Treatment of aggression in Swedish prisoners with the support of virtual reality

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | | |
|-------------------|--|--|--|--|--|
| 01/11/2022 | | [X] Protocol | | | |
| Registration date | Overall study status Completed | [X] Statistical analysis plan | | | |
| 15/12/2022 | | [X] Results | | | |
| Last Edited | Condition category | Individual participant data | | | |
| 06/12/2023 | Mental and Behavioural Disorders | | | | |

Plain English summary of protocol

Background and study aims

Individuals who are cared for and incarcerated in forensic institutions are a group with a variety of problems in addition to crime, such as substance abuse in combination with various psychological and psychiatric difficulties. For instance, it is common that violent offenders lack social problem-solving skills and the ability to regulate negative feelings and impulsivity. These problems are associated with aggressive behavior. Even though treatment programs for offenders are effective in decreasing recidivism (reoffending) in crime, the results are often modest at best. In addition, complex needs in the target group place high demands on individually adapted treatment. Key features of effective treatment for violent offenders are behavioral and skills training through role-plays based on social problem-solving. In other words, treatment needs to address concrete and specific situations that have a risk for violent crime and seek to find sounder and non-destructive solutions to these situations. A recurring challenge in interventions provided within prisons is the difficulty to create individually tailored practice situations, for both practical and safety reasons. The prison context is for obvious reasons different from other contexts that humans find themselves in. Learning to generalize skills from treatment in prisons into everyday life outside the walls is hampered within forensic institutions, probably affecting the offenders' rehabilitation back to society. There is an urgent need for the development of clinical practice in forensic settings where, for example, new technology in the form of virtual reality (VR) can provide opportunities to respond to this need. The study is a part of a doctoral thesis where the overarching aim is to increase the knowledge of VR as a method in the development and quality of interventions that aim at reducing the risk of recidivism in criminal behavior for offenders in forensic settings.

Who can participate?

Prisoners sentenced for a violent crime in need of treatment for aggression

What does the study involve?

The study involves the program Virtual Reality Aggression Prevention Training (VRAPT) and all participants will take part in VRAPT. VRAPT is a treatment program targeting aggression through skills training in emotion recognition, aggression management and social problemsolving. Participants are followed from the start of treatment to follow up at 3 months after treatment has ended. The measurements used in the study are self-assessments of aggression,

emotion regulation difficulties and anger, as well as factors that might impact treatment outcome, childhood trauma, pro-criminal attitudes, externalizing behavior and mental health problems.

What are the possible benefits and risks of participating?

The benefits of participating are a reduction in expressed aggression, as well as an increase in emotion regulation and balance in anger and other negative emotions. This impact could then reduce the risk of relapse in crime, and this is measured in this study. There is a risk of experiencing nausea or dizziness, called cybersickness. This is not harmful but can be uncomfortable and distressing. The VR exposure can be ended at any time if needed and participants can always choose to end their participation in the study at any time, should this be too distressing. There is a risk that the treatment (VRAPT) is not helpful and therefore in theory hinders other potentially effective treatments to be given to the participant. This is a risk that is hard to get rid off when trying out new forms of treatment in order to develop an effective treatment.

Where is the study run from?

The study is run by the Swedish Prison and Probation Services (SPPS) in collaboration with Lund University and the regional forensic mental health clinic in Växjö in Kronoberg region. Participants are recruited from the SPPS prisons in the cities Borås and Kumla (Sweden).

When is the study starting and how long is it expected to run for? September 2019 to April 2022

Who is funding the study?

- 1. Swedish Prison and Probation Services (Sweden)
- 2. Region Kronoberg (Sweden)

Who is the main contact? David Ivarsson, david.ivarsson@med.lu.se, david.ivarsson@kriminalvarden.se

Contact information

Type(s)

Public

Contact name

Mr David Ivarsson

ORCID ID

https://orcid.org/0000-0002-4004-939X

Contact details

Slottsgatan 78 Norrköping Sweden 60180 +46 (0)705833700 david.ivarsson@med.lu.se

Type(s)

Principal investigator

Contact name

Dr Märta Wallinius

ORCID ID

https://orcid.org/0000-0003-0530-9560

Contact details

Rättspsykiatriska regionkliniken Johan Allgulins väg 1 Växjö Sweden 35257 +46 (0)470 589933 marta.wallinus@med.lu.se

Type(s)

Scientific

Contact name

Mr David Ivarsson

ORCID ID

https://orcid.org/0000-0002-4004-939X

Contact details

Slottsgatan 78 Norrköping Sweden 60180 +46 (0)705833700 david.ivarsson@med.lu.se

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Pinpointing change in virtual reality assisted treatment for violent offenders: a pilot study of Virtual Reality Aggression Prevention Training (VRAPT)

Study objectives

Virtual Reality Aggression Prevention Training (VRAPT) will increase emotion regulation abilities and strategies and decrease aggression in imprisoned, violent offenders.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/01/2020, Swedish Ethical Review Authority (Box 2110, 750 02 Uppsala, Sweden; +46 (0)010-475 08 00; registrator@etikprovning.se), ref: 2019-02337

Study design

Interventional pilot study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Treatment of aggression in violent offenders

Interventions

The study will describe and evaluate the treatment program VRAPT in an interventional pilot study within the Swedish prison and probation service (SPPS) - prison setting - targeting violent offenders (n \sim 15). The design is a multicenter within-group case series design where the impact of VRAPT is measured through pre- (T1), post- (T2), and follow-up (T3). Measures focus on relevant criminogenic needs such as emotion dysregulation, aggression and, hostility affecting aggressive behaviors and potential confounders. The study will provide information on the impact of VR-assisted aggression training within a prison context, as one of the first studies on the subject ever. Data will be analyzed with descriptive statistical analysis, using measures of frequency, central tendency, and dispersion of variation, effect sizes and graphical illustrations of change.

