

Beat Victimization! Feasibility study for a psychomotor assertiveness training with elements of kickboxing for people with a psychotic disorder

Published: 20-11-2014

Last updated: 21-04-2024

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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-OMON41040

Source

ToetsingOnline

Brief title

BEVIC

Condition

- Schizophrenia and other psychotic disorders

Synonym

psychotic disorders and schizophrenia spectrum disorders

Research involving

Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen

Source(s) of monetary or material Support: NWO

Intervention

Keyword: martial arts, psychomotor therapy, psychotic disorder, victimization

Outcome measures

Primary outcome

We hypothesise that the assertiveness intervention is applicable and its effects can be measured in a RCT using the chosen outcome measures, and that the chosen set up will lead to a sufficient number of participants. We constructed three goals to investigate this hypotheses. First of all we want to evaluate and improve intervention protocols. Trainers, participants, and involved psychiatric workers are asked for feedback and asked about wanted and unwanted effect of the sessions. After the intervention participants fill in an qualitative questionnaire about the subjective experience of the training. We expect that 80% of the participants indicate on this questionnaire that the intervention was **helpful** or **very helpful**. We also expect that the trainers and involved psychiatric workers have a positive opinion on the interventions protocol. Second, we want to explore parameters that are needed for the RCT. The feasibility study will tell us more about the willingness of therapist to refer clients to the intervention and the willingness of clients to participate. The coordinating researcher will monitor intervention adherence, drop-outs, and keep track of the time schedules and intervention procedures. We expect to find 24 patients willing to participate and drop-out rate will not be higher than 20%. Third, we want to explore suitable outcome measures to estimate sample size and power calculation for the RCT. We will use a

theory-based selection of the instruments stated in Table 2. We expect that the effect sizes of these instruments are small to moderate.

Secondary outcome

see primary study parameters

Study description

Background summary

Contrary to what is generally thought, people with psychotic disorder have an increased risk of victimization, instead of being possible offenders. Research shows several factors associated with victimization in patients with psychotic disorder. These factors are partly due to the clinical syndrome. 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 people who want to take advantage of them. In addition, the traumatic experience of the victimization could induce strong physiological responses to external stimuli resulting in aggression regulation problems. Consequently, once being a victim chances for revictimization are high. Aim of this study is to prevent (re)victimization using a new psychomotor assertiveness training with elements of kickboxing that addresses the risk factors.

Study objective

In preparation for a multicentre randomized controlled trial (RCT) we want to test the psychomotor assertiveness training in a feasibility study. The aim of this study is threefold: 1) We want to evaluate and improve intervention protocol also using participants experience. 2) We want to explore parameters that are needed for the RCT. For example: the willingness of onsite therapist to select patients and the willingness of patients to participate in an intervention that includes kickboxing, and adherence rate. 3) We want to explore suitable outcome measures and estimate sample size and power calculation for the RC.

Study design

To test the effects of the intervention we want to perform a feasibility study with a pretest-posttest quasi-experimental design without a control group.

Intervention

To address these specific risk factors we developed a psychomotor assertiveness training with elements of kickboxing. The intervention consists of 20-sessions of group training divided into five modules. There is one session per week with a duration of 75 minutes. One group has eight participants and there are three groups in total. All the sessions will be given by a psychomotor trainer and an expert by experience in cooperation with a fighting sport expert and a psychologist.

Study burden and risks

We don't expect any adverse events to happen for this reason no risks are associated with participation.

We expect that the psychomotor assertiveness training will increase social participation and prevent (re)victimization of people with a psychotic disorder.

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

- A 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

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	09-12-2014
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO	
Date:	20-11-2014
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	NL49520.042.14