

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)

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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 Bamonar, 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

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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

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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

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6

Recruitment center

Name of recruitment center

Shohada-E-Tajrish hospital

Full name of responsible person

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Street address

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

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7

Recruitment center

Name of recruitment center

Emam Hossein Hospital

Full name of responsible person

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Street address

shahid madani St, Emam Hossein Sq, Tehran

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Tehran

8

Recruitment center

Name of recruitment center

Hazrat-E- Rasool Akram Hospital

Full name of responsible person

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Nyayesh street, Satarkhan street, Tehran

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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