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Psychological impact of shortness of breath

Submission date
23/03/2018

Recruitment status
No longer recruiting

Registration date
09/04/2018

Overall study status
Completed

Last Edited
22/04/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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Contact information

Type(s)
Public

Contact name
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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.

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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

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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes