Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

A comparative study on the use of traditional Thai stomachics and consumption of plums on constipation in elderly women

Protocol summary

Study aim
Determining and comparing the effect of abdominal massage with traditional Thai medicine and plum on constipation in elderly women

Design
This study is a clinical trial with a control group, parallel groups, and a blind. 105 elderly people will be divided into 3 groups (two intervention and one control group) by simple random division method using random numbers table and will be divided again separately.

Settings and conduct
The research is a single-blind clinical trial study. The research community will be elderly women referring to the number one comprehensive health service center in Rafsanjan city, and according to Rome 3 tool, constipation will be confirmed in them. 105 people were selected from among those who met the criteria for entering the study and the samples were divided into three groups of 35 people by a simple random method.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 60-75 years Mental alertness and ability to answer questions The presence of primary type constipation and its confirmation based on Rome 3 criteria Absence of sores at the pressure point Not having a special diet to treat constipation Exclusion criteria: 1- lack of personal satisfaction to continue the research, 2- treatment of constipation with drugs, 3- foot, 4- travel, 5- failure to follow up according to the plan

Intervention groups
The recipient group will receive abdominal massage for 8 weeks, two sessions per week, and each session will last for 20 minutes. Abdominal massage will be performed 2 hours after breakfast by an elderly person trained by the researcher. The other intervention group consumes 50 grams of plums half an hour after lunch two days a week for 8 weeks. The control group will only receive routine care such as blood pressure measurement on a monthly basis.

Main outcome variables
Constipation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150519022320N35**
Registration date: **2024-08-12, 1403/05/22**
Registration timing: **prospective**

Last update: **2024-08-12, 1403/05/22**
Update count: **0**

Registration date
2024-08-12, 1403/05/22

Registrant information

Name
Tayebeh Mirzaei

Name of organization / entity
Rafsanjan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 34 3425 5900

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-22, 1403/06/01

Expected recruitment end date
2024-11-20, 1403/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study on the use of traditional Thai stomachics and consumption of plums on constipation in elderly women

Public title
A comparative study of the effect of traditional Thai abdominal massage and plum consumption on constipation in elderly women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 60-75 years Mental alertness and ability to answer questions The presence of primary type constipation and its confirmation based on Rome 3 criteria Absence of sores at the pressure point Not having a special diet to treat constipation Lack of regular physical activity No dependence or addiction to any drugs No history of recent abdominal trauma No skin disease Not using anti-constipation and anticholinergic drugs No history of neurodegenerative diseases Not having a body mass index greater than 34.9 (due to the increase in abdominal fat in obese people, it is not possible to perform a massage with the right pressure)

Exclusion criteria:
Lack of personal consent to continue the research Treatment of constipation with medicine Death Travel Failure to follow up according to plan

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: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
After entering the people with indicators into the study and listing them, they are divided into 3 groups of 35 people A, B and C by simple random division method using a random number table, and then again the groups are divided by simple random division and the type of they give. Intervention on each group (two intervention groups and one control group) It will be determined what intervention will be done on each group.

Blinding (investigator's opinion)
Single blinded

Blinding description
In the study, the researcher is kept blind and at the end of each week, the constipation measurement scale is completed by the researcher's colleague in all three groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Rafsanjan University of Medical Sciences

Street address
Emam Ali Bolv

City
Rafsanjan

Province
Kerman

Postal code
7718174715

Approval date
2024-07-31, 1403/05/10

Ethics committee reference number
IR.RUMS.REC.1403.076

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 on days 7, 14, 21, 28, 35, 42, 49, 56 after the intervention

Method of measurement
Constipation Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: in the group receiving abdominal massage for 8 weeks and two sessions per week (Saturday and Tuesday), each session for 20 minutes abdominal massage 2 hours after breakfast (according to the requirements of Thai massage, which must be one hour from the meal is past) will be done by a person from the elderly family trained by the researcher.

Category

Treatment - Other

2

Description

Intervention group 2: The other intervention group consumes 50 grams of plums that are hygienically packed by the researcher, half an hour after lunch, for 8 weeks and two days a week (Saturday and Tuesday). The group of people will visit the center on a weekly basis and receive their weekly allowance

Category

Treatment - Other

3

Description

Control group: The control group will only receive routine care such as blood pressure measurement on a monthly basis

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center No. 1 in Rafsanjan city

Full name of responsible person

Tayyebeh mirzaei

Street address

Faculty of Nursing، Nurse Blvd، Jomhury street، Rafsanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr.Reza Vazirinejad

Street address

Rafsanjan University of Medical Sciences, Imam Ali Blvd, Rafsanjan

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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

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

Tayebeh Mirzaei

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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