

# Biofeedback in treatment of aggression

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<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON21893

### Bron

NTR

### Verkorte titel

BiToA

### Aandoening

This research project will be performed among forensic outpatients with a proven lack of anger management skills; caused by different psychiatric disorders according to DSM-V criteria.

### Ondersteuning

**Primaire sponsor:** Not applicable

**Overige ondersteuning:** Dutch Department of Safety and Justice

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

Psychophysiological awareness and aggression-related concepts during the ABA-design (baseline, intervention, and follow-up phase using Ecological Momentary Assessment) and at

T1 by use of the Agression Questionnaire (AQ) and Anger Bodily Sensations Questionnaire (ABSQ). Also, physiological measures (heart rate) are measured during the ABA-design (baseline, intervention and follow-up).

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

Aggressive behaviour is causing a wide range of problems for victims, offenders and the society. Given the current trend to prefer outpatient interventions over residential treatment, and the high treatment drop-out rates in forensic populations, further improvement of forensic outpatient treatment methods is needed. In this, biofeedback – informing psychiatric patients about their physiological state – is a promising intervention for clinical practice. Real-time biofeedback, provided in real-life, is expected to help patients to signal heightened arousal in response to emotional events in an early stage. By strengthening physiological awareness and supporting use of prevention skills, we suppose that biofeedback can aid to reduce aggressive behaviour. In the first part of our study, we examined the feasibility of the addition of real-time biofeedback (using a biosensor and a mobile application, named Sense-IT) to treatment as usual on reduction of aggressive behaviour among forensic outpatients. In the main study, the effectiveness of the biofeedback-intervention will be investigated using a Single Case Experimental Design (SCED). We will use a randomized, nonconcurrent, multiple baseline across participants design; in which efficacy is evaluated within and between participants, controlling for time and repeated assessment.

### **Doel van het onderzoek**

By strengthening physiological awareness and supporting use of prevention skills, we suppose that biofeedback can aid to reduce aggressive behaviour. More specific, we expect the participating patients to show more insight in physiological stress signals during the intervention phase compared to baseline- and follow-up.

### **Onderzoeksopzet**

December 2021

### **Onderzoeksproduct en/of interventie**

In our study, real-time biofeedback will be added to regular aggression regulation treatment for two weeks (during the intervention phase).

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Proven lack of anger management skills, indicated by either a recently committed violent crime and/or a high risk of committing one;
2. Assigned to individual outpatient Aggression Regulation Treatment after multidisciplinary consultation;
3. Basic understanding of mobile applications;
4. Aged 16 years or above.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Acute manic or psychotic symptoms according to the clinician and/or DSM-V criteria as measured with the (revised) Mini International Neuropsychiatric Interview (MINI), indicated by a score of 3 (or higher) on item 6 or addendum item 1 of the Health of the Nations Outcome Scales (HoNOS);
2. Current high risk of suicide requiring immediate intervention according to the clinician and/or DSM-V criteria as measured with the MINI, indicated by a score of 3 (or higher) on item 2 of the HoNOS;
3. Severe addiction problems, indicated by a score of 4 on the HoNOS, or severe conditions requiring immediate intervention or hospitalisation;

4. Insufficient understanding of the spoken and written Dutch language.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

### Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-11-2019
Aantal proefpersonen:	24
Type:	Verwachte startdatum

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

### Toelichting

Not applicable

## Ethische beoordeling

Positief advies	
Datum:	27-11-2019
Soort:	Eerste indiening

## Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

<b>Register</b>	<b>ID</b>
NTR-new	NL8206
Ander register	METC Amsterdam UMC (VUmc) : Protocol-nummer 2017.574, NL63911.029.17

## Resultaten

### Samenvatting resultaten

Not applicable (yet)