ISRCTN55538093 https://doi.org/10.1186/ISRCTN55538093

Treatment of aggression with Virtual Reality

Submission date	Recruitment status	[ ] Prospectively registered
03/06/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/11/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/12/2021	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The evidence base for forensic psychiatric care is severely lacking, and there are no available treatment methods that have been established as effective in Swedish forensic psychiatry. Lately, new treatment methods using Virtual Reality (VR) have been developed for various mental disorders. Using Virtual Reality as a tool in the treatment could provide possibilities for forensic psychiatry to assist patients with skills training in contexts that are relevant to the "regular" life, and not just life as an inpatient in forensic psychiatry.

In this study, a newly developed method for VR-assisted treatment of aggression (the VRAPT), specifically designed for forensic psychiatry, will be translated (from Dutch) to Swedish and tested in a small study on forensic psychiatric inpatients to see how effective it is in treating aggression.

Who can participate?
Adult inpatients sentenced to forensic psychiatric care for treatment at a maximum security forensic psychiatric hospital in Sweden with a history of aggression and/or current problems with aggression.

What does the study involve?
During participation, participants will undergo the 16-session individual VRAPT treatment delivered by specially trained VR therapists. Data is collected on a total of 4 occasions: 1) 12 weeks before the start of treatment, 2) at the start of treatment, 3) at end of treatment and 4) 12 weeks after the end of treatment. Data will be collected on 1) current and past aggression, violence, and criminality, 2) sociodemographic data and psychosocial background, 3) mental health history and current status including emotion regulation, 4) sense of presence in the virtual environment, and 5) patients' and therapists' experiences of the VRAPT.

What are the possible benefits and risks of participating?
The participation in the study is in no way related to the treatment of the patients, why no direct benefits related to their forensic psychiatric treatment are available. All participating patients will receive a minor reimbursement (of approximately 12 euro) after completed participation.

Possible risks are handled through only including patients who have been assessed as capable of providing informed consent. All participation is conducted under strict, clinical safety routines with observation and support available for all participants.

Where is the study run from?
Regional Forensic Psychiatric Clinic (Sweden)

When is the study starting and how long is it expected to run for?
From February 2019 to December 2020

Who is funding the study?
Southern Healthcare Region, Region Kronoberg, and The Research Council for Health, Work Life and Welfare (Sweden)

Who is the main contact?
Märta Wallinius, marta.wallinius@kronoberg.se

Study website
https://celam.gu.se/forevidence/for-vr/?languageId=100001&disableRedirect=true&returnUrl=http%3A%2F%2Fcelam.gu.se%2Fsvenska%2Fforevidence%2Ffor-vr%2F

Contact information

Type(s)
Scientific

Contact name
Miss Märta Wallinius

ORCID ID
http://orcid.org/0000-0003-0530-9560

Contact details
Johan Allgulins väg 1
Växjö
Sweden
352 57
+46 470 589933
marta.wallinius@kronoberg.se

Type(s)
Scientific

Contact name
Mr Fernando Gonzalez Moraga

Contact details
Johan Allgulins väg 1
Växjö
Sweden

352 57
+46 470 58 95 65
fernando.gonzalezmoraga@kronoberg.se

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
FOR-VR001

Study information

Scientific Title
Virtual Reality Aggression Prevention in Forensic Psychiatric Patients in Sweden - a pilot study

Acronym
VRAPT-SF

Study objectives
This pilot study aims to test the feasibility and applicability of Virtual Reality Aggression Prevention Training (VRAPT) in a sample of Swedish forensic psychiatric inpatients, with the following, primary aim:
1. To investigate the effect of VRAPT on the occurrence and severity of aggressive behaviours in forensic psychiatric patients.

Secondary research questions are:
1. How does VRAPT affect emotion regulation in forensic psychiatric patients?
2. Which important confounders (e.g., sense of presence in the virtual environment, psychosocial background and mental health characteristics including personality of the patients, presence of other externalizing behaviours including substance use) need to be considered in evaluation of treatment effect of VRAPT?
3. How is VRAPT experienced by participating patients and staff?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/05/2019, the Swedish Ethical Review Authority (Etikprövningsmyndigheten Box 2110, 750 02 Uppsala, Sweden; registrator@etikprovning.se; + 46 (0)10 475 08 00), ref: 2019-02337.

