Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Oct 2026

The effect of acupressure on anxiety, pain and quality of life in patients with inflammatory bowel disease

Protocol summary

Study aim
Determining the effect of acupressure on anxiety, pain and quality of life in patients with inflammatory bowel disease referred to the emergency department of Shahid Chamran Hospital in Tehran

Design
Clinical trial with control and experimental groups, with parallel groups, one-way blind, randomized, on 56 patients. A simple method will be used for randomization.

Settings and conduct
Patients diagnosed with inflammatory bowel disease who will be referred to Shahid Chamran Hospital in Tehran are placed in the experimental and control groups by simple random method. In this plan, patients do not know their group.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: 1. Willingness to participate in the study 2. Inflammatory bowel disease 3. No other diseases and obvious intestinal disorders 4. Do not have known autoimmune diseases such as cancer 5. Absence of any wounds, scratches, deformities and numbness in the desired points of acupressure, 6. Be literate, 7. No history of using acupressure, 8. Do not smoke, take drugs or take sedatives and anti-anxiety pills 9. No mental illness, including anxiety disorders 10. No pregnancy 11. No varicose veins, tumors, infectious skin, the possibility of bone fractures and acute abdomen during the study 12. Age between 18 and 60 years Exclusion criteria include: 1. The patient's unwillingness to continue cooperation 2. No feeling of warmth, heaviness, swelling or numbness when performing acupressure at the desired point for any reason 3. Failure to intervene in a quarter of the designated days

Intervention groups
Experimental group: The effect of acupressure (pressure) on the studied variables Control group: Investigation of the effect of placebo (touch) on the studied variables

Main outcome variables
Anxiety the pain Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210306050603N1**
Registration date: **2021-05-12, 1400/02/22**
Registration timing: **prospective**

Last update: **2021-05-12, 1400/02/22**
Update count: **0**

Registration date
2021-05-12, 1400/02/22

Registrant information

Name
Zahra Abasi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2795 1428

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zahraabasi6506@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-17, 1400/02/27

Expected recruitment end date
2021-07-21, 1400/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of acupressure on anxiety, pain and quality of life in patients with inflammatory bowel disease

Public title
The effect of acupressure on anxiety, pain and quality of life in patients with inflammatory bowel disease
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients are diagnosed with inflammatory bowel disease Patients are not in acute health condition Patients range in age from 18 to 60 years
Exclusion criteria:
Patients in need of emergency medical procedures are not included in the study A patient who is unwilling to participate in the project
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into experimental and control groups by simple randomization method
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients are divided into experimental (pressure) and control (touch) groups by simple randomization method and the patient does not know her group
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Aja University of Medical Sciences
Street address
Shariati Ave. Kaj Ave. Aja Nursing College.
City
Tehran
Province
Tehran
Postal code
۱۶۱۵۱۱۶۱۳۹
Approval date
2021-01-06, 1399/10/17
Ethics committee reference number
IR.AJAUMS.REC.1399.197

Health conditions studied

1

Description of health condition studied
bowel syndrome disease(Ulcerative colitis)
ICD-10 code
K51
ICD-10 code description
Ulcerative colitis

2

Description of health condition studied
bowel syndrome disease(Crohn's disease)
ICD-10 code
K50
ICD-10 code description
Crohn's disease [regional enteritis]

Primary outcomes

1

Description
Quality of Life
Timepoint
Before the intervention and four weeks after the intervention
Method of measurement
Short form of IBDQ-9 quality of life questionnaire

2

Description
Anxiety
Timepoint
Before the intervention and four weeks after the intervention
Method of measurement
Spielberger Anxiety Questionnaire

3

Description
the pain
Timepoint
Before the intervention and four weeks after the intervention
Method of measurement
Visual numerical questionnaire for pain intensity

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: pressure is applied at the pressure points determined in the study. After teaching these points and how to do it by the researcher in person, it is recommended that the intervention be performed three times a day for four weeks. During these four weeks, the researcher monitors the intervention daily by phone. Anxiety, pain and quality of life questionnaires are completed by the patient before the intervention and four weeks after the intervention. The pressure points are selected from st, kid, sp, and li4 pressure points according to the opinion of the acupressure specialist.

Category

Lifestyle

2

Description

Control group: Touching is performed at the pressure points specified in the study. The training is performed by the researcher in person. Touch the pressure points three times a day for four weeks. The researcher monitors the intervention daily by telephone. The patient completes the Anxiety, Pain and Quality of Life questionnaires before the intervention and four weeks after the intervention. The pressure points are selected from st, kid, sp, and li4 pressure points according to the opinion of the acupressure specialist.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Chamran Hospital
Full name of responsible person
Zahra Abbasi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Artesh 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
Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Zahra Abbasi
Position
Student
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the fact that this research has been approved by the military university, we are not allowed to publish these cases
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available