning, between 08:30 and 11:30am, through unstimulated salivary collection, before and after the dental appointment. In all, there will be 186 samples, two collections per patient: the first performed 10 minutes before the procedure, and the second 10 minutes after its completion. Each salivary sample will be labeled, centrifuged for 10 minutes at 3200 RPM, and stored at -20° C until additional biochemical analysis for Cortisol, which will be measured using an Enzyme Immunoassay kit (LUCIO-Medical ELISA Salivary Cortisol Kit, Nal von Minden, Germany), as recommended by other studies in the literature (Gadicherla et al., 2018; Skrinjar et al., 2019; Zhu et al., 2019).

After the treatment consultation, the graduate student will report on a visual analogue scale (VAS), showed in Figure 3, their level of stress during treatment, while the child will answer the FPS-R scales, anxiety questions (state-trait and monitoring-blunting) and performing the final collection of salivary cortisol. The scale consists of a small, unmarked ruler of 100 mm, with extremes indicating: “nothing” and “as stressed as possible”, indicating how you felt after the instruction: “Indicate how stressed you felt at the consultation”. The use of VAS for clinical stress assessment has already been tested (Mitchell et al., 2008). According to the authors, this scale is particularly suitable for the clinical assessment of self-reported stress.

Figure 3 - Visual Analogue Scale (VAS) is used to measure the level of stress of the dentists.

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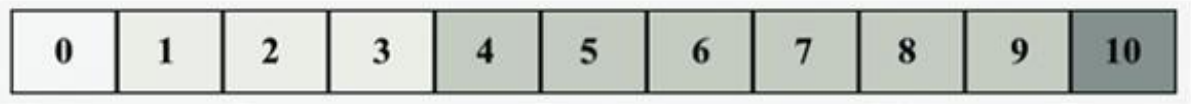

Participant timeline

The study will be recruiting patients from June 2023 to December 2024.

Sample size

To calculate the sample size, based on a previous study (Mittal et al., 2015) patients per group will be needed (significance level of 5% and power of 80%) considering an average of 1.37 on the pain scale in the group intervention and 2.57 in the control group. To compensate for the losses, the sample will be increased by 10% (n=92).

Recruitment

Recruitment will take place at the Faculty of Dentistry, once the child is attended at the Children's Clinic. Patients will be selected randomly and on a first -come, first served basis.

Assignment of interventions

Allocation: Sequence generation and concealment mechanism

The generated numbers will be organized in sealed envelopes, with 46 envelopes containing (G1) the control group, which will receive only the conventionally used anesthesia techniques and 46 containing the (G2) who will receive computerized anesthesia. The RCT will include children on a first-come, first-served basis and will be randomized. Two patients will be treated simultaneously, performing computerized anesthesia in one patient and conventional anesthesia in another. Patients will be seen only once, even if they need other procedures.

Implementation

An assistant not involved in the design or evaluation of the study will complete the questionnaires.

Blinding

There will be a single blind: both the typist and the person who analyzed the data will not have prior knowledge about the groups to which the participants belong. The evaluators who will apply the questionnaires and the scales will be exclusively for these tasks, as well as those who will analyze the data. Children will be identified by numbers and operators will not have access to children's responses to questionnaires and scales.

Data collection, management and analysis

The data will be entered into a spreadsheet in the Microsoft® Excel® 2016 program. Initially, a descriptive analysis of the data will be performed, obtaining the absolute and relative frequencies. The characteristics of the groups at the first visit will be compared using the chi-square test. Comparisons in the outcomes of interest between groups will be made using the chi-square test for dichotomous variables and the t test for comparison of means. A significance level of 5% will be adopted for all the analyses.

Monitoring

Data monitoring

The independent regulation of data collection, management and analysis will be assumed independently (F.V.A).

Harms

The procedures performed offer minimal risk to the patients' oral health. Adverse effects are represented by teeth with episodes of pain, which require endodontic treatment and extraction. In dental treatment, the possibility of occurrence of these effects is usually present.

