Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Acupressure on Falls Self-Efficacy in Older Adults: A Sham-Controlled Randomized Clinical Trial

Protocol summary

Study aim
Determining the effect of acupressure on the self-efficacy of falling in the elderly

Design
A clinical trial of two parallel groups, single-blind, randomized by the random sequence method generated from the Randomization site will be conducted on 60 elderly patients.

Settings and conduct
After coordinating the visit days, the researcher, being present in the nursing home environment, will perform acupressure for the real acupressure intervention group and non-real massage for the sham group. In the first session, the demographic and FES questionnaire will be completed through interviews in both groups. Two groups receive massage at 4 points for 3 sessions of 11 minutes per week for four weeks. The massage will be done with fingertip pressure and in a semi-circle rotation in the clockwise direction.

Participants/Inclusion and exclusion criteria
1. Consent to participate in the study 2. Age 65 and above 3. A score of 7 and above from the AMT test 4. A score of 19 and above from FES questionnaire 5. Not having acute cognitive and mental disorders 6. Not having severe vision and hearing disorders 7. Not having acute neurological disorders, musculoskeletal disorders that disturb movement and balance, vestibular disorders and severe dizziness requiring medical care, cardiac and respiratory problems, and end-stage disease that may affect participation. 8. The ability to move independently or with an auxiliary device 9. The ability to communicate verbally and understand the Persian language 10. Not having wounds, fractures and lesions at the place of the intervention 11. Not having a parallel massage program

Intervention groups
The intervention group receives acupressure at Bai hui, Yin tang, Tai chong and Shen men pressure points. the sham group receives unreal massage at Feng fu, Cheng jiang, Yang lao and Da dun pressure points.

Main outcome variables
falls self-efficacy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221002056074N1**
Registration date: **2022-10-09, 1401/07/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-09, 1401/07/17**
Update count: **0**

Registration date
2022-10-09, 1401/07/17

Registrant information
Name
Mahdieh Mohajer
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-10-07, 1401/07/15
Expected recruitment end date
2022-12-06, 1401/09/15
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Acupressure on Falls Self-Efficacy in Older Adults: A Sham-Controlled Randomized Clinical Trial

Public title
The Effect of Acupressure on Older Adults Falls Efficacy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Consent to participate in the study 65 years or older A score of 7 and above from the AMT test A score of 19 or more from the FES questionnaire Ability to move independently or with an assistive device (walking aids) The ability to communicate verbally and understand the Persian language

Exclusion criteria:
Having acute cognitive and mental disorders Having severe vision and hearing impairments Having acute neurological disorders, musculoskeletal disorders that impair movement and balance, vestibular disorders and severe dizziness requiring medical attention, cardiac and respiratory problems, and end-stage disease that may affect participation. Having wounds, fractures and lesions at the place of intervention Having a parallel massage program

Age
From **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The random block method of four AABB, ABAB, BBAA, BABA prepared using the Randomization site will be used to allocate the research units to two groups. Preparation of blocks will be done before the start of sampling. The random sequence will be kept in a sealed envelope until the time of sampling.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, two groups of elderly participants who will receive acupressure intervention will be blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Nursing and Midwifery Faculty, Ibne-sina int., Taghiabad sq., Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2022-08-02, 1401/05/11

Ethics committee reference number
IR.MUMS.NURSE.REC.1401.060

Health conditions studied

1

Description of health condition studied
falling

ICD-10 code
R29. 6

ICD-10 code description
Tendency to fall because of old age or other unclear health problems

Primary outcomes

1

Description
The falls efficacy scale international (FES-I) score

Timepoint
Before the intervention, after the intervention in the fourth week

Method of measurement
The falls efficacy scale international (FES-I) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The massage receives pressure points in Bai hui, Yin tang, Tai chong and Shen men (respectively on the scalp, between the eyebrows, on the

back of the foot and on the wrist). This intervention will be carried out during 4 weeks (12 sessions) and 3 times a week for 11 minutes (8 minutes massage of 4 points + 3 minutes rest between pressure points 1-2, 2-3 and 3-4).

Category
Treatment - Other

2

Description
Control group: In sham or unreal acupressure group, massage will be performed on Feng fu, Cheng jiang, Yang lao and Da dun pressure points (back of the neck, on the chin, on the back of the wrist and on the big toe). This intervention will be carried out during 4 weeks (12 sessions) and 3 times a week for 11 minutes (8 minutes massage of 4 points + 3 minutes rest between pressure points 1-2, 2-3 and 3-4).

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Farzangan nursing home

Full name of responsible person
sharifi

Street address
No. 232, 31 Azadi corner, West Ibn Sina st., Esteghlal sq., Mashhad, Iran

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2

Recruitment center

Name of recruitment center
Bahar nursing home

Full name of responsible person
Maryam Haqi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
afsaneh kalani

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Nursing and Midwifery Faculty, Ibne-sina int., Taghiabad sq., Mashhad, Iran

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Mahdieh Mohajer

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Mashhad University of Medical Sciences
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Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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mohajerm992@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Part of the data, such as the information related to the fall self-efficacy score, and part of the research variables, such as osteoporosis, history of falls, smoking, etc., will be shared.
When the data will become available and for how long
The access period starts from 1402
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
Those who need to review the literature and have results and variables similar to this research.
From where data/document is obtainable
To receive, refer to the postal address mohajerm992@mums.ac.ir.
What processes are involved for a request to access data/document
After providing explanations and justifications for receiving the data files, the data will be sent via email.
Comments