ISRCTN13209531 https://doi.org/10.1186/ISRCTN13209531

Motor learning and performance with different levels of oxygen-enriched air

Submission date 25/01/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 31/01/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 31/01/2023	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
It is not known whether normobaric 100% oxygen treatment (increasing the fraction of inspired oxygen under normal pressure) improves motor learning. The increase in oxygenated hemoglobin (HbO2) level may be a hub for adaptive processes in the brain and brain networks involved in motor learning and performance since the neural cells are heavily dependent on oxygen supply. The present study aims to investigate whether normobaric 100% oxygen treatment has a positive effect on motor learning and skill acquisition in healthy individuals. If the treatment has a positive effect on motor learning and skill acquisition in healthy adults, the study could be expanded to investigate the effects of normobaric 100% oxygen treatment during rehabilitation practices that aim at regaining motor functions in participants with brain trauma. If this treatment would also be effective, it may prove to be a simple, widely accessible, and potentially cost-effective therapeutic strategy that could be used to improve motor skill recovery in stroke patients or patients with other brain traumas or neurological diseases.

Who can participate?
Healthy young adults aged 18-35 years old

What does the study involve?
The study will test 100 participants. In each age group, one-half of the participants will be treated with 100 % oxygen during a skill acquisition period of a motor learning experiment, and the other half will be treated with regular air.

What are the possible benefits and risks of participating?
There are no direct benefits from participation in the study. However, the information gained from this study will be used to gain insight into how the central nervous system coordinates movements when performing eye-hand coordination tasks. Individuals belonging to the LSU student community may receive extra credit for research participation in one of their classes if available.

No risks are foreseen; participation in the present study would involve no more risk than risks associated with computer tasks performed during daily life. There are no discomforts expected by breathing an altered level of oxygen under normal ambient pressure conditions. You may feel

a little discomfort with wearing a nasal cannula. There is the inadvertent risk that anonymity will not be kept. However, every effort will be made to ensure confidentiality is maintained. All data and participant information will be kept separate and on a password-protected computer. Signed consent forms will be kept in a locked cabinet in a locked room.

Where is the study run from?
Louisiana State University (USA)

When is the study starting and how long is it expected to run for?
January 2019 to October 2022

Who is funding the study?
Louisiana State University (LSU) College of Human Sciences and Education (CHSE) Deans' Faculty Research grant

Who is the main contact?
Marc Dalecki, PhD (Associate Professor), mdalecki@lsu.edu

Contact information

Type(s)
Principal investigator

Contact name
Prof Marc Dalecki

ORCID ID
https://orcid.org/0000-0003-1359-7312

Contact details
Louisiana State University
School of Kinesiology
College of Human Sciences & Education
112 Long Fieldhouse
Baton Rouge
United States of America
70803
+1 225578 6087
mdalecki@lsu.edu

Type(s)
Scientific

Contact name
Dr School of Kinesiology College of Human Sciences & Education

Contact details
1246 Pleasant Hall
Baton Rouge
United States of America
LA 70803

+1 225 578 2036
not@provided.com

Type(s)
Public

Contact name
Dr School of Kinesiology College of Human Sciences & Education

Contact details
1246 Pleasant Hall
Baton Rouge
United States of America
LA 70803
+1 225 578 2036
not@provided.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Boost your brain: Can a simple 100% normobaric oxygen treatment improve human motor learning processes?

Study objectives
An oxygen treatment improves motor learning processes

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/02/2020, Human Subjects Institutional Review Board at Louisiana State University (Institutional Review Board, C/o: Dr Dennis Landin, 130 David Boyd Hall, Baton Rouge, LA 70803, USA; +1 225 578 8692; irb@lsu.edu), ref: 4341

Study design
Single-center interventional double-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Healthy young adults

Interventions
In our experiment, we provided a 100% normobaric oxygen treatment (5L/min) via a nasal cannula during the adaptation phase of a visuomotor adaptation task. The control group received a similar treatment but with normobaric medical-grade air (AirTr).

Participants are randomly assigned to one of two gas treatment groups, an oxygen tank group and the regular air tank group, by Excel function and will undertake a skill acquisition period of a motor learning experiment.

Only the experimenter who administered the gas treatment saw which participant was assigned to which treatment group. The other experimenter who guided the participant through the experiment did not know to which treatment group the participant was assigned, and was also not able to see the gas administration, the view was blocked by a wall, as described below.

During the motor learning experiment, participants are equipped with a nasal cannula (Salter 1600HF High Flow Nasal Cannula) connected to an oxygen regulator (Oxygen Gas Regulator, CGA-540, Single Stage, Brass, 4 to 80 psi) connected to an oxygen tank (Airgas Medical oxygen (100% oxygen, size 200), or to a regular flow regulator (Regular Gas Regulator, Single Stage, Brass, 4 to 80 psi) connected to a tank with regular air (Airgas Regular Medical Air, 21% oxygen, size 200). The oxygen tank and the regular air tank are both secured in a separate cylinder stand and stored behind a wall outside the participants' sight. A standard bubble humidifier (Salter Labs 6-15 LPM High Flow 350cc Bubble Humidifier) is installed between the nasal cannula and the flow regulator. An air measuring device (BW Honeywell Clip 2 Year O2 Single Gas Detector BWC2-X) is placed in the experiment room to monitor ambient air continuously, and a pulse oximeter with continuous blood oxygen saturation recording function (EMO-80, EMAY) is placed on the dexterity finger of the left hand to record the oxygenated hemoglobin (HbO2) level of the participants during the experiment.

Intervention Type
Other

Primary outcome(s)
All primary outcome measures were assessed using a digitalized tablet, stylus pen (Wacom Intuos Pro Pen and Touch Tablet), Movalyzer Software (Neuro-Script LLC, Tempe, AZ), and customized Matlab program, and measured continuously for each trial of the motor learning experiment:
1. Initial direction error
2. Path length
3. Reaction time
4. Movement time
5. Correctness rate
6. Endpoint error

Key secondary outcome(s))

Blood oxygenation levels measured using a standard pulse oximeter on the left index finger continuously throughout the experiment

Completion date
01/10/2022

Eligibility

Key inclusion criteria
Individuals from the community of Baton Rouge, including the college community, who are between the age of 18 and 35 years old.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
100

Key exclusion criteria
1. Do not have a normal or corrected-to-normal vision and/or hearing
2. Unable to use their hands unassisted
3. Psychological, neurological, and/or other altered physical conditions affecting control of the upper dominant limb and/or eyes
4. Pregnancy

Date of first enrolment
12/02/2020

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Louisiana State University
112 Long Field House
Baton Rouge
United States of America
70803

Sponsor information

Organisation
Louisiana State University

ROR
https://ror.org/05ect4e57

Funder(s)

Funder type
University/education

Funder Name
Louisiana State University

Alternative Name(s)
Louisiana State University and Agricultural and Mechanical College, Seminary of Learning of the State of Louisiana, Louisiana State University Agricultural & Mechanical College, University of Louisiana, LSU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be published as a supplement to the 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?
Participant information sheet	Summary sheet		31/01/2023	No	Yes
Participant information sheet	consent form		31/01/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			31/01/2023	No	No