Original Article

Cognitive behavioural therapy (CBT) for patients with chronic lung disease and psychological comorbidities undergoing pulmonary rehabilitation

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Background: The study aimed to determine the effects of adding cognitive behavioural therapy (CBT) to pulmonary rehabilitation to treat patients with chronic lung disease and comorbid anxiety and/or depression symptoms.

Methods: An open, parallel group, randomised controlled trial (RCT) was conducted, with longitudinal follow-up of 12 months. CBT was delivered in 2 face-to-face sessions and 4 phone sessions to patients with depression or anxiety undergoing pulmonary rehabilitation. The main outcome measures were change in Geriatric Depression Scale (GDS) and Geriatric Anxiety Inventory (GAI); secondary outcomes were St. Georges Respiratory Questionnaire (SGRQ), 6-minute walk test (6MWT) and pulmonary rehabilitation attendance.

Results: A total of 65 patients were randomized to Intervention (n=24) and Control (n=41) groups. Of the 24 patients in the Intervention group, 6 patients (25%) withdrew and 4 patients (12.5%) failed to attend more than 2 CBT sessions, which was significantly more than the Control group. The majority of patients (75.4%) had chronic obstructive pulmonary disease. Fourteen (21.5%) had symptoms of depression only, 12 (18.4%) had symptoms of anxiety only, and 39 (60.0%) had symptoms of both anxiety and depression. In the Intervention group, GDS significantly improved at the end of pulmonary rehabilitation (mean difference −3.1, 95% CI: −4.39 to −1.70; P=0.0001), 3 months follow-up (mean difference −1.5, 95% CI: −4.17 to −0.75; P=0.008), and at 12 months follow-up (mean difference −1.6, 95% CI: −3.29 to −0.03, P=0.04), compared to baseline. The Control group demonstrated improvement in GDS by the end of pulmonary rehabilitation (mean difference −1.3, 95% CI: −2.4 to −0.27; P=0.01) which was not maintained at 3 months (P=0.14) and 12 months (P=0.25). GAI significantly improved by the end of rehabilitation in both the Intervention (mean difference −2.6, 95% −4.69 to −0.57; P=0.01) and Control groups (mean difference −2.6, 95% −4.16 to −1.14; P=0.001) and there was no significant improvement at 3 and 12 months. No statistically significant differences in changes in GDS or GAI were observed between the Intervention and Control groups at any time point. There was no significant improvement in SGRQ or 6MWT. There was a significant increase in attended pulmonary rehabilitation sessions in the Intervention group, compared to the Control group (mean difference 1.59; 95% CI: 0.11 to 3.07; P=0.03).

Conclusions: In this RCT of patients with chronic lung diseases attending pulmonary rehabilitation, there was no evidence found for improved symptoms of anxiety or depression or health-related quality of life with the addition of CBT given in a mixed face-to-face and telephone format, compared to usual care. Slower

than anticipated recruitment, leading to a smaller than planned sample size, and a high dropout rate in the group allocated to CBT may have limited the effectiveness of the behavioural intervention approach in this study.

Keywords: Rehabilitation; lung diseases; telephone; psychology

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Introduction

Chronic lung conditions such as chronic obstructive pulmonary disease (COPD), asthma, interstitial lung disease (ILD) and bronchiectasis are common conditions with high rates of mortality and morbidity (1). Although pathophysiological changes secondary to each respiratory condition has an impact on the well-being of patients, psychological comorbidities also have an important negative influence on these patients. Psychological comorbidities are highly prevalent among patients with chronic lung disease (2-5) and are correlated with worsened quality of life (3,5,6), increased exacerbation rates (7), poor adherence to treatment (8), and in COPD their presence has been correlated with increased mortality (9-11). The presence of anxiety and depression is common with incidence varying among each chronic lung disease (3,4,12-14), disease severity (12,14-17) and poor quality of life (3,6,14,15,18,19).

Cognitive behavioural therapy (CBT) is a type of psychotherapy used in the management of a range of psychiatric disorders. It is based on an information-processing model in which emotional symptoms are thought to be driven by negatively-biased evaluations of the world, the future, or the self (including bodily sensations) (20). CBT has demonstrated promising results in reducing anxiety and depression symptoms in patients with COPD (21-30), asthma (31) and bronchiectasis (32). CBT is likely to be as effective when delivered face-to-face or by telephone (33-35), with telephone delivery potentially improving adherence to CBT (27). Pulmonary rehabilitation is an important standard of care for patients with symptomatic chronic lung diseases (36,37) and after completion of a comprehensive pulmonary rehabilitation program symptoms of anxiety and depression have been shown to improve (38-42). Conversely, anxiety and depression have been associated with non-completion of pulmonary rehabilitation programs (43,44), reduced adherence (45) and fear of exercise (46). In patients with COPD, the addition of face-to-face CBT to pulmonary rehabilitation improved 6-minute walk test (6MWT), and symptoms of depression, anxiety and stress (28,47).

CBT and pulmonary rehabilitation are both forms of therapy with strong evidence for treating anxiety and depression in patients with chronic lung disease, and although distinct, they are theoretically synergistic therapies. CBT could, therefore, be incorporated into pulmonary rehabilitation programs to potentiate the beneficial effects of both therapies (26,48,49). The study aimed to assess the impact and feasibility of CBT given through a mixed face-to-face and telephone format as a treatment for patients with chronic lung disease and coexisting anxiety and/or depression symptoms who were undergoing pulmonary rehabilitation.

Methods

Design

This was a prospective, randomized controlled trial in patients with chronic lung diseases undertaking pulmonary rehabilitation. The Intervention group received CBT given in 6 sessions, with the first 2 sessions being delivered face-to-face and the last 4 sessions delivered by telephone. The face-to-face sessions occurred during the 8 weeks of pulmonary rehabilitation. The telephone sessions occurred after the pulmonary rehabilitation sessions. Telephone-based CBT has shown to be an effective treatment approach for treating depression and anxiety in patients with COPD (27,50). The use of mixed approach with initial face-to-face sessions then telephone-based therapy, was intended to have the established face-to-face therapy to improve therapeutic alliance and minimise the possibility of reduced effectiveness of a solely telephone-based therapy and then continue with telephone-based therapy to maximise adherence. The Control group received usual treatment and 4 brief sham telephone calls at approximately similar time

points as the Intervention group. Due to the nature of the therapy, the therapists, investigators and participants were not blinded to the allocated group.

Data were collected at the end of the pulmonary rehabilitation program, 3 months and 12 months following completion of the program for each participant. The study was approved by the ethics committee of The University of Queensland and The Prince Charles Hospital in Queensland, Australia, and is registered with the ANZCTR (ACTRN12614000915651). Written informed consent was obtained from all participants before enrolling in the study.

Participants

This study included patients above 18 years of age with chronic lung diseases including COPD, asthma, ILD, or bronchiectasis diagnosed by a thoracic physician and undertaking pulmonary rehabilitation at The Prince Charles Hospital, Brisbane, Australia. COPD diagnosis was based on Global Initiative in Obstructive Lung Disease (GOLD) criteria. Asthma diagnosis was determined by the presence of variable symptoms and bronchodilator reversibility present on spirometry. ILD was diagnosed based on CT scan, respiratory lung function and/or by histopathology findings. Bronchiectasis was diagnosed by high-resolution CT chest scan. The presence of clinical or subclinical anxiety or depression in COPD patients based on previous studies was defined by GDS of ≥4/15 (51) and GAI score ≥3/20 (52), respectively.

Patients were excluded if they had a known psychotic disorder, were undergoing psychological therapy, unable to give written informed consent or were participating in another research project. Patient with cognitive impairment, defined by impairment determined by Mini Mental State Examination (MMSE) score of <23/30 (53) were excluded.

Randomization and intervention

Screening forms were sent before rehabilitation program commencement. Forms review and recruitment were done during the first 2 weeks of a comprehensive 8-week pulmonary rehabilitation program with exercise and education. Patients enrolled in the study were randomised in a 1:1 basis to the Intervention group (CBT) or Control group (usual care) using pre-printed sealed assignments generated by a computer-generated software package. No minimum block size was used in the randomization.

