ISRCTN65723653 https://doi.org/10.1186/ISRCTN65723653

Human mental performance under acute stress

Submission date	Recruitment status	[ ] Prospectively registered
03/02/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/04/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/04/2022	Other	[ ] 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, Chemnitzer 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
Dr. Robert Miller, 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

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

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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 DresdenFetscherstrasse 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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes