Virtual Reality Training for Aggression Control in a Dutch prison-based population - a randomized controlled trial.

Published: 25-04-2022
Last updated: 27-12-2024

The primary objective of this randomized controlled trial is to investigate the effect of the VR-TRAC on aggression in a prison-based population.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49888

Source
ToetsingOnline

Brief title
VR-TRAC

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 Medisch Centrum Groningen
Source(s) of monetary or material Support: PI Vught

Intervention

Keyword: Agression, Prison-Based, Randomized controlled trial, Virtual Reality

Outcome measures

Primary outcome

The primary objective of this randomized controlled trial is to investigate the effect of the VR-TRAC on aggression in a prison-based population. Firstly, through staff observation, secondly, through self-report measurements and lastly, with scripted role-plays.

The primary outcome will be measured through a self-report measurement, the *Aggression Questionnaire (AQ)*, wich measures four different types of aggression.

Secondary outcome

Self-report questionnaires

Individual changes are measured through self-report measurements. Self-report will consist of questionnaires that are filled in by participants with help of the research assistant, measuring different types of aggression (overt and covert), anger, impulsiveness, and emotion regulation. 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.

Five questionnaires will be used as secondary study parameters:

- The Difficulties in emotion regulation (DERS) consists of 36 items measuring difficulties in emotion regulation.
- The Novaco Anger Scale and Provocation Inventory (NAS-PI) consists of two parts, The NAS part contains 48 questions and measures three factors; cognitive, arousal and behavior.
- The Reactive-Proactive Questionnaire (RPQ) consists of two 23 items (11 items on reactive aggression and 12 items on proactive aggression).
- The Short Anger Measure (SAM) is a self-report and consists of 12 items measuring angry feelings and aggressive impulses over the last week.
- The Barratt Impulsiveness Scale (BIS-11) measures the personality/behavioral construct of impulsiveness.

One questionnaire will measure the experience of presence in VR (I group Presence Questionnaire).

Staff observation

For the staff observation, the Observation Scale for Aggressive Behaviour (OSAB) will be used (Hornsveld, Nijman, Hollin, & Kraaimaat, 2007). The OSAB consists of 40 items measuring emotions/mood, aggressive behavior, the reason for the aggressive behavior, sanction for the patient, and socially competent behavior.

Scripted role-plays

To measure the effectiveness of the skills trained in the VR-TRAC, scripted role-play assessments will be conducted. The role-play will be scheduled at two-time points. For the treatment group, this will be before the training will start and once after the treatment has ended. For the control group, this will be scheduled right after they have signed the informed consent. The second role-play will be scheduled approximately two months after the first role-play.

Vignettes

Vignettes consist of two written scenarios (slightly different but comparable to the role-plays). They will be conducted on two-time points (once before the treatment starts and once after treatment has ended).

Other outcomes

Sociodemographic characteristics and (history of) conviction

- Age
- Cultural background
- Highest level of education
- Current conviction
- Earlier convictions

Self-report questionnaires

- The Adverse Childhood Experiences (ACE): is a questionnaire consisting of 8 main themes on adverse childhood experience (with additional questions in each theme), rated on a *yes* or *no* scale (World Health Organization, 2012).

- Measurement in the Addiction for Triage & Evaluation (MATE) is a questionnaire developed to measure and diagnose substance abuse.

- Every session will be evaluated with the Session Rating Scale (SRS).

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 of treating individuals with aggression problems in detention.

