

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of implementing relaxing music and aromatherapy on anxiety in patients undergoing root canal therapy

Protocol summary

Study aim

The effect of aromatherapy and relaxing music on anxiety index and vital signs during dental treatment

Design

A randomized controlled clinical trial with parallel, single-blind, randomized groups

Settings and conduct

72 patient sampling method will be selected from patients referring to root canal treatment in Afz Esfahan Dental Clinic based on inclusion criteria. Control group (group one), patients treated with lavender aroma (group two), patients treated with music listening (group three), patients treated with lavender aroma and music listening (group four). None of the patients were given any explanation about the effects of music and the aroma of lavender on their anxiety in order to avoid the psychological and placebo effects. Patients fill out the Dental Anxiety Questionnaire before starting treatment. Their blood pressure and heart rate will be measured in two stages before and after treatment.

Participants/Inclusion and exclusion criteria

Patients referred to the Specialty Clinic of Dentistry will be selected at the examination session for patients with irreversible pulpitis, in terms of healthy olfactory and hearing, non-smoker, non-pregnant, no history of allergies, cardiovascular disease, diabetes and mental disorders. If patient is not willing to cooperate during treatment session, colds, allergies, painkillers, sedation, emergency treatment during treatment, injection of more than one carpal anesthetic, prolonged treatment, patient from The study will be deleted.

Intervention groups

Control, Music, Lavender Aroma, Music and Lavender Aroma

Main outcome variables

Decrease in cardiovascular parameters and anxiety during treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191228045910N1**

Registration date: **2020-06-21, 1399/04/01**

Registration timing: **retrospective**

Last update: **2020-06-21, 1399/04/01**

Update count: **0**

Registration date

2020-06-21, 1399/04/01

Registrant information

Name

fateme nasiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5742 2950

Email address

f.nasiri.8090100@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-01, 1398/10/11

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of implementing relaxing music and aromatherapy on anxiety in patients undergoing root canal therapy

Public title
Effect of implementing relaxing music and aromatherapy on anxiety in patients undergoing root canal therapy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients referred to the Special Clinic of Dentistry patients with irreversible pulpitis in terms of healthy olfactory in terms of healthy hearing non-smoker non-pregnant no history of allergies no history of cardiovascular disease no history of diabetes no history of mental disorders
Exclusion criteria:
If patient is not willing to cooperate during treatment session common colds allergies painkillers or sedative medication injection of more than one carpal anesthetic prolonged treatment emergency during treatment

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: 72

Randomization (investigator's opinion)
Randomized

Randomization description
For individual Randomization We will add 72 patients to the desired population size. Then we have 2 single-digit columns in the table of random numbers. We will then randomly select a starting point for patient selection. Finally, we started the selection process from this point and considered any number that is smaller or equal to 72 as the sample of choice

Blinding (investigator's opinion)
Single blinded

Blinding description
None of the patients are given any explanation about the effects of music and lavender aromas on their anxiety in order to avoid the psychological and placebo effect.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice chancellor for research, Isfahan University of Medical Sciences
Street address
Hezar jerib St.
City
Isfahan
Province
Isfahan
Postal code
8174673461
Approval date
2019-12-04, 1398/09/13
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.526

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety Disorder

Primary outcomes

1

Description
blood pressure
Timepoint
Before and after treatment
Method of measurement
Digital blood pressure monitor

Secondary outcomes

1

Description
Pulse rate
Timepoint
Before and after treatment
Method of measurement
Digital pulse detector

2

Description
Anxiety
Timepoint
before and after treatment
Method of measurement
Questionnaire

Intervention groups

1

Description

Control group: Five drops of water as placebo dispersed in an electronic deodorizing chamber in an area of 20square meters during the treatment (30-60 minutes).

Category

Placebo

2

Description

Intervention group: music listening during treatment (30-60 minutes) via external spaekers

Category

Treatment - Other

3

Description

Intervention group: Five drops of lavender essential oils produced by Kazerun Agro Company at a concentration of 2% and containing emulsifiers dispersed in an electronic deodorizing chamber in an area of 20square meters during the treatment (30-60 minutes).

Category

Treatment - Other

4

Description

Intervention group: Intervention # 1 and # 2 are performed simultaneously

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzal private clinic,isfahan dental faculty

Full name of responsible person

Seyed Amir Mousavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Saeed Nosouhian

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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

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

Fateme Nasiri

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable