

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

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

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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

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Position

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Latest degree

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Other areas of specialty/work

Nursery

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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