Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)
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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

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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.

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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

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No 11,20/1 Alley, Shariati Street

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Person responsible for updating data

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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