Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 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 research2_Have a minimum age of 18 and a maximum of 65 years 3_have a diagnosis of schizophrenia or schizoaffective disorder4_ 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

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Iran (Islamic Republic of)

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+98 24 23345

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farahnaz.yosefi76@gmail.com

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

Public title
treatment for schizophrenia patients: double-blind randomized controlled trial study
Purpose
Other
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
Age
From **18 years** old to **65 years** old
Gender
Both

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
Parallel
Other design features

Secondary Ids

empty

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

Health conditions studied

1

Description of health condition studied
Schizophrenia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

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.

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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Sponsors / Funding sources

1

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Name of organization / entity
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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
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Other areas of specialty/work
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Person responsible for updating data

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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