Virtual Reality Aggression Prevention Training in forensic clinics

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

Summary

ID

NL-OMON43576

Source
ToetsingOnline

Brief title
Virtual Reality Aggression Prevention Training (VRAPT)

Condition

- Other condition
- Personality disorders and disturbances in behaviour

Synonym
Aggression; Violence

Health condition

Agressie; en psychotische stoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Centrum Psychiatrie
Source(s) of monetary or material Support: NWO - geweld tegen psychiatrische patiënten;grant nr. 432-13-802

Intervention

Keyword: aggression, forensic psychiatry, victimisation, Virtual Reality

Outcome measures

Primary outcome

Primary outcome: The number and the severity of incidents in the Forensic Psychiatric Centers, Forensic Psychiatric Clinics and Forensic Psychiatric Departments. Aggression incidents will be recorded on a weekly basis with the social dysfunction and aggression scale (SDAS) for patients participating in the current research to document the aggressive state of patients. The SDAS measures a broad range of aggressive behavior, including very mild forms of aggression. Primary outcome variables are number and the severity of aggressive incidents in which subjects are victim and/or perpetrator of aggression by patients.

Secondary outcome

Secondary outcomes: A patient's individual changes in aggression, arousal, coping and the way a patient reacts on provocation of others. This is measured by means of self-report questionnaires and physiological data on different moments before, during and after treatment. The self-report questionnaires are the: AVL, BDHI-D, STAXI-2, BIS-11 and NAS-PI. The physiological data include heart rate variation measured by electrocardiogram (ECG), muscle tension by

electromyography (EMG) and skin conductance by galvanic skin response (GSR).

Study description

Background summary

A majority of patients staying in Forensic Psychiatric Centers (in Dutch: FPC's), Forensic Psychiatric Clinics (in Dutch: FPK's) or Forensic Psychiatric Departments (in Dutch: FPA*s) are admitted under the judicial measure TBS-order (terbeschikkingstelling: this translates as *detained under a treatment order*). A TBS-order is imposed by court on offenders who have committed a serious violent offense and are considered to be at high risk for re-offending and who have diminished responsibility for the offense because of severe psychopathology. Besides being perpetrators of aggression, forensic patients are also frequently victimized by aggressive behavior of fellow patients. Standard aggression regulation training follows a cognitive behavioral therapy (CBT) approach. Effects in forensic settings are small, because possibilities for controlled exposure to real-life provocation and practicing new behavior are limited. In this study, a Virtual Reality Aggression Prevention Training (VRAPT) is developed. VRAPT offers an interactive three-dimensional virtual *real-life* world in which social situations and interactions can be experienced and practiced. In a randomized controlled trial, the effect of VRAPT (intervention-condition) compared to waiting list (control-condition) is investigated.

Study objective

Primary objective
The main objective of this study is to examine whether Virtual Reality aggression prevention training (VRAPT) is effective in reducing aggression and victimization among inpatient forensic psychiatric patients. This is assessed using the social dysfunction and aggression scale (SDAS; Widstedt et al., 1990) on a weekly basis for all forensic psychiatric patients at their ward. Participants in the VRAPT condition (intervention group) will be compared with the participants on the waitlist (control group).

Secondary objective
The effect of VRAPT on individual factors as arousal, coping and the way a patients reacts to provocation is measured in an objective way by using physiological measurements: electrocardiogram (ECG), electromyography (EMG) en galvanic skin response (GSR). Again, participants in the VRAPT condition (intervention group) will be compared with the participants on the waitlist (control group). Furthermore, participants individual progress can be measured, by the use of their own physiological measurements at different

moments during the study.

Additionally, the effect of VRAPT on individual self-report measures of aggression, anger and impulsivity shall be examined. This will be done on three moments in time, namely: before treatment start, end of treatment and at 3 months follow-up. Firstly, the Buss-Durkee Hostility Inventory-Dutch (BDHI-D; Lange, Pahlich, Sarucco, Smits, Dehghani, & Hanewald, 1995) will be used to measure two factors of aggression: overt of direct aggression (20 items) and covert or indirect aggression (20 items) rated on a *true*- *not true* dichotomous scale (Lange, Hoogendoorn, & Wiederspahn, 1995). The combination of verbal and physical aggression represents direct aggression, whereas hostility and anger are the core concepts of indirect aggression. Secondly, the State-Trait Anger Expression Inventory-2 (STAXI-2; Hovens, Lievaart & Rodenurg, 2014) is used to measure the experience, expression, and control of anger. The STAXI-2 is a reliable and valid 57-item measure with scales developed to assess anger as situational anger (state anger scale), a dispositional characteristic (trait anger scale), and the expression of anger (anger expression scale) (Spielberger, 1999; Spielberger & Sydeman, 1994). Thirdly, the Barratt Impulsiveness Scale (BIS-11; Patton, Stanford & Barratt, 1995) is a gold-standard 30-item measure that has been influential in shaping current theories of impulse control, and has played a key role in studies of impulsivity and its biological, psychological, and behavioral correlates (Reise, Moore, Sabb, Brown, & London, 2013). The BIS-11 has three subscales, namely: attentional impulsiveness, motor impulsiveness and non-planning impulsiveness. Participants in the VRAPT condition (intervention group) will be compared with the participants on the waitlist (control group). Fourthly, the Dutch version of the Aggression Questionnaire (AVL; Meesters, Muris, Bosma, Schouten, & Beuving, 1996) is used. This questionnaire is based on the fact that the personality trait of aggression consists of four subtraits. Namely, physical aggression, verbal aggression, anger and hostility (Buss & Perry, 1992). Fifthly, the Novaco Anger Scale and Provocation Inventory (NAS-PI; Novaco, 1994) is a two-part test of 73 items designed to assess anger as a problem of psychological functioning and physical health and to assess therapeutic change (Novaco, 1994). Lastly, to see whether there is re-victimization involved, the Child Trauma Questionnaire-Short Form (CTQ-SF; Bernstein & Fink, 1998) is used to measure childhood neglect and abuse, which are predictive factors for victimization and being a perpetrator in adulthood because of disturbed (cognitive) emotion regulation (Kamperman, Henrichs, Bogaerts, Lesaffre, Wierdsma, Ghauharali et al., 2014).

