Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of foot reflexology on the severity of constipation of elderly women Residents of the Kahrizak Geriatric Nursing Home

Protocol summary

Summary

The purpose of this study was to determine the effect of reflexology on the severity of constipation of elderly women Residents of the Kahrizak Geriatric Nursing Home. The informed consent form stated that the elderly may receive massage reflexology or nonspecific. Patients and assessor is responsible for monitoring the trend of constipation patients were unaware of the intervention, and therefore the study was double-blind, parallel clinical trial. Inclusion criteria included: Having over 65 years of age, mentally alert and able to answer questions, constipation approved in accordance with the physician's medical records and diagnosed according to the Rome III diagnostic criteria , informed consent, no history of gastrointestinal obstructive disorders, gastrointestinal inflammatory diseases, spinal cord injuries, Parkinson's disease, systemic lupus erythematosus, hypothyroidism, hyperparathyroidism, hypopituitarism, progressive leg varicose veins, thrombophlebitis, bone tuberculosis and psychiatric disorders, according to medical records; lack of history of foot reflexology; lack of use Antiparkinsonian drugs, and Sympathomimetics, opiates, anti-diarrheal drugs; lack of history of substance abuse, alcohol and psychotropic drugs; lack of history of injuries, open wounds and foot surgery in the past two years, according to history, medical records and observed a researcher. Exclusion criteria were: emergency medical symptoms and side effects during treatment; change their diet to relieve constipation during testing; lack of personal satisfaction to continue the research at any time during the study. In order to prevent interference and abuse of subjects were selected from two distinct sections. 56 elderly women with constipation in Kahrizak nursing home residents who were eligible were randomly assigned to experimental and control groups of 28 persons. The experimental group received a 6-week session and a 30 minute foot reflexology intervention was performed and to remove the effects of touch and maintain blind conditions, similar to the control group, the experimental group received nonspecific massage at the same time. Constipation is the main outcome variable in this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101319516N1**
Registration date: **2014-11-12, 1393/08/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-12, 1393/08/21

Registrant information

Name

Mina Jabbarzad Zaki

Name of organization / entity

Islamic Azad University Tehran Medical Branch

Country

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University, Tehran Medical Branch

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-08-22, 1393/05/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of foot reflexology on the severity of constipation of elderly women Residents of the Kahrizak Geriatric Nursing Home

Public title
Effect of foot reflexology on constipation of elderly women Residents of the Kahrizak Geriatric Nursing Home
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: women aged 65 years old and over; mentally alert and able to answer the questions; constipation approved in accordance with the physician's medical records and diagnosed according to the Rome III diagnostic criteria; informed consent for participation in the study and informed consent (by the elderly person or a legal guardian); no history of gastrointestinal obstructive disorders, gastrointestinal inflammatory diseases, spinal cord injuries, Parkinson's disease, systemic lupus erythematosus, hypothyroidism, hyperparathyroidism, hypopituitarism, progressive leg varicose veins, thrombophlebitis, bone tuberculosis and psychiatric disorders, according to medical records; lack of history of foot reflexology; lack of use Antiparkinsonian drugs, and Sympathomimetics, opiates, anti-diarrheal drugs; lack of history of substance abuse, alcohol and psychotropic drugs; lack of history of injuries, open wounds and foot surgery in the past two years, according to history, medical records and observed a researcher. Exclusion criteria were: emergency medical symptoms and side effects during treatment; change their diet to relieve constipation during testing; lack of personal satisfaction to continue the research at any time during the study.
Age
From **65 years** old to **100 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Islamic Azad University Tehran Medical Branch
Street address
Tehran Medical Branch , Islamic Azad UniversityT, khaghani st, shariati Ave , Tehran, Iran
City
tehran
Postal code
193951495
Approval date
2013-07-10, 1392/04/19
Ethics committee reference number
1021- 92/4

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
Basline, at the end of each week during the intervention, after intervention
Method of measurement
Constipation Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description
In the experimental group foot reflexology for 6 weeks, one session per week for 30 minutes was performed.
Category
Treatment - Other

2

Description
To eliminate the effects of touch and maintain blind conditions similar to the experimental group, the control group received nonspecific massage at the same time.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kahrizak Charity Foundation
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University Tehran Medical Branch Vice chancellor for research
Full name of responsible person
Dr Seyed Shahabeddin Mohseni
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Tehran Medical Branch, Islamic Azad University, Khaghani st., Shariati Ave., Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University Tehran Medical Branch Vice chancellor for research
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty