Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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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Full name of responsible person
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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
Nursing student of Arak University of Medical Sciences

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