Both groups attended together a comprehensive 8-week pulmonary rehabilitation program. Each week of the program consisted of 2 sessions of 2 hours duration, involving 1 hour of supervised exercise (walking and/or stationary cycling and upper and lower limb strengthening) and 1 hour of multidisciplinary education. All participants received a hard copy of the Lung Foundation Australia's Better Living with COPD patient information booklet, which contained a chapter on stress, anxiety and depression (54).

The Intervention group received CBT conducted by postgraduate psychology interns under the supervision of a qualified psychologist. The CBT intervention was based on a manualised approach that was developed by the Psychology Department of The Prince Charles Hospital. One session was videotaped and later reviewed by a specialist in clinical psychology to ensure adherence to the manual and quality of the intervention. The intervention comprised 2 face-to-face sessions of 1 hour each, just before or after the pulmonary rehabilitation classes. In addition, 4 telephone sessions of 45 minutes each were undertaken for counselling, within the first 2 months after the face-to-face sessions. The CBT intervention was tailored to the patient's individual needs.

CBT sessions aimed to build skills in self-management, behavioural activation, identifying and challenging unhelpful thinking, improving relaxation and breathing skills, and promoting effecting coping through training in problem-solving. Components of the intervention included: Cognitive interventions; Psychoeducation about the interaction between anxiety and physical symptoms (the anxiety-dyspnoea cycle); Challenging and modifying unhelpful cognitions; Problem-solving training to address barriers to effective coping; Behavioural interventions: Relaxation and distraction techniques; Breathing techniques (in conjunction with Pulmonary Rehabilitation nurses); Reinforcement of activity scheduling; Planning and "pacing" skills; Development of a personalized "good coping plan" (55-57).

To minimise the difference caused by social interaction gained by CBT in the Intervention group, participants in the Control group received telephone contacts with the study personnel at similar time points as the Intervention group. The telephone call to the Control group participants was of a shorter duration (5 to 10 minutes) than the CBT calls to the Intervention group and consisted of a brief assessment of respiratory symptoms.

Outcomes and follow-up

The primary outcome of interest was the efficacy of CBT as an effective treatment of depression and anxiety among patients with chronic lung disease attending a pulmonary rehabilitation program. GDS and GAI were used to assess depression and anxiety symptoms respectively. Secondary measures included the St George's Respiratory Questionnaire (SGRQ) to assess quality of life (58); 6-minute walk distance at baseline and the end of pulmonary rehabilitation to assess exercise capacity, and pulmonary rehabilitation attendance and participation.

Demographic and clinical data, body mass index (BMI), Montreal cognitive assessment (MoCA) score (to identify frontal dementia) (59) and MMSE score (to identify cognitive impairment) (53) were assessed in all patients. In COPD patients, modified Medical Research Council dyspnoea scale (mMRC) and the body-mass index, airflow obstruction, dyspnoea, and exercise capacity index were assessed, to calculate the BODE score (60).

Statistical analysis

Descriptive statistics were used for exploratory analysis. To determine correlation coefficients between continuous variables, Pearson's correlation was used. To determine differences between the Intervention and Control groups, *t*-tests and χ^2 tests were undertaken for continuous and categorical outcomes, respectively. Intention to treat analysis was performed. A P value (two-tailed) <0.05 was considered statistically significant.

For data collected at multiple points in time, a longitudinal analysis was undertaken, by comparing the change in outcomes over time in the Intervention and Control group using repeated measures tests. For these paired measures, a Wilcoxon signed-rank test was used to determine any significant difference over time. Statistical analyses were run using Stata 17 (StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC).

A power calculation estimated that a sample size of 50 Intervention and 50 Control participants would have 80% power at alpha (significance) level 0.05 to detect a 3-fold increase in significant improvement of anxiety or depression scores, based on the assumption of improvement of 10% of the Control group and 33% of the Intervention group.

Results

Baseline characteristics of participants

Of the 193 patients screened, 126 patients (65.3%) were eligible to be enrolled in the study, based on a GDS ≥4 and/or GAI ≥3. Twenty-two (11.4%) patients declined enrolment in the study, 9 (4.7%) did not attend pulmonary rehabilitation for further assessment, and another 19 (9.8%) were excluded. Results are outlined in the CONSORT diagram (*Figure 1*).

