Regular Re-ART versus Virtual Reality Re-ART: an RCT study

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

Summary

ID

NL-OMON49931

Source
ToetsingOnline

Brief title
Treatment of aggression regulation problems with VR

Condition

- Other condition
- Impulse control disorders NEC

Synonym
Aggression and impulsivity

Health condition

Agressieregulatieproblematiek

Research involving
Human

Sponsors and support

Primary sponsor: De Waag
Source(s) of monetary or material Support: Financiering is vanuit de Forensische Zorgspecialisten / de Waag

Intervention

Keyword: Aggression, Forensic outpatients, Re-ART, VR

Outcome measures

Primary outcome

The primary outcome measure on which the two conditions are compared is the

degree of aggression regulation.

Secondary outcome

A secondary outcome measure on which the two conditions are compared is

Cognitive Biases.

The variables Patient motivation and Therapist motivation, which are expected

to have a moderating effect, are also included in the study.

Study description

Background summary

Delinquent aggressive behavior is a common problem, with significant consequences for society, victims and perpetrators. Several studies provide evidence of the effect of various aggression regulation treatments on aggressive behavior and overall recidivism, as well as on factors that are believed to influence recidivism risk. An example of a treatment method is Responsive Aggression Regulation Therapy (Re-ART).
Studies show that role-playing is a working element in aggression regulation therapy, and VR role-playing is more effective than analog role-playing.
Virtual Reality (VR) offers the opportunity to train skills in a realistic context, and to make the patient aware of tension and emotions. This is done in a safe, controlled environment.
Research on the use of VR in the treatment of mental disorders has shown that

VR interventions are effective across a variety of disorders, syndromes, and behaviors and may be a promising addition to existing treatments.
Little research has been done on the effectiveness of VR in the forensic setting. Although VR is seen as a promising supporting e-health treatment application, research will need to show to what extent, and in what way, VR can add value to treatments in forensic mental health care.
We investigate whether adding VR to three modules of the Re-ART treatment leads to a greater improvement in degree of aggression regulation compared to the three modules of the Re-ART treatment without VR.

Study objective

Our study at 'de Waag' (an outpatient forensic mental health institution) would provide a first impression of the added value of adding VR to the treatment of aggression regulation problems.
Results from the study are also useful for forensic treatment in general, as the outcome measures (degree of aggression regulation, cognitive biases, patient motivation and therapist motivation) are also (partly) applicable to other care programs, such as the treatment of Acquisition Offenses, Intimate Partner Violence and Sexual Offenses.
This study will primarily examine whether offering three modules of the Re-ART treatment with VR leads to a greater improvement in degree of aggression regulation compared to the three Re-ART modules without VR.
An improvement in cognitive biases is also examined, this is included as a secondary outcome measure. Since it is expected that patients treated with VR have greater treatment motivation and working with VR can also increase treatment motivation among therapists, it is examined whether these two variables have a moderating effect.

Study design

A Randomised Controlled Trial (RCT) will be performed at two outpatient clinics at *de Waag*. Adult male patients who are indicated for the treatment Re-ART outpatient for adults on the basis of the indication criteria in the Theoretical Manual are asked to participate. When patient consents to participate in the study, written informed consent is obtained. The researcher randomly assigns participants to condition (Treatment as Usual or Treatment as Usual with VR).
The number of sessions required to complete a module according to the guidelines varies. The estimated number of sessions for research purposes (the three modules combined) is 15 to 20. This equates to a treatment duration of approximately 3 to 6 months.
Prior to the study, patient complete the intake and risk assessment phase, as well as follows a part of the Re-ART treatment, plus other interventions if indicated. After completion of the study intervention period, all participants will continue with the treatment according to the treatment plan, or will stop

treatment if the treatment goals are achieved.
The primary outcome measure degree of aggression regulation is measured with the Aggression, Anger and Impulsivity subscales of the Forensic Symptoms Inventory - Revised (FSI-R). The secondary outcome measure cognitive biases is measured with the Brief Irrational Thoughts Inventory (BITI), patient motivation is measured with the Treatment Motivational Scales for forensic outpatient treatment (TMS-F) and the motivation of therapists will be measured with the Motivation Therapist Questionnaire (a (short) questionnaire drafted for this study).
Participants will fill out the FSI-R, BITI and TMS-F prior to the start and after the study intervention period.

Intervention

In the Treatment as usual condition (TAU), the regular Re-ART treatment is offered to patients. For the study, this concerns the modules Controlling skills, Infuence of Thinking and Handling Conflicts. Prior to the study, patients have already followed one or more modules of the Re-ART treatment. After the study intervention period, clients will follow further modules, if indicated.
In the experimental condition (EXP), various experiential exercises and role plays from the modules Controlling skills, Infuence of Thinking and Handling Conflicts are offered with Virtual Reality. The treatment otherwise remain the same.

Study burden and risks

Since the treatment in this study is (almost) identical to the regular treatment there will be hardly any additional burden for study participants. Patients in both conditions will fill out a number of questionnaires at the beginning and after the study (estimated time 40 minutes). Some of the questionnaires are part of the regular treatment as part of Routine Outcome Monitoring (ROM).
Patients may experience symptoms of cyber sickness (nausea, dizziness, sweating) during a VR session.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

-Age of 18 years or older;
-Male;
-The patient is indicated for the treatment Re-ART Outpatient for adults.

Exclusion criteria

-Being offered a combined treatment (e.g., other Re-ART modules, EMDR, treatment of substance abuse) is an exclusion criterion.
-Medication treatment can take place during the study, if the patient was already on medication before the start of the study. If a medication change occurs during the study, patient will be excluded from the study.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-01-2022
Enrollment:	34
Type:	Actual

Medical products/devices used

Generic name:	Social Worlds VR-CBT
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-11-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL78265.018.21