

# Effects of a combination of heat and hypobaric hypoxia on cognitive performance.

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We examine how a combination of these two physical stressors affect cognitive performance and (subjective) feelings of cognitive (over)load, and which mechanisms are associated with the anticipated decline in performance. Although effects of heat...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON49264

### Source

ToetsingOnline

### Brief title

Hypoxia and heat load

### Condition

- Other condition

### Synonym

cognitive performance deterioration, effort

### Health condition

cognitieve prestatie(verlies)

### Research involving

Human

## Sponsors and support

**Primary sponsor:** TNO

**Source(s) of monetary or material Support:** bestedingsovereenkomst tussen TNO & Ministerie van Defensie V1917

## Intervention

**Keyword:** Cognition, Heat, Hypoxia, Physiology

## Outcome measures

### Primary outcome

Cognitive performance measured by:

- Multi-Attribute Task battery-II (MATB-II)

The outcome variables are as follow:

- System monitoring:

Number of successfully tuned off/on lights

Percentage omissions

Mean response time

Number of false reactions

- Tracking task

Root mean square (RMS) target tracking error

- Resource management task

Mean absolute deviation from target fuel level

- Communication

Number of successful radio and frequency tunings

Number of false reactions

Mean response time

- SYNWIN multiple-task battery

Individual task performance metrics include:

- Memory task percent correct and RT for correct responses;
- Math task percent correct and RT for correct responses;
- Visual Monitoring task point score and lapse rate (number of times subject allowed gauge to reach zero divided by number of sampling periods);
- Auditory Monitoring percent correct.

- The Vigilance & Tracking (VigTrack)

- Root mean square tracking error
- Percentage omissions
- Number of false reactions
- Reaction times

- Psychomotor Vigilance Task (PVT)

- Reaction time
- Lapses
- Misses

### **Secondary outcome**

- Perceived workload measured with the NASA-Task load Index (TLX)
- Rating of subjective mental effort (RSME)
- Skin temperature in degrees Celsius
- Core temperature in degrees Celsius
- Percentage SpO2

- Heart Rate in beats per minute
- Sweat rate
- Score on visual task

Other outcome measures

- Subjective thermal perception score
- Experienced hypoxia symptoms
- Operative temperature (WBGT)

Besides this, participants\* age and gender will be recorded in order to describe our sample and for possible later use as covariates.

## Study description

### Background summary

Driven by technological advancements, the role of the pilot within the fifth-generation air force is shifting from platform-driven to strongly information-driven operations. New technology will more and more support and supplement the human operator\*s perception and decision-making. Nevertheless, the human operator must still be able to perform his tasks given these expanded capabilities and availability of information. Moreover, fifth-generation pilots need to perform these tasks in a new role of information manager, under mentally and physically demanding circumstances that are intrinsic to military operations. Research program V1917 is funded by the Dutch Ministry of Defense to acquire knowledge on the effects of internal and external operational conditions on the physical and cognitive capabilities of the pilot. The main program objective is to gain knowledge on the effect of (a combinations of) physical and cognitive stressors on aircrew performance. This knowledge can be applied to improve simulation environments used for training of aircrew, and to develop human models that predict operator performance in adverse operational conditions, such as related to hypoxia, heat, spatial disorientation and information overload.

Based on several interviews with experts about relevant scenarios, use-cases,

stressors and associated performance measures, two physical stressors (heat and hypoxia) have been chosen for this study. This study focuses on simulating an aircrew-mission (transport helicopters) in a warm climate. During such missions crew regularly fly at an altitude between 10.000 - 13.000 ft without the use of supplementary oxygen mask, after being exposed to heat load in the cockpit during ground procedures and flight preparation. During these missions, aircrew wear a military flight suit with underneath it a fire-resistant Nomex shirt and pants. This can lead to an insulation layer on the body, which causes an extra thermal burden.

## **Study objective**

We examine how a combination of these two physical stressors affect cognitive performance and (subjective) feelings of cognitive (over)load, and which mechanisms are associated with the anticipated decline in performance. Although effects of heat and hypobaric hypoxia stressors on cognitive performance have been studied in isolation (Martin et al., 2019), little is known about the possibly interacting effects of the combination of these stressors on cognitive performance, or about the potentially underlying mechanisms of these effects.

Research questions:

- A. What are the effects of hypobaric hypoxia on cognitive performance?
- B. What are the effects of heat load on cognitive performance?
- C. What are the effects of the combination of these two stressors on cognitive performance?

Questions pertaining possible underlying (physiological) processes:

- D. What are the effects of hypobaric hypoxia and heat load, as well as their combined effect, on blood oxygen saturation, heart rate, mean body temperature, skin temperature, visual perception, and self-reported mental effort?

