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Efficacy of a minimal home-based psychoeducative intervention versus usual care for managing anxiety and dyspnoea in patients with severe chronic obstructive pulmonary disease: a randomised controlled trial protocol

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ABSTRACT

Introduction: In its final stages, chronic obstructive pulmonary disease is a severely disabling condition that is characterised by dyspnoea, which causes substantial anxiety. Anxiety is associated with an impaired quality of life and increased hospital admissions. Untreated comorbid anxiety can have devastating consequences for both patients and their relatives. Non-pharmacological interventions, including cognitive–behavioural therapy, have been effective in managing anxiety and dyspnoea in patients with chronic obstructive pulmonary disease. However, the majority of existing interventions have tested the efficacy of relatively intensive comprehensive programmes and primarily targeted patients who have moderate pulmonary disease. We present the rationale and design for a trial that focused on addressing the challenges experienced by severe pulmonary disease populations. The trial investigates the efficacy of a minimal home-based psychoeducative intervention versus usual care for patients with severe chronic obstructive pulmonary disease.

Methods and analysis: The trial is a randomised controlled trial with a 4-week and 3-month follow-up. 66 patients with severe chronic obstructive pulmonary disease and associated anxiety will be randomised 1:1 to either an intervention or control group. The intervention consists of a single psychoeducative session in the patient's home in combination with a telephone booster session. The intervention is based on a manual, with a theoretical foundation in cognitive–behavioural therapy and psychoeducation. The primary outcome is patient-reported anxiety as assessed by the Hospital and Anxiety and Depression Scale (HADS).

Ethics and dissemination: This trial complies with the latest Declaration of Helsinki, and The Ethics Committee of the Capital Region of Denmark (number H-1-2013-092) was queried for ethical approval. Trial results will be disseminated in peer-reviewed publications and presented at scientific conferences.

Trial registration number: NCT02366390.

Strengths and limitations of this study

- The trial addresses an under-researched area and is the first to test the effect of a minimal home-based psychoeducative intervention for managing anxiety and dyspnoea in patients with severe chronic obstructive pulmonary disease.
- It is designed to give nurses and other health professionals an instrument that is clinically applicable to providing care for patients with severe chronic obstructive pulmonary disease and accounts for challenges that are characteristic of patients with severe pulmonary disease.
- We are aware of the risk of selection bias because patients with a high level of anxiety and/or advanced lung disease are less likely to participate than patients less affected by their disease. We will account for this bias risk during recruitment and in data analysis.

BACKGROUND

Chronic obstructive pulmonary disease (COPD) is currently the fifth leading cause of death worldwide. In the last stages of the disease, COPD is a severely disabling condition in which the disease trajectory is characterised by a gradual decline in health status punctuated by acute exacerbations that can be life-threatening and are associated with an increased risk of dying.[1–3] In patients with severe COPD, anxiety and dyspnoea are the primary symptoms that have a high impact

on patients' quality of life and use of social services.[4–7] To date, no longitudinal studies have examined the incidence of anxiety disorders in patients with COPD; however, the prevalence is estimated to range between 10% and 58%.[5 8 9] Anxiety can be manifested as acute anxiety and panic attacks that are related to acute exacerbations, or as a continuous state of anxiety related to the future, death, loss of control and reliance on others.[10–12] Accordingly, worsening dyspnoea is often interpreted as a feeling of suffocating and imminent death, which leads to acute and latent anxiety. Patients become anxious about becoming breathless and avoid exertions that may trigger unpleasant symptoms. This increase in sedentary behaviour leads to physical deconditioning, thereby compounding dyspnoea as well as reducing confidence and the feeling of being in control, which collectively exacerbate a vicious circle.[13–15]

Anxiety is a significant predictor of the frequency of hospital admissions and readmissions for acute COPD exacerbations. As such, untreated comorbid anxiety can have devastating consequences by overwhelming the coping strategies of patients with COPD and their informal caregivers, and increasing healthcare utilisation.[15 16] Despite the recommendation that health professionals should address anxiety in patients with COPD, this rarely occurs in practice.[17 18] Anxiety management can be divided into pharmacological and non-pharmacological approaches. The available evidence for pharmacological treatment, specifically selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs) or azapirones, is inconclusive and associated with side effects, especially in the elderly where polypharmacy or treatment refusal is common.[19] This emphasises the relevance of focusing on non-pharmacological and unharmful interventions for managing anxiety and dyspnoea in patients with COPD.

