The TEMP II Study: the central and peripheral body temperature response after social stress: a follow up study

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Study Objective: Primary objectives:1 To determine and confirm whether the Trier Social Stress Test will lead to a stress-induced changes in body temperature increase in male and female volunteersSecondary objectives: 1 To determine whether stress-…

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

Summary

ID

NL-OMON34706

Source
ToetsingOnline

Brief title
The TEMP II Study

Condition

- Other condition

Synonym
physiological autonomic stress reactivity

Health condition

normale fysiologische stressrespons

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: autonomic stress response, body temperature, stress

Outcome measures

Primary outcome

The primary outcome measure is the body temperature reaction in response to the

TSST.

Secondary outcome

The Secondary outcome measures are:

- heart rate responses after the TSST

- saliva cortisol levels in response to the TSST

- various stress questionnaire outcomes before and after the TSST

- correlation of temperature responses with heart rate, cortisol and stress

questionnaires

Study description

Background summary

Rationale: Acute stress elicits an autonomic stress response, causing body temperature to rise in all organisms (stress-induced hyperthermia, SIH). This autonomic stress response also causes the heart rate and blood pressure to increase, and plays an important part in the manifestation of anxiety disorders, when it is activated inappropriately. Extensive animal research has shown that this stress-induced temperature response can be robustly blocked with a wide range of anxiolytic drugs. Furthermore, the SIH response has excellent translational properties for anxiety research, because the parameter is identical in animals as well as humans. So far, very little structural

research on the temperature response in humans has been carried out. The TEMP study has shown that exposure to stress increased skin temperature on the upper arm in male and female subjects, whereas it resulted in a small but statistically significant decrease in intestinal core temperature in male subjects only. Interestingly, the core temperature decrease correlated significantly (R=-0.59) with the subjective stress increase. These results indicate that a direct translation of the preclinical SIH paradigm to a human version is possible but not without difficulty as the direction of stress-induced temperature changes depends on the site of temperature measurement. Therefore, the TEMP II study aims to extend these findings by repeating and extending the finding that stress-induced central and peripheral body temperature changes are present in healthy men and women exposed to standardized social stress (the Trier Social Stress Test). In addition to the central (intestinal) temperature and peripheral (upper arm skin) temperature that were already measured in the TEMP study, we additionally measure auricular and arterial core temperature using specialized thermometers as well as the peripheral exposed skin temperature (facial and extremities) using an infrared camera. This way, we may confirm and extend our earlier findings of the TEMP study. Also, stress-induced changes in heart rate are monitored using an automatic heart rate monitor. Furthermore, we aim to correlate the stress-induced temperature response to subjective perceived anxiety levels in humans by using a set of different anxiety and stress questionnaires. Saliva cortisol levels are known to be increased after the Trier Social Stress Test. Therefore, stress-induced saliva cortisol samples will be collected as a positive control. The TEMP II study will lead to more information on the basal SIH response and possible gender differences, and will serve as a basis for future studies in which the effects of a registered anxiolytic drug on the SIH response will be studied. The possibility to screen for anxiolytic effects using temperature measurements could be of great value for the development of new anxiolytic drugs, facilitating progress in anxiety research.

Study objective

Study Objective:
Primary objectives:
1 To determine and confirm whether the Trier Social Stress Test will lead to a stress-induced changes in body temperature increase in male and female volunteers

Secondary objectives:

1 To determine whether stress-induced temperature changes correlate.
2 To determine whether stress-induced temperature changes correlate with stress-induced increases in saliva cortisol.
3 To determine whether stress-induced temperature changes correlate with subjective anxiety/stress questionnaires.
4 To determine whether the SIH response is comparable in male and female

volunteers.

Study design

Study Design: 24 adult volunteers (12 male and 12 female volunteers) will participate in the TEMP II study in which they will be exposed to 10-min lasting standardized social stress in the validated Trier Social Stress Test or a placebo stress test. The stress test consists of a short public speech test and an arithmetic test and does not lead to extreme perceived stress levels. Body temperature will be measured before, during and after the stress exposure using telemetry (an ingested pill and a dermal patch), an infrared camera and an arterial and auricular thermometer. Also heart rate levels will be measured throughout the study using a heart rate monitor. Also, saliva samples will be taken throughout the experiment to determine cortisol levels. Subjects will also complete anxiety/stress questionnaires before and after the Trier Social Stress Test.

