Amygdala Neurofeedback in Military Aggression: A Pilot Study

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The primary objective of the proposed study is to test the practical feasibility and tolerability of real-time fMRI neurofeedback training of amygdala signal in military personnel and veterans with impulsive aggression. The secondary objective of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Impulse control disorders NEC
Study type	Interventional

Summary

ID

NL-OMON48677

Source
ToetsingOnline

Brief title
ANiMA (pilot)

Condition

- Impulse control disorders NEC

Synonym
aggression regulation problems, Reactive aggression

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Militaire GGZ;Ministerie van Defensie

Intervention

Keyword: amygdala, impulsive aggression, real-time fMRI neurofeedback

Outcome measures

Primary outcome

The main study parameters of the proposed study are (i) the tolerability of the training procedure, as measured by a short self-report questionnaire, (ii) the degree to which self-regulation training is successful, measured by statistical analysis of the amygdala signal during feedback runs, and (iii) transfer of the training effects, measured by statistical analysis of the amygdala signal during transfer runs.

Secondary outcome

The secundary study parameters of the proposed study are (i) the extent to which the neurofeedback procedure reduces symptoms related to impulsive aggression, as measured by five self-report questionnaries, and (ii) the extent to which functional connectivity between the amygdala and prefrontal cortex is increased as a result of the training procedure, as measured by functional connectivity analysis.

Study description

Background summary

Problems with impulsive aggression are common in the military and veteran population, and are linked to a heightened amygdala response to emotional facial stimuli. Real-time fMRI neurofeedback is a training method in which participants learn to self-regulate the (re)activity of their amygdala, and holds the promise of a potential and effective new treatment strategy for

military impulsive aggression.

Study objective

The primary objective of the proposed study is to test the practical feasibility and tolerability of real-time fMRI neurofeedback training of amygdala signal in military personnel and veterans with impulsive aggression. The secondary objective of the proposed study is to test the potential therapeutic efficacy and neural effects of the training procedure.

Study design

The proposed study concerns a feasibility pilot with an uncontrolled open-label design.

Intervention

Participants are asked to self-regulate their amygdala signal, as represented by a thermometer, in response to pictures of human faces that change from a neutral expression to an angry one. A transfer run will additionally be added wherein participants are asked to self-regulate their amygdala response to the same dynamic face stimuli, only in the absence of feedback information.

Study burden and risks

Participants will undergo two sessions of real-time fMRI neurofeedback training of amygdala signal (± 40 min, each), separated by (±) one week; a resting-state scan will additionally be administered on the first, but not the second, visit (± 9 min). Self-report questionnaires on anger (BPAQ), aggression (STAXI-2), anxiety (STAI), impulsiveness (BIS-11), and depressive symptoms (BDI-II) will be administered before (first visit) and after (second visit) the main training procedure (± 30 min, each). A short screening list on traumatic brain injury will additionally be administered on the first but not the second visit. The risks (i.e., discomfort) and costs (i.e., time, effort) of participation are considered minimal relative to the potential benefits (i.e., possible therapeutic effects, overall interest in the experiment).

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

- Dutch military personnel or veterans
- Age 18-60
- The presence of impulsive aggression problems according to the criteria as described by Coccaro (2012)
- Provide written informed consent

Exclusion criteria

- Alcohol or drug abuse and/or dependence
- A history of neurological disorders (e.g., Parkinson*s disease, CVA, multiple sclerosis)
- Claustrophobia
- The presence of a pacemaker or other metallic implant that might interfere with MRI acquisition

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-07-2019
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	09-05-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	13-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-07-2019
Application type:	Amendment
Review commission:	METC NedMec

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	NL64377.041.18