Non-pharmacological treatment approaches

Pulmonic rehabilitation (PR) has been shown to be effective for reducing levels of anxiety and dyspnoea of patients with COPD and increasing their quality of life. PR consists of physical exercise that is often in combination with patient education and breathing exercises.[11 20] A few studies have investigated the adjuvant effect of adding educational interventions to exercise training, compared to exercise training alone, and found no adjuvant effect.[21 22] However, one Cochrane review found that breathing exercises for patients with COPD had a positive effect on exercise capacity, but there were inconsistent results for effects on dyspnoea and Health-Related Quality of life (HRQL).[23] Another Cochrane review found that educational programmes are associated with improved quality of life and reduced subsequent hospitalisations in patients with COPD.[24 25] Both PR and educational interventions are characterised as being complex and resource intensive, as they consist of several weekly sessions that are 1–3 h in duration and require attendance at a hospital, which leads to low adherence and high dropout rates among patients with severe illnesses. A systematic review found that 8–50% of the patients offered PR did not attend and 10–32% of the enrolled patients dropped out. Travel and transport were consistently identified as barriers to uptake and completion.[26]

Cognitive–behavioural therapy (CBT), including psychoeducative initiatives, has been shown to be effective in treating anxiety and has demonstrated effectiveness for older adults[27] and adults with COPD.[28–31] However, most studies are based on group sessions that require attendance at a treatment centre.[28 29 32] These requirements are difficult for patients with severe COPD to comply with in real life and in research settings. This causes a lack of knowledge and a request for interventions that meet the needs of patients with severe COPD, who do not want or do not have the resources to transport themselves to a treatment centre or to participate in group sessions.

Although most CBT-based interventions consist of several sessions that are scheduled over a longer period of time, Kunik *et al*[32] showed that one session of group CBT with six telephone follow-ups reduced anxiety and depression in elderly patients with COPD. Similarly, Lamers *et al*[33] found that a minimal nurse-led CBT-based intervention reduced anxiety symptoms and improved HRQL in elderly people with COPD. In an ongoing trial, Heslop *et al* are investigating the effectiveness of a nurse-initiated CBT intervention for anxiety in patients at all stages of COPD. The intervention consists of 2–6 sessions of therapy, and the primary outcome is anxiety as assessed by Hospital and Anxiety and Depression Scale anxiety (HADS-A).[34]

Despite the lack of studies that test the effects of a single face-to-face CBT session, we believe that it is plausible that patients with severe COPD can benefit from a minimal home-based psychoeducative intervention. Bourbeau *et al*[35] showed that patients with COPD with a high disease burden can be taught self-management skills in the event of exacerbations leading to fewer healthcare visits and hospital admissions. By introducing the intervention in the patient's home environment, we believe that we facilitate knowledge transfer and enhance the probability of the patient finding the intervention usable. By teaching patients valuable and enduring skills to cope with their dyspnoea and anxiety, we hope to ensure a lasting effect that extends beyond treatment completion. However, there is a lack of knowledge about the minimal duration of psychoeducation that is required to achieve beneficial outcomes for managing anxiety and dyspnoea in patients with severe COPD.

OBJECTIVES

This trial's primary objective is to investigate the efficacy of a minimal home-based psychoeducative intervention versus usual care for patients with severe COPD.

The primary hypothesis is that the intervention reduces anxiety as assessed by the HADS by 1.5 points from baseline to the final follow-up at 3 months

post-treatment, in the intervention group compared to the control group. The estimated decrease in HADS is based on a study that examines the HADS minimally important difference in patients with COPD.[36]

The secondary hypothesis is that the intervention increases dyspnoea mastery as assessed by the Chronic Respiratory Disease Questionnaire (CRQ-M) by 0.5 points. The estimated increase in mastery as assessed by the CRQ-M is based on a systematic review of the CRQ's measurement properties and interpretability.[37]

Additional secondary hypotheses are that the HRQL, which is measured by the St. George's Respiratory Questionnaire (SGRQ), improves by 4 points; depression scores as measured by the HADS-D decrease by 1.5 points; and the number of readmissions and length of stay (LOS) decrease in the intervention group compared to the control group. The estimated improvement on the SGRQ scale is based on a methods article by Jones[38] that discusses the thresholds for clinically significant changes on the SGRQ scale. The estimated change on the depression subscale on the HADS (HADS-D) is based on a retrospective analysis that examined if PR results in a clinically meaningful improvement in anxiety and depression on the HADS in patients with COPD.[39] The questionnaires (HADS, CRQ, SGRQ) were chosen because of their psychometric properties and because they are widely used in COPD and anxiety research.

METHODS

The study is a single-centre clinical randomised controlled trial (RCT) with randomisation to either a minimal home-based psychoeducative intervention or usual care. This trial is part of a PhD project (DIACOL) that contributes to evidence-based knowledge about palliation of patients with severe COPD.

Study population and eligibility criteria

Patients with a confirmed COPD diagnosis, who were classified as category C or D according to the Global Initiative for Obstructive Lung Disease (GOLD),[18] had an HADS-A subscale score of ≥8 and were willing to participate and able to provide written consent, were eligible for participation. Exclusion criteria were patients with HADS-A subscale score of <8, a psychiatric diagnosis, pulmonary cancer or involvement in a different interventional clinical trial. A preliminary diagram that shows the participant's flow through each stage of the randomised trial is illustrated in figure 1.

Experimental intervention

The intervention consists of a minimal psychoeducative intervention that is delivered in the patient's home and is followed by a telephone booster session.

