Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of foot reflexology on pain and constipation in patients with irritable bowel syndrome referred to Imam Reza Clinic in Khomein

Protocol summary

Study aim
Determining the effect of reflexology on persistent pain and constipation in patients with irritable bowel syndrome

Design
A randomized, randomized, three-way, clinical trial on 64 patients with irritable bowel syndrome. A quadruple block was used for randomization.

Settings and conduct
People who refer to Imam Reza Clinic in Khomein, receive massage therapy twice a week for 6 weeks. Reflexology is performed using a lubricant to reduce friction on the foot. First, a general massage is performed for 5 minutes on the right foot and then reflexology is performed by performing specific movements of the hands in the area related to the gastrointestinal tract for 10 minutes. After this stage, reflexology is performed with the same technique on the left foot. For patients in the control group, foot pressure massage is applied without pressure to simulate interventions similar to the intervention group. patients and statistical analysts do not know the members of the intervention and control group and the type of reflexology.

Participants/Inclusion and exclusion criteria
Willingness to participate in the study Age 20 to 50 years Not pregnant Irritable bowel syndrome according to diagnosis of gastroenterology No history of any major bowel surgery. No epilepsy, diabetes, hypertension, kidney and gallstones, hepatitis, heart disease, hyperlipidemia Do not take medications to control blood sugar, blood pressure, blood thinners, corticosteroids and nonsteroidal anti-inflammatory drugs.

Intervention groups
This intervention is designed to investigate the effect of foot reflexology on pain and constipation in patients with irritable Ward syndrome. The subjects are given massage therapy twice a week (each time for 30-40 minutes) and for 6 weeks. Reflexology is performed using a lubricant (natural sunflower oil) to reduce foot friction.

Main outcome variables
Reflexology

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200307046709N1**
Registration date: **2022-02-17, 1400/11/28**
Registration timing: **prospective**

Last update: **2022-02-17, 1400/11/28**
Update count: **0**

Registration date
2022-02-17, 1400/11/28

Registrant information

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Mohammad Rostamkhani

Name of organization / entity
Khomein university of medical science

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on pain and constipation in patients with irritable bowel syndrome referred to Imam Reza Clinic in Khomein

Public title

The effect of foot reflexology on pain and constipation in patients with irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Age 20 to 50 years Not pregnant Irritable bowel syndrome according to diagnosis of gastroenterology No history of any major bowel surgery, no epilepsy, diabetes, high blood pressure, kidney and gallstones, hepatitis, heart disease, hyperlipidemia Do not take medications to control blood sugar, blood pressure, blood thinners, corticosteroids and nonsteroidal anti-inflammatory drugs.

Exclusion criteria:

unwillingness to continue research for any reason Pregnancy during the study Feeling uncomfortable doing research

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are selected based on purpose and randomly (by quadruple block method) are placed in two groups of intervention and control. Patients are randomly assigned to one of the intervention and control groups by block randomization with quadruple blocks. By assigning the letter A to the intervention group and the letter B to the control group, the six modes AABB, BBAA, BABA, ABBA, BAAB and ABAB are written on separate sheets and thrown into a container and one of the sheets is randomly Is taken out of the container and the composition written on it is written down and that sheet is thrown back into the container. Because the sample size in this study is 80 patients, this operation is repeated 20 times and each time the composition is written on each sheet in the sequence written on the previous sheet. Then, for each letter, a number from one to eighty is assigned in the order of the letters written in a row, and each letter is placed inside an envelope and the letter number is written on the envelope. Each time the disease is selected, one of the envelopes is opened in the order written on the envelope and it is specified that the patient should be in the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The intervention performed by the researcher is performed in both intervention and control groups, with the difference that the depth of the massage is different, and because the intervention is performed on both groups, people will not know the details. The division into two groups will not be known, so the two-way study is blind.

Placebo

Not used

Assignment

Other

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Khomein university of Medical Sciences

Street address

Quds Boulevard، Khomein university of Medical Sciences

City

Khomein

Province

Markazi

Postal code

3881743364

Approval date

2022-01-15, 1400/10/25

Ethics committee reference number

IR.KHOMEIN.REC.1400.018

Health conditions studied

1

Description of health condition studied

Irritable Bowel Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain and constipation score in the Constipation Assessment Scale and Visual Analgesia Scale
Timepoint
Measurement of pain and constipation before intervention and 6 weeks after reflexology
Method of measurement
"Constipation Assessment Scale"، "Visual Analgesia Scale"

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the intervention group receive massage therapy twice a week (each time for 30-40 minutes) for 6 weeks. Reflexology is performed using a lubricant (natural sunflower oil) to reduce foot friction. First, a general massage is performed for 5 minutes on the right foot and then reflexology by performing specific movements of the hands in the area of the gastrointestinal tract for 10 minutes (stomach, liver, small intestine, large intestine and solar plexus). After this stage, reflexology is performed with the same technique on the left foot.
Category
Treatment - Other

2

Description
Control group: Patients in the control group applied pressure-free foot surface massage to simulate interventions similar to the intervention group
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital
Full name of responsible person
Mohammad Rostamkhani
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Sponsors / Funding sources

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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
Khomein university of medical science
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
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Mohhamad Rostamkhani
Position
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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
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All information can be shared after identifying individuals

When the data will become available and for how long
Start data access after printing results

To whom data/document is available
Academic and industrial researchers

Under which criteria data/document could be used
After obtaining permission from the main executor of the project

From where data/document is obtainable
Mohammad RostamKhani Email: Moh.rostamkhani1993@gmail.com

What processes are involved for a request to access data/document
You will receive a reply after sending the email as soon as it is read

Comments