

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of telenursing on caregiver burden of care and incidence of complications in patients with acute stroke discharged from neurological ward in the hospitals affiliated to Qom University of Medical Sciences, 2019

Protocol summary

Study aim

The effect of tele-nursing on caregiver burden and complications in acute stroke patients discharged from neurology wards of

Design

Two arm parallel group, single-blind randomized clinical trial

Settings and conduct

After approving the study proposal and obtaining permission from the Ethics Committee and relevant authorities at Qom University of Medical Sciences and after obtaining permission from the relevant authorities of hospitals affiliated to Qom University of Medical Sciences, refer to and coordinate with the neurology department and select patients with inclusion criteria for the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Acute stroke diagnosis. Willingness to participate in research. Access to telephone. Having a normal hearing, vision and mental strength. Having a caregiver under the following conditions: Fluency in Farsi language, Not having neurological and mental disorders, Not being a medical staff member. Exclusion criteria: Readmission, History of previous hospitalization due to stroke, Patient death, Unwillingness to continue cooperation or disconnection. Presence of bed wounds and urinary problems at discharge.

Intervention groups

After discharge, patients in the intervention group receive counseling and training on effective measures to reduce caregiver burden of care, as well as prevention of pressure ulcers, falls, and urinary tract problems in addition to the discharge time training. They can contact the researcher any hour of the day if needed. But in the control group, only routine discharge training is provided by department personnel.

Main outcome variables

The incidence of pressure ulcer; The number of falls; The incidence of urinary problems; Mean score of caregiver burden of care, in acute stroke patients discharged from neurology wards.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190806044455N1**

Registration date: **2019-10-23, 1398/08/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-23, 1398/08/01**

Update count: **0**

Registration date

2019-10-23, 1398/08/01

Registrant information

Name

Amir Hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3662 2188

Email address

amirhoseini750@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of telenursing on caregiver burden of care and incidence of complications in patients with acute stroke discharged from neurological ward in the hospitals affiliated to Qom University of Medical Sciences, 2019

Public title

The effect of telenursing on caregiver burden of care and incidence of complications in patients with acute stroke discharged from neurological ward

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of acute stroke with the approval of a neurologist
Willingness to participate in the research
Access to the phone after discharge
Have normal hearing, vision and mental ability to communicate
Having a primary caregiver at home with the following conditions:
Ability to speak, read and write in Farsi, no neurological and mental disorders (based on self report), no member of the health care staff

Exclusion criteria:

Patient readmission after discharge. history of previous hospitalization for stroke
The patient died
Unwillingness to continue cooperation or disconnect telephone conversation
The presence of bed sore at different degrees at the time of discharge
Urinary complications and problems at discharge (according to the complication checklist)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into two groups of experimental and control by Block randomization and adaptive sampling. The table is first set up by random sampling block method. Then, according to the preset table, patients will be divided into experimental and control groups. Since even with favorable randomization the patients in the two groups may not be quite similar in terms of confounding factors, after collecting half of the samples the patients characteristics such as

age, susceptibility to bed sore and collapse will be monitored, basis on the Morse and Braden scales. If the distribution of these variables in two groups are significant difference then, by weighing method patients will be directed to groups whose frequency of characteristics are less.

Blinding (investigator's opinion)

Single blinded

Blinding description

General information about the study will be provided to all participants. But consultations are only given to the test group based on the patient's needs and the control group not aware of its content. Obviously, after one month and evaluating the patients in the control group, the necessary information and guidance based on the patients' needs, will given to them.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

School of Nursing. Namazi Hospital. Namazi Square.

City

Shiraz

Province

Fars

Postal code

71936-13119

Approval date

2019-05-05, 1398/02/15

Ethics committee reference number

IR.SUMS.REC.1398.297

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

Acute stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

The burden score on the Novak questionnaire.

Timepoint

30 days

Method of measurement

Novak Barriers Care Questionnaire .

2

Description

Percentage of patients with urinary complications, bed sores and falls after discharge

Timepoint

30 days

Method of measurement

A researcher-made questionnaire on disease complications

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to the discharge time training provided by the neurology staff, in the first week, all content training is provided in at least three telephone calls, followed by telephone counseling and follow-up for 3 weeks and the duration of each call. It will take about 15 to 20 minutes on average

Category

Prevention

2

Description

Control group: In the control group, only routine discharge training is provided by department personnel.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology Care Departments of Qom University of Medical Sciences Hospitals

Full name of responsible person

Amir Hoseini

Street address

Nursing School.Namazi Hospital. Namazi Square.

City

Shiraz

Province

Fars

Postal code

7293613119

Phone

+98 25 3662 2188

Email

amirhoseini750@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Yunes Ghasemi

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

Phone

+98 71 3235 7282

Fax

+98 71 3212 2430

Email

vcrdep@sums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Amir Hoseini

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery
Street address
Shiraz - Namazi Square - School of Nursing and Midwifery (SA)
City
Shiraz
Province
Fars
Postal code
7193613119
Phone
+98 71364742548
Email
amirhoseini750@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Nasrin Sharifi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
Faculty of Nursing and Midwifery of Hazrat Fatemeh, Namazi Square
City
Shiraz
Province
Fars
Postal code
7193613119
Phone
+98 71364742548
Fax
Email
sharifin@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Amir Hoseini
Position
Student

Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery - Namazi Square
City
Shiraz
Province
Fars
Postal code
7193613119
Phone
+98 25 3662 2188
Fax
+98 71 3647 4252
Email
amirhoseini750@gmail.com

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

A portion of the information, such as information on the main outcome can be shared.

When the data will become available and for how long

Start the access period 6 months after publishing article

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

The data will be available for similar scientific research with respect to the rights of early researchers.

From where data/document is obtainable

Data can be accessed by email to the the person who responsible for answering.

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

Contact the responsible person by email:
amirhoseini750@gmail.com

Comments