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Hyperventilation and consciousness

Submission date 06/03/2025	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 07/03/2025	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 19/03/2025	**Condition category** Other	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Recent research suggests that non-ordinary states of consciousness (NSCs) could be effective in healthcare, particularly for pain management and treating conditions like depression, anxiety disorders, and addictions. Techniques such as hypnosis, meditation, and psychedelic-assisted therapies are used to induce NSCs. Hyperventilation techniques also show promise in triggering NSCs with potential therapeutic effects, but more rigorous research is needed. This study aims to better understand how these techniques trigger NSCs and their effects on the brain.

Who can participate?
Adults affiliated with a social security scheme.
Individuals not in situations of physical vulnerability (e.g., pregnant women) or social vulnerability (e.g., under curatorship, guardianship, or deprived of liberty).
Native French speakers.
Individuals who have received and understood complete information about the study and have given written consent to participate.

What does the study involve?
Participants will be included by a study investigator when they visit the laboratory. Each volunteer will participate in three visits to the respiratory pathophysiology laboratory on the same day. During the first two visits (V1 and V2), which will last 2 hours and 45 minutes each, participants will fill out questionnaires, be equipped with measuring equipment, and perform a 20-minute hyperventilation session. They will complete another questionnaire 14±2 days later (V3).

What are the possible benefits and risks of participating?
The study aims to provide insights into the therapeutic potential of hyperventilation techniques in triggering NOSCs. While there may be potential benefits, such as contributing to scientific knowledge and possibly experiencing therapeutic effects, there are also risks, including discomfort from hyperventilation and the time commitment required for participation.

Where is the study run from?
Pitié Salpetriere Hospital (France)

When is the study starting and how long is it expected to run for?
December 2024 to January 2028

Who is funding the study?
Association pour le Développement et l'Organisation de la Recherche en Pneumologie et sur le Sommeil (France)

Who is the main contact?
For more information, you can contact:

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Contact information

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Additional identifiers

Protocol serial number
2024-A02766-41

Study information

Scientific Title
Comparison of the effects of various modalities of hyperventilation on consciousness and EEG activity

Acronym
Hyperphysiol

Study objectives
Current study hypothesis as of 18/03/2025:
The project aims to test the effects of different hyperventilation modalities on the state of consciousness. More specifically, the main objective is to determine which hyperventilation modalities are most effective in inducing non-ordinary states of consciousness (NSCs) in naïve healthy volunteers, in a neutral environment

Previous study hypothesis:
The project aims to test the effects of different hyperventilation modalities on the state of consciousness.
More specifically, the main objective is to determine which hyperventilation modalities are most effective in inducing ENOC in naïve healthy volunteers, in a neutral environment

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/01/2025, Comité de protection des personnes Ile de France VIII (Hôpital AMBROISE PARE 9, avenue Charles de Gaulle 92100 - BOULOGNE BILLANCOURT Cedex, Paris, 92100, France; +33 149095814; cppidf8@orange.fr), ref: 24.06022.000263

Primary study design
Interventional

Study design
Open-label parallel-arm randomized experimental study

Study type(s)
Other

Health condition(s) or problem(s) studied
Hyperventilation

Interventions
One of the study investigators will include participants when they come to the laboratory. Randomization will be performed using Microsoft Excel’s RAND function, and volunteers will participate in three visits to the respiratory pathophysiology laboratory on the same day. During visits V1 and V2, which will last 2h45 hours, they will fill in questionnaires, be equipped with

measuring equipment and perform a 20-minute hyperventilation session. They will complete a questionnaire 14±2 days later (V3).

Intervention Type
Other

Primary outcome(s)
Modification of the State of consciousness, measured using the 5D-ASC questionnaire after the respiratory sequence.

Key secondary outcome(s)
1. Emotional state, measured using the WHO5 questionnaire before the respiratory sequence and two weeks after, and a verbatim two weeks after the respiratory sequence
2. Anxiety, measured using the STAI questionnaires before and after the respiratory sequence
3. Sympathic/parasympathic balance, measured using an electrocardiogram (ECG) and a Galvanic Skin Response (GSR) during the respiratory sequence
4. Brain activity, measured using an electroencephalogram (EEG) during the respiratory sequence
5. "Real-time" modification of the state of consciousness, measured using a visual analog scale (VAS) during the respiratory sequence
6. Modification of the state of consciousness, measured using a verbatim after the respiratory sequence

Completion date
31/01/2028

Eligibility

Key inclusion criteria
1. Adults and affiliated to a social security scheme.
2. Not in a situation of physical vulnerability (pregnant women) or social vulnerability (curatorship, guardianship, deprivation of liberty).
3. Have French as their mother tongue.
4. Affirm having received and understood complete information on the study from qualified personnel, and declare in writing that they consent to participate.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. History of cardio-respiratory, neurological, or psychiatric pathology, such as depression or anxiety disorder (including panic disorder with or without agoraphobia).
2. Chronic cardio-respiratory, neurological, or psychiatric pathology that has been identified and is requiring treatment.
3. Regular consumption of narcotic or psychotropic drugs or a history of psychedelic use.
4. Regular practice of yoga or meditation more than one session per week.
5. Pregnancy.
6. BMI < 18.5 and > 30 kg/m².
7. Score > 23 on the Nijmegen questionnaire.
8. Previous participation in experiments involving the induction of hypnosis or ENOC.
9. Smoking or former smoking with a cumulative smoking exceeding the limit of 5 pack-years.
10. Minors, protected adults, or those deprived of liberty.
11. Not affiliated with social security.

Date of first enrolment
01/02/2025

Date of final enrolment
31/01/2028

Locations

Countries of recruitment
France

Study participating centre
Pitié Salpetriere Hospital
Respiratory Neurophysiology Laboratory
83 Bd de l'Hopital
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Sponsor information

Organisation
Adoreps

Funder(s)

Funder type
Research organisation

Funder Name
Association pour le Développement et l'Organisation de la Recherche en Pneumologie et sur le Sommeil

Alternative Name(s)
ADOREPS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
France

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be communicated upon reasonable request
bureau@adoreps.fr

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	French version 1.1	13/01/2025	07/03/2025	No	Yes