Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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. Thay 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

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Iran (Islamic Republic of)

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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 bedsore 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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Position
Student
Latest degree
Bachelor
Other areas of specialty/work

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Person responsible for updating data

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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
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