Sixty-five patients were enrolled in the study and randomized (24 patients to Intervention and 41 patients to Control). Ten of 24 patients (41.7%) in the Intervention group failed to complete the intervention, consisting of 6 patients (25%) who withdrew before the commencement of CBT and 4 patients (16.7%) who started but did not complete CBT therapy (with an average of one CBT session attended). 3 of these patients also did not continue pulmonary rehabilitation. 4 of 41 patients (9.75%) in the Control group did not complete the study, consisting of 1 patient (2.4%) who withdrew, 2 patients (4.9%) who failed to attend 6 or more pulmonary rehabilitation sessions, and 1 patient (2.4%) who died during the pulmonary rehabilitation study period (*Figure 1*).

Demographic details of the patients enrolled are described in *Table 1*. The mean age of the group studied was 68.8 years and 60% were females. The majority of patients had COPD (75.4%), and the remainder had asthma (10.8%), bronchiectasis (9.2%) and ILD (4.6%). A wide range of lung function impairment was observed. Fourteen (21.5%) had only symptoms of depression and 12 (18.4%) had symptoms of anxiety while 39 (60.0%) had both symptoms of depression and anxiety.

Twenty-two percent of patients had a known mood disorder and 22% were on antidepressants, with selective serotonin reuptake inhibitors (SSRI) being the most common antidepressant. Twenty percent of the population enrolled had a low MoCA score. There were no statistically significant differences in baseline parameters between the Intervention and Control groups (*Table 1*).

There was a weak but statistically significant correlation between failure to attend pulmonary rehabilitation (<6 sessions) and GDS (r=0.18, P=0.01) but not for GAI (r=0.12, P=0.09).

