

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effectiveness of Mental Imagery on the Occupational Performance and Life Habits of Persons with Stroke

Protocol summary

Study aim

Evaluating the effectiveness of mental imagery on work performance and daily life habits of people with stroke

Design

The present study is a randomized, single-blind clinical trial. It has a control and intervention group that a total of 68 people are studied. Block randomization method is also used for randomization.

Settings and conduct

Samples will be selected from people with stroke in hospital centers affiliated to Tehran University of Medical Sciences, public and private centers in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion: 1. Age range: 30-65 2. Individuals with at least one chronic one-sided stroke, where the duration between the times of the disease is six months or more. 3. Ability to walk at least 10 meters with or without crutches. 4. No perceptual aphasia. 5. No unilateral negligence. 6. Absence of severe depression. 7. Ability to read and write. 8. No articular contractures affecting movement. 9. Appropriate communication skills and minimum mental state examination (MMSE) score of 21 or more. 10. Severe hemiplegic spasticity (modified Ashworth scale score of at least 3). Exclusion: 1. Severe upper extremity pain with a score greater than or equal to 5 on the visual analog scale. 2. Poor general conditions such as medical or orthopedic problems that have made the client unable to participate in regular rehabilitation. 3. Combined neurological diseases such as Parkinson's disease.

Intervention groups

In the intervention group, there is mental imaging with routine occupational therapy, and in the control group, there is only routine occupational therapy, which is the same time period for both groups.

Main outcome variables

Daily life habits, occupational performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220430054702N1**

Registration date: **2023-06-20, 1402/03/30**

Registration timing: **retrospective**

Last update: **2023-06-20, 1402/03/30**

Update count: **0**

Registration date

2023-06-20, 1402/03/30

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-21, 1401/02/31

Expected recruitment end date

2022-08-21, 1401/05/30

Actual recruitment start date

2022-06-05, 1401/03/15

Actual recruitment end date

2022-11-16, 1401/08/25

Trial completion date

2023-02-15, 1401/11/26

Scientific title

Effectiveness of Mental Imagery on the Occupational Performance and Life Habits of Persons with Stroke	
Public title	The effectiveness of mental imagery in people with stroke
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: People with adult stroke are in the age range of 30-65 who have at least one chronic unilateral stroke, on the other hand, the interval between the onset of the disease is six months or more. References can walk at least 10 meters with or without a cane. Lack of perceptual aphasia No unilateral neglect No severe depression Be literate Lack of articular contractures affecting movement Clients have appropriate communication skills and have a minimum mental state examination score (MMSE) of 21 and above to be able to be intervened. Severe hemiplegic spasticity (modified Ashworth Scale score at least 3) Exclusion criteria: Any severe upper limb pain, with a score greater than or equal to 5 on the analog visual scale Bad general conditions such as medical or orthopedic problems that have prevented clients from participating in normal rehabilitation Combined neurological diseases such as Parkinson's disease are present in clients
Age	From 30 years old to 65 years old
Gender	Both
Phase	N/A
Groups that have been masked	• Participant • Care provider • Outcome assessor • Data analyser
Sample size	Target sample size: 68 Actual sample size reached: 68
Randomization (investigator's opinion)	Randomized
Randomization description	The samples will then be divided into control and intervention groups by block randomization method. In the block randomization method, first all 4 blocks that contain two letters A and B are prepared (6 blocks) and we assign a number from 1 to 6 to each of them. Then, using a table of random numbers, numbers from one to six are selected (15 numbers) and the corresponding block will be written based on the selected random number. Doing so will result in a sequence of 60 letters A and B. Each sample will have a number from 1 to 60 if they enter the study, which will receive an A or B code based on the letter list based on each person's number. This is both a coincidence and both groups will be approximately the same.
Blinding (investigator's opinion)	Single blinded
Blinding description	In this study, the evaluation is performed by an occupational therapist who is fluent in the tests and is not part of the research team and is not aware of the study process (the evaluator is blind).
Placebo	Not used
Assignment	Factorial
Other design features	
Secondary Ids	empty
Ethics committees	1 Ethics committee Name of ethics committee Ethics Committee of Tehran University of Medical Sciences Street address Tehran, Enghelab St., Pich Shemiran, corner of Safi Alishah St., School of Rehabilitation City Tehran Province Tehran Postal code 1148965111 Approval date 2022-05-29, 1401/03/08 Ethics committee reference number IR.TUMS.MEDICINE.REC.1401.186
Health conditions studied	1 Description of health condition studied Stroke ICD-10 code G46 ICD-10 code description Vascular syndromes of brain in cerebrovascular diseases
Primary outcomes	1 Description The score of daily life habits in the life habit(H-LIFE) questionnaire Timepoint The time periods of measuring life habits for the samples are done two weeks before the intervention and two weeks after the intervention. Method of measurement Life habits(H-LIFE) questionnaires

2

Description

Occupational performance score in the Canadian Occupational Performance measure(COPM)

Timepoint

Occupational performance measurements for the samples are performed two weeks before the intervention and two weeks after the intervention.

