Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Occupational Therapy Intervention Process Model (OTIPM) on occupational performance and satisfaction of patients with chronic stroke and comparing it with conventional occupational therapy

Protocol summary

Study aim

to investigate the effect of occupational therapy based on the OTIPM model on occupational performance and the level of satisfaction of chronic stroke patients in comparison with traditional occupational therapy.

Design

A concealed clinical trial with control group, parallel groups, single blind,and block randomization by using random numbers table. Sample are recruited from stroke rehabilitation clinics in Tehran and sample size will be determined after a pilot study.

Settings and conduct

Setting for control and intervention groups are outpatient clinic and home respectively. Patients participate in one hour for each session, three times per week during ten weeks interventions. Assessor will be blind in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: stroke patients with age range of 18 to 65 years, Brunnstrom score over 3, MMSE ≥ 21, living at home, at least 6 months post stroke with occupational therapy referral. People with acute heart diseases, serious psychological problems or other neurological diseases, are excluded from the study.

Intervention groups

The traditional occupational therapy interventions: neurodevelopmental treatment, Bobath technique, proprioceptive neuromuscular facilitation, pain management, gross and fine manual dexterity training are provided to the participants. The occupational therapy intervention based on the OTIPM model includes: 1- Prioritization of Activity Daily Living (ADL) by client 2- Observation and analysis of client while performing challenging ADL by the occupational therapist 3-Defining contributing factors for ineffective occupational performance 4- Defining treatment goals 5- Implementation of interventions (compensatory, educational, acquisition and restoration).

Main outcome variables

Occupational performance and satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160808029260N5**
Registration date: **2023-05-13, 1402/02/23**
Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**
Update count: **0**

Registration date

2023-05-13, 1402/02/23

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-05-19, 1403/02/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Occupational Therapy Intervention Process Model (OTIPM) on occupational performance and satisfaction of patients with chronic stroke and comparing it with conventional occupational therapy

Public title
Investigating the impact of occupational therapy based on daily life activities on the performance and satisfaction level of stroke patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Occurrence of a stroke Age 18 to 65 years Branstrom above 3 MMSE above 21 Living at home At least 6 months have passed since the stroke The doctor has referred the person to receive occupational therapy services
Exclusion criteria:
People have acute heart diseases (such as acute heart attack) People have serious psychological diseases (such as depression and psychiatric disorders) People have neurological diseases (such as recurrent stroke, Parkinson's, dementia, seizures)
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Using a table of random numbers by a person who has no contact with the patients, the patients are placed in two groups in the form of random blocks, the patients in the first group received conventional occupational therapy treatments and in the second group received occupational therapy based on the OTIPM model (the main intervention).
Blinding (investigator's opinion)
Single blinded
Blinding description
The present study is single blind (evaluator).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Next to Milad tower, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2023-05-01, 1402/02/11
Ethics committee reference number
IR.IUMS.REC.1402.078

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 (a dynamic interaction involving the person, context/environment, and activity or occupation) is the focus of occupational therapy practice. including skills (purposeful actions to perform occupations such as motor skills, processing skills, social interaction skills), patterns (temporal elements of occupation such as routines, habits, roles, rituals) and domains (work/productivity, play/leisure (such as play), sports, hobbies) are the basic and functional activities of daily living such as rest/sleep)
Timepoint
Before the intervention, after 10 weeks of intervention, the first and third month after the end of the intervention
Method of measurement
Occupational performance is measured with the help of COPM and ADL taxonomy scores

2

Description

Satisfaction: the degree of satisfaction of people with occupational performance and the match between occupational participation and performance expectations

Timepoint

Before the intervention, after 10 weeks of intervention, the first and third month after the end of the intervention

Method of measurement

The score of the COPM questionnaire

Secondary outcomes

1

Description

Functional performance: Physiological functions of body systems

Timepoint

Before the intervention, after 10 weeks of intervention, the first and third month after the end of the intervention

Method of measurement

In this study, body functions are measured with the help of ARAT, FMA and SIS questionnaire scores.

Intervention groups

1

Description

Intervention group: The intervention of the second occupational therapy group is based on the OTIPM model (main intervention). In this group, once the client has prioritized which activities of daily living should be addressed, the occupational therapist, after observing the challenging activities of daily living of the person in the natural context of the client, analyzes the ineffective skills and tasks in performing the performance of each prioritized task (occupation). And it takes into account person effective factors, including body function, task needs, or the influence of the environment in the implementation of occupation. After completing the performance analysis, the occupational therapist and the clients work together to create client-centered and occupation-centered goals, and there are four choices in the intervention stage: compensatory, educational, acquisition, and restoration (steps of implementing this intervention in the attached file) The full length has been described (23, 33). This group of interventions with the presence of an occupational therapist at home and three sessions a week, for ten weeks and each session is one hour, These interventions are implemented by the researcher who has trained the model implementation courses.

Category

Rehabilitation

2

Description

Control group: The intervention of the first group includes conventional occupational therapy interventions. These interventions included neurodevelopmental treatment, Bobath technique, facilitation of neuromuscular proprioception, pain management, hand manipulation skills and dexterity training were provided to the participants. These interventions are performed in the outpatient occupational therapy center in three sessions per week, for ten weeks and each session is one hour, These interventions are implemented by an occupational therapist who has at least 2 years of practical experience.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation Sciences of Iran University of Medical Sciences

Full name of responsible person

Esmail sadeghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
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
Demographic data of the study participants after making them unidentifiable; Primary and secondary outcome information

When the data will become available and for how long
After publishing the results of the study

To whom data/document is available
Researchers who are working in academic and scientific institutions

Under which criteria data/document could be used
For doing meta-analysis review studies

From where data/document is obtainable
Esmail sadeghi Phone number:00989120302534 Email

address: sadeghi.ot87@gmail.com Address: School of Rehabilitation, Madadkaran Alley, Shahnazari Street, Madar Square, Mirdamad Boulevard, Tehran, Iran 2) Afsoon Hassani Mehraban Phone number: 0098 21 22228051 Email address: mehraban.a@iums.ac.ir Address: School of Rehabilitation, Madadkaran Alley, Shahnazari Street, Madar Square, Mirdamad Boulevard, Tehran, Iran

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

The researcher can access the data of this research up to one month after sending the request and attaching the registered protocol of the review article to the introduced emails.

Comments