## **Study design**

Participants will visit the test center on four separate days. Both the stressors \*hypobaric hypoxia\* (sea level vs. hypobaric hypoxia) and heat load (normal temperature vs. heat load) have a within-subjects (2x2) design. The participants will be exposed to these stressors in a counterbalanced design for the following four conditions:

- Condition 1: sea level + no heat load
- Condition 2: sea level + heat load
- Condition 3: hypobaric hypoxia + no heat load
- Condition 4: hypobaric hypoxia + heat load

Because the stressors will be noticeable for the participants, it is not possible to do (double-)blind research. The four conditions will take place in

a (incomplete) Latin-square crossover design (block of 4 x 7). On each test day, 3 subjects will be tested at once. This means that a total of 7 possible sequences can be used (for a total of 21 subjects).

## **Intervention**

The exposure to a single condition takes a total of 105 minutes, where the first 60 minutes simulate the \*flight preparation/ground procedures part\* (with potential heat load stimuli) and the next 45 minutes the \*actual flight\* (with potential hypobaric hypoxia). In order to simulate hypoxia, participants will be exposed to hypobaric hypoxia in the RNLAf hypobaric chamber at the Centre for man in Aviation in Soesterberg. Heat load will be induced by 35 degrees Celsius air temperature, radiant heat from an artificial sun (<1000W/m<sup>2</sup> from infrared heat lamps), and by wearing a flight suit and vest. After the first 60 minutes in the heat load condition, the temperature will be decreased to normal temperatures of about 25-30 degrees Celsius, while the heat lamps remain on (simulating sun radiation). During the no heat load condition, a normal air temperature of about 20-25 degrees Celsius will be used.

## **Study burden and risks**

Burden on test subjects will not be very high, aspects of the study are quite standard and do not pose high risks. Participants will visit the CML on four different days with at least seven-day washout between each test day. Each test day will take approximately 3 hours of testing and participants will be exposed to four conditions:

- Condition 1: sea level + no heat load
- Condition 2: sea level + heat load
- Condition 3: hypobaric hypoxia + no heat load
- Condition 4: hypobaric hypoxia + heat load

Exposure to these conditions is divided into two separate phases during a test day, so that exposure to heat and hypobaric hypoxia will not occur simultaneously. The research focuses on cognitive performance and which physiological processes underlie maintaining or loss of performance. The emphasis of this research is not on health effects.

Prior to taking part in the study a medical (heat- and hypoxia related) questionnaire is filled in by the participant and approved by the medical doctor related to this study. In case the medical doctor does find contraindications, the participant is excluded from participation in this study. We will monitor the participant during the experiment thoroughly on the parameters given chapter 5 (core temperature, saturation and heart rate). In addition, we will regularly observe and communicate with the participant, and a medical doctor will be available on call. Based on the physiological parameters, stop criteria (see chapter 5; stop criteria) will be maintained.

Participants are instructed to indicate if they are not feeling well. In that case, the experiment will be paused or even terminated. In case one participant in the hypobaric hypoxia condition (3 or 4) has to stop the experiment, all other participants at that moment have to stop as well.

Counter measures:

- A. Participants are screened by a medical doctor using a medical screening checklist;
- B. Participants will have a cardiovascular screening (ECG) assessed by a medical doctor;
- C. During the experiment a medical doctor is available on call at the location;
- D. Back-up oxygen bottles are present in the hypobaric chamber;
- E. Participants will be monitored continuously (core temperature, heart rate and saturation) and stop criteria are maintained.
- F. After the experiment, participants can drink water.

Different studies focus on the effects of hypobaric hypoxia and heat load in isolation on cognitive- and physiological responses. However, the combination of heat and simulated altitudes is less clear. The results of this study can help to improve simulation environments used for training of aircrew, and to develop human models that predict operator performance in adverse operational conditions.

## 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

- Healthy (as defined by exclusion criteria)
- Age between 18 - 35 years
- BMI between 18 and 25 kg/m<sup>2</sup>
- No alcohol the evening before the start of a test day
- No drugs used in the last 3 months
- Medically screened: questionnaire & electrocardiogram (ECG)
- Physically capable of sitting in a warm environments for about 2 hours

### Exclusion criteria

- Cardio-vascular disorders (including cardiac implantable devices like pacemakers and ICDs)
- Psychiatric or neurological disorders
- Claustrophobic
- Hypersensitive to air sickness
- Color blindness
- Smoking
- Pregnant
- Being at altitude (above 2 kilometers) in the last 3 months for longer than a week

## Study design

### Design

Study type: Interventional

Intervention model: Crossover



Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
<b>Primary purpose:</b>	Other

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	16-09-2020
Enrollment:	21
Type:	Actual

## Ethics review

Approved WMO	
Date:	11-03-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	21-10-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

## 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**

CCMO

**ID**

NL72710.028.20