Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Fatemeh Esteki

Name of organization / entity

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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

1

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
Isfehan
Postal code
8174673461
Approval date
2016-11-05, 1395/08/15
Ethics committee reference number
IR.MUI.1395.3.046

Health conditions studied

1

Description of health condition studied
Stroke
ICD-10 code
G46.3
ICD-10 code description
Brain stem stroke syndrome

Primary outcomes

1

Description
Functional Capacity
Timepoint
Before and 3 months after the intervention
Method of measurement
Fugl-Meyer

2

Description
Range of motion
Timepoint
Before and 3 months after the intervention
Method of measurement
Fugl-Meyer

3

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

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Sponsors / Funding sources

1

Sponsor

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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
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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