Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of rTMS on working memory of patient with stroke

Protocol summary

Study aim
The effect of rTMS on working memory of people with stroke

Design
Sampling by available method of clients and individuals based on gender is divided into two groups of men and women. They were randomly divided into two groups of intervention and control. If there is no significant difference in age and Wechsler score, the intervention begins.

Settings and conduct
At the site of the Qasr Rehabilitation Clinic, an initial N-Back test is taken from all individuals by those who are unaware of the groupings (first blindness). Then everyone attends the RTMS sessions. In the control group, changing the angle of the coil will prevent the waves from reaching the brain, and thus the second blinding will occur. In addition, everyone will receive computer-based cognitive therapy services with Captain Log software. Finally, all the n-back tests are taken

Participants/Inclusion and exclusion criteria
1. Having a stroke for the first time 2. Age between 55 and 75 3. A minimum of 6 months and a maximum of 2 years have elapsed since the stroke 4. Lesion on the left side of the brain 5. The right side of the body dominates 6. Absence of obvious symptoms of psychosis 7- No history of seizures in the last 6 months 8. Do not take drugs that affect cognition 9 - Minimum literacy 10- Obtaining the average raw score of 2.8 حاف digits of memory, in the working memory subscale in Wechsler intelligence test 11- Not receiving TMS services before entering the study

Intervention groups
The intervention group will receive standard therapies, including occupational therapy and physiotherapy using RTMS, and the control group will receive only standard treatments. Both groups will also receive cognitive rehabilitation treatment.

Main outcome variables
Increase the quality of life Improve working memory Accelerate the process of cognitive therapy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201016049041N1**
Registration date: **2020-10-28, 1399/08/07**
Registration timing: **prospective**

Last update: **2020-10-28, 1399/08/07**
Update count: **0**

Registration date
2020-10-28, 1399/08/07

Registrant information

Name
Yaser Farahmandi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3629 2578

Email address
yaser.ot91@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-05, 1399/08/15

Expected recruitment end date
2020-12-12, 1399/09/22

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of rTMS on working memory of patient with stroke

Public title
The Effect of rTMS on stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a stroke for the first time based on the available medical records. Age between 55 to 75 years of patients At least 6 months and at most 2 years after the stroke The lesion is on the left side of the brain. The right side of the body should be dominant. No obvious symptoms of psychosis in a person (according to the doctor's diagnosis) No history of seizures in the last 6 months Do not use drugs that affect cognition Having a minimum literacy of reading and writing Obtaining the average raw score of 5 digits of memory, in the working memory subscale in Wechsler intelligence test Not receiving TMS services before entering the study Favorable opinion of caregivers and patients based on participating in the research.
Exclusion criteria:
Age
From **55 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the double-blindness of the study, a person other than the researcher, as an assessor who is also proficient in taking the Wechsler test, completes the consent form, demographic questionnaire and also the software version of the adult Wechsler working memory test. From the beginning of the evaluation and intervention process, the researcher is unaware of which group is the intervention or control group. The subjects do not know which of these two groups they belong to. Both groups will receive cognitive rehabilitation intervention and TMS. The control group TMS will have the same conditions as active TMS. The difference is that changing the angle of the coil will prevent waves from reaching the brain, and the coil will be at a 45-degree angle to the surface of the skull. This condition gives the person a similar somatosensory sensation from the TMS, except that it will not affect the brain. The TMS will be performed by the device operator during the initial assessor's order.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Chamran Highway Yemen St. - Shahid Arabi St. next to Ayatollah Taleghani Hospital, Tehran
City
Tehran
Province
Tehran
Postal code
1985717434
Approval date
2020-06-28, 1399/04/08
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.277

Health conditions studied

1

Description of health condition studied
stroke
ICD-10 code
G46.4
ICD-10 code description
Cerebellar stroke syndrome

