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 completed by the elderly caregivers and the intervention group receives the educational contens 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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karimeim@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mehtab Memarpour
Street address
Razi Blvd., in front of Bargh Club, Faculty of Health
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Email
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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
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Other areas of specialty/work
Medical doctor, MPH
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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 willbe 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