Training Reappraisal under Stress

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51282

Source
ToetsingOnline

Brief title
TRuSt

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
stress-related mental health problems; stress-related psychopathology

Health condition

stress-gerelateerde klachten

Research involving
Human

Sponsors and support

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

Forschungsgesellschaft)

Intervention

Keyword: cognitive reappraisal, emotion regulation, reslience, stress

Outcome measures

Primary outcome

The main study endpoint is to assess the effectiveness of emotion regulation under acute stress after a cognitive reappraisal training, which is operationalized as the successful downregulation of negative affect in response to negative pictures when applying the trained emotion regulation strategy. We predict successful downregulation of negative affect under acute stress in the training but not in the no training group.

Secondary outcome

In addition, by means of functional MRI, we want to investigate the associated neural mechanisms underlying effective emotion regulation under acute stress after a cognitive reappraisal training vs. no such training. We will also investigate psychophysiological reactions as a secondary outcome measure of effective emotion regulation (corrugator electromyography [cEMG], skin conductance responses [SCRs], pupil dilation responses [PDRs]).

Study description

Background summary

Stressful life events have a major impact on our mental health. Despite this high clinical relevance and associated societal costs, successful and cost-efficient treatment options and preventative measures are still sparse. Many of the symptoms of stress-related psychopathologies, including overly

strong attention toward and processing of negative information as well as excessive fear responding, are at least partly driven by stress-induced impairments in effective emotion regulation abilities and the use of maladaptive emotion regulation strategies may pose an important risk factor for the development of several psychopathologies. Cognitive reappraisal has been proposed as a key mechanism for resilience. Stress-induced impairments in reappraisal likely result from the high cognitive demands that this strategy imposes on prefrontal cortex (PFC) functioning. A potential solution to this problem is repeated training which is known to cause cognitive processes to become more efficient and less dependent on PFC regions, and therefore less sensitive to the effects of stress. Earlier research indeed showed that four sessions of guided reappraisal practice improved downregulation of self-reported negative affect.

Study objective

The aim of this experiment is to investigate whether training reappraisal will prevent stress-induced impairments in effective emotion regulation, and if this training effect is associated with reduced negative effects of acute stress on PFC functioning during emotion regulation.

Study design

In this functional MRI (fMRI) experiment we use a randomized between subjects design with the between subjects factors training (training vs. no training) and stress (stress induction vs. control).

Intervention

To reduce the burden on participants, instead of inviting them regularly to the lab to do the training, we will use a smartphone-based training that participants can easily follow in their daily lives. Participants will use an adapted version of the original ReApp (Reappraisal Application), a smartphone-based training developed by the University of Zürich(Marciniak et al, in preparation). Their study showed that ReApp is feasible to offer short trainings to students in their daily lives (Marciniak et al, in preparation). User adherence and commitment, as well as user experience were very high in this study. During this training, participants are asked to challenge and reinterpret negative thoughts they may have had about an actual, hypothetical, or future event. Participants do this 3x per day and are instructed to trigger the training themselves whenever they experience negative thoughts. The study from Zürich (Marciniak et al., in preparation) showed that mean adherence was 34 out of 21 notifications (166% of the planned trainings), meaning that participants liked to trigger the training in addition to the required 3x per day. This also shows that the burden for the participants is very low.
To test the effectiveness of the training in preventing stress-induced

impairments in effective emotion regulation, participants will be exposed to a laboratory stress induction (a combination of the Socially Evaluative Cold Pressor Test [SECPT] and the ScanSTRESS) or a control procedure before performing an emotion regulation task inside the MRI. These are very common procedure to increase acute stress levels.

Study burden and risks

The estimated burden and risks of this study are negligible. Subjects may experience slight discomfort when filling in mood questionnaires, collecting saliva samples and when being exposed to the laboratory stress induction. Also, participants may experience the daily time investment of the training as burdensome. However, since a previous study showed that participants even invested more time in the training than was required, this is not expected. Loud noise in the scanner and lying in a small confined space may lead to discomfort in some participants. These procedure are widely used in humans and are completely save.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Healthy volunteers between 18 and 35 years
Right-handed
Normal uncorrected hearing
Normal or corrected-to-normal vision

Exclusion criteria

Pregnancy
Contraindications for MRI scanning (e.g. pacemaker, implanted metal, claustrophobia)
Current or history of any psychiatric disorder
Disorders of the autonomic system
Disorders of the endocrine system
Body mass index lower than 18 or higher than 30

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-11-2022
Enrollment:	128

Type:	Actual

Ethics review

Approved WMO Date:	26-10-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-05-2023
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	NL81174.091.22

Study results

Date completed:	04-03-2024
Actual enrolment:	112