Home-based psychoeducative intervention

The goal of the psychoeducative intervention is that patients learn to interpret and react to physical and psychological symptoms that are related to dyspnoea and associated anxiety. The intervention is theoretically based on a patient-centred approach and a holistic view of the patient that focuses on handling of life with COPD, including managing anxiety and dyspnoea.[40] The intervention has a planned duration of approximately 1 h, and occurs in the patient's home with or without the presence of a spouse and/or informal caregiver. The primary investigator (PI), who is a trained nurse, is responsible for delivering the psychoeducative intervention. To ensure that the intervention is transparent and can be replicated, it is based on a manual that was inspired by CBT as described by Aaron Beck.[41–43] The intervention is based on the cognitive model, which is illustrated as a negative (figure 2) and positive (figure 3) circle. This model illustrates the interaction between thoughts, emotions, bodily sensations and behaviours; therefore, it is suitable for examining anxiety-related situations. The purpose is to help and guide the patient to restructure unfavourable thoughts and behaviour patterns that are related to dyspnoea, thereby changing interpretations of critical situations, as exemplified in figures 2 and 3. The dialogue is based on Socratic questioning, in which the PI is curious and asks open-ended questions about the patients' interpretations of dyspnoea and anxiety situations. The PI explores the patient's feelings, cognitions, behaviours and bodily sensations in relation to situations with dyspnoea by asking questions that include: try to describe what you think when you experience breathlessness? This is followed by questions such as which emotions did that trigger? What happened in your body and what did that make you feel? Is it possible that you could interpret it in a different way? The purpose of this approach is to challenge the way that patients interpret situations which should help to change inappropriate patterns of thoughts, behaviours, emotions and bodily sensations (ie, cognitive restructuring). To enhance the patient's management of dyspnoea in acute and stable phases of the illness, breathing strategies were included in the psychoeducative intervention. The breathing strategies consisted of two techniques: pursed lip and diaphragmatic breathing (figure 4). Patients are encouraged to practise these techniques twice a day.

Telephone booster session

Two weeks after the home-based psychoeducative session was delivered, the patient was contacted by telephone. The telephone follow-up is a booster session, which has been shown to be effective in CBT treatment.[44 45] The 2-week time interval is based on a pragmatic assumption that patients will have the intervention fresh in mind and, at the same time, have additional experiences to share. The purpose of the booster session is to repeat and refresh elements from the intervention and reinforce progress that has been made. The PI begins the session by asking how the patient has been and moves on to inquire about the patient's experiences using the cognitive model and