Although the terms *aggression* and *violence* are used interchangeably, it is important to differentiate between the two terms (McGuire, 2008; Ramírez & Andreu, 2006). The term *violence* is generally described as personal (physical) violence committed by one individual to another and is mostly defined and used in formal law (McGuire, 2008). Aggression is defined as *any behavior to harm another person* (Ramírez & Andreu, 2006), which means it can consist of different dimensions. Literature, in general distinguishes two main types of aggression: reactive and proactive aggression (Crick & Dodge, 1996). Reactive or expressive aggression is described as an impulsive, angry, hostile, or defensive response to a frustrating or provocative situation. The goal is to decrease an unpleasant internal feeling (for example the physiological arousal or tension). Whereas proactive aggression is deliberate controlled behavior to obtain the desired goal (Crick & Dodge, 1996; McGuire, 2008).
One important determinant of aggressive behavior is the hostile attributional

bias (HAB), which states that negative experiences in childhood and adolescence may cause individuals to interpret behavior as more hostile, especially when behavior is more ambiguous or unpredictable (Dodge et al., 2015). It is also thought that these individuals are more likely to evaluate behavior as aggressive and they expect more favorable outcomes for aggressive behavior (Coccaro, Fanning, & Lee, 2017).
A more general and extended explanation of the hostile attributional bias is the social information processing theory (SIP) (Dodge & Crick, 2007). Although this model was initially developed to explain aggression in children, more evidence is rising that HAB is also applicable in adults (Klein Tuente, Bogaerts, & Veling, 2019; Lim, Day, & Casey, 2011). The SIP describes six steps in which an individual processes information to interpret different situational cues to choose appropriate behavior (Coccaro et al., 2017).
The first step includes encoding a situational cue (cognitive and emotional cues). The second step includes the interpretation of the social cue, and attributions are made. The third step is to consider the goals in the given situation. In the fourth step, the potential responses are considered. The fifth step consists of selecting a response. The last step is choosing a response and act on it (Coccaro et al., 2017). Later, emotional factors were also included in this model (changing the name to Social-Emotional Information Processing (SEIP) model), including the role of negative affect in aggressive behavior, which made the model applicable to both types of aggression (Coccaro et al., 2017).

Many forms of aggression-based therapies have been developed, mostly consisting of cognitive or behavioral 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 general works in reducing recidivism rates (McGuire, 2008). In prison-based samples, highly structured treatments with a focus on criminogenic factors showed to be more effective. Also, a more therapeutic approach in an institutional regime seems to be more effective (Auty, Cope, & Liebling, 2017). However, results in prison-based populations are still inconclusive, mostly due to the low quality of the studies (Auty et al., 2017; McGuire, 2008). McGuire (2008) indicated that this can be best interpreted as: *absence of evidence rather than evidence of absence* (p. 2591), stating that more and better quality research is needed.

For therapy to be successful, a couple of factors are of importance. One of these factors is the motivation or the willingness of the offenders to change their behavior (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. In addition, most therapies are very theoretical, which may not be successful for some specific populations. It is recommended, for example for individuals with 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 behavior 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. Individuals wear a headset with controllers to move around in the VR environment (El Beheiry et al., 2019). 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 behavior (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 randomized controlled trial is to investigate the effect of the VR-TRAC on aggression in a prison-based population.

Study design

This study will be a randomized controlled trial.

Procedure
1. All detainees 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 on the ward and information on a special prison tv channel.
2. When a detainee is interested to participate, a research assistant will visit him to give information about the study and check if they meet the inclusion criteria. As screening with the Aggression Questionnaire (AQ) is needed for assessment of eligibility, informed consent for the study is obtained before the AQ is administered.
3. When participants are included in the study they are randomized to one of the two conditions: VR-TRAC or waiting list.
4. Both groups will start with filling in the SAM weekly and the OSAB will be filled in with staff members, also weekly (this will start four weeks before treatment and will continue until four weeks after the last session has taken place).
5. After four weeks, the other self-report questionnaires and vignettes are filled in by the participants in both conditions for baseline measurements (DERS NAS-PI, RPQ, BIS-11, ACE, and MATE). The research assistant will assist with filling in the questionnaires (explain the content of the questionnaires, assist when participants don*t understand the questions and check if any questions are accidentally forgotten). To motivate the waiting list condition,