The final number of participants (n=65) was

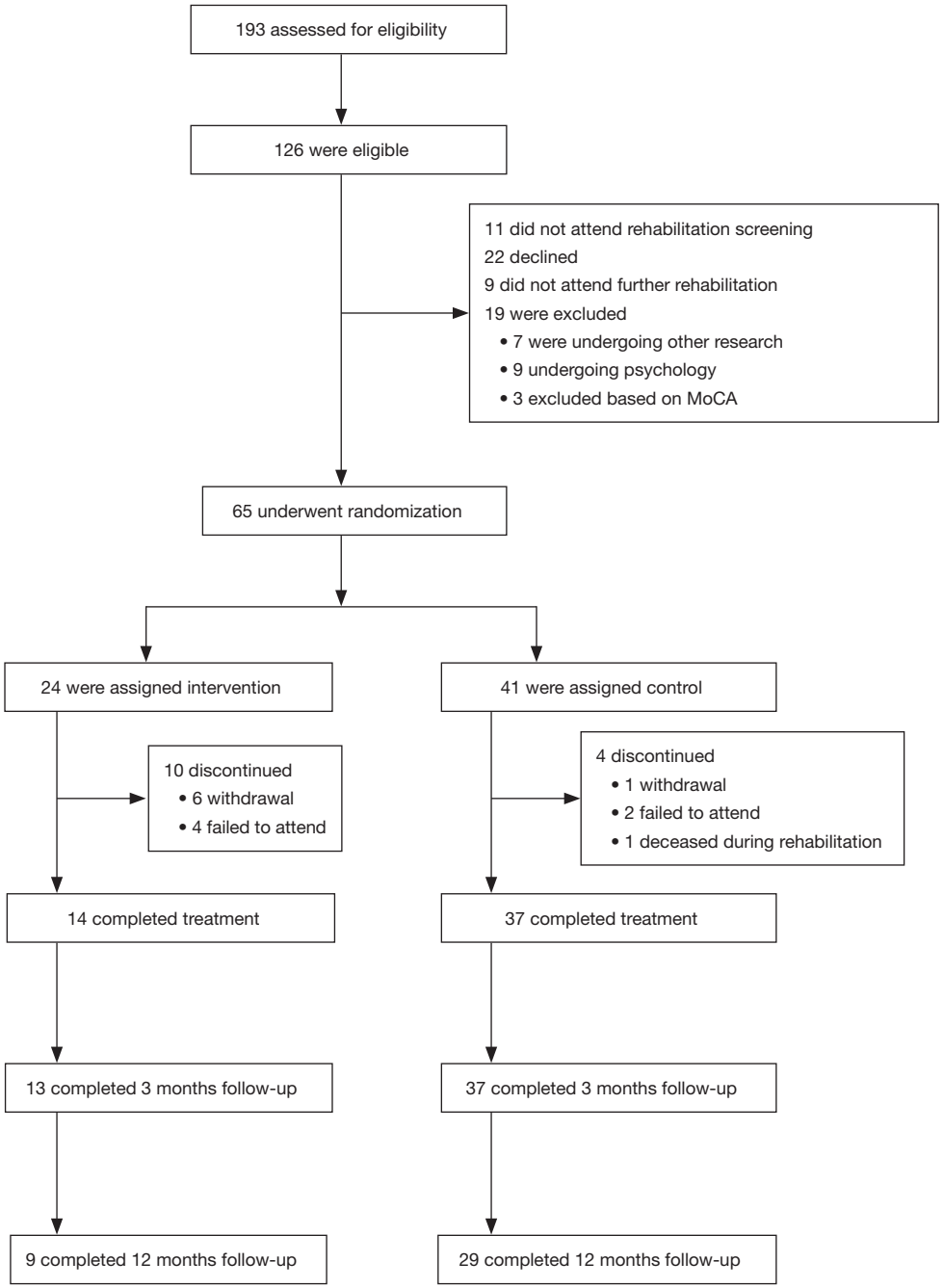

Figure 1 CONSORT diagram of enrolment, randomization, and follow-up.

approximately two-thirds of the total number originally planned (n=100), due to the slower than anticipated recruitment rate, limited resources available and the high dropout rate from the Intervention (CBT) group. A decision was therefore made to finish the study early at a total of 65 randomised participants.

Outcomes at end of pulmonary rehabilitation

At the end of pulmonary rehabilitation, there was a statistically significant decrease in GDS (improvement in depression symptoms) compared to baseline, in both the Intervention and Control groups. The mean decrease in

Table 1 Demographics of all patients enrolled and by intervention (n=65)

Characteristics	All patients (n=65)	Intervention (n=24)	Control (n=41)	P value
Gender				
Female (n, %)	39 (60%)	12 (50%)	27 (65.85%)	0.27
Age ± SD [range]	68.8±9.7 [40–86]	69.6±11.15 [49–86]	68.5±9.2 [40–85]	0.65
Conditions				0.69
COPD	49 (75.4%)	20 (83.3%)	29 (70.7%)	
Asthma	7 (10.8%)	1 (4.1%)	6 (14.6%)	
ILD	3 (4.6%)	2 (8.3%)	2 (4.9%)	
Bronchiectasis	6 (9.2%)	2 (8.3%)	4 (9.8%)	
Depression				
GDS ≥4	53 (81.5%)	20 (83.3%)	33 (80.5%)	0.6
Only symptoms of depression	14 (21.5%)	4 (16.7%)	10 (24.4%)	
Mean GDS ± SD [range]	6.1±3.3 [0–15]	6.5±3.3 [(0–13]	5.8±3.3 [0–15]	0.46
Anxiety				
GAI ≥3	51 (78.4%)	20 (83.3%)	31 (75.6%)	0.68
Only symptoms of anxiety	12 (18.5%)	4 (16.7%)	8 (33.3%)	
Mean GAI ± SD [range]	7.3±5.6 [0–20]	6.7±5.5 [0–20]	7.4±5.7 [0–20]	0.63
Symptoms of both anxiety and depression	39 (60.0%)	16 (66.7%)	23 (56.1%)	
6MWT (m)	362.2±118.7	338.4±114.8	376.1±118.6	0.23
BODE	3.0±2.3	3.1±2.3	2.8±2.4	0.72
SGRQ baseline		50.2±19.3	56.5±16.9	0.18
Previously diagnosed anxiety or depression	15 (23.1%)	3 (12.5%)	12 (37.5%)	0.15
Only anxiety	2 (13.3%)	0	2 (16.6%)	
Only depression	8 (53.3%)	1 (33.3%)	6 (50%)	
Both anxiety and depression	5 (33.3%)	2 (66.7%)	3 (25%)	
Comorbidity score, No. (%)				
≤3	34 (54.8%)	11 (47.8%)	23 (59%)	0.94
4	13 (21%)	6 (26.1%)	7 (17.9%)	
5	7 (11.3%)	3 (13%)	4 (10.3%)	
≥6	8 (12.9%)	3 (13%)	5 (12.8%)	
Antidepressants	15	2	13	0.06
SSRI	8 (53.3%)	2	6	
SNRI	4 (26.7%)	0	4	
TCA	3 (20.0%)	0	3	
MMSE	29.06±0.99 [26–30]	29.2±0.8 [28–30]	29±1.1 [26–30]	
MoCA	26.6±2.1 [20–30]	26.3±2.4 [20–29]	26.7±1.9 [21–30]	0.49
MoCA (<26)	13 (20.0%)	4 (16.7%)	9 (22.0%)	

