Introduction of a Dyspnea Service in the Netherlands

Published: 09-08-2019
Last updated: 10-04-2024

Primary objective:to assess feasibility of ADD. Pre-defined criteria for feasibility is: 75 percent of included patients complete the intervention.Secondary objectives:1. To describe the components and practical aspects of ADD. These will be...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON48131

Source
ToetsingOnline

Brief title
Introduction of a Dyspnea Service in the Netherlands

Condition

- Bronchial disorders (excl neoplasms)

Synonym
COPD

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Gasthuis
Source(s) of monetary or material Support: Eigen ziekenhuis (Spaarne Gasthuis)

Intervention

Keyword: COPD, dyspnea

Outcome measures

Primary outcome

Main feasibility criteria:

1. 75% of included patients complete the intervention.

Secondary outcome

1. Description of components and practical aspects of ADD.

2. semi-structured interviews with patients and carers to evaluate ADD after

six weeks.

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is a progressive disease causing about 7000 deaths in the Netherlands each year, thereby being the fourth leading cause of death
(1). Studies have shown a high symptom burden in patients with end-stage COPD, at least similar to patients with incurable lung cancer (2). The main symptom is dyspnea, or breathlessness, which increases as disease progresses. It often results in emergency hospital admissions, which results in a high burden of disease on both patient, relatives and the health care system. Patients with COPD who experience refractory symptoms may be referred to a tertiary rehabilitation centre, where adequate patient education is provided including help with breathlessness, in an inpatient setting. However, patients with advanced respiratory failure are not always eligible for such programmes due to their instability, or they do not wish to be away from home for such a long period of time. Those patients are mostly dependent on their physiotherapist for breathlessness management. However, dyspnea is a complex symptom with cognitive and behavioural aspects. Most physiotherapists are not trained to address breathlessness in its full complexity.
In recent years, Booth and Spathis have developed the breathing-thinking-functioning model (BTF), which conceptualizes the three cognitive and behavioural reactions to dyspnea (3).

Breathing domain: Dyspnea causes dysfunctional breathing patterns with an increased respiratory rate and use of accessory muscles, leading to inefficient (dead space) ventilation. Furthermore, Patients with COPD who feel breathless tend to focus on the in-breath instead of on the out-breath.This promotes dynamic hyperinflation which increases the breathlessness and the work of breathing.
Thinking domain: misconceptions such as *I will suffocate*, but also memories of earlier episodes of dyspnea, lead to anxiety and distress in many patients. This leads to tachypnea which increases dyspnea.
Functioning domain: Many breathless patients avoid physical activity. This leads to both isolation and deconditioning, which supports the vicious circle of dyspnea.

The intervention that will be investigated in this study is called Ademen Denken Doen (ADD). ADD is a Dutch version of BTF, adjusted to the health care situation in the Netherlands. There are two noteworthy differences between ADD and breathlessness services that have previously been investigated in other countries (mostly the UK and Germany) (6,7,8,9,10):
The first difference concerns participating health care professionals.
In existing breathlessness services, palliative care teams have a leading role, including occupational therapists. The Dutch situation is different since in most hospitals, palliative care is only available as an inpatient service. In the Netherlands, respiratory nurses and physiotherapists play an important role in supporting patients with COPD. Therefore, for this study we will set up an ADD training for respiratory nurses and physiotherapists. If this pilot study is successful (see chapter 2 for objectives), we aim to make the intervention applicable to physiotherapists and respiratory nurses outside our own hospital.
The second difference between existing dyspnea services and ADD concerns the targeted population. ADD is set up primarily for patients with COPD. Existing dyspnea services are not disease-orientated but symptom-orientated, and treat all patients with refractory dyspnea. The main reason for our focus on COPD is that ADD is set up by a pulmonology department instead of a palliative care team. The majority of dyspnoic patients that we see suffer from COPD. As mentioned before, this is a large patient category with a high burden of disease who frequently have unmet needs, which justifies our choice to focus on COPD for this pilot. Furthermore, the etiology of dyspnea is different in COPD from dyspnea in heart failure, cancer or pulmonary fibrosis. COPD leads to dynamic hyperinflation, which is worsened by rapid shallow breathing * a pattern of breathing promoted by anxiety (11). Anxiety is highly prevalent in COPD (12), probably due to its unpredictable course and due to the dyspnea itself. Many patients with COPD report fear of suffocation. Both the dysfunctional breathing pattern and the irrational fears elicited by breathlessness, are key elements of BTF/ADD. We therefore assume that specifically patients with COPD have even more to gain from ADD than patients with other casues of dyspnea. Nevertheless, if this intervention is successful, in the future the service should be made available to other patient groups.