Intervention

On each testing day (total: two testing days, day1 : TSST; day 2: placebo stress test)

1 Telemetry pill
All participants receive and ingest a telemetry pill and attach a skin patch (Vitalsense Minimitter, size 2.3 x 0.87 cm) on the day of the TSST, at least 1 hour before commencing the TSST. Immediately after taking the pill and attaching the patch, temperature data will be checked to establish a good functioning of the telemetry pill. The pill will be present until it leaves the alimentary tract after an average passage time of 1 day. The pill will leave the body without any known hazard or discomfort. Details about the system and MDD/FDA approval are included as an appendix.

2 Heart rate monitor
All volunteers will be equipped with an automatic heart rate monitor at least 1 hour before commencing the TSST which will measure the heart rate continuously

3. Non-invasive Thermometer
Auricular and arterial temperature will be non-invasively measured from all participants at discrete intervals using a tympanic thermometer and a temporal artery thermometer. Moreover, temperature of the visible skin (extremities, face and neck) will be continuously measured before, during and after the TSST using infrared cameras (FlIR T360). After analysis, recordings will be discarded.

4 Saliva samples
All volunteers will be asked to donate saliva at discrete intervals before, during and after the experiment.
Saliva samples will be collected in tubes after arrival (-60 min), immediately before the preparation phase
(pre-stress levels, -1 min), directly (+2 min) and 10, 20, 30, 45, 60 and 120 min after stress. Saliva samples
are kept at room temperature throughout the test session and are then stored at -20 ° C. Free cortisol, the
biologically active fraction of cortisol will be assayed. Samples will be coded with the participant number. After
analysis, saliva samples will be destroyed. Saliva samples will only be used to determine cortisol levels.

5 Stress questionnaires
All participants will be asked to fill in several stress questionnaires twice. The first time, questionnaires have
to be completed as a baseline before the Trier Social Stress Test. The second time, questionnaires have to be
completed just after the Trier Social Stress Test and indicate a stress-induced state. Questionnaires that will
be taken are the STAI-score (state-trait anxiety inventory) (Spielberger 1989), the BIS/BAS test
and visual analog scales.

6 (placebo) Trier Social Stress Test
The Trier Social Stress Test will be taken in the morning since body temperature and cortisol levels are subject
to circadian rhythmicity. The Trier Social Stress Test consists of a standardized public speaking test as well as
a short arithmetic task which will take around 10 minutes (excluding 2 minute explanation and 3 minute
preparation time). For a precise protocol of the (placebo) Trier Social Stress Test we refer to the attached stress
protocol.

7 Urine sample
A urine sample will be obtained at arrival to conduct a drug test (MDMA, barbiturates, cannabinoids,
benzodiazepines, cocaine and opiates) and to test for nicotine use.

8. Wake up call
Alle participants receive a wake up call at least 1 hour before commencing the study.

Study burden and risks

Risks for volunteers are minimal. The ingestion of a telemetric pill is not associated with any known risks. The
stress test consists of a short public speech test and an arithmetic test and does not lead to extreme
perceived stress levels. The time spent in the laboratory is limited, and participants have sufficient time for
breaks. No direct benefits are present for volunteers

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

Adults (18 years or older) who provide written informed consent are eligible for the present study

Exclusion criteria

General exclusion criteria are:
- smoking
- any psychiatric disorder
- any significant medical condition including any gastrointestinal condition that would lead to a
contraindication for the telemetric pill
- current or past drug use (positive urine screen on the presence of amphetamines (including MDMA), barbiturates, cannibinoids, benzodiazepines, cocaine and opiates)
- participation in current psychological or psychopharmacological research
- present use of any medication which might influence autonomic response, including benzodiazepines, psychotropics, beta blockers, ACE inhibitors and any hormonal treatment including oral anticonceptives.
- women in the follicular phase of the menstrual cycle
- lack of fluency in the Dutch language
- speech impairments
Acute exclusion criteria are:
- any acute illness
- fever
- having a severe cold
- recent physical exertion within the last 2 hours
- large meals within the last 2 hours
- caffein use on the test day
- high basal stress level (measured with a STAI state anxiety score over 50, average 34.3 in male
students (Ploeg 2000))

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):	23-10-2010
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	ingestable radiotelemetry pill / heart rate monitor / non-invasive thermometer
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-05-2010
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	NL31419.041.10