Primary outcomes

1

Description
Working memory score in N-BACK test
Timepoint
Assessment of working memory at the beginning of the study (before the intervention) and 5 weeks after TMS
Method of measurement
N-BACK test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group receives rehabilitation services including occupational therapy and physiotherapy in cases related to physical-motor problems in the form of two sessions of physiotherapy and two sessions of occupational therapy per week. Then they participate in RTMS intervention sessions. In addition, people will receive computer-based cognitive therapy services using Captain Log software for 15 sessions three days a week for 30 to 40 minutes. This treatment will be performed for people immediately after performing RTMS. The exercises used are related to the working memory rehabilitation exercises in Captain Log software. The software exercises have three levels for three age groups of children, adolescents and adults. The treatment plan in this study is based on the use of the adult level. Each level has 15 stages and each stage takes an average of 1.5 to 3 minutes, which increases the difficulty of the exercises as the stages increase. . For example, in each exercise, step number two has more challenges than step number one of that exercise. How to perform cognitive rehabilitation of working memory in Captain Log software will be that after defining a specific profile named person, 5 specified exercises will be performed for them. In this way, after explaining how to perform each exercise and how to answer the questions of that exercise, the occupational therapist immediately performs the same exercise for the person. After answering, the software will go to the second exercise and again the occupational therapist will give the necessary explanations to perform that exercise. Depending on the amount of correct answers or the speed of the answers, the software will automatically increase the complexity of the exercises or reduce the complexity of the exercises in case of incorrect answers or low response speed. For example, a person responds correctly to the first to third exercises and makes a mistake in answering the fourth and fifth exercises. After completing five exercises, the software enters the second round of exercises again, but with the difference that in this round, for the first to third exercises, level two is performed, and for the fourth and fifth exercises, when the person's answers were incorrect, the same level Will repeat one. After the end of each session, information about the process of performing exercises for the person is stored in the software and in the next sessions, the continuation of the levels of exercises for that person can be performed. RTMS Interference: Sessions RTMS intervention is performed by the device operator, who is aware of how the intervention and control groups are classified. RTMS interventions for each patient will be 15 sessions three days a week and each session will last for 6 minutes. During each session, frequent active TMS with a frequency of 10 Hz will include 60 1-second stimuli (10 pulses) with a 5-second rest period between stimuli and a total of 600 pulses with a power of 100% of the movement threshold on the dorsultral perry. The left frontal cortex is applied. The control group TMS will have the same conditions as the active TMS. The difference is that changing the angle of the coil will prevent waves from reaching the brain, and the coil will be at a 45-degree angle to the surface of the skull. This condition gives the person a similar somatosensory sensation from TMS, except that it has no effect on the brain.

Category

Rehabilitation

2

Description

Control group: This group receives rehabilitation services including occupational therapy and physiotherapy in cases related to physical-motor problems in the form of two sessions of physiotherapy and two sessions of occupational therapy per week. Then they participate in RTMS intervention sessions. In addition, people will receive computer-based cognitive therapy services using Captain Log software for 15 sessions three days a week for 30 to 40 minutes. This treatment will be performed for people immediately after performing RTMS. The exercises used are related to the working memory rehabilitation exercises in Captain Log software. The software exercises have three levels for three age groups of children, adolescents and adults. The treatment plan in this study is based on the use of the adult level. Each level has 15 stages and each stage takes an average of 1.5 to 3 minutes, which increases the difficulty of the exercises as the stages increase. . For example, in each exercise, step number two has more challenges than step number one of that exercise. How to perform cognitive rehabilitation of working memory in Captain Log software will be that after defining a specific profile named person, 5 specified exercises will be performed for them. In this way, after explaining how to perform each exercise and how to answer the questions of that exercise, the occupational therapist immediately performs the same exercise for the person. After answering, the software will go to the second exercise and again the occupational therapist will give the necessary explanations to perform that exercise. Depending on the amount of correct answers or the speed of the answers, the software will automatically increase the complexity of the exercises or reduce the complexity of the exercises in case of incorrect answers or low response speed. For example, a person responds correctly to the first to third exercises and makes a mistake in answering the fourth and fifth exercises. After completing five exercises, the software enters the second round of exercises again, but with the difference that in this round, for the first to third exercises, level two is performed, and for the fourth and fifth exercises, when the person's answers were incorrect, the same level Will repeat one. After the end of each session, information about the process of performing exercises for the person is stored in the software and in the next sessions, the continuation of the levels of exercises for that person can be performed. RTMS Interference: Sessions RTMS intervention is performed by the device operator, who is aware of how the intervention and control groups are classified. RTMS interventions for each patient will be 15 sessions three days a week and each session will last for 6 minutes. During each session, frequent active TMS with a frequency of 10 Hz will

include 60 1-second stimuli (10 pulses) with a 5-second rest period between stimuli and a total of 600 pulses with a power of 100% of the movement threshold on the dorsultral perry. The left frontal cortex is applied. The control group TMS will have the same conditions as the active TMS. The difference is that changing the angle of the coil will prevent waves from reaching the brain, and the coil will be at a 45-degree angle to the surface of the skull. This condition gives the person a similar somatosensory sensation from TMS.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Qasr Physical Medicine and Rehabilitation Clinic

Full name of responsible person

Dr Ali Farkhani

Street address

,Alley 26 (Dahesh). in front of Bank Mellat, Qasr Crossroads,Shamsabadi St.,Isfahan

City

Esfahan

Province

Isfehan

Postal code

8511223344

Phone

+98 31 3236 7465

Email

dr.farkhani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

next to Ayatollah Taleghani Hospital- Shahid Arabi St.Shahid Chamran Highway Yemen St. Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Minoo Kalantari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street address

Faculty of Rehabilitation Sciences. in front of Bouali Hospital - Damavand St., Tehran

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7754 2057

Email

rehab@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Minoo Kalantari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street address

Faculty of Rehabilitation Sciences. in front of Bouali Hospital - Damavand St., Tehran

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7754 2057

Email

rehab@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Minoo Kalantari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street address

Faculty of Rehabilitation Sciences. in front of Bouali Hospital - Damavand St., Tehran

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7754 2057

Email

rehab@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Study protocol Informed consent form Clinical study report

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

For all people

Under which criteria data/document could be used

No special conditions are considered

From where data/document is obtainable

They can contact the authors' emails

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

Finally a month

Comments