

Human mental performance under acute stress

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Registration date 05/04/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/04/2022	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The SMART study investigates the fundamental question of how acute stress affects different aspects of mental abilities (cognitive processing) in humans. To explain such stress effects on cognitive processing, many different stress effect models have been developed to date. These models primarily differ in their assumptions about (1) the processes that are most strongly affected by acute stress and (2) the neurophysiological mediators of these stress effects, with the stress hormones (nor)epinephrine and cortisol being among the most promising candidates.

Who can participate?

Healthy right-handed males aged between 18 and 30 years without a history of psychiatric disorders, chronic medication use, current nicotine dependence, and current drug consumption

What does the study involve?

To investigate cognitive processing under acute stress, the study randomly administers a standardized stress-induction protocol (i.e., Maastricht Acute Stress Test) after pharmacological manipulations of exposure to stress hormones. The latter is achieved by double-blinded oral administration of a combination of 10 mg Hydrocortisone and 40 mg Atomoxetine (or corresponding pharmaceutical placebos). By manipulating both the treatment (stress) and its neurophysiological effect mediators, the study aims to identify the cognitive stress effect model that can best explain how acute stress unfolds its impact on performance change in a rapid-serial-visual-presentation (RSVP) task, a stop-signal task, a switch task, and dual task that are repeatedly completed by the participants over a prolonged period of time (i.e., 180 min before and after intervention).

What are the possible benefits and risks of participating?

All participants receive financial compensation. The individual risks associated with the study interventions are detailed in the participant information sheet. To minimize the overall participant burden due to adverse drug reactions, the maximum sample size of 328 participants will be adjusted based on the results of an internal pilot study.

Where is the study run from?

The study is run at the cognitive laboratory of the Faculty of Psychology, Technische Universität Dresden, Chemnitz Straße 46a, 01187 Dresden, Germany.

When is the study starting and how long is it expected to run for?
January 2018 to December 2023

Who is funding the study?
The study is funded by the German Research Foundation (DFG).

Who is the main contact?
Dr. Lisa Weckesser, lisa.weckesser@tu-dresden.de
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Study website

https://tu-dresden.de/mn/psychologie/ikpp/sufo/studienteilnahme/projekt-smart?set_language=de

Contact information

Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

493122017

Study information

Scientific Title

The temporal dynamics of acute stress effects on cognitive processing in humans: An empirical evaluation of three cognitive stress effect models

Acronym

SMART

Study objectives

Only one out of three competing models about how acute stress affects human mental performance - that is, by (1) narrowing of attention, (2) resource depletion, or (3) network shifting - can provide valid predictions about the effects of acute stress (and its physiological mediators (nor-)epinephrine and cortisol) on performance in a rapid-serial-visual-presentation task, a stop-signal task, a switch task, and dual task. The following effect patterns are predicted for these tasks by the respective model: (1) increase/increase/decrease/decrease, (2) none /decrease/decrease/decrease, (3) decrease/increase/increase/increase. The study hypothesizes that one of these effect patterns is supported by data.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/08/2018, TU Dresden Ethics Committee, (IRB00001473/IORG0001076, Ethikkommission an der TU Dresden Fetscherstrasse 74, 01307 Dresden, Germany; no telephone number provided; ethikkommission@mailbox.tu-dresden.de), ref: EK 493122017

Study design

Interventional double-blind randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Acute stress in healthy young males

Interventions

Randomized, blinded oral administration of 40 mg Atomoxetine + Hydrocortisone-Placebo, Atomoxetine-Placebo + 10 mg Hydrocortisone, 40 mg Atomoxetine + 10 mg Hydrocortisone, or Atomoxetine-Placebo + Hydrocortisone-Placebo before randomized exposure to Maastricht Acute Stress Test (MAST) or Psychophysiological Non-Stress Comparator (C-MAST). Exposure to MAST and C-MAST is crossed over two study visits.

Intervention Type

Mixed

Primary outcome measure

Performance (response time and accuracy) is measured using a rapid-serial-visual-presentation task, a stop-signal task, a switch task, and a dual task over 90 minutes

Secondary outcome measures

1. Cortisol exposure measured using Salivary Cortisone Levels over 90 minutes
2. (Nor-)epinephrine exposure measured using Blood Pressure and Heart Rate over 90 minutes
3. Mood, Awakeness, and Calmness measured using the Multidimensional Mood State Questionnaire (MDBF) over 90 minutes

Overall study start date

01/01/2018

Completion date

31/12/2023

Eligibility

Key inclusion criteria

1. Male sex
2. Right-handed
3. Age 18-30 years
4. Normal or corrected-to-normal vision

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

30 Years

Sex

Male

Target number of participants

328

Key exclusion criteria

1. History of psychiatric disorders
2. Chronic medication use
3. Current nicotine dependence
4. Current drug consumption

Date of first enrolment

16/06/2020

Date of final enrolment

01/12/2023

Locations**Countries of recruitment**

Germany

Study participating centre

Technische Universität Dresden

Falkenbrunnen / NIC B

Chemnitzer Straße 46a

Dresden

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Sponsor information**Organisation**

TU Dresden

Sponsor details

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Sponsor type

University/education

Website

<https://tu-dresden.de/>

ROR

<https://ror.org/042aqky30>

Funder(s)

Funder type

Government

Funder Name

Deutsche Forschungsgemeinschaft

Alternative Name(s)

German Research Association, German Research Foundation, DFG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Publication and dissemination plan

All study results will be published in a high-impact peer-reviewed journal.

Intention to publish date

15/03/2023

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication.

IPD sharing plan summary

Published as a supplement to the results publication