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Efficiency of ER:YAG laser therapy in combination with behaviour management technique in reducing anxiety among paediatric dental patients – a study protocol for a randomised clinical trial

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ABSTRACT

Introduction When providing dental care to children with a high level of dental anxiety, the range of approaches is divided into two sections: use of behaviour management techniques (BMTs) and application of alternative methods for caries removal. In an attempt to reduce dental anxiety, they can be mixed and matched in accordance with the dentists' choice. Owing to its promoted advantages, erbium-doped yttrium aluminium garnet (Er:YAG) laser turns into an ideal alternative technique for hard dental tissue therapy in anxious paediatric patients. The aim of the study is to assess the efficacy of a modified version of the BMT 'Latent inhibition' in combination with Er:YAG laser for achieving a reduction of dental anxiety in paediatric dental patients.

Methods and analysis This is a protocol for a randomised controlled clinical trial. The participants will be children aged 6–9 years, requiring conservative treatment of occlusal carious lesion on a second primary molar. Patients will be randomly assigned to the experimental or control group via a computer-generated sequence. In both groups, 'Latent inhibition' will be used as an anxiety-management technique. In the experimental group, caries treatment will be performed with Er:YAG laser, whereas that in the control group it will be performed with conventional rotary instruments. Outcome measures will be dental anxiety felt before and after the treatment, reported by the patient on a modified version of the Faces Scale by LeBaron et al., and the dynamics of heart rate, registered during the treatment session, which will be measured with a mobile pulse oximeter. Data will be analysed by independent sample t-test and paired t-test ($p<0.05$).

Ethics and dissemination The study protocol has been approved by the Committee for Scientific Research Ethics, Medical University–Plovdiv, Bulgaria (reference number P-2839, protocol of approval number 3/30.04.2015) and registered on a publicly accessible database. This research received institutional funding from the Medical University–Plovdiv, Bulgaria. The results will be presented through peer-reviewed publications and conference presentations.

Trial registration number NCT04924452.

Strengths and limitations of this study

- ⇒ The study focuses on the implementation of a known behaviour management technique in the alternative caries treatment method.
- ⇒ A key strength of this study is that all participants meeting eligibility criteria will receive active treatment.
- ⇒ Both subjective and objective tools are used to assess dental anxiety in this study.
- ⇒ A limitation of this study is that it is not a split-mouth design whose advantage is the reduction of the outcome variability estimation.

INTRODUCTION

Background and rationale

When providing dental care to children with a high level of dental anxiety, most paediatric dentists find the conventional rotary treatment method inefficient and uncomfortable. According to the principles of behavioural dentistry, as part of paediatric postgraduate education, the so-called '4S' principle must be adapted and modified to the individual clinical situation to provide adequate dental care to anxious paediatric patients.[1] The range of approaches can be divided into two sections: behaviour management techniques (BMTs), on one hand, and alternative methods for caries removal, on the other hand. In an attempt to reduce dental anxiety, they can be mixed and matched in accordance with the dentists' choice.

As it has been found for more than 20 years that lasers are effective for caries excavation, laser paediatric dentistry has been rapidly developed. It offers total innovation and changes the conventional restorative treatment in pedodontics.[2] Owing to the

promoted advantages such as minimal intervention and prevention, safety due to the low penetration depth of the laser beam, selective removal of caries lesion, lack of thermal damage, no pain perception and use of local anaesthesia, a significant decrease of patient discomfort and dental anxiety, and increase of subjective acceptance and tolerance of laser therapy in children, erbium-doped yttrium aluminium garnet (Er:YAG) laser turns into an ideal laser for hard dental tissue therapy in anxious paediatric patients.[2–4]

Based on the concepts of minimal invasive dentistry, the use of BMTs during the treatment of anxious children to reduce their anxiety is required.[5] Several specific BMTs are not part of the regular curricula of dental students and have been used by paediatric dentists only.[4 6 7] Such a psychological technique is 'Latent inhibition,' also known as gradual exposure.[8 9] It involves a series of several positive non-painful check-ups and preventive procedures, before any invasive or painful dental manipulations. Step by step, the child is exposed to potential anxiety-provoking procedures or instruments, resulting in an acquaintance with the dental setting and personnel, as well as being accustomed to dental treatment. Despite the specific indications, required preparation and higher time consumption, the use of this technique is very rewarding as the paediatric patient eventually becomes comfortable with the dental procedure and creates a feeling of ability to cope within the child.[6 7 10]

Over the recent years, dentists advance in using alternative methods for caries removal as part of their everyday practice. Therefore, the investigation of this synergetic effect of laser caries removal and the different BMTs is crucial for the present and future development of paediatric dentistry and will improve the quality of dental care.

Objectives

The aim of the study is to assess the efficacy of a modified version of the BMT 'Latent inhibition' in combination with Er:YAG laser for achieving a reduction of dental anxiety in paediatric dental patients. The main objectives are to compare dental anxiety felt during the laser and conventional dental treatment. The outcomes will be dental anxiety assessment by self-reported anxiety scale during treatment in both groups as well as the measurement of heart rate dynamics during the procedures.

Trial design

The research is designed as a randomised parallel-group controlled clinical study. Table 1 presents the recruiting, allocation, interventions, monitoring and analysis of the research in accordance with the Standard Protocol Items: Recommendations for Interventional Trials recommendations.[11] In accordance with the 'Latent inhibition' technique, patients will have two visits to the dental office—a preventive procedure, the first one, and treatment of caries lesion, the second one. Two groups will be compared. In the experimental group, the enamel conditioning of the occlusal surfaces of the permanent molars before sealant application as well as the standardised caries treatment will be performed with Er:YAG laser, whereas in the control group, the conventional rotary instruments—high-speed and low-speed dental handpieces—will be used for the caries treatment.

METHODS AND ANALYSES

Study setting

The study setting of this research includes the Department of Paediatric Dentistry and the Laser Centre of the

Table 1 Trial design

	Study period				
	Enrolment	Allocation	Post allocation		
Timepoint*	$-t_1$	0	t_1	t_2	t_3
Enrolment					
Eligibility screening	×				
Informed consent	×				
Allocation		×			
Interventions					
Experimental group (BMT+laser treatment of dental caries)				×	
Control group (BMT+caries treatment with conventional rotary instruments)				×	
Assessments					
Self-reported dental anxiety			×		×
Heart rate			◄	———	►

The table summarises the enrolment, allocation, interventions and assessments in the trial.
*Postallocation time frame: t1 -before the start of the treatment; t_2 - during laser or conventional treatment; t_3- end of the treatment, before leaving the dental chair.
BMT, behaviour management technique.

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Eligibility

Inclusion criteria

- Participants in the study are children aged 6–9 years, compliant with the cognitive development of the child.
- Children requiring conservative treatment of occlusal carious lesions on a second primary molar, without spontaneous unprovoked pain, percussion or palpation pain or other symptoms, indicating pulp involvement or periodontal pathology. Lesions are classified as a distinct cavity with visible dentin without prior restoration or sealants by the International Caries Detection and Assessment System with code 05.[12–14] Included are caries lesions only on vital teeth.
- Children with one or more permanent molars giving indications for pit and fissure sealing.
- Patients without previous experience with laser treatment of carious lesions.
- Children who are not considered medically compromised or medically complex patients.
- Verbal assent from the child willing to comply with all study procedures and protocol.
- Obtained written informed consent by the patient's parent/guardian for participation in the study (see online supplemental file S1, 'Patient consent form', and online supplemental file S2, 'Information leaflet').

Exclusion criteria

1. Patients who were undergoing therapy with neurological, sedative, analgesic and/or anti-inflammatory drugs 7 days prior to treatment that might affect the heart rate.
2. Children who were first-time dental patients.
3. Children with systemic diseases or physiological development delays.
4. Children with mental or cognitive problems.
5. Active infectious diseases such as influenza, scarlet fever, etc.
6. Excluded are molars which are affected by disturbances in the development of dental structures (hypoplasia, hypomineralisation and fluorosis).

