

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Investigating the effectiveness of Transcranial direct current stimulation on reducing positive symptoms of schizophrenic patients and improving their quality of life

#### Protocol summary

##### Study aim

Investigating the effectiveness of TDCS on reducing positive symptoms and improving the quality of life in people with schizophrenia and the durability of its effect in one month of not receiving electrical stimulation

##### Design

non-randomized, single-blinded, sham-controlled clinical trial, phase-II clinical trial with 40 patients

##### Settings and conduct

the patients were admitted to Razi Psychiatric Hospital in Tehran, Iran. 40 eligible participants will be included and divided into two experimental and control groups. The participants in the intervention group received 10 times stimulation for 20 minutes on five consecutive days in two sessions with a current of 2 mA and assembly of the anode in the F3 area and the cathode in the T3 area. No intervention was provided in the control group.

##### Participants/Inclusion and exclusion criteria

inclusion criteria include: Schizophrenia diagnosis based on DSM-5 criteria by a psychiatrist Having a history of multiple hospitalizations Two weeks have passed since the last hospitalization Being literate in reading and writing Exclusion criteria include: Psychoses caused by drug =use History of epilepsy, brain surgery, intracranial metal implantation, concussion History of ECT

##### Intervention groups

The participants in the intervention group received ten sessions of stimulation for 20 minutes on five consecutive days in two sessions in the morning and in the afternoon with a current of 2 mA and assembly of the anode in the F3 area and the cathode in the T3 area. Participants in the control group did not receive any intervention.

##### Main outcome variables

Schizophrenia's Positive Symptoms; The Patient's Quality of Life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221227056947N1**

Registration date: **2023-09-05, 1402/06/14**

Registration timing: **prospective**

Last update: **2023-09-05, 1402/06/14**

Update count: **0**

##### Registration date

2023-09-05, 1402/06/14

##### Registrant information

##### Name

Milad Kadkhoda

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 4224 6026

##### Email address

ac.milad95@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2024-03-20, 1403/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Investigating the effectiveness of Transcranial direct current stimulation on reducing positive symptoms of schizophrenic patients and improving their quality of life

## Public title

Investigating the effectiveness of transcranial direct current stimulation in schizophrenic patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Schizophrenia diagnosis by a psychiatrist based on DSM-5 criteria Having a history of multiple hospitalizations 2 weeks have passed since the last hospitalization literate in reading and writing

### Exclusion criteria:

Psychoses caused by drug use History of epilepsy History of Brain Surgery Intracranial metal implantation Clinically significant concussion History of having ECT

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: 40

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

This study was single-blinded and full explanations about the treatment process are given to the patients. However an explanation about which patients belong to the experimental or control group will not be given.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of University of Social Welfare and Rehabilitation Sciences

##### Street address

University of Rehabilitation Sciences and Social Health Tehran, Koodakyar Deadend, Daneshju Blvd,

Evin.

#### City

Tehran

#### Province

Tehran

#### Postal code

1985713834

#### Approval date

2023-08-22, 1402/05/31

#### Ethics committee reference number

IR.USWR.REC.1402.092

## Health conditions studied

### 1

#### Description of health condition studied

Schizophrenia

#### ICD-10 code

F20

#### ICD-10 code description

Schizophrenia

## Primary outcomes

### 1

#### Description

Positive symptoms of schizophrenia

#### Timepoint

The positive and negative syndrom Scale was completed by the subjects in 3 stages, at the beginning of the study, after the implementation of the treatment protocol and one month after the intervention in order to evaluate the effect of the intervention before and after the treatment protocole and check the effects of the treatment over time.

#### Method of measurement

Positive and Negative Syndrome Scale (PANSS)

## Secondary outcomes

### 1

#### Description

The Quality of Life Score

#### Timepoint

The World Health Organization Quality of Life - Brief (WHOQoL-Bref) Scale was completed by the subjects in 3 stages, at the beginning of the study, after the implementation of the treatment protocol, and one month after the intervention in order to evaluate the effect of the intervention before and after the treatment protocol and check the effects of the treatment over time.

