

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the effect of “Cognitive Orientation to Daily Occupational Performance” (CO-OP) with “Motivational Interviewing” (MI) on occupational performance in chronic stroke patients: a randomized controlled trial

#### Protocol summary

##### Study aim

- Comparison of the effect of "Cognitive Orientation to Daily Occupational Performance" and "motivational interviewing" on the functional independence of chronic stroke patients in performing activities of daily living. 2- Comparing the effect of "Cognitive Orientation to Daily Occupational Performance" and "motivational interviewing" on the occupational performance of chronic stroke patients. 3- Comparing the effect of "Cognitive Orientation to Daily Occupational Performance" and "motivational interviewing" on self-efficacy of chronic stroke patients.

##### Design

Clinical trial with control group, with parallel groups, single-blind, randomized, on 60 stroke patients. Randomization is done using the block random allocation using the website [www.sealedenvelope.com](http://www.sealedenvelope.com).

##### Settings and conduct

Patients who are eligible to enter are referred to a private clinic. After obtaining the written consent, the evaluations will be done by an evaluator who is unaware of the allocation. people will be randomly placed in each of the three groups. The intervention in all three control groups will be CO-OP and MI two sessions per week for five weeks for chronic stroke patients.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: A volunteer to enter the study, chronic ischemic stroke, over 18 years old, sufficient cognitive ability, the lowest level of depression or mild depression to moderate depression, being in stage 3 or higher of Brunnstrom, no disorder in verbal comprehension. Exclusion criteria: non-cooperation of the patient during the intervention or unwillingness to continue cooperation in the intervention, non-follow-up of the patient to participate in at least two treatment sessions, recurrence of stroke

##### Intervention groups

1-Control Group 2- Cognitive Orientation to Daily Occupational Performance (CO-OP) 3- Motivational Interviewing (MI)

##### Main outcome variables

Occupational Performance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180515039676N1**

Registration date: **2023-12-11, 1402/09/20**

Registration timing: **prospective**

Last update: **2023-12-11, 1402/09/20**

Update count: **0**

##### Registration date

2023-12-11, 1402/09/20

##### Registrant information

##### Name

Shiva Abedi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2218 0063

##### Email address

shiva.abedi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-21, 1402/11/01  
**Expected recruitment end date**  
2024-06-20, 1403/03/31  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparing the effect of "Cognitive Orientation to Daily Occupational Performance" (CO-OP) with "Motivational Interviewing" (MI) on occupational performance in chronic stroke patients: a randomized controlled trial

**Public title**  
"Comparing Cognitive Orientation to Daily Occupational Performance with Motivational Interviewing on occupational performance in stroke patients"

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Be a volunteer to enter the study (completion of the consent form) Chronic ischemic stroke (at least one year has passed since the stroke) diagnosed by a neurologist. Age 18 years and above Sufficient cognitive ability (minimum score of 22 on the Montreal Cognitive Test) Scores 5-18 in the Beck Depression Questionnaire (short form) (minimum level of depression or mild depression to moderate depression) Being in stage 3 and above Brunnstrom Absence of disorder in verbal understanding such as Wernicke's and Global aphasia.

**Exclusion criteria:**

Patient's non-cooperation during the intervention or unwillingness to continue cooperation in the intervention  
2- Failure to follow up the patient to participate in at least two treatment sessions  
3- Reoccurrence of stroke

**Age**  
From 18 years old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**  
Target sample size: 60

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Block random allocation method is used for data allocation. This allocation is done in several steps. First, using the website [www.sealedenvelope.com](http://www.sealedenvelope.com), a random sequence with blocks of six is created. Then, to hide the random allocation, sealed and waxed opaque envelopes are used in a random sequence. Based on the size of the research sample, a number of envelopes with aluminum wrapping (in view of the lack of clarity of the contents of

the envelopes), preparation and each of the random sequences created on a card are recorded and the cards inside the envelopes are called They are placed in order. In order to preserve the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box in order. At the time of registration of the participants, according to the order of entry of the eligible participants to the study, one of the letter envelopes will be opened and the assigned group of that participant will be revealed.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This will be a single-blind study. It should be noted that all evaluations are done by a trained evaluator therapist who does not know about the allocation of people in each of the groups, which is different from the examiner who performs the intervention in three groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of University of Social Welfare and Rehabilitation Sciences

