

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effect of self-efficacy training on quality of life and self-efficacy of stroke patients

Protocol summary

2018-08-17, 1397/05/26

Study aim

Determining the effect of self-efficacy training on quality of life and self-efficacy of stroke patients

Design

This study is a clinical trial with control group. Among the stroke patients referred to Rafideh Rehabilitation Hospital, 80 available stroke patients based on inclusion criteria were selected and randomly assigned to two intervention and control groups.

Settings and conduct

This study is carried out at Rofeideh Hospital in Tehran. The study is done single blind in which patients won't know what intervention will be done for them.

Participants/Inclusion and exclusion criteria

Entry requirements: Patients with confirmed ischemic stroke. People who have been stroke for more than 4 months and less than two years. Being aged 55 to 70 years; Conditions of failure: history of previous stroke

Intervention groups

The control group receives only routine hospital care and the intervention group, in addition to the 5 sessions of group training based on the self-efficacy model, participates for 90 minutes.

Main outcome variables

Quality of life score; self-efficacy score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170619034625N1**

Registration date: **2018-08-17, 1397/05/26**

Registration timing: **prospective**

Last update: **2018-08-17, 1397/05/26**

Update count: **0**

Registration date

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0083

Email address

na.abolfathi@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-21, 1397/05/30

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of self-efficacy training on quality of life and self-efficacy of stroke patients

Public title

Effect of self-efficacy training on quality of life and self-efficacy of stroke patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with confirmed ischemic stroke by CT scan or MRI Patients who have been stroke for more than 4 months and less than two years Patients in terms of severity of mild to moderate stroke are based on the

contents of the case Patients are in the age group of 55 to 70 years Patients who have the ability to communicate verbally Patients who receive an MMSE census score of more than 18 points

Exclusion criteria:

History of previous stroke Previous training on self-efficacy

Age

From **55 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are selected on the basis of the criteria for entering the study, and are assigned by random appointment and randomized block method, which consists of the first two groups of the intervention and the second two groups of control

Blinding (investigator's opinion)

Single blinded

Blinding description

The samples in the intervention and control group were unaware of which group were placed

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Welfare and Rehabilitation Sciences

Street address

Welfare and Rehabilitation Sciences., Kodakyar Ave., Daneshjo Blvd., Evvin, Tehran

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2017-09-22, 1396/06/31

Ethics committee reference number

IR.USWR.REC.1396.285

Health conditions studied

1

Description of health condition studied

Stroke patients

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

The quality of life score

Timepoint

The beginning of the intervention and two months after the intervention

Method of measurement

Quality of life questionnaire for patients with stroke

2

Description

Self-efficacy score

Timepoint

The beginning of the intervention and two months after the intervention

Method of measurement

Self-efficacy questionnaire for chronic patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, in addition to receiving hospital routine care, the patient participates in 5 sessions of the group education that is based on the structures of the self-efficacy theory. These 90 minute sessions are conducted twice a week at the hospital. At the last session, a booklet containing the content of the training sessions will be provided to the intervention team.

Category

Rehabilitation

2

Description

Control group: In this research, only the routine care of the hospital, which includes physiotherapy and occupational therapy is provided. After the completion of the research, due to the ethical considerations, the

contents of the training booklet are also provided to the control group

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeideh hospital

Full name of responsible person

Nafise Abolfathi

Street address

Rofeideh Rehabilitation Hospital, Nemati alley, Shahid Baradaran Soleymani Avenue, Ghaytrieh

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Phone

+98 21 2220 5326

Fax

+98 21 2220 5326

Email

nafise.f.2015@gmail.com

Web page address

<http://www.uswr.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Nafise Abolfathi

Street address

University of Social Welfare and Rehabilitation Sciences Tehran, Kodakkar blind alley, Daneshjo Blvd., Evin

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Phone

+98 21 2218 0083

Fax

+98 21 2218 0083

Email

Nafise.f.2015@gmail.com

Web page address

<http://www.uswr.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

nafise Abolfathi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Kodakkar blind alley, Daneshjo Blvd., Evin

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Phone

+98 21 4446 7079

Fax

+98 21 4446 7079

Email

nafise.f.2015@gmail.com

Web page address

<Http://www.uswr.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Nafise Abolfathi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Tehran University of Social Welfare and Rehabilitation

Sciences, Kodakyar blind alley, Daneshjo Blvd., Evin
City
Tehran
Province
Tehran
Postal code
۱۹۸۵۷۱۳۸۳۴
Phone
+98 21 4446 7079
Fax
+98 21 4446 7079
Email
nafise.f.2015@gmail.com
Web page address
<http://www.uswr.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Nafise Abolfathi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Tehran University of Social Welfare and Rehabilitation
Sciences, Kodakyar blind alley, Daneshjo Blvd., Evin
City
Tehran
Province

Tehran
Postal code
۱۹۸۵۷۱۳۸۳۴
Phone
+98 21 4446 7079
Fax
+98 21 4446 7079
Email
nafise.f.2015@gmail.com
Web page address
<http://www.uswr.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

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