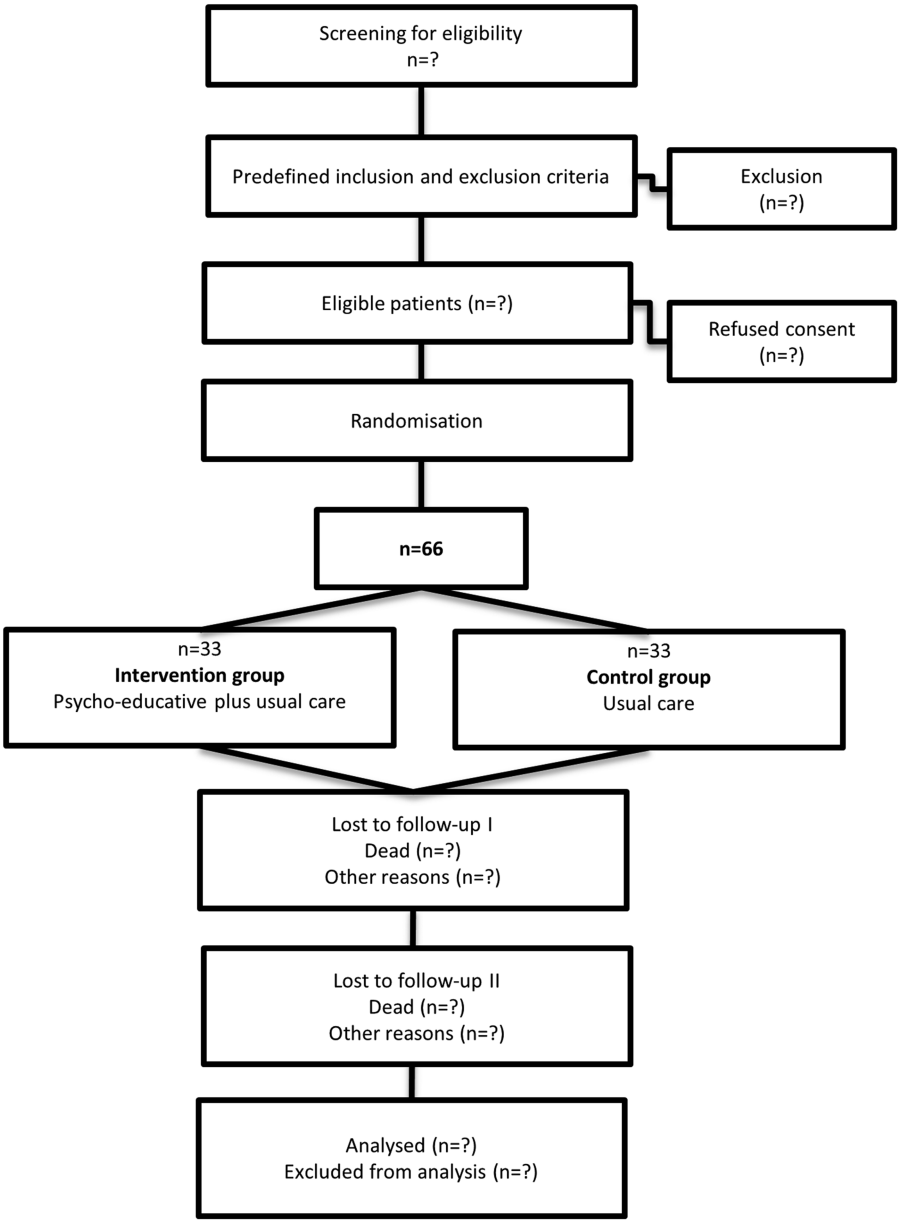


Figure 1 Flow chart.

breathing strategies, which include restructuring dysfunctional assumptions and strategies. Any problems are addressed and discussed in relation to how the patient can manage their dyspnoea and anxiety in the future. The telephone booster session has a planned duration of 15 min. The PI records the telephone booster session duration.

Pilot test

The intervention was pilot tested in February 2015 with three patients. The primary focus of the pilot was to test whether the intervention could be conducted in its current form or if adjustment were required. Tests and subsequent adjustments of the intervention were conducted under supervision of a trained psychologist (JM). The pilot test resulted in minor amendments.

Usual care

Participants in the intervention and control groups received usual care according to current guidelines. PR is an integrated part of usual care in Denmark and was available to all participants, including patients in the control group. Pulmonary Rehabilitation extends across 10 weeks and includes physical training combined with patient education. All sessions are group based and have a mean weekly duration of 1.5 h. Moreover, patients in intervention and control groups are seen by a physician in the Pulmonary Outpatient Clinic as part of their usual annual controls. One or 2 months after this control visit, patients are seen by a respiratory nurse, either in the Pulmonary Outpatient Clinic or at a home visit. Topics such as advanced care planning, quality of life and mastery of everyday life with severe COPD are discussed during the respiratory nurse consultation.

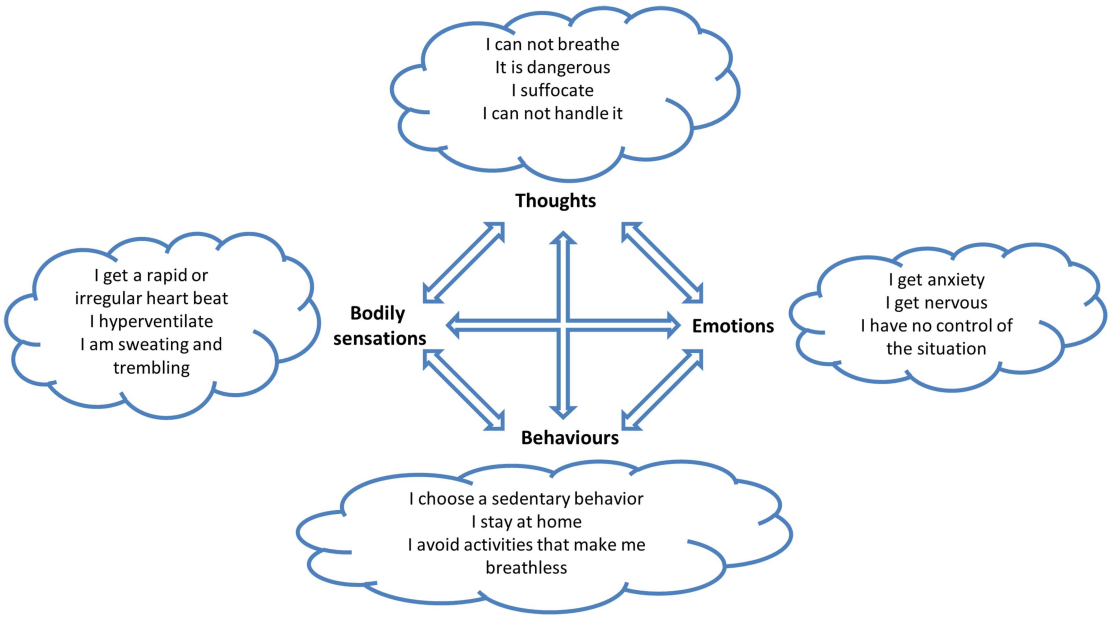


Figure 2 Cognitive model, negative circle.

The nurse consultation has a duration of approximately 1 h. All patients have the opportunity to call a nurse at the Pulmonary Outpatient Clinic and discuss disease-related issues on weekdays, just as they can be seen by a pulmonary physician ad hoc. The way that the outpatient pulmonary care is organised is inspired by palliative care recommendations and advanced care planning for patients with severe COPD or pulmonary cancer.[46–48] To assess outcomes, patients in the control group completed the same questionnaires as did participants in the intervention group. Participation and adherence to pulmonary rehabilitation was recorded for all participants at baseline and follow-up.

Outcomes and data collection

To evaluate the efficacy of the intervention, numerous data will be collected (table 1).

Primary outcome measures

The primary outcome is anxiety measured by HADS-A. The HADS was constructed by Zigmond and Snaith in 1983[49] as a self-completed questionnaire and a quick way to measure general anxiety and depression symptoms in patients in non-psychiatric clinics. Anxiety (HADS-A) and depression (HADS-D) are assessed as separate components, each with seven items that are rated on a four-point scale: 0 (not present) to 3

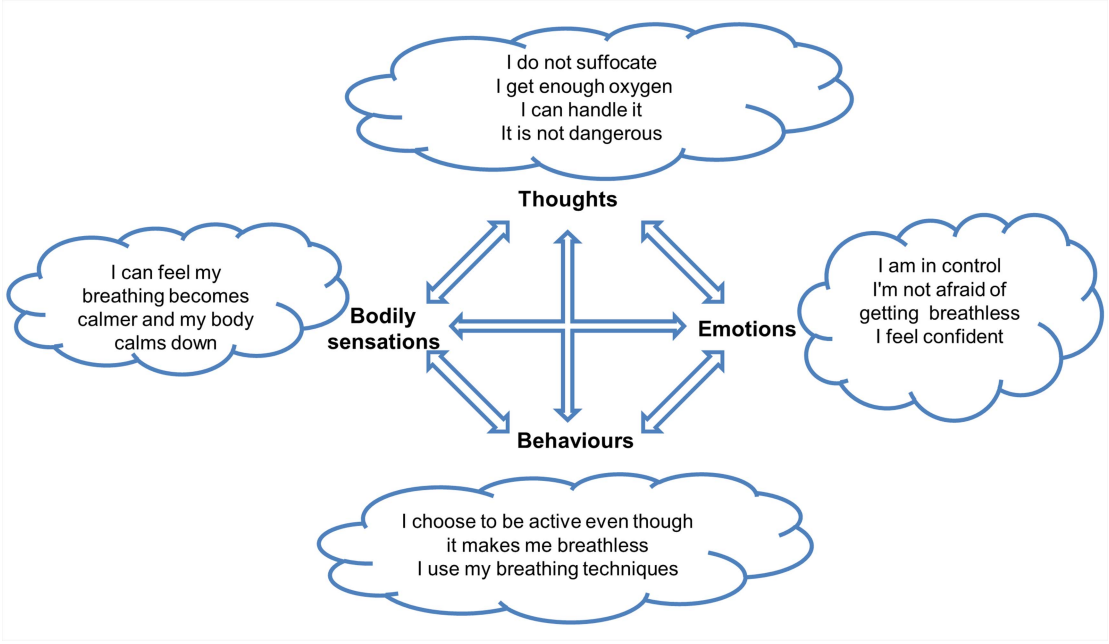
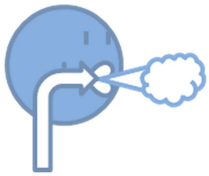


Figure 3 Cognitive model, positive circle.



Pursed lip breathing
Breathe in (inhale) slowly through your nose for two counts, keeping your mouth closed. Don't take a deep breath; a normal breath will do. Count to yourself: one, two. Purse your lips as if you were going to whistle or blow out a candle. Breathe out (exhale) slowly and gently through your pursed lips while counting to four. It may help to count to your self: one, two three, four.

Diaphragmatic Breathing
Place one hand on your chest and the other on your abdomen. Inhale through your nose for about two seconds. As you breathe in, your belly should move outward. Your abdomen should move more than your chest. As you breathe out slowly through pursed-lips, gently press your belly. This will push on your diaphragm to help your air out. Feel how your abdomen returns to its normal size.

Figure 4 Breathing techniques.

(significant symptoms). The scores range from 0 to 21 for anxiety and from 0 to 21 for depression. Higher scores indicate more severe symptoms. A cut-off point for the HADS-A subscale or the HADS-D subscale of ≥8 indicates clinically significant anxiety or depression,[49 50] with a specificity and sensitivity range between 0.70 and 0.90 for both scales. The HADS has been validated in patients with COPD[51] and in a Scandinavian population.[52] A Danish version is available from the Mapi Research Trust.

