Virtual Reality aggression prevention training for people with mild intellectual disabilities (VRAPT-ID)

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Primary Objective: The objectives of this study are to adapt the VRAPT protocol and manuals for people with MBID, and to test the feasibility of VRAPT-ID in a sample of people with MBID and aggressive behavior. Feasibility will be assessed by...

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

Summary

ID

NL-OMON48327

Source
ToetsingOnline

Brief title
VRAPT-ID

Condition

- Other condition
- Psychiatric and behavioural symptoms NEC

Synonym
aggression; mild intellectual disabilities to borderline intellectual functioning (MBID)

Health condition

verstandelijke beperking

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Stichting tot Steun VCVGZ

Intervention

Keyword: - Aggression, - Intellectual disabilities, - Virtual Reality

Outcome measures

Primary outcome

- Feasibility and utility: The Session Rating Scale (SRS; Duncan et al., 2003) will be used at the end of each session to assess how satisfied clients are about VRAPT-ID. The SRS consists of four items: (1) Relationship (i.e., I felt heard, understood, and respected); (2) Goals and Topics (i.e., we worked on and talked about what I wanted to work on and talk about); (3) Approach or Method (i.e., the therapist*s approach is a good fit for me); (4) Overall (i.e., overall, today*s session was right for me). In addition, after each VRAPT-ID session, participants are asked:

(1) *What was the most important part of this session for you personally?*,

(2) *How easy was this session to understand?*,

(3) *What do you think about the VR assessments?*.

Finally, participants will be asked to rate the session with a grade from 1 (very low) to 10 (high). After completion of all VRAPT-ID sessions and the post- intervention measurements, we will have a semi-structured interview with each participant and therapist individually. During this interview, participants are for example asked what they understood of VRAPT-ID, whether they think they benefited from it, if they liked it and what should be improved

or changed.

- Aggression: the Modified Overt Aggression Scale (MOAS; Kay, Wolkenfeld, & Murrill, 1988) will be used. The MOAS is a four-part behavior rating scale designed to measure four types of aggressive behavior: (1) verbal aggression; (2) physical aggression against objects; (3) physical aggression against self; and (4) physical aggression against others, as witnessed by staff members on a day-to-day basis. Furthermore, the MOAS is standardized in a sample of people with intellectual disabilities (Oliver, Crawford, Rao, Reece, & Tyrer, 2007). Clinicians will fill out the MOAS once a week starting four weeks before the start of the intervention, during the intervention, and four weeks after the last session of the intervention.
- Emotions: Participants are asked to complete the Outcome Rating Scale (ORS) weekly, starting four weeks before the intervention. Before the start of every VR-session and once a week after the last VR-session. In total 20 ORS will be gathered to receive an impression of the emotions (especially anger) of participants.

Secondary outcome

N.A.

Study description

Background summary

Recently, an innovative highly interactive Virtual Reality aggression prevention training (VRAPT) has been developed and studied in a multicenter randomized controlled trial in forensic psychiatric centers (FPCs) in the Netherlands (Klein Tuente, Bogaerts, Ijzendoorn, & Veling, 2018;

https://nos.nl/l/m/2209845). Inclusion of 128 clients is completed. Our first impression, based on evaluations with both therapists and participants, is that VRAPT helps clients to understand how aggression works, how they can control their aggression and de-escalate aggression of other people. Therapists and participants are enthusiastic, and although the analyses of the data are still ongoing, the participating FPCs already decided unanimously to continue working with VRAPT. This VR training is likely to be of added value for people with mild intellectual disabilities to borderline intellectual functioning (MBID). Many people with MBID have problems with processing social information, as a result of which they react inappropriate in social interactions (Nieuwenhuijzen, Vriens, Scheepmaker, Smit, & Porton, 2011). Also, they lack the social-emotional skills needed to handle challenging social situations. Because of this, they are often involved in conflicts and engage in aggressive behaviour. The existing aggression regulation therapies for people with MBID are not effective in many cases (VOBC, 2014), because it takes people with MBID relatively long to learn new behaviour, whereas repeated practising in real life is not always possible or safe. Also, they experience difficulties generalizing the skills they have learnt in therapy to their daily life (Kleinert, Browder, & Towles- reeves, 2005). Furthermore, therapies are often predominantly verbal, whereas people with MBID often experience difficulties processing verbal information (Iglesia, Buceta, & Campos, 2005).