Study design
Single-center, observational, case-series pilot study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Forensic psychiatric inpatients with aggression regulation problems

Interventions
The Virtual Reality Aggression Prevention Training (VRAPT) consists of 16 individual treatment sessions, delivered by specially trained VRAPT therapists using the VRAPT treatment manual and workbooks together with Virtual Reality technology. Before, during, and after VRAPT treatment, participants are followed with staff observations, self-reports, and medical file reviews. After completed participation, individual interviews with patients and therapists on their experiences from the VRAPT will be performed.

Each session is delivered according to the VRAPT-manual, with the first 6 sessions being devoted to mapping aggression problems, formulating treatment goals, practicing emotion recognition, and practicing recognition and management of physical tension. During sessions 6-15, the treatment focuses on practicing de-escalation strategies and aggression management. The final session considers the treatment evaluation. The sessions are provided 1-2 times a week.

Intervention Type
Behavioural

Primary outcome measure
Occurrence and severity of aggressive behaviours demonstrated by forensic psychiatric patients, assessed through staff reports using The Social Dysfunction and Aggression Scale-9, self-reports (Aggression Questionnaire-Revised Swedish Version; State-Trait Anger eXpression Inventory-2), and collected from medical files. Staff reports and information from medical files will be collected continuously from baseline (12 weeks prior to treatment start), through the treatment, and 12 weeks after completed treatment. Self-reports will be conducted directly before treatment start, directly after completed treatment, and 12 weeks after completed treatment.

Secondary outcome measures
1. Self-reported emotion regulation (Difficulties in Emotion Regulation Scale) will be collected from patients directly before treatment start, directly after completed treatment, and 12 weeks after completed treatment

2. Treatment fidelity will be assessed through the therapist's workbook, where the therapist assesses fidelity for each session directly after the session, which will be collected continuously during treatment in the VRAPT treatment protocol
3. Importance of confounders will be investigated through collecting information on psychosocial background including childhood adversities (self-report with Childhood Trauma Questionnaire- Short Form; medical files), mental health characteristics and history (medical files), and history of externalizing behaviours and callous aggression (Externalizing Spectrum Inventory-Brief Form; medical files) which will be collected directly before the treatment start
4. Sense of presence in the virtual environment will be assessed through self-report (I-group Presence Questionnaire) directly after completed treatment
5. Experiences from the VRAPT treatment will be assessed through interviews with therapists and participating patients conducted after completed participation

Overall study start date
01/02/2019

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Sentenced to forensic psychiatric care and are being treated as inpatients at a maximum security forensic psychiatric hospital in Sweden
2. History of aggression and/or current problems with reactive aggression

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
15

Key exclusion criteria
1. Inability to understand the meaning of participating in the study, and insufficient psychiatric status to provide informed consent
2. Insufficient skills in the Swedish language that impede active participation in all parts of the study
3. Epilepsy
4. Intellectual disabilities (IQ <70)
5. Autism spectrum disorder with severely impaired functioning
6. Acute psychotic state
7. Current and serious security risks that prevent safe participation

Date of first enrolment

18/11/2019

Date of final enrolment
31/08/2020

Locations

Countries of recruitment
Sweden

Study participating centre
Regional Forensic Psychiatric Clinic
Johan Allgulins väg 1
Växjö
Sweden
352 57

Sponsor information

Organisation
Regional Forensic Psychiatric Clinic

Sponsor details
Johan Allgulins väg 1
Växjö
Sweden
352 57
+46 470586220
ps-regpsyk@kronoberg.se

Sponsor type
Hospital/treatment centre

Website
http://www.regionkronoberg.se/halsa-vard-tandvard/rattspsykiatri/

Funder(s)

Funder type
Government

Funder Name

Forskningsrådet om Hälsa, Arbetsliv och Välfärd

Alternative Name(s)
Swedish Research Council for Health, Working Life and Welfare, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Region Kronoberg, Sweden

Funder Name
Southern Healthcare Region, Sweden

Results and Publications

Publication and dissemination plan
Results at the group level will be made public in international, scientific journals, through debate articles in trade journals or established media, and presented to user organizations, family associations, patients in forensic psychiatric care, and adjacent health organizations and authorities through an established dissemination plan at the responsible research department. Preliminary results are expected to be presented early 2021, with scientific publications during 2021-2022.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from principal investigator, Märta Wallinius, marta.wallinius@med.lu.se. Data will be available after data preparation have been finished, and only available for group level analyses, in accordance with ethical approval. All data will be anonymized, and data that may risk identification will be deleted before sharing.

IPD sharing plan summary
Not expected to be made available