

Beat Victimization! A body-oriented resilience training with elements of kickboxing for individuals with a psychotic disorder.

Submission date 16/02/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/03/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/04/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

People with a psychotic disorder are at an increased risk of becoming a victim of a crime. Research has revealed that there are several possible reasons, or risk factors, for this, including impaired social cognition (how they perceive information about other people and social situations), aggression problems, assertiveness, self-stigma and self-esteem). To address these risk factors and prevent victimization, a body-oriented resilience training with elements of kickboxing (the intervention) has been developed. The present study aims to test how well this intervention works.

Who can participate?

Adults (aged at least 18) diagnosed with a psychotic disorder.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 (body-oriented training group) are taught the basic techniques of kickboxing by a body-oriented therapist, once a week over 20 weeks. Participants in group 2 (control group) attend befriending sessions, the main goal of which is to create a welcoming atmosphere in which participants can socially interact with each other, once a week over 20 weeks. All participants are asked to fill out questionnaires just before and after the 20 week intervention period. Further follow-ups occur after 6, 18 and 20 months, where the effect of the intervention on victimization is investigated. Some participants are also asked to have fMRI scans before and after the intervention period in order to assess potential haemodynamic changes (blood flow changes) associated with the effects of the training.

What are the possible benefits and risks of participating?

Benefits associated with participation in the body-oriented resilience training are taking part in supportive, fun kickboxing lessons in which basic kickboxing techniques are learned. Kickboxing may have a positive effect on physical health because of endurance and muscle training. Benefits with regard to the befriending meetings are meeting new people and weekly social interactions in a warm setting. Benefits associated with participation in this study in general is contribution

to clinical research which eventually may result in better care and compensation for all of the measurements.

Where is the study run from?

University of Groningen (Netherlands)

When is the study starting and how long is it expected to run for?

February 2016 to October 2020

Who is funding the study?

Netherlands Organisation for Scientific Research

Who is the main contact?

1. Mrs Marieke Pijnenborg (scientific)

g.h.m.pijnenborg@rug.nl

2. Mrs Joeske van Busschbach (scientific)

j.t.van.busschbach@umcg.nl

Contact information

Type(s)

Scientific

Contact name

Mrs Marieke Pijnenborg

Contact details

Grote Kruisstraat 2/1

Groningen

Netherlands

9712 TS

050 363 4637

g.h.m.pijnenborg@rug.nl

Type(s)

Scientific

Contact name

Mrs Joeske van Busschbach

Contact details

Hanzeplein 1

Groningen

Netherlands

9713 GZ

050 361 2069

j.t.van.busschbach@umcg.nl

Additional identifiers

Protocol serial number

ABR NL52202.042.15

Study information

Scientific Title

A body-oriented resilience training with elements of kickboxing: a novel intervention to reduce victimization in individuals with a psychotic disorder: a multi-center RCT.

Acronym

BeatVic

Study objectives

1. The primary objective of this study is to investigate whether the body-oriented resilience training with elements of kickboxing reduces the risk of victimization.
2. The secondary objective of this study is to investigate whether the body-oriented resilience training with elements of kickboxing has a positive effect on risk factors of victimization in individuals with a psychotic disorder, such as aggression regulation, self-stigma, self-esteem, social behavior (behavioral level) and social cognition (behavioral and cerebral level). Furthermore the effect on quality of life, recovery and societal participation will be investigated at the long term.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medisch Ethische Commissie - University Medical Center Groningen (Medical Ethical Committee), 29/02/2015, ref: NL52202.042.15, METc nr 2015/303

Study design

Multicenter randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Individuals with a diagnosis in the psychosis spectrum

Interventions

Participants are randomly allocated to one of two groups:

1. Individuals allocated to the treatment condition receive a body-oriented resilience training with elements of kickboxing. This training consists of 20 weekly sessions during which basic kickboxing techniques are taught and risk factors of victimization are addressed by means of various exercises
 2. Participants allocated to the control condition receive 20 weekly befriending sessions, during which social interaction is most important
- Follow-ups are at 6, 18 and 30 months.

Intervention Type

Behavioural

Primary outcome(s)

1. Victimization, measured using the Integrale Veiligheidsmonitor (IVM) and the Conflicts Tactics Scale - revised (CTS2) at baseline (pre), directly after the intervention-period (post) and 6/18/30 months following the intervention.

Mediating factors:

We expect that the effect of the intervention on victimization is mediated by several risk factors, on which our intervention is based. Mediation factors will be measured at baseline (pre), directly after the intervention-period (post) and at 6 months follow-up. Mediating factors we defined in our study are:

1. Social cognition (Faux Pas task)
2. Aggression regulation (Self-Expression and Control Scale, ZECV)
3. Internalized stigma (Internalized Stigma of Mental Illness Scale, ISMI)
4. Social behavior (Interpersonal Behavior Scale, SIG)
5. Self-esteem (Self-esteem Rating Scale - Short Form, SERS-SF)
6. Insight (Psychosis Insight Scale, PI)

Key secondary outcome(s)

1. Quality of live (MANSA)
2. Recovery (National Recovery Scale, NHS)
3. Societal participation (Social Functioning Scale, SFS)
4. Symptoms (Brief Negative Symptom Scale, BNSS)
5. Trauma (Trauma Screening Questionnaire)
6. Physical activation (Pedometer, Yamax EX 510)
7. Endurance (Modified Shuttle Test, MST)

Measured at baseline, directly after the intervention and at 6, 18 and then 30 months follow-up.

Completion date

01/10/2020

Eligibility

Key inclusion criteria

1. A diagnosis in the psychosis spectrum according to Diagnostic and Statistical Manual of Mental Disorders, 4th edition
2. 18 years or older

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

105

Key exclusion criteria

1. Severe psychotic symptoms (mean positive symptoms > 5 measured by PANSS)
2. Substance dependence (not substance abuse), verified by Miniscan.
3. Co-morbid neurological disorder, verified by onsite therapist.
4. Co-morbid personality disorder, verified by onsite therapist.
5. Estimated IQ < 70, onsite therapist decides if the patients' intelligence is sufficient for participation.
6. Pregnancy.

Date of first enrolment

22/02/2016

Date of final enrolment

01/12/2016

Locations**Countries of recruitment**

Netherlands

Study participating centre

University of Groningen

Grote Kruisstraat 2/1

Groningen

Netherlands

9712 TS

Sponsor information**Organisation**

University Medical Center Groningen

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Government

Funder Name

Nederlandse Organisatie voor Wetenschappelijk Onderzoek

Alternative Name(s)

Netherlands Organisation for Scientific Research, Dutch National Scientific Foundation, Dutch National Science Foundation, Dutch Research Council (Nederlandse Organisatie voor Wetenschappelijk Onderzoek), NWO:Nederlandse Organisatie voor Wetenschappelijk Onderzoek, Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO), Dutch Research Council, The Dutch Research Council (NWO), Dutch Research Council, Netherlands, NWO

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	6-month results	21/12/2022	30/03/2023	Yes	No
Results article		24/01/2020	10/04/2024	Yes	No
Protocol article	protocol	08/07/2016	05/08/2019	Yes	No
Other publications		09/09/2019	10/04/2024	Yes	No
Protocol (other)		10/04/2024	No	No	