

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

###### Country

Iraq

###### Phone

+964 773 569 2723

###### Email address

seror.kh@s.uokerbala.edu.iq

##### 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 for 14th 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**

Baghdad street

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AL-Musayib district  
**Postal code**  
56001  
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seror.kh@s.uokerbala.edu.iq

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
University of Karbala  
**Full name of responsible person**  
Suror Khalil Ibrahim  
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AL-Musayib district  
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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**  
University of Karbala  
**Full name of responsible person**  
Suror Khalil Ibrahim  
**Position**  
Master student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Adult Nursing Department  
**Street address**

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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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**