Virtual Reality Aggression Prevention Training in a Dutch prison-based population * a pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48341

Source
ToetsingOnline

Brief title
VRAPT-GW (Virtual Reality Aggression Prevention Training - Gevangeniswezen)

Condition

- Other condition
- Personality disorders and disturbances in behaviour

Synonym
Aggression; Violence

Health condition

Emotie regulatie problematiek: agressie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Centrum Psychiatrie
Source(s) of monetary or material Support: PI Vught

Intervention

Keyword: Aggression, Pilot-Study, Prison-Based, Virtual Reality

Outcome measures

Primary outcome

To investigate which adjustments are necessary for the upcoming randomized controlled trial, different evaluations are organized. Before the treatment will start, we will have two focus groups: one with detainees (maximum of 5 in one group) and one with therapists (maximum of 5 in one group) to discuss the VRAPT protocol and ask feedback on the content, the difficulty and the suitability of the protocol. The focus group will take place once and will last a maximum of 2,5 hours.
After the treatment starts, every session will be evaluated with the Session Rating Scale (SRS) and additional questions for participants and the trainers.

Secondary outcome

The secondary objective of this study is to examine the results of the VRAPT in a prison-based population.

This is firstly measured on the unit through observation by the prison staff. Observation will be measured through a behaviour-observatory questionnaire by penitentiary institution workers on the unit where the participant is detained.
The Social Dysfunction and Aggression Scale (SDAS-9) will be scored, by the

mentor of the participant four weeks before treatment starts and will end four weeks after the last treatment. The SDAS-9 is a behaviour-observatory scale in which aggressive behaviour can be measured. The SDAS-9 consists of 9 items measuring the extent of outward physical and verbal aggressive behaviour over a time period of a week (Kobes, Nijman, & Bulten, 2012; Wistedt et al., 1990).

Secondly, individual changes are measured through self-report. Self-report will consist of questionnaires which are filled in by participants with help of the research assistant, measuring different types of aggression (overt and covert), anger, impulsiveness, emotion regulation, substance abuse and childhood trauma. The questionnaires will be scored on three different moments during the study: before the treatment, at the end of the treatment and two- months after the treatment ended (in the study of Klein Tuente et al. (2018) a follow-up of three months was used, however in a prison-based sample the duration of imprisonment changes constantly. Using a two-month follow-up increases the chance of follow-up measurements).

Four questionnaires will be used to measure different types of aggression, namely the Aggression Questionnaire (AQ), Difficulties in Emotion Regulation (DERS), the Novaco Anger Scale and Provocation Inventory (NAS-PI) and the Reactive-Proactive Questionnaire (RPQ). To measure impulsiveness the Barratt Impulsiveness Scale (BIS-11) will be used.

Further, as it is known that individuals who have experienced childhood trauma and substance abuse, are more likely to use aggressive behaviour (Håkansson & Berglund, 2012; Klein Tuente et al., 2018), we also included a questionnaire

for childhood trauma (the Adverse Childhood Experiences (ACE)): and substance

abuse (the Measurement in the Addiction for Triage & Evaluation (MATE)).

Study description

Background summary

Violent crimes (violence directed against a person or matters) are still one of the most common crimes in a Dutch prison-based population. Violent crimes alone take up to 29% of all offenses. If property crimes with violence and sexual assaults are also included, this number can increase up to half of all offenses. When looking at the recidivism rates of these types of crimes, it has been estimated that 22% of these offenders will return to prison within two years after they have been released (*DJI in getal 2013-2017,* 2018). Research also shows that individuals with violent crimes during their incarceration, recidivate more often and even sooner than inmates without violent crimes (Mooney & Daffern, 2015), which indicates the importance on treating individuals with aggression problems in detention.

Many forms of aggression-based therapies have been developed, mostly consisting of cognitive or behavioural methods, or a combination of the two (Shelton, Sampl, Kesten, Zhang, & Trestman, 2009). The focus is mostly on reshaping cognitions, improve problem solving, exposure and skill training (Shelton et al., 2009). Research has shown that treatment for aggression in generally works in reducing the recidivism rates (McGuire, 2008) However, results in prison-based populations the results are still inconclusive, mostly due to the low quality of the studies (Auty et al., 2017; McGuire, 2008).

For therapy to be successful, a couple of factors are of importance: firstly, the motivation or the willingness of the offenders to change their behaviour (Jochems et al., 2012; McGuire, 2008; Smeijers, Bulten, Buitelaar, & Verkes, 2018). Individuals may be convinced that they have no problem or may have followed therapy earlier without success, demotivating them to follow therapy again. Secondly, most therapies are very theoretically, which may not be successful for some specific populations. It is recommended, for example in individuals with low intellectual disabilities, to use less language-dependent therapies (Simpson, Mizen, & Cooper, 2016). Lastly, a known difficulty in imprisoned individuals is the inability to practice learned behaviour in real life situations (McGuire, 2008).

A solution to the above encountered problems may lay in the use of Virtual Reality (VR). VR uses artificial computer-generated environments to imitate real-world situations. VR makes it possible to practice situations in an

interactive computer-generated environment and therefore combines theoretical information with practical learning situations. Situations can be altered as much as needed to fit the precise conditions in which the individual wants to practice the problematic behaviour (Freeman et al., 2017). This technique may also trigger the motivation of individuals, as it is new and interesting, and may also be attractive to the younger generation since they grew up with technology and innovation.

