Transdiagnostic Mechanisms in Fearful Avoidance

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We aim to obtain a transdiagnostic mechanistic understanding of the neural and psychophysiological correlates of avoidance behaviour

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

Summary

ID

NL-OMON52219

Source
ToetsingOnline

Brief title
The Brain in Avoidance

Condition

- Anxiety disorders and symptoms

Synonym
anxiety, depression

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: NWO + ERC

Intervention

Keyword: Anxiety, Avoidance, Individual differences, Psychobiology

Outcome measures

Primary outcome

• Functional Magnetic Resonance Imaging (fMRI)

• Psychophysiological recordings (heart rate, electromyography)

• Behavioural measures of avoidance behaviour (choice: approach/avoid)

• Self-report questionnaires (treatment outcome, avoidance questionnaire)

Secondary outcome

• Resting state fMRI

• Electrodermal activity

• Breathing rate

• Questionnaires (anxiety symptoms, depressive symptoms, cognitive avoidance,

intolerance of uncertainty, motivational systems)

Study description

Background summary

Anxiety and depressive disorders are the most common and costly psychiatric diseases worldwide. Strikingly, patients often benefit insufficiently from available treatments, such as psycho- and pharmacological therapy. While these therapies initially show strong effects, more than 50% of the patients eventually relapse. Therefore, improving knowledge about potential underlying causes of these diseases is of great and timely importance to improve treatment. Excessive avoidance behaviour is a predictor of poor prognosis and a key symptom of anxiety and depressive disorders. However, most previous mechanistic studies of anxiety and depression did not assess behavioural responses, such as avoidance. Therefore, it remains unclear what drives excessive avoidance behaviour.

Study objective

We aim to obtain a transdiagnostic mechanistic understanding of the neural and

psychophysiological correlates of avoidance behaviour

Study design

Observational study

Study burden and risks

In this study, participants will undergo an established behavioural task and MRI scans. This task involves components of fear conditioning that may cause a moderate level of subjective stress. Our research centre has extensive previous experience with these procedures in healthy controls and patients (see e.g., CMO protocol numbers 2010/257, 2011/382, 2013/553, 2013/551, 2018/091). All procedures described in this protocol are well established, carry negligible risk, and constitute a minimal burden for the participants. MRI is a non-invasive imaging technique. Participation in an MRI investigation is not associated with any risks or long-term consequences for the participant. The potentially threatening context of an fMRI investigation itself might cause discomfort for the participant. To minimize the discomfort, participants first have a practice session in a dummy fMRI scanner to get accustomed to the MRI environment. The practice session is a chance for participants to overcome potential feelings of anxiety and discomfort in an unfamiliar environment under guidance of a trained researcher. No pharmacological or otherwise invasive interventions are applied.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Above 18 years of age
• Fluent in Dutch
• Eligible for MRI
• Normal or corrected-to-normal vision
• Normal uncorrected hearing
• Willingness and ability to give written informed consent and willingness and ability to understand the nature and content, to participate and comply with the study requirements
For patients:
• Current or recent (i.e. last year) Axis I diagnosis of anxiety (Generalized Anxiety Disorder, Social Anxiety Disorder, Panic Disorder, Agoraphobia), PTSD or OCD and/or depression) Major Depressive Disorder, Persistent Depressive Disorder) diagnosis (assessed using the Mini-international Neuropsychiatric Interview)

Exclusion criteria

• Insufficient comprehension of the Dutch language
• Abnormal hearing or (uncorrected) vision
• Drug or alcohol addiction in the past 6 months
• Diagnosis of bipolar disorder, schizophrenia, schizophreniform disorder, schizoaffective illness
• Current psychosis
• Current neurological disorder, past neurological disorder within the last three months
• Physical, cognitive, or intellectual impairments interfering with participation, such as deafness, blindness, or sensorimotor handicaps
• History of cardiac disease

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2021
Enrollment:	207
Type:	Anticipated

Ethics review

Approved WMO Date:	12-05-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-04-2022
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	NL75184.091.20