Conditioning of the Cortisol Awakening Response

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24596

Source
NTR

Brief title
TBA

Health condition

The study is conducted in a sample of healthy male volunteers

Sponsors and support

Primary sponsor: Leiden University (Health, Medical & Neuropsychology, PI: Prof.dr. Andrea W.M. Evers)
Source(s) of monetary or material Support: Netherlands Organisation for Scientific Research (NWO) - Research Talent funding (406.16.542)

Intervention

Outcome measures

Primary outcome

The primary study outcome is the cortisol awakening response (CAR) during evocation in the experimental group compared to the control group, controlling for relevant moderators.

Secondary outcome

As secondary analyses, the effect of conditioning on other outcome parameters (e.g., affect) will be explored. Additionally, the impact of personality and sleep parameters (e.g., sleep duration) on the conditionability of the CAR will be explored.

Study description

Background summary

In the present study we will research whether it is possible to condition the cortisol awakening response - a major characteristic of the circadian cortisol rhythm – using an olfactory conditioning paradigm during sleep. To this aim, a randomized, controlled, single-blinded trial design of 2 weeks duration will be used. In the first week, cortisol levels will be measured once using saliva swabs to determine a baseline cortisol awakening response. In the second week, first an association is formed between the naturally occurring steep rise in cortisol before awakening (Unconditioned Stimulus, US) and a neutral but distinctive scent (Conditioned Stimulus, CS) several minutes before the regular awakening time of the participant (the association phase). Subsequently, it is studied whether the scent (CS) as compared to another scent (non-CS) can evoke the conditioned reaction (CAR increase) when presenting it before their regular awakening.

Study objective

The primary objective is to investigate the effect of olfactory conditioning during sleep on the circadian rhythm-related cortisol awakening response. It is expected that in the experimental group, conditioning will either cause: a) a higher overall cortisol awakening response in the experimental compared to the control group, or b) a higher cortisol value at the first cortisol sample measured after awakening in the experimental, but not in the control group.

Study design

The study consists of a screening session at the university, followed by a 2-week long protocol at participants' homes. On the same day in both weeks, participants will take saliva samples in the hour after awakening in order to determine cortisol levels for the primary outcome.

Intervention

The manipulation used in this study is a previously validated conditioning paradigm consisting of two phases. In the first phase, the association phase, an association is formed between an unconditioned stimulus (US) and a conditioned stimulus (CS). In this study, an association will be formed by coupling the naturally occurring steep rise in cortisol before

awakening (US) to a neutral but distinctive scent (CS) several minutes before the regular awakening time of the participant. In the second phase, the evocation phase, it is then studied whether the CS can now evoke the conditioned reaction in the experimental, but not in the control group, when awakened several hours before their regular awakening time. In this phase, the CS will be presented to the participants several hours before their regular awakening time up to early awakening. In the control group, a different neutral but distinctive scent (non-CS) will be used during the evocation phase in order to ensure equal demand characteristics and expectations.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male gender
2. Between 21 and 34 years of age
3. Good understanding of written and spoken Dutch

Exclusion criteria

1. Refusal to give written informed consent
2. Severe somatic or psychiatric conditions that would adversely affect participant’s safety or that might interfere with the study protocol
3. Olfactory impairments
4. Known sensitivity or hypervigilance to one of the ingredients of the scents used in this experiment
5. Heavy use of (illegal) drugs including cannabis and habits of heavy drinking
6. Irregular sleep pattern or sleep problems

7. Use of medication that interferes with the study protocol
8. Factors known to influence the cortisol awakening response:
a. Having an acute illness, or experienced an illness in the past seven days (e.g. influenza, common cold)
b. Experienced jet lag or shift work in the past seven days
c. Use of (oral) glucocorticoid medication
d. HPA-axis related endocrine disorders (e.g., Cushings disease or Addisons disease)
e. Brain damage, particularly hippocampal brain damage
f. Obesity

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-06-2019
Enrollment:	88
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
The deidentified data will be shared immediately after the project through DANS according to standard conditions.

Ethics review

Positive opinion

Date:	07-06-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43008
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7791
CCMO	NL58792.058.16
OMON	NL-OMON43008

Study results