Improving outcome through improving cognition in Severe Mental Illness: Cognitive Remediation Training combined with transcranial Direct Current Stimulation, a pilot study.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20040

Source
NTR

Brief title
Improving cognition in SMI

Health condition

Severe Mental Illness

Sponsors and support

Primary sponsor: This study is funded by Stichting tot Steun VCVGZ.
Source(s) of monetary or material Support: This study is funded by Stichting tot Steun VCVGZ.

Intervention

Outcome measures

Primary outcome

The main objective of this pilot study is to investigate the effect of cognitive remediation training with CIRCuiTS on cognitive and daily functioning in a population of service users with severe mental illness that requires long-term intensive psychiatric treatment and support in a clinical setting. Also, the acceptability and feasibility of CIRCuiTS will be evaluated.

Secondary outcome

A secondary aim of this pilot study is to evaluate if mild non-invasive brain stimulation using prefrontal transcranial Direct Current Stimulation (tDCS) in combination with CIRCuiTS has a superior effect on cognitive performance and daily functioning over CIRCuiTS + sham tDCS.

Study description

Background summary

Cognitive deficits are related to poor community functioning in people with severe mental illness who need long-term intensive psychiatric support. This pilot study is the first study to assess the combined effect of Computerised Interactive Remediation of Cognition – a Training for Schizophrenia (CIRCuiTS), and Transcranial Direct Current Stimulation (tDCS) on cognition and daily functioning. 26 service users, living in one of the residential treatment or sheltered living facilities of the cluster Active Recovery Triad (ART) of Lentis, will be randomly assigned to CIRCuiTS plus sham tDCS or CIRCuiTS plus active tDCS. We hypothesize that participants in both groups improve on cognitive functioning after the intervention period, and that participants who will receive CIRCuiTS in combination with active tDCS will improve more than the participants who receive CIRCuiTS + sham tDCS. Moreover, given the focus of CIRCuiTS on the practice in daily life, we hypothesize that participants will also improve in daily functioning.

The effects will be measured using a set of cognitive tests for verbal fluency, cognitive flexibility, memory, and attention (including the Controlled Oral Word Association Test, the Modified Card Sorting Test, the Digit Span Forward Test, the Digit Span Backward Test, the Rey Complex Figure Test and Recognition Trial, the Stroop Color Word Test, and the 15-word Learning Task). Subjective effects of the intervention will be evaluated with a short interview on feasibility, acceptability and effectiveness with the participant, and a questionnaire for subjective cognitive functioning (Cognitive Failure Questionnaire), and a questionnaire for negative symptoms (Sels-evaluation of Negative Symptoms). Case managers complete the Nurses' Observation Scale of Cognitive Abilities and the Life Skills Profile for daily functioning.

Study objective

We hypothesize that participants in both groups improve on cognitive functioning after the intervention period, and that participants who will receive CIRCuiTS in combination with active tDCS will improve more than the participants who receive CIRCuiTS + sham tDCS. Moreover, given the focus of CIRCuiTS on the practice in daily life, we hypothesize that participants will also improve in daily functioning.

Study design

September 2019 – February 2020: preparation phase.
March 2020 – February 2021: data gathering phase.
March 2021 – August 2021: evaluation phase.

Intervention

Cognitive training with CIRCuiTS, in combination with (active/placebo) tDCS

Contacts

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Eligibility criteria

Inclusion criteria

Service users can be included if they meet the criteria for SMI (Delespaul et al., 2013):
- A psychiatric disorder that requires care/treatment (no remission of positive, negative and cognitive symptoms);
- Severe disabilities in social and/or societal functioning (no functional remission);
- Disabilities are the result of a psychiatric disorder
- Disabilities are structural (at least several years);
- Coordinated professional care is necessary to realize a treatment plan.
Each participant in the study should sign informed consent, and only those who are fully

capable of making their own decision regarding participation in the study will be included. Additional criteria for inclusion are an age of 18 years or older and sufficient mastery of Dutch language.

Exclusion criteria

Service users will be excluded from tDCS if they have:
- Metal implants inside the skull or eye;
- Severe scalp skin lesions;
- A history of previous seizures.
- Alcohol or drug abuse;
- Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2019
Enrollment:	26
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-08-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7954
Other	METC UMCG : METC2018555

Study results