Secondary outcomes

Secondary outcomes include mastery of dyspnoea, HRQL and depression. The CRQ subscale for mastery (CRQ-M) measures mastery of dyspnoea; the SGRQ measures HRQL; and the depression subscale from the HADS (HADS-D) measures depression. The original version of the CRQ was developed in 1987 by Guyatt *et al*[53] as an interviewer administered instrument (CRQ-IA) that measured HRQL in chronic respiratory disease. The CRQ has subsequently been developed and is currently available as a self-administered and standardised questionnaire (CRQ-SAS). We use the self-administered standardised (CRQ-SAS), instead of the individualised and interviewer-administered CRQ (CRQ-IA), due to the ease and cost of administration. The CRQ-SAS is available in Danish through the Mapi Research Institute. The CRQ-SAS consists of 20 items across four dimensions: dyspnoea (5 items), fatigue (4 items), emotions (7 items) and mastery (4 items). Each question is rated on a seven-point scale, ranging from 1 to 7. Lower scores indicate greater impairment. The SGRQ was developed by Jones in 1992[54] as a disease-specific instrument to measure impacts on overall health, daily life and perceived well-being in patients with obstructive airway disease, which is also described as HRQL. The questionnaire has 50 items and is divided into three domains: a symptom score that measures the frequency and severity of respiratory symptoms; an activity score that measures activities that are limited by breathlessness; and an impact score that measures aspects of social functioning and psychosocial disturbances that are caused by airway disease. Scores range from 0 to 100 for each domain, and a high score reflects decreased HRQL. The HADS-D is described in the primary outcome section. Additional secondary outcomes are the numbers of admissions and the LOS during the follow-up period.

Exploratory variables

Demographic and clinical data are collected from the patients' record: marital status, residence in a nursing home, social service utilisation, medicine, oxygen treatment, forced expiratory volume in 1 s, Medical Research Council, body mass index and smoking status.

The following retrospective data are recorded for the previous 12 months: number of admissions; number of periods treated with NIV; number of and LOS in an intensive care unit; number of emergency calls; number of contacts with the Danish prehospitalisation emergency services (1813); participation in a rehabilitation programme; number of dialogues with a respiratory nurse; and public appropriation for terminal care.

Table 1 Exploratory characteristics for post hoc analysis

Characteristics	Time of administration	Type of quantity
Demographic		
Age, height, weight	Baseline	Continuous
Marital, educational, occupational status, nursing home	Baseline	Categorical
Use of social services, smoking	Baseline	Binary (Y/N)
Clinical and paraclinical		
FEV_1	Baseline	Continuous
MRC, BMI, CAT	Baseline	Categorical/ordinal
Oxygen treatment	Baseline	Binary (Y/N)
Days treated with NIV within 12 month	Baseline	Continuous
Days in intensive care within 12 month	Baseline	Continuous
Number of admissions within 12 month	Baseline	Continuous
LOS within 12 month	Baseline	Continuous
Medications		
SSRI, TCA, azapirones	Baseline	Binary (Y/N)
Opioids, benzodiazepines	Baseline	Binary (Y/N)
Comorbidities		
Chronic heart failure, diabetes mellitus, cancer, osteoporosis	Baseline	Binary (Y/N)
Usual care		
Pulmonary rehabilitation during the past 12 month	Baseline	Binary (Y/N)
Dialogues with a respiratory nurse during the past 12 month	Baseline	Binary (Y/N)
Public appropriation for terminal care	Baseline	Binary (Y/N)
Number of emergency calls during the past 12 month	Baseline	Continuous
Number of contacts with help line 1813* during the past 12 month	Baseline	Continuous
Questionnaires		
HADS, CRQ, SGRQ	Baseline	Continuous

*Helpline 1813 offers advice and guidance when a general practitioner cannot be contacted and is part of the Danish prehospitalisation emergency services.
BMI, body mass index; CAT, The COPD Assessment Test (CAT); CRQ, Chronic Respiratory Disease Questionnaire; FEV_1, forced expiratory volume in 1 s; HADS, Hospital and Anxiety and Depression Scale; LOS, length of stay; MRC, Medical Research Council dyspnoea scale; NIV, non-invasive ventilation; SGRQ, St. George's Respiratory Questionnaire; SSRI, selective serotonin reuptake inhibitors; TCA, tricyclic antidepressants; Y/N, yes/no.

Blinding

This trial is not blinded, but the outcome measures are masked for health professionals and participants until the end of the study.

Data management

Since the PI handles all of the data, an independent staff member, who is not research active or employed at the department of pulmonary disease, will randomly control for the concordance between the original questionnaires and the entered data. This control includes 20% of all entered data.

Sample size

Anxiety on the HADS subscales, HADS-A, is the basic for the power calculation. Our primary outcome of interest is the intra-individual differences in HADS-A scores between baseline and follow-up II. The design is paired with a power of 0.80 and an α at p=0.05. To identify a difference of 1.5 points, with an SD equal to 2.5 points, 22 patients are required in each group. The minimal clinically important difference of 1.5 points and the SD value are based on other COPD studies.[36 39 55] However, those studies did not screen for anxiety in their eligibility criteria, and therefore are estimated to have a larger SD in HADS-A scores compared to this study. Since the trial population consists of severely ill patients with high morbidity and mortality rates, approximately one-third (33.3%) of the sample are estimated to drop out. Therefore, this study requires 66 patients, with 33 in each group.

