

# 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)

##### Phone

+98 22227124

##### Email address

mehraban.a@iums.ac.ir

##### 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

##### Street address

Karim khan-Beh afarin

##### City

Tehran

##### Province

Tehran

##### Postal code

1593748711

##### Phone

+98 21 8214 1600

##### Email

Shamilia@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr Seyed Kazem Malakoti

##### Street address

Hemmat highway

##### City

tehran

##### Province

Tehran

##### Postal code

۱۴۴۹۶۱۴۵۳۵

##### Phone

+98 21 8670 2503

##### Email

Shamilia@tbzmed.ac.ir

#### 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

##### Street address

Mirdamad

##### City

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##### Province

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Mehraban.a@iums.ac.ir

## Person responsible for scientific 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**

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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**

Master

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Mirdamad

**City**

tehran

**Province**