

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Evaluation of the Effect of Fall Prevention Education with Video on Fall Occurrence and Fear of it (Fall) among Older Hospital Inpatients

Protocol summary

Study aim

The aim of this study was to determine the effect of fall prevention education video on the occurrence of fall and fear of it (fall) in the elderly hospitalized

Design

A clinical trial with a control group with parallel, randomized groups on 132 patients that will be used for randomization from <https://www.Randomization.com>

Settings and conduct

This study will be performed in Shahid Beheshti Hospital in Qom on the elderly who meet the inclusion criteria. The fall prevention education video will be shown to the experimental group using the researcher's phone and the fall incident and fear of falling questionnaires will be used to assess the impact of the intervention. Blinding will be provided to researchers, outcome evaluators, and data analysts

Participants/Inclusion and exclusion criteria

Inclusion criteria including age over 60 years, functional dependence, ability to walk and move in the ward, no psychological memory impairment, ability to communicate and speak in Persian, no history of participation in fall prevention education programs, length of hospital stay From a week and at least once a history of falls before hospitalization Exclusion criteria also include death, exacerbation of the disease, or transfer from the ward

Intervention groups

For the experimental group, the intervention in the form of two short training videos is less than 15 minutes in total about the fall. There is no intervention for the control group and it receives the usual training of the department. In order to observe the ethics in the research and if the intervention is effective, the educational video will be provided to the control group via WhatsApp

Main outcome variables

fall occurrence and fear of it

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210910052427N1**

Registration date: **2021-09-17, 1400/06/26**

Registration timing: **prospective**

Last update: **2021-09-17, 1400/06/26**

Update count: **0**

Registration date

2021-09-17, 1400/06/26

Registrant information

Name

Nasrin Valieiny

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3776 8937

Email address

nasrin.valieiny1997@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-02-18, 1400/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Fall Prevention Education with Video on Fall Occurrence and Fear of it (Fall) among Older Hospital Inpatients

Public title

The Effect of Fall Prevention Education with Video on the Occurrence of Fall and Fear of it (Fall) in Hospitalized Elderly

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients over 60 years of age Patients who have the ability to walk and move in the ward Patients who have the ability to communicate and speak in Persian Patients who have at least one history of falls before hospitalization Patients who have been hospitalized for more than a week

Exclusion criteria:

Patients with functional dependence Patients with psychological memory impairment Patients who have a history of participating in fall prevention education programs

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

the samples are allocated by the block random allocation method in two groups of control and intervention. Depending on the sample size, 33 blocks of 4 are required for random allocation. The intervention group will be displayed with A and the control group with B. The website <https://www.Randomization.com> will be used to randomly determine the blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to hide the random allocation from the researcher, a dark envelope sample size is prepared and each of the random sequences created is recorded on a card and placed inside the envelope. At the beginning of the registration of individuals, according to the order of arrival of the samples, one of the envelopes is opened in order and the assigned group of that sample is specified

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Working Group / Research Ethics Committee School of Nursing and Midwifery and School of Rehabilitati

Street address

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Tohid Square, East Nosrat St., Tehran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2021-08-04, 1400/05/13

Ethics committee reference number

IR.TUMS.FNM.REC.1400.095

Health conditions studied**1****Description of health condition studied**

fall occurrence and fear of it

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Fear of Falling in the International Scale of Fall Efficiency

Timepoint

Before the start of the study, at the time of discharge, one and three months after discharge will be completed by the two control and test groups

Method of measurement

Questionnaire International Fall Efficiency Scale

Secondary outcomes**1****Description**

Percentage of people who have fallen

Timepoint

Before the start of the study, at the time of discharge, one and three months after discharge will be completed by the two control and test groups

Method of measurement

Fall Questionnaire

Intervention groups

1

Description

Intervention group: The intervention in the form of two short educational videos is less than 15 minutes in total. In these videos, the patient gets acquainted with the importance of the fall and its prevalence, the consequences of the fall, the risk factors for the fall, and how to use these mobility devices, as well as how to adjust the risk factors. The film is provided to the intervention group with the help of the researcher's mobile phone

Category

Prevention

2

Description

Control group: The control group will not receive any intervention and will benefit from the usual training in the ward. But at the end of the study, in order to observe the ethics in the research and if the educational video is effective on the fall occurrence and the fear of it, this video will be provided to the control group via WhatsApp.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Nasrin Valieiny

Street address

Shahid Beheshti Blvd, Shahid Dr. Beheshti
Educational Research and Treatment Center

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Web page address

<https://bmc.muq.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehrnaz Geranmayeh

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Tehran, Tohid Square, Nosrat Sharghi St, School of
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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

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

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahzad Pashaeypoor

Position

Associate Professor of Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In this study, all the information obtained after completing the fall and fear of falling questionnaire and after not identifying people can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

All researchers working in academic and scientific institutes can use the results of this study without any preconditions

From where data/document is obtainable

Shahzad Pashaeypoor, Associate Professor of Nursing, Department of Community Health Nursing and Elderly Nursing, School of Nursing and Midwifery, Tehran University of Medical Sciences 00989124913843 sh-pashaeipour@tums.ac.ir Postal code: 1419733171

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

Without providing any specific documentation, the information will be available to them as soon as possible in the form of set instructions

Comments