

# 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)

##### Phone

+98 31 5472 5963

##### Email address

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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

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kodakyar Ave., daneshjo Blvd.,Evin

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**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 fraility

#### 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 hospitalization

#### 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

##### Street address

5th of Qotb -e Ravandi Blvd

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Kashan

##### Province

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
University of social welfare and rehabilitation sciences  
**Full name of responsible person**  
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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**  
Ph.D.  
**Other areas of specialty/work**  
Geriatrics  
**Street address**

#### Person responsible for scientific inquiries

##### Contact

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

##### Contact

**Name of organization / entity**  
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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