Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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
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Iran (Islamic Republic of)
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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
City
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Province
Hamadan
Postal code
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
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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