

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of lifestyle education based on pender model on frailty outcomes in community-dwelling older adults

Protocol summary

Study aim

Determine the impact of lifestyle education based on pender model on frailty outcomes in community-dwelling older adults

Design

Clinical trial with control group, single-blind, randomized by 4-block method, 50 patients (25 people in each group).

Settings and conduct

The study population includes all the elderly referred to Omid Comprehensive Rehabilitation Clinic. Samples will be selected from those who meet the inclusion criteria. The calculated sample size is 50 people who will be randomly placed in the intervention and control group by the 4-block method. One-way blinding method will be used to prevent information bias. The present intervention will be performed for 3 months in 6 sessions of 30 minutes. The training will be done using a booklet based on the dimensions of a healthy lifestyle and through lectures, discussions and questions and answers. After the end of the training sessions until the end of the third month, telephone follow-up will be done on a weekly basis to follow up on the recommendations and fix the patients' problems. After the intervention, educational documents such as booklets and pamphlets will be provided to the control group.

Participants/Inclusion and exclusion criteria

inclusion criteria include: Having a desire to participate in research; Having frailty syndrome based on the Tilberg scale; Not Having moderate or severe cognitive impairment; Not Participation in other interventions (physiotherapy, occupational therapy, intra-articular injections) in Omid Clinic or other centers. Exclusion criteria: Reluctance to continue the intervention; Having an acute or severe illness that makes it impossible to continue the intervention.

Intervention groups

Intervention group: Lifestyle education based on Pender model. Control group: without intervention.

Main outcome variables

Ability to perform activities of daily living; Hospital readmissions; Fear of falling; Limitations in physical function.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201108049310N1**

Registration date: **2020-12-01, 1399/09/11**

Registration timing: **retrospective**

Last update: **2020-12-01, 1399/09/11**

Update count: **0**

Registration date

2020-12-01, 1399/09/11

Registrant information

Name

milad moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8889 8440

Email address

mimoradi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-23, 1399/06/02

Expected recruitment end date

2020-11-30, 1399/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lifestyle education based on pender model on frailty outcomes in community-dwelling older adults

Public title

Effect of lifestyle education based on pender model on frailty outcomes in community-dwelling older adults

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

A willingness to participate in research Having frailty syndrome based on the Tilberg scale Not Having Moderate or severe cognitive impairment Do not participate in other interventions (physiotherapy, occupational therapy, intra-articular injections) in Omid Clinic or other centers

Exclusion criteria:

Having an acute or severe illness Reluctance to participate in the intervention

AgeFrom **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

Block randomization method was used to assign samples to each of the intervention and control groups; Initially, the size of the blocks was considered to be 4, according to the number of samples, 13 blocks were selected based on a table of random numbers and individuals were assigned to groups based on the position of the blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to prevent bias in the work results, one-way blinding will be used and data collection will be done by a trained nurse who has no knowledge of the intervention and control groups and the studied outcomes.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

School of Nursing and Midwifery and Rehabilitation-
Tehran University of Medical Sciences

Street address

Enghelab St, 9 Vesal Shirazi St, 9 Vesal Student
Dormitory

City

Tehran

Province

Tehran

Postal code

1417743855

Approval date

2020-08-23, 1399/06/02

Ethics committee reference number

IR.TUMS.FNM.REC.1399.080

Health conditions studied**1****Description of health condition studied**

frailty syndrome

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Activities of Daily Living

Timepoint

Before the intervention and 3 months after the
intervention

Method of measurement

Katz Activities of Daily Living Inventory

2**Description**

Fear of fall

Timepoint

Before the intervention and 3 months after the
intervention

Method of measurement

Falls Self-Efficacy Scale questionnaire

3**Description**

Physical performance

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Short Physical Performance Battery Questionnaire & International Physical Activity Questionnaire

4

Description

Hospital readmissions

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Self-report

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The present intervention will be performed for 3 months in 6 sessions of 30 minutes. The training will be done using a booklet based on the dimensions of a healthy lifestyle and through lectures, discussions and questions and answers. After the end of the training sessions until the end of the third month, telephone follow-up will be done on a weekly basis to follow up on the recommendations and fix the patients' problems.

Category

Other

2

Description

Control group: After the intervention, educational documents such as booklets and pamphlets will be provided to the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Rehabilitation Clinic

Full name of responsible person

Neda Omid

Street address

South to North Valiasr St., Motahhari Intersection, Hosseini Rad Alley, No. 34

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Phone

+98 21 8880 1800

Email

miladmoradi3843@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology

City

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1417613151

Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

Web page address

<https://vcr.tums.ac.ir/>

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

Milad Moradi

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information about outcomes and demographic information can be published

When the data will become available and for how long

Data access period since the results were published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

All researchers working in academic and scientific institutions can request for access to information

From where data/document is obtainable

Milad Moradi Email: miladmoradi3843@gmail.com Phone: 09366663843

What processes are involved for a request to access data/document

Request information via email and it will be answered within a week.

Comments