# The effects of single session Competitive Memory Training (COMET) and yohimbine on the saliency of positive autobiographical memories.

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

## Summary

### ID

NL-OMON46647

**Source**
ToetsingOnline

**Brief title**
Enhancing the saliency of positive autobiographical memories

### Condition

- Other condition

**Synonym**
Boost memory effects of COMET

**Health condition**

Geen aandoening: geneesmiddel wordt gebruikt om de effecten van een klinische interventie te verstevigen

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universiteit Utrecht
**Source(s) of monetary or material Support:** ZonMW TOP subsidie

## Intervention

**Keyword:** COMET, Emotional arousal, Positieve memories, Yohimbine

## Outcome measures

### Primary outcome

Ease of recollection, specificity, vividness and positive affectivity of positive autobiographical memories at pre-test (baseline), post-test (after medication intake and COMET intervention) and 2-day follow-up measured with 100mm VASs.

### Secondary outcome

Prior to and during the intervention, salivary *-amylase (sAA) levels, Skin Conductance Level (SCL) and Heart Rate (HR) are measured, as a manipulation check and in order to correlate noradrenaline/arousal levels with significant outcomes.

# Study description

### Background summary

Increasing the accessibility and emotional intensity of positive autobiographical episodic memories may improve the wellbeing of clinical populations who suffer from positive memory deficits (e.g., depression and PTSD) or anhedonia (e.g., depression, social phobia and schizophrenia). In this study we combine two novel methods to increase the saliency of positive autobiographical memories: Competitive Memory Training (COMET) and

administration of the cognitive enhancer Yohimbine. COMET is an autobiographical episodic memory training and has proven to be effective for increasing self-esteem and decreasing specific symptomology in several internalizing clinical samples. It is assumed that COMET increases self-esteem, because it increases memory saliency. However, a proof-of-principle study is lacking. We investigate the effect of COMET on memory and hypothesize that COMET procedures increase the ease of recollection, specificity, vividness and positive affectivity of positive autobiographical memories. The efficacy of COMET may be maximized by short-acting medication that enhances emotional arousal. One such enhancer is yohimbine, which facilitates the release of noradrenaline in the amygdala. Yohimbine has been found to enhance the (re)consolidation of emotional memory and boost exposure therapy effectiveness. Therefore, we hypothesize that yohimbine administration will boost COMET memory effects.

### Study objective

The first goal of the present research proposal is to investigate whether single session COMET imagery procedures, relative to no intervention control, increase the ease of recollection, the specificity, vividness and positive affectivity of positive autobiographical memories in healthy subjects. The second goal is to investigate whether the induction of emotional arousal (noradrenaline) by yohimbine vs. placebo can boost these memory effects. The third goal is to investigate whether noradrenaline/arousal levels prior to and during the intervention are related to changes in memory after the intervention. This is the first study to test the efficacy of yohimbine on positive autobiographical material.

### Study design

The study will use a double-blind, placebo-controlled, experimental, repeated measures, cross-over design. Medication group (yohimbine, placebo), intervention (COMET, control) and time (pre-test, post-test, 2-day follow-up) will serve as within-subjects independent variables.

### Intervention

Participants select four mildly positive autobiographical memories. They receive two intervention sessions. During each session, one memory will be activated using COMET procedures and one memory will receive no intervention. During one of these sessions, yohimbine HCL (20mg) will be administrated and during the other session placebo. In total there are four within-subjects conditions: yohimbine+COMET, yohimbine+no intervention, placebo+COMET, and placebo+no intervention.

### Study burden and risks

This project involves a low risk study. The low dosage (20mg) of yohimbine HCL has minimal side-effects (see IB for an overview), and serious adverse events are very unlikely. Participants are screened for contraindicative conditions and medication use. The intervention (recalling positive autobiographical memories) is unlikely to produce psychological discomfort. sAA levels are measured by chewing on a cotton swab, which is not painful. Another burden for the subjects is that they have to invest some time (4 visits; 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. Participants can withdraw at any time.

## 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

The inclusion criteria match a previous study from our lab that involves yohimbine administration in healthy subjects (Protocol ID NL46836.041).
- Age 18-30
- Written informed consent
- 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

The exclusion criteria match a previous study from our lab that involves yohimbine administration in healthy subjects (Protocol ID NL46836.041).
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:
- Inability to adequately read or speak Dutch
- Known sensitivity to yohimbine
- History of affective psychiatric disorders in the past 2 years
- 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
- Specified: use of anti-inflammatory painkillers in the past 3 dagen
- Specified: 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

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| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Double blinded (masking used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 22-05-2018 |
| Enrollment: | 30 |
| Type: | Actual |

## Medical products/devices used

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

# Ethics review

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| Approved WMO Date: | 13-02-2018 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 25-04-2018 |
| 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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2017-004165-27-NL |
| CCMO | NL63641.041.17 |