Improving Cognition in Severe Mental Illness: Cognitive Remediation Training combined with transcranial Direct Current Stimulation, a feasibility study.

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

Summary

ID

NL-OMON46594

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: Lentis

Intervention

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

Outcome measures

Primary outcome

The primary outcome measure of this study is the feasibility of Circuits and Compensatory Cognitive Training for cognitive training in service users with severe mental illness and low levels of cognitive functioning. This will be measured using a self-designed feasibility assessment. The program that best meets our criteria for feasibility will be applied in a randomized controlled trial for the improvement of cognitive functioning in service users with SMI. For exploratory reasons only, an observational assessment for cognitive abilities is performed for each participant before and after the training period, to look at possible improvements in cognition.

Secondary outcome

none

Study description

Background summary

7% 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 cognitive dysfunctioning.

Study objective

The primary goal is of this feasibility study is to compare two often used cognitive remediation programs, Circuits and Compensatory Cognitive Training, on the feasibility for the described group of service users. The program demonstrating the most optimal feasibility will be applied in a large randomized controlled trial aimed at improving cognitive functioning in this group of services users. Additionally, non-invasive brain stimulation with transcranial Direct Current Stimulation (tDCS) may promote improvements of CRT. To investigate whether the combination of CRT and tDCS is well tolerated by the study population, both interventions will be applied simultaneously in one session.

Study design

In this open label feasibility study, service users will be randomized over six weeks of cognitive remediation training with either Circuits or Compensatory Cognitive Training. Training sessions will be given twice weekly, for the duration of 30 minutes. All participants will receive one session of tDCS in combination with CRT. Before randomization and after the training period, an observation-based assessment for cognitive abilities will be performed. The participants receive a short assessment after the training period, concerning feasibility of both CRT programs and CRT in combination with tDCS.

Intervention

During six weeks, service users will receive two sessions of cognitive remediation training per week, using either Circuits or Compensatory Cognitive Training. One training session will be combined with brain stimulation using transcranial Direct Current Stimulation.

Study burden and risks

Firstly, an observational assessment for cognitive abilities is performed by the participant's casemanager, so that it does not require effort from the participant. The casemanagers are also asked to fill in a questionnaire about a participant's life skills. This will take 10 minutes. The participants is asked to perform two tasks that will take 10 minutes. Next, participants will receive twelve 30-minute CRT sessions (six weeks, twice weekly). CRT will be given using either the computer-based program Circuits, or pen-and-pencil based program Compensatory Cognitive Training. One training session will be combined

with brain stimulation using transcranial Direct Current Stimulation (tDCS). During the tDCS procedure, participants are exposed to a very low electrical current of 2 Ma. The use of tDCS to date has 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. Shortly after the training period, participants' casemanager are asked to again complete the observational assessment and participants are asked several questions about the feasibility of the training programs and tDCS. This will take approximately 20 minutes. As this study applies CRT over a short period, aimed at the investigation of the feasibility of both CRT programs and the combination of CRT with tDCS, the probability that cognitive performance will improve is small. Therefore, participating in this study does not have direct benefits for the service users. However, the results of this study will be used in the development of a large randomized controlled trial that will have improvement of cognition as its main study parameter.

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 between 18 to 55 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2018
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	15-08-2018
Application type:	First submission
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	NL64733.042.18