Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of family-centered empowerment education model on quality of life of menopausal women with stroke and their caregivers

Protocol summary

Study aim
Determining the effect of family-based empowerment training on the quality of life of postmenopausal women with stroke and their caregivers at Farshchian Hospital in Hamadan

Design
This is a randomized clinical trial study in which 88 patients and their caregivers who are eligible to enter the study will be randomly assigned to two intervention and control groups.

Settings and conduct
Women who are hospitalized in the neurology department of Farshchian Hospital due to a stroke and their main caregiver will enter the study if they are eligible and will be randomly assigned to the intervention and control groups by the method of 4 blocks randomization.

Participants/Inclusion and exclusion criteria
Patient inclusion criteria: Hospitalization due to stroke Willingness to participate in the study Be alert Having hearing health More than 48-72 hours have passed since the stroke (passed the acute stage) The patient's level of disability is moderate and mild (based on the Bartel index) Be woman Be menopause More than 40 years old Family caregiver inclusion criteria: Age 18 years old and up Should not have psychological problems Having reading and writing skills and ability to speak Persian Patient exclusion criteria:The patient's physical and mental condition is acute Inability to communicate Family caregiver exclusion criteria: Receiving an educational program except the normal schedule of the hospital Lack of regular participation in the implementation of family-center empowerment model steps

Intervention groups
Intervention group: routine care of the ward plus training based on the family-centered empowerment model in 4 sessions, each session for one hour, control group: only routine care of the ward

Main outcome variables
Patient quality of life Family care quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200530047596N1**
Registration date: **2020-06-08, 1399/03/19**
Registration timing: **prospective**

Last update: **2020-06-08, 1399/03/19**
Update count: **0**

Registration date
2020-06-08, 1399/03/19

Registrant information

Name
Mansoureh Refaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2021-06-22, 1400/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of family-centered empowerment education model on quality of life of menopausal women with stroke and their caregivers

Public title
The effect of family-centered empowerment education model on quality of life of women with stroke and their caregivers

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patient inclusion criteria: Hospitalization due to stroke Willingness to participate in the study Be alert Having hearing health More than 48-72 hours have passed since the stroke (passed the acute stage) The patient's level of disability is moderate and mild (based on the Bartel index) Be woman Be menopause More than 40 years old Family caregiver inclusion criteria: Age 18 years old and up Should not have psychological problems Having reading and writing skills and ability to speak Persian

Exclusion criteria:
Patient exclusion criteria:The patient's physical and mental condition is acute Inability to communicate Family caregiver exclusion criteria: Receiving an educational program except the normal schedule of the hospital Lack of regular participation in the implementation of family-center empowerment model steps

Age
From **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **88**
More than 1 sample in each individual
Number of samples in each individual: **2**
Patient and caregiver

Randomization (investigator's opinion)
Randomized

Randomization description
Patients randomly assigned to the intervention and control groups by using 4 random blocks will be conducted.The randomization unit is the individual. For this purpose, before the intervention, a random allocation sequence will be determined by one of the researchers. The sequence is determined so that the states of the 4 blocks, which are 6 states (AABB-ABAB - BBAA-BABA-ABBA-BAAB) are written on paper and randomly removed 22 times (88 samples) by replacement and The order is recorded. Group A will be the intervention group and B will be the control group. The prepared sequence remains with the researcher and then, when performing the intervention, it is presented to the other researcher who is not aware of the sequence (concealment).

Blinding (investigator's opinion)
Single blinded

Blinding description
First, the goals of the study are explained to the patient, and then, in dealing with each sample, the patient is randomly assigned to a group.Then the intervention is done and the questionnaires are completed. Finally, the data will be analyzed by the analyst without specifying the type of group.

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
Shahid Fahmideh

City
Hamadan

Province
Hamadan

Postal code
65167-19657

Approval date
2020-05-23, 1399/03/03

Ethics committee reference number
IR.UMSHA.REC.1399.216

Health conditions studied

1

Description of health condition studied
Stroke, not specified as haemorrhage or infarction

ICD-10 code
G46.4

ICD-10 code description
Cerebellar stroke syndrome

Primary outcomes

1

Description
Patient quality of life

Timepoint
Before intervention , 2 month after intervention

Method of measurement
Strocke Specific-Quality of Life Scale

2

Description
Family care giver quality of life
Timepoint
Before intervention , 2 month after intervention
Method of measurement
Short Form-36 (SF-36) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: There are no interventions in this group.
Category
N/A

2

Description
Intervention group: Intervention group: Implementation of family-centered empowerment model for patients and family caregivers in the intervention group, in 4 sessions of one hours and in 4 consecutive days while the patient is hospitalized in the ward. The duration of each session is 1 hour, which will be provided according to the educational needs and patient tolerance during the day (depending on the circumstances, it may take longer). The first step (to increase the perceived threat): The first step in a family-centered empowerment model is to increase the perceived threat of the empowering agent, the family system, consisting of the client and his or her family. The perceived threat includes perceived sensitivity and perceived intensity. To increase a person's level of perceived threat to the disease, his or her perceived sensitivity and severity to the disease, complications, and treatment process must be increased. n order to increase the perceived threat, it is used by lecturing and questioning based on the objectives of this step. The content of this step includes information about the importance, definition, symptoms, risk factors, prevention, care and treatment of stroke. Which is performed by one of the researchers. Step 2 / Session 2 (Improving Self-Efficacy by Problem Solving): To improve self-efficacy, a problem-solving training session is held. So that the possible or existing problems of the patient and the main caregiver are identified, defined and the solutions are presented, discussed and prioritized by themselves. Then, important and skillful problems are practically taught by practical demonstration method. Patients and caregivers are given the opportunity to practice and repeat activities to the extent that they are able to do so without the presence of their researcher. Step 3 / Session 3 (Increasing Self-Confidence by Educational Participation Method): The researcher designs the educational participation stage in such a way that the patient and his / her caregiver actively participate in the project. In this step, the topics discussed in the previous sessions and a summary of the educational pamphlets are passed on to other family members by the primary caregiver. The main caregiver's activity is also evaluated. The primary caregiver is also asked to teach the patient during the week after discharge. Step 4 (Evaluation): This step involves two types of evaluation. Process evaluation and final evaluation. Process evaluation will be performed at the end of each step. Thus, in the first stage, in order to evaluate the perceived threat with the oral question from the patient and the main caregiver, in the second stage, to evaluate the self-efficacy, by requesting to show or perform the skill related to using the skill by the patient and the main caregiver and the third step in assessing self-esteem (self-confidence) is by examining the level of cooperation of the primary caregiver in educational participation. In order to finally evaluate the family-centered empowerment model on the fourth day, all three previous steps are re-evaluated.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshcian Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Assistant professor
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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