The effect of acute stress on executive functioning and decision-making in healthy military personnel.

Published: 02-02-2023
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To study if acute stress has a significant effect on executive functioning scores in healthy military personnel.

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

Summary

ID

NL-OMON53867

Source
ToetsingOnline

Brief title
ENDURE

Condition

- Other condition

Synonym
arousal, tension

Health condition

stress en hogere cognitieve functies

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: Acute Stress, Cognition, Decision-making, Military

Outcome measures

Primary outcome

To study if acute stress has a significant effect on executive functioning

scores in healthy military personnel.

Secondary outcome

a) To study if acute stress affects individual cognitive domains

(situational awareness, working memory, inhibition, cognitive flexibility).

b) To study if acute stress affects decision-making.

c) To study if acute stress induces a significant change in objectively

measured psychophysiological stress parameters (cortisol, alpha-amylase, HR,

HRV, respiration, and skin temperature).

d) To study if there is a difference in objectively measured stress levels

between groups exposed to different stressors (control vs. low stress vs. high

stress).

e) To study if acute stress induces a significant change in subjectively

measured stress parameters (STAI and VAS scores).

Study description

Background summary

Military personnel that engage in military operations are increasingly faced with acute stress by means of physical, environmental, social, and psychological stressors. These stressors have an impact on hormonal balance and overall performance (e.g., cognition). The relationship between acute stress and cognitive performance has been described as an inverted U; meaning that there is an optimal stress level at which cognitive functioning is maximally enhanced. In contrast, at both ends of the curve (too low or too high stress), cognition seems to be impaired. In a military setting, cognitive functioning, or rather executive functioning is of great importance to adequate performance and decisions. Specifically, decision-making relies heavily on prefrontal executive functions, which have been shown to be impaired by acute stress. How decision-making and cognition is affected by realistically induced acute stress has not yet been researched extensively in a laboratory setting.

Study objective

To study if acute stress has a significant effect on executive functioning scores in healthy military personnel.

Study design

The proposed study is a single-blind randomised controlled between-subjects trial.

Intervention

Subjects are placed in one of two groups:
1) intervention group 1, low stress in VBS environment
2) intervention group 2, high stress in VBS environment + heat stress

Study burden and risks

The burden and risk of the research is negligible to low. In the VBS environments the subjects are sitting, so there is no risk of physical harm during. The participants in the climate room are exposed to a higher burden because high temperature and humidity adds additional risk. Risks in the climate room include heat exhaustion, overheating. However, these risks are often only present when subjects undergo physical exercise/exertion, which they will not.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Military personnel of the Dutch Defence organisation who serve for the Kingdom of the Netherlands
- Aged 18 - 40 years

Exclusion criteria

* Diagnosis of current psychiatric (except ADHD) or (severe) neurological disorder (e.g., learning disabilities, epilepsy, traumatic brain injury, brain tumors)
* Diagnosis of endocrine disorder
* Diagnosis of cardiovascular or pulmonary disorder
* Current use of prescribed medication (except ADHD medication and anticonception)
* Psychotherapeutic treatment
* Diagnosis of sleep disorder
* Alcohol or drug dependence
* History of heat-related medical issues

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-07-2023
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO Date:	02-02-2023
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	15-02-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-04-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-06-2023
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	01-08-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NL82445.041.22