#### Method of measurement

World Health Organization Quality of Life - Brief (WHOQoL-Bref)

## Intervention groups

### 1

#### Description

Intervention group: The participants in the intervention group received 10 sessions of stimulation for 20 minutes on five consecutive days in two sessions in the morning and in the afternoon with a current of 2 mA and assembly of the anode in the F3 area and the cathode on the T3 area.

#### Category

Treatment - Devices

### 2

#### Description

Control group: The participants in the control group, like the intervention group, consisted of treatment-resistant schizophrenic patients who Recieve sham intervention.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi Psychiatric Hospital

##### Full name of responsible person

Fereshteh Mo'meni

##### Street address

Razi Psychiatry Training and Treatment Center,  
Shahid Rostgar Blvd, Taghi Abad Road, Shahreri,  
Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1867612016

##### Phone

+98 21 3340 1220

##### Fax

+98 21 3340 1600

##### Email

razi.pr@uswr.ac.ir

##### Web page address

<https://razi.uswr.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University of social welfare and rehabilitation sciences

##### Full name of responsible person

Ali Nazeri

##### Street address

Shahid Chahardehi Building, Razi Psychiatry Training

Center, Shahid Rostgar Blvd, Varamin Road,  
Shahrerei, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1866958891

##### Phone

+98 21 3341 6084

##### Fax

+98 21 3340 1600

##### Email

psychosisrc@uswr.ac.ir

##### Web page address

<https://psychosis.uswr.ac.ir/>

#### Grant name

#### Grant code / Reference number

1865

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

No

#### Title of funding source

Psychosis research center

#### 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

Fereshteh Mo'meni

##### Position

Associate Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Psychology

##### Street address

University of Rehabilitation Sciences and Social  
Health Tehran, Koodakyar Deadend, Daneshju Blvd,  
Evin.

##### City

Tehran

##### Province

Tehran

##### Postal code

1985713834

##### Phone

0098 21 7173200

##### Email

momenipsy@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Fereshteh Mo'meni

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

University of Rehabilitation Sciences and Social Health Tehran, Koodakyar Deadend, Daneshju Blvd, Evin.

**City**

Tehran

**Province**

Tehran

**Postal code**

1985713834

**Phone**

+98 21 7173 2000

**Email**

momenipsy@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Milad Kadkhoda

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

No. 101, Daraee alley, West Taleqani Street, Mahabad, West azarbaiejan

**City**

Mahabad

**Province**

West Azarbaijan

**Postal code**

5916738159

**Phone**

+98 44 4224 6026

**Email**

ac.milad95@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information.

**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**

No - There is not 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**

No - There is not a plan to make this available

**Title and more details about the data/document**

All data except the part directly related to the disorder itself, along with the duration of the disease, the number of hospitalizations, the severity of the disease, and the questionnaires given to the patient can be cited. Things such as age, gender, and the department in which they are admitted cannot be cited or shared.

**When the data will become available and for how long**

Once the sampling is complete, the data is usable for 6 months.

**To whom data/document is available**

1. Members of the practical board of Universities 2. People who work in research centers affiliated to the Ministry of Science or Health 3. Ph.D. students in the field of psychology or psychiatry interns

**Under which criteria data/document could be used**

If the purpose of using the data is for educational and research purposes, the data can be shared.

**From where data/document is obtainable**

Applicants can contact the responsible author, Dr. Fereshte Momeni, via e-mail to receive the data.

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

In this process, the applicant sends an email to the responsible author and requests for the data to be sent. In the e-mail, they should provide a full introduction of themselves and organizational affiliations, alongside a CV (if it's possible), the purpose of the request, and the use of the data. If the responsible author agrees with the request, this issue will be discussed with the Psychosis Research Center, and if the research team approves and provides permission, this data will be sent.

**Comments**