

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The Effect of Education Basis of the Roy's adaptation model on the quality of life and resilience of Family caregivers of stroke patients

Protocol summary

Study aim

Evaluation of the Effect of Education Basis of Roy's adaptation model on the quality of life and resilience of Family caregivers of stroke patients

Design

A clinical trial, with a control group, with parallel groups, Randomized block design on 104 family caregivers of stroke patients, The site (www.sealedenvelope.com) was used to generate a block random allocation sequence.

Settings and conduct

This study is a randomized clinical trial and will be conducted on family caregivers of stroke patients hospitalized in two neurology departments in the Besat Educational and Therapeutic Center, Hamadan. After acquiring informed consent, caregivers are randomly allocated to one of two intervention or control groups. Caregivers in the intervention group will get four education sessions every other day and the adaptation, quality of life, and resilience of the groups will be evaluated on the primary day before the intervention and 2 months after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient's affliction with stroke (hemorrhagic or ischemic) - The patient's Barthel index score lower than 75 - Caregiver's dominant role in patient care. Exclusion criteria: Readmission or patient death before final evaluation - Lack of regular participation in education sessions.

Intervention groups

In the intervention group, each family caregiver will receive an education based on Roy's adaptation model every other day and during 4 sessions. In the control group, they will only receive routine education.

Main outcome variables

Adaptation and quality of life and resilience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230208057360N2**
Registration date: **2023-06-21, 1402/03/31**
Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**

Update count: **0**

Registration date

2023-06-21, 1402/03/31

Registrant information

Name

Amin Monjezi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 938 604 9016

Email address

aminnurseajums@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-10-07, 1402/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Education Basis of the Roy's adaptation model on the quality of life and resilience of Family caregivers of stroke patients

Public title

The Effect of Education on the quality of life and resilience of Family caregivers of stroke patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient's affliction with stroke (hemorrhagic or ischemic). Patient's first time experience of stroke. At least 24 hours have passed since the patient was admitted to the neurology department The patient's Barthel index score lower than 75. patient should be taken home after discharge. The patient must be older than 45 years old. Caregiver's dominant role in patient care. The caregiver must be Introduced by the patient or the person's statement as the patient's dominant caregiver. Lack of academic education in medical sciences in the caregiver of the patient or other members of the patient's family (parents and spouse, sister, brother, child). The caregiver must be at least 18 years old. The caregiver must be literate and able to read and write in Persian. Caregiver's availability via phone. Family caregivers shouldn't have a mental illness or be treated with psychoactive medications.

Exclusion criteria:

Readmission or patient death before final evaluation Caregiver or patient receive an educational program except the usual hospital program during the study period. Lack of regular participation in education sessions caregiver doesn't complete the questionnaires appearance a crisis in the caregiver's life (such as divorce - loss of loved ones, etc.)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method will be accomplished using the permutation block method in such a way that first, the blocks of four ABBA, AABB, and ABAB, BBAA, BAAB, and BABA will be produced by the website (www.sealedenvelope.com), And each block will be placed in an envelope. Then, when the family caregivers enter the study, one of the envelopes will be randomly selected, and according to the desired block, the first four family caregivers will be assigned to two groups. This process will continue until the total number of samples is completed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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6517838695

Approval date

2023-01-28, 1401/11/08

Ethics committee reference number

IR.UMSHA.REC.1401.933

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

stroke

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

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

Quality of Life

Timepoint

before intervention and two months after intervention

Method of measurement

Adult Caregiver Quality of Life Questionnaire (AC-QoL)

2**Description**

Resilience

Timepoint

before intervention and two months after intervention

Method of measurement

Connor-Davidson Resilience Scale

Secondary outcomes

1

Description

adaptation

Timepoint

Before the intervention and two months after the intervention

Method of measurement

Roy Questionnaire

Intervention groups

1

Description

Intervention group: The intervention group will receive four sessions of education based on Roy's adaptation model every other day for 30 to 45 minutes in the patient education room of the neurology department of Hamedan Besat Education and Treatment Center, in addition to routine medical care. Educational content is gathered based on nursing and medical literature review. Educational sessions include: identifying the educational needs in 4 dimensions based on Roy's model and educating the physiological dimension to the caregivers - education the self-concept dimension - education the role function dimension - education the interdependence dimension, respectively. During the intervention, caregivers will be followed up through phone calls. A training booklet will be given to the intervention group. Assessment of the quality of life, resilience, and adaptation of the family caregivers will be done before the intervention and two months after the last educational session.

Category

Behavior

2

Description

Control group: there are no interventions in this group. Measures for measuring the variables of the research will be carried out as in the intervention group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Amin Monjezi

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Shahid Beheshti Blvd., Besat hospital, Hamadan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Amin Monjezi

Position

Nursing student

Latest degree

Master

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available