

Hyperventilation and consciousness

Submission date 06/03/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/03/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/03/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 NOSC. 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 Salpêtrière 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:

Christian Straus: christian.straus@aphp.fr
Marie-Cécile Nierat: marie-cecile.nierat@orange.fr

Contact information

Type(s)

Principal investigator

Contact name

Mr Christian Straus

ORCID ID

<https://orcid.org/0000-0003-1564-0046>

Contact details

47-83 boulevard de l'hôpital
Paris
France
75013
+33 142178578
christian.straus@aphp.fr

Type(s)

Public, Scientific

Contact name

Miss Marie Cécile Niérat

ORCID ID

<https://orcid.org/0000-0001-9370-7301>

Contact details

47-83 boulevard de l'hôpital
Paris
France
75013
+33 142178196
marie-cecile.nierat@orange.fr

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

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

Study design

Open-label parallel-arm randomized experimental study

Primary study design

Interventional

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 Salpêtrière Hospital

Respiratory Neurophysiology Laboratory

83 Bd de l'Hopital

Paris

France

75013

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