Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The Effects of Auricular Acupressure and Foot Reflexology on Constipation and Quality of Life in Elderly Women Attending Comprehensive Health Service Centers in Rafsanjan, 2026

Protocol summary

Study aim
Comparing the effects of ear acupressure and foot reflexology on constipation and quality of life in elderly women

Design
This phaseless clinical trial includes three groups (ear acupressure and foot reflexology intervention groups and control). A simple randomization method (random number table) will be used to randomly assign 90 eligible elderly people to the three intervention groups above.

Settings and conduct
The intervention is performed on elderly women with constipation who refer to comprehensive health centers. Ear acupressure interventions are one session by the researcher in person and nine sessions remotely at home by the elderly themselves, and foot reflexology is also one session in person and 11 sessions remotely at home.

Participants/Inclusion and exclusion criteria
• Age 60-75 years. • Mental alertness and ability to answer questions. • Minimum literacy. • No ulceration at the pressure point. • Diagnosis of constipation according to Rome III criteria. • Owning a smartphone

Intervention groups
This study has three groups (two intervention groups and a control group). The auricular acupressure and foot reflexology group includes clients with constipation according to Rome III criteria who receive the interventions. The control group also includes clients with constipation according to Rome III criteria who perform their usual daily activities.

Main outcome variables
Constipation and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150519022320N39**
Registration date: **2026-08-22, 1405/05/31**
Registration timing: **prospective**

Last update: **2026-08-22, 1405/05/31**
Update count: **0**

Registration date
2026-08-22, 1405/05/31

Registrant information
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01

Expected recruitment end date
2026-11-22, 1405/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effects of Auricular Acupressure and Foot

Reflexology on Constipation and Quality of Life in Elderly Women Attending Comprehensive Health Service Centers in Rafsanjan, 2026

Public title
effect of foot reflexology and auricular acupressure on constipation and quality of life
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Mental alertness and ability to answer questions Minimum literacy No wound at the pressure point. Diagnosis of constipation according to Rome III criteria. Having a smartphone
Exclusion criteria:
Unwillingness to continue collaborating in research Incomplete completion of questionnaires Sores on the legs or ears Treating constipation with medication Death of the client travel Allergy to Vaccaria seeds
Age
From **60 years** old to **75 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
After selecting the samples based on the characteristics of the study, the samples were randomly divided into three intervention groups: ear acupressure, foot reflexology, and control. In this way, they were randomly selected based on numbers and a random number table and placed in three groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Rafsanjan University of Medical Sciences
Street address
Rafsanjan, Nurse Street, Rafsanjan School of Nursing and Midwifery
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Province
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Postal code
7718796755
Approval date
2026-06-03, 1405/03/13
Ethics committee reference number
IR.RUMS.REC.1405.030

Health conditions studied

1

Description of health condition studied
constipation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Constipation in older women
Timepoint
All participants completed the Rome III questionnaire and the Constipation Assessment Tool before and after the intervention.
Method of measurement
ROME 3 criteria and constipation assessment scale

2

Description
Quality of life of elderly women
Timepoint
All participants will complete the Patient Assessment of Constipation Quality of Life (PAC-QOL) questionnaire before and after the intervention.
Method of measurement
Patient Assessment of Constipation Quality of Life (PAC-QOL) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The reflexology group will receive foot reflexology treatment for four weeks, three sessions per week, each session lasting fifteen minutes, each foot for seven minutes and thirty seconds. In the first session, which will be held in person, the researcher will meet with the participants and teach reflexology techniques. Key points including the large intestine, small intestine,

stomach and diaphragm will be introduced, and the training will begin with a 3D foot model and a standard educational video to improve visual understanding.The researcher practically demonstrates gentle circular and longitudinal pressure and uses colored educational pamphlets with a reflexology map and step-by-step images. After training, participants perform the massage in the presence of the researcher to verify the correctness of the technique, and a standard ten-item checklist is used to assess skill. If correct, permission to perform at home is issued. In subsequent sessions, participants continue at home at least three times a week, and it is recommended that the massage be performed after a warm bath and before bedtime.For monitoring and follow-up, the researcher will set up a schedule of three weekly phone or online calls for individuals to report their experiences and progress and raise challenges. A daily logbook will be provided including date, duration, massaged points, and optional photo or short video recording of the technique for visual feedback. An instruction booklet containing key points, images, and warnings will also be given to participants.

Category

Treatment - Other

2

Description

Intervention group: The ear acupressure group underwent ear acupressure for ten days, five consecutive days per ear. This method was designed based on the international standards of the Reflexology Association and the Academy of Ear Acupressure and in accordance with recent authoritative research. In this intervention, Vaccaria seeds are used as pressure stimuli, which are placed on specific points on the earlobe. The selected points include the colon, rectum, San Jiao, spleen, sympathetic lung, and subcortex areas, which, based on scientific evidence, are most closely related to digestive function and the regulation of bowel movements. These points are selected with the aim of stimulating the autonomic nervous system, improving bowel movements, and reducing symptoms of constipation.Before the intervention begins, the researcher, who has received specialized training in ear acupressure, identifies the exact location of each point using standard anatomical maps of the ear. Then, with sterile forceps, he places the Vaccaria seeds on the selected points and fixes them with a special (hypoallergenic) adhesive.After the beads are placed, the researcher applies gentle pressure to each point with their index finger or thumb to provide initial stimulation. The pressure should be just enough for the participant to feel a slight warmth or tingling sensation, without causing pain, redness, or discomfort. The initial pressure is applied for about three minutes for each point. The researcher then provides a training session to the elderly participants on how to safely stimulate these points at home. The training includes a practical demonstration of the pressure method, how to identify the points by touching the bead location, adjusting the pressure intensity, and maintaining ear hygiene.To facilitate learning, a visual ear map and simple instructional videos are used. The elderly are instructed to gently press each point using their fingers for 30 to 60 seconds three times a day (morning, noon, and night). The pressure should be just enough to cause mild stimulation, and if pain, redness, or itching occurs, the stimulation should be reduced or stopped.

Category

Treatment - Other

3

Description

Control group: The control group is given the same conditions as the intervention groups, but no intervention is performed and they are told to continue their usual daily activities.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Service Centers in Rafsanjan City

Full name of responsible person

Dr. Taybeh Mirzaei Khalilabadi

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Rafsanjan Universityof 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available