

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effect of self-management program on self-efficacy in stroke patients at the time of discharge from hospitals

#### Protocol summary

##### Study aim

The effect of self-management program on self-efficacy of stroke patients at discharge from university affiliated hospitals

##### Design

A randomized clinical trial with control, parallel, single-blind and randomized groups. Sample size consisted of 72 persons divided into two groups of Intervention and control groups.

##### Settings and conduct

The self-management program begins at the time of discharge from stroke patients and then goes home to complete the steps taken from Model 5A and continues with model stages including Assess, Advice, Agreement, Assistance, and Arrange. Initially, the needs assessment will be done, followed by a profit-and-loss guidance, followed by an agreed-upon training program between the trainer and the trainer. In the Assistance phase, the Assessment will be carried out with the Operational Plan, according to the 4 priority needs identified in the Agreement and with the Assessment Needs Assessment, and will ultimately be followed up by the ongoing program review

##### Participants/Inclusion and exclusion criteria

Willingness to participate in the study  
Lack of global aphasia and Perceptive aphasia (ability to communicate at least)  
Stroke for the first time participating in other self-management and training studies  
communication barrier

##### Intervention groups

Self-management program adapted from Model 5A for patients with stroke at discharge and begins with Assess, Advice, Agreement, Assist and Arrange for up to 12 weeks. For the control group we will follow up with follow-up phone calls during the training.

##### Main outcome variables

self efficacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190712044181N2**

Registration date: **2019-11-05, 1398/08/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-11-05, 1398/08/14**

Update count: **0**

##### Registration date

2019-11-05, 1398/08/14

##### Registrant information

##### Name

shahla Abolhassani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7548

##### Email address

abolhasani@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-23, 1398/08/01

##### Expected recruitment end date

2020-06-09, 1399/03/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of self-management program on self-efficacy in stroke patients at the time of discharge from hospitals

**Public title**

The effect of self-management program on self-efficacy of stroke patients

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willingness to participate in the study Lack of global aphasia and Perceptive aphasia (ability to communicate at least) Stroke for the first time

**Exclusion criteria:**

Participating in other self-management and training studies Communication barriers

**Age**

From **54 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization Tool

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

A double-blind study, in which individuals such as the researcher and participants were blind. By using randomization tool (envelope in asymptomatic package), individuals are divided into two groups of test and control.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

**Street address**

School of Nursing and Midwifery, Isfahan University of Medical Sciences, Azadi Square, Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code****Approval date**

2019-09-27, 1398/07/05

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1398.387

**Health conditions studied****1****Description of health condition studied**

stroke

**ICD-10 code**

G46.4

**ICD-10 code description**

Cerebellar stroke syndrome

**Primary outcomes****1****Description**

The primary outcome variable is the self-efficacy score of patients with stroke self-efficacy questionnaire.

**Timepoint**

Before the intervention, immediately after the intervention and three months after the intervention

**Method of measurement**

Using visual self-efficacy questionnaire for patients with stroke

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: After selecting the samples by random sampling and entering the study, the intervention will start with self-management method based on Model 5A. First and Second Stage: Assessment and Guidance The same needs assessment is done. Stage Three: Agreeing on the five basic needs for defining and fulfilling behavioral goals. Stage Four: The help stage is a need assessment performed with the help of professors and based on evidence of nursing services. Psychiatric nursing and physiotherapy. The fifth step is follow-up, which is by phone call, in-person appointment, and self-report check.

**Category**

Behavior

**2****Description**

Control group: Control group: After random selection in the control group, they will receive training (verbal,

brochure and pamphlet) according to the hospital training by the ward nurse for home care. They will be followed up for a 12-week follow-up, as in the internal team, and will be reminded of their discharge training by phone once a month.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Alzahra Medical Educational Center

**Full name of responsible person**

Mehdi Nasr Isfahani

**Street address**

Soffeh Blvd; Alzahra Hospital

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746757731

**Phone**

+98 31 3620 2020

**Fax**

+98 31 3669 1510

**Email**

alzahra@mui.ac.ir

**Web page address****2****Recruitment center****Name of recruitment center**

Amin Medical Educational Center

**Full name of responsible person**

Mohamad Ali Pourmirzaei

**Street address**

Sonbolestan Alley; Ibne Sina Ave; Amin Hospital

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 34 4531 5051

**Email**

Amin@mui.ac.ir

**3****Recruitment center****Name of recruitment center**

Kashani Medical Educational Center

**Full name of responsible person**

Iman Adibi

**Street address**

Ayatollah Kashani Ave.Kashani Hospital

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3233 0091

**Email**

Kashani@mui.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjooy Javanmard

**Street address**

Hezar jareeb Ave;

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

research@mui.ac.ir

**Web page address****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**

Shahla Abolhassani

**Position**

Assistant professor of nursing Education

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jerib Ave.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 7548

**Email**

abolhasani@nm.mui.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shahla Abolhasani

**Position**

Assistant Professor of Nursing Education

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shahla Abolhasani

**Position**

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**Latest degree**

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**Phone**

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**Email**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The original data can be shared after identifying individuals (using code for each individual) and adhering to the privacy principle in the thesis file and the extracted article.

**When the data will become available and for how long**

Start access to thesis file 6 months after student's final thesis defense; Start accessing the article file immediately after printing

**To whom data/document is available**

Anyone, whether academics or researchers working in other institutions, including the private sector, can apply for shared data.

**Under which criteria data/document could be used**

To use the results of this study to plan for more comprehensive similar studies or to use the results of this study to design appropriate supportive educational interventions for patients.

**From where data/document is obtainable**

Isfahan University of Medical Sciences; School of Nursing and Midwifery; Department of Adult Health Education; Dr. Shahla Abolhasani Phone 00989131095395  
abolhasani@nm.mui.ac.i

**What processes are involved for a request to access data/document**

Within 7 business days of receiving a written request by email and a full description of the applicant, together with the organization or institution in which they work and where the data is used; Documentation can be sent.

**Comments**