Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Effectiveness of supportive educative program on the Burden in family caregivers of stroke patients

Protocol summary

Study aim
Determining the effect of the implementation of an educational-support program on the care burden of the caregivers of stroke patients in Zahedan city

Design
The method of providing educational content is individually and face-to-face to each caregiver, and during each session, the training items will be taught first, then it will be practiced practically with the caregiver, and finally, it will be done independently by him and after the researcher's assurance. Learning will be provided by the caregiver in the next training and another case. The educational program will be implemented in the form of 6 sessions with the opinion of the patient's caregiver and in a place that is comfortable for him

Settings and conduct
The researcher examined the cases hospitalized during the last 6 months in the medical center affiliated to Zahedan University of Medical Sciences (Khatam (pbuh), Ali Ibn Abi Talib (pbuh) and Bu Ali hospitals) that accepts patients with stroke. will get In the intervention group, the needs assessment questionnaires, demographic information and disease information and care burden questionnaire are provided to the caregivers of the patients to be completed by them.

Participants/Inclusion and exclusion criteria
Entry criteria: (patients) 1- Confirmation of the diagnosis of stroke (of the ischemic type for the first time) by the attending physician 2-Consciousness level (GCS) 11 or higher when they are discharged from the intensive care unit of the ICU) Having a caregiver at home 3-Having a 3rd or 4th degree rating scale within 48 hours after a stroke (the scale for examining the level of functional disability of patients following a stroke, where the patient's disability is graded from 0 to 5)

Intervention groups
Caregivers of ischemic stroke patients

Main outcome variables
burden of care

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231120060120N1**
Registration date: **2024-02-02, 1402/11/13**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-02, 1402/11/13**
Update count: **0**

Registration date
2024-02-02, 1402/11/13

Registrant information

Name
Mahla Dahmardeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3348 6610

Email address
mahla.dahmardeh.nurse1999@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effectiveness of supportive educative program on the Burden in family caregivers of stroke patients

Public title
Effectiveness of supportive educative program on the Burden

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Entry criteria: (patients) 1- Confirmation of the diagnosis of stroke (of the ischemic type for the first time) by the attending physician 2-Consciousness level (GCS) 11 or higher when they are discharged from the intensive care unit of the ICU) Having a caregiver at home 3- According to the different needs of patients after a stroke, patients will be selected who suffer from problems of lack of self-care in the fields of self-care (such as bathing, feeding, movement problems and inability to move the body, etc.). 4- Patients will be included in the study who are in the age range of 20 years and above (because in addition to elderly people who suffer from strokes due to chronic diseases, one of the types of CVA is due to trauma and accidents and it is possible involve young people as well) 5-Having a 3rd or 4th grade rating scale within 48 hours after a stroke (the scale for examining the level of functional disability of patients following a stroke, where the patient's disability is graded from 0 to 5) Determining the severity of patients' disability in 72 hours after the onset of stroke: Rankin's standard scale with grades 0-5 Classification of severity of disability is used: Grade zero, the patient has no abnormal neurological symptoms. Grade 1 has disability without significant symptoms. It means the patient is capable to perform all his normal duties and activities. Grade 2 has mild disability. It means able to do everything It is not the previous activities, but it is able to take care of itself without the help of others. Grade 3 has moderate disability. It means that he needs the help of others, but he is able to walk without the help of others. Grade 4 has moderate to severe disability. That is, he is unable to walk without the help of others. Grade 5 has severe disability. It means that the patient is always in bed and needs round-the-clock nursing measures. Entry criteria: (careful) Willingness to participate in the study. (Having consent to participate in the study) Caregiver does not have experience working in the therapy team The age of the caregiver should be between 20 and 70 years. (for the ability to care for a person with a stroke) Do not have a speech or hearing or vision impairment. Be literate in reading and writing. Physically, he should be able to take care of the patient and not have any illness or disorder. Having direct responsibility in patient care for at least 8 hours a day Having a family relationship with the patient, including wife, child, brother, sister Failure to receive payment for care

Exclusion criteria:

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Table of random numbers

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of zahedan University of Medical Sciences

Street address
Zahedan Meydan Mashahir Faculty of Nursing and Midwifery

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
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Approval date
2023-11-11, 1402/08/20

Ethics committee reference number
IR.ZAUMS.REC.1402.293

Health conditions studied

1

Description of health condition studied
Ischemic stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
supportive educative program

Timepoint
3 month
Method of measurement
Novak and Gast care pressure questionnaire (1989

Secondary outcomes

1

Description
Burden
Timepoint
3 month
Method of measurement
Novak and Gast care pressure questionnaire (1989

Intervention groups

1

Description
Intervention group: In the intervention group, the needs assessment questionnaires, demographic information and disease information and care burden questionnaire are provided to the caregivers of the patients to be completed by them. In the intervention group, the designed educational program is given to the caregivers of the patients and they are taught. The method of providing educational content is individually and face-to-face to each caregiver. During each session, the training items will be taught first, then it will be practiced practically with the caregiver, and finally it will be done independently by him and after the assurance of the researcher. Learning will be provided by the caregiver in the next training and another case. The educational program will be implemented in the form of 6 sessions with the opinion of the patient's caregiver and in a place that is comfortable for him. 6 training sessions will be held, attendance in all sessions is optional, but attendance in sessions where their problem will be known will be mandatory. After three months after the completion of the training, the questionnaires are again given to the caregivers of the patients to be completed. In the control group, the questionnaires are first given to the caregivers of the patients and according to the same routine training that they received in the hospital. They are not given any other training, and after three months, the questionnaires are provided to the caregivers in the control group to complete. During this study, the patients are continuously followed up by the researcher, and the researcher is informed about the patient's condition by following up and being with the caregivers and answers the questions and doubts of the caregivers. In the end, the educational materials will be provided to the control group in order to comply with the ethical principles.
Category
Rehabilitation

2

Description
Intervention group:
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Ibn Abi Talib Hospital, Zahedan
Full name of responsible person
Hanieh dahmardeh
Street address
Zahedan - Mashahir Square - Zahedan School of Nursing and Midwifery
City
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Sistan-va-Balouchestan
Postal code
9816743463
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+98 54 3344 2481
Email
zahedannursingandmidwifery@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Mohsen Taheri
Street address
Zahedan_Doctor Hasabi Square_Medical Sciences Campus
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Province
Sistan-va-Balouchestan
Postal code
009817
Phone
+98 54 3337 2151
Email
info@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
80
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

hanieh dahmardeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Hanieh dahmardeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mahla dahmardeh

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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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

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

The data will be published as an article

When the data will become available and for how long

3 months

To whom data/document is available

Every one

Under which criteria data/document could be used

The results will be published in the form of chapter 4 of the thesis and the results of the article

From where data/document is obtainable

chapter 4 of the thesis and the results of the article

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

Take a E-mail

Comments