

# 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)

##### Phone

+98 21 6552 4357

##### Email address

sogandsarmadi@sbmu.ac.ir

##### 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

##### Street address

No 291, East 10 and 11 Ave., Donyamali Blvd., Andishe Town

##### City

Andishe  
**Province**  
Tehran  
**Postal code**  
3354383423  
**Phone**  
+98 21 6562 4357  
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sogandsarmadi@sbmu.ac.ir

## 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  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
4631- 19395  
**Phone**  
+98 21 2387 2206  
**Email**  
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

Ph.D.

#### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

#### Contact

#### Name of organization / entity

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#### Position

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#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nursery

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## Person responsible for updating data

#### 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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**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