Auditing

The data entered will be conducted by one of the study authors. Data will be inspected weekly. Inconsistencies will be checked, corrected and recorded.

Ethics and dissemination

Research ethics approval

This study was submitted and approved by the Ethics Committee of the Faculty of Dentistry of the Federal University of Pelotas (nº5.299.880).

Consent and assent

Informed consent will be provided and given by guardians, participants and post-graduation students.

Confidentiality

Identification numbers will be used to ensure participant confidentiality during data analysis. Participant files will be stored in a secure database.

Availability of data

Datasets used and/or analyzed during the current study will be made available by the corresponding author (F.V.A) upon reasonable request.

Ancillary and post-trial care

Participants will continue to receive dental treatment during and after the end of the study.

Dissemination Policy

Findings will be reported in full via national and international journals, patient newsletters and websites.

3. Discussion

Previous studies that have evaluated pain perception and behavior showed similar results comparing the computerized method with the traditional method of local anesthesia (Baghlaf et al., 2015; Deepak et al., 2017; Mittal et al., 2015). However, in terms of anxiety there are controversial results in the literature: in the study of Deepak et al., 2017 (Deepak et al., 2017), children who received computerized anesthesia had a lower mean anxiety score than children who received anesthesia using the conventional technique and in the study of Queiroz et al., 2015 (Queiroz et al., 2015) there was no statistically significant difference between the two techniques evaluated in relation to anxiety traits. Also, other studies did not observe any significant difference in anxiety levels during local anesthesia with conventional or computerized methods in children and adolescents (Smolarek et al., 2020; Tahmassebi et al., 2009; Versloot et al., 2005).

The outcomes evaluated (anxiety, behavior and pain perception) are related in a very particular way with each individual, and can be modified according to the context in which each child is inserted. It is important to consider these factors, such as anxiety, because they can act as a barrier in the dental treatment, especially when it involves dental anesthesia (Garret-Bernardin et al., 2017). Also, anxiety can be related to the behavior, as it can contribute to the presence of non-collaborative behavior (Cademartori & Martins, et al., 2017; Mathias et al., 2020).

When it comes to the study design, randomized clinical trials are considered the gold standard in the hierarchical scale of designs; therefore, they are considered as studies with low level of bias and high reliability. Only one study used the computerized anesthesia Morpheus device (Smolarek et al., 2020), which is a popular device in Brazil and the only one available for use in the country. The use of computerized anesthesia increases the costs of treatment. Therefore, it is important to carry out other clinical trials with this device, to evaluate its effectiveness comparing with conventional anesthesia. It is

important that a broader age group and evaluation of pain perception, behavior and anxiety are included, considering the conflicting findings available in the literature. Also, it should consider that a study previously done with the Morpheus device did not show a significant difference compared with the traditional method in relation to these outcomes.

It is important to improve the anesthetic procedure in order for it to become less threatening in the dental environment, as the pain perception is major issue in the dental treatment of children. This improvement should promote greater comfort and tranquility to patients, and effectiveness in its primary function, which is the possibility of performing the treatment (Feda et al., 2010). Computerized anesthesia aims to reduce this pain and fear/anxiety as it provides a constant flow rate of local anesthetic, regardless of the location, density and resilience of the soft tissues at the injection site (Hochman et al., 1997), lower dose and safer for the patient and the dentist.

As positive points of this present study protocol, we have reliable methods used to assess the outcomes. The primary outcome, pain perception, will be evaluated through the FPS-R scale that evaluates the child's pain intensity, through the presentation of six faces aligned with pain expression in an increasing ordinal gradation (Bieri et al., 1990; Hicks et al., 2001). This scale is widely used with different types of pain and in different countries, having been translated and adapted to several languages, including Portuguese – Brazil (Willis et al., 2003). Also, this instrument has good reliability and validity for measuring the pain intensity, even in younger children (Hicks et al., 2001). Pain will also be evaluated by the FLACC scale, which was developed with the aim of reducing the obstacles associated with the use of behavioral scales. Several studies have indicated that the FLACC is easily applicable and has excellent validity when used to show changes in pain scores before and after analgesic administration (Spielberger, 1972).

