Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of Acupressure and Abdominal massage on constipation of elderly women

Protocol summary

Study aim
Determination and comparison of the effect of acupressure and massage on constipation of elderly women

Design
Clinical trials, with parallel groups, randomized

Settings and conduct
This study is a single-blind clinical trial. The research population of the elderly women referred to the first and second comprehensive health centers of Rafsanjan, who are suffering from constipation according to the Roman instrument. The sample size was estimated based on the statistical formula of 60 people. The samples were randomly divided into two intervention groups. So, after determining the elderly who are eligible to enter the study, their names are in the list, then the samples are included in the study according to the random numbers table.

Participants/Inclusion and exclusion criteria
Entry criteria include: 1- Elderly women 75-60 years old 2. Individuals who are mentally conscious and capable of answering questions 3. Constipation is confirmed in accordance with Roman criteria 3 and the constipation is the primary type. 4. The consent form has been completed 5. Amputations of the limb or the wound at the point of compression 6. No specific diet for constipation 7. Dependence or addiction to any drug 8. No history of recent trauma to the abdomen 9. Not having skin disease 10. Non-use of anti-constipation and anti-cholinergic drugs Exit criteria include: 1) Individual dissatisfaction to continue the research 2- Change the diet during the study to eliminate constipation

Intervention groups
One intervention group for 5 days is trained by a trainee specialist for 3 minutes each day for 3 minutes under acupressure at ST36 (Zusanli). The other intervention group also has 5 days, 20 minutes by a researcher trained under a classical abdominal massage

Main outcome variables
Constipation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150519022320N12**
Registration date: **2018-08-21, 1397/05/30**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-21, 1397/05/30**
Update count: **0**

Registration date
2018-08-21, 1397/05/30

Registrant information

Name
Tayebeh Mirzaei
Name of organization / entity
Rafsanjan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-01, 1397/05/10

Expected recruitment end date
2018-11-01, 1397/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of Acupressure and Abdominal massage on constipation of elderly women

Public title
Comparing the effect of Acupressure and Abdominal massage on constipation of elderly women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Elderly women 75-60 years old Individuals who are mentally conscious and capable of answering questions Constipation is confirmed in accordance with Roman criteria 3 and the constipation is the primary type. The consent form has been completed Amputations of the limb or the wound at the point of compression No specific diet for constipation Dependence or addiction to any drug No history of recent trauma to the abdomen Not having skin disease Non-use of anti-constipation and anti- cholinergic drugs

Exclusion criteria:
Individual dissatisfaction to continue the research Change the diet during the study to eliminate constipation

Age
From **60 years** old to **75 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
In this research, a blind researcher has been kept. At the end of each day, a questionnaire for the measurement of constipation is completed by a researcher-fellow in both groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Rafsanjan University of Medical Sciences ethics committee

Street address
School of Nursing and Midwifery, Nurse Avenue, Rafsanjan

City
Rafsanjan

Province
Kerman

Postal code
7718796755

Approval date
2018-07-17, 1397/04/26

Ethics committee reference number
IR.RUMS.REC.1397.018

Health conditions studied

1

Description of health condition studied
Constipation

ICD-10 code
K59.0

ICD-10 code description
Constipation

Primary outcomes

1

Description
Constipation

Timepoint
Before the intervention and at first,second,third,forth and fifth after intervention

Method of measurement
Constipation Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group is subjected to acupressure at ST36 (Zusanli) for 5 minutes, each day for 3 minutes by a researcher trained by an acupuncturist.

Category
Treatment - Other

2

Description
Intervention group: The intervention group is subjected

to classical abdominal massage for 5 days, each 15 to 20 minutes each day, by a trained researcher. Classic abdominal massage involves circular movements that are performed on the abdomen with surface and deep methods clockwise along the colon.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Health centers No. 1 and six cities in Rafsanjan

Full name of responsible person
Tayyebeh mirzaei

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Rafsanjan nursing faculty

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor of Research, Rafsanjan University of Medical Sciences

Full name of responsible person
Dr Shamsizade Ali

Street address
Rafsanjan University of Medical Sciences, Imam Ali Blvd, Rafsanjan

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T.mirzaei@rums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor of Research, Rafsanjan 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
Rafsanjan University of Medical Sciences

Full name of responsible person
Dr Tayebeh Mirzaei

Position
PhD, assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Geriatric Care Research Center, Jomhoori Eslami Bolv

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Person responsible for scientific inquiries

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Name of organization / entity
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Dr Tayebeh Mirzaei

Position
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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

No more information.

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