Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating The effect of a supportive educational program based on COPE model on the burden of care and quality of life in family care provider with Ischemic Stroke dischared of intensive care units of selected hospitals

Protocol summary

Study aim
To determine the score of care burden and quality of life in patient caregivers

Design
Clinical trial with a pre-test and post-test design in the form of two test and control groups and three stages (before, immediately and one month after the intervention) on 32 caregivers of patients with ischemic stroke and random allocation of samples using a table of numbers Computerized randomness

Settings and conduct
The intervention group will participate in a training-support course that will be conducted based on the coop model and based on needs assessment, in the form of 3 face-to-face sessions and two telephone sessions. The participants, caregivers of patients with ischemic stroke discharged from medical training centers affiliated to Isfahan University of Medical Sciences, will complete the questionnaires in the pre-test and post-test stages.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Caregiver's age between 18 and 60 years. Caregiver should not be a member of the health team. DO not participate in another similar study at the same time. Do not take care of two patients at the same time. One month has passed since providing care. Does not have a chronic disease.

Intervention groups
For the people who entered the intervention group, the problem solving method is explained based on the COPE model (increasing creativity, optimism, planning and specialized information). A booklet about common problems and necessary training is given to the caregiver and he is asked to choose a problem and teach how to use the model and booklet to solve the problem. The control group only receives hospital training at the time of discharge.

Main outcome variables
Quality of life of caregivers of patients; Care burden of caregivers of patients

General information

Reason for update

Acronym
COPE

IRCT registration information
IRCT registration number: **IRCT20230303057597N1**
Registration date: **2023-10-25, 1402/08/03**
Registration timing: **retrospective**

Last update: **2023-10-25, 1402/08/03**
Update count: **0**

Registration date
2023-10-25, 1402/08/03

Registrant information

Name
Masoumeh Raeesi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3462 5336

Email address
raeesi63@nm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating The effect of a supportive educational program based on COPE model on the burden of care and quality of life in family care provider with Ischemic Stroke dischared of intensive care units of selected hospitals

Public title

Effect of a supportive educational program on the burden of care and quality of life in family care provider

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Family caregivers of people with ischemic stroke One month has passed since the time of providing care

Exclusion criteria:

Caregiver's age shouldn't be below 18 years and above 60 years Not to participate in another similar study at the same time Take care of two patients at the same time

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are selected in an easy continuous method from among the family caregivers of patients with ischemic cerebral stroke discharged from the intensive care unit in need of family care who meet the entry criteria for the study. Then they are randomly assigned to two control and test groups. In order to randomly assign the samples using a computerized random number table, a code is first assigned to each of the participants, then the first 32 codes are assigned to the control group and the next 32 codes are assigned to the intervention group.

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 Committees of Nursing, Rehabilitation and Management schools- Isfahan University of m

Street address

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences and Health Services, Hazar Jarib St

City

Isfahan

Province

Isfehan

Postal code

8193761925

Approval date

2022-12-26, 1401/10/05

Ethics committee reference number

IR.MUI.NUREMA.REC.1401.127

Health conditions studied

1

Description of health condition studied

Ischemic Stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Care burden score

Timepoint

Measurement of care burden score before and immediately and one month after the intervention

Method of measurement

Zarit Caregiver Burden Scale

2

Description

The overall quality of life score before and immediately and one month after the intervention

Timepoint

Measuring the overall quality of life score before and immediately and one month after the intervention

Method of measurement

World Health Organization Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the people who entered the intervention group, first a face-to-face meeting will be held at the hospital, where the method of solving the problem will be explained based on the Koop model. In the creativity component, care problems are taught from different perspectives to develop new strategies to solve them. (For example, "I will be creative in my patient's daily activities.") In optimism, families should have a positive but realistic attitude toward the problem-solving process. As much as possible in planning, they convey realistic optimism to the patient (eg, "I believe that daily activities can be done.") In planning, reasonable care goals are set and steps are taken. What is necessary to achieve those goals is determined in advance (for example, "I plan my patient's daily activities so that he can also be present in the crowd."). In professional information, families are taught what nonprofessionals need to know about the nature of the problem, when to seek professional help, and what family caregivers can do on their own to cope (eg, I use available resources). I will use). Then a booklet about common problems and necessary training is given to the caregiver and he is asked to choose a problem and teach how to use the model and booklet to solve the problem. In this meeting, educational needs assessment is done by the individual and the family. The educational content and goals in the first session include: greetings, expressing goals and needs assessment, familiarizing the person with the disease, signs and symptoms, and at the end of the first session, an agreement is made about a phone call with him. Based on the patient's condition, face-to-face sessions will be between one and two hours, and phone sessions will last between 15 and 20 minutes.Three days after the first session, the researcher made a reminder phone call to the caregiver and read the booklet and asked questions about the implementation of the care according to the training program and agreed on a face-to-face meeting with the caregiver at the hospital to review the results of the previous session/fix the problems. be madeIn the second face-to-face meeting on the 16th day, the process is reviewed again and the caregiver is discussed about another problem and the use of models and booklets, and the time of the next phone call with him to teach new educational concepts is determined.In the next phone call, which will be made two days later, the carer's questions will be answered and he will be encouraged to use the model, and the time to complete the questionnaire will be agreed with him one month after the start of the program.The control group only receives hospital training at the time of discharge and follow-ups from the relevant hospital's health education unit, and after one month, the questionnaire is completed for them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra Medical and Education Center

Full name of responsible person
Mehrdad noroozi

Street address
Al-Zahra Medical Education Center, Sofe St

City
Isfahan

Province
Isfehan

Postal code
8193861925

Phone
+98 913 227 1978

Email
raeesi63@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Gholamreza askari

Street address
Central Headquarters, Isfahan University of Medical Sciences and Health Services, Hazar Jarib St

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 913 227 1978

Email
eaeesi63@nm.mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Masoumeh Raeesi

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 22, No. 4 Alley, Kaveh Ave, Aboureyhan St, Isfahan

City
Isfahan

Province
Isfehan

Postal code
8193761925

Phone
+98 913 227 1978

Email
raeesi63@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Masoumeh Raeesi

Position
Master student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 22, No. 4 Alley, Kaveh Ave, Aboureyhan St, Isfahan

City
Isfahan

Province
Isfehan

Postal code
8193761925

Phone
+98 913 227 1978

Email
raeesi63@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Masoumeh Raeesi

Position
Master Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 22, No. 4 Alley, Kaveh Ave, Aboureyhan St, Isfahan

City
Isfahann

Province
Isfehan

Postal code
8193761925

Phone
+98 913 227 1978

Email
raeesi63@nm.mui.ac.ir

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
No - There is not 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