Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effectiveness of Cognitive Rehabilitation on Frontal Network Functional Connectivity in Schizophrenia

Protocol summary

Study aim
The Effectiveness of cognitive Rehabilitation Therapy on Frontal Network Functional Connectivity in Schizophrenia

Design
The research plan includes two experimental and control groups. The participants include 27 schizophrenia patients who will be selected through purposeful sampling and will be randomly placed in two experimental and control methods.

Settings and conduct
The statistical population of the present study includes all patients with schizophrenia who are treated in Razi Psychiatric Hospital in Tehran in 1400-1401. Individuals will be selected through purposive sampling and randomly divided into experimental and control groups. The experimental group will receive cognitive rehabilitation treatment, while the control group will not receive this intervention.

Participants/Inclusion and exclusion criteria
This study will be conducted on people with schizophrenia and individuals based on inclusion criteria (1. Age range 18 to 45 years 2. Active communication and answering questions) and exclusion criteria (1. Brain Injury 2. Brain disorder 3. Changes in antipsychotic treatment in the last 1 month) were divided into treatment and control groups.

Intervention groups
Participants will be selected through purposive sampling and randomly assigned to experimental and control groups. Then cognitive rehabilitation treatment is applied to the experimental group for 8 weeks. While the control group will not receive this intervention.

Main outcome variables
Functional Connectivity of Frontal Network

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210727052001N1**
Registration date: **2022-10-29, 1401/08/07**
Registration timing: **retrospective**

Last update: **2022-10-29, 1401/08/07**
Update count: **0**

Registration date
2022-10-29, 1401/08/07

Registrant information

Name
Motahareh Eslamnejad
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-04, 1400/03/14

Expected recruitment end date
2022-09-05, 1401/06/14

Actual recruitment start date
2021-10-12, 1400/07/20

Actual recruitment end date
2022-03-21, 1401/01/01

Trial completion date
2022-03-21, 1401/01/01

Scientific title
The Effectiveness of Cognitive Rehabilitation on Frontal Network Functional Connectivity in Schizophrenia

Public title

The Effectiveness of Cognitive Rehabilitation Therapy in Schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range between 18 and 45 years Ability to communicate and answer questions

Exclusion criteria:

History of brain injury History of brain disorder Changes in antipsychotic treatment in the last 1 months

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **27**

Randomization (investigator's opinion)

Randomized

Randomization description

The way to randomize the research is as follows: The first step is to create a random sequence. Simple randomization will be used in this research. Randomization based on a single sequence of random assignments is called simple randomization. The randomization unit in this research is individual. There are various randomization tools for this type of randomization, in this research, the table of random numbers is used. The table of random numbers is a collection of numbers that are generated without a pattern and in a certain order, completely randomly, and are put in the form of a table. How to make a random sequence is as follows: First, we determine the direction of reading the numbers, which are two from the top. The numbers for the different groups considered here are as follows: even numbers obtained from this table are assigned to the control group and odd numbers to the intervention group. Then we place our finger on one of the table numbers and act according to the described process (i.e. we move up 2) and record the numbers and assign them to the control or intervention group according to whether they are odd or even. to give In the next stage, which is called concealment, which refers to the method used to perform a random sequence on the subjects, so that the allocated group is not known before the allocation of the individual. For concealment in this research, non-transparent sealed envelopes or random sequence will be used. In this method, first, the random sequence, which is here by the table of random numbers, is performed. Then, based on the sample size (30 people), a number of envelopes are prepared and each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. At the end, the lids of the envelopes are glued and placed in a box. At the time of the registration of subjects, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Social Welfare and Rehabilitation Sciences

Street address

University of Social Welfare and Rehabilitation Sciences., koodakyar street., velenjak Blvd., Tehran Town

City

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Province

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Postal code

1985713834

Approval date

2021-07-17, 1400/04/26

Ethics committee reference number

IR.USWR.REC.1400.112

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Frontal Functional Connectivity

Timepoint

Before the start of the intervention and 2 weeks after the end of the intervention

Method of measurement

Electroencephalography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cognitive rehabilitation therapy. First, a psychiatric interview and a Panss questionnaire are used to enter this group to confirm schizophrenia. Then, in order to evaluate the functional connections of the frontal network, patients in this group have an electroencephalogram (eeg); Also, N_back and Wisconsin tests are taken before the intervention to check working memory performance and executive functions. Immediately after the initial assessments, the first session of cognitive rehabilitation practice is performed. The number of sessions is 16 sessions 2 times a week, which takes a total of 8weeks. In each training session, the patient performs a set of cognitive rehabilitation exercises using Captain Log software. The time required for each exercise is 2 to 3 minutes. Each training session is 45 minutes for each subject. This program is adaptively designed so that the process and difficulty of the program matches the capacity and ability of each person individually, but after the start of training, the degree of difficulty automatically increases. This training program is designed in such a way that in each section, by providing appropriate visual and audio feedback and recording the scores and timing of each step, the person is guided step by step.

Category

Rehabilitation

2

Description

Control group: The members of the control group are first selected by psychiatric interview and Panss questionnaire and then a eeg is received from them to check the functional communication of the frontal network and a pre-test is taken from them by N_back and Wisconsin tests. After 7 weeks and without any intervention, they will be measured again by the same instruments and the post-test will be performed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Psychiatric Center

Full name of responsible person

Motahareh Eslamnejad

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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

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

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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
Undecided - It is not yet known if there will be 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
All research data is available under the title of the article and thesis.
When the data will become available and for how long
Access period starts 6 months after the results are published.
To whom data/document is available
Everyone for whom the data is useful and usable has to access it.
Under which criteria data/document could be used
To be aware of results and reference.
From where data/document is obtainable
Visit the Central library of the University of Social Welfare and Rehabilitation Science. Address: Tehran, Daneshjoo Blvd., Koodkiar St., University of Social Welfare and Rehabilitation Science. Phone number: 0098 021 71732818
What processes are involved for a request to access data/document
After visiting or calling the library of the University of Social Welfare and Rehabilitation Science the desired data will be provided to you.
Comments