

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Evaluation of the Effect of Speech Instruction on Patients Anxiety with Irrevocable Pulpitis

Protocol summary

Study aim

Determination of the Effect of Speech Instruction on Patients Anxiety with Irrevocable Pulpitis

Design

Clinical trial with control group, with parallel groups, without blindness, Randomized

Settings and conduct

A sequential selection of 96 patients in Yazd Khatam al-Anbia Clinic, completing the questionnaire before each action in both groups, giving the verbal description in the intervention group, and no explanation in the control group, then being treated by an identical endodontist and then filling Repeated questionnaire in two groups

Participants/Inclusion and exclusion criteria

1) Patients who are willing to participate in the study 2) Patients aged 20-65 years 3) No hearing problems 4) Not having diseases such as heart problems, other advance systemic diseases and immunosuppressive diseases 5) Non-pregnant patients 6) Patients who can undergo local anesthesia 7) No history of mental illness 8) Non-use of psychiatric drugs 9) Patients with history of root canal therapy in one of the teeth. Non-entry criteria: Not having entry criteria and 1) Patients who need to root canal therapy except maxillary premolars 2) Patients who need to root canal therapy in maxillary premolar teeth but without irreversible pulpitis, and patients who getting into unpredictable incident during the study

Intervention groups

Providing verbal explanations for 15 minutes before start of the treatment in the intervention group about the diagnosis of the dentist, other alternative treatments if the dentist is diagnosed, how is the treatment, the number of treatment sessions, instruments used in treatment, including turbine, angel, rotary handpiece, dental explorer, Files and other devices, the type of anesthetic used and possible complications after treatment, and don't provide this description for the control group

Main outcome variables

Anxiety Scale in Dental Anxiety Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044242N1**

Registration date: **2019-07-24, 1398/05/02**

Registration timing: **retrospective**

Last update: **2019-07-24, 1398/05/02**

Update count: **0**

Registration date

2019-07-24, 1398/05/02

Registrant information

Name

Fatemeh Ayatollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3625 5881

Email address

f.ayatollahi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-24, 1397/11/04

Expected recruitment end date

2019-05-05, 1398/02/15

Actual recruitment start date

2019-02-09, 1397/11/20

Actual recruitment end date

2019-06-03, 1398/03/13

Trial completion date

2019-06-03, 1398/03/13

Scientific title

Evaluation of the Effect of Speech Instruction on Patients Anxiety with Irrevocable Pulpitis

Public title

Evaluation of the Effect of Speech Instruction on Patients Anxiety with Irrevocable Pulpitis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are willing to participate in the study
Patients aged 20-65 years No hearing problems No diseases such as heart problems, other advance systemic diseases and immune suppressive diseases Non-pregnant patients Patients who can undergo local anesthesia No history of mental illness No use of psychiatric drugs Patients with history of root canal therapy in one of the teeth

Exclusion criteria:

Patients who need root canal therapy except maxillary premolars Patients who need maxillary premolars root canal therapy but without irreversible pulpitis Patients who getting into unpredictable incident during the study

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Actual sample size reached: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Regarding the inclusion criteria one patient was considered in the intervention group and the next patient in the control group in succession

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study is done with the Parallel scheme and its integration with the design of B and A (Before and After)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

School of Dentistry, Dahe Fajr BLV, Yazd

City

Yazd

Province

Yazd

Postal code

8914815667

Approval date

2019-01-22, 1397/11/02

Ethics committee reference number

IR.SSU.REC. 1397.152

Health conditions studied

1

Description of health condition studied

Evaluation of the effect of speech instruction on patients anxiety with irrevocable pulpitis

ICD-10 code

ICD-10 code description

Unspecified mental disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety Score in the Dental Anxiety Scale

Timepoint

Measure the anxiety level in the intervention group before intervention and starting treatment and in the control group before and after the treatment

Method of measurement

Dental Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: before starting root canal therapy, provide speech instruction about the final diagnosis of the dentist, other alternative treatments if the dentist is diagnosed, how is the treatment, the number of treatment sessions, the instruments used in treatment, including turbine, angel, rotary handpiece, dental explorer, file and other equipment. type of anesthesia to be used and possible complications after treatment for 15 minutes

Category
Behavior

2

Description

Control group: before starting root canal therapy don't provide any speech instruction and doing usual root canal therapy

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam-ol-Anbia Specialized and Advanced Clinic
Full name of responsible person
Fatemeh Ayatollahi
Street address
Khatam-ol-Anbia Specialized and Advanced Clinic,
Adjacent to the Central Laboratory, Taleghani Blv,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Alireza Daneshkazemi
Street address
School of dentistry, Dahe Fajr BLV, Yazd
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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh Ayatollahi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Postal code

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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

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

Not applicable

Data Dictionary

Not applicable