

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of Home Modification on Falling, Occupational Performance and Life Habits in Elderly with Dementia

Protocol summary

Study aim

Effectiveness of Home Modification on Falling, Occupational Performance and Life Habits in Elderly with Dementia

Design

a clinical trial with a control group; with parallel groups; one-way blinded; randomized;

Settings and conduct

Participants are randomly selected from the available samples referred to hospitals under the auspices of the University of Medical Sciences in Tehran. After obtaining written consent and completing a questionnaire of some demographic information, other questionnaires are filled out for the intervention. Then, after 1 month and 2 months of the intervention, the home adaptation is re-evaluated and the scores are recorded. Finally, after 3 months of the intervention, the questionnaires used as outcome measurement tools are used to determine the impact of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Elderly people 65 and older have symptoms of dementia and have been approved by a neurologist. The level of dementia in the elderly is mild; (Dementia clinical rating test score is 4.5 to 9) Elderly with dementia, stay at home. Exclusion criteria: The elderly with dementia lives in a nursing home or is bedridden. The elderly have a history of other neurological problems, orthopedic and rheumatological disorders, acute psychiatric disorders based on the information in the medical record.

Intervention groups

Intervention: home modification is performed as an intervention. Home modification is a set of strategies that include home improvement and renovation, the use of assistive devices, the use of visual cues and memory aids, the re-arrange or removal of furniture and household hazardous items, and the simplify of activities. Control: They are waiting in line to receive the intervention.

Main outcome variables

Fall; Occupational Performance; Life Habits; Home Modification

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210106049950N1**

Registration date: **2021-05-31, 1400/03/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-31, 1400/03/10**

Update count: **0**

Registration date

2021-05-31, 1400/03/10

Registrant information

Name

Hamed Setoudeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 6497

Email address

h_setoudeh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-12, 1399/10/23

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effectiveness of Home Modification on Falling, Occupational Performance and Life Habits in Elderly with Dementia

Public title
Effectiveness of Home Modification on Falling, Occupational Performance and Life Habits in Elderly with Dementia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Elderly people 65 and older have symptoms of dementia and have been approved by a neurologist. The level of dementia in the elderly is mild; (Clinical Dementia Rating (CDR) test score is 4.5 to 9) Elderly with dementia, stay at home.
Exclusion criteria:
 The elderly with dementia lives in a nursing home or is bedridden. The elderly have a history of other neurological problems, orthopedic and rheumatological disorders, acute psychiatric disorders based on the information in the medical record.

Age
From **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be allocated into two groups using a permuted balanced block randomization method with the size of blocks 4 and 6. The random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Concealment is also guaranteed due to the use of permuted balanced block randomization method.

Blinding (investigator's opinion)
Single blinded

Blinding description
Only the statistical analyzer is blind and does not know about the assignment of individuals to groups and the data is provided to the analyzer in encrypted form.

Placebo
Not used

Assignment
Parallel

Other design features
p

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

No. 52, Vesal Shirazi Ave., Keshavarz, Blvd., Tehran University Town

City

Tehran

Province

Tehran

Postal code

1417743855

Approval date

2020-12-27, 1399/10/07

Ethics committee reference number

IR.TUMS.FNM.REC.1399.163

Health conditions studied

1

Description of health condition studied

dementia

ICD-10 code

F01

ICD-10 code description

Vascular dementia

Primary outcomes

1

Description

Fall

Timepoint

before intervention, 30, 60 and 90 days after intervention

Method of measurement

Home Falls and Accidents Screening Tool (HOME FAST)

2

Description

Occupational Performance

Timepoint

before intervention and 90 days after intervention

Method of measurement

Canadian Occupational Performance Measure (COPM)

3

Description

Life Habits

Timepoint

before intervention and 90 days after intervention

Method of measurement

Life Habits questionnaire (Life-H)

4**Description**

Home Modification

Timepoint

before the intervention and 30, 60 and 90 days after the intervention

Method of measurement

Home Falls and Accidents Screening Tool (HOME FAST)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: home modification. First, the demographic information questionnaire, the Canadian Occupational Performance Measure, and the Life Habits Questionnaire are completed for the participant. The home environment is then evaluated with Home Falls and Accidents Screening Tool. Then, for different environments of the house (kitchen, bathroom, stairs, ...) modification actions will be implemented if necessary. (Modifications actions for the intervention group include the following: 1. Modification for access, which includes; Doors, locks, handles, barriers, corridors, ramps, and bathroom modifications. 2. Check the edges of the stairs inside and outside the house 3. Check the condition of the floor coverings inside and outside the house, bathroom, and toilet 4. Check the floor surfaces for slipperiness 5. Check the floor coverings (carpet, rug, carpet, and padding) 6. Check the light access to the bedside lamp from bed 7. Check the brightness of outdoor paths, stairs, and entrances at night, which have enough light 8. Check the brightness of outdoor and indoor lights (Rooms, reception, hallway, bathroom, toilet, and kitchen) 9. Check the existence of non-slip floors for safe entry into the bathroom and bathtub and toilet 10. Check the installation of handles in the bathroom and next to the bathtub and shower 11. Check the direction Easy and safe access to the kitchen utensils 12. Check the railings of the inside and outside stairs of house 13. Check the safe access for pet care 14. Check the use of slippers and shoes that are perfectly suitable for the person's feet 15. Eliminate clutter and Indoor crowds 16. Check the required assistive devices 17. Check the arrangement of furniture and appliances 18. Use visual and auditory tips 19. Provide solutions to simplify activities)

Category

Rehabilitation

2**Description**

Control group: control

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ziaian Hospital

Full name of responsible person

Zahra Vahabi

Street address

20 meters from Abuzar, Abuzar Square, Qapan Crossroads, Qazvin St.

City

Tehran

Province

Tehran

Postal code

1366736511

Phone

+98 21 5517 6814

Email

ziaeian@tums.ac.ir

Web page address

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

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hamid Dalvand

Street address

Department of Occupational Therapy, Tehran University of Medical Sciences, Faculty of Rehabilitation, Faculty of Rehabilitation, Enghelab St.

City

Tehran

Province

Tehran

Postal code

6511111489

Phone

+98 21 7753 3939

Email

hdalvand@sina.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

University Town

City

Tehran

Province

Tehran

Postal code

1417743855

Phone

+98 74 3333 6497

Fax**Email**

h_setoudeh@razi.tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Hamed Setoudeh

Position

Master of Science

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

Street address

No. 52, Vesal Shirazi Ave., Keshavarz, Blvd., Tehran

University Town

City

Tehran

Province

Tehran

Postal code

1417743855

Phone

+98 74 3333 6497

Fax**Email**

h_setoudeh@razi.tums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hamed Setoudeh

Position

Master of Science

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

Street address

No. 52, Vesal Shirazi Ave., Keshavarz, Blvd., Tehran

University Town

City

Tehran

Province

Tehran

Postal code

141774385

Phone

+98 917 662 1050

Email

h.setoudeh7@gmail.com

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

Tehran University of Medical Sciences

Full name of responsible person

Hamed Setoudeh

Position

Master of Science

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

Street address

No. 52, Vesal Shirazi Ave., Keshavarz, Blvd., Tehran

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available