Trauma & Control: Self-Regulation of Brain Networks in PTSD

Published: 23-02-2022
Last updated: 05-04-2024

Our main objective is to investigate the feasibility and cognitive effects of applying self-regulation strategies learned from large-scale brain network balance neurofeedback training on active memory suppression in a PTSD patient population.

Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Observational invasive

Summary

ID

NL-OMON52214

Source
ToetsingOnline

Brief title
TraumaCtrl

Condition

- Anxiety disorders and symptoms

Synonym
Posttraumatic stress disorder, PTSD

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Contol, Memory, Neurofeedback, PTSD

Outcome measures

Primary outcome

The primary outcome of the study is the behavioural effect of the application of self-regulation strategies learned from neurofeedback training on suppression-induced forgetting in the cognitive task. We expect that PTSD patients can apply learned self-regulation strategies to improve memory suppression.

Secondary outcome

Secondary outcome measures include an assessment of self-regulation performance based on fMRI data, as well as effects of the application self-regulation strategies on daily EMA survey outcomes.

Study description

Background summary

Post-traumatic stress disorder (PTSD) is a common and debilitating psychiatric disorder that occurs after the experience of severely distressing trauma. Current standard treatment - trauma-focused therapy - alone is insufficiently effective for many patients and there is a critical need to investigate innovative forward-facing interventions that may enhance long-term treatment success by empowering patients to stay healthy. Recent findings in the domains of cognitive psychology and neuroscience have started to shift the focus in PTSD research away from the contents of the trauma memories itself, and rather suggest that maladaptive control of those memories is a crucial underlying core-deficit in PTSD. In particular, PTSD patients appear to have difficulties with the suppression of thoughts and memories. Recent neuroimaging research has proposed a network-based model of PTSD that attributes the underlying neural mechanism to an imbalance in large-scale brain net-works. We have recently developed a novel network-based rtfMRI neurofeedback paradigm for training

control over the relative balance between large-scale networks, which is ideally suited for regaining the impaired executive control needed to successfully suppress unwanted memories in PTSD by directly learning to voluntarily self-regulate PTSD-related large-scale brain network balance. The aim of the proposed study is to investigate the feasibility of applying large-scale brain network balance neurofeedback training to a PTSD patient population, and to assess the effects of learned self-regulation strategies on memory suppression.

Study objective

Our main objective is to investigate the feasibility and cognitive effects of applying self-regulation strategies learned from large-scale brain network balance neurofeedback training on active memory suppression in a PTSD patient population.

Study design

We will recruit individuals with a clinical PTSD diagnosis from collaborating treatment centres in Nijmegen and Maastricht. Interested participants will start with an intake procedure, including an intake interview, a short MRI session and three questionnaires. After the intake day, participants will fill in short daily surveys of ecologically momentary assessments (EMA; intrusion, dissociation, mood and stress-related questions) for one week. Participants will then take part in a three-day fMRI-based neurofeedback training procedure, followed by the application of the self-regulation strategies learned from that training in a cognitive task which assesses active memory suppression by explicitly suppressing and recalling negative emotional pictures associated with a neutral cue. After the cognitive task, participants will fill in short daily EMA surveys for two more weeks. During the second week, participants will be asked to additionally apply learned self-regulation strategies at least 3 times a day.

Study burden and risks

Negligible risk is associated with this study. Laying in an MRI scanner may be uncomfortable for some participants. However, care is taken to get participants accustomed to the scanning environment. Participants are additionally screened for claustrophobia beforehand to minimize the potential of subjects experiencing discomfort due to being in a small space. Watching negative emotional pictures might also induce discomfort in some individuals. We will hence brief participants on the content of the scenes they will view both before they give consent to participate in the study and before the procedure itself. Aware of the increased vulnerability of our study population, we will take extensive additional measures in order to reduce the discomfort produced by study procedures (outlined in chapter 13.2). Although there is no direct

benefit for participants, this study aims to provide new empirical insights that will facilitate translation of scientific findings to clinical practice. Findings of the proposed study have the potential to be directly translatable to clinical settings, which may lead to improved and personalised treatment for PTSD in the foreseeable future.

Contacts

Public
Radboud Universitair Medisch Centrum

Kapittelweg 29
Nijmegen 6525 EN
NL
Scientific
Radboud Universitair Medisch Centrum

Kapittelweg 29
Nijmegen 6525 EN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

PTSD symptoms, according to DSM-5 criteria, as noted by participant's clinician

Exclusion criteria

• History of episode of psychotic or manic symptoms.
• Daily intake of benzodiazepines, or otherwise irregular intake of benzodiazepines (*when needed*) but unable to withhold intake from the day prior to each test session until the end of the each test session. An exception is made for low doses of short-acting benzodiazepines that are prescribed for insomnia (i.e. as sleep medication).
• A relevant neurological disorder (e.g., stroke, epilepsy, Multiple Sclerosis) or severe physical disorder which is likely to impact assessment procedures or results.
• Reports to be unable or unwilling to withhold recreational drug use and limit alcohol use to maximally two units per day from the day prior to each test session until the end of the each test session.
• Reports to be unable or unwilling to discuss frequency and timing of smoking during and around study procedures, and adhere to an agreed smoking schedule (personally adjusted to balance feasibility, participant needs and reliability of study outcomes).
• General learning disability, or known to have intelligence Quotient (IQ) < 70
• Body weight >250 Kg.
• For women: pregnancy
• Contraindications for MRI scanning (e.g., pacemaker, implanted metal parts, metal in or around the body, deep brain stimulation, severe claustrophobia).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2022
Enrollment:	32
Type:	Anticipated

Ethics review

Approved WMO Date:	23-02-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-05-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-06-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL78616.091.21