

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of educating skills on using mobility assistive devices on self-esteem and self-efficacy of patients with stroke

Protocol summary

Study aim

The effect of training skills for using the mobility assistive devices on self-esteem and self-efficacy of hospitalized patients with stroke

Design

The study is a randomized single blind controlled trial

Settings and conduct

This study will be done at neurology ward of Kashani hospital in Shahre-kord on post stroke patients. Participants will be allocated into intervention and control groups using "random allocation" software. Intervention group will receive educations on how to use mobility assistive devices. Control group will receive only routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of stroke by a neurologist, Passed 48 hours from the onset of stroke. (the acute stage be passed), Having muscle force of 3.5 or 4.5, Patient's age should be less than 70 years old, willingness to participate in this study.

Intervention groups

Patients participating in this study will be divided into intervention and control groups. Intervention group will receive educations about how to use mobility assistive devices (walker and walking stick). control group will receive only routine care.

Main outcome variables

Self-efficacy, self-esteem

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180419039362N1**

Registration date: **2018-06-28, 1397/04/07**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-28, 1397/04/07**

Update count: **0**

Registration date

2018-06-28, 1397/04/07

Registrant information

Name

Bakhtiar Peikfalak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3333 5982

Email address

ba.peikfalak@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educating skills on using mobility assistive devices on self-esteem and self-efficacy of patients with stroke

Public title

The effect of training on self-efficacy and self-esteem in stroke patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of stroke by a neurologist Passed 48 hours from the onset of stroke (acute stage be passed) Having muscle force of 3.5 or 4.5 Patient's age should be less than 70 years old willingness to participate in this study

Exclusion criteria:
Having verbal and visual cognitive impairment, previous dementia, global aphasia or any visual impairment Having any underlying disease that can cause motor dysfunction History of previous stroke

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

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be selected by simple sampling method and then will be randomly assigned into control or intervention group based on numbers generated by "Random allocation" software.

Blinding (investigator's opinion)
Single blinded

Blinding description
Data analyzer will not play any role in implementing interventions and will be unaware of what group is intervention or control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University of Social Welfare and Rehabilitation Sciences

Street address

Kodakyar blind alley, Daneshjo Blvd., Evin

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2018-04-11, 1397/01/22

Ethics committee reference number

IRUSWRREC.1396.327

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Self-efficacy score in Sherer's questionnaire

Timepoint

before and two weeks after interventions

Method of measurement

Sherer's self efficacy questionnaire

2

Description

self-esteem score in Rosenberg questionnaire

Timepoint

before and two weeks after interventions

Method of measurement

Rosenberg's self steem questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group complete self-efficacy and self-esteem questionnaires before discharge from the hospital and in addition to receiving routine therapies, they also receive training on using assistive device. They complete the questionnaires after two weeks.

Category

Rehabilitation

2

Description

Control group: This group complete self-efficacy and self-esteem questionnaires before discharge from the hospital and they receive just the usual treatment within two weeks. After that, they complete the questionnaires again.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals affiliated by Shahrekord University of Medical Sciences

Full name of responsible person

Bakhtiar Peikfalak

Street address

Ayatollah Kashani Hospital, Shreati Street

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8814658699

Phone

+98 38 3333 5982

Email

B.peikfalak@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Sayyed Kamal Solati

Street address

Shahrekord University of Medical Sciences, Kashani St.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3333 0061

Email

Ba.peikfalak@uswr.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Vice chancellor for Research, Shahrekord 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**

Shahre-kord University of Medical Sciences

Full name of responsible person

Bakhtiar Peikfalak

Position

Headnurse

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

No 11,20/1 Alley, Shariati Street

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8814658699

Phone

+98 38 3333 5982

Email

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Person responsible for scientific inquiries

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be shareable after making them
unidentifiable

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Employed researchers in universities and scientific
centers, students

Under which criteria data/document could be used

If a researcher wants to know about methodology of this
study.

From where data/document is obtainable

To the e-mail address of the researcher
ba.peikfalak@uswr.ac.ir

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

Applicant will send his/her email and phone number and
about 2 weeks after Validation, data will send to him/her.

Comments