Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Development of self-care supportive Programe for family caregivers and stroke patients and its effects on quality of life and resilience; A Mixed-method study

Protocol summary

Study aim

Development of a self-care support program for family caregivers and stroke patients and its impact on quality of life and resilience

Design

Completion of demographic questionnaires and Barthel criteria before the intervention and before random allocation Completion of quality of life and resilience questionnaires two months after the diagnosis in a specialized clinic Intervention "2 face-to-face sessions to examine the patient and the patient's family caregivers and prioritize the goals and care planning of each family caregiver and patient, then follow-up during 4 consecutive weeks" 2 months later,the questionnaire is completed..

Settings and conduct

A randomized clinical trial study with a two-group pre-test-post-test design was conducted at Ba'ath Hospital in Hamedan in 1401 on patients and family caregivers of post-stroke. The control group will be cared for according to the routine of the hospital, and the intervention group will be subjected to intervention based on the care plan, and pre-test and post-test will be taken from them in the interval between entering the study and the routine intervention, which is 4 months.

Participants/Inclusion and exclusion criteria

Inclusion: Family caregivers:Having at least primary education-Age above 18 years-Having a family relationship with the patient Patients:Having suffered a stroke for the first time-The average degree of dependence based on Bartlel's criteria Exclusion: unwillingness to participate

Intervention groups

For the people of the test group, 2 face-to-face meetings,Then, the follow-up will be done for 4 consecutive weeks. Then, 2 months after the intervention, through phone coordination with the patient, who will go to their specialist doctor's office or neurology clinic for a repeat visit, or are under care at home. The control group is also used according to the care plan.

Main outcome variables

quality of life; Resilience;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220903055859N1**
Registration date: **2022-09-24, 1401/07/02**
Registration timing: **prospective**

Last update: **2022-09-24, 1401/07/02**
Update count: **0**

Registration date

2022-09-24, 1401/07/02

Registrant information

Name

Ahmad Nooreddini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Development of self-care supportive Programe for family caregivers and stroke patients and its effects on quality of life and resilience; A Mixed-method study

Public title
Development of self-care supportive Programe for family caregivers and stroke patients and its effects on quality of life and resilience

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Family caregivers: Having at least primary education Age above 18 years Having a family relationship with the patient (daughter, son, sister, brother, father, mother and wife) The main caregiver of the patient in the family at least 4 days a week for at least 2 months Lack of history of specific psychological illness according to self-report Patients : Having suffered a stroke for the first time The average degree of dependence based on Barthel's criteria (the patient has the ability to speak). The patient is hospitalized in the neurology department.

Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Before randomly assigning to two intervention and control groups, questionnaires of demographic characteristics and Barthel scale for the patient to enter the study (in case of scoring between 40-55 and moderate dependency because they must have the ability to speak and cooperate to complete the questionnaires) will be. Based on the score obtained using Barthel's index, they will be placed in two test groups (40 pairs of caregivers and patients) and control (40 pairs of caregivers and patients).Blocked randomization is for the purpose of making sure that exactly equal number of participants are included in the intervention and control groups at consecutive but equal time intervals.

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
Hamedan University of Medical Sciences, Shahid Fahmida Street

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Postal code
6517838736

Approval date
2022-08-23, 1401/06/01

Ethics committee reference number
IR.UMSHA.REC.1401.240

Health conditions studied

1

Description of health condition studied
CVA

ICD-10 code
G46

ICD-10 code description
Vascular syndromes of brain in cerebrovascular diseases

Primary outcomes

1

Description
Quality of life of patients, quality of life of family caregivers, resilience of family caregivers

Timepoint
Upon entering the study, two months later, four months later.

Method of measurement
Standard questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: The self-care support program designed for patients and family caregivers will be implemented in four stages: Assessment of self-care needs in the studied units and planning based on nursing diagnoses: in this stage, needs assessment based on the survey form and capacity recognition. Self-care of stroke patients and family caregivers will be done based on the needs assessment of the adjusted self-care program of the Orem model (needs related to growth and development, general needs, usual health patterns, and needs of deviation from health). In the self-care ability section, the questions will be in the three dimensions of awareness, motivation and skill. The awareness dimension includes 11 and the motivation includes 6 questions that will be measured with "yes and no", the skill dimension includes 16 questions that will be measured with "never, rarely, sometimes, most of the time and always", completed questionnaires will be analyzed by the clients in the test group and the existing problems will be addressed based on priority and it will be determined which public needs have been met and which needs have not yet been met, what factor caused these needs not to be met and the researcher What should he do to meet these needs? For example, nursing diagnoses can include the following: 1. Lack of self-care in the field of nutrition 2. Lack of self-care in the field of mobility and activity 3. Lack of self-care in the field of basic medication use 4. Lack of self-care in the field of mental and psychological support 5. Lack of self-care in the context of social behavior. Self-care program design in the form of training sessions: in this stage, the type of training and selection and the type of nursing system depending on the deficiencies of care information that will be listed in the first stage, and the clients are selected in two educational-supportive nursing systems. Implementation of self-care support program: holding 2 training sessions depending on the patient's condition after discharge and when visiting the clinic or home and based on the needs of patients and family caregivers, each session will be 0.5 hours. was, placing educational pamphlets at the clients' disposal, establishing telephone and face-to-face communication with clients and caregivers on specific days of the week and strengthening their morale, using self-care checklists that will be designed to be completed in the second month of hospitalization. Evaluation : Based on the goals in the field of reducing needs and increasing abilities in performing self-care activities and by measuring self-care ability, their self-report checklists will be collected.

Category

Lifestyle

2

Description

Control group: The control group is also used according to the care plan that will be taught at the time of discharge and is the routine of the neurology department. The questionnaires of the control group will also be completed within 2 months after visiting the specialized clinic in coordination with the neurologist and family caregivers. For the people of the test group, the number and duration of self-care support program sessions will be determined based on the number of goals and wishes of family caregivers and patients during coordination (by phone or in a specialized clinic). 2 face-to-face meetings at home or at a specialized clinic will be held individually and face-to-face to examine family caregivers and patients and prioritize goals and plan self-care support for each family caregiver and patient. Then the follow-up will be done in 4 consecutive weeks, by phone or through social networks. Family caregivers will be taught how to use the authorized social network program during the face-to-face meeting. Then, 2 months after the intervention, through telephone coordination with the patient who goes to their specialist doctor's office or neurology clinic for a return visit or is under care at home, face-to-face and self-declaration of family caregivers' resilience questionnaires and The quality of life of family caregivers and their patients will be improved.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan Beesat Hospital

Full name of responsible person

Ahmad Nooreddini Avaz Mohammad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
seyyed reza Bourzo

Position
Faculty member

Latest degree
Ph.D.

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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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable