

# Human mental performance under acute stress

<b>Submission date</b> 03/02/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/04/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/04/2022	<b>Condition category</b> 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](mailto:lisa.weckesser@tu-dresden.de)  
Dr. Robert Miller, [robert.miller@tu-dresden.de](mailto:robert.miller@tu-dresden.de)

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Lisa Weckesser

### Contact details

Institut für Klinische Psychologie und Psychotherapie, TU Dresden  
Chemnitzer Straße 46a  
Dresden  
Germany  
01187  
+49 351 46332343  
[lisa.weckesser@tu-dresden.de](mailto:lisa.weckesser@tu-dresden.de)

### Type(s)

Principal investigator

### Contact name

Dr Robert Miller

### ORCID ID

<https://orcid.org/0000-0002-8665-5248>

### Contact details

Institut für Klinische Psychologie und Psychotherapie, TU Dresden  
Chemnitzer Straße 46a  
Dresden  
Germany  
01187  
+49 351 46332343  
[robert.miller@tu-dresden.de](mailto:robert.miller@tu-dresden.de)

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

**Protocol serial number**

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

30 years

**Sex**

Male

**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

Germany

01187

## Sponsor information

**Organisation**

TU Dresden

**ROR**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

Deutsche Forschungsgemeinschaft

**Alternative Name(s)**

German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**  
Germany

## Results and Publications

### 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes