

BEATVIC, a body-oriented resilience therapy using kickboxing exercises for people with a psychotic disorder: a feasibility study

Submission date 09/11/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2020	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/02/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Contrary to what is generally thought, people with a psychotic disorder are more likely to be a victim of a crime rather than an offender. A recent Dutch study showed that severely mentally ill outpatients reported 14 times more incidents regarding personal crime (e.g. sexual harassment or assault, threats of violence, and physical assault) in the past year, compared with the general population. To reduce the victimization risk a psychomotor assertiveness training has been developed with elements of kickboxing. The aim of this study is to explore the feasibility of the intervention, improve the study protocol and explore suitable outcomes measures for a future study.

Who can participate?

Patients with a diagnosis in the psychotic spectrum

What does the study involve?

Research has revealed several risk factors to be associated with victimization in patients with psychotic disorders. BEATVIC addresses some of the important risk factors using kickboxing exercises. The intervention consists of 20 group sessions given by a psychomotor therapist and expert by experience. Before and after the intervention the participants fill in questionnaires and are involved in evaluating the intervention protocol.

What are the possible benefits and risks of participating?

The effects are measured in a future study but it is expected that the intervention will reduce victimization in people with a psychotic disorder. In this study it is expected that the intervention will be feasible and the intervention protocol will be improved.

Where is the study run from?

Department of psychotic disorders of GGZ-Drenthe (Netherlands)

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

September 2014 to April 2015

Who is funding the study?
Netherlands Organisation for Scientific Research

Who is the main contact?
Miss Bertine de Vries
b.de.vries@rug.nl

Study website
<https://beatvic.com/>

Contact information

Type(s)
Scientific

Contact name
Miss Bertine de Vries

Contact details
Rijksuniversiteit Groningen
Grote Kruisstraat 2/1
Groningen
Netherlands
9712 TS
+31 (0)630571665
b.de.vries@rug.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NWO grant nr 432-12-807

Study information

Scientific Title
BEAT Victimization, a body-oriented resilience therapy using kickboxing exercises for people with a psychotic disorder: a feasibility study

Acronym
BEATVIC

Study objectives

The trialists 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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The medical ethics board of the University Medical Center Groningen, Groningen, 20/11/2014, NL52202.042.15

Study design

Feasibility study with a pretest-posttest quasi-experimental design without a control group

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Prevent victimization of people with a psychotic disorder

Interventions

BEATVIC consists of 20 weekly group sessions of 75 minutes. All sessions are led by a psychomotor therapist and an expert by experience. The intervention contains five modules each targeting specific risk factors.

Every session starts with a warming-up followed by kickboxing exercises and one or two thematic (kickboxing) exercises. The first module focusses on self-stigma and is an introductory module during which participants get to know each other and are introduced to kickboxing techniques. The focus of the second module, entitled "recognizing dangerous behaviour", lies on social cognition and participants practice identifying threatening non-verbal signals. They are stimulated to share and verify their own perception of situations and to consider other people's perspectives. The third module focuses on insight and again on social cognition and is entitled "how others see me": people learn to look at themselves through the eyes of others. Special attention is given to the way body posture influences the interaction both for others and for oneself. The fourth module concerns the theme "aggression regulation", during which participants learn not only how to cope with aggression of others but also to recognize, regulate and control their own anger. The aim of this module is to adequately balance between improving

resilience, while also preventing aggressive behaviour. Module five repeats and combines the themes and exercises that were important for each specific group.

Intervention Type

Behavioural

Primary outcome measure

1. The feasibility of the intervention, assessed using recruitment rate, dropout and attendance at pre and post measurement as well as during the intervention after each session
2. Intervention protocols evaluated and improved by feedback from trainers, participants, and involved psychiatric workers about wanted and unwanted effects of the sessions at pre and post measurement

Secondary outcome measures

To explore suitable outcome measures to estimate sample size and power calculation for the RCT, the following outcomes were measured at baseline and post intervention:

1. Victimization, measured using the Integrale Veiligheidsmonitor (IVM) (the Dutch victimization screening questionnaire) and the revised Conflict Tactics Scale (CTS2).
2. Social functioning, measured using the Inventory of interpersonal situation (IIS)
3. Aggression regulation, measured using the Self-expression and Control scale (ZECV) and the Novaco Anger Scale-Provocation Inventory (NAS-PI)
4. Symptoms, measured using the Positive and Negative Syndrome Scale (PANSS).
5. Trauma, measured using the Trauma Screening Questionnaire (TSQ)
6. Alcohol and drugs use, measured using the screening risico op verslavingsproblemen (Dutch screening questionnaire for substance abuse)

Overall study start date

01/09/2014

Completion date

01/04/2015

Eligibility

Key inclusion criteria

A diagnosis in the psychotic spectrum, according to DSM-IV-TR criteria, verified by MiniScan

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

24

Total final enrolment

Key exclusion criteria

1. Florid psychosis (mean positive symptoms > 5 measured by PANSS)
2. Substance dependence (not substance abuse) of alcohol, marijuana, opiates, stimulants and cocaine, verified by Miniscan
3. Estimated IQ < 70, onsite therapist decides if the patients intelligence is sufficient for participation
4. Co-morbid neurological disorder, verified by onsite therapist
5. Co-morbid personality disorder, verified by onsite therapist
6. Pregnancy before the start of the first training session

Date of first enrolment

20/11/2014

Date of final enrolment

01/12/2014

Locations**Countries of recruitment**

Netherlands

Study participating centre

Department of psychotic disorders of GGZ-Drenthe

Dennenweg 9

Assen

Netherlands

9404 LA

Sponsor information**Organisation**

University of Groningen

Sponsor details

Grote Kruisstraat 2/1

Groningen

Netherlands

9712 TS

+31 (0)50 36 34637

www.g.h.m.pijnenborg@rug.nl

Sponsor type

University/education

Website

<https://www.rug.nl/>

ROR

<https://ror.org/012p63287>

Funder(s)

Funder type

Government

Funder Name

Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO grant nr 432-12-807)

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, Dutch Research Council, Netherlands, NWO

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Netherlands

Results and Publications

Publication and dissemination plan

The trialists want to publish the results of the feasibility study in one paper.

Intention to publish date

01/01/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Bertine de Vries (b.de.vries@rug.nl): a dataset with questionnaire outcomes and a logbook with all the monitored information on dropout, attendance, evaluation of the sessions. All data will be available for five years. Participants are aware and have given an informed consent to use the data anonymous for research purposes. Scientists can email their research questions with specification of the data that they are interested in.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/12/2018	14/02/2020	Yes	No