

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### A comparative study of the effect of music therapy and virtual reality on the amount of pain during anesthesia injection

#### Protocol summary

##### Study aim

The effect of music therapy and virtual reality in creating distraction and reducing pain perception during anesthesia injection in patients referred to the endo ward of Isfahan University of Medical Sciences

##### Design

Group A: Virtual Reality Group Group B: Music therapy group Group C: Control group Blinding of samples to record pain using VAS (Appendix) is done in such a way that after injecting VR or mp3 player is taken from the patient and the project partner who does not know the intervention method to record VAS (0-10) (Appendix) Refer and register it. Then the collected information is entered into the statistical software Spss version 22. Statistical data analysis in terms of descriptive calculation of mean and standard deviation and drawing of bar and box diagrams, and analytically in case of necessary conditions for one-way analysis of variance and Tukey multiple comparisons, and otherwise Kruskal-Wallis parametric bread test and I will be Whitney.

##### Settings and conduct

Patients referred to the endodontics department of the School of Dentistry of Isfahan University of Medical Sciences Blinding of samples to record pain using VAS (Appendix) is done in such a way that after injecting VR or mp3 player is taken from the patient and the project partner who does not know the intervention method to record VAS (0-10) (Appendix) Refer and register it

##### Participants/Inclusion and exclusion criteria

18-40 years old, consent to participate in the study, non-pregnant patients, patients undergoing local anesthesia, patients with negative percussion test and normal periapical and without periodontal disease. No smoking, nicotine and alcohol

##### Intervention groups

Group A: Virtual Reality Group Group B: Music therapy group Group C: Control group

##### Main outcome variables

VAS score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200127046277N2**

Registration date: **2021-09-08, 1400/06/17**

Registration timing: **retrospective**

Last update: **2021-09-08, 1400/06/17**

Update count: **0**

##### Registration date

2021-09-08, 1400/06/17

##### Registrant information

##### Name

ali ghazalgoo

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 5547

##### Email address

alighazalgoo@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-16, 1400/05/25

##### Expected recruitment end date

2021-09-06, 1400/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative study of the effect of music therapy and virtual reality on the amount of pain during anesthesia injection

#### Public title

Investigating the effect of music and virtual reality on pain during anesthesia injection

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients aged 18-40 years patients who are willing to participate in the study, No hearing or vision problems no diseases such as heart problems and other advanced systemic diseases non-pregnant patient Patients who do not smoke, nicotine or alcohol Patients admitted to the general ward of the facult Patients with negative pericardial test and normal periapical and without periodontal disease no history of anesthesia injection in the anterior maxilla

##### Exclusion criteria:

The need for more complex treatment in the specialized department Patients with immunodeficiency or hypertension Patients who refuse to continue treatment and cooperation

#### Age

From **18 years** old to **40 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients were randomly assigned the number 1-30 to men. 31-60 We group women with a random number application in such a way that: If the number 1-10 or 31-40 comes, they are in group A. If the number 11-20 comes with 41-50, they are in group B. If the numbers are 21-30 or 51-60, they are in group C. The random number application is such that without human intervention, we give the application a range of 1 to 30, for example, and select a number for each patient.

Which group should we be in?

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Blinding of samples to record pain using VAS (Appendix) is done in such a way that after injecting VR or mp3 player is taken from the patient and the project partner who does not know the intervention method to record VAS (0-10) (Appendix) Refer and register it.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

#### Ethics committees

##### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

###### Street address

isfahan, janbazan Ave, molana Blvd, Erfan St, 12th Alley

###### City

isfahan

###### Province

Isfahan

###### Postal code

8174796884

##### Approval date

2021-08-09, 1400/05/18

##### Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.209

#### Health conditions studied

##### 1

##### Description of health condition studied

Pain during anesthesia injection

##### ICD-10 code

Z01.2

##### ICD-10 code description

Encounter for dental examination and cleaning

#### Primary outcomes

##### 1

##### Description

Pain score in the patient-filled VAS questionnaire

##### Timepoint

Measuring the amount of pain during anesthesia injection at the end of the injection

##### Method of measurement

Patient-filled VAS questionnaire

#### Secondary outcomes

empty

#### Intervention groups

##### 1

##### Description

Intervention group: Patients who wear IMV260 Personal Eyewear Cinema VR glasses on their face during

anesthesia injection and the selected video is played for 5 minutes before the injection and until the end of the injection.

**Category**

Prevention

**2****Description**

Intervention group: Group B: Patients whose favorite music is played with the headphone and mp3 player 5 minutes before the injection until the end of the injection.

**Category**

Prevention

**3****Description**

Control group: Group C: Patients for whom no intervention is performed during anesthesia injection.

**Category**

Prevention

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

School of Dentistry Isfahan University of Medical Sciences

**Full name of responsible person**

Ali Ghazalgoo

**Street address**

Isfahan, Shohada Sofeh St., Isfahan University of Medical Sciences, School of Dentistry

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**Email**

AliGhazalgoo@yahoo.com

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Nakisa Torabinia

**Street address**

Isfahan, Shohada Sofeh St., Isfahan University of Medical Sciences, School of Dentistry

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**Email**

Torabinia@dnt.mui.ac.ir

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ali Ghazalgoo

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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

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**Full name of responsible person**

Ali Ghazalgoo

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

The patient's personal details are not required

**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**

Yes - There is a plan to make this available

**Data Dictionary**

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

**Title and more details about the data/document**

The patient's personal details are not required

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

In case of research on a similar subject, she can use the data of this research.

**From where data/document is obtainable**

Dr. Ali Ghazalgoo with e-mail address:

Alighazalgoo@yahoo.com

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

Correspond with Dr. Ali Ghazalgoo by e-mail and receive the data at her discretion

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Ali Ghazalgoo

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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