

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The effect of tele-nursing on the outcome of care by caregivers of patients with head trauma after discharge from hospital

Protocol summary

Summary

The effect of tele-nursing on the outcome of care by caregivers of patients with head trauma after discharge from hospital. This study is conducted on home caregivers of patients with head trauma. Using convenient sampling method, a sample size of 72 patients is selected from among patients presenting with head trauma for the first time, who are then placed in intervention and control groups (36 patients in each) using random block method. Intervention is conducted on patients' family in the form of telephone follow-up and outcomes (readmission or incidence of pressure wounds) on patients are assessed. Data are collected using a checklist comprising "patient's condition" and "outcome of care" sections. Validity and reliability of the checklist are confirmed using content validity and internal consistency with Cronbach's alpha, respectively. A day before patient's discharge, all caregivers (in both intervention and control groups) are trained on how to perform patient care at home, and a booklet is also given to them. The questioner phones caregivers in the intervention group once a week for 12 weeks and collects data on patient's condition. Caregivers in this group are also able to contact the questioner at any time they require further information about the patient.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014110919868N1**

Registration date: **2015-12-04, 1394/09/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-04, 1394/09/13

Registrant information

Name

Atousa Amouzegar

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3335 9303

Email address

a.amouzegar@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

governmental, vice chancellor for research of Qazvin University of Medical Sciences.

Expected recruitment start date

2015-05-10, 1394/02/20

Expected recruitment end date

2015-06-20, 1394/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of tele-nursing on the outcome of care by caregivers of patients with head trauma after discharge from hospital

Public title

The effect of tele-nursing on head trauma patients' situation

Purpose

Supportive

Inclusion/Exclusion criteria

Study inclusion criteria for patients include age range 18-60 years, level of consciousness 11 to 15 based on Glasgow Coma Scale, admission for the first time following head trauma, with no known urinary or respiratory infections and no infectious pressure wounds, no grade 3 or 4 pressure wound, no diagnosed with known diabetes, no tracheostomy, and no PEG. Study inclusion criteria for caregivers are having minimum literacy (reading and writing), Family member who is responsible for the care and at least half of the time of day to take care of patient, availability on the phone (landline or mobile), no speech or hearing impairments, non-employment in healthcare professions, and willingness to take part. Study exclusion criteria is use of caregivers from nursing homes

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Patients would be allocated to study and control by balanced block randomization.

Secondary Ids

empty

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

Ethics Committee of Qazvin university of medical sciences

Street address

Nursing & Midwifery School, Qazvin university of medical sciences, Bouvl. Shahid Bahonar, Qazvin

City

Qazvin

Postal code

3419759811

Approval date

2014-10-15, 1393/07/23

Ethics committee reference number

D/20/9376

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

Head trauma

ICD-10 code

VI

ICD-10 code description

Other specified disorders of brain in diseases classified elsewhere

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

readmission

Timepoint

For study group telephone follow up every week during 12 weeks period of time, and for controls just telephone contact after 12 weeks.

Method of measurement

Questionnaire

2**Description**

pressure wound incidence

Timepoint

For study group telephone follow up every week during 12 weeks period of time, and for controls just telephone contact after 12 weeks.

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

Caregivers' viewpoints about telenursing

Timepoint

after 12 weeks telephone follow

Method of measurement

Questionnaire

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

Telephone follow up (via landline or mobile) of patients' condition in 12 weeks period of time through contact with family caregivers once a week

Category

Other

2**Description**

Control: During patient discharge and after 12 weeks

,control patients are assessed in terms of readmission and pressure wound incidence.
Category
 Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Atousa Amouzegar

Street address

Hasan Abad Sq, Emam Khomeini St, Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Atousa Amouzegar

Street address

End of Boul. Keshavarz, Tehran

City

Tehran

3

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Atousa Amouzegar

Street address

Three-way Jalal Ahmad, North Kargar St, Tehran

City

Tehran

4

Recruitment center

Name of recruitment center

Baharloo Hospital

Full name of responsible person

Atousa Amouzegar

Street address

Behdari St. Rah ahan Sq, Tehran

City

Tehran

5

Recruitment center

Name of recruitment center

Ziaeeian Hospital

Full name of responsible person

Atousa Amouzegar

Street address

Region 17, municipality, Abuzar Street, Crossroads ghapan, Qazvin Street, Tehran

City

Tehran

6

Recruitment center

Name of recruitment center

Shohada-E-Tajrish hospital

Full name of responsible person

Atousa Amouzegar

Street address

Btween Tajrish Sq and Quds Sq, Shahrdari St, Tajrish Sq, Tehran

City

Tehran

7

Recruitment center

Name of recruitment center

Emam Hossein Hospital

Full name of responsible person

Atousa Amouzegar

Street address

shahid madani St, Emam Hossein Sq, Tehran

City

Tehran

8

Recruitment center

Name of recruitment center

Hazrat-E- Rasool Akram Hospital

Full name of responsible person

Atousa Amouzegar

Street address

Nyayesh street, Satarkhan street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Qazvin University of Medical Sciences

Full name of responsible person

Dr Fatemeh Mohamadi

Street address

Nursing & Midwifery School, Qazvin university of medical sciences, Blvd Bahonar, Qazvin

City

Qazvin

Grant name

-

Grant code / Reference number

-

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

Yes
Title of funding source
Vice Chancellor for research of Qazvin University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Atousa Amouzegar
Position
Nursing master degree student
Other areas of specialty/work
Street address
App. 2, N. 52, Golestan 7, Nahid street, Blvd.
Marzadaran, Tehran
City
Tehran
Postal code
1461664844
Phone
+98 21 4424 3502
Fax
+98 28 3323 7268
Email
atousa.amouzgar@gmail.com
Web page address
www.qums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of medical sciences
Full name of responsible person
Akram Shahrokhi
Position
MSc. Faculty member
Other areas of specialty/work
Street address

Room 236, Nursing&Midwifery school,Qazvin
University of Medical Sciences, Bamonar Blvd
City
Qazvin
Postal code
3419759811
Phone
+98 28 3333 9569
Fax
+98 28 3323 7268
Email
a.shahrokhi@qums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Atousa Amouzegar
Position
Master degree student,Critical Care Nursing
Other areas of specialty/work
Street address
App. 2, N. 52, Golestan 7, Nahid street, Blvd.
Marzadaran, Tehran
City
Tehran
Postal code
1461664844
Phone
+98 21 4424 3502
Fax
Email
atousa.amouzgar@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty