

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3625 5881

##### Email address

f\_rashidi63@ssu.ac.ir

##### Recruitment status

**recruiting**

##### 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

**Province**

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**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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**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

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## 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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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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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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**Position**

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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