

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.

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 intervention2- Failure to follow up the patient to participate in at least two treatment sessions3- 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, 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

164

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

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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

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Province
Isfahan

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8145613353

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shiva.abedi.ot@gmail.com

Person responsible for scientific inquiries

Contact

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Full name of responsible person
Nazila Akbarfahimi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

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

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Person responsible for updating data

Contact

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Phone

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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