Interventions

Patients will be divided into two groups (41 per group): experimental and control groups. All treatments will be carried out by the same operator (MS), without anaesthesia. A baseline dental self-reported anxiety will be recorded using a Faces Anxiety Scale as well as the dynamics of heart rate, measured with a mobile pulse oximeter.

Er:YAG laser therapy protocol (experimental group)

Er:YAG laser (LiteTouch, Light Instruments), emission wavelength 2940 nm will be used for enamel conditioning of the occlusal surfaces of the permanent molars before sealant application as well as the standardised caries treatment. Chosen protocol parameters are modified based on previously conducted studies[2–4 15 16]:

- HERE IT IS NECESSARY TO REMOVE THE LIST BULLET, IT STARTS FROM THE LINE BELOW - A LOW-SPEED ……Preventive procedure—sealant application.
- A low-speed rubber cup and pumice paste (Clean-Polish, Kerr) will be used for 30 s for cleaning and polishing of the occlusal surface of the chosen permanent molar.
- Tooth surface will be washed for debris and organic residue removal and dried with air spray.
- Isolation with rubber dam.
- Laser conditioning of the occlusal enamel surface. The parameter settings used will be tip-to-tissue distance, 1.5 mm from the tooth surface; tip diameter, 600 µm; laser energy, 70 mJ; pulse frequency, 10 Hz; water spray level, 8; average power, 0.7 W; and energy density, 67 J/cm^2.
- The tooth surface will be etched with 35% phosphoric acid gel (Etching Gel, DMP) for 30 s and rinsed for the same time.
- The tooth surface will be dried with air spray for 15 s.
- Fissure sealant application (Pit&Fisssure Sealant, DMP).
- Light cured for 20 s.
  - HERE IT IS NECESSARY TO REMOVE THE LIST BULLET, Caries removal—parameters: enamel removal—energy, 100-200 mJ; density 9.84–13.03 J/cm^2; pulse frequency, 20 Hz; tip diameter, 800 µm; water spray level, 8; tip-to-tissue distance, 0.5÷1.0 mm from the tooth surface; dentin removal—energy, 100 mJ; density, 9.84 J/cm^2, pulse frequency, 20 Hz; tip diameter, 800 µm; water spray level, 8; tip-to-tissue distance, 0.5÷1.0 mm from the tooth surface; restoration with compomer; time for caries removal procedure—max 8 min.[17–20]

Conventional therapy protocol (control group)

- HERE IT IS NECESSARY TO REMOVE THE LIST BULLET, IT STARTS FROM THE LINE BELOW - A LOW-SPEED ……Preventive procedure—sealant application.
- A low-speed rubber cup and pumice paste (Clean-Polish, Kerr) will be used for 30 s for cleaning and polishing of the occlusal surface of the chosen permanent molar.
- The tooth surface will be washed for debris and organic residue removal and dried with air spray.
- Isolation with rubber dam.
- The tooth surface will be etched with 35% phosphoric acid gel (Etching Gel, DMP) for 30 s and rinsed for the same time.
- The tooth surface will be dried with air spray for 15 s.
- Fissure sealant application (Pit&Fisssure Sealant, DMP).
- Light cured for 20 s.

– HERE IT IS NECESSARY TO REMOVE THE LIST BULLET.Caries removal—conventional rotary instruments will be used: high-speed and low-speed dental handpieces. For the bur preparation, 1.2 mm diameter diamond round bur Drendel & Zweiling No. 801.314 and Komet Steel round bur 016, Komet Dental Gebr were used. A new bur was used for each preparation. Restoration was performed with compomer. Time for caries removal procedure was a maximum of 4 min.

Clinical protocol

First visit

1. Parents/guardians are informed about the protocol of the study and the laser technique. They sign the informed consent form (see online supplemental files S1 and S2). Verbal assent from the child is obtained.
2. Oral examination and sealant application are performed according to the assigned intervention.
3. Patient's self-report of dental anxiety before leaving the dental chair.

