Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Early Balance Exercise on Dependency Level among Patients with Stroke

Protocol summary

Study aim
To examine the effect of sitting balance exercises on dependency level among patients with stroke

Design
A nonprobability (purposive) sampling method consist of 60 patients acute stroke was included in this study, the participants will be assigned randomly into two groups: experimental group and control group (conventional care).

Settings and conduct
was conducted at the medical words of Imam Al-Hussein Medical City in Holy Kerbala, Iraq.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: -Had a stroke in the previous 2 months (ischemic or hemorrhagic, all brain regions) -We’re not able to stand independently for more than 1 minute Exclusion Criteria: -Tetraplegia or hemiplegia -Had vestibular deficits or vertigo

Intervention groups
The level of dependency was measured using a Modified Barthel index before application of the interventional protocol. Then a sitting balance exercises was performed 15-30 minutes through two sessions per day for 14th days

Main outcome variables
Minimize dependency level after stroke

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230704058671N1**
Registration date: **2023-07-08, 1402/04/17**
Registration timing: **retrospective**

Last update: **2023-07-08, 1402/04/17**
Update count: **0**

Registration date
2023-07-08, 1402/04/17

Registrant information

Name
Suror Khalil

Name of organization / entity
College of Nursing/ University of Kerbala

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Iraq

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-01, 1401/11/12

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Early Balance Exercise on Dependency Level among Patients with Stroke

Public title
Early Balance Exercise on Dependency Level among Patients with Stroke

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Had a stroke in the previous 2 months (ischemic or

hemorrhagic, all brain regions) and were attending inpatient rehabilitation Could sit independently for at least 1 minute without support We're not able to stand independently for more than 1 minute

Exclusion criteria:

 Cognitive deficits Tetraplegia or hemiplegia Had vestibular deficits or vertigo

Age

From **19 years** old to **69 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 in college of nursing at university of kerbala

Street address

Baghdad street

City

AL-Musayib district

Postal code

56001

Approval date

2023-11-06, 1402/08/15

Ethics committee reference number

1506.68

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I67.9

ICD-10 code description

Cerebrovascular disease, unspecified

Primary outcomes

1

Description

Primary outcome variable is the level of dependency among stroke patients that can be minimized by applying sitting balance exercises

Timepoint

before intervention and two weeks after intervention

Method of measurement

Modified Barthel Index Scale will be used to assess level of dependency

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Interventional groups consist of 30 patients with acute stroke , after assessing the level of dependency using a Modified Barthel index.Then a sitting balance exercises was performed 15-30 minutes through two sessions per day for 14th days, the sitting balance exercises was consisted of five exercises: shift weight side to side, reaching, seated leg lift, single-leg knee extensions, and reach with clasped hands. The levels of dependency were measured immediately after the completion of the intervention; all participants continued to receive their conventional stroke care.

Category

Treatment - Other

2

Description

Control group: consist of 30 patients with acute stroke , after assessing the level of dependency using a Modified Barthel index. Then participants were received conventional stroke care for14th days period. The levels of dependency were measured immediately after the completion of 14th days period.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Al- Hussein Medical City

Full name of responsible person

Karbala Health Directorate

Street address

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Sponsors / Funding sources

1

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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
University of Karbala and the author of trails is the funding source
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
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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
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
Title and more details about the data/document
The data will be the results of the Modified Barthel index that measure patients' dependency level in both the control and intervention groups.
When the data will become available and for how long
God Willing, once the article is published, the data will be available after 6 months of publication. If the article will be published in a subscribed journal, the data will be available after one year because of the policy of the subscribed journals.
To whom data/document is available
With academic nurses and any researcher who is interested in the data.
Under which criteria data/document could be used
The data could be used after getting permission via email. Also, users need to acknowledge the owner.
From where data/document is obtainable
Users can ask for the data and permission via email. Suror Khalil Ibrahim is the corresponding author. She will contact whoever he requests the information from. His email is seror.kh@s.uokerbala.edu.iq Suror Khalil Ibrahim study at the University of Kerbala/College of Nursing. The address is AL-Musayib district, Babylon, Iraq.
What processes are involved for a request to access data/document
Suror Khalil Ibrahim is the corresponding author. She will contact whoever he requests the information from. His email is seror.kh@s.uokerbala.edu.iq
Comments