Method of measurement

Canadian Occupational Performance Measure(COPM)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: available samples are included in the study based on the inclusion criteria. Then clients fill part of the demographic information questionnaire and enter the intervention group (routine occupational therapy with mental imagery), daily life habits are measured using the life habits questionnaire (H-Life). Then, the work performance priorities of the samples in the three areas of productivity, self-care and leisure time are determined using the Canadian Work Performance Scale (COPM), and the intervention should be carried out on these priorities. Clients perform their priority functions with the healthy side and using video rotation software, the prepared video is returned and sent to the clients. In the video made, it seems that the person with the involved side is doing an activity, and the video contains 5 functions that are a priority for the reference, and the duration of the video for each function is one minute (5 minutes in total). . Clients should view this video of priority functions before performing the visualization. which later visualizes these priority functions during the therapy session. Intervention protocol: 1- Mental imagery intervention for the intervention group: Mental imagery includes three parts: relaxation, imagination (visualization of prioritized functions) and normalization. The relaxation part (three minutes), fantasy or visualization of priority functions (5 minutes) and normalization (two minutes), which are 10 minutes in total. Mental imagery exercises are performed three times a day (for a total of 30 minutes), 3 times a week for 4 weeks. In all parts, the person should sit in a relaxed and comfortable position (the environment should have minimal noise and distractions). The first part of relaxation: relaxation; It includes three stages of breathing exercises, visualization of a relaxing environment and muscle relaxation. The whole relaxation part lasts for 3 minutes. The first stage of sedation or respiratory sedation; The person is asked to count to 4 and inhale through the nose while counting and then hold his breath and count to 4, then while breathing out to count to 4, finally without breathing again or Exhale for a count of 4 and repeat this process for 25 seconds. The second stage of relaxation; Imagining a relaxing

environment: In this step, the person is asked to create a relaxing environment by remembering a relaxing environment or through imagination (for example, a day at the beach or in the forest). The elements of the environment using each of the five senses using commands such as: What do you see? (for example, the blue color of water), . what do you hear (eg waves crashing along the shore), what do you smell? (For example, the fruity scent of sunscreen), what do you smell? (eg, salty sea air), how do you feel? (for example, the heat of the sun). In total, this stage of relaxation takes 50 seconds. The third stage of relaxation; It is muscle relaxation, which consists of 6 steps and includes the following exercises: 1. Starting from the foot, bend the toes under and contract the leg muscles. Hold for 5 seconds, then slowly release for 10 seconds. 2. Contract the calf muscles. Hold for 5 seconds, then release slowly for 10 seconds. 3. Contract the buttock muscles. Hold for 5 seconds, then slowly release for 10 seconds. 4. Contract the abdominal and chest muscles. Hold for 5 seconds, then slowly release for 10 seconds. 5. Contract the shoulder muscles. Hold for 5 seconds, then release slowly for 10 seconds. 6. Contract the muscles of the face (for example, squeeze the eyes). Hold for 5 seconds, then slowly release for 10 seconds. 7. Contract the hand muscles and make a fist. Hold for 5 seconds, then slowly release for 10 seconds. A total of 105 seconds are spent on relaxing the muscles. Second part: imagining and visualizing priority functions; In this section, the references visualize the video made of the priority functions, the duration of which is 5 minutes, and one minute of visualization is considered for each function. The third part: normalization; in this stage, the client is asked to pay attention to the surrounding environment and the real position of his body, and the duration of this stage is 2 minutes. In total, it takes 10 minutes to complete all the mental imaging sections. Therefore, in every session that the client intends to visualize, he must repeat it 3 times a day, which takes a total of 30 minutes of visualization. 2- Routine occupational therapy intervention for the intervention group: Routine occupational therapy includes; Upper body exercises for 15 minutes: carrying a cube, pegboard, holding a cup and sliding objects on the table. Also, 15 minutes of exercises for the lower body: changing from sitting to standing, reaching sitting positions, walking and crossing obstacles, turning and transferring), 30 minutes per session, 3 times a week for 4 weeks. Takes.

Category

Rehabilitation

2

Description

Control group: Includes routine occupational therapy, which includes upper extremity exercises for 15 minutes: carrying a cube, pegboard, holding a cup, and sliding objects on a table. Also, 15 minutes of exercises for the lower body: changing from sitting to standing, reaching sitting positions, walking and crossing obstacles, turning and transferring), 30 minutes per session, 3 times a week for 4 weeks. Takes.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Ziaian hospital

Full name of responsible person

Zeynab Sori

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Sponsors / Funding sources

1

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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

Tehran 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

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data related to demographic questionnaires and Canadian life habits and performance are presented in summary form, separately and in files.

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

Clients and professors, advisors, guides and all researchers

Under which criteria data/document could be used

The general researchers are allowed to use any type of analysis.

From where data/document is obtainable

Send to the recipient's email address.

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

Send to the recipient's email address.

Comments