Study procedure

Recruitment, screening and enrolment

The setting for the trial is a suburban population in the North of Zealand, Denmark. The trial population consists of patients with severe COPD affiliated to the Department of Pulmonary Disease at Nordsjællands Hospital, Hillerød or Frederiksund Hospitals or the Helsingør Health Centre. In total, approximately 1000 patients compose the recruitment base. Patients are recruited either by telephone or when they visit the Pulmonary Outpatient Clinic as part of their annual or semi-annual control visits with their respiratory physician and/or nurse. Patients who have been in the Pulmonary Outpatient Clinic during the past 6 months and do not have scheduled appointments within the next 3 months are contacted by telephone. A respiratory nurse briefly informs patients about the trial face to face or by telephone and asks them for permission for the PI to

contact them by telephone within 14 days to provide detailed information about the trial and inquire whether they are interested in participating. If the patient consents, they are either handed or mailed an invitation to participate, an information leaflet, a consent form and a folder with basic information about trials, personal rights and baseline questionnaires. This provides the patient with an opportunity to read the material in advance and prepare questions. Then the PI contacts the patient by telephone and gives detailed verbal information about the trial. If the patient consents to participate in the trial, he or she is screened for eligibility, which includes an anxiety screening that is performed by the PI, who reads seven questions and possible answers aloud to the patient on the phone. If the patient does not meet the inclusion criteria, he or she is thanked for showing interest and the conversation is politely ended.

Randomisation

If a patient is eligible and willing to participate in the trial, he or she will be randomised to intervention plus usual care or usual care alone. Random allocation is conducted by using a system of sequentially numbered opaque sealed envelopes. Two employees, who are not involved in the research project or linked to the PI, place 33 notes stamped 'intervention group' and 33 stamped 'control group' in 66 identical envelopes. Subsequently, the envelopes are shuffled and numbered from 1 to 66. The envelopes are stored in a locked cabinet in a locked office in the central research unit. An independent co-worker from the research unit is given responsibility for randomisation and is instructed to keep the envelopes inaccessible to the research team. Participants are allocated to either the intervention or control group on a 1:1 basis. The PI contacts the independent co-worker by email and asks her to open the next envelope in line and report whether this patient is allocated to the intervention or control group. The independent co-worker marks the envelope with a patient ID, date and time to ensure and document that the envelopes are opened in the correct sequence. The PI informs the patients about whether they are randomised to the intervention or control group. Thus, the PI, patients and informal caregivers cannot influence patients' assigned group. Patients are instructed to read and complete the consent form and the baseline questionnaires and return them by post (prepaid postage) or keep them until the PI's visit as part of the intervention. The time and place of the intervention is scheduled by the participant and the PI and optimally occurs within 1 week from randomisation.

Follow-up

For both groups, follow-up assessments will occur after 4 weeks (follow-up I) and 3 months (follow-up II) post-intervention (figure 5). In the telephone booster session, the PI informs participants that they will receive the follow-up I questionnaire by mail within 4 weeks, and follow-up II questionnaire within 12 weeks. They are asked to complete and return the questionnaires within 1 week. If no response is received within 2 weeks, the PI sends a reminder by mail and, as a last resort, contacts the patient by telephone. The purpose of contacting the patients by telephone is to encourage them to complete and return the questionnaires, or identify that they no longer want to participate in the trial. The recruitment process is estimated to last approximately 8–10 months and will continue until 66 participants have been enrolled.