Also, the objective measure of anxiety will be through heart rate, using a pulse oximeter, and unstimulated salivary collection to assess salivary cortisol. The subjective measure of anxiety will be used to evaluate the sample in trait anxiety (constant level of anxiety) and state anxiety (immediate emotional response), as it is considered a stable personality trait (Spielberger, 1972). In addition to classifying them as monitoring (those who reduce their insecurity and are able to focus on what is known and safe) and blunting (those who avoid and prefer to be distracted) (Cademartori, Da Rosa, et al., 2017), a division is proposed to assess the safety of children facing dental care.

4. Conclusion

This is the first protocol for a clinical trial to evaluate the effect of computerized anesthesia in relation to conventional anesthesia, evaluating behavior, pain perception and anxiety in children. Given the conflicting results in the literature about computerized anesthesia, results will help define the best strategy to reduce perception of pain, anxiety and behavior during the pediatric dentistry consultation. Moreover, we expect that the present study protocol encourages researchers to conduct new well - designed randomized clinical trials on the topic to enhance the quality of the evidence.

References

Allen, K. D., Kotil, D., Larzelere, R. E., Hutfless, S., & Beiraghi, S. (2002). Comparison of a computerized anesthesia device with a traditional syringe in preschool children. *Pediatric Dentistry*, *24*(4).

Amoudi, N. Al, Feda, M., Sharaf, A., Hanno, A., & Farsi, N. (2008). Assessment of the anesthetic effectiveness of anterior and middle superior alveolar injection using a computerized device versus traditional technique in children. *Journal of Clinical Pediatric Dentistry*, *33*(2). https://doi.org/10.17796/jcpd.33.2.d666m2l43334274p

Asarch, T., Allen, K., Petersen, B., & Beiraghi, S. (1999). Efficacy of a computerized local anesthesia device in pediatric dentistry. *Pediatric Dentistry*, *21*(7).

Baghdadi, Z. D. (1999). Evaluation of electronic dental anesthesia in children. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontics*, *88*(4). https://doi.org/10.1016/S1079-2104(99)70055-7

Baghlaf, K., Alamoudi, N. M., Elashiry, E., Farsi, N., El Derwi, D. A., & Abdullah, A. M. (2015). The pain-related behavior and pain perception associated with computerized anesthesia in pulpotomies of mandibular primary molars: A randomized controlled trial. *Quintessence International*, *46*(9). https://doi.org/10.3290/j.qi.a34553

Barlow, D. H. (2002). The nature of anxious apprehension. In *Anxiety and its disorders: The nature and treatment of anxiety and panic* (Vol. 704).

Berrendero, S., Hriptulova, O., Salido, M. P., Martínez-Rus, F., & Pradíes, G. (2021). "Comparative study of conventional anesthesia technique versus computerized system anesthesia: a randomized clinical trial." *Clinical Oral Investigations*, *25*(4). https://doi.org/10.1007/s00784-020-03553-5

Bieri, D., Reeve, R. A., Champion, D. G., Addicoat, L., & Ziegler, J. B. (1990). The faces pain scale for the self-assessment of the severity of pain experienced by children: Development, initial validation, and preliminary investigation for ratio scale properties. *Pain*, *41*(2), 139–150. https://doi.org/10.1016/0304-3959(90)90018-9

Cademartori, M. G., Da Rosa, D. P., Oliveira, L. J. C., Corrêa, M. B., & Goettems, M. L. (2017). Validity of the Brazilian version of the Venham's behavior rating scale. *International Journal of Paediatric Dentistry*, *27*(2). https://doi.org/10.1111/ipd.12231

Cademartori, M. G., Martins, P., Romano, A. R., & Goettems, M. L. (2017). Behavioral changes during dental appointments in children having tooth extractions. *Journal of Indian Society of Pedodontics and Preventive Dentistry*, *35*(3). https://doi.org/10.4103/JISPPD.JISPPD_195_16

