The role of emotional arousal in Eye Movement Desensitization and Reprocessing (EMDR). Part II: the effects yohimbine on the plasticity of emotionally neutral episodic memories.

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

Summary

ID

NL-OMON45064

Source
ToetsingOnline

Brief title
The role of emotional arousal in EMDR: a yohimbine investigation

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: ZonMW TOP subsidie

Intervention

Keyword: Arousal, EMDR, Memory reconsolidation, Yohimbine

Outcome measures

Primary outcome

Vividness of the memories during pretest, posttest and follow-up as measured

with:

- VAS vividness

- Memory Experiences Questionnaire short form (MEQ-SF)

Secondary outcome

Correlation between the level of arousal experienced during the EM intervention

and the magnitude of the effect at posttest and follow-up (pretest-posttest and

pretest-follow-differences in memory vividness). Measures of arousal include

mean skin conductance levels (SCL) and heart rate (HR).

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 reenter 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 emotional arousal and the accompanying release of noradrenaline (NA) in the brain. In EMDR emotional material is recollected and reconsolidated. Therefore, it is expected that emotional arousal is experienced and NA is released. EMDR might work because despite emotional arousal or becáuse of this arousal i.e., emotional arousal enhances the reconsolidation of the blúrred emotional memories.

Study objective

The primary goal of the present research proposal is to investigate whether emotional arousal plays a role in the effectiveness of EMDR therapy.

Recent studies by our group have shown that vivid, emotionally neutral memories cannot be blurred by EM. In the present study we seek to find out whether the stimulation of arousal by yohimbine during the retrieval of neutral memories leads the common EMDR effects as observed for emotional memories (reduced vividness/emotionality)

Study design

The proposed study will use a double-blind, placebo-controlled, experimental, repeated measures design, with medication group (placebo, yohimbine) as between-subjects independent variable, condition (recall + EM, recall only, no recall) and time (pretest, posttest, followup)
as within-subjects independent variables, and VAS-rated vividness and phenomenological qualities of the memory (as measured with the short form for Memory Experiences Questionnaire* MEQSF) as dependent variables.

Intervention

Half of the participants will receive 20 mg of the alpha-adrenergic receptor antagonist yohimbine and half will receive a placebo. Of the three memories participants have to retrieve during the pretest (and are scored on a VAS/MEQ-SF), 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 and the follow-up all three memories will be

retrieved again and scored on vividness and the MEQ-SF.

Study burden and risks

This project encompasses a low risk study. The low dosage (20 mg) of yohimbine has minimal side-effects (see 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 3 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 and heart rate 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

- Age 18-50
- Written informed consent
- Normal or corrected-to-normal vision
- Body Mass Index (BMI) between 17.5 and 26
- Passing the medical screening (heart rate and blood pressure, medical interview)
- In females: the use of reliable contraceptives (birth control pills or a hormonal intrauterine device)

Exclusion criteria

Assessed by physical exam:
High blood pressure: systolic blood pressure over 140 mmHg, diastolic over 90 mmHg
High heart rate: >90 beats per minute (bpm).;Assessed by interview:
Familiarity with mechanisms behind EMDR
Inability to adequately read or speak Dutch
Known sensitivity to yohimbine
History of psychiatric disorder in the past 2 years (e.g., depression, mania, psychosis, anxiety)
Lifetime history of neurological disease (attention/memory disorders, epilepsy, convulsions)
Current attention/memory problems
Lifetime history of any cardiovascular problem, coronary insufficiency, congestive heart failure, heart block, tachycardia, myocardial infarction, hypertension, chronic obstructive pulmonary disease, bronchial asthma, renal disorders, liver disorders, diabetes
Early age cardiovascular problems in first degree family members
Fainting easily (can be indicative of cardiovascular problems)
Chronic or frequent migraines
Use of any medication
Use of anti-inflammatory painkillers in the past 3 days
Use of anxiolytics or antacids in the past week
A score of * 26 on the Anxiety Sensitivity Index (ASI: Reiss, Peterson, Gursky, & McNally, 1986) (in order to eliminate individuals who might have difficulty with any temporary symptoms induced by the yohimbine manipulation).
Alcohol use of >2 units per day on one or more days during the past week
Any drug use during the past month
A score of *4 on the Fagerström Test for Nicotine Dependence (FTND: Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991) (in order to eliminate individuals that are moderately or heavily dependent smokers).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-01-2017
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Yohimbine HCL
Generic name:	Yohimbine HCL

Ethics review

Approved WMO Date:	30-11-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-05-2016
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: 26672
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2015-003246-10-NL
CCMO	NL46836.041.15
OMON	NL-OMON26672

Study results

Date completed:	27-11-2018
Actual enrolment:	58