Exploration of the modulation of skin microbiota and odor components by introduction of stress in healthy male subjects.

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To determine whether the adapted Sternberg short-term working memory task (STMST) is an effective method to induce emotional stress-induced malodour.

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

Summary

ID

NL-OMON44360

Source
ToetsingOnline

Brief title
MOIST

Condition

- Other condition

Synonym
Malodor, Sweat odor

Health condition

Stress-induced malodor formation

Research involving
Human

Sponsors and support

Primary sponsor: Procter & Gamble
Source(s) of monetary or material Support: The Procter & Gamble Company; Cincinnati;OH 45241; USA

Intervention

Keyword: Malodor, Skin microbiota, Stress, Sweat

Outcome measures

Primary outcome

The aim of this study is to assess whether the adapted Sternberg short-term working memory task (STMST) is an effective method to induce malodor formation by emotional stress, as assessed by expert assessments of stress-induced malodor formation in the armpits of healthy male volunteers.

Secondary outcome

Secondary objectives:

* To determine whether the adapted Sternberg short-term working memory task (STMST) is an effective and valid method to induce emotional stress, as assessed by measurable stress biomarkers (cortisol in saliva);

* To determine whether the adapted Sternberg short-term working memory task (STMST) is an effective and valid method to induce emotional stress, as assessed by self-assessed mood state;

* To explore the volatile malodor compounds formation during conditions of emotional sweating induced by the adapted STMST;

* To explore the correlation between skin microbial species that are known to induce the formation of malodor components (i.e. Corynebacterium species, C. tuberculostearicum, C. jeikeium, C. mucifaciens, C. minutissimum, C. striatum, C. bovis, C. urealyticum, and Staphylococus species, S. epidermidis, S. haemolyticus, S. lugdunensis, S. hominis S. capitis, S. caprae) and the production of malodor components induced by the adapted STMST;

* To explore the correlation between other relevant skin microbial species and the formation of malodor compounds induced by the adapted STMST;

Tertiary objectives:

* To explore the effects of the presence of microbial genes known to be involved in malodor formation on malodor compounds formation induced by the adapted STMST;

* To explore the effects of the activity of genes known to be involved in malodor formation on malodor compounds formation induced by the adapted STMST.

Study description

Background summary

Stress is a primary physiological response to physical and/or social threats resulting from a complex interplay of neurophysiological and psychological factors. Cognitive interpretations of social-evaluative threats have been found to be very potent emotional stressors. Apocrine sweat glands are stimulated by

emotional stress, fear or mental tension. Upon secretion, apocrine sweat is odorless. By enzymatic action of the bacterial microbiome on apocrine sweat in particular, body malodor is formed. This is perceived as offensive by most societies. As a result, self-confidence and social relationships can be influenced by undesired body odor. A good understanding of the complex sweat-microbiome interactions leading to malodor formation is required for the development of effective malodor remedies.

Study objective

To determine whether the adapted Sternberg short-term working memory task (STMST) is an effective method to induce emotional stress-induced malodour.

Study design

During a run-in period of 10 days subjects will need to follow specific guidelines regarding the use of personal care products, personal hygiene and consumption of specific food. After 9 days of run-in period, subjects are asked to assess their present feelings of anxiety and embarrassment and to collect a saliva sample at home before coming to the study facilities for malodor assessment by expert judges. Only subjects with an odor score of * 4* 8 are asked to keep a 24h no wash period and to visit NIZO the day after to be subjected to the adapted STMST to induce emotional sweating. Prior to testing, subjects will complete a short psychological assessment questionnaire, The Trait Shame and Guilt Scale (TSGS), assessing long-term experience of shame, guilt and pride. Before, during and after being exposed to the adapted version of the STMST, saliva will be collected to determine cortisol levels, subjects have to rate their momentary feelings of anxiety and embarrassment and heart rate variability will be monitored continuously with a wireless signal transmission device. Before and after exposure to the adapted STMST, malodor levels will be assessed by two expert judges, axillary volatiles will be collected by cup scrubbing and microbiota samples will be taken to determine microbial species

Intervention

In order to expose subjects to external stressors that induce emotional stress responses, they will be submitted to a cognitively and emotionally challenging task: the adapted STMST. In the basic STMST a set of items presented on a computer screen needs to be memorized. Subjects then indicate as fast as possible whether subsequently shown items were in the memory set or not. In the adapted STMST, this protocol is augmented by adding relevant additional stress factors like lowering the controllability of the outcome, adding a social-evaluative threat, presenting disrupting sounds upon failure and adding (negative) monetary rewards.

Study burden and risks

The subjects will not benefit directly from participation to the study. A subject fee is provided, which includes repayment of traveling expenditures. The burden of the subjects producing malodor scores of * 4* 8 that participate in this study consist of investing 7,5 hours in total for screening, following study guidelines, and 2 study visits. These subject will receive a 100 euro subject fee. Subjects producing malodor scores of 3 or lower will leave during the run-in period and will be provided with 70 euro. To our opinion, the risks of participation in this study for physical or mental wellbeing are negligible.

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

1. Male
2. Age 18-34 yrs
3. BMI between 18,5-25 kg/m2
4. Healthy as assessed by the NIZO lifestyle and health questionnaire (*Verklaring leefgewoonten en gezondheid*).
5. Non-smoking
7. Access to internet

Exclusion criteria

1. Alcohol consumption > 15 units/week and > 3/day.
2. Drug abuse
3. Heavy exercise or sports training > 10 hours/week.
4. Hyperhidrosis , Hypohidrosis or Anhidrosis
5. Known allergy to cosmetics
6. Psychiatric disorders
7. Use of anti-anxiety medications or beta-blockers, statins or blood pressure medication
8. Use of antibiotics during the six (6) months prior to study start.
9. Use of topical medications in underarm area during two (2) weeks prior to study start
10. Active eczema or psoriasis on any portion of the body.;Procedural:
1. Personnel of the research institute(s) involved in execution of the study, their partner and their first and second degree relatives
2. Not having a general practitioner, not allowing disclosure of participation to the general practitioner or not allow to inform the general practitioner about abnormal results.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	31-10-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	28-08-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-10-2017
Application type:	Amendment
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	NL62290.041.17