Da Silva, F. C., & Thuler, L. C. S. (2008). Cross-cultural adaptation and translation of two pain assessment tools in children and adolescents. *Jornal de Pediatria*, *84*(4). https://doi.org/10.2223/JPED.1809

Deepak, V., Challa, R., Kamatham, R., & Nuvvula, S. (2017). Comparison of a new auto-controlled injection system with traditional syringe for mandibular infiltrations in children: A randomized clinical trial. *Anesthesia: Essays and Researches*, *11*(2). https://doi.org/10.4103/0259-1162.194535

Elbay, Ü. Ş., Elbay, M., Kaya, E., & Cilasun, Ü. (2016). Intraligamentary and supraperiosteal anesthesia efficacy using a computer controlled delivery system in mandibular molars. *Journal of Clinical Pediatric Dentistry*, *40*(3). https://doi.org/10.17796/1053-4628-40.3.193

Feda, M., Amoudi, N. Al, Sharaf, A., Hanno, A., Farsi, N., Masoud, I., & Almushyt, A. (2010). A comparative study of children's pain reactions and perceptions to AMSA injection using CCLAD versus traditional injections. *Journal of Clinical Pediatric Dentistry*, *34*(3). https://doi.org/10.17796/jcpd.34.3.3201l74255560520

França, A. J. B. de, Barbirato, D. da S., Vasconcellos, R. J. de H., Pellizzer, E. P., Moraes, S. L. D. de, & Vasconcelos, B. C. do E. (2022). Do Computerized Delivery Systems Promote Less Pain and Anxiety Compared to Traditional Local Anesthesia in Dental Procedures? A Systematic Review of the Literature. In *Journal of Oral and Maxillofacial Surgery* (Vol. 80, Issue 4). https://doi.org/10.1016/j.joms.2021.11.018

Gadicherla, S., Shenoy, R. P., Patel, B., Ray, M., Naik, B., & Pentapati, K. C. (2018). Estimation of salivary cortisol among subjects undergoing dental extraction. *Journal of Clinical and Experimental Dentistry*, *10*(2). https://doi.org/10.4317/jced.54369

Garret-Bernardin, A., Cantile, T., D'Antò, V., Galanakis, A., Fauxpoint, G., Ferrazzano, G. F., De Rosa, S., Vallogini, G., Romeo, U., & Galeotti, A. (2017). Pain experience and behavior management in pediatric dentistry: A comparison between traditional local anesthesia and the wand computerized delivery system. *Pain Research and Management*, *2017*. https://doi.org/10.1155/2017/7941238

Helmy, R. H., Zeitoun, S. I., & El-Habashy, L. M. (2022). Computer-controlled Intraligamentary local anaesthesia in extraction of mandibular primary molars: randomised controlled clinical Trial. *BMC oral health*, *22(1)*, 194. http://doi.org/10.1186/s12903-022-02194-2

Hicks, C. L., Von Baeyer, C. L., Spafford, P. A., Van Korlaar, I., & Goodenough, B. (2001). The Faces Pain Scale - Revised: Toward a common metric in pediatric pain measurement. *Pain*, *93*(2). https://doi.org/10.1016/S0304-3959(01)00314-1

Hochman, M., Chiarello, D., Hochman, C. B., Lopatkin, R., & Pergola, S. (1997). Computerized local anesthetic delivery vs. traditional syringe technique. Subjective pain response. *The New York State Dental Journal*, *63*(7).

