

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Effects of high-frequency repetitive transcranial magnetic stimulation combined with Physiotherapy in Rehabilitation of Functional outcomes, Balance, Quality of life and depression in stroke patients: A randomized controlled trial.

#### Protocol summary

##### Study aim

Comparison of effects of treatment with HF-rTMS(High-Frequency Repetitive Transcranial Magnetic Stimulation) and rehabilitation, with rehabilitation alone, on balance, functional independence, quality of life and depression of patients after stroke

##### Design

Two arms parallel-group randomized trial on 36 patients with blinded outcome assessment

##### Settings and conduct

Stroke patients are visited in the specialty clinic of Emam Reza hospital of Tabriz by an experienced neurologist and then referred for initial assessments. Patients undergo interventions based on their group in Physigo Rehabilitation center, and assessment is done immediately after, and 1 month after interventions. Neurologist, researcher, outcome evaluators and the statistician are blinded.

##### Participants/Inclusion and exclusion criteria

Adult patients with proven ischaemic or hemorrhagic stroke, suffering from movement disorders of lower limbs; without a past history of epilepsy or other contraindications of rTMS

##### Intervention groups

Subjects that conform to inclusion criteria are allocated to these two groups: 1- Intervention: Real HF-rTMS and conventional rehabilitation 2- Control: Sham HF-rTMS and conventional rehabilitation

##### Main outcome variables

Berg Balance Scale(BBS) score; Berg Depression Short Inventory (BDI-S) score; Adults' Activities of Daily Living (ADL) Questionnaire score; WHO Short-form Quality of Life Questionnaire (WHOQOL-BREF) score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100720004422N8**

Registration date: **2020-09-01, 1399/06/11**

Registration timing: **prospective**

Last update: **2020-09-01, 1399/06/11**

Update count: **0**

##### Registration date

2020-09-01, 1399/06/11

##### Registrant information

##### Name

Seyed Kazem Shakouri

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1336 3518

##### Email address

shakourik@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-05, 1399/06/15

##### Expected recruitment end date

2020-11-21, 1399/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effects of high-frequency repetitive transcranial magnetic stimulation combined with Physiotherapy in Rehabilitation of Functional outcomes, Balance, Quality of life and depression in stroke patients: A randomized controlled trial.

**Public title**

Effects of rTMS in rehabilitation after stroke

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Proven CVA via MRI At least 3 months after stroke Stroke in MCA artery Motor disorder in lower limbs due to recent stroke Mild to moderate disorder of balance measured by Berg balance scale

**Exclusion criteria:**

Flaccid paraplegia Presence of a cardiac pacemaker, cochlear implant or any metal implant in patient's skull Previous treatment sessions with rTMS History of severe psychiatric disorders, including suicidal thoughts Pregnancy History of epilepsy History of other Neurologic disorders of balance Consumption of drugs with a potential disruptive effect on patient's balance Recent brain or spinal cord surgery Recent brain or spinal cord surgery Severe musculoskeletal disorders of lower limbs

**Age**

From **20 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A block randomization method will be used to allocate participants to the groups with a 1:1 allocation using random allocation software (RAS) with block sizes of 2 and 4. Similar sealed envelopes will be used to conceal the allocation in a sequentially numbered opaque package

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

An independent researcher will randomise eligible participants. The researcher administering rTMS will be unblinded. To ensure allocation concealment, the independent researcher (randomiser) will provide allocation details (stimulation type) via a participant ID-

coded email to the rTMS administrator immediately before the rTMS session. Participants will be remained blind to stimulation type until the end of procedures, as the researcher conducting assessments.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Tabriz University of Medical Sciences central offices building No.2, Golgasht St, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166969396

**Approval date**

2020-04-28, 1399/02/09

**Ethics committee reference number**

IR.TBZMED.REC.1399.069

**Health conditions studied****1****Description of health condition studied**

Stroke

**ICD-10 code**

I63

**ICD-10 code description**

Cerebral infarction

**Primary outcomes****1****Description**

Berg Balance Scale Score

**Timepoint**

Before Intervention, After Intervention, After 1 month

**Method of measurement**

Berg Balance Scale Score

**2****Description**

Berg Depression Short Inventory (BDI-S) score

### **Timepoint**

Before Intervention, After Intervention, After 1 month

### **Method of measurement**

Berg Depression Short Inventory (BDI-S) score

### **3**

#### **Description**

Adults activities of daily living Questionnaire

#### **Timepoint**

Before Intervention, After Intervention, After 1 month

#### **Method of measurement**

Adults activities of daily living Questionnaire Score

### **4**

#### **Description**

WHO Short-form Quality of Life Questionnaire (WHOQOL-BREF) score

#### **Timepoint**

Before Intervention, After Intervention, After 1 month

#### **Method of measurement**

WHO Short-form Quality of Life Questionnaire (WHOQOL-BREF) score

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: 10 sessions of HF-rTMS, delivered to lesional primary motor cortex area (M1), Frequency is set to 10 HZ. Dose for every session is 1000 pulses delivered in 10 trains of 10 seconds, with 50 seconds of rest in between. The total time for every session is 10 minutes. Patients undergo conventional rehab for stroke such as ROM and strengthening exercises, sitting and standing training, gait training with mirror and electrical stimulation based on the severity of symptoms.

#### **Category**

Rehabilitation

### **2**

#### **Description**

Control group: Sham rTMS sessions are performed with a protocol similar to the intervention group, although the orientation of the coil is different and the intensity is set to minimum and simulated sounds are played through a speaker. The rehabilitation protocol is the same as the intervention group.

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Physical Medicine & Rehabilitation Clinic of Emam Reza Hospital

##### **Full name of responsible person**

Seyyed Kazem Shakouri

##### **Street address**

Physical medicine and rehabilitation ward, Emam Reza Hospital, Golgasht st, Tabriz

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Tabriz

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##### **Phone**

+98 41 3380 5274

##### **Email**

imamreza@tbzmed.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr. Ata Mahmoudpour

##### **Street address**

Attar Neyshaburi St., Tabriz University of Medical Sciences, Tabriz

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##### **Email**

info@medfac.tbzmed.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Kiarash Kordshakeri

**Position**

Medical Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Latest degree**

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## 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**

Undecided - It is not yet known if there will be 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**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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