

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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

Iran (Islamic Republic of)

Phone

+98 21 2200 6660

Email address

s_esmaeilpour@sbm.ac.ir

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

Baseline, 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

Street address

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

Name of organization / entity

Islamic Azad University Tehran Medical Branch

Full name of responsible person

Mina Jabbarzad Zaki

Position

Master of Science in Nursing

Other areas of specialty/work

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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)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty