

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of home based rehabilitation continuous care program based on BASNEF model on functional capacity and increasing range of motion and flow mediated dilatation in stroke survivors

Protocol summary

Study aim

Investigating the effect of home based rehabilitation intervention on functional Capacity in stroke survivors

Design

This study is a randomized controlled clinical trial with parallel group design

Settings and conduct

This study was performed in al-Zahra hospital in Isfahan. The predicted sample at the beginning of the study was 70, which fell to 40 for the lack of eligible patients. 40 stroke patients were randomly assigned to intervention and comparison groups based on random numbers table. Then, the intervention group participated in a two-part face to face training session. At the time of discharge from the hospital, a CD regarding home base rehabilitation exercises were delivered to the intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who suffered from first stroke without wernicke's aphasia with stroke severity 7 < NIH < 20
Exclusion criteria: Patients with subarachnoid hemorrhage and cardiac abnormality

Intervention groups

Intervention group: Two intervention sessions were provided to the patients in the intervention group at the time of hospitalization based on the constructs of the BASNEF model. Then they were given a CD related to rehabilitation exercises at home when they were discharged from the hospital. Control group: Received usual rehabilitation interventions in the hospital and rehabilitation centers.

Main outcome variables

Functional capacity; Range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180827040885N1**

Registration date: **2018-12-12, 1397/09/21**

Registration timing: **retrospective**

Last update: **2018-12-12, 1397/09/21**

Update count: **0**

Registration date

2018-12-12, 1397/09/21

Registrant information

Name

Fatemeh Esteki

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-05-12, 1394/02/22

Expected recruitment end date

2016-12-23, 1395/10/03

Actual recruitment start date

2015-05-12, 1394/02/22

Actual recruitment end date

2018-02-14, 1396/11/25

Trial completion date

2018-06-01, 1397/03/11

Scientific title

The effect of home based rehabilitation continuous care

program based on BASNEF model on functional capacity and increasing range of motion and flow mediated dilatation in stroke survivors	
Public title	The effect of home based rehabilitation program on functional capacity in stroke survivors
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	First 24 to 72 hours after stroke First stroke patients Stroke severity based on 7<NIH <20 Disability and disorders due to stroke in the upper and lower limbs from 25 to 90 according to the fugl-Meyer test Without wernicke's aphasia
Exclusion criteria:	Patients with Subarachnoid Hemorrhage and Uncontrollable Blood Pressure Cardiac Abnormality, Sever Heart Arrhythmia and Hyper tonic cardiomyopathy Oxygen Dependency Severe renal and hepatic failure
Age	No age limit
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 70 Actual sample size reached: 40
Randomization (investigator's opinion)	Randomized
Randomization description	In this study, the number of primary samples was estimated to be 70, but due to the low number of eligible patients, this number was reduced to 40.40 patients who were admitted to Isfahan Alzahra Hospital due to stroke were selected by convenience sampling and assigned to intervention and control groups using systematic sampling and random number table.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Isfahan University of Medical Sciences
Street address	Hezarjerib Ave, Isfahan University of Medical Sciences
City	Isfahan
Province	Isfahan
Postal code	8174673461
Approval date	2016-11-05, 1395/08/15
Ethics committee reference number	IR.MUI.1395.3.046
Health conditions studied	
<u>1</u>	
Description of health condition studied	Stroke
ICD-10 code	G46.3
ICD-10 code description	Brain stem stroke syndrome
Primary outcomes	
<u>1</u>	
Description	Functional Capacity
Timepoint	Before and 3 months after the intervention
Method of measurement	Fugl-Meyer
<u>2</u>	
Description	Range of motion
Timepoint	Before and 3 months after the intervention
Method of measurement	Fugl-Meyer
<u>3</u>	
Description	Flow mediated dilatation
Timepoint	Before and 3 months after the intervention
Method of measurement	Ultra sound imaging
Secondary outcomes	empty
Intervention groups	

1

Description

Intervention group: Initially, for the patients with a stroke who had the criteria for entering the study, during the hospital stay, two training sessions(each session 30 minutes) based on the structures of the BASNEF model were presented face to face. During these sessions, initial training was provided on the importance of rehabilitation exercises to patients and their family members. Then, at the time of discharge from the hospital, each patient received an instructional CD-ROM on how to do home-based rehabilitation exercises. The follow up was done weekly for 3 months by the researcher for each patient.

Category

Rehabilitation

2

Description

Control group: The control group received routine rehabilitation care at the hospital and after discharge.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Fatemeh Estaki ghashghaei

Street address

Alzahra hospital, Soffeh BLvd, Shahid Keshvari highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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Web page address

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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

Fatemeh Esteki Ghashghaei

Position

Resident

Latest degree

Master

Other areas of specialty/work

Neuroscience

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available