The study consists of three phases.
Phase 1: VRAPT treatment protocol and software will be developed (current - August 2016)
Phase 2: VRAPT will be tested in a pilot (September 2016 - December 2016)
Phase 3: the effectiveness of VRAPT is investigated in a cluster randomized controlled trial (RCT; February 2017 - August 2018)

Study design

Phase 1 development of VRAPT protocol
Software for VRAPT will be developed by TU Delft (TUD) and CleVR. CleVR is a company specialized in VR applications for psychiatric disorders. TUD will develop markers of fear and anger related aspects of behavior on the basis of the available sensors (GSR, ECG, EMG, Kinect). The scientific and engineering challenge here is to observe and identify behavior of the patient as fearful or aggressive as well as identify by which means (posture, body movements, voice, gestures) this behavior is displayed. Based on this information, the VRAPT system and therapist have to determine the appropriate responses of the avatar that the patient is exposed to (responsibility of UMCG and TiU). Virtual environments used in our other, ongoing projects (Veling et al., 2014) will be used as a basis for VRAPT. In the developmental phase, a panel of forensic psychiatric patients and therapists will be asked to comment on concepts, content, interface and user friendliness of possible solutions. The protocol will be made in an iterative process. A pilot study with 3-5 patients will be conducted when the VRAPT protocol is ready. Changes will be made to the protocol based on experiences in the pilot study.

Phase 2 Pilot
To test the feasibility of VRAPT a pilot study will be conducted in the three participating centers, namely: FPC van Mesdag, FPC de Kijvelanden and FPC Pompestichting. In each clinic 4 patients and 5 therapists will participate. This means in total 12 patients 15 and therapists will be involved in the pilot.

Phase 3 Effect evaluation
The effect study will be a single blind randomized controlled trial with two conditions: VRAPT (intervention-condition) and waiting list (control-condition). The intervention and control conditions are compared 3 months before treatment, at the start of treatment, during treatment and 3 months after the end of treatment. The waiting list condition will receive VRAPT treatment after 3 months.

Intervention

VRAPT has a maximum of 16 training sessions of 60 minutes. The therapists receive 16 hours of training in the protocol; all sessions are recorded. Topics in VRAPT are based on evidence-based elements of existing aggression regulation trainings, such as emotional self-management, interpersonal skills and social problem solving (McGuire, 2008). All sessions lead to and center around Virtual Reality exposure. The procedure in the VRAPT sessions will follow a gradual exposure paradigm, starting with exposure exercises for social situations with the lowest risk for victimization, followed by situations where aggression is increased. Exercises include both situations with aggressive other persons and

situations provoking aggression in patients. The exposure exercises will take place during the therapy sessions, using the Virtual Reality system.

Study burden and risks

Forensic psychiatric inpatients will be tested at 3 times, this will take approximately 1 hour. The other tests will be administered during appointed sessions. The patients will have a maximum of 16 sessions, with a maximum duration of 60 minutes each, during a 8-week timeframe. We expect patients to benefit from training. We expect training to decrease both victimization and aggression. It is possible some patients may experience simulator sickness symptoms during VRAPT. No major adverse events are expected or have been documented.

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

- Forensic Psychiatric inpatient in a Forensic Psychiatric Centers (FPC's), Clinics (FPK's) or Sections (FPA*s);
- Forensic Psychiatric inpatients are screened with the Reactive-Proactive aggression Questionnaire (RPQ; Raine et al., 2006) and/or referred to aggression training by their treatment supervisors;
- Age 18 * 65.

Exclusion criteria

- IQ under 70
- Insufficient command of the Dutch language
- Epilepsy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-10-2016
Enrollment:	128
Type:	Actual

Ethics review

Approved WMO

Date:	14-06-2016

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-09-2017
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	NL52939.042.15