Study objective

The primary objective of this pilot study is to adjust the VRAPT protocol to make it applicable in a prison-based sample and to investigate if the protocol of the pilot study is feasible for a larger effect study. Several questionnaires will be filled in with the main goal to investigate if they are suitable for the study and if any problems are encountered if participants or staff will fill them in.
The goal is to resolve any issues, before an effect study can be conducted.

The secondary objective of this study is to examine the effect of the VRAPT on aggression in a prison-based population.
This will be evaluated with the same two methods that are used in the previous VRAPT effect study in forensic inpatients (Klein Tuente et al 2018) and will be applied in our upcoming randomized controlled trial: staff observation and self-report measurements with additional physiological measurements.

Study design

This study will be an uncontrolled pilot study. As mentioned in the introduction and rationale, the previous VRAPT study is being conducted in four Dutch Forensic Psychiatric Centers (FPC*s), and will be used as the base for the VRAPT study in a prison-based population (Klein Tuente et al 2018).

Procedure
1. All participants meeting the inclusion criteria, will be made aware of the study through the psychologist, the case manager or the mentor on the ward. Also, there will be flyers with information about the study, so participants who want to join also can apply on one*s own initiative.
2. When participants are signed up, a researcher will pay the participant a visit to give information about the study and check if they meet the inclusion criteria. As screening with the Aggression Questionnaire is needed for assessment of eligibility, informed consent for the study is obtained before the AQ is administered.
3. The mentor of the participant will be instructed how to score the Social Dysfunction and Aggression Scale (SDAS-9). They will be asked to fill out the SDAS weekly, four weeks before the treatment will start, until four weeks after the training is over. Research assistants will check if the scores are complete

and support the staff with filling out the questionnaire.
4. Self-report questionnaires are filled in by the participants for baseline measurements (DERS NAS-PI, RPQ, BISS-11, ACE and MATE). The research assistant will assist with filling in the questionnaires (explain the content of the questionnaires and assist when participants don*t understand the questions).
5. Treatment consists of 16 twice-weekly individual sessions with a maximum duration of 60 minutes per session. Physiological measurements will start in the 6th session.
6. After every session, the SRS is filled in and additional evaluating questions are asked.
7. At the end of treatment, baseline measures (only AQ, BIS-11, DERS, NAS-PI, RPQ) are repeated in all participants. The research assistant will assist the participants with filling in the questionnaires.
8. Two months after the end of the VRAPT sessions, measures are repeated again.

Intervention

The VRAPT protocol that will be used in this study is the protocol that is currently used in the study of Klein Tuente et al. (2018). This protocol is based on the Social Information-Processing (SIP) model of Crick and Dodge (1994). The first five sessions focus on the early stages of information processing (what is happening and what does is mean). Session six through 16 focus on the late information processing stages (what goals am I trying to achieve, what options do I have to react, what am I going to do and what is the reaction or behaviour). To train the aforementioned stages, different aggressive inducing situations are formed in VR.
During the VRAPT sessions, patients wear headsets with controllers and walk in a simulated virtual environment. The virtual environment is adapted to the specific needs of the patients, with different themes (for example a store, bar or mall) and avatars (for example a security guard, a group of females or males with different ethnic backgrounds) to choose from. The trainer takes the role of the avatar by using a microphone with voice distortion, controlling the facial expressions and bodily movements throughout the VRAPT session.
In the sessions, patients are able to train de-escalating behaviour in interaction with the avatars. The VRAPT is a 16 -twice-weekly individual training session of 60 minutes.

Study burden and risks

Participants will have a maximum of 16 sessions twice-weekly, with a maximum of 60 minutes per session. Participants will undergo two types of measurement during the study. The first measurements will consist of questions about experiences during the session (1 short questionnaire and additional questions after each session) and physiological measurements during sessions. The questions about the experience of the session will approximately take a half an hour to complete after each session. The physiological measurements are part of

the intervention.
The second measurements consists of self-report measurements, filled in before intervention starts (7 questionnaires about childhood trauma, substance abuse, emotion regulation, anger, aggression and impulsiveness), after the intervention ends (6 questionnaires about emotion regulation, anger, aggression, impulsiveness, and the *real-life experience* in VR) and 2-months follow-up (5 questionnaires about emotion, regulation, anger, aggression and impulsiveness). It will take approximately three hours in total to fill in the questionnaires before the treatment, after the treatment and at follow up. Research assistants will be available to support when questionnaires are filled in. We expect participants to benefit from the training as they will learn to control their emotions and use de-escalating behaviour. It is also thought that the burden en risk will be minimal, as no major adverse events have been documented before with VR research.

Contacts

Public
Selecteer

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Selecteer

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, subjects must meet all of the following criteria:
- Detainees who are imprisoned in P.I. Vught, The Netherlands.
- Detainees with aggression regulation problems in the last month, as measured with the AQ (minimum score of 70).
- Minimum age of 18 years old.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:
- IQ below 70.
- Acute suicidal behaviour or current psychotic episode.
- Insufficient command and understanding of the Dutch language.
- Epileptic seizure in the last year.

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):	19-11-2019
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	21-10-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-03-2021
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
CCMO	NL70477.042.19