Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Effectiveness of HELP (Hospitalized Elder Life program) care model to prevent delirium in hospitalized older patients

Protocol summary

Study aim
Determination of delirium incidence in intervention group and comparison with control group

Design
Clinical trials with control group, with parallel, double blind, randomized clinical trials

Settings and conduct
This study will be conducted on the elderly who are admitted to the internal wards of the Shahid Beheshti hospital in Kashan. Patients are assessed for delirium risk factors by two trainees assessor. Then, based on the initial assessment results, they are under the intervention of the HELP program. At the time of discharge, trained assessors pay for the patient's assessment. Patients in the control group are under routine hospital care. This group is also evaluated at the time of admission and discharge. Patients in both groups are evaluated for delirium in the hospitalization time. In the present study for blinding, Simple Blind method is used. Patients and assessor will be unaware of their study and assumptions.

Participants/Inclusion and exclusion criteria
Inclusion criteria: For this study, older patients (70 years and older) admitted to the hospital are screened for enrollment. Exclusion criteria: The selected patients should be have one of the risk factors for Delirium (visual, hearing, cognitive, sleep disturbance, impaired mobility and dehydration) and have a hospital stay of more than 7 days.

Intervention groups
Nursing interventions are designed based on delirium risk factors. Interventions in the intervention group include interventions such as therapeutic activity,early Mobilization, daily orientation, Sleep enhancement, Feeding Assistance/Fluid Repletion, and helping to resolve visual and auditory disorders. Patients in the control group receive routine patient interventions.

Main outcome variables
incidence of delirium.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180910040995N1**
Registration date: **2019-02-07, 1397/11/18**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-07, 1397/11/18**
Update count: **0**

Registration date
2019-02-07, 1397/11/18

Registrant information

Name
afsaneh kogaie Bidgoli

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 5472 5963

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-07, 1397/07/15

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effectiveness of HELP (Hospitalized Elder Life program) care model to prevent delirium in hospitalized older patients

Public title
Effect of HELP Model on Prevention of Delirium
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 70 years and older Patients admitted to the internal wards At least one risk factor for delirium at admission (visual impairment, hearing impairment, cognitive impairment , sleep problem, Mobilization impairment, and Dehydration The willingness to participate in the study by the patient and his care Able to communicate verbally Able to communicate in writing in Nonverbal patients Absence of delirium at admission
Exclusion criteria:
Age
From **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Since the delirium risk (moderate and severe) as a confounding variable can lead to imbalance in the intervention and control groups, the Allocation Stratified Block Random method is used in this study. Initially, a sample of 110 (in each group of 55) predicted for this study, based on the risk of delirium, is divided into two groups of moderate (55) and severe (55), then for each group with moderate risk and severe 14 blocks of 4 (2: 2 ratio, each with two controls and two persons) are considered. Determine the number of blocks and layout of individuals in each block using a random number table and determined by someone other than the researcher and those who participate in the sampling. The researcher will be informed by telephone by contacting him about how the block is arranged.
Blinding (investigator's opinion)
Double blinded
Blinding description
The researcher uses the following methods to reduce contact between patients in both control and intervention groups. 1. Considering that the hospital wards of the sampling site have 4-bed rooms, it is possible to observe and learn the interventions by patients or their carers in the control group so only one patient's room is selected for participation in the study. In case of non-limitation in time for sampling, the researcher can choose a patient to participate in the study in order to prevent the association of patients in the control and intervention groups from each ward. 2. In this study patients will be evaluated and interventions will be conducted by different people. Teaching people who take initial and daily evaluations of patients and those who are selected for interventions is conducted in separate educational sessions.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of university of Social Welfare and Rehabilitation Sciences
Street address
kodakyar Ave., daneshjo Blvd.,Evin
City
Tehran
Province
Tehran
Postal code
1985713834
Approval date
2018-02-26, 1396/12/07
Ethics committee reference number
IR.USWR.REC.1396.304

Health conditions studied

1

Description of health condition studied
delirium
ICD-10 code
F05
ICD-10 code description
Delirium due to known physiological condition

Primary outcomes

1

Description
delirium incidence according to CAM tool
Timepoint
Assessment of Delirium is done from patient's admission to the hospital and then every day until his discharge.
Method of measurement
Confusion Assessment Method tool

Secondary outcomes

1

Description
score of Activity daily living abilities
Timepoint
Assessment of Activity daily living ability is done at the time of the patient's admission to the hospital (before the intervention) and then the discharge time
Method of measurement
ADL-Barthel tool

2

Description
level of frailty
Timepoint
Assessment of frailty is done at the time of the patient's admission to the hospital (before the intervention) and then the discharge time
Method of measurement
Clinical Frailty Index

3

Description
Number of cases of falling during the hosptalization
Timepoint
The number of falls is checked during days of hospitalization
Method of measurement
documentation survey

4

Description
use of anti psychotics drugs or their dose
Timepoint
use of anti psychotics drugs or their dose are checked during days of hospitalization
Method of measurement
documentation survey

5

Description
Number of readmission after discharge of hospital
Timepoint
Number of readmission is checked 3 month after discharge of hospital
Method of measurement
telephone follow

Intervention groups

1

Description
Intervention group: Interventions are provided by nursing students in the form of a care program for elderly patients admitted to the hospital. Interventions include the following: 1.Develop & update individualized care plans. 2.Orientation/Daily Visitor: All patients are enrolled in the Daily Visitor/ Orientation Program. This program is done by Orientation board that a board that is written on with names of care team members and daily schedule) 3.Therapeutic Activities Program: All patients are enrolled in the Therapeutic Activities Program. This program is included activities e.g., discussion of current events, and word games.4. Sleep Enhancement: Patients who have difficulty falling asleep or sleep poorly at home or in the hospital are enrolled in The Sleep Protocol. This Protocol is included Nonpharmacologic Interventions e.g., to drink at bedtime, warm milk drink, relaxation recordings or music, and back massage.To use Unit-wide noise reduction strategies (e.g., quiet hallways) and schedule adjustments to allow uninterrupted sleep (e.g., rescheduling of medications and procedures). 5.Early Mobilization Program: All patients are enrolled in the Early Mobilization Program.This Program is Ambulation or active range-of-motion exercises three times daily.6. Vision Protocol: Patients are enrolled if near vision in both eyes that Visual aids is used e.g., glasses or magnifying lenses for them 7.Hearing Protocol: Patients are enrolled if they hear <3 whispers from each ear on the Whisper Test or are unable to hear fingers lightly rubbed on the Finger Rub Test. There are used for them Portable amplifying devices and special communication techniques 8.Feeding Assistance Program: Patients who rate their appetite as “poor” are enrolled into the Feeding Assistance Protocol. Level of feeding assistance is also determined by physical and cognitive impairment. This program is included Feeding assistance and encouragement patients during meals.9. Fluid Repletion is Early recognition of dehydration and oral volume repletion, i.e., encouragement of oral intake of fluids
Category
Prevention

2

Description
Control group: Patients in the control group are receiving routine cares in hospital. Usual care consisted of standard hospital care provided by physicians, nurses, and support staff (eg, dietitians, physical therapists) on hospital.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashan Shahid Beheshti Hospital
Full name of responsible person
Afsaneh Kogaie Bidgoli
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
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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
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Afsaneh Kogaie Bidgoli
Position
PHD Candidate
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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