

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparative study of the effect of music playback and use of 3D Audiovisual glasses on pain and severity of anxiety rate during injection in 4-10 year-old children referred to Anzali s Dental Clinic

Protocol summary

Study aim

Comparison of two methods of playing music and using 3D audio-visual glasses in controlling pain and anxiety during injection in children 4-10 years old

Design

Intervention clinical trial with control group, block randomization in which all possible modes will be written for 3 sessions of treatment in terms of receiving the intervention and 6 modes or blocks will be created. Then 5 people will be randomly placed in each block up to 30 people.

Settings and conduct

Samples are randomly blocked from children referred to the pediatric ward of Anzali Dental Clinic, which will be injected and treated by a final year student.

Participants/Inclusion and exclusion criteria

Children 4-10 years old who need infusion injection behind the maxilla and refer to the clinic of Anzali School of Pediatrics. Non-entry criteria: need for medical treatment to cooperate; medical problems such as history of seizures, gastrointestinal disorders, eye problems, autism and any mental or psychological illness that according to the Frankl scale is negative or completely negative cooperation.

Intervention groups

Depending on the blocks in which they are randomly placed, the children will be shown Tom and Jerry cartoons through 3D glasses for 1 minute, Uncle Purang's music will be played through headphones, or basic behavioral control will be used. Basic Behavior The dentist communicates with the patient through speech without the use of distraction (using glasses or playing music).

Main outcome variables

Pain score on FLACC criterion; anxiety intensity score on FIS scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210108049963N1**

Registration date: **2021-02-03, 1399/11/15**

Registration timing: **prospective**

Last update: **2021-02-03, 1399/11/15**

Update count: **0**

Registration date

2021-02-03, 1399/11/15

Registrant information

Name

Seyedeh nazanin Mazloumi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 56 3282 8204

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-06, 1399/11/18

Expected recruitment end date

2021-02-23, 1399/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of music playback and use of 3D Audiovisual glasses on pain and severity of anxiety rate during injection in 4-10 year-old children referred to Anzali s Dental Clinic

Public title

A comparative study of two methods of playing music and the use of 3D audio-visual glasses in controlling pain and anxiety during injection in children

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Requires one examination session and three sessions of dental treatment and requires infiltration injection behind the maxilla Parental consent patient The child's consent to the use of distractions Good general health Do not enter children who have epilepsy According to the Frankel scale, positive cooperation (accepts treatment, sometimes shows cautious behavior, sometimes reluctant to follow a dentist but follows him directly) or completely positive (reports dentist That the child has a lot of cooperation in the work process and laughs and enjoys) Lack of pediatric dental history (be the first visit to the dentist)

Exclusion criteria:

Need medication to cooperate Medical problems such as history of seizures or seizure disorders, gastrointestinal or balance disorders, eye problems, autism and any other mental illness Children who have a negative or completely negative cooperation according to the Frankl scale The presence of any abscess in the area of the injection site

Age

From **4 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly blocked from children referred to the pediatric ward of Anzali Dental Clinic, which will be injected and treated by a final year student under the supervision of a pediatric dentist. Block randomization will be done in such a way that all possible modes will be written for 3 sessions of treatment in terms of receiving the intervention and 6 modes or blocks will be created. Then 5 people will be randomly placed in each block to get 30 people in the blocks. Block 1: The first session of music - the second session of video - the third session of behavioral control Block 2: The first session of music - The second session of behavioral control - The third session of video Block 3: The first session of the video - the second session of music - the third session of

behavioral control Block 4: The first session of the video - the second session of behavioral control - the third session of music Block 5: The first session of behavioral control - the second session of video - the third session of music Block 6: The first session of behavioral control - the second session of music - the third session of video

Blinding (investigator's opinion)

Single blinded

Blinding description

The FLACC criteria will be used to assess the child's pain. The recording of this scale is done by the assistant so that he does not know the type of intervention, in other words, the study will be done single-blind. The child's face, legs, activity, crying, and submissiveness are assessed. This criterion is classified from zero (completely calm) to 10 (severe pain / anxiety). Also, the child's anxiety will be assessed immediately after the infiltration injection in the posterior maxilla using the FIS (facial image scale). Previously, the assistant explained the smileys and how to show the feeling to the child, and after the injection, the child is asked to mark the appropriate smile depending on the degree of discomfort.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Guilan University of Medical Sciences

Street address

In front of 17 Shahrivar Hospital, Shahid Siadati St., Namjoo St.

City

Rasht

Province

Guilan

Postal code

4194173774

Approval date

2021-01-13, 1399/10/24

Ethics committee reference number

IR.GUMS.REC.1399.503

Health conditions studied**1****Description of health condition studied**

Anxiety

ICD-10 code

ICD-10 code description

In this disorder there is a wariness of strangers and social apprehension or anxiety when encountering new, strange, or socially threatening situations. This category should be used only where such fears arise during the early years, and are both unusual

Primary outcomes**1****Description**

Pain score on FLACC criteria

Timepoint

During injection of infiltrator behind the maxilla

Method of measurement

The FLACC criterion will be used to assess the child's pain. The recording of this scale is done by the assistant so that he does not know the type of intervention. The state of the child's face, legs, activity, crying and surrender are evaluated. This criterion is classified from zero (completely calm) to 10 (severe pain / anxiety).

2**Description**

Anxiety score on the FIS scale

Timepoint

During injection of infiltrator behind the maxilla

Method of measurement

The child's anxiety will be assessed immediately after the infiltration injection in the posterior part of the maxilla using a facial image scale (FIS), in which the assistant first explains the smileys and how to show the feeling to the child and asks the child after the injection. Depending on the degree of discomfort, mark the appropriate face.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients will visit 4 times a week, in the first session will be examined and prescribed radiographs and recorded medical and dental history and completed the file and fluoride prophylaxis. Children who interact negatively or completely negatively with the Frankel scale will be excluded from the study. In the second, third, and fourth sessions, the children will receive the necessary dental treatment, and depending on the block in which they are randomly placed, the first intervention for them is a full-length cartoon for 1 minute while injected with 3D glasses (Shinecon VR model) is played

Category

Prevention

2**Description**

Intervention group: Uncle Purang's music is played by headphones for 1 minute during injection

Category

Prevention

3**Description**

Control group: In the basic behavioral control group, the dentist communicates with the patient through speech without the use of distraction (using glasses or playing music).

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Pediatric ward of Anzali Dental Clinic

Full name of responsible person

Seyedeh nazanin mazloumi

Street address

30 meters boulevard

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Naghipour

Street address

In front of 17 Shahrivar Hospital, Shahid Siadati St., Namjoo St.

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Seyedeh hedyeh daneshvar

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific**inquiries****Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Seyedeh hedyeh daneshvar

Position

Specialist doctor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Seyedeh nazanin mazloumi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data such as information about reducing

pain and anxiety during infiltration injection is shared

When the data will become available and for how long

After printing the results

To whom data/document is available

Dentists, Pediatricians, researchers working in academic and scientific institutions

Under which criteria data/document could be used

Using intervention groups such as 3D glasses or music instead of basic behavioral control to reduce pain and anxiety

From where data/document is obtainable

Guilan University of Medical Sciences International Campus Library

What processes are involved for a request to access data/document

Visit the library site of Bandar Anzali International Faculty and search for defended dissertations and approved research projects from 2020 onwards

Comments