

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of home-based training on the incidence of pressure ulcer and family caregiver`s of burden patients discharged with stroke

Protocol summary

Study aim

Determining the effect of home-centered education on family caregivers' caring burden and incidence of bed sore in patients with discharge stroke

Design

In this study, 70 patients with a stroke who have entered the study are randomly divided into two groups of intervention and control and each participant is given a special code.

Settings and conduct

A study on stroke patients and their carers in Imam Ali hospital in Zahedan.

Participants/Inclusion and exclusion criteria

Patient login criteria: 1. The patient has no symptoms of bed sore or skin disorders at the start of the study. 2. Patients with a Brad's benchmark score of less than 14 in their baseline scores. 3- Stay in Zahedan. 4- Age 45 to 75 years. Patient exit criteria: 1- Readmission or death of the patient during the study period. 2- To take the patient to the care centers. 3- Skin disease during the study. 4. Having suspicious wounds. Family Career Entry Criterion: 1. Age over 18 years. 2. Be careful of the main responsibility of the patient. 3. Having reading and writing skills. 4- Residing in the city of Zahedan. 5. The absence of other family members, the maintenance of a mental illness or elderly in the family. Family Care Exit Criteria: 1- Absence of more than 1 session of training sessions. 2- The occurrence of any burden stress incident for the caregiver during the study.

Intervention groups

In the control group, the questionnaires were then taken to the patient's address and call number again. After 12 weeks, no intervention was given to the patient and the caregiver to receive the post-test. The intervention group filled out the questionnaire from the caregiver and the patient. Then the intervention was given as 3 sessions of 1 week interval. In the case of stroke, subcutaneous wound, anxiety control, after 12 weeks of post-test.

Main outcome variables

Prevent bed sores and attendant care burden

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20171105037236N4**

Registration date: **2018-12-23, 1397/10/02**

Registration timing: **retrospective**

Last update: **2018-12-23, 1397/10/02**

Update count: **0**

Registration date

2018-12-23, 1397/10/02

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 33442481

Email address

askarihas77@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-22, 1396/07/30

Expected recruitment end date

2018-06-09, 1397/03/19

Actual recruitment start date

2017-10-22, 1396/07/30

Actual recruitment end date

2018-06-09, 1397/03/19

Trial completion date

2018-11-21, 1397/08/30

Scientific title

The effect of home-based training on the incidence of pressure ulcer and family caregiver's of burden patients discharged with stroke

Public title

Home-centered teaching of stroke patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patient login criteria: 1. The patient has no symptoms of bed sore or skin disorders at the start of the study. 2. Patients with a Brad's benchmark score of less than 14 in their baseline scores. 3- Stay in Zahedan. 4- Age 45 to 75 years. Family Career Entry Criterion: 1. Age over 18 years. 2. Be careful of the main responsibility of the patient. 3. Having reading and writing skills. 4- Residing in the city of Zahedan. 5. The absence of other family members, the maintenance of a mental illness or elderly in the family.

Exclusion criteria:

Patient exit criteria: 1- Readmission or death of the patient during the study period. 2- To take the patient to the care centers. 3- Skin disease during the study. 4. Having suspicious wounds Family Care Exit Criteria: 1- Absence of more than 1 session of training sessions. 2- The occurrence of any burden stress incident for the caregiver during the study.

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **2**

70

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

this way, red cards (intervention) and control cards (prefixes) will be pre-numbered and randomly ordered. Then, with the choice and gradual entry of patients and caregivers to study, each of the above-mentioned cards will determine the allocation of the group

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

does not have

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of zahadan university of medical sciences

Street address

School Of Health, Zahedan University Of Medical Sciences, Jannat Blvd, Prof. Hesabi Sq, Zahedan, Iran. Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Approval date

2018-01-13, 1396/10/23

Ethics committee reference number

ir.zaums.rec.1396287

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quality Of Life

Timepoint

Before And 12 Weeks After Intervention

Method of measurement

Zarit's Care Load Questionnaire, Braden's Wound Burden Risk Evaluation Score

Secondary outcomes

1

Description

Recurrent stroke

Timepoint

3 months later

Method of measurement

Individual medical records

Intervention groups

1

Description

Intervention group: 3 training sessions on bed stroke and lowering of care burden in the form of a hospital discharge day meeting and two sessions at a weekly interval at the patient's home and at the hospital.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital Zahedan

Full name of responsible person

Hasan Askari

Street address

School Of Health, Zahedan University Of Medical Sciences, Jannat Blvd, Prof. Hesabi Sq, Zahedan, Iran.
Zahedan Sistan And Baluchestan Iran,

City

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Email

askarihas77@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Nor Muhammad Bakhsani

Street address

University of Medical Sciences and Health Services,
Zahedan University of Medical Sciences, Dr. Hesabi -
Persian Gulf Blvd

City

Zahedan

Province

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Email

bakhsani@zaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Hasan Askari

Position

Nursing Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Zahedan -
Fellowship

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hasan Askari

Position

Nursing Instructor

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Faculty of Nursing and Midwifery, Zahedan, Zahedan
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Email
askarihas77@yahoo.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

The main outcomes of the participants are public.

When the data will become available and for how long

6 months after the results

To whom data/document is available

Researchers at academic and academic institutions

Under which criteria data/document could be used

Statistical result

From where data/document is obtainable

Nursing and Midwifery Faculty of Zahedan Phone and
Fax: 05433442481 Zip Code: 9816913396 Address:
Faculty of Nursing and Midwifery, Zahedan, Zahedan
Nursing and Midwifery Faculty, Fellowship Square

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

Contact the Nursing Faculty Library section.

Comments

does not have.