Reducing aggression of forensic inpatients with Virtual Reality Aggression Prevention Training - Intellectual Disability (VRAPT-ID)

Published: 31-08-2022
Last updated: 06-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON51394

Source
ToetsingOnline

Brief title
Reducing aggression of forensic inpatients with VRAPT-ID

Condition

- Personality disorders and disturbances in behaviour

Synonym
Aggression regulation disorder - Aggression

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Aggression, Forensic, Intellectual Disability, Virtual Reality

Outcome measures

Primary outcome

The primary outcome measure is aggression, consisting of staff-report and objective data (number of aggression incidents and measures because of aggression). Staff is asked to score the Social Dysfunction and Aggression Scale (SDAS; Wistedt et al., 1990) on a weekly basis for each patient. This scale measures observed aggressive behaviour on the ward. Besides, staff scores a patient twice a day green, orange or red according to Early Recognition Method (Fluttert et al., 2010).

Secondary outcome

Secondary outcome: participant's individual changes in stress and self-regulation over time and therapy compliance. Stress is measured in phase B before, during and after each VRAPT-ID session in two ways. The first is by using self-report to rate stress on an Outcome Rating Scale (ORS; Miller et al., 2003), which is also part of the VRAPT-ID protocol. Second, stress will be measured using the Empatica 4 (Schuurmans et al., 2020), a wristband that measures different biomarkers. This study will use heart rate (HR) and electrodermal activity (EDA) to measure stress. Self-regulation will be measured with a specific VR session which is a part of Social Worlds 4.0 called 'VR catwalk'. During this VR session the patient is confronted with several social situations. Therapy compliance is measured by the number of drop-outs

and by means of the Session Rating Scale (SRS) after each session and a

qualitative questionnaire at the end of the training at during the follow-up.

Study description

Background summary

Patients with (mild) intellectual disability (MID) are overrepresented in forensic settings compared to the general population. This can be explained by the fact that people with MID have more risk factors for risk behaviour and psychiatric disorders than people without MID. Criminal risk factors include e.g., increased impulsivity, limited coping skills, and problems with metallization. Patients with MID have difficulties processing verbal information and generalizing, making patients with MID in forensic psychiatric centres less responsive for current treatments reducing aggression. Current psychotherapies for reducing aggression in forensic patients with MID are usually ineffective because it is not adapted to their limited cognitive skills, specific needs, learning style, and IQ. Besides, patients in an FPC often resist therapy and are less motivated because of the forced TBS order, which makes them less responsive for therapy with greater risk of drop-out and no-show.

Study objective

The main objective of this study is to examine whether Virtual Reality Aggression Training - Intellectual Disability (VRAPT-ID) is effective in reducing ag gressive behavior over time among inpatient forensic psychiatric patients, specifically those with MID. The second objective is to examine whether VRAPT-ID improves therapy compliance in forensic psychiatric patients in comparison to other therapies.

Study design

This is a protocol study to examine both the effect of the intervention ands therapy compliance. It is a single case experimental design (SCED), specifically a multiple baseline design (MBD). It is a non-concurrent multiple baseline design across patients, in which 12 patients will be randomly assigned to five different baseline lengths. There are three phases: baseline phase (A) - experimental phase (B) - follow up phase

Intervention

All patients in this study will receive aggression training using Virtual

Reality Aggression Prevention Training - Intellectual Disability (VRAPT-ID). Treatment duration is 12 weeks with a bi-weekly VRAPT-ID session and patients will be followed-up at four weeks and at 12 weeks after finishing the intervention.

Study burden and risks

Patients are asked to participate in the 'VR catwalk' intervention at the beginning of their training and during the follow-up at four and 12 weeks after finishing the training. Besides, patients are asked to wear the Empatica 4 wristband during the VRAPT-ID sessions to measure the biomarkers (skin sympathetic nerve activity and heart rhythm). Participants receive bi-weekly VRAPT-ID which consists of 24 sessions in total, with a maximum session duration of 60 minutes over a period of twelve weeks. VRAPT-ID treatment is not yet part of the treatment of aggressive behaviour in an FPC. This treatment will be indicated in addition to the regular treatment program. The main goal of VRAPT-ID is to enable patients to deal with (upcoming) escalating (social) situations more effectively. We expect patients to benefit from the training. VRAPT-ID provides patients with tools that are intended to improve their self-regulation in escalating situations. We expect VRAPT-ID to reduce aggressive behaviour and stress in patients and to improve their self-regulation. In this way, the main goal of admission to a high security forensic psychiatric centre can be met, which is to reduce future recidivism in violent behaviour. Besides, we expect that VR treatment improves therapy compliance. Low treatment motivation and treatment dropout is common in forensic settings (Dixon et al., 2016; Brunner et al., 2019). In a recent research with VR treatment in forensic inpatients, patients reported enjoying working with VR and looking forward to undergo more treatment with VR (Klein Tuente, 2020). Besides, VR can be seen as a form of *''gamification'*' which is a growing phenomenon in education to enhance motivation in learning (Caponetto et al., 2014). Therefore we expect VR to reduce the number of drop-outs and no-shows. VR is a safe and controlled way to expose forensic inpatients to social stimuli (Klein Tuente, 2020). There is a small chance that patients will experience transient *cyber sickness* (such as sweating and dizziness) during the VR training, but no major side effects of VR are known (La Viola, 2000) nor have been documented in previous studies. Therefore, no major adverse events of VRAPT-ID are expected.

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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 inpatients residing at FPC *De Kijvelanden* under entrustment act;
- age 18 and above;
- IQ between 50 and 85;
- diagnosed with Mild Intellectual Disability (MID) according to code 317 of the DSM-5;
- convicted to TBS for a violent crime;
- referred to aggression training by their head of treatment.

Exclusion criteria

- suffering form an active psychotic episode;
- following aggression regulation therapy (*Grip op Agressie*/ Schema Focused Therapy) at the same time.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-10-2022
Enrollment:	12
Type:	Anticipated

Ethics review

Approved WMO

Date:	31-08-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL81300.028.22