Study objective

Primary objective:
to assess feasibility of ADD. Pre-defined criteria for feasibility is: 75 percent of included patients complete the intervention.

Secondary objectives:
1. To describe the components and practical aspects of ADD. These will be described in each patients CRF. Off note, ADD is an intervention that is different for each patient: depending on the most important component for them (breathing/thinking/functioning) and how many sessions they need to learn to control their breathlessness. Therefore we describe the number of sessions in each CRF.
2. To evaluate patiens* experiences with ADD, assessed with semi-structured interviews with patients and carers after 6 weeks.

Study design

The intervention will be delivered by a multidisciplinary team, formed by a pulmonologist, a physiotherapist with expertise in COPD, and 3 respiratory nurses.
Prior to start of the study, physiotherapist and respiratory nurses receive ADD training by pulmonologist, who has received an BTF training in Cambridge.
Step 1: All pulmonologists, residents and respiratory nurses of the Spaarne Gasthuis recruit patients with COPD with refractory breathlessness who fullfill the inclusion critera (see chapter 4).
Step 2: Patients who are eligible are given an information letter by the recruiting health care professional. Within 1 to 7 days, they receive a call from a member of the ADD team, asking if they have any questions concerning the study and whether they want to participate.
Step 3: Assessment for eligibility by pulmonologist (if not eligible, this is noted in case record form); first appointment within one week.
Step 4: First appointment (approximately 1.5 hrs). Patient comes with key (informal) carer.
- Explanation of ADD by pulmonologist and nurse.
- Patient signs informed consent form
- Aided by nurse, patient fills in the CRQ
- Informal caregiver gives NRS rating for distress due to patient*s breathlessness
- Patient meets physiotherapist
- Current medication is reviewed by pulmonologist. Medication for symptom control is optimised if necessary (e.g., morphine for dyspnea).
- Patient receives ADD booklet with breathing exercises and relaxation exercises and a handheld fan
Step 5: At the end of the first appointment, the customized intervention program is made together with the patient.

1. All patients will have at least one session with the physiotherapist. The maximum number of sessions is six (once every week).
2. All patients will have weekly contact with the respiratory nurse; at least two times in the hospital (combined with physiotherapist), other contacts may be by telephone. If it is too burdensome for patients to come to the hospital, they will receive a home visit. During these contacts, the nurse will go through the given information again, coach the patient, and assess whether the intervention is helpful for the patient.
3. Patients will receive a handheld fan and a leaflet with instructions for relaxation and breathing techniques. The use of those techniques and the handheld fan will be practiced with the nurse and the physiotherapist.
Step 6: After the six week study period, patient comes for the final visit together with informal caregiver.
- Aided by nurse, patient fills in the CRQ
- Informal caregiver gives NRS rating for distress due to patient*s breathlessness
- Member of ADD team conducts a semi-structured interview with both patient and informal caregiver to explore their experiences with ADD.
Step 7: After the last patient has fulfilled the intervention, the ADD team undergoes a structured interview regarding the intervention.

Intervention

See under Study design.

Study burden and risks

The only burden for participants will be the hospital visits. However, these visits will be minimised as much as possible by combining them with other hospital visits where possible. If visiting the hospital is too burdensome, home visits will be arranged.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- COPD, diagnosed by a pulmonologist, with postbronchodilatator FEV1/FVC below the lower limit of normal
- refractory dyspnea (troubled by breathlessness in spite of optimization of COPD treatment, MRC dyspnea score at least 2 points).
- able to visit the outpatient clinic
- able to read and understand the Dutch language
- mentally competent, as assessed by recruiting health care professional

Exclusion criteria

- An acute exacerbation of COPD, leading to hospitalisation, in 6 weeks before inclusion.
- An acute exacerbation during the study period, will lead to exclusion with the possibility to re-enter after stabilization. In that case, patients will follow the same study procedures again.
- Active participation in another trial

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2019
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-08-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL69647.029.19