

Treatment of cognitive deficit in schizophrenia patients with transcranial direct current stimulation augmented with cognitive training

Submission date 21/07/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/08/2021	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/03/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Schizophrenia is a serious mental illness that affects how a person thinks, feels, and behaves. In recent years, cognitive function impairments have become prominent key symptoms that limit patients' return to normal life. They can include problems with working memory, attention and speech. The effect of antipsychotic medication on cognition improvement is repeatedly being reported as rather low. For this reason, there has been an increased focus on the use of alternative methods. One of these methods is cognitive training, which has repeatedly been found to have a long-term positive effect on cognitive improvement. Other possible treatments include non-invasive neurostimulation methods such as transcranial direct current stimulation (tDCS), which also shows potential effects. This study focuses on the effect of the combination of computer-based cognitive training and tDCS. The combination of those two methods will bring a significantly higher improvement in cognitive performance and reduce the cognitive deficit in schizophrenic patients.

Who can participate?

Adults aged 18-50 years with schizophrenic disorder

What does the study involve?

The participants will undergo an examination at the beginning of the study lead by a doctor-researcher. The examination will involve the assessment of cognitive functions (such as attention and working memory) and current symptoms of the schizophrenic disorder using standardized tests and questionnaires. This will take about one to two hours. The study will assess the effect of a combination of tDCS and cognitive training. The participants will be randomly allocated to one of two groups with either active or placebo (dummy) tDCS stimulation. The cognitive training will be the same for both groups. Application of the tDCS (active/placebo) and cognitive training will occur once daily during the following 5 -15 workdays, each session lasting about 1 hour.

What are the possible benefits and risks of participating?

The possible benefits are the improvement of the cognitive deficit experienced by schizophrenic

patients. The study does not include many risks for participants, as cognitive training does not have any clinical risks. tDCS adverse effects include possible short-term temporary itching, tingling or erythema (reddening of the skin) under the electrodes, and other most common adverse effects are headache and fatigue, both of a brief nature. The researchers will take preliminary measures to reduce any of the aforementioned side effects.

Where is the study run from?

National Institute of Mental Health (Czech Republic)

When is the study starting and how long is it expected to run for?

June 2018 to March 2025

Who is funding the study

PharmaBrain (Germany)

Who is the main contact?

Dr Monika Klirova

monika.klirova@nudz.cz

Contact information

Type(s)

Scientific

Contact name

Dr Monika Klirova

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CZ.02.1.01/0.0/0.0/16_0250007444

Study information

Scientific Title

Transcranial Direct Current Stimulation (tDCS) in the treatment of cognitive deficit in schizophrenia

Study objectives

Cognitive training (CT) and tDCS applied simultaneously will induce a significantly higher improvement in cognitive performance measured by the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) compared to cognitive training (CT) and placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/06/2018, National Institute of Mental Health Ethics Committee (Topolova 748, 250 67, Klecany, Czech Republic; +420 (0)283 088 312; ek@nudz.cz), ref: č.j.150/18

Study design

Randomized parallel-group double-blind placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Amelioration of cognitive deficit in schizophrenia

Interventions

Patients included in the study will be examined by RBANS to determine cognitive deficit and the current symptom severity is assessed by psychiatric scale (PANSS) at the beginning of the study. Patients will be randomly allocated according to permuted block design to one of two intervention groups:

1. Active anodal tDCS simultaneously with active cognitive training (CT)
2. Active CT and placebo anodal tDCS

Each session will be scheduled as follows: CT will last 60 min. tDCS (active or placebo) will last 30 min, applied simultaneously from the beginning of CT.

CT will be carried out with the REHACOM program.

The HDCStim programmable stimulator (Newronika, Italy) available for a double-blind design will be used for the application of tDCS.

Application of the tDCS (active/placebo) and cognitive training will take place once daily during the following 5 -15 workdays, each session lasting for about 1 hour.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

HDCStim programmable stimulator (Newronika, Italy)

Primary outcome(s)

Cognitive functions assessed using the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) at baseline, 1-week endpoint and 3-week endpoint

Key secondary outcome(s)

Symptom severity measured by the Positive and Negative Syndrome Scale (PANSS) at baseline, 1-week endpoint and 3-week endpoint

Completion date

31/03/2025

Eligibility**Key inclusion criteria**

1. Male and female inpatients or outpatients aged 18-50 years
2. Meet ICD-10 criteria for schizophrenia (F20)
3. The mental ability to understand and sign the Informed Consent Form
4. Being on a stable and adequate dose of antipsychotics (monotherapy or combination) for at least two weeks before enrollment and if clinically appropriate to continue on an unchanged dose of antipsychotics during the trial
5. The score for mildly to moderately ill patients in the Positive and Negative Syndrome Scale (PANSS \leq 75) at the initial visit

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

50 years

Sex

All

Total final enrolment

30

Key exclusion criteria

1. Psychiatric comorbidity on axis I and II according to DSM V in the 6 months before enrollment to the study

2. Contraindications of tDCS (skin disease, superficial injury and fracture or infraction of skull in the stimulation area, epilepsy, metallic plates in the head)
3. Inadequate treatment of psychosis according to recommended guidelines (duration, dose)
4. Pregnancy or breastfeeding
5. Patients with severe and/or unstable somatic disorders (cardiovascular, disease, neoplasms, endocrinology disorders etc)
6. Patients treated with electroconvulsive therapy less than 3 months before enrollment or suffering from neurological disorder (e.g. epilepsy, head trauma with loss of consciousness)
7. Substantial suicidal risk as judged by the treating psychiatrist
8. History of substance-induced disorders in the last year except for nicotine dependency
9. Sensory and motor impairment precluding the participation in CT

Date of first enrolment

01/11/2018

Date of final enrolment

31/01/2025

Locations

Countries of recruitment

Czech Republic

Study participating centre

National Institute of Mental Health

Topolova 748

Klecany

Czech Republic

25067

Study participating centre

Hospital Ceske Budejovice

B. Nemcove 585/54

Ceske Budejovice

Czech Republic

37001

Study participating centre

Bohnice Psychiatric Hospital

Ustavni 91

Prague

Czech Republic

18102

Sponsor information

Organisation

National Institute of Mental Health

ROR

<https://ror.org/05xj56w78>

Funder(s)

Funder type

Industry

Funder Name

PharmaBrain

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Monika Klirova (monika.klirova@nudz.cz).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			05/08/2021	No	No
Statistical Analysis Plan			05/08/2021	No	No