Kandiah, P., & Tahmassebi, J. F. (2012). Comparing the onset of maxillary infiltration local anaesthesia and pain experience using the conventional technique vs. the Wand in children. *British Dental Journal*, *213*(9). https://doi.org/10.1038/sj.bdj.2012.988

Langthasa, M., Yeluri, R., Jain, A. A., & Munshi, A. K. (2012). Comparison of the pain perception in children using comfort control syringe and a conventional injection technique during pediatric dental procedures. *Journal of Indian Society of Pedodontics and Preventive Dentistry*, *30*(4). https://doi.org/10.4103/0970-4388.108931

Lin, J., Zhao, H., Shen, J., & Jiao, F. (2017). Salivary Cortisol Levels Predict Therapeutic Response to a Sleep-Promoting Method in Children with Postural Tachycardia Syndrome. *Journal of Pediatrics*, *191*. https://doi.org/10.1016/j.jpeds.2017.08.039

Malamed SF. (2013) Handbook of Local Anesthesia-sixth edition. Elsevier. 314 p., Elsevier (2013).

Mathias, F. B., Cademartori, M. G., & Goettems, M. L. (2020). Factors associated with children's perception of pain following dental treatment. *European Archives of Paediatric Dentistry*, *21*(1). https://doi.org/10.1007/s40368-019-00456-2

Meechan, J. G., Howlett, P. C., & Smith, B. D. (2005). Factors influencing the discomfort of intraoral needle penetration. *Anesthesia Progress*, *52*(3). https://doi.org/10.2344/0003-3006(2005)52[91:FITDOI]2.0.CO;2

Merkel, S. I., Voepel-Lewis, T., Shayevitz, J. R., & Malviya, S. (1997). The FLACC: a behavioral scale for scoring postoperative pain in young children. *Pediatric Nursing*, *23*(3).

Miller, S. M. (1987). Monitoring and blunting: Validation of a questionnaire to assess styles of information seeking under threat. *Journal of Personality and Social Psychology*, *52*(2). https://doi.org/10.1037//0022-3514.52.2.345

Mitchell, A. M., Crane, P. A., & Kim, Y. (2008). Perceived stress in survivors of suicide: Psychometric properties of the perceived stress scale. *Research in Nursing and Health*, *31*(6). https://doi.org/10.1002/nur.20284

Mittal, M., Kumar, A., Srivastava, D., Sharma, P., & Sharma, S. (2015). Pain Perception: Computerized versus Traditional Local Anesthesia in Pediatric Patients. *Journal of Clinical Pediatric Dentistry*, *39*(5), 470–474. https://doi.org/10.17796/1053-4628-39.5.470

Muzumdar, P. G., Bendgude, V., & Mathur, A. (2021). Comparative evaluation of pain related behavior during administration of local anesthesia using the conventional syringe and the computerized controlled local anesthetic device in children exhibiting different levels of anxiety: In vivo study. *Journal of Pharmaceutical Research International*, *33(41A)*, 285-294. http://doi.org/10.9734/jpri/v33i41A32328

Nabwera, H. M., Bernstein, R. M., Agbla, S. C., Moore, S. E., Darboe, M. K., Colley, M., Jallow, A. T., Bradbury, R., Karafin, J., Fulford, A. J., & Prentice, A. M. (2018). Hormonal correlates and predictors of nutritional recovery in Malnourished African Children. *Journal of Tropical Pediatrics*, *64*(5). https://doi.org/10.1093/tropej/fmx075

Palm, A. M., Kirkegaard, U., & Poulsen, S. (2004). The Wand versus traditional injection for mandibular nerve block in children and adolescents: Perceived pain and time of onset. *Pediatric Dentistry*, *26*(6).

Queiroz, A. M., Carvalho, A. B., Censi, L. L., Cardoso, C. L., Leite-Panissi, C. R., da Silva, R. A. B., de Carvalho, F. K., Nelson-Filho, P., & da Silva, L. A. B. (2015). Stress and anxiety in children after the use of computerized dental anesthesia. *Brazilian Dental Journal*, *26*(3). https://doi.org/10.1590/0103-6440201300211

Ramos-Jorge, M. L., Marques, L. S., Pavia, S. M., Serra-Negra, J. M., & Pordeus, I. A. (2006). Predictive factors for child behaviour in the dental environment. *European Archives of Paediatric Dentistry : Official Journal of the European Academy of Paediatric Dentistry*, *7*(4). https://doi.org/10.1007/BF03262561

