Beat Victimization! Psychomotor assertiveness training with elements of kickboxing for people with a psychotic disorder.

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Ethical review Approved WMO

Status Recruitment stopped

Health condition type Schizophrenia and other psychotic disorders

Study type Interventional

Summary

ID

NL-OMON41849

Source

ToetsingOnline

Brief title

BeatVic

Condition

Schizophrenia and other psychotic disorders

Synonym

psychotic disorders and schizophrenia spectrum disorders

Research involving

Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen

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Source(s) of monetary or material Support: NWO Intervention Keyword: martial arts, psychomotor therapy, psychotic disorder, victimization **Outcome measures Primary outcome** Victimization **Secondary outcome** Risk factors of victimization: Social cognition Social behavior Aggression regulation Internalized stigma Self-esteem And: Negative symptoms Quality of life Trauma Recovery Sociale participation **Fitness**

Background summary

Contrary to what is generally thought, people with psychotic disorders are more likely to be a victim of a crime, than an offender. Research has revealed several factors to be associated with victimization in patients with psychotic disorder. These factors are partly due to clinical symptoms. Impaired social cognition, decreased insight and problems in aggression regulation may lead to inadequate social behavior that increase the risk of victimization. In turn victimization can increase self-stigma resulting in reduced self-esteem, empowerment, and assertiveness, making patients more vulnerable for victimization. In addition, the traumatic experience of the victimization could induce strong physiological responses to external stimuli resulting in fear regulation problems. Consequently, becoming a victim significantly enhances risk for revictimization. The aim of this study is to investigate a new intervention that addresses the risk factors that may help people emerge from the vicious victimization cycle.

Study objective

The proposed study aims to investigate the effects of a psychomotor assertiveness training by means of a multicentre randomized controlled trial (RCT). Effects will be examined at the behavioural level by means of questionnaires and interviews, and at the cerebral level with an fMRI task. Firstly, effects on risk factors of victimization (e.g. social cognition, internal stigma, assertiveness) and fitness will be examined, since these are direct targets of the intervention. Long term effects on victimization will also be investigated, because the prevalence of incidents is low and we expect effects of the intervention will only be visible after a longer period of time.

Study design

To test the effectiveness of the intervention an RCT with a pretest-posttest and follow-up will be performed.

Intervention

To adress specific risk factors of victimization, we developed a psychomotor assertiveness training with elements of kickboxing. The intervention consists of 20 weekly group-training sessions of 75 minutes. Each group includes 8 participants. The intervention consists of five modules. All sessions will be given by a psychomotor trainer and and expert by experience.

Study burden and risks

We don't expect risks associated with participation. However, participants may find the questionnaires exhausting and confronting to some extent. The training might cause light muscle pain. Although exercises are built up carefully and participants wear protection, it is still possible to get a bruise.

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

- Diagnosis in the psychotic spectrum
- Being able to give informed consent
- 18 years or older

Exclusion criteria

- Florid psychosis (mean positive symptoms > 5 measured by PANSS)
- Substance dependence (not substance abuse)
- IQ < 70
- Co-morbid neurological disorder
- Co-morbid personality disorder cluster B
- Pregnancy before the start of the first training session. When a participant gets pregnant once the training started she can only participate during the first three months of her pregnancy.

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 23-03-2016

Enrollment: 120
Type: Actual

Ethics review

Approved WMO

Date: 28-10-2015

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Not approved

Date: 12-01-2016
Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 24-02-2016

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 21-12-2016

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 10-05-2017

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

Other 201500429

CCMO NL52202.042.15