Mindset. A cognitive remediation training for young adults with psychiatric disorders to support their participation in education: A pilot study

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This study aims to examine the effectiveness, feasibility, and applicability of the adapted and translated CR from Mullen and colleagues (2017), named Mindset, for students with psychotic problems in the Netherlands.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON46682

Source
ToetsingOnline

Brief title
Mindset

Condition

- Schizophrenia and other psychotic disorders

Synonym
schizophrenic and psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Lectoraat Rehabilitatie Hanzehogeschool Groningen

Source(s) of monetary or material Support: Stichting Agis Zorginnovatiefonds

Intervention

Keyword: Cognitive remediation, education, psychotic spectrum disorders, school performance

Outcome measures

Primary outcome

A checklist derived from evaluation interviews with both trainers and participants will be used as main outcome parameter of the training feasibility and applicability. Training fidelity will be measured using written evaluation from the trainers. The main study parameters of the effect measurements will be school functioning, school satisfaction, strategy use, subjective cognitive functioning, and early school leaving.

Secondary outcome

Secondary study parameters include objective cognitive functioning and quality of life.

Study description

Background summary

Most severe mental illnesses have their onset between the age of 18 and 25 and include having cognitive problems. At this age, many adolescents participate in higher education. Students with severe mental illnesses are therefore at risk of early school leaving. Leaving school without receiving a degree reduces the chances of employment later on in life, leading to decreased social participation of these students. It is known that reduced social participation worsens the long-term prognosis of the disorder. A training that focuses on school participation may therefore increase social inclusion and social participation, making implementation of such a training important on a personal and societal level. A group of researchers in the United States (US) have developed a training that focuses on the remediation of cognitive abilities,

specifically focusing on educational participation (Mullen et al., 2017). This type of cognitive remediation (CR) is not available in the Netherlands yet. This study aims to adapt and translate the CR developed by the researchers in the US (Rutgers University), and apply this training to students diagnosed with psychotic spectrum disorder. The study will be in collaboration with four Dutch Mental Health Care institutes (MHC; in Dutch: Geestelijke Gezondheidszorg, GGz), namely GGz Drenthe, GGz Friesland, GGz Groningen (Lentis), and UCP Groningen. The developers of the training, will be available for consultation during the study.

Study objective

This study aims to examine the effectiveness, feasibility, and applicability of the adapted and translated CR from Mullen and colleagues (2017), named Mindset, for students with psychotic problems in the Netherlands.

Study design

The study will be a mixed methods single blind randomized controlled trial focusing on evaluating the feasibility and applicability of the intervention, and pilot testing the adapted and translated CR from Mullen and colleagues (2017), named Mindset.

Intervention

This study will include 60 participants from four Dutch MHC institutes, namely GGz Drenthe, GGz Friesland, GGz Groningen (Lentis), and UCP Groningen. Half of the participants (N=30) will receive the training whereas the other half will act as an active control group. The CR-group will receive the CR consisting of thirteen individual-based meetings of one hour spread over thirteen weeks. The control group will receive twelve weekly assignments per email of one hour, plus a session zero for the assessment of their personal goals. The students in the control group get the opportunity to receive the training one year after the CR-group when desired.

Study burden and risks

We do not expect that the intervention causes any risk for the participants. Participants in the CR-group will attend one introduction session (session zero) and twelve training sessions of one hour. In addition, participants will do twelve homework assignments of approximately fifteen minutes. Participants in the control group will receive twelve assignments of one hour spread over twelve weeks, plus a session zero for the assessment of their personal goals. Three measurement points of 90 minutes (for overview see 6.3 *Study procedures*) will be scheduled to fill in the questionnaires. In addition, an evaluation interview will be scheduled, with a duration of approximately one

hour. The time participants invest in the study will therefore be sixteen hours for the training (thirteen hours for the control group) and 5,5 hours for the research measurements, making it 21.5 hours in total for the study per participants in the CR group and 18,5 hours per participant in the control group.

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

Diagnosed with psychotic spectrum disorder, perceived cognitive disabilities which interfere with the ability to participate in regular education, aged above 18, in treatment at one of the participating Mental Health Care centers, participating in regular education namely MBO (intermediate vocational education), HBO (higher vocational education), and WO (university education), and at least one year participating in education after start of the training

Exclusion criteria

Participation in supported education or cognitive remediation program within the past year

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	15-08-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-09-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	15-05-2019

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

ID: 26227
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL62069.042.17
OMON	NL-OMON26227