

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The impact of prefrontal tRNS on schizophrenia clinical symptoms and cognitive deficits

Protocol summary

Study aim

Determining the rate of reduction of clinical symptoms and improvement of cognitive defects in schizophrenic patients through treatment of stimulation with random noise currents on the prefrontal cortex

Design

The present study is a clinical trial with pre-test, post-test and follow-up. The statistical population of this study is 40 people and they will be randomly assigned to two groups of 20. Random allocation is done by dividing the participants into target groups

Settings and conduct

Location of Beheshti Hospital - non-identical examiner and therapist - pre-test, post-test and one- and two-month follow-up

Participants/Inclusion and exclusion criteria

1- Having the ability of informed consent to participate in research
2_ Have a minimum age of 18 and a maximum of 65 years
3_ have a diagnosis of schizophrenia or schizoaffective disorder
4_ The same dose and drug used
5_ Being right-handed
6_ Stabilization in drug treatment for at least 7 weeks before the start and during the research

Intervention groups

The intervention group will receive random stimulation treatment with a frequency of 100_640 Hz, with an average of 1 mA and a range of 2 mA for 10 sessions of 20 minutes. The sham group will also receive random stimulation treatment with a frequency of 100_640 Hz, with an average of 1 mA and a range of 2 mA for 10 sessions of 30 seconds. And after the sessions, all the tools will be run again in the post-test, and after two months, the same tools will be run again on the subjects.

Main outcome variables

Positive symptoms, negative symptoms, cognitive abilities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210608051514N2**

Registration date: **2021-10-08, 1400/07/16**

Registration timing: **prospective**

Last update: **2021-10-08, 1400/07/16**

Update count: **0**

Registration date

2021-10-08, 1400/07/16

Registrant information

Name

farahnaz yousefi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-20, 1400/10/30

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of prefrontal tRNS on schizophrenia clinical symptoms and cognitive deficits		Parallel
Public title treatment for schizophrenia patients: double-blind randomized controlled trial study		Other design features
Purpose Other		Secondary Ids empty
Inclusion/Exclusion criteria Inclusion criteria: 1- Having the ability of informed consent to participate in research 2_ Have a minimum age of 18 and a maximum of 65 years 3_ have a diagnosis of schizophrenia or schizoaffective disorder 4_ The same dose and drug used before the start and during the research 5_ Being right-handed 6_ Stabilization in drug treatment for at least 7 weeks Exclusion criteria: 1_ Have a history of suicide and abuse of alcohol and substances other than caffeine and tobacco 2_ Have a history of neurological diseases 3_ Have a disease related to the scalp 4_ Have a history of head trauma 5_ Existence of device or tool in the head 6- Leaving the research after being absent in two consecutive sessions 7- Pregnancy or breastfeeding		Ethics committees 1 Ethics committee Name of ethics committee Ethics Committee of Zanjan University of Medical Sciences Street address Shahid Beheshti Hospital, Ark Gate, Saadi Crossroads, Zanjan Province City zanjan Province Zanjan Postal code 8431575143 Approval date 2021-09-21, 1400/06/30 Ethics committee reference number IR.ZUMS.REC.1400.260
Age From 18 years old to 65 years old		Health conditions studied 1 Description of health condition studied Schizophrenia ICD-10 code F20 ICD-10 code description Schizophrenia
Gender Both		Primary outcomes 1 Description Negative symptoms:Theoretical definition: It is one of the clinical symptoms in schizophrenia that includes superficial emotion, poor speech, lack of motivation, unhappiness and social transgression.Operational definition: The score that a person gets from the positive and negative symptoms of schizophrenia.Positive symptoms: Theoretical definition includes delusions, delusions, disturbed speech, and disturbed behavior that persist throughout a one-month period.Operational definition: The score that a person gets from the positive and negative symptoms of schizophrenia. Timepoint Pre-test-post-test-one-month follow-up-3 moth follow-up Method of measurement The score that a person gets from the questionnaire for measuring positive and negative symptoms in schizophrenia.
Phase N/A		
Groups that have been masked • Participant • Care provider		
Sample size Target sample size: 40		
Randomization (investigator's opinion) Randomized		
Randomization description Subjects are selected from Convenience judgmental Sampling method ,They will also be randomly assigned to the desired groups. then which subjects are assigned to the two groups of control and experiment by tossing coins.This method is used for two-group clinical trials, according to which one group is called a lion, and the other is called a line, and thus the number of coin samples is tossed		
Blinding (investigator's opinion) Double blinded		
Blinding description In this study, the clinical evaluator and therapist will be blind to assigning subjects to control and experimental groups. In addition, we use the clinical evaluator separately for baseline assessments and follow-up, and the therapist separately for treatment.Subjects will also be assigned to control groups or blind experiments, so that subjects will not meet outside of the sessions and will visit at times when no other subjects will be present.		
Placebo Not used		
Assignment		

Secondary outcomes

1

Description

Working memory:Theoretical definition: means the ability to store and manipulate information in memory, which is an essential prerequisite for complex cognitive tasks such as learning, reasoning and comprehension.

Timepoint

Pre-test-post-test-one-month follow-up_2 month follow-up

Method of measurement

The score that a person gets from the working memory test in the CANTAB collection.

2

Description

executive function: Theoretical definition: A general structure that encompasses a wide range of cognitive processes and behavioral abilities that include reasoning, problem solving, planning, organizing, working memory, ordering, the ability to pay constant attention, deal with interference, benefit from feedback, and practice. Includes multitasking.

Timepoint

Pre-test-post-test-one-month follow-up_2 month follow-up

Method of measurement

The score that a person gets from the executive function measurement test in the CANTAB collection.

3

Description

Emotion Recognition: A Theoretical DefinitionThe ability to recognize people's emotions through non-verbal expression such as face, voice, or gestures and body movements is a key ability in social interactions and a prerequisite for understanding and predicting and responding appropriately to one's behavior.

Timepoint

Pre-test-post-test-one-month follow-up-two-month follow-up

Method of measurement

The score that a person gets from the emotional recognition test in the CANTAB collection.

4

Description

DepressionTheoretical definition: Depression is a transient or long-term decline in mood. The main characteristic is the feeling of dissatisfaction, which means lack of interest or lack of feeling of pleasure for the activities that the person already enjoys.

Timepoint

Pre-test-post-test-one-month follow-up_2 month follow-up

Method of measurement

A person's score on the Revised Depression Scale.

Intervention groups

1

Description

The intervention group will receive random stimulation treatment with a frequency of 100_640 Hz, with an average of 1 mA and a range of 2 mA for 10 sessions of 20 minutes.

Category

Treatment - Other

2

Description

The control group will receive random stimulation treatment with a frequency of 100_640 Hz, with an average of 1 mA and a range of 2 mA for 10 sessions of 30 seconds.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Men's emergency department of Shahi

Full name of responsible person

Dear Dr. Ramin Maleki

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Shahid Beheshti Hospital, Ark Gate, Saadi Crossroads, Zanzan Province

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Mohsen Dadashi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

All information of individuals except names and confidential information will be published at the end of the research. Publishable information including: treatment changes, results of questionnaires, statistical results of analyzes, dosage and medication used

When the data will become available and for how long

The results of this research will be published three months after the end of the research.

To whom data/document is available

All researchers, researchers, colleagues, and others

Under which criteria data/document could be used

To carry out similar projects and if all the material and intellectual rights of researchers are observed.

From where data/document is obtainable

Contact the following email address to receive the documentation: Farahnaz Yousefi Master of Clinical Psychology farahnaz.yosefi76@gmail.com Address: Department of Clinical Psychology and Psychiatry, Beheshti Hospital, Ark Gate, Chahar Ra Saadi, Zanjan Province

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

The data will be provided to the applicant after receiving the e-mail of the applicant and observing the material and intellectual rights of the researchers.

Comments