

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of solar plexus point reflexology of plantar and palmar on anxiety and physiological parameters of patients undergoing colonoscopy

#### Protocol summary

##### Study aim

The effect of solar plexus point reflexology of plantar and palmar acupressure on anxiety and physiological parameters of patients undergoing colonoscopy is examined.

##### Design

In this clinical trial study, 105 patients admitted to Amir Al-Momenin Hospital in Arak who have eligible criteria for the study are randomly divided into three groups of intervention 1, intervention 2 and control.

##### Settings and conduct

Massage intervention in intervention group 1, using 3 milliliters of olive oil for 15 minutes for each patient's foot in the reflex points (head, pituitary gland, diaphragm, lungs, solar plexus, and adrenal gland) is performed. To measure the main outcome variables, the number of breaths, heart rate, arterial blood oxygen saturation percentage, blood pressure, and patient anxiety are recorded; in intervention group 2, the researcher also performs the above steps on the patient's hand like group 1, so that the patient's right hand is first lubricated for 1 minute and then the reflex massage intervention is performed on 5 points including head, pituitary gland, diaphragm, lungs, and kidney/adrenal. Then the same steps are performed for the left hand.

##### Participants/Inclusion and exclusion criteria

Entry conditions: 1) Colonoscopy candidate 2) Age range 18 to 65 years 3) Colonoscopy candidate for the first time 4) Have a minimum reading and writing literacy to complete the questionnaire No entry conditions: 1) Having emergency colonoscopy order 2) Have previous experience or knowledge of the effects of acupressure

##### Intervention groups

Intervention group 1: Performing reflexology intervention on the reflection points of plantar Intervention group 2: Acupressure in the palm of patient's Control group: No

intervention

##### Main outcome variables

Respiration rate, heart rate, arterial blood oxygen saturation, blood pressure, anxiety

#### General information

##### Reason for update

Update based on pilot study results

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190524043687N3**

Registration date: **2021-12-24, 1400/10/03**

Registration timing: **prospective**

Last update: **2024-03-04, 1402/12/14**

Update count: **1**

##### Registration date

2021-12-24, 1400/10/03

##### Registrant information

##### Name

Ali Safdari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 5861 5962

##### Email address

asafdari.nu@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-08, 1400/10/18

##### Expected recruitment end date

2022-08-09, 1401/05/18

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of solar plexus point reflexology of plantar and palmar on anxiety and physiological parameters of patients undergoing colonoscopy

**Public title**

Comparison of the effect of solar plexus point reflexology of plantar and palmar on anxiety and physiological parameters of patients undergoing colonoscopy

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Colonoscopy candidate Age range 18 to 65 years Signing an informed consent form Colonoscopy candidate for the first time Have a minimum reading and writing literacy to complete the questionnaire

**Exclusion criteria:**

Having emergency colonoscopy order Have previous experience or knowledge of the effects of acupressure Lack of full consciousness, having mental, visual and auditory disorders Drug addiction Existence of an obstacle at the site of pressure (wounds, skin diseases, etc) Existence of sensory and motor disorders in the legs and minimal ability to walk on the legs (peripheral neuropathy or vascular problems in the lower extremities)

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **105**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples are selected in an available sampling way from all colonoscopy candidate patients admitted to Amir Al-Momenin Hospital in Arak. Then patients with an equal number of members are randomly assigned to each of the intervention and control groups. The block randomization method will be used. To avoid the bias of random selection of individuals to study, groups are hidden and this sequence remains hidden until the intervention. For this purpose, consecutive dark and numbered envelopes are used to enclose the sequences.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The blind groups in this study include patients, data collectors, and a statistician; in such a way that none of the data collectors were aware of the allocation of patients to the two intervention and control groups, and also the data obtained from this study without informing the statistical expert about the allocation of data to each intervention and control groups, will be analyzed.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of the Arak University of Medical Sciences

**Street address**

Sardasht St., Basij Square, Ethics Committee of Arak University of Medical Sciences

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Approval date**

2021-11-14, 1400/08/23

**Ethics committee reference number**

IR.ARAKMU.REC.1400.226

**Health conditions studied****1****Description of health condition studied**

Abnormal findings on diagnostic imaging and in function studies, without diagnosis

