Extinction of fear after acquired brain injury

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON51087

Source
ToetsingOnline

Brief title
Extinction of fear after ABI

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
Anxiety disorder

Health condition

executieve functiestoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Er is geen specifieke financiering voor dit onderzoek. Dit onderzoek wordt mogelijk gemaakt binnen de opleiding tot KNP. Zie CV Anema

Intervention

Keyword: Acquired Brain Injury, Executive functioning, Extinction, Fear learning

Outcome measures

Primary outcome

The main study parameters are 1) the proportion of patients with ABI who are classified into the dysfunctional poor extinction class, that is hypothesized to be at least similar or potentially larger to the proportion in an anxiety disordered population, and significantly different from a healthy population, both derived from previous studies. 2) the association between the extinction class membership and executive strength, or, a composite score of cognitive switching, updating and inhibition.

Secondary outcome

n/a

Study description

Background summary

Acquired Brain Injury (ABI) often leads to depressive and/ or anxiety disorders, particularly when coping mechanisms are not sufficient for an individual to adequately adapt to the new situation with often moderate to severe loss of cognitive and physical function. Treatment for these disorders may be inadequate when the treatment commonly used for anxiety and depressive symptoms (cognitive behavioral therapy) relies on control, or executive function mechanisms that are often impaired in this population. One function

that may be impaired is prefrontal regulation, including emotion regulation. A laboratory model for prefrontal emotion regulation is the extinction of conditioned fear. Previous data-driven analysis of individual differences in the extinction of conditioned fear has shown that different learning patterns can be distinguished that could be clinically relevant in the light of etiology and treatment of anxiety and mood symptoms. This research uses a short (15-min) conditioning experiment to classify these learning patterns. In populations of patients with anxiety disorders, more people are classified in dysfunctional learning patterns (impaired extinction and overreaction to stimuli that are not threatening) compared to healthy subjects. Disrupted extinction can be a reason that in some people learned fears are maintained, even when no longer adaptive. This protocol therefore explores these processes in a population with acquired brain injury (ABI). We hypothesize that the percentage of people with ABI who are classified into the disrupted extinction group is similar to the percentage found in the previous study in a population with an anxiety disorder without ABI. Alternatively, this percentage may be even larger in the ABI group due to additional vulnerability relating to impaired executive functions. If so, it will be investigated in a follow-up study (not part of the current proposal) whether this poor extinction group may profit less from ABI-adapted cognitive behavioral therapy.

Study objective

The main research goals in this protocol are 1) to determine whether disrupted extinction is also more common in patients with acquired brain injury (ABI) that are treated for anxiety and depression as in the previously studied anxiety population, and 2) whether in this population disturbed executive functions are associated with disturbed extinction. In a follow-up study, longitudinal data may also be collected to determine the success of whether a disturbance of extinction is also related to treatment success in this population (for this part separate approval will be requested).

Study design

This is an observational study, cross-sectional study.

Study burden and risks

Burden of participation consists of participation in a short conditioning experiment and a neuropsychological test battery. The burden of the conditioning is reduced by making it as short as possible and by using a relatively mild unconditioned stimulus (a brief human scream). The neuropsychological test battery is also kept as short as possible, is divided across different occasions and includes as many breaks as necessary. Testing will also be kept at a minimum by using results of neuropsychological tests

that have already been done as part of regular care if available.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Potential participants are selected from a ambulant patient population that are following standard outpatient clinical care within the *Zorgpad Affectief*, one of our care pathways, that is composed of multidisciplinary treatment for anxiety and/or depression symptoms using CBT (standard, or adapted to cognitive problems) in which cognitive, behavioural and exposure techniques are used. A multidisciplinary team in which a neurologist and/or a psychiatrist participates indicate whether participants are regarded to be cognitive, intellectually and physically fit enough to profit from CBT. Patients in this treatment program are therefore regarded to be fully able to provide informed consent and be eligible to participate in the current study. The outpatients

that receive care at this clinic typically have light to moderate brain damage in a chronic phase and are medically and neurologically stable, have mild to moderate cognitive dysfunction, are independent in terms of activities of daily living or receive some sort of coaching, but with persistent psychological symptoms that are difficult to alleviate. No further criteria are set for the severity of the symptoms.

In order to be eligible to participate in this study, a subject must meet all of the following criteria: age 18-65 years, with acquired brain injury (chronic phase) and anxiety and/or depression symptoms, that are selected for CBT by a multidisciplinary team as part of standard care typically for Thalamus specialized mental care outpatient clinic (Pro Persona Wolfheze).

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: severe comorbidity (diagnosed with severe chronic depression, bipolar disorder and/or psychosis) or substance abuse disorder, hearing problems and inability to read or speak Dutch. Medication, age, gender and diagnosis are used as cofounders for the analysis.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-09-2021
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	21-07-2021
Application type:	First submission
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	NL77838.041.21