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

Published: 11-02-2019
Last updated: 19-08-2024

The primary goal is of this pilot study is to investigate the effects of Computerised Interactive Remediation of Cognition - a Training for Schizophrenia (CIRCuiTS), on the cognitive functioning of the described group of service users. It is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON50031

Source
ToetsingOnline

Brief title
Improving cognition in SMI.

Condition

- Psychiatric disorders NEC

Synonym
Psychiatric Disorders, Severe Mental Illness

Research involving
Human

Sponsors and support

Primary sponsor: Lentis (Groningen)
Source(s) of monetary or material Support: Stichting tot Steun.

Intervention

Keyword: Cognitive Remedion Training, Severe Mental Illness, Transcranial Direct Current Stimulation

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. CIRCuiTS is especially developed and tested for service users with schizophrenia. It is, until date, not investigated in service users with SMI that need long-term intensive psychiatric treatment in a clinical or sheltered setting. In the case of positive results, we aim to initiate a large multicenter randomized controlled trial, using CIRCuiTS.

Secondary outcome

A secondary aim of this pilot study is to evaluate if mild non-invasive brain stimulation using transcranial Direct Current Stimulation (tDCS) in combination with CIRCuiTS has a superior effect on cognitive performance and daily functioning over CIRCuiTS alone. As neural plasticity may be reduced in service users with SMI, effects of cognitive training may not sustain. Applying tDCS to neural networks simultaneously with their engagement in cognitive tasks of

CIRCuiTS, it is expected that plasticity of these networks will be increased, resulting in long lasting improvements in cognitive and daily functioning. Also, the acceptability and feasibility of this combined intervention will be evaluated. When tDCS appears to have an additive effect, it will be applied in combination with CIRCuiTS in a large multicenter randomized controlled trial.

Study description

Background summary

Seven per cent of service users suffering from severe mental illness needs long-term intensive treatment and support in a clinical setting or sheltered living (Van Hoof et al., 2015). In this group of service users, the illness is often chronic and characterized by an incomplete recovery (Trieman & Leff, 2002; Uggerby et al., 2011). Service users often experience problems on multiple domains, such as persistent complaints as a result of medication resistance (Meltzer, 1997), physical health problems (McEvoy et al., 2005) and self-care (Wiersma et al, 2000), psychosocial (Harvey et al., 2012), and cognitive dysfunctioning (Palmer et al., 2009; Velligan et al, 1997). The recovery process in this group of service users is therefore complex. A fundamental challenge in the treatment of these service users is how to deal with cognitive dysfunctioning. Moreover, neural plasticity in service users with SMI appears to be reduced; a factor that might hinder newly learnt cognitive skills to sustain.

Study objective

The primary goal is of this pilot study is to investigate the effects of Computerised Interactive Remediation of Cognition - a Training for Schizophrenia (CIRCuiTS), on the cognitive functioning of the described group of service users. It is expected that cognitive remediation training with CIRCuiTS will lead to improved cognitive functioning. In addition, a non-invasive brain stimulation technique transcranial Direct Current Stimulation (tDCS), is used to promote neural plasticity. By applying this stimulation to neural networks simultaneously with engagement in the cognitive tasks of CIRCuiTS, it is expected that plasticity of these networks will be increased, resulting in longer lasting improvements in cognitive functioning than with CIRCuiTS training only. Improvements in cognitive functioning may subsequently positively influence daily functioning.

Study design

Participants will be randomized over two groups: CIRCuiTS in combination with sham tDCS (group 1) or CIRCuiTS in combination with active tDCS (group 2). The trial will start with a waiting period of 16 weeks, which will serve as the control condition. Next, the participants will receive 16 weeks of either CIRCuiTS + sham tDCS or CIRCuiTS + active tDCS. All sessions will be given on an individual basis. The duration of each training session will be 30 minutes (and 20 minutes of tDCS simultaneously in group II) and will be given twice weekly.

Intervention

Cognitive remediation training will be given with CIRCuiTS. This program is built of computerized tasks that are mainly aimed at improving attention, memory and planning, by training in many different ways and by learning to use strategies to improve meta-cognition and to transfer these skills to daily life situations. In addition, by practicing in daily life, generalization of the newly learnt skills is stimulated.
tDCS is a non-invasive brain stimulation technique that uses two electrodes to apply a small electrical current to alter excitability of neurons, such that it increases or decreases spontaneous network activity, and may promote neural plasticity. In this study, the target region is the left dorsolateral prefrontal cortex, as an important hub of the fronto-parietal brain network.

Study burden and risks

During the baseline measurement (T0), an observational assessment for cognitive abilities is performed by the participant's case manager (10 minutes). The case managers are also asked to fill in a questionnaire about a participant's life skills (10 minutes). These measures do not require effort from the participant. The participants are asked to perform a series of cognitive tasks and two questionnaires, which will take approximately 70 minutes. The study will follow a stepped-wedge design in which participants will first receive care as usual for 16 weeks (waiting period), after which participants are randomly allocated to either 32 30-minute training sessions (16 weeks, twice weekly) with CIRCuiTS + prefrontal sham tDCS, or with CIRCuiTS + prefrontal active tDCS. After the 16-week waiting period and after the 16-week training period, a second (T1) and third measurement (T2), respectively, will take place comprising the same measurements as at T0. During the tDCS procedure, participants are exposed to a very low electrical current of 2 mA. The use of tDCS has, to date, not resulted in significant adverse effects, apart from mild headache or a mild tingling sensation underneath the electrodes. The stimulation parameters are well within international safety guidelines. To assess possible long-term effects, we will do a follow-up measurement after six months after the intervention (T3), similar to the other three measurements.

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. In case the results of this study indicate that cognitive performance can be improved with CIRCuiTS, and whether or not tDCS will lead to additional improvement, this intervention will be further investigated in a large randomized multicenter study. If the intervention appears to be effective, it can be implemented as standard care for service users that need long-term support in a clinical or sheltered setting.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Service users can be included if they meet the criteria for Severe MEntal Illness (Delespaul et al., 2013):
- A psychiatric disorder that requires care/treatment (no symptomatic remission);
- 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 or older and sufficient mastery of Dutch language.

Exclusion criteria

- Metal implants inside the skull or eye;
- Severe scalp skin lesions;
- A history of previous seizures.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2020

Enrollment:	26
Type:	Actual

Ethics review

Approved WMO Date:	11-02-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-03-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-06-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-08-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL67725.042.18