Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of participating in support groups on social frailty and balance confidence among community-dwelling older adults

Protocol summary

Study aim
Determining the effect of participating in support groups on social frailty and balance confidence among community-dwelling older adults

Design
A randomized clinical trial with two intervention and control groups will be conducted on 132 elderly people who meet the inclusion criteria. Allocation of participants to intervention and control groups will be done by random block allocation method.

Settings and conduct
The place of study will be comprehensive health centres in south of Tehran affiliated to Tehran University of Medical Sciences. The initial sampling will be done by convenience sampling method. Then, 132 elderly people who meet the inclusion criteria will be allocated to two groups of intervention (66 people) and control (66 people) by random block allocation method. blinding will not be done.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Participants aged 65 to 75, literacy for writing and reading, having informed consent to participate in the study, ability to make eye contact and verbal communication Exclusion criteria: Suffering from cognitive impairment, unwillingness to participate in research, membership in similar groups

Intervention groups
For the intervention group support group sessions will be held 8 times. Each session will last 1 to 1.5 hours in 4 weeks. In these sessions the scenarios based on the components of social frailty and the balance confidence will be presented, then the participants will have group discussion about scenarios. The control group will receive the usual care provided in the health center. After the end of the intervention the content will also be available to the control group.

Main outcome variables
Social frailty, Balance confidence

General information

Reason for update
Considering the interim analysis, the lack of access to a larger sample size, and the limitations of the study, as well as the need to save time and resources, the sample size was reduced to 132 participants after the interim analysis and with the approval of the statistical advisor.

Acronym

IRCT registration information
IRCT registration number: **IRCT20240403061405N1**
Registration date: **2024-04-29, 1403/02/10**
Registration timing: **prospective**

Last update: **2025-05-19, 1404/02/29**
Update count: **1**

Registration date
2024-04-29, 1403/02/10

Registrant information

Name
Mina Zarrin

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6692 7171

Email address
mi.zarrin97@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-08, 1403/03/19

Expected recruitment end date
2024-12-09, 1403/09/19

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of participating in support groups on social frailty and balance confidence among community-dwelling older adults

Public title

The effect of participating in support groups on social frailty and balance confidence

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Participants aged 65 to 75 literacy for reading and writing Having Informed consent to participate in the study Ability to make eye contact and verbal communication

Exclusion criteria:

Membership in similar groups Unwillingness to participate in research Suffering from cognitive impairment

Age

From **65 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Elderly people who meet the inclusion criteria will be allocated to two groups of intervention and control by random block allocation method. for this purpose six blocks produced on www.randomizer.org will be used. In order to hide the random sequence, dark envelopes will be used to the number of samples.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Nursing, Midwifery and rehabilitation school of Tehran University of Medical Sci

Street address

School of Nursing and Midwifery, Tehran University of Medical Sciences, Mirkhani st, Tohid sq, Tehran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2024-03-17, 1402/12/27

Ethics committee reference number

IR.TUMS.FNM.REC.1402.254

Health conditions studied

1

Description of health condition studied

Social frailty

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Balance confidence

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Social frailty

Timepoint

Before the start of the intervention, straightaway and after 4 weeks from the last intervention session the questionnaires will be completed by the members of the intervention and control groups

Method of measurement

Makizako Social frailty Index

Secondary outcomes

1

Description

Balance Confidence

Timepoint

Before the start of the intervention, straightaway and after 4 weeks from the last intervention session the questionnaires will be completed by the members of the intervention and control groups

Method of measurement

Activities-specific balance confidence Scale

Intervention groups

1

Description
Intervention group: support group sessions will be held 8 times. Each session will last 1 to 1.5 hours in 4 weeks. In these sessions the scenarios based on the components of social frailty (Going out less frequently than last year, Living alone, Visiting friends sometimes , Feeling like helping friends or family, Talking with someone every day) and scenarios in relation to the balance confidence will be presented, then the participants will have group discussion about scenarios.

Category
Other

2

Description
Control group: This group will receive the usual care provided in the health center and no intervention will be performed

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive health centres in south of Tehran affiliated to Tehran University of Medical Sciences

Full name of responsible person
Mina Zarrin

Street address
School of Nursing and Midwifery, Tehran University of Medical Sciences, Mirkhani st, Tohid sq, Tehran

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mi.zarrin97@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ali Akbari sari

Street address
Sixth floor, Central office of Tehran University of Medical Sciences, Qods st, Keshavarz Blv

City
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Postal code
1417613151

Phone
+98 21 8163 3685

Email
info@tums.com

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mina Zarrin

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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
The participants' information will be kept confidential and can be made available by contacting the corresponding author with a justified reason
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
Researchers who work in academic and scientific institutions
Under which criteria data/document could be used
The data obtained from the study will be kept confidential and will be available to the corresponding author. If there is a need to access the data, it can be made available by contacting the corresponding author with a justified reason.
From where data/document is obtainable
Dr Sarieh Poortaghi s-poortaghi@tums.ac.ir School of Nursing and midwifery, Tehran University of Medical sciences
What processes are involved for a request to access data/document
The applicant will receive the information required after sending the request via email
Comments