

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of tele-nursing education on the incidence and extent of post-discharge pressure ulcer in stroke patients

Protocol summary

Study aim

Determining the effect of tele-nursing education on the incidence and extent of post-discharge pressure ulcer in stroke patients

Design

A randomized trial using color cards, with two parallel intervention (n=30) and control (n=30) groups, not blinded

Settings and conduct

This study will be conducted in the post-discharge phase of stroke patients admitted to Ghaem Hospital in Mashhad. Eligible patients are randomly divided into two groups via tele-training using (bale) messengers and routine practice. Finally, the incidence and extent of pressure ulcer will be compared between two groups.

Participants/Inclusion and exclusion criteria

Inclusion: Braden Scale for pressure ulcer less than 14. Age between 45 to 75 years old. Speak in Farsi. BMI between 13-32 kg/m². Have reading and writing literacy. Access to mobile phone with internet (patient or his relatives). Exclusion: Symptoms of pressure ulcer or skin disorders at the beginning of the study. Speech and/or hearing problems.

Intervention groups

Intervention group: At discharge, an educational session will be held for the patient or his primary caregiver. After registering an address and phone number, the patient or the primary caregiver will join the channel and group of "Bale" Messenger. Educational contents in the form photos, videos, text, audio files, and more are offered to them to prevent pressure ulcer. At discharge of control groups, an educational session will be held and educational pamphlets are given to them as routine.

Main outcome variables

Incidence and the extent of pressure ulcer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190824044595N1**

Registration date: **2020-02-26, 1398/12/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-26, 1398/12/07**

Update count: **0**

Registration date

2020-02-26, 1398/12/07

Registrant information

Name

Fatemeh Fashaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

fashaeif951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of tele-nursing education on the incidence and extent of post-discharge pressure ulcer in stroke patients

Public title

The effect of tele-nursing education on the incidence of pressure ulcer

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient has no symptoms of pressure ulcer or skin disorders at the beginning of the study. Braden Scale less than 14 Age between 45 to 75 years Residency in Mashhad Willingness to participate in the study Speak Farsi BMI between 13-32 kg/m² Have reading and writing ability Mobile phone with internet access (patient or his attendance)

Exclusion criteria:

Has movement restriction (e.g. hemiplegia or paraplegia or quadriplegia) Has speech and/or hearing problem

Age

From **45 years** old to **75 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

Randomization will be done using color cards. In this way, the red (intervention) and green (control) cards will be randomly arranged in an envelope. Then, with the gradual entry of patients into the study, one of the cards that determines group allocation, respectively, will be awarded.

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 Mashhad University of Medical Sciences

Street address

School of Nursing and Midwifery ,Ibn Sina Street, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2019-11-26, 1398/09/05

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.072

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

Stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes**1****Description**

Incidence of pressure ulcer

Timepoint

At the beginning and one month after the intervention

Method of measurement

Pressure ulcer grading scale EPUAP/NPUAP

2**Description**

Extent of pressure ulcer

Timepoint

At the beginning and one month after the intervention

Method of measurement

Push scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: At the discharge, a training session will be held at the hospital for the patient or his primary caregiver. Then all the necessary educational contents about preventing bed ulcers, susceptible areas, diet and skin care ... in the different formats as photos, videos, text and audio are presented via the channel created in the (Bale) messenger (according to the Ministry of Health protocol). Communicating with the patient or their primary caregiver is performed through this messenger during 24 hours a day, as personal message or group message.

Category

Prevention

2

Description

Control group: At discharge, an educational session will be held for the patient or his primary caregiver. Then they are given educational pamphlets as routine.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Fatemeh Fashaei

Street address

Ghaem Hospital, Ali Shariati Square, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical 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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Fashaei

Position

MsC student of Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Razieh Froutan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

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

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable