Determinants of stress and relaxation:effects of orange odor

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

Summary

ID

NL-OMON34694

Source
ToetsingOnline

Brief title
Determinants of stress and relaxation

Condition

- Other condition

Synonym
Stress; tension

Health condition

stress en angst, niet in een klinische context, dus normale stressvorming bij gezonde personen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: onkosten worden vergoed door TNO,TNO

Intervention

Keyword: Anxiety, Aromachology, Odor, Stress

Outcome measures

Primary outcome

The main endpoints are salivary cortisol (psychophysiological) as direct

measure of social, autonomic stress, and self-reported stress and anxiety.

Secondary outcome

The secundary endpoints are skin conductance response and heart rate as

measures of autonomic stress, and mood.

Study description

Background summary

Orange odor has been used in public places to reduce stress or anxiety. This application seems to be based on two published quasi-experimental studies with humans, that we have been unable to replicate. We here propose a laboratory experiment aimed at investigating the effect of exposure to orange odor on psychophysiological measures of stress and subjective self-report.

Study objective

The primary objective of the study is to determine whether inhalation of orange odor leads to a reduced stress response as evidenced by blunted cortisol response and a reduction of self-reported stress and anxiety compared to inhalation of room air. The secondary objective is to determine effects of orange odor exposure on skin conductance response and heart rate, as well as mood. The objective of the study is not to determine whether the purported effects are pharmacological or psychological.

Study design

The proposed study is a single-blind randomized placebo-controlled trial. It is emphasized that this study is not a clinical drug trial, because the intervention concerns a commercially available essential oil, not an investigational medicinal product.

Intervention

In order to induce stress, the Trier Social Stress Test will be administered: Participants will be asked to give an oral presentation to an expert panel of judges, followed by a sequential arithmetic task. There will be two conditions in a between-subjects design. Participants will be exposed to the odor of the essential odor of orange or to room air.

Study burden and risks

The TSST is an effective stress induction paradigm that has been widely used. Although stressful, the levels of stress are considered mild to moderate and bearable for most people. The burden on the participant is therefore relatively small. Participants will be allowed to relax after the task. There are no known risks from exposure to the essential oil of orange. The potential benefits are that if orange oil shows to be effective, it can be easily applied without much effort or risk to reduce social stress.

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

Students who are generally healthy, between 18-25 years of age, do not have a psychiatric condition specifically an anxiety disorder or post-traumatic stress disorder, who are not pregnant or possibly pregnant, who have a good (self-reported) sense of smell, no severe allergies, no asthma, will be included in the study. Participants will not be on any prescribed medications other than oral contraceptives. Participants who have a severe cold or the flu at the time of the lab visit will be rescheduled.

Exclusion criteria

Students who indicate not to be healthy in general, are below 18 years or above 25, to have a psychiatric condition, or, specifically an anxiety disorder or post-traumatic stress disorder, low-average sense of smell, to be pregnant or possibly pregnant, to have severe allergies or asthma will be excluded from the study. Orange odor may have anxiolytic or sedative effects. Participants who are on prescribed medications will be excluded from the study. We will not check whether these are anxiolytics or sedatives in order not to invade the participant*s privacy too much (advice of M.D. involved in study, Dr. Klopping-Ketelaars).
There is no specific reason for excluding pregnant women in the sense that this procedure is potentially harmful for pregnant women (or the unborn foetus), but we think it is undesirable to expose pregnant women to undue stressors.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-04-2010
Enrollment:	156
Type:	Actual

Ethics review

Approved WMO

Date:	22-03-2010
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
CCMO	NL30527.041.10