**Street address**

kodakyar Ave., daneshjo Blvd., Evin

**City**

Tehran

**Province**

Tehran

**Postal code**

1985713834

**Approval date**

2023-08-28, 1402/06/06

**Ethics committee reference number**

IR.USWR.REC.1402.122

**Health conditions studied**

1

**Description of health condition studied**

stroke

**ICD-10 code**

I64

**ICD-10 code description**

Stroke, not specified as hemorrhage or infarction

## Primary outcomes

1

### Description

occupational performance

### Timepoint

Before the intervention, five weeks and one month after the intervention

### Method of measurement

Canadian Occupational Performance Measure Scale (COPM), Performance Quality Rating Scale (PQRS)

## Secondary outcomes

1

### Description

Self-efficacy

### Timepoint

Before the intervention, five weeks and one month after the intervention

### Method of measurement

General Self-Efficacy Scale (GSE-10)

2

### Description

Independence in daily activities of life

### Timepoint

Before the intervention, five weeks and one month after the intervention

### Method of measurement

Functional Independence Measurement (FIM)

## Intervention groups

1

### Description

Intervention group: Cognitive Orientation to Daily Occupational Performance (CO-OP)

### Category

Rehabilitation

2

### Description

Intervention group: Motivational Interviewing (MI)

### Category

Rehabilitation

3

### Description

Control group: Usual treatment (occupational therapy)

### Category

Rehabilitation

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Alzahra Medical and Education Center

#### Full name of responsible person

Shiva Abedi

#### Street address

AgharebParast Highway.,Sofe Blvd ., Isfahan Town

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174675731

#### Phone

+98 31 3822 0000

#### Email

alzahra@mui.ac.ir

#### Web page address

<https://alzahra.mui.ac.ir/en>

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

University of social welfare and rehabilitation sciences

#### Full name of responsible person

Nazila Akbarfahimi

#### Street address

kodakyar Ave., daneshjo Blvd.,Evin, Tehran Town

#### City

Tehran

#### Province

Tehran

#### Postal code

1985713871

#### Phone

+98 21 2218 0083

#### Fax

#### Email

fahimi1970@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

University of Social Welfare and Rehabilitation 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**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Shiva Abedi

**Position**

PhD Student in Occupational Therapy

**Latest degree**

Master

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Bagh Goldaste Ave., Goldis Center, Isfahan Town

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8145613353

**Phone**

+98 31 3224 5327

**Email**

shiva.abedi.ot@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Nazila Akbarfahimi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

**Street address**

kodakyar Ave., daneshjo Blvd.,Evin., Tehran Town

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**Email**

fahimi1970@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Shiva Abedi

**Position**

PhD student in Occupational Therapy

**Latest degree**

Master

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Bagh Goldasteh., Goldis Center., Isfahan Town

**City**

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8145613353

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**Email**

shiva.abedi.ot@gmail.com

## 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data is potentially shareable after de-identifying individuals.

**When the data will become available and for how long**

The access period starts 6 months after the results are published.

**To whom data/document is available**

The data will be available to researchers working in academic and scientific institutions and rehabilitation professionals in clinical settings.

**Under which criteria data/document could be used**

Providing the medical system card to ensure the clinical competence of people to provide services.

**From where data/document is obtainable**

Sending an email to an address named Shiva Abedi, sending an SMS to the contact number of Shiva Abedi, making a call to the number of Shiva Abedi, visiting in person Dr. Nazila Akbarfahimi at the University of Social Welfare and Rehabilitation Sciences.

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

First, the applicant must send a request to receive the documents to an email address named Shiva Abedi, if there is no response after 10 days, send an SMS or call the contact number of Shiva Abedi, then the responsible person ( Abedi) makes the necessary arrangements to send the documents to the applicant. If the responsible person (Abedi) did not respond within 7 days after

sending the text message and making the call, the requesting person can send his request to the email

address of Dr. Nazila Akbarfahimi.  
**Comments**