Salameh, E., Alshaarani, F., Hamed, H. A., & Nassar, J. A. (2015). Investigation of the relationship between psychosocial stress and temporomandibular disorder in adults by measuring salivary cortisol concentration: A case-control study. *Journal of Indian Prosthodontist Society*, *15*(2). https://doi.org/10.4103/0972-4052.158075

Shetty, S., Dalvi, S., Katge, F., Patil, D., Chimata, V. K., & Shetty, A. (2022). Comparison of pain perception between computer-controlled local anesthetic delivery and the conventional syringe for inferior alveolar nerve block in children. *Dental and medical problems*, *59(4)*, 523-529. http://doi.org/10.17219/dmp/135897

Skrinjar, I., Vidranski, V., Brzak, B. L., Juras, D. V., Rogulj, A. A., Brailo, V., & Boras, V. V. (2019). Salivary cortisol levels in patients with oral lichen planus - A pilot case-control study. *Dentistry Journal*, *7*(2). https://doi.org/10.3390/dj7020059

Smaïl-Faugeron, V., Muller-Bolla, M., Sixou, J. L., & Courson, F. (2015). Split-mouth and parallel-arm trials to compare pain with intraosseous anaesthesia delivered by the computerised Quicksleeper system and conventional infiltration anaesthesia in paediatric oral healthcare: Protocol for a randomised controlled trial. *BMJ Open*, *5*(7). https://doi.org/10.1136/bmjopen-2015-007724

Smaïl-Faugeron, V., Muller-Bolla, M., Sixou, J. L., & Courson, F. (2019). Evaluation of intraosseous computerized injection system (QuickSleeper™) vs conventional infiltration anaesthesia in paediatric oral health care: A multicentre, single-blind, combined split-mouth and parallel-arm randomized controlled trial. *International Journal of Paediatric Dentistry*, *29*(5). https://doi.org/10.1111/ipd.12494

Smolarek, P. de C., da Silva, L. S., Martins, P. R. D., Hartman, K. da C., Bortoluzzi, M. C., & Chibinski, A. C. R. (2020). Evaluation of pain, disruptive behaviour and anxiety in children aging 5-8 years old undergoing different modalities of local anaesthetic injection for dental treatment: a randomised clinical trial. *Acta Odontologica Scandinavica*, *78*(6). https://doi.org/10.1080/00016357.2020.1757752

Spielberger, C. D. (1972). Anxiety as an emotional state. In *Anxiety*. https://doi.org/10.1016/b978-0-12-657401-2.50009-5

Tahmassebi, J. F., Nikolaou, M., & Duggal, M. S. (2009). A comparison of pain and anxiety associated with the administration of maxillary local analgesia with Wand and conventional technique. *European Archives of Paediatric Dentistry : Official Journal of the European Academy of Paediatric Dentistry*, *10*(2). https://doi.org/10.1007/BF03321604

Versloot, J., Veerkamp, J. S. J., & Hoogstraten, J. (2005). Computerized anesthesia delivery system vs. traditional syringe: Comparing pain and pain-related behavior in children. *European Journal of Oral Sciences*, *113*(6). https://doi.org/10.1111/j.1600-0722.2005.00252.x

Willis, M. H. W., Merkel, S. I., Voepel-Lewis, T., & Malviya, S. (2003). FLACC Behavioral Pain Assessment Scale: a comparison with the child's self-report. *Pediatric Nursing*, *29*(3).

Zhu, Y., Chen, X., Zhao, H., Chen, M., Tian, Y., Liu, C., Han, Z. R., Lin, X., Qiu, J., Xue, G., Shu, H., & Qin, S. (2019). Socioeconomic status disparities affect children's anxiety and stress-sensitive cortisol awakening response through parental anxiety. *Psychoneuroendocrinology*, *103*, 96–103. https://doi.org/10.1016/j.psyneuen.2019.01.008