

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The Effects of meaningful Action Observation on occupational performance and brain physiological changes in chronic stroke patients

Protocol summary

Study aim

The aim of this study is to investigate the efficacy of meaningful action observation on occupational performance and brain physiological changes of chronic stroke patients.

Design

A single randomized clinical trial, with a parallel group of 15 patients

Settings and conduct

The location of the study is Firoozagar Hospital and assessor has been blinded before and after the interventions in two groups.

Participants/Inclusion and exclusion criteria

Inclusion: History of Only one cerebrovascular accident A score of +21 in Mini-mental state examination +6 months post since a stroke in Medial cerebral artery Motor recovery stage 3 to 5 in Brunnstrom's test No visual impairment due to the ability to watch and precept a video film No disease comorbidity that interferes with the study Independent walking ability with or without an assistive device Ability to sit independently at least for 1 hour Exclusion: Implant or prosthesis in the skull Lack of cooperation in the evaluation sessions

Intervention groups

In the Intervention group After selecting tasks from some predefined tasks, for about 30 minutes, the participant should watch a video film of a standard performance of the selected task by a model and then execute the viewed task while the affected hand has the main role in that performance. At the beginning of each session, preparatory techniques for the upper extremity including stretching, weight bearing, and active/passive exercise will be performed about 10 minutes. In the control group also the selected task will be performed with this difference that the participant will just watch a video film of static pictures and/or landscapes without a creator being. At the beginning of each session, preparatory techniques for the upper extremity including stretching, weight bearing, and active/passive exercise will be

performed about 10 minutes.

Main outcome variables

Occupational Performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160808029260N2**

Registration date: **2019-03-08, 1397/12/17**

Registration timing: **prospective**

Last update: **2019-03-08, 1397/12/17**

Update count: **0**

Registration date

2019-03-08, 1397/12/17

Registrant information

Name

Afsson Hassani Mehraban

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 22227124

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-20, 1398/02/30

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of meaningful Action Observation on occupational performance and brain physiological changes in chronic stroke patients

Public title

The effects of action observation on chronic stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

History of Only one cerebrovascular accident At least a score of 21 in Mini-mental state examination(MMSE) At least 6 months post since stroke in Medial cerebral artery(Neurologist diagnosis) Motor recovery stage 3 to 5 in Brunnstrum`s test No visual impairment due to ability to watch and precept a video film(Optometrlist verification) No disease comorbidity that interfere with the study Independent walking ability with or without assistive device Ability to sit independently at least for 1 hour

Exclusion criteria:

A recurrent stroke Implant or prosthesis in the skull Lack of cooperation in the evaluation sessions Participation in other therapeutic programs

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Block: In this method, the number of participants is assigned to each group are the same and the size of all blocks is equal (for example, in a double-blind trial, 8 blocks are containing 4 participants in the intervention group and 4 participants in the control group)

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome evaluator: The person or people who evaluate the outcome or non-outcome of the outcome in the participants or collect data on the outcome variables.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Mirdamad

City

Tehran

Province

Tehran

Postal code

۱۳۴۸۷ - ۱۵۴۵۹

Approval date

2019-01-17, 1397/10/27

Ethics committee reference number

IR.IUMS.REC.1397.840

Health conditions studied**1****Description of health condition studied**

Stroke

ICD-10 code

I67

ICD-10 code description

Other cerebrovascular diseases

Primary outcomes**1****Description**

Occupational Performance

Timepoint

first, final, one month after intervention

Method of measurement

Canadian Occupational Performance Measure

Secondary outcomes**1****Description**

Physiologic Changes of the brain

Timepoint

Before and after the intervention

Method of measurement

Motor evoked potential

Intervention groups

1

Description

Intervention group: After selecting tasks from some pre defined tasks, for about 30 minutes participant should watch a video film of standard performance of the selected task by a model and then execute the viewed task while the affect hand has the main role in the task performance. In beginning of each session preparatory techniques for the upper extremity including stretching, weight bearing, and active/passive exercise will be performed about 10 minutes.

Category

Rehabilitation

2

Description

Control group: In the control group also the selected task will be performed with this difference that the participant will just watch a video film of static pictures and/or landscapes without a creator being. In beginning of each session preparatory techniques for the upper extremity including stretching, weight bearing, and active/passive exercise will be performed about 10 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Aryan Shamili

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Kazem Malakoti

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Tehran

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Afsoon hassani mehraban

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

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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

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments

-

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Aryan Shamili

Position

Phd Candidate

Latest degree

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Other areas of specialty/work

Occupational Therapy

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