Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Isfehan
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

Isfehan

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

Isfehan

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

Isfehan

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

Isfehan

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

Isfehan

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 Abolhassani

Position

Assistant Professor of Nursing Education

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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 Abolhassani

Position

Assistant Professor of Nursing Educational

Latest degree

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Other areas of specialty/work

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Phone

+98 31 3792 7548

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