ISRCTN12867198 https://doi.org/10.1186/ISRCTN12867198

Repetitive transcranial magnetic stimulation of the primary motor cortex improves movement performance by regulating neural oscillations

Submission date
07/10/2024

Recruitment status
No longer recruiting

Registration date
11/10/2024

Overall study status
Completed

Last Edited
10/10/2024

Condition category
Nervous System Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Transcranial magnetic stimulation (TMS) could improve motor cortical excitability and balance dysfunction. However, the underlying neurophysiological mechanism of repetitive TMS (rTMS) combined with task-related brain state (TCBS) intervention remains unclear. This study investigates which brain oscillatory activities in which brain regions are involved in the TCBS intervention.

Who can participate?
Healthy adult volunteers aged between 20 and 75 years old

What does the study involve?
To investigate the neurophysiological mechanisms, rTMS will be applied to the motor cortex of subjects during movement tasks. Multichannel electroencephalography (EEG) signals in various frequency bands (θ, α, β, γ) will be obtained before, during, and after the intervention. The phase-locking value, conventional entropy, and coupling entropy will be introduced to investigate cross-frequency coupling characteristics (CFCC), within-frequency dynamic characteristics (WFDC), and cross-frequency coupling dynamic characteristics (CFCDC) respectively.

What are the possible benefits and risks of participating?
The study aims to quantify TMS-induced coupling and differences in dynamic characteristics and objectively evaluate the effects of TCBS. These calculations are significant for understanding the coupling characteristics and neurodynamic characteristics after TCBS modulation, potentially guiding the TCBS treatment of movement-related diseases.

The risk of rTMS in inducing a seizure is low ranging from 1/100,000 to 33/100,000, even in patient populations taking drugs acting on the central nervous system, at least with the use of traditional stimulation parameters and focal coils for which large data sets are available. While this is reassuring and helpful information for subjects, it remains necessary to be prepared to deal with a seizure that might arise in any experimental protocol.

Where is the study run from?
Key Laboratory of Intelligent Rehabilitation and Neuromodulation of Hebei Province, Yanshan University, China

When is the study starting and how long is it expected to run for?
September 2021 to August 2023

Who is funding the study?
1. National Key Research and Development Program of China
2. National Natural Science Foundation of China
3. Outstanding Youth of Hebei Natural Science Foundation
4. Hebei Key Research and Development Program
5. Hebei Province of Introduction of Overseas Talent
6. Central Government Guides Local Projects
7. Hebei Innovation Capability Improvement Plan Project

Who is the main contact?
Dr Lingdi Fu, ldfu@ysu.edu.cn

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
TMPRNO: rTMS of M1 improves movement performance by regulating neural oscillations

Acronym
TMPRNO

Study objectives
The present study aims to explore the regulator mechanism and look for potential biomarkers of repetitive transracial magnetic stimulation (TMS) intervention when combined with movement-related brain state.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/03/2022, First Hospital of Qinhuangdao Research Ethics Committee (The First Hospital of Qinhuangdao, 258 Wenhua Road, Qinhuangdao, 066005, China; +86-18830466169; 895638791@qq.com), ref: 2022A107

Study design
Randomized controlled study

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Improve motor cortical excitability and balance dysfunction to provide practical guidance for the task-related brain state (TCBS) treatment of movement-related diseases, such as stroke

Interventions
Electroencephalography (EEG) signals were collected from 32 Ag-AgCl scalp electrodes located according to the International 10-10 system using a BrainAmp system (Brain Products, Gilching, Germany). The experimental sessions began with a resting state with eyes open (pre-REST), followed by task familiarization and 30 additional trials before intervention (TASK), 5 minutes after intervention (TASK5), and 20 minutes after intervention (TASK20). Movement-related EMG signals were recorded to estimate the participants' reaction time (RT) and monitor their movement performance during the three task-related periods. Transcranial magnetic stimulation (TMS)-evoked EEG responses were collected before intervention (PRE), immediately after intervention (POST0), and 15 minutes after intervention (POST15) using 100 TMS pulses. Stimulus intensity was set at 120% of the resting motor threshold (RMT). Sessions concluded with a resting state 25 minutes after intervention (post-REST).

The intervention provider has over 10 years of experience using TMS, EEG, and electromyography (EMG) technology. Throughout the experiment, participants sat in a comfortable chair and rested their right-hand index finger on a keypad without electronic

devices. EMG signals were recorded from the right hand's first dorsal interosseous (FDI) and abductor digiti minimi (ADM) muscles. Repetitive TMS (rTMS) was administered at a frequency of 10Hz, with 1200 pulses delivered over a 10-minute stimulation duration. TMS pulses were delivered over the M1 of the FDI “hot spot” where the largest motor-evoked potentials (MEPs) could be acquired. The interventions consisted of 90 trials of a movement task, during which 10Hz rTMS at 80% of the RMT with 1200 pulses over a 10-minute stimulation duration was implemented.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Transcranial magnetic stimulation device

Primary outcome(s)
The following primary outcome measures were assessed using electromyography before intervention (TASK), 5 min after intervention (TASK5), and 20 min after intervention (TASK 20):
1. Reaction time, characterized between the ‘0’ cue and feedback
2. Movement performance, defined as the percentage of the sum of OK and GOOD among total trials

Key secondary outcome(s))
Motor cortical excitability measured using electroencephalography (EEG) during a resting state with eye open (pre-REST), 0 min after intervention (POST0) and with a resting state 25 min after intervention (post-REST)

Completion date
16/08/2023

Eligibility

Key inclusion criteria
1. Criteria specified in the TMS safety guidelines
2. Right-handed hand
3. Age range: 20-75 years old
4. No metal implants on the head
5. Healthy, No neurological or psychiatric disorders
6. No severe visceral diseases such as liver, lung, heart, kidney, etc
7. Voluntarily participate and sign an informed consent form
8. No severe motor function and able to complete exercise tests
9. Not receiving any drug treatment

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
20 years

Upper age limit
75 years

Sex
All

Total final enrolment
24

Key exclusion criteria
1. A history of neurological or psychiatric disorders
2. Receiving any drug treatment
3. Unwilling to have TMS
4. Unwilling to record EEG
5. Contraindications to magnetic stimulation

Date of first enrolment
05/04/2022

Date of final enrolment
09/08/2023

Locations

Countries of recruitment
China

Study participating centre
Key Laboratory of Intelligent Rehabilitation and Neuromodulation of Hebei Province
Institute of Electrical Engineering, Yanshan University
Qinhuangdao
China
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Sponsor information

Organisation
Yanshan University

ROR
https://ror.org/02txfnf15

Funder(s)

Funder type
Government

Funder Name
National Key Research and Development Program of China

Alternative Name(s)
, National Basic Research Program of China (973 Program), Special Fund for the National Key Research and Development Plan, China National Key Research and Development Plan Project, National Key Research and Development of China, National Key Research and Development Program, National Key R&D Program of China, National Key R&D Programmes of China, China's National Key R&D Programmes, National Basic Research Program of China, 973 Program, National Program on Key Basic Research Project (973 Program), National Plan on Key Basic Research and Development, National Basic Research Program, NKRDPC, NKPs

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

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Location
China

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Central Government Guides Local Projects

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Hebei Innovation Capability Improvement Plan Project

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon reasonable request at the end of the study from Dr Lingdi Fu, ldfu@ysu.edu.cn.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			10/10/2024	No	No