Second visit

1. Patients will be asked to report their dental anxiety, pointing to the face or choose the number which most closely depicted its state of anxiety using a modified version of the self-report Faces Scale by LeBaron[21] (see online supplemental file S3).
2. The pulse oximeter is connected to the patient's index finger. The start of heart rate monitoring and recording will be 5 min prior to treatment. Time frame: at least 5 min after the dental treatment, before leaving the dental chair.
3. Caries treatment is performed according to the assigned intervention.
4. Patient's self-report of dental anxiety before leaving the dental chair.

Outcomes

Primary outcome measures

The primary outcome will be the dental anxiety before and after the treatment session, reported by the patient on a modified version of the self-report Faces Scale by LeBaron et al. The scale comprises a row of five faces ranging from 'relaxed' to 'very worried' in combination with a visual analogue scale of 0–10. Each child was asked to point to the face or choose the number which most closely depicted its state of anxiety.

Secondary outcome measures

The secondary outcome will be the dynamics of heart rate, registered during the treatment session measured with a mobile pulse oximeter (CMS50F, CONTEC), placed on the index finger of the left hand.[22] Throughout the whole procedure of each dental visit, data were recorded and analysed by a specially developed digital processing and graphic visualisation software SPO2 Review V.1.2 rel.

Participant's timeline

Each eligible patient undergoes two visits. The first appointment includes screening, consenting and assenting, recording of dental anxiety and sealant application according to the assigned interventions for each group. The second appointment at the 1-week recall includes a recording of dental anxiety and treatment of a carious lesion according to the assigned interventions for each group. The manipulations will be performed by one operator.

Sample size calculation

The sample size calculation is performed based on data from a pilot study with 20 subjects. To estimate sample size for the primary outcome—self-reported anxiety felt, according to the Faces Scale by LeBaron—a t-test for paired groups has been used (G* Power software V.3.1,6 since we have two groups). The effect size was determined using the formula

$$ES = \frac{Control - Treated}{SDpooled} = \frac{2.33 - 0.33}{3.25} = 0.62,$$

where SD is the pooled SD, an average of the SD of the experimental and control groups. The sample size is calculated to assure a test power greater than 95% and a significant level of α=0.05. We estimated a sample size of 41 patients per group to detect significant differences. Thus, the final sample size for this study will be 82 patients.

Recruitment

The patients at the Department of Paediatric Dentistry of the Faculty of Dental Medicine, Medical University–Plovdiv, Bulgaria, who meet the inclusion criteria, will be screened for eligibility. Once identified, patients will be informed about this research project and will receive information about the possibility of potential study participation. Patient recruitment starts obtaining the full quota of participants within a 1-year time frame. It begins in September 2021 with an estimated enrolment capacity of five patients per month.

Participating centres

The patients are randomly selected from the visitors in the Department of Paediatric Dentistry of the Faculty of Dental Medicine, Medical University–Plovdiv, Bulgaria, and are treated in the Laser Centre of the same university.

Assignment of the intervention

Sequence generation

The patients will be randomly allocated to either the control group or the experimental group (41 patients in each group) according to the enrolment number in the trial. The randomisation will be created using a computerised random generator.

Allocation concealment mechanism and implementation

A randomisation list will be created by a random generator before the start of the treatment and kept in a locked drawer. Assignments will be kept in separate, closed opaque, sequentially numbered envelopes, enabling

the sequence to be concealed until the intervention is assigned.

Blinding

The randomisation will be independent, that is, the patients and parents/guardians will remain blinded to group status. The operator will get acquainted with the procedure to be performed prior to the first session. The operator is selected to be the only one performing the manipulation to prevent bias. The statistician will be blinded to treatment assignment as data will be masked before the analysis without giving the statistician the key.

Data collection, confidentiality, storage and monitoring of the study documents

Collection, coding, storage and evaluation of personal data within the project will be carried out in accordance with The General Data Protection Regulation (EU) 2016/679. A prerequisite for data collection will be the voluntary written informed consent of the patient's parent or guardian. Confidentiality will be guaranteed by a coded ID number; access will be granted exclusively to the study investigators. The information from the paper forms will be exported to a database file and stored on a password-protected computer. Only the investigators and statistician will have access to the final data set. All data collected will be stored in sealed containers in areas of the Department of Paediatric Dentistry, Faculty of Dental Medicine, Medical University–Plovdiv, Bulgaria, with limited access.

