

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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

--

#### 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**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Phone**

+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

**City**

Zahedan

**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

**Street address**

Zahedan Meydan Mashahir FacultyOf Nursing and  
Midwifery

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Phone**

09805433442481

**Email**

haniedahmardeh@gmail.com

**Person responsible for scientific 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

**Street address**

Zahedan Meydan Mashahir FacultyOf Nursing and  
Midwifery

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Phone**

09805433442481

**Email**

haniedahmardeh@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mahla dahmardeh

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Zahedan Meydan Mashahir FacultyOf Nursing and  
Midwifery

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816113876

**Phone**

09833486610

**Email**

mahla.dahmardeh.nurse1999@gmail.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**

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**