Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Studying the effect of diaphragmatic breathing (deep breathing) in reducing anxiety in patients undergoing scaling and root planing treatment

Protocol summary

Study aim
Determining the effect of diaphragmatic breathing in reducing anxiety in patients undergoing scaling and root planing

Design
Clinical trial with control group, parallel group, unblinded, block randomization on 60 patients

Settings and conduct
Forty patients aged 20 to 55 years referring to the Department of Periodontology, Yazd Dental School, who meet all the specified inclusion criteria and are candidates for scaling and root planing (SRP) as the first experience, will be selected. Patients will be divided into two intervention and control groups. Intervention group: Training in diaphragmatic breathing and performing diaphragmatic breathing during scaling. Control group: No training or intervention was performed.

Participants/Inclusion and exclusion criteria
Exclusion criteria: No heart or lung disease such as asthma; No smoking; No diagnosed mental health problems such as anxiety or depression; No use of anti-anxiety medications; No pregnancy or breastfeeding, and No chemotherapy; No pain medication; No anxiety medication or antidepressants; No medications that affect heart rate and blood pressure, such as diuretics and beta-blockers; No anticonvulsant medications; No immunosuppressive medications; or No local anesthesia during treatment.

Intervention groups
Intervention group: The group that practiced diaphragmatic breathing during the screening. Control group: The group that did nothing during the screening.

Main outcome variables
Subjective anxiety score; systolic blood pressure; diastolic blood pressure; pulse rate; arterial blood oxygen saturation percentage; pain level; treatment satisfaction level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230615058492N4**
Registration date: **2026-05-05, 1405/02/15**
Registration timing: **prospective**

Last update: **2026-05-05, 1405/02/15**
Update count: **0**

Registration date
2026-05-05, 1405/02/15

Registrant information

Name
Fahimeh Rashidimeibodi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-29, 1405/03/08

Expected recruitment end date
2026-08-21, 1405/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the effect of diaphragmatic breathing (deep breathing) in reducing anxiety in patients undergoing scaling and root planing treatment

Public title
The effect of diaphragmatic breathing in reducing anxiety in patients undergoing treatment for crime.

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 20 and 55 years Need for scaling treatment (with accumulation of local factors and development of Stage II-IV periodontitis) No previous experience with root canal treatment and root planing

Exclusion criteria:
Not having heart or lung disease such as asthma No smoking No diagnosed mental health problems such as anxiety and depression Not taking anti-anxiety medications Not pregnant or breastfeeding Not receiving chemotherapy; receiving painkillers; taking anti-anxiety or antidepressant medications; taking medications that affect heart rate and blood pressure, such as diuretics and beta-blockers; taking anticonvulsants; using immunosuppressant medications; or receiving local anesthesia during treatment

Age
From **20 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is performed using the block random allocation method. First, using the PASS 2021 software, we generate a random sequence using the block random allocation method of 15 blocks of 4. The software output is in the form of an Excel file containing a sequence of numbers from one to 60 and a unique code for the research units. Eligible individuals are assigned numbers from one to 60 and are assigned to an intervention group (A or B). The first eligible individual to refer is assigned number 1, the second individual is assigned number 2, and so on, up to 60 patients are assigned to the groups. In order to blind the random assignment of the clients, we seek the help of a third person who is unaware of the interventions and this table is given to him. When the eligible person refers to the study, the third person is asked by voice over the telephone based on the individual number of the intervention group and the individual's assignment to one of the groups is determined and carried out.

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 Faculty of Dentistry_ Shahid Sadoughi University of Medical Sciences, Yazd

Street address
Faculty of Dentistry, the beginning of Imam Reza Blvd, Imam Reza Square

City
Yazd

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Yazd

Postal code
8914881167

Approval date
2025-08-02, 1404/05/11

Ethics committee reference number
IR.SSU.DENTISTRY.REC.1404.030

Health conditions studied

1

Description of health condition studied
Patients with periodontitis

ICD-10 code
K05

ICD-10 code description
Gingivitis and periodontal diseases

Primary outcomes

1

Description
Mental anxiety

Timepoint
Before the intervention, after two-thirds of the treatment

Method of measurement
Spielberger’s State-Trait Anxiety Inventory–State Scale

Secondary outcomes

1

Description
Heart rate

Timepoint

Before starting treatment, after completing two-thirds of the treatment

Method of measurement

Pulse oximeter device

2

Description

Blood oxygen

Timepoint

Before starting treatment, after completing two-thirds of the treatment

Method of measurement

Pulse oximeter device

3

Description

Systolic blood pressure

Timepoint

Before starting treatment, after completing two-thirds of the treatment

Method of measurement

Digital sphygmomanometer

4

Description

Diastolic blood pressure

Timepoint

Before starting treatment, after completing two-thirds of the treatment

Method of measurement

Digital sphygmomanometer

5

Description

Satisfaction from treatment

Timepoint

Immediately after treatment

Method of measurement

Ask questions in the questionnaire

Intervention groups

1

Description

Intervention group: In this group, patients are taught diaphragmatic breathing and during treatment, patients are asked to perform diaphragmatic breathing.

Category

Behavior

2

Description

Control group: This group is not given training and does not perform any actions during treatment.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Faculty of Dentistry, Yazd

Full name of responsible person

Fahimeh Rashidi Maybodi

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Faculty of Dentistry, the beginning of Imam Reza Blvd, Imam Reza Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amir Hoshang Mehrparvar

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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
Zahra Zare Mehrjardi

Position
Dentistry student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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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
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