

# Training Reappraisal under Stress

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	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

## Intervention

**Keyword:** cognitive reappraisal, emotion regulation, resilience, 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**

### **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

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