The role of β-adrenergic stress hormones in Eye Movement Desensitization and Reprocessing (EMDR). Part I: the effects of β-adrenergic receptor antagonist propranolol on the plasticity of emotionally arousing episodic memories.

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

Summary

ID

NL-OMON40004

Source
ToetsingOnline

Brief title
The role of β-adrenergic stress hormones in EMDR: a propranolol study

Condition

- Other condition

Synonym
Neurobiology of EMDR, underlying mechanisms of EMDR therapy

Health condition

Geen aandoening: geneesmiddel wordt gebruikt om de onderliggende neurobiologische processen te onderzoeken van een therapie voor PTSD, namelijk EMDR

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: EMDR, Emotional memory, Noradrenalin, Propranolol

Outcome measures

Primary outcome

The emotionality and vividness of recollected memories at pretest (baseline),

posttest (after medication intake and each experimental manipulation) and after

24 hour follow-up measured with corrugator EMG, HR, SC, a VAS for emotionality,

and a VAS for vividness.

Secondary outcome

Not applicable

Study description

Background summary

Eye Movement Desensitization and Reprocessing (EMDR) is a widely used, effective psychological treatment for posttraumatic stress disorder (PTSD). Its core intervention is that patients recall trauma memories while simultaneously making lateral eye movements. It is largely unknown how EMDR works, however, much evidence has been obtained for the working memory hypothesis. This hypothesis comprises that both recalling traumatic memories and making eye movements (EM) tax working memory (WM), which has limited capacity.

Simultaneously performing both tasks leads to a competition for WM, rendering the traumatic memories less vivid and emotional. When memories are recollected they re-enter a labile state and become malleable and, because of this, the traumatic memory is overwritten by the memory that is blurred by EM. Emotional material is better (re) consolidated than emotional neutral material, i.e., it is prioritized and is (re) consolidated more vividly and in greater detail. This is caused by the release of noradrenaline (NA). In EMDR emotional material is recollected and reconsolidated. Therefore, EMDR might work because of NA release, i.e., NA enhances the reconsolidation of the blurred emotional memories.

Study objective

The goal of the present study is to investigate whether the blockade of NA-transmission by beta-antagonist propranolol reduces the common EMDR effects (reduced vividness/emotionality of emotional memories) in order to find out if NA-release (evoked by the emotionality of the memories) plays an important role in the blurring of traumatic memories during EMDR.

Study design

The proposed study will use a double-blind, placebo-controlled, experimental, repeated measures design, with medication group (placebo, propranolol) as between subjects independent variable, condition (recall + EM, recall only, no recall) and time (pretest, posttest-1, posttest-2) as within subjects independent variables, and VAS-rated vividness and emotional arousal, and physiological response (heart rate, skin conductance and facial electromyography (EMG)) as dependent variables.

Intervention

Half of the participants will receive 40 mg of the beta-blocker propranolol and half will receive a placebo. Of the three memories participants have to retrieve during the pretest (and will be scored on VASs), one will be recalled while making EM (recall + EM), one without EM (recall only), and one will not be retrieved (no recall) during the intervention. During the posttest all three memories will be retrieved again and scored on vividness/emotionailty.

Study burden and risks

This project encompasses a low risk study. The low dosage (40 mg) of propranolol has minimal side-effects (see SPC and IB for an overview), and serious adverse events are very unlikely. Participants are carefully screened for contraindicative conditions and medication use. Another burden for the subjects is that they have to invest some time (approximately 5 hours) in participating in the study. The burdens of the test can be justified by the

clinical and scientific relevance of the study. Skin conductance, heart rate, and currugator EMG measures are non-invasive. Participants can withdraw at any time from the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Passing the medical screening (ECG, blood pressure and heart rate examination, two-step test and interview)
- Age 18-35
- BMI 17.5-26
- Normal (or corrected to normal) vision
- In females: the use of reliable contraceptives (birth control pills or a hormonal intrauterine device)

Exclusion criteria

Assessed with physical exam:
- Abnormal ECG
- Systolic blood pressure < 60mmHg; Diastolic blood pressure < 90 mmHg
- Heart rate < 60 bpm or > 100 bpm
- No <10% increase in heart rate after 1 minute of stepping up and down a stepladder.;Assesed with interview:
- Familiarity with EMDR and/or prior participation in EMDR research
- Lifetime history of psychiatric disorder (depression, mania, psychosis, anxiety)
- Lifetime history of neurological disease (attention/memory problems and disorders, epilepsy, convulsions)
- Lifetime history of any cardiovascular problem, coronary insufficiency, congestive heart failure, heart block, bradycardia, myocardial infarction, hypotension, chronic obstructive pulmonary disease, bronchial asthma, renal disorders, liver disorders, uraemia, hyperthyroidism, acidosis.
- Early age cardiovascular problems in first degree family members
- Fainting easily (can be indicative of cardiovascular problems).
- Inability to adequately read or speak Dutch
- Use of any contraindicative medication:
- Medication that decreases blood pressure, or cardiac contractility or conductivity
- Medication for migraine, dizziness, asthma, tuberculosis, psoriasis
- Medication that lowers blood sugar levels
- Anti-inflammatory painkillers
- Anti-depressives
- Anti-psychotics
- Anxiolytics
- Antacids
- Recreational drug use other than alcohol in the past 3 months
- Known sensitivity to propranolol
- Daily smoking (>=10 cigarettes per day)
- Excessive drinking (>=4 glasses per day)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-10-2013
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Propranolol HCL
Generic name:	Propranolol
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	19-12-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	10-06-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22254
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2012-003901-90-NL
CCMO	NL41743.041.12
OMON	NL-OMON22254

Study results

Date completed:	05-08-2014
Actual enrolment:	60