Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Training Based on The Seven-Step (7E) Learning Cycle on The Quality of Life of Stroke Patients and The Care Burden of Their Caregivers

Protocol summary

Study aim
Determining the impact of training based on the seven-step learning cycle model (E7) on the quality of life of stroke patients and the care burden of their caregivers.

Design
Two-group, single-blind, randomized, block-based parallel clinical trial study with 65 patients in each group.

Settings and conduct
The design of the training program will be done to determine the needs and the intervention plan for the caregivers and patients with ischemic stroke. The training program is based on the 7 step learning model in the EG in 3 sessions of 30 to 40 min of face-to-face and 2 sessions of virtual training after discharge. The 1st session will be held individually for the patient and caregiver in the hospital. The 2nd and 3rd sessions will be conducted as group training. The CG will receive common neurology training.The sampling site of the selected hospitals of Shahid Beheshti University of Medical Sciences includes the neurology department and clinic.

Participants/Inclusion and exclusion criteria
Inclusion criteria: people between 18 and 70 years of age / willingness to participate in research / awareness of the time, place and person / not receiving thrombolytic .Exclusion criteria: suffering from known physical and mental diseases / not attending two (or more) sessions/participation in another educational program during the research/entering the acute phase of the disease and re-hospitalization/failure to complete or incompletely complete the tools

Intervention groups
Intervention group: In total, there are 5 training sessions between 30 and 40 minutes, of which 2 face-to-face sessions and 3 virtual sessions are conducted according to the 7-step learning cycle model.The control group received routine care.

Main outcome variables
Quality of life of patients and care burden of caregivers

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240205060913N1**
Registration date: **2024-07-06, 1403/04/16**
Registration timing: **prospective**

Last update: **2024-07-06, 1403/04/16**
Update count: **0**

Registration date
2024-07-06, 1403/04/16

Registrant information

Name
Sogand Sarmadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-21, 1403/04/31

Expected recruitment end date
2025-01-19, 1403/10/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Training Based on The Seven-Step (7E) Learning Cycle on The Quality of Life of Stroke Patients and The Care Burden of Their Caregivers

Public title

The effect of training based on the seven-step learning cycle on stroke patients and their caregivers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The age range of people is between 18 and 70 years. Willingness to participate in research Refer to the stroke clinic The patient has not received thrombolytic medicine and is hospitalized due to problems caused by stroke. Admitted to the neurology department of the hospitals covered by Shahid Beheshti University of Medical Sciences The patient is alert and aware of the time, place and person, and can be trained

Exclusion criteria:

Suffering from known physical and mental diseases that affect the quality of life (according to the patient's self-report). People who do not attend two (or more) sessions out of the total number of follow-up sessions. People who have participated in another educational program during the research. People who have hearing, visual and touch disorders or who are not able to speak Persian language. People who have hearing, visual and touch disorders or who are not able to speak Persian language

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in this research will be done by block randomization method with a volume of four. The sequence of random allocation and the list of blocks will be obtained by the statistical consultant and with the help of R software. In this method, blocks are formed based on the variables in question. Block randomization is performed by randomizing participants into blocks, so that equal numbers are assigned to each group (intervention and control). Equal numbers of participants enter the groups in consecutive but equal time intervals. After each patient and family enters the ward, according to the prepared block of four (15 blocks of four) based on the sample size, in the first stage, each patient will be randomly placed in the A test group or the B control group. For example, after randomly selecting a block such as the ABAB block, patients are randomly placed in the test, control, test and control groups. After generating the random sequence, sampling is done by hiding the generated sequence. So that before assigning the individual, the assigned group is not known for the samples. This is done by putting a random sequence inside the envelope and choosing a non-transparent envelope. First, a random sequence is created, then based on the size of the research sample, a number of envelopes are prepared and each of the created random sequences is recorded on a card, and the cards are placed in the envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the envelopes is glued and placed in a box in order. At the time of starting the registration of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes is opened in order and the assigned group of that company The doer is revealed. Each patient's code will be assigned to his family member. People are assigned to the desired group in the order of their entry into the study and randomly through randomized blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data were collected by research assistants who were blinded to treatment allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculties of Pharmacy, Nursing and Midwifery - Shahid Beheshti University of Medical Sciences

Street address

Tehran, Vali Asr St., intersection of Ayat A... Hashemi Rafsanjani Highway, in front of Heart Hospital

City

Tehran

Province

Tehran

Postal code

1996835119

Approval date

2024-01-21, 1402/11/01

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.198

Health conditions studied

1

Description of health condition studied
Stroke
ICD-10 code
I67.82
ICD-10 code description
Cerebral ischemia

Primary outcomes

1

Description
"Quality of life" of stroke patients
Timepoint
Before the intervention and two months later
Method of measurement
Specific Quality of Life Questionnaire for Stroke Patients (SS-QOL)

2

Description
Family care burden
Timepoint
Before the intervention and two months later
Method of measurement
The family care burden questionnaire includes 24 items on a 5-point Likert scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First of all, the demographic information questionnaire of the patient, caregivers and the quality of life questionnaire of stroke patients are completed by the patient and the CBI care burden questionnaire is completed by the caregiver. Then, based on the randomized blocks of four and the prepared envelopes, each patient and caregiver will be randomly assigned a code based on the order of entry into the study, and the patients will be placed in two test and control groups based on the random codes. . In the continuation of the beginner's training program based on the 7-step learning model in the test group, in 3 sessions of 30-40 minutes of face-to-face training (one individual session and two group sessions including groups of 4-6 people) and two virtual training sessions after discharge individually, about Definition of stroke disease, types of stroke (ischemic/hemorrhagic/transient ischemic), the importance of continuing treatment, the degree of compliance with the drug compliance program and the importance of drugs, the problems of stroke patients (special food program for patients with swallowing disorders, movement and speech rehabilitation program treatment), the principles of prevention of re-infection and team structure for treatment (the importance of the presence of the family with the patient and interaction in the educational program, the importance of playing the role of the patient and the family in various meetings and the treatment and care plan of the patient) and daily care of stroke patients and Prevention of reoccurrence includes teaching recommendations to prevent reoccurrence of stroke (control of anger, control of stressful stimuli, proper nutrition, adherence to medication and care) and education of the reasons for reoccurrence (non-compliance with medication and care plan, lack of family cooperation) In the treatment and care process of the patient, the patient's non-cooperation with the treatment staff and non-compliance with treatment and medication plans (to stroke based on the 7E learning cycle model) (inferring, involving, exploring, explaining, expanding, evaluating and expand) will be present. The first training session will be held individually for the patient and caregiver in the hospital. The second and third session will be conducted as a group training (including patient and caregiver) and after the clearance of other training content, it will be provided through virtual training at intervals of one session every week, and questionnaires will be completed again two weeks after the completion of the intervention. At the end of the study, in order to comply with ethical principles, educational content will be prepared from what was explained in the meetings and will be provided to all participants (control group). Then the data will be analyzed.
Category
N/A

2

Description
Control group: The control group will receive common training and routine care of the neurology department. In order to comply with ethical principles, educational content will be prepared from what was explained in the meetings and will be provided to all participants (control group).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospitals covered by Shahid Beheshti University of Medical Sciences and Stroke Clinic
Full name of responsible person
Sogand Sarmadi
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No 291, East 10 and 11 Ave., Donyamali Blvd., Andishe Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Tehran - Shahid Chamran Highway - Yemen Street - Arabi Street, Shahid Beheshti University of Medical Sciences and Healthcare Services - building number two of the university headquarters - sixth floor
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4631- 19395
Phone
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urm@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Neda Sanaie
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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