ISRCTN21423535 https://doi.org/10.1186/ISRCTN21423535

# 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

**Registration date**
30/03/2016

**Overall study status**
Completed

**Last Edited**
10/04/2024

**Condition category**
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
People with a psychotic disorder are at in increased risk of becoming 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-orientated training group) are taught the basic techniques of kickboxing by a body-orientated 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 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 Jooske 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 Jooske 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 Ilness 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol (other) | | | 10/04/2024 | No | No |