The participants will undergo the manualized VRAPT treatment, where documentation of all interventions is made in a treatment protocol. The treatment includes 16 treatment sessions and is given by specially trained program facilitators at relevant institutions who have access to methodological support from a designated VRAPT supervisor. The VRAPT program constitutes of modules targeting getting to know virtual reality (VR), emotion recognition and differentiation, aggression management skills training and social problem-solving and skills training.

Intervention Type

Behavioural

Primary outcome(s)

- 1. Aggression is measured using Aggression Questionnaire-Revised Swedish Version (AQ-R): self-assessment of aggression and hostile behavior, at pre-, (T1), post-, (T2) and follow-up (T3)
- 2. Emotion dysregulation is measured using the Difficulties in Emotion Regulation Scale (DERS):

self-assessment of emotion recognition and emotion regulation strategies, at pre-, (T1), post-, (T2) and follow-up (T3)

3. Anger is measured using State-Trait Anger Expression Inventory-2-S (STAXI-2S): self-assessment of aggression, both current and in habitual state, at pre-, (T1), post-, (T2) and follow-up (T3)

T1: Before start of VRAPT; T2:Directly after VRAPT; T3: 3 months follow up

Key secondary outcome(s))

Secondary measures are targeting potential confounders on the primary outcome and use both file data from SPPS file registers and self-assessment data:

- 1. Mental illness and psychiatric disorders measured using Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) at (T1)
- 2. Lifelong externalizing behaviors measured using the Externalizing Spectrum Inventory-Brief Form (ESI-BF) at (T1)
- 3. Procriminal attitudes measured using Measures of Criminal Attitudes and Associates (MCAA) at (T1)
- 4. Childhood trauma measured using the Childhood Trauma Questionnaire-Short Form (CTQ-SF) at (T1)

Other secondary measures are:

5. Participant experiences of virtual reality measured using the I-group presence questionnaire (IPQ) at (T2). Note that the version used in the current study is revised specifically based on the needs of the current study and so as not to burden the clients with unnecessary questions.

T1: Before start of VRAPT; T2:Directly after VRAPT; T3: 3 months follow up

Completion date

19/04/2022

Eligibility

Key inclusion criteria

Offenders who are:

- 1. Sentenced to prison at the sites for the study
- 2. Have been assessed with an increased risk of recidivism in violent crimes (medium to high risk)
- 3. Indications of a need for treatment of aggression problems (identified through screening for study inclusion)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Total final enrolment

14

Key exclusion criteria

- 1. Inability to understand and provide informed consent
- 2. Major deficits in understanding the Swedish language preventing active participation
- 3. Epilepsy
- 4. Indications of acute psychotic state
- 5. Intellectual disabilities (IQ <70)
- 6. Suicide risk
- 7. Current and serious security risks that prevent participation in a safe way
- 8. Less than 10 weeks remaining time at the prison

The criteria are set for the study to be conducted in a safe way for offenders, staff, and researchers. For those offenders who are excluded from participation, the violence prevention interventions offered in their regular care will continue as usual.

Date of first enrolment

01/03/2020

Date of final enrolment

01/01/2022

Locations

Countries of recruitment

Sweden

Study participating centre Borås prison

Brinellgatan 13 Borås Sweden 504 62

Study participating centre Kumla prison

Viagatan 4 Kumla Sweden 692 35

Sponsor information

Organisation

Swedish Prison and Probation Services

Organisation

Region Kronoberg

Funder(s)

Funder type

Government

Funder Name

Swedish Prison and Probations Service

Funder Name

Region Kronoberg

Alternative Name(s)

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from David Ivarsson (david.ivarsson@kriminalvarden.se).

The type of data that will be shared: Group data

When the data will become available: Available upon request after publication of results

For how long: at least 10 years after publication

By what access criteria data will be shared including with whom: To other researchers

For what types of analyses: Group-level analysis

By what mechanism: Not specified

Whether consent from participants was obtained: Informed consent was obtained

Comments on data anonymization: All data is fully anonymized.

Any ethical or legal restrictions: No Any other comments: No

IPD sharing plan summary Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient- facing? |
|-------------------------------|---|-----------------|----------------|-------------------|---------------------|
| Results article | | 16/11/2023 | 05/12 /2023 | Yes | No |
| Basic results | | | 31/05 /2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11 /2025 | No | Yes |
| Protocol file | | | 31/05 /2023 | No | No |
| Protocol file | Self-assessment protocol T1 | | 31/05 /2023 | No | No |
| <u>Protocol file</u> | Self-assessment protocol T2 after treatment | | 31/05 /2023 | No | No |
| Protocol file | Self-assessment protocol T3 follow-up | | 31/05 /2023 | No | No |
| Statistical Analysis Plan | Data collection protocol files | | 31/05 /2023 | No | No |