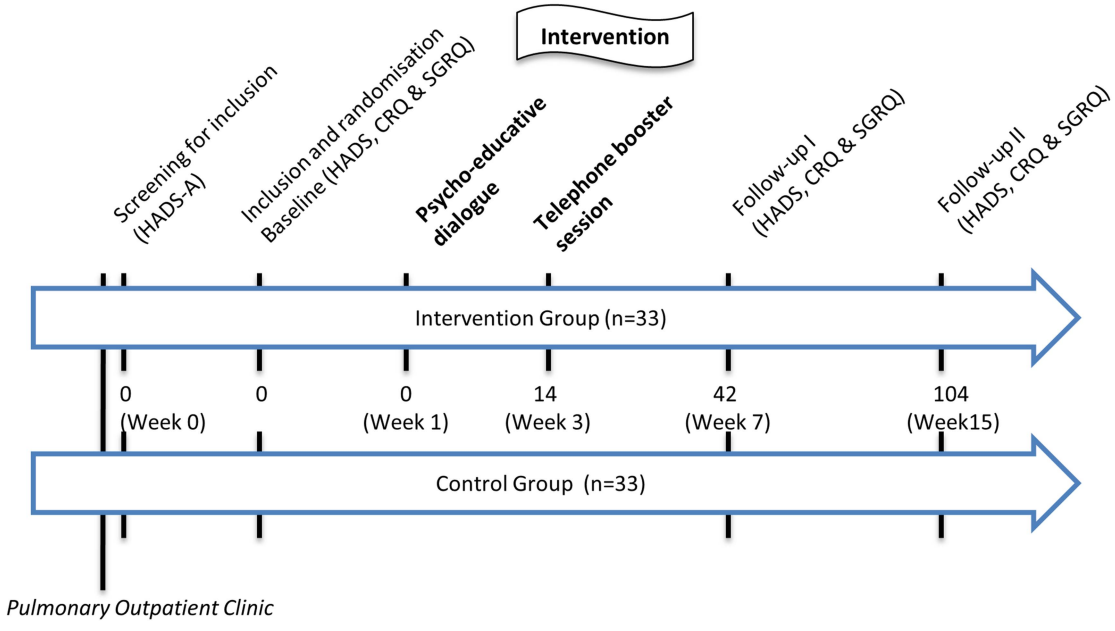


Figure 5 Timeline chart. The numbers refer to the number of days (CRQ, Chronic Respiratory Disease Questionnaire; HADS, Hospital and Anxiety and Depression Scale; SGRQ, St. George's Respiratory Questionnaire).

Statistical analysis

The standardised questionnaires will be scored according to the guidelines from the instrument developers, as the researcher has obtained licenses for the questionnaires pre-trial. Demographic and clinical data, as well as data from the assessment instruments, are entered into an access database and the most recent version of SAS (SAS Institute Inc, Cary, North Carolina, USA). Demographic and clinical data are presented as frequencies for categorical data and as means with SD or medians with a range for continuous data when appropriate. To assess whether the randomisation resulted in two comparable groups at baseline, we will use t tests for continuous data and Fisher's exact test for categorical data. We expect that the HADS, CRQ and SGRQ scores, with possible transformations, will be normally distributed. To analyse within-group differences in outcome scores, we use paired t tests or Wilcoxon signed-rank test. Similarly, differences between the groups will be assessed with two-sample t tests or Wilcoxon rank-sum tests. To include all three follow-up points (baseline, follow-up I and follow-up II) and evaluate the development within-groups and between-groups while controlling for confounders, we will use a longitudinal regression model. The analysis is planned according to 'intention to treat' and 'per protocol' principles. Owing to an expected high number of dropouts, the censoring due to death and missing data due to possible loss to follow-up will be handled using maximum likelihood methods. All analyses are conducted under the supervision of and in collaboration with an experienced biostatistician.

Ethics and dissemination

This trial complies with the latest Declaration of Helsinki, and is registered at ClinicalTrial.gov (NCT02366390). Patients are informed about the trial in writing as well as verbally and are only included when they provide written informed content. Patients who are eligible and want to participate will be enrolled in the trial. Trial participants are free to withdraw their consent at any time and be treated according to the department's standard treatment procedures. Patients will be informed that terminating the trial will have no implications for future treatment. Those who leave the trial for reasons other than death will be asked permission to use previously collected data. If the patient refuses, all of his or her data will be destroyed. All patient data will be handled and stored in accord with Danish Data Protection Agency rules (registration number 2007-58-0015), and patients are ensured anonymity. Data in paper form are stored in a locked cabinet in a locked office and destroyed after 5 years. Computerised data are anonymised by a code-key, which is stored in a locked cabinet in a locked office, separate from personal data. The code-key will be destroyed after 5 years, at which point all data will be completely anonymous.

To the best of our knowledge, there is no documentation of the risks associated with participating in CBT or psychoeducative interventions. The intervention is perceived as unharmful and should not have adverse effects. During the intervention or follow-up, the PI will encourage the participants to seek help from the general practitioner or in the pulmonary outpatient clinic if there is a need for additional professional consultation.

Dissemination plan

Positive, neutral and negative results of the trial will be submitted to an international peer-reviewed journal in the fields of thoracic medicine, education, palliation or nursing. In addition, results will be presented at national and international conferences. Authorship will be allocated using the guidelines for authorship defined by the International Committee of Medical Journal Editors and depends on each person's involvement.

DISCUSSION

There is a need to address and investigate the efficacy of interventions that relieve symptoms of patients with severe COPD, while accounting for the uptake and attendance challenges that are characteristic for patients with severe COPD. To the best of our knowledge, this is the first trial in its field to test a minimal home-based manualised psychoeducative intervention on patients with severe COPD.

Although the trial is focused on addressing the issues characteristic for a severe ill population, we cannot rule out the risk of selection bias. Patients who are highly marked by anxiety and/or advanced lung disease are likely to be less willing or able to participate compared to patients who are less affected by their disease. In addition, our trial would be strengthened by monitoring adherence to the intervention during the 3 months follow-up. However, the patients who participated in the pilot test clearly stated that it was not realistic to ask patients to keep a log book or to monitor when they use the breathing techniques or the cognitive model to restructure thoughts, behaviours, emotions or bodily sensations.

The trial is expected to contribute with results that can improve the HRQL related to managing anxiety and dyspnoea in patients with severe COPD. It is designed to give nurses and other health professionals an instrument that is clinically applicable to providing care for patients with severe COPD and anxiety. Regardless of intervention effects, this trial will contribute to evidence in the field and focus on the need for palliative and applicable interventions aimed at patients with severe COPD.

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