ISRCTN48274234 https://doi.org/10.1186/ISRCTN48274234

Is it possible to have a chronic obstructive pulmonary disease (COPD) specific breathlessness service in the Netherlands?

Submission date
01/11/2021

Recruitment status
No longer recruiting

Registration date
06/11/2021

Overall study status
Completed

Last Edited
05/11/2021

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease, or COPD, refers to a group of diseases that cause airflow blockage and breathing-related problems. Refractory (treatment resistant) breathlessness is a devastating symptom in COPD. Breathlessness services (BS), usually collaborations of palliative and respiratory teams, offer a multidisciplinary approach. In the Netherlands, few palliative care teams work in an outpatient setting, and BS do not exist.
The study involves training for people with COPD (chronic obstructive lung disease). The aim is to develop training for patients who are troubled by breathlessness. The training cannot take away the breathlessness but should help patients cope with the symptom.

Who can participate?
Patients with COPD and refractory breathlessness.

What does the study involve?
Participants attended at least two sessions with a pulmonologist and a respiratory nurse and one session with a physiotherapist who practiced the breathing techniques with them. The toolkit that was given to patients consisted of a booklet with breathing exercises and a hand-held fan. There was not a set number of sessions.

What are the possible benefits and risks of participating?
Benefits: patients who participate might improve their coping skills regarding breathlessness. They also help us set up training that is appropriate for patients. There are no risks in participating; however, the intervention takes up some of the participants' time

Where is the study run from?
Spaarne Gasthuis (Netherlands)

When is the study starting and how long is it expected to run for?
April 2019 to November 2020

Who is funding the study?
Spaarne Gasthuis (Netherlands)

Who is the main contact?
Kris Mooren, k.mooren@spaarnegasthuis.nl

Contact information

Type(s)
Scientific

Contact name
Mrs Kris Mooren

ORCID ID
https://orcid.org/0000-0001-7815-0488

Contact details
Spaarne Gasthuis
Boerhaavelaan 22
Haarlem
Netherlands
2035 RC
+31232245969
k.mooren@spaarnegasthuis.nl

Additional identifiers

Study information

Scientific Title
Testing the waters for a COPD-specific breathlessness service in the Netherlands: a feasibility study

Study objectives
Our primary aim was to demonstrate the feasibility of setting up a BS specifically for COPD patients, with the view of undertaking a randomized controlled clinical trial to test the effectiveness of this BS on breathlessness mastery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/08/2019, Medical Ethics Review Committee of the Amsterdam University Medical Centre (Medisch Ethische Toetsingscommissie VUmc, Van der Boechorststraat 7, kamer H-443, Postbus 7057
1007 MB Amsterdam, Netherlands; +31 20 444 5585; no email provided), ref: 2019.199

Primary study design

Interventional

Study design
Non-randomized single-center feasibility study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Improvement of quality of life in COPD patients with refractory dyspnea

Interventions
For this study, the authors were trained by the Cambridge Breathlessness Intervention Service (CBIS). Their Breathing Thinking Functioning model (BTF) was translated into a Dutch toolkit (Ademen Denken Doen, ADD) with full consent of, and in collaboration with, the Cambridge team. The content of the Dutch intervention is similar to the original. However, the service in Cambridge is delivered by occupational therapists, physiotherapists and a consultant in palliative medicine, whereas the Dutch service is delivered by a pulmonologist, a respiratory nurse and a physiotherapist.

The model helps the patients to understand the vicious circles that influence breathlessness. A well-known example is the dyspnea-anxiety-dyspnea cycle: patients have catastrophic thoughts (I need oxygen, I am going to suffocate) (thinking domain), leading to shallow, exhausting ‘dead space’ breathing (breathing domain), leading to worsening of the symptom that can spiral into a panic attack. These episodes of breathlessness can lead to avoidance of exercise (functioning domain), in turn causing deconditioning that worsens the symptom.

ADD was set up as a brief intervention: patients had at least two sessions with a pulmonologist and a respiratory nurse, and one session with a physiotherapist who practiced the breathing techniques with them. The toolkit that was given to patients consisted of a booklet with breathing exercises and a hand-held fan. If necessary, extra sessions were scheduled. Since we had no experience with giving the intervention in this setting and specifically for COPD patients, we decided not to fix the number of sessions. However, the average number of sessions for a future randomized multicenter controlled clinical trial shall be derived from this feasibility study.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcome: number of patients completing the intervention measured using patient records at the end of the study

Key secondary outcome(s)
1. Respiratory problems measured using a Dutch translation of the Chronic Respiratory Questionnaire (CRQ), subset mastery domain at baseline and final visit
2. Pulmonary function tests were taken from the patient’s medical file at baseline
3. Patient and professional satisfaction measured using a postal survey with multiple choice questions after the final visit

Completion date
01/11/2020

Eligibility

Key inclusion criteria
Patients with COPD (diagnosed by a pulmonologist, post-bronchodilatator FEV1/FVC below the lower limit of normal) were eligible for the study if they experienced refractory dyspnea (troubled by breathlessness despite optimization of COPD treatment) and were able to visit the outpatient clinic.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
19

Key exclusion criteria
1. Terminal phase
2. Cognitive impairment
3. Unable to speak Dutch

Date of first enrolment
01/10/2019

Date of final enrolment
01/11/2020

Locations

Countries of recruitment
Netherlands

Study participating centre
Spaarne Gasthuis
Boerhaavelaan 22
Haarlem
Netherlands
2035RC

Sponsor information

Organisation
Spaarne Gasthuis

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Spaarne Gasthuis

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (k.mooren@spaarnegasthuis.nl)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 4	01/08/2019	05/11/2021	No	No