ISRCTN10029862 https://doi.org/10.1186/ISRCTN10029862

Can hypnosis be used to manage breathlessness and anxiety in people with severe COPD?

Submission date
19/12/2019

Recruitment status
No longer recruiting

Registration date
07/01/2020

Overall study status
Completed

Last Edited
28/02/2023

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Patients with chronic obstructive pulmonary disease (COPD) are prone to asthma-like wheezing, breathlessness, chest tightness and other anxiety-inducing symptoms. Drug treatments for the condition focus on improving these symptoms and preventing exacerbations (short periods where the disease becomes much worse). However, as the disease progresses, the drugs stop working as effectively as previously. Patients with advanced COPD and those who are dying often feel less benefit from the treatment in terms of relief from their symptoms and relief from anxiety about their breathing. This lack of relief can worsen their illness over time. Hypnosis is known to induce immediate changes in how a person thinks and experiences their body. These changes can break vicious cycles of anxiety. Hypnosis has already been used successfully people with breathing problems to reduce anxiety and improve breathing. This trial aims to investigate the effect of hypnosis on breathlessness and anxiety in severe and dying COPD patients.

Who can participate?
Patients who suffer from severe COPD, already admitted at the Bligny Hospital Center (CHB)

What does the study involve?
Each participant will receive a 15-min session of hypnosis and a 15-min session of active listening in a random order. Active listening involves the therapist reading aloud and the participant will be encouraged to pay attention and visualize the images that are being described. Participants will have their anxiety level, breathing rate and blood oxygen level measured before and after each session.

What are the possible benefits and risks of participating?
The risks are minimal because hypnosis poses no real threat or adverse effects to a person's mental or physical health. As long as people accept 15 minutes of 'playing the game', it should make them relax and feel good. The same applies to active listening.

Where is the study run from?
Bligny Hospital Center (France)

When is the study starting and how long is it expected to run for?
September 2017 to January 2020

Who is funding the study?
Bligny Hospital Center (France), Fondation pour les Soins Palliatifs (France) and the Japanese Society for the Promotion of Science (JSPS)

Who is the main contact?
Dr François Larue, head of the Palliatve Care Unit at the CHB, flarue@chbligny.fr

Contact information

Type(s)
Scientific

Contact name
Dr Hernan Anllo

ORCID ID
https://orcid.org/0000-0002-1663-1881

Contact details
Watanabe Cognitive Science Laboratory
School of Fundamental Science and Engineering
Rm 407-1B, 59th Bldg
Waseda University
3-4-1 Ohkubo
Shinjuku
Tokyo
Japan
2110063
+81 7018205004
subcomarc@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2019-A02016-51, NTS 19.07.16.35413.

Study information

Scientific Title

Hypnosis for management of breathlessness and anxiety in severe and palliative-care COPD patients: a sham-controlled crossover trial

Acronym
HYPNOBPCO_1

Study objectives
Hypnosis constitutes a non-drug complementary procedure capable of diminishing subjective feelings of breathlessness and anxiety, while improving patient's awareness and subjective appreciation of their breathing mechanics. We posit that hypnosis will diminish anxiety in severe and terminal COPD patients, improving their breathing and quality of life (QoL).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/11/2019, Comité de Protection des Personnes Ile de France 1 (Hôtel-Dieu-1, Place du Parvis Notre-Dame, 75181, Paris, France; +33 (0)1 42 34 80 52; cpp.iledefrance1@htd.aphp.fr /cppiledefrance1@orange.fr), ref: CPPIDF1-2019-ND75

Study design
Randomized sham-controlled crossover study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Dyspnea (breathlessness) in patients with severe chronic obstructive pulmonary disease (COPD)

Interventions
Treatment: Hypnosis (15-minute script, available on request)
Sham: Active listening session (15-minute script, available on request)

6-week, randomized, sham-controlled, crossover, non-drug interventional study conducted at the Bligny Hospital Center in Briis-sous-Forges, France. Patients underwent two 15-minute individual interventions, hypnosis (A) and sham (B), in randomly assigned order (AB or BA), with a 24-h washout period between sessions.

20 COPD patients (mean FEV1/FVC <0.7) underwent two 15-minute individual sessions, Active Listening and Hypnosis, in the form of a crossover trial with a 24-h washout period. A total of 4 pairs of investigators (medical practitioners specialized in pneumonology and/or palliative care, trained in hypnotherapy) are charged with administering both sessions and obtaining patient data. Session order and assignment of investigator pair (Mp1, Mp2, Mp3 or Mp4) are counterbalanced across patients, so that in a random fashion:
1. Approximately half of the sample goes through Active Listening first and Hypnosis second, and approximately the other half goes through Hypnosis first and Active Listening second.
2. Each pair of experimenters is in charge of testing at least one patient belonging to the first

half, and one patient belonging to the second half.
3. No prior clinical relationship shall exist between patients and medical practitioners.

Intervention Type
Behavioural

Primary outcome(s)
Anxiety assessed using the STAI-6 questionnaire at baseline and immediately after intervention

Key secondary outcome(s))
1. Respiratory rate in cycles/min measured manually, following the accepted standard procedure, at baseline and immediately after intervention
2. Oxygen saturation (SpO2) measured with a pulse oximeter at baseline and immediately after intervention

Completion date
20/02/2020

Eligibility

Key inclusion criteria
1. Aged 35-80 years
2. Affiliated to a Social Security scheme or beneficiary of such a scheme
3. Absence of neurological disease interfering with the passing of tests
4. Capable of giving free, informed consent.
5. Severe COPD with dyspnea and distension
6. Hospitalized, with or without a tracheotomy
7. Non-obese
8. Predicted FEV1 <60% and FEV/FVC <70%, with distension evidenced by chest x-ray or predicted TLC >120% in pulmonary function tests
9. Severity marked by ongoing hospitalization, with at least one prior instance of decompensation
10. Dyspneic, with resting Borg Scale score ≥3
11. Not having yet participated in the complementary care protocol offered by the hospital, a pulmonary rehabilitation program (PRP) protocol, or any hypnosis protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
21

Key exclusion criteria
1. Pregnancy
2. Mechanical ventilation during the session
3. Known severe cardiac insufficiency
4. Known severe pulmonary arterial hypertension
5. Cancer diagnosis
6. Significant cognitive impairment, hypercapnic encephalopathy or confusional syndrome
7. Deafness
8. Anemia (hemoglobin ≤8 g/dl)
9. Psychotic pathology
10. Anti-epileptic treatment

Date of first enrolment
10/12/2019

Date of final enrolment
18/02/2020

Locations

Countries of recruitment
France

Study participating centre
Bligny Hospital Center
Rue de Bligny
Briis-sous-Forges
Paris
France
91640

Sponsor information

Organisation
Bligny Hospital Center

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Centre Hospitalier de Bligny

Funder Name
Japanese Society for the Promotion of Science (JSPS)

Funder Name
Fond pour les Soins Palliatifs

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be made public alongside the results publication.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2020	23/10/2020	Yes	No
Protocol article		07/02/2022	28/02/2023	Yes	No
Participant information sheet	version v2	19/06/2019	07/01/2020	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes