

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The Effect of Home-based care Educational Program on the Severity of Delirium and Functional Status of the Elderly Discharged from Imam Reza Hospital in Mashhad and the Burden of Care and Quality of Life of The informal Caregivers.

Protocol summary

Study aim

the impact of the delirium home care education on the severity of delirium and the functional status of the elderly after being discharged from Imam Reza Hospital in Mashhad and the burden of care and the quality of life of their caregivers.

Design

Randomized controlled educational experiment, 60 elderly people with delirium will be assigned to the intervention and control groups using permutation blocks. 30 people in each group.

Settings and conduct

the study will be conducted in Imam Reza Mashhad Hospital. the patients who meet the inclusion criteria will enter the study . People are divided into two intervention and control groups using permuted blocks randomization. The questionnaires will be completed by the elderly caregivers and the intervention group receives the educational contents for 2 months. Then the questionnaires are completed in both groups two months after the intervention.

Participants/Inclusion and exclusion criteria

The severity of delirium in the elderly is moderate or higher based on the DRS-98 questionnaire (score higher than 13.5); Not taking psychoactive drugs (such as opiates, antihistamines, etc.).

Intervention groups

An educational booklet containing information about delirium disease will be available to their caregivers when the patients in the intervention group are discharged. with the formation of the virtual group, educational materials and short films in the fields of common problems patients will be gradually provided to the participants. Individual consultations will also be provided to the caregivers based on the problems expressed by themselves, in the context of virtual

space. During this period, the control group will receive the usual interventions in the health system.

Main outcome variables

Delirium; caregivers' burden.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190225042843N1**

Registration date: **2023-01-31, 1401/11/11**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-31, 1401/11/11**

Update count: **0**

Registration date

2023-01-31, 1401/11/11

Registrant information

Name

Masoud Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 1001

Email address

karimeim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Home-based care Educational Program on the Severity of Delirium and Functional Status of the Elderly Discharged from Imam Reza Hospital in Mashhad and the Burden of Care and Quality of Life of The informal Caregivers.

Public title
The Effect of Home-based care Educational Program on the Severity of Delirium and Functional Status of the Elderly and the Burden of Care and Quality of Life of The informal Caregivers.

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Age 60 to 80 years for the patient (male and female) The elderly suffer from delirium (according to the 4AT screening test) One of the family members, as the main caregiver of the person, should take the main responsibility of taking care of the patient. The willingness of the elderly informal caregiver to participate in the study and sign the informed consent form The elderly caregiver should have at least reading and writing skills and have a smart mobile phone to communicate and receive educational messages. Be a resident of Mashhad city
Exclusion criteria:
The elderly do not suffer from obesity, physical disabilities, and chronic diseases that usually prevent them from performing daily tasks, before being admitted to the hospital.

Age
From **60 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
participants will assign to two intervention and control groups by the permuted block randomization (block size 4) using NCSS PASS software. By default, the software defines letters for the control and intervention groups, the user can, for example, define the letter A for the control group and the letter B for the intervention group. Finally, the output of the software is in the form of a list of 60 letters A and B which will be arranged randomly. The people under the study will be placed in one of the

two groups according to the order of the diagnosis and entering the study.

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 Shiraz University of Medical Sciences
Street address
Zand St., central building of Shiraz University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
71345-1978

Approval date
2022-04-17, 1401/01/28

Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1401.018

Health conditions studied

1

Description of health condition studied
delirium

ICD-10 code
Z74.2

ICD-10 code description
Other problems related to care-provider dependency

Primary outcomes

1

Description
Severity of delirium

Timepoint
before the start of the intervention and after the completion of the intervention

Method of measurement
Questionnaire Delirium Rating Scale-revised-98 (DRS-R-98)

2

Description

Performance in terms of activities of daily living

Timepoint

before the start of the intervention and after the completion of the intervention

Method of measurement

Questionnaire activities of daily living (ADL)

3

Description

Performance in terms of instrumental activities of daily living

Timepoint

before the start of the intervention and after the completion of the intervention

Method of measurement

Questionnaire of instrumental activities of daily life (IADL)

4

Description

Caring load in caregivers based on the Zarit questionnaire

Timepoint

After the intervention

Method of measurement

Zarit questionnaire

5

Description

Quality of life based on SF-12 questionnaire

Timepoint

before the start of the intervention and after the completion of the intervention

Method of measurement

Short Form Health Survey - 12 Item

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After completing the questionnaires, the intervention group will receive the educational program for two months. The educational content in this study will be in the form of an educational booklet containing information about delirium, its diagnostic and behavioral characteristics, and methods of controlling and dealing with delirium patients during the care of these patients. This educational booklet will be provided to the caregivers at the beginning of the program and when the intervention group patients are discharged. In addition, with the formation of a virtual group, educational materials and short films in the field of

common problems of delirium patients (such as sleep problems, hallucinations and delusions, confusion and aggression, disorientation, personality and behavior problems, etc.) The written educational content has been prepared and will be gradually provided to the study participants. In addition, in order to individualize the educational program, individual consultations will be provided to the caregivers based on the problems expressed by themselves, in the context of virtual space.

Category

Treatment - Other

2

Description

Control group: During the intervention, the control group as well will receive the usual interventions of the health system.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Mashhad

Full name of responsible person

Masoud Karimi

Street address

Razi Blvd., in front of Bargh Club, College of Health

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71536-75541

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mehtab Memarpour

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Masoud Karimi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical doctor, MPH

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Health Promotion

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

all collected deidentified IPD will be shared

When the data will become available and for how long

for six month from october 2023

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

Any analysis will be allowed, but it is not allowed to publish it without mentioning the source

From where data/document is obtainable

request data via email adress karimeim@sums.ac.ir

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

The data will be sent within two weeks after the request

Comments