STATISTICAL METHODS

The obtained data will be recorded, tabulated, processed, and analysed using SPSS (Statistical Package for Social Science software) V.21.0 (IBM, USA). In all tests, the significance level of 5% probability or the corresponding *P*-value will be adopted. Descriptive statistics will be calculated. Discrete variables will be summarised by frequencies or proportions. Continuous variables will be presented as means and SD. We will compare anxiety mean scores according to the Faces Scale by LeBaron as well as heart rate mean score. Comparisons among groups will be performed by using the Independent sample t-test and paired t-test.

Patient and public involvement

The development of the research question and outcome measures will be based on the review of available evidence in this research area. Patients will not be involved in the development of the study protocol. However, their questions and concerns will be addressed during patient recruitment and study implementation. During the conduction of the study, patients will not be informed about the results of the ongoing trial since there is no planned interim analysis. The results will be disseminated to the study participants through email and routine follow-up dental check-ups.

Ethics and dissemination

The clinical study will be conducted in accordance with the conditions and principles of the Declaration of Helsinki, the existing EU Clinical Trial Directive (EC) No. 2001/20/EC, the recommendations of the Ethical Committee at the Medical University–Plovdiv, Bulgaria, and the international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects - *Good Clinical Practices (GCP*).

Research ethics approval

The study was approved by the Committee for Scientific Research Ethics, Medical University–Plovdiv, Bulgaria (reference number P-2839, protocol of approval number 3/30.04.2015) and registered on a publicly accessible database (ClinicalTrials.gov, Registration number:NCT04924452). Ethical approval for the study protocol was provided by and written informed consent for all subjects' parents/guardians was approved by the ethics committee of the Medical University–Plovdiv, Bulgaria.

Consent

The operators will obtain written consent from patients' parents/guardians willing to participate in the trial. Additional information will be provided for all parents for the study. Completed informed consent will be collected at the Department of Paediatric Dentistry, Medical University–Plovdiv by the study investigators. A copy of the signed consent form will be handed over to the participating child's parent/guardian. After providing age-appropriate information about the study, verbal assent will be obtained as an affirmative agreement for participation from children.

Confidentiality

Information on the participants collected during the study will be kept strictly confidential and will not be disclosed to third parties. Confidentiality will be guaranteed by a coded ID number; access will be granted exclusively to the study investigators.

Conflict of interests

The investigators have no conflicts of interest to declare. They agree with the protocol and the informed consent of the study, and there is no financial interest to report.

Access to data

All data collected will be stored in sealed containers in areas of the Department of Paediatric Dentistry, Faculty of Dental Medicine, Medical University–Plovdiv, Bulgaria, with limited access. The information from the paper forms will be exported to a database file and stored on a password-protected computer. Only the investigators and statistician will have access to the final data set.

Dissemination policy

The results of the trial will be presented through peer-reviewed publications and conference presentations. In

addition, our results will be disseminated to clinicians, as well as key stakeholders, including scientific directors of postgraduate programmes 'Master of Science in Lasers in Dentistry', academic courses in Pedodontics and Preventive dentistry. The principal investigator (MS) and the scientific expert (AB) will write the first draft of the manuscript without the use of professional writers.

Trial status

The trial is not yet recruiting patients. The process will start in September 2021 and will continue until September 2022.

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Contributors AB and MS conceived the ideas; MS was the primary operator, AB and MS were outcomes assessors and data collectors; and developed the design and protocol for this study. Writing was led by AB and MS. All authors made substantial contributions, participated in the analysis and reporting of the results, refined the study protocol and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Consent obtained from parent(s)/guardian(s).

Ethics approval This study involves human participants and was approved by The study was approved by the Committee for Scientific Research Ethics, Medical University–Plovdiv, Bulgaria (reference number P-2839, protocol of approval number 3/30.04.2015) and registered on a publicly accessible database (ClinicalTrials.gov). Ethical approval for the study protocol was granted by and written informed consent from all subjects' parents/guardians was approved by the Ethics Committee of the Medical University–Plovdiv, Bulgaria. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

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