

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The study of music impact on children`s cooperation during the dentistry operations : Based on the 2nd and 3rd initial Franckle behavioural

Protocol summary

Study aim

The primary objective of the study is to find out the music impact on children`s cooperation based on the 2nd and 3rd Frankle during the dentistry operations.

Design

The clinical trial is divided into two groups of 22 people who are treated simultaneously in both groups, one as an intervention group and the other as a control group. (The effect of intervention in each individual is compared with that person himself)

Settings and conduct

place of study: dental clinic of the Medical Sciences of the University of Tehran Methods: Children are divided into two groups based on the Frankel 2 and 3. In each group, pulpotomy or restoration dentistry is performed at the lower mandibular molar, once with music playback by headphones and once without any music. Before the onset of treatment, the anxiety level is measured by the questionnaire and after completion of the treatment, level of pain is recorded by VAS index, cooperation by Frankl's classification and anxiety is recorded by the Vinkam questionnaire.

Participants/Inclusion and exclusion criteria

Entry requirements: Only Children between 4 - 8 years old are allowed, only the patients with 2nd and 3rd initial Franckle behaviour are allowed, The volunteers must be in need of restorative or pulpotomy treatment of any of the lower jaw primary molar Non-intervention conditions: The volunteers with systemic, mental, physical disease, The volunteers must be with intense dental pain, The volunteers must be with need for Dental Emergency treatment

Intervention groups

A group of 4 to 8 years old children that once are appointed as the intervention group and then as the control group. (In each person, the treatment is performed once in a non-musical session (control) and then through a session with music (intervention).

Main outcome variables

study's effect on cooperation, pain and stress level of the patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190220042779N1**

Registration date: **2019-06-04, 1398/03/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-04, 1398/03/14**

Update count: **0**

Registration date

2019-06-04, 1398/03/14

Registrant information

Name

Parisa Ghezloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3420 4968

Email address

parisagh910@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-24, 1398/02/04

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of music impact on children`s cooperation during the dentistry operations : Based on the 2nd and 3rd initial Franckle behavioural

Public title

The study of music impact on children`s cooperation

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Only Children between 4 - 8 years old are allowed Only the patients with 2nd and 3rd initial Franckle behaviour are allowed The volunteers must be in need of restorative or pulpotomy treatment of any of the lower jaw primary molar.

Exclusion criteria:

The volunteers with systemic, mental, physical disease The volunteers must be with intense dental pain The volunteers must be with need for Dental Emergency treatment

Age

From **4 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

More than 1 sample in each individual

Number of samples in each individual: **2**

Dental therapy is done on one side of the mandible by playing music, and on the other side without playing any music.

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method in which there is a single sequence of random allocations, has been used. Individual randomization unit is used to randomize random number tables and non-transparent envelopes are used for concealment.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of dentistry faculty of Tehran medical science university

Street address

6th floor, central department, Keshavarz blv., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-04-23, 1398/02/03

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1398.013

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

Restorative treatment or dental pulpotomy on primary molar

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

cooperation level

Timepoint

before and after the treatment process

Method of measurement

franckle measure

Secondary outcomes**1****Description**

pain level

Timepoint

after treatment process

Method of measurement

VAS Test

2**Description**

anxiety level

Timepoint

before and after the treatment

Method of measurement

Intervention groups

1

Description

Intervention group: 4-8 year-old children who need dental treatment that undergoes treatment on one side of the lower jaw along with music playback through headphones.

Category

Treatment - Other

2

Description

Control group: 4-8 year-old children who need dental treatment that undergoes treatment on the other side of the lower jaw without music playback.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of dentistry of Tehran university

Full name of responsible person

Donya Alinejad

Street address

Faculty of dentistry of Tehran university, End of north Kargar st., Tehran .Iran

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۹۵۵۹۹۱

Phone

+98 21 8801 5950

Email

dentistry@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Marzieh Alikhasi Habib Abadi

Street address

Tehran University of Medical Sciences, next to Atomic Energy organization, North Kargar St, Enghelab Sq, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۹۵۵۹۹۱

Phone

+98 21 8801 5950

Email

dentistry@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Donya Alinejhad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Faculty of dentistry of Tehran university, End of north Kargar st., Tehran .Iran

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۹۵۵۹۹۱

Phone

+98 21 8835 1250

Email

donya_alinejhad@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Donya Alinejhad

Position

استادیار

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Faculty of dentistry of Tehran university, End of north Kargar st., Tehran .Iran

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۹۵۵۹۹۱

Phone

+98 21 8835 1250

Email

donya_alinejhad@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Parisa Ghezloo

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No. 9, 7th Golbar alley, Biskooran St. Garmsar, Iran

City

Garmsar

Province

Semnan

Postal code

3581677819

Phone

+98 23 3420 4968

Email

parisagh910@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available