ISRCTN13247154 https://doi.org/10.1186/ISRCTN13247154

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

Registration date
18/08/2021

Overall study status
Completed

Last Edited
06/03/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

ORCID ID
https://orcid.org/0000-0002-8092-9586

Contact details
Topolova 748
Klecany
Czech Republic
25067
+420 (0)283 088 146
monika.klirova@nudz.cz

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 </= 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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			05/08/2021	No	No
Statistical Analysis Plan			05/08/2021	No	No