Reconsolidation intervention for burnout.

Published: 31-12-2020
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Here, we aim to test whether disrupting reconsolidation by a noradrenergic *-blocker provides long-term relief of panic symptoms in burned-out employees.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON51177

Source
ToetsingOnline

Brief title
#burnout

Condition

- Anxiety disorders and symptoms

Synonym
panic disorder | burnout

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: TNO

Intervention

Keyword: burnout, memory, panic disorder, reconsolidation

Outcome measures

Primary outcome

Our primary output will be the decrease in frequency and severity of panic

symptoms, from screening to post-treatment and follow-up.

Secondary outcome

Our secondary output will be the decrease in the levels of burnout, from

screening to post-treatment and follow-up.

Study description

Background summary

Panic attacks are common in burnout * either contributing to its onset or hindering reintegration into the workplace. Even though some effective strategies for the treatment of panic attacks exist, a substantial proportion of patients experience a relapse even after initial treatment success. However, recent years have witnessed rapidly emerging evidence for the plasticity of fear memories. Upon its retrieval memory may be rendered labile and vulnerable to the disruptive effects of amnestic agents: this process is referred to as *disrupting reconsolidation* and may point to a novel therapeutic strategy for the permanent reduction of fear in employees suffering from work-related panic and anxiety.

Study objective

Here, we aim to test whether disrupting reconsolidation by a noradrenergic *-blocker provides long-term relief of panic symptoms in burned-out employees.

Study design

An open-label pilot study.

Intervention

A single reactivation of panic symptoms at work through hyperventilation provocation, followed by the oral administration of 40 mg of the noradrenergic

*-blocker propranolol.

Study burden and risks

Patients are receiving a short treatment that is expected to diminish their panic symptoms. Hyperventilation provocation causes symptoms of arousal and fear, but these are of short duration and harmless. Exposing individuals to fear-inducing hyperventilation is common in treatment for panic disorder. Based on the Summary of Product Characteristics we expect that propranolol HCl will be well tolerated and do not anticipate any serious adverse events.

Contacts

Public
TNO

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Scientific
TNO

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. aged between 18 and 65 years;
2. a score of > 8 on the Panic Disorder Severity Scale;
3. a score of > 2.79 on both the core symptoms and secondary symptoms of the work-related version of the Burnout Assessment Tool;
4. a score of at least 4 on the panic and anxiety item of the BAT.

Exclusion criteria

1. other relevant treatment for panic symptoms or burnout within 3 months before start of the study;
2. life-time psychosis;
3. depression;
4. current state of asthma or COPD, which necessitates medication use;
5. cardiovascular diseases or irregular heartbeat;
6. hypotension or hypertension;
7. pregnancy or breastfeeding;
8. epilepsy;
9. any medication contra-indicative of the use of propranolol.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2022
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	te genereren door farmaceutisch bedrijf
Generic name:	propranolol hydrochloride
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	31-12-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-03-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2020-005885-33-NL
CCMO	NL76167.018.20