# Virtual Reality Aggression Prevention Training (VRAPT) - Arousal Module: a Pilot Feasibility Study in Forensic Psychiatric Inpatients.

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Psychiatric and behavioural symptoms NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON57299

**Source**
ToetsingOnline

**Brief title**
VRAPT Arousal Pilot Study

### Condition

- Psychiatric and behavioural symptoms NEC

**Synonym**
Aggression Regulation disorder - Aggression

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit van Tilburg

**Source(s) of monetary or material Support:** Fivoor

## Intervention

**Keyword:** Aggression, Arousal, Forensic, Virtual Reality

## Outcome measures

### Primary outcome

The primary study parameter is the experience with the VRAPT-Arousal module. This study parameter is measured using both qualitative and quantitative measures. Qualitative data will be collected through semi-structured interviews, while the quantitative measure is composed of the Session Rating Scale (SRS; Duncan et al., 2003).

### Secondary outcome

The secondary study parameters entail biomarker data from the wearable that patients wear during sessions, combined with the data from the Anger Bodily Sensations Questionnaire (ABSQ; Zwets et al., 2014) and the Multidimensional Assessment of Interoceptive Awareness (MAIA; Mehling et al., 2018). This data will be used to investigate the validity of using the Nowatch wearable as a measurement device for arousal and its corresponding biomarkers (skin sympathetic nerve activity and heart rhythm).

# Study description

### Background summary

Aggression in forensic psychiatry is common. One of the ways in which the origins and expression of aggression and aggressive behavior are being described, is the General Aggression Model. One of the aspects that affect the response and therefore aggressive behavior is arousal. Arousal, as stated

above, refers to the body*s adaptive responses to environmental stimuli, altering physiological states to facilitate the recognition and regulation of emotions. Problems with emotion regulation or appraisal of arousal thus result in problematic responses, often aggressively. Reducing aggressive behavior necessitates a different appraisal of situations or social interactions. This current pilot study specifically focuses on arousal.

## Study objective

The primary objective of the VRAPT Arousal Pilot Study is to explore the feasibility, appropriateness and acceptability of the developed VRAPT Arousal intervention among forensic psychiatric inpatients and forensic healthcare practitioners working with forensic inpatients. For the purpose of reaching the primary objective, several research questions have been posed:
- Does the content of the VRAPT Arousal module align with its proposed goals?
- How satisfied are patients with the design of the module?
- What are the experiences with VRAPT Arousal of patients, trainers and social workers?

The secondary objective of the VRAPT Arousal Pilot Study is to explore the feasibility, appropriateness and acceptability of the use of a wearable during the VRAPT Arousal intervention among forensic psychiatric inpatients and forensic healthcare practitioners working with forensic inpatients. The wearable is used for two interrelated purposes: 1) to measure biomarkers during the sessions, which will aim to give a more objective measurement of arousal through heart rate variability and skin conductance, and 2) to provide real-time biofeedback to the patient during various therapeutic exercises of the VRAPT Arousal intervention.
For the purpose of reaching the secondary objective, several research questions have been posed:
- Does the Nowatch generate sufficiently valid data (skin conductance and heart rate variability) that provides insight into bodily arousal?
- To what extent does the arousal measured by the wearable align with the self-reported arousal of the patient?
- To what extent is an increase in arousal/biomarkers measured by the wearable during sessions?
- Does baseline arousal decrease over time throughout the sessions?
- To what extent is a patients* ability to recognize bodily sensations associated with their participation in the Arousal module, and how does biofeedback data correspond with self-reports?

## Study design

To get insight into the acceptability and feasibility of the arousal module, a mixed methods data collection will be carried out, in two phases. In the first phase, focus groups will be carried out to see to what extent the health care

professionals are able to perform the module adequately, whilst taking the intended goals of the intervention into account. In the second phase, a pilot intervention will be carried out with patients from FPC *de Kijvelanden*. We aim to include six to ten patients. These patients will receive the newest version of the VRAPT-Arousal module. After finishing the intervention, these patients will also be invited to a semi-structured interview to evaluate their experiences with the module.

### Intervention

This research has initiated the development of a new, modular version of VRAPT. Within the scope of the present study, the feasibility of the first module - VRAPT Arousal - is studied. All patients in this study will receive a training using Virtual Reality Aggression Prevention Training (VRAPT) Arousal module. Treatment duration is 10 weeks with a weekly VRAPT-Arousal session.

### Study burden and risks

Patients will complete two questionnaires before starting the intervention. During the training sessions, patients will wear the Nowatch wristband, which measures biomarkers (skin sympathetic nerve activity and heart rhythm). Participants receive weekly VRAPT-Arousal, which consists of 10 sessions in total, of approximately 45 minutes to 60 each over 10 weeks. The VRAPT-Arousal module treatment is not yet part of the standard treatment for aggressive behaviour in a Forensic Psychiatric Centers (FPC) and will be an addition to the regular treatment program. The main goal of VRAPT-Arousal module is to help patients recognize arousal and manage potentially (upcoming) escalating (social) situations more effectively. We expect patients to benefit from the training, as VRAPT-Arousal provides tools designed to improve their arousal regulation in high-stress and escalating situations. In combination with other VRAPT modules, we expect a reduction in aggressive behaviour. This approach alligns with the main goal of admission to a high security FPC to reduce future violent recidivism. VR is a safe and controlled way to expose forensic inpatients to social stimuli (Klein Tuente et al., 2020). There is a small chance that patients may experience temporary *cyber sickness* (such as sweating and dizziness) during the VR training. No severe 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.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- 18 years of age and older.
- Forensic psychiatric inpatient in FPC *De Kijvelanden'.
- The presence of aggression regulation problems.
- Convicted to TBS for a violent crime.
- Referred to aggression prevention training by their head of treatment.
- Understanding of Dutch language.

## Exclusion criteria

- Active use of narcotics.
- Experiencing an active psychotic episode.
- (history) of epilepsy

# Study design

## Design

**Study type:** Interventional

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

## Recruitment

NL

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| Recruitment status: | Pending |
| Start date (anticipated): | 01-02-2025 |
| Enrollment: | 10 |
| Type: | Anticipated |

# Ethics review

Approved WMO

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| Date: | 06-02-2025 |
| 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 | NL88100.028.24 |