

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

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

Protocol summary

Anxiety the pain Quality of Life

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

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)

Phone

+98 21 2795 1428

Email address

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

Street address

Shahid Chamran Hospital, Shahid Fakhri-zadeh St., Nobniad ,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Ms. Nahid Rajaei

Street address

nursing school, Kaj St., Tehran

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Tehran

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1615116139

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Email

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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

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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