Effect of tactile breathing guidance on oxygen saturation during exposure to hypoxia

Published: 06-12-2022
Last updated: 19-08-2024

The primary objective is to determine whether tactile breathing guidance is effective in increasing SpO2 while engaged in a cognitive task during exposure to hypobaric hypoxia.The secondary objectives are:1. Determine whether a difference in SpO2…

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

Summary

ID

NL-OMON51648

Source
ToetsingOnline

Brief title
Tactile breathing guidance during exposure to hypoxia

Condition

- Other condition

Synonym
hypobaric hypoxia, Reduction in blood oxygen saturation (SpO2)

Health condition

Oxygen shortage in body tissue

Research involving
Human

Sponsors and support

Primary sponsor: Royal Netherlands Air Force, Center for Man in aviation
Source(s) of monetary or material Support: Ministry of Defence

Intervention

Keyword: Hypoxia, Oxygen saturation, Tactile breathning guidance

Outcome measures

Primary outcome

The SpO2 (%) differences between natural breathing and guided slow and deep breathing at 15,000 ft, measured while engaged in a cognitive task.

Secondary outcome

1. The SpO2 level that will be measured while pilots are at rest while breathing naturally, as well as during guided slow and deep breathing at 15,000 ft.

2. The physiological parameters heart rate (HR), End-tidal CO2 (EtCO2), End-tidal O2 (EtO2), respiratory frequency (RF), tidal volume (VT) and minute ventilation (VE) are continuous variables. These parameters will be monitored during each of the breathing conditions and compared between the two breathing conditions.

3. The ability of the pilots to follow the tactile breathing guidance while engaged in a cognitive task will be assessed by comparing respiratory frequency values measured at rest and during the execution of a cognitive task.

4. Self*perceived state of alertness: the Stanford Sleepiness Scale (SSS) is a self-rating 7 point scale (1 to 7) used to assess how alert a person is feeling. Analysis of the data will be performed to discover if a significant difference in alertness exist between: 1. the start and end of each of the breathing conditions, 2. the start and end between breathing conditions.

5. A short questionnaire will be given at the end of each breathing session. The questionnaire at the end of the session will ask the pilots to mark their hypoxia symptoms out of a list. The questionnaire after the slow and deep breathing will also contain questions regarding how useable the tactile breahting guidance is. The pilots will be asked about the strength of the signal, how intuitive was the signal pattern. The questions will be answered by placing a vertical line on a 10cm VAS scale.

Study description

Background summary

The brain is dependent on oxygen in order to maintain normal function. Oxygen deficit as a result of exposure to hypoxia has been shown to effect pilot performance. Slow and deep breathing could help military aircrew increase their SpO2 and reduce the effects of hypoxia. However, the aircrew is not always aware of becoming hypoxic and might not start using the technique on time. Therefore, an external stimuli could be given to the aircrew to guide slow and deep breathing. The sense of touch might be used to guide slow and deep breathing.

Study objective

The primary objective is to determine whether tactile breathing guidance is effective in increasing SpO2 while engaged in a cognitive task during exposure to hypobaric hypoxia.

The secondary objectives are:

1. Determine whether a difference in SpO2 exists in the following conditions: between the two breathing conditions when the pilots are at rest and within breathing condition between rest and cognitive task.

2. Determine the changes in the following physiological variables between the two breathing conditions: end-tidal CO2 (ETCO2) and O2 (ETO2), minute ventilation (VE), heart rate (HR), respiratory frequency (RF) and tidal volume (VT).

3. Determine whether tactile breathing guidance can be followed even when the pilots engaged in a cognitive task.

4. Determine the changes in alertness levels of the pilots between both breathing conditions.

5. Evaluate the usability of tactile breathing guidance.

Study design

This study will be a repeated measures design.
The independent variable is guided slow and deep breathing and the dependent variable is SpO2.
The two levels of breathing condition are: 1. natural breathing and 2. guided slow and deep breathing.

Intervention

The pilots will be exposed to a simulated altitude of 15,000 ft (4572 m) in a hypobaric chamber. During a single exposure, the pilots will perform two different breathing conditions: 1. natural breathing, and 2. guided slow and deep breathing while engaged in cognitive task.

Study burden and risks

We expect the risks for the pilots in the study to be very small. It is expected that during exposure to the 15,000 ft. altitude the pilots will experience hypoxia related symptoms. However, as observed in hypobaric chamber training performed at this altitude the symptoms vanish after descent is complete and the pilots start breathing ambient air.In addition, pilots of RNLAF receive hypoxia training every five years. Therefore, they are familiar with the symptoms of hypoxia. In addition the pilots will not be exposed to extreme altitudes or additional risks compared to the normal hypoxia training they follow during their flight career.

Each pilot will spend a total of two hours, in one day, participating in this study. This includes familiarization and test session. Four times during the tset session the pilots will fill in a short questionnaire contaning questions regarding their alertness (SSS), hypoxia symptoms and the usability of the tactile breathing guidance.

Contacts

Public
Royal Netherlands Air Force, Center for Man in aviation

Kampweg 53
Soesterberg 3769DE
NL
Scientific
Royal Netherlands Air Force, Center for Man in aviation

Kampweg 53
Soesterberg 3769DE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Pilots of the Royal Netherlands Air Force
Male
Age 22-55
The pilots need to pass their mandatory medical examination and be declaered "fit to fly

Exclusion criteria

Pilots who stayed at altitudes higher than 8000 ft (2438m) for a duration longer than seven days consecutively three months before they start this study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2023
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	06-12-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL81837.018.22