

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The impact of educational intervention on the self-efficacy and patient falls of hospitalized patients: A quasi-experimental, before-after trial

Protocol summary

Study aim

The impact of patient education in preventing patient falls

Design

This is a quasi-experimental study that will be performed before and after the intervention. The study population will be including inpatients of one of the selected hospital in Tabriz's in the year 2020. The sample size will be 173 based on a similar study and sampling formula. Samples will be randomly selected based on inclusion criteria. Prior to the study, participants will complete informed consent and a questionnaire will be provided to patients.

Settings and conduct

The intervention will be conducted for approximately 6 months. Patients (according to the inclusion criteria) will be educated and their knowledge and self-efficacy before and after the education will be calculated, and finally, the fall rate (as a final outcome) will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria included: Being at least 18 years old, having a minimum hospital stay of at least 4 days, and having a Morse risk score above 25. Exclusion criteria include Being unwilling to participate in the study, being unconscious and having a Morse risk score lower than 25.

Intervention groups

In this study, patients will be trained based on an educational program aimed at increasing their knowledge and self-efficacy about falling patients. Educational content is formulated through a review of the literature and clinical experience of specialists. A trained nurse will educate patients throughout the study. Face to face and pamphlets will be used for this purpose. Patients' knowledge and self-efficacy will be measured by valid questionnaires before and after education.

Main outcome variables

Knowledge and self-efficacy and rates of patient fall

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200109046067N1**

Registration date: **2020-03-29, 1399/01/10**

Registration timing: **prospective**

Last update: **2020-03-29, 1399/01/10**

Update count: **0**

Registration date

2020-03-29, 1399/01/10

Registrant information

Name

Zahra Chegini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 1048

Email address

cheginiz@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of educational intervention on the self-efficacy and patient falls of hospitalized patients: A quasi-experimental, before-after trial

IR.TBZMED.REC.1397.617

Health conditions studied

1

Description of health condition studied

Fall involving bed

ICD-10 code

W06

ICD-10 code description

Fall from bed

2

Description of health condition studied

Fall involving wheelchair, Fall involving chair

ICD-10 code

W05

ICD-10 code description

Fall from non-moving wheelchair, nonmotorized scooter and motorized mobility scooter

3

Description of health condition studied

other fall on same level

ICD-10 code

W01

ICD-10 code description

Fall on same level from slipping, tripping and stumbling

Primary outcomes

1

Description

Patients' knowledge about patient falls

Timepoint

Before patient education and 7 days after training

Method of measurement

Using a valid questionnaire consisting of 20 items with three options of correct, false and do not know about patient knowledge to prevent falls

2

Description

Self-efficacy of patients to prevent patient falls

Timepoint

Before patient education and 7 days after training

Method of measurement

A validated 15-item questionnaire on self-efficacy for preventive falls with a four-choice Likert scale

3

Description

Number of patient falls in six months

Timepoint

At the end of intervention (end of September)

Method of measurement

Public title

The impact of patient education in preventing patient falls

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Hospital stay of at least 4 days Morse risk score above 25

Exclusion criteria:

Morse risk score lower than 25 Patients' unconsciousness

Patients' Unwillingness

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **170**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

School of Management and Medical Informatics, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz 5165665811, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665811

Approval date

2018-10-22, 1397/07/30

Ethics committee reference number

Based on the patient fall data recorded in the hospital information system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with high risk of falls as intervention group before and after intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital at Tabriz

Full name of responsible person

Zahra Chegini

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School of Management and Medical Informatics,
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Z.cheginy@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Khosro Asibkia

Street address

International Relations Office, No 2 Central Building,
Tabriz University of Medical Sciences, University
Street, Tabriz, PO Box: 5165665931, Iran

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+98 41 3334 4280

Email

z.cheginy@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

zahra chegini

Position

phd candidate

Latest degree

Master

Other areas of specialty/work

Health Service Management

Street address

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Person responsible for scientific inquiries

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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

The data from the questionnaire information will be presented in tables.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Patient data at the request of the responsible author

From where data/document is obtainable

Email to Corresponding Author: Zahra Chegini
Z.cheginy@gmail.com

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

About a week after emailing the request to the announced address

Comments

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Chegini

Position

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Latest degree

Master

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