Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

Investigation of the Effect of Tele-nursing on Care Burden in Caregivers of Elderly Patients with Stroke

Protocol summary

Study aim

Due to the meaningful increase in the elderly population in Iran and the high spread of stroke in the elderly and its complicationsand incidence of care burden in caregivers on elderly with stroke, in this regard a study was designed to investigate the effect of tele- nursing on the care burden of caregivers of elderly stroke patient.

Design

The present study is a randomized clinical trial study on caregivers of stroke patients that will be conducted after getting permission .

Settings and conduct

First, elderly 60 years and older patients with a diagnosis of stroke that were hospitalized in the neurology department of Bu-Ali hospital during 1 to 6 past months were extracted and if they have inclusion criteria and fixed caregiver they will be contracted and will enter the study after obtaining the consent letter. Then, participants will be randomly divided into intervention and control groups using a 4-block randomized method.

Participants/Inclusion and exclusion criteria

Study entry for study: Having the consent having direct resposibility for the care of the elderly patient Having a family relationship with the patient Having a mobile phone Resident of Qazvin having a minimum primary education minimum age 18 years and older non payment for care Exclusion criteria for caregivers: enabling to communicate simultaneous care of both stroke and non-stroke patients. Unwillingness to cooperate or disconnect the phone connection the use of nursing service offices Mental illness diagnosed

Intervention groups

A training booklet will be provided to both intervention and control groups, then training will be provded during tele-nursing according to the patients problem to the intervention group during phone connection and through social networks. Questionnaires before and after will be filled out in both groups.

Main outcome variables

Elderly, tele-nursing,caregiver burden, caregivers, stroke

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200222046585N1**
Registration date: **2020-07-29, 1399/05/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-29, 1399/05/08**
Update count: **0**

Registration date

2020-07-29, 1399/05/08

Registrant information

Name

Name of organization / entity

Country

Phone

Email address

hoda.ar485@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Effect of Tele-nursing on Care Burden

in Caregivers of Elderly Patients with Stroke

Public title
Tele-nursing and Care Burden in Caregivers
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having the consent to participate in the study having direct resposibility for the care of the elderly patient at least 8 hours a day Having a family relationship with the patient, including the spouse, child, brother, sister that living with the patient. Having a mobile phone with the capability to install soroush app Resident of Qazvin having a minimum primary education minimum age 18 years and older non payment for care
Exclusion criteria:
enabling to communicate simultaneous care of both stroke and non-stroke patients Unwillingness to cooperate or disconnect the phone connection for two weeks in the first months of intervention(experiment) and for three weeks in the second and third months of intervention
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Firstly, the sampling method will be purposeful and accessible. participants will be randomly divided into intervention and control groups using a 4-block randomized method.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Given that both groups have got primary education at discharge time, a training booklet will be provided for the intervention and control groups. Also, considering the patients problem, after the needs assessment, training in tele-nursing time will be done in the first contact with the caregiver, then in the intervention group the training will be provided during phone connection through social network.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Qazvin University of Medical Sciences; Shahid Bahonar Boulevard; Qazvin
City
Qazvin
Province
Qazvin
Postal code
3419759811
Approval date
2020-05-27, 1399/03/07
Ethics committee reference number
IR.QUMS.REC.1399.037

Health conditions studied

1

Description of health condition studied
stroke
ICD-10 code
G46.3
ICD-10 code description
Brain stem stroke syndrome

Primary outcomes

1

Description
The care burden questionnaire was made by zarit etal. to measure care burden. the questionnaire includes 22 questions about personal,social,emotional and economic burdens that will be completed by the researcher through interviews with family caregivers. in this tool,based on the questions the care burden in caregivers is divided into two objective and mental groups.
Timepoint
Measurement of care burden before and 12 weeks after intervention
Method of measurement
Zarit Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
intervention group:caregivers of elderly stroke

patients(above 60 years old) are firstly selected with a diagnosis of stroke then if they have inclusion criteria and consrnt letter, they will participate in the study.An educational booklet will be given to intervention groups and questionnaire will be completed first. Then, training during tele- nursing due to the patients problem after the needs assessment, which will be done in the first contact with the care giver in the intervention group through 12 weeks phone connection and social network. The questionnaire will be filled out again after 12 weeks.

Category

Lifestyle

2

Description

Control group:caregivers of elderly stroke patients(above 60 years old) are firstly selected with a diagnosis of stroke then if they have inclusion criteria and consent letter, they will participate in the study.An educational booklet will be given to intervention groups and questionnaire will be completed first.The questionnaire will be filled out again after 12 weeks without any intervention.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali Hospital

Full name of responsible person

Hoda Baniardalan

Street address

Booali Hospital; Street Booali; Qazvin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Mahdi Emamjome

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Hoda Baniardalan

Position

Master student of eldrly nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Qazvin, University of Medical Sciences,Shahid Bahonar Boulevard,Qazvin

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person
Fatemeh Mohammadi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Geriatrics

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Person responsible for updating data

Contact

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hoda bani ardalan

Position
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Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available