VRAPT may offer a solution to these issues. The advantages of VR are: 1) the main focus of VR is on visual information processing and practising instead of verbal information processing; 2) the VR environment can be adjusted to the level of the participant; 3) VR offers a safe, controlled environment, which allows repeated and tailored practising All in all, it is expected that VRAPT overcomes the limitations of current aggression regulation therapies and provides a more suitable method to treat aggressive behaviour in people with ID. However, the limitation of VRAPT as it is currently used, is that the training is not adapted to the cognitive disabilities of people with MBID. First, VRAPT is based on the theoretical framework of the Social Information Processing (SIP) model and this model is intertwined and very prominently present in the VRAPT materials. Understanding and using this model demands a certain level of cognitive functioning, especially to integrate this model in daily life (i.e., transfer of training). Second, VRAPT is designed for forensic psychiatric inpatients, so clients residing in highly secured environments. Therefore, currently there are no homework assessments, and this makes it difficult to practice the new learned skills in everyday life. Third, the language used in the VRAPT manuals is often too complicated, also for people with mild to moderate ID, which makes people with MBID not able to use VRAPT whereas we think they could certainly benefit from this method. To overcome these limitations, we will adapt the current VRAPT protocol and manuals, and test those in a sample of people with MBID and aggressive behavior.

Study objective

Primary Objective: The objectives of this study are to adapt the VRAPT protocol and manuals for people with MBID, and to test the feasibility of VRAPT-ID in a sample of people with MBID and aggressive behavior. Feasibility will be assessed by measuring: user experiences, acceptability, utility and preliminary efficacy of VRAPT-ID.

Study design

Two focus group meetings will be organized to improve and finalize the adaptations of the protocol and manuals. These focus groups will consist of people with MBID, clinicians working with people with MBID, and researchers. After developing the VRAPT-ID protocol, 15 participants will be recruited. Baseline measures will be conducted by staff with an aggressive behavior observation scale (MOAS). After these four weeks of observation, 15 people with MBID and aggressive behaviour will receive the VRAPT-ID. Four weeks before the intervention starts, participants are asked about their emotions once a week with the ORS.
Before each VR-session participants are asked about their emotions with the ORS. After each session, participants are asked to complete the SRS by/together with their therapist.
During (weekly) and after the intervention (4 weeks), participants will be rated by staff with the aggressive behavior observation scale (MOAS).

Intervention

Current VRAPT intervention
VRAPT consists of 12-biweekly individual training sessions. In an interactive three-dimensional virtual environment, participants have the opportunity to practice new behavior with virtual characters and learning to cope with their own aggressive behavior in an adequate manner. In the last part of the VRAPT the different exercises will be integrated in more challenging interactive virtual role-plays. Different interactive provocative social scenarios were designed during an iterative process with software engineers, VR experts, clinicians, and researchers. The primary focus of these provocative social scenarios is teaching participants to cope with their reactive aggression in an adequate manner. During the VRAPT sessions, participants wear headphones and a head-mounted display while interacting with a virtual character that is controlled by the trainer. The trainer takes the role of the virtual character using a microphone with voice distortion for speech, and also manually controlling facial emotion expression and body movements of the virtual character. This highly dynamic interactive nature of the VR system means VRAPT can be tailored to the specific needs of the participants, and participants have the opportunity to practice with their own learning goals and difficulties. At all times the trainer is in control of the virtual environment and is able to immediately change and/or stop the virtual environment if necessary.

Study burden and risks

Benefits and risks assessment, group relatedness

The participating clients are expected to benefit from the given therapy. Worsening of the symptoms is not expected to happen. Currently, our VR mental health lab has performed several studies using VR as therapeutic tool, and based on our experience(s) no risks are expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- residing and/or in therapy at one of the participating health care institutions for people with MBID (and other psychiatric diagnoses);
- referred to aggression training by their therapist, or primary caretaker;
- a sufficient command and understanding of the Dutch language;
- an IQ between 50-85;
- age 16 * 65;

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- A (history of) epilepsy;
- A substance use disorder.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2020
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	19-12-2019

Application type:	First submission
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	NL71646.042.19

Study results

Date completed:	01-07-2021
Actual enrolment:	9