

Psychological impact of shortness of breath

Submission date 23/03/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 09/04/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/04/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Dyspnea (shortness of breath) is an unpleasant defining symptom in various diseases including respiratory, cardiac, cancer-related, neuromuscular and psychological disorders, and is highly common in the general population. It is frequently associated with low mood, severe suffering, limited quality of life, high socioeconomic costs and even increased mortality risk. The physical pathways of dyspnea are partly unknown. Inducing dyspnea in healthy subjects in a controlled, laboratory situation (experimental dyspnea) is a common approach to understand the mechanisms of dyspnea and to describe its impact on various bodily functions. Little attention has been paid to the possible unwanted psychological impact of experimental dyspnea in subjects participating in experiments. It is possible that subjects exposed to experimental dyspnea could experience acute suffering that would be out of proportion with the value of the scientific information sought for by the study (therefore questioning the ethical balance of the research). This risk does not seem to have been specifically assessed previously.

The present study aims to test whether healthy volunteers could develop psychological changes related to post-traumatic stress. If this is true, the study also aims to find out whether this situation can be predicted through certain personal characteristics.

Who can participate?

Healthy adult volunteers who already take part in a laboratory-induced dyspnea experiment.

What does the study involve?

Participants will fill in questionnaires just before, and just after the laboratory-induced dyspnea experiment, as well as a structured interview 7 days after the last experiment and an online questionnaire 3 months after the experiment to assess the presence of post-traumatic stress syndrome.

What are the possible benefits and risks of participating?

The protocol is based on the free participation of healthy subjects. The procedure used has no risk to physical health, and the purpose of this study is to determine whether there are possible psychological consequences.

Where is the study run from?

The study will be conducted at the physiopathology respiratory laboratory of the hospital Pitié-Salpêtrière (Paris, France)

When is the study starting and how long is it expected to run for?

Start date : 01/05/2018 for 3 years

Who is funding the study?

There is no funding for this study

Who is the main contact?

Sophie Lavault, PhD

sophie.lavault@aphp.fr

Contact information

Type(s)

Public

Contact name

Miss Sophie Lavault

Contact details

Service de Pneumologie et Réanimation médicale

GH Pitié-Salpêtrière

Paris

France

75013

Additional identifiers

Protocol serial number

PSYCHOPNEA

Study information

Scientific Title

Psychological impact of experimental dyspnea in healthy subjects and its determinants

Acronym

PSYCHOPNEA

Study objectives

Healthy volunteers could develop a post-traumatic stress disorder after experimental dyspnea.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Evaluation ongoing at the CPP Sud-Est III (France), submitted 21/03/2018

Study design

Longitudinal cohort study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Post-traumatic stress disorder induced by dyspnea

Interventions

Current intervention as of 30/12/2021:

Experimental induced dyspnea and questionnaires (mood and psychological aspects)

Observational study :

- duration of participation for a subject : 3 months

- duration of the study : 3 years

- each participant will experiment 2 types of induced dyspnea (2 visits are necessary).

Healthy volunteers who are participating in other studies involving experimental dyspnea (ethical approval already obtained) will complete some questionnaires before and after the experimental dyspnea to assess the psychological dimension of this kind of experimentation.

1 week after the second experiment participants will have structured interview with the psychologist (for qualitative analysis and 3 months after the second experiment participants will have an online questionnaire to assess the presence of post-traumatic stress syndrome.

Previous intervention:

Experimental induced dyspnea and questionnaires (mood and psychological aspects)

Observational study :

- duration of participation for a subject : 1 month

- duration of the study : 3 years

- each participant will experiment 2 types of induced dyspnea (2 visits are necessary).

Healthy volunteers who are participating in other studies involving experimental dyspnea (ethical approval already obtained) will complete some questionnaires before and after the experimental dyspnea to assess the psychological dimension of this kind of experimentation.

(added 30/09/2020)

1 week after the second experiment participants will have a semi-structured interview with the psychologist (for qualitative analysis)

Intervention Type

Other

Primary outcome(s)

Current primary outcome measure as of 30/12/2021:

Presence of post-traumatic stress disorder, assessed with the validated French version of the PCL-5 questionnaire (score >38), 3 months after the experiment

Previous primary outcome measure:

Presence of post-traumatic stress disorder, assessed with the validated French version of the PCL-5 questionnaire (score >38), 4 weeks after the experiment.

Key secondary outcome(s)

1. Change in "state anxiety" (STAI A questionnaire) compared with baseline (online, 1 week and 4 weeks after the experiment)
2. Correlation between score using Peritraumatic Distress Inventory (PDI) and score using PCL-5, 4 weeks after the experiment

(added 30/09/2020)

3. Persistence of a psychological impact (bad memories, negative emotions, nightmares) 7 days after the last experiment using a semi-structured interview

Completion date

14/04/2021

Eligibility

Key inclusion criteria

Aged 18 years or over

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Pregnant
2. Protected adult
3. Person deprived of liberty
4. Existing respiratory pathology
5. Existence of any chronic pathology identified and subject to treatment, including psychiatric disorders
6. Absence of affiliation to social security
7. Vulnerable

Date of first enrolment

01/05/2018

Date of final enrolment

14/03/2021

Locations

Countries of recruitment

France

Study participating centre

Service de Pneumologie et Réanimation médicale, Hôpital Pitié-Salpêtrière

47-83, boulevard de l'hôpital

Paris

France

75013

Sponsor information

Organisation

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

Funder(s)

Funder type

Not defined

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 data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Not expected to be made available