participants are given the option to play a game in the VR surrounding for a maximum duration of half an hour. The surrounding is different from the surrounding in which participants follow the VR-TRAC and does not contain any aggression like situations.
6. Next, participants in both conditions will be scheduled for the role-play assessment.
7. Participants randomized to the VR-TRAC condition will then start treatment. Treatment consists of 16 twice-weekly individual sessions with a maximum duration of 60 minutes per session.
8. After every session, the SRS is filled in and additional evaluating questions are asked.
9. At the end of treatment, vignettes and 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 and participants in the waiting list condition are given the option to play a game in the VR surrounding.
10. All participants will be scheduled for the post-treatment role-play assessment.
11. Two months after the end of the VR-TRAC sessions, self-report measures are repeated. Participants in the waiting list condition are also given the option to play a game in the VR surrounding.

Intervention

The protocol that will be used in this study is based on the protocol that has been developed by Klein Tuente et al. (2018). In our pilot (METc 2019/381, registered under file number NL71610.042.19) we tested this protocol in a prison-based population. After the pilot, some minor adjustments were made. The current protocol is still based on the Social Information-Processing (SIP) model of Crick and Dodge (1994) and consists of 16 sessions in total, with a duration of 60 minutes each.
The first session will focus on the introduction of the training and formulating goals for the participant. It is also important for the participant to get acquainted with the VR (how it all works, but also how the VR world looks like). Session two and three will focus on the early stages of information processing (what is happening and what does it mean). Session five through eight focuses 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 behavior). Session 10 through 15 combines the early and late stages, as all new learned behavior will be incorporated in the interactive scenarios. To train the aforementioned stages, different aggressive-inducing situations are formed in VR.

During the VR-TRAC 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 session.
In the sessions, patients are able to train de-escalating behaviour in interaction with the avatars. The VR-TRAC is a 16 twice-weekly individual training session with a maximum duration of 60 minutes.

Study burden and risks

participants will undergo two types of measurements during the study (self-report measurements and performance-based assessments). The self-report measurements will approximately take an hour on each timepoint to fill in. The vignettes will take approximately half an hour to fill in (before the treatment starts and after treatment has ended). The weekly questionnaire on angry feelings will approximately take a maximum of 10 minutes to fill in. Research assistants will be available to support when questionnaires are filled in.
The performance-based assessments, which will take place before the treatment starts and after the treatment has ended will take approximately half an hour.
Risks associated with participating with this study are cybersickness and aggression during the sessions. The risks are kept to a minimum as the VR scenarios to provoke angry feelings are build up slowly. Cybersickness is a mild side-effect as a result of exposure to the VR environment and symptoms reduce when VR is stopped. The risks of being on the waiting list are limited because aggression therapy is not standard part of the therapy program in prison. Detainees can register voluntarily for individual psychological therapy (where they can also follow aggression therapy), but for following individual therapy there is a waiting list as well. When they have participated in the study they are offered the opportunity to follow the VR-TRAC after the last follow-up.
We understand that filling in these questionnaires and participating in the role-plays may be intensive, but we expect participants to benefit from the training as they will learn to control their emotions, gain more insight in their aggressive behavior and use de-escalating skills. We also think that adding the role-plays and vignettes as an extra measurement will help to understand the learned skills and if they extend to the *real-world*, instead of focusing solely on the broad terms of aggression.

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

- Detainees who are imprisoned in P.I. Vught, The Netherlands, for at least 20 weeks.
- Detainees with aggression regulation problems in the last month, as measured with the AQ (a minimum score of 70).
- Minimum age of 18 years old.

Exclusion criteria

- SCIL score of 14 or lower.
- Acute suicidal behavior or current psychotic episode.
- Insufficient command and understanding of the Dutch language.
- Photosensitive epileptic seizure in the past year.
- An estimated stay of 5 months or shorter
- Following other treatments with the aim to control aggression.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-04-2023
Enrollment:	128
Type:	Actual

Ethics review

Approved WMO Date:	25-04-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-04-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-11-2024
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	NL78475.042.21