**ICD-10 code**

R93.8

**ICD-10 code description**

Abnormal findings on diagnostic imaging of other specified body structures

**2****Description of health condition studied**

Anxiety

**ICD-10 code**

F41.1

**ICD-10 code description**

Generalized anxiety disorder

## Primary outcomes

### 1

#### Description

Anxiety

#### Timepoint

Before intervention, immediately before intervention and after intervention

#### Method of measurement

The State-Trait Anxiety Inventory-Spielberger

## Secondary outcomes

### 1

#### Description

Heart beat

#### Timepoint

Before the intervention, immediately before the intervention, after the intervention

#### Method of measurement

Number of beats per minute - pulse oximeter

### 2

#### Description

Arterial blood oxygen saturation (SPO2)

#### Timepoint

Before the intervention, immediately before the intervention, after the intervention

#### Method of measurement

Percentage - pulse oximeter

### 3

#### Description

Respiratory rate

#### Timepoint

Before the intervention, immediately before the intervention, after the intervention

#### Method of measurement

Count per minute - count breathing by observation

### 4

#### Description

Blood pressure

#### Timepoint

Before the intervention, immediately before the intervention, after the intervention

#### Method of measurement

By sphygmomanometer

## Intervention groups

### 1

#### Description

Intervention group1: Performing massage intervention in the reflection points of the sole of the foot. For this purpose, the researcher will start the massage

intervention 10 minutes after the patients enter the bed where they are hospitalized, after passing the reflexology training course and gaining the necessary skills. First, the researcher takes out his watch, ring, and jewelry and washes and warms his hands. Then, the researcher intervenes by being at the end of the patient's bed and observing a suitable position (to create better comfort, a small pillow is placed under the patient's knees). In the intervention group, to facilitate massage and better reflexology effect, 3 ml of pure olive oil with a temperature of 18-25 ° C is used. In the first step, lubricate the patient's foot for 1 minute and begin reflexology intervention. The massage of the right foot at a slow pace, with a regular rhythm and with a depth that is tolerable by the patient lasts for 15 minutes. Reflex points include the head, pituitary gland, diaphragm, lungs, solar plexus, and adrenal gland. Then the same steps are performed on the patient's left foot. In order to reduce the likelihood of distraction in patients, the intervention will be performed in a quiet and closed environment (if possible). It should be noted that massage intervention is performed for male patients by male researcher assistance and for female patients by a female colleague.

#### Category

Treatment - Other

### 2

#### Description

Intervention group2: In intervention group 2, the researcher performs the above steps on the patient's hand as in intervention group 1, so that the researcher first lubricates the patient's right hand for 1 minute and begin reflexology intervention. The massage of the right hand at a slow pace, with a regular rhythm and with a depth that is tolerable by the patient lasts for 15 minutes. Reflex points include the head, pituitary gland, diaphragm, lungs, solar plexus, and adrenal gland. Then the same steps are done for the left hand

#### Category

Treatment - Other

### 3

#### Description

Control group: There is no special intervention in the control group and these patients receive only routine care.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amiralmomenin hospital

##### Full name of responsible person

Ali Safdari

##### Street address

No. Arak, Sardasht, Basij Square, Amiralmomenin hospital

**City**

Arak

**Province**

Markazi

**Postal code**

3818649433

**Phone**

+98 86 3367 5001

**Email**

asafdari.nu@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Aliraza Kamali

**Street address**

No. Arak, Sardasht, Basij Square, Arak University of Medical Sciences

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**Phone**

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**Email**

alikamaliir@yahoo.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Ali Safdari

**Position**

Nursing student of Arak University of Medical Sciences

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Razieh Mokhtari

**Position**

Member of Arak Nursing Faculty

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Ali Safdari

**Position**

Nursing student of Arak University of Medical Sciences

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**Province**

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

Yes - There is a plan to make this available

**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**

No - There is not 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**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

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

Shared data include demographic information of participants' patients, type and method of intervention, information about anxiety, pain and physiological indicators of participants before and after the intervention.

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

Start the access period 6 months after the results are published.

**To whom data/document is available**

Researchers and people working in nursing as well as people working in clinical nursing

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

The obtained data can be used for education, research and clinic of nursing. The applicant must be in the field of nursing. The data applicant should use the data only for education, research and clinic of nursing.

**From where data/document is obtainable**

Ali Safdari, Department of critical care nursing, school of nursing, Arak university of medical sciences E mail:asafdari.nu@gmail.com

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

After confirming that the data requester is in the field of nursing, the type of request will be answered immediately via email.

**Comments**