# 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

**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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**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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Shahid Chamran Hospital,Shahid Fakhrizadeh 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
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nursing school، Kaj St.،Tehran
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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 updating data

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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