SD, standard deviation; BODE, Body-mass index, airflow Obstruction, Dyspnoea, and Exercise; Comorbidity score, Charlson comorbidity score; COPD, chronic obstructive pulmonary disease; interstitial lung disease; ILD; GAI, Geriatric Anxiety Index; GDS, Geriatric Depression Score; MMSE, Mini Mental State Examination; MoCA, Montreal Cognitive Assessment; SGRQ, St. Georges Respiratory Questionnaire; SNRI, serotonin and noradrenaline reuptake inhibitors; SSRI, selective serotonin reuptake inhibitors; TCA, tricyclic antidepressants; 6MWT, 6-minute walk test.

Table 2 Changes in GDS and GAI scores in the Intervention and Control groups

End point (n=14)	Intervention, median (IQR)	Patients	Difference (95% CI) from baseline	P value	Control, median (IQR)	Patients	Difference (95% CI) from baseline	P value
GDS								
Baseline	5.5 (4 to 10)	19			5 (4 to 8)	37		
End of rehabilitation	3 (1 to 5)	19	–3.1 (–4.39 to –1.71)	0.0001	4 (1 to 7)	37	–1.3 (–2.4 to –0.27)	0.01
3 months	4 (3 to 5)	15	–1.5 (–4.17 to –0.75)	0.008	5 (3 to 8)	37	–0.6 (–1.31 to 0.28)	0.22
12 months	3.5 (2.5 to 5.5)	12	–1.6 (–3.29 to –0.03)	0.04	5 (2 to 8)	29	–0.5 (–1.41 to 0.38)	0.25
GAI								
Baseline	7.5 (3 to 8.5)	19			7 (3 to 12)	39		
End of rehabilitation	3 (0 to 6)	19	–2.6 (–4.69 to –0.57)	0.01	3 (0 to 8)	39	–2.6 (–4.16 to –1.14)	0.001
3 months	2 (0 to 8)	15	–1.6 (–5.11 to 0.31)	0.07	5 (2 to 11)	39	–0.8 (–2.36 to 0.36)	0.14
12 months	5 (1.5 to 11)	12	–0.9 (–4.98 to 3.31)	0.66	3 (2 to 11)	29	–1.1 (–3.2 to 0.84)	0.24
SGRQ								
Baseline	53.8 (32.9 to 64.8)	19			59.8 (43.8 to 68.6)	37		
End of rehabilitation	44.8 (29.4 to 59.5)	19	–6.3 (–17.34 to 4.63)	0.24	52.4 (37.0 to 61.5)	35	–6.0 (–14.84 to 2.84)	0.17
3 months	45.9 (32.8 to 61.2)	13	–3.8 (–15.12 to 7.4)	0.47	51.7 (38.9 to 62.9)	32	–5.6 (–15.33 to 4.04)	0.24
12 months	57.9 (46.0 to 71.1)	11	4.2 (–11.52 to 20)	0.56	50.2 (30.5 to 63.5)	27	–8.2 (–19.35 to 2.93)	0.14
6MWT								
Baseline	320 (266 to 430)	19			375 (307 to 465)	32		
End of rehabilitation	339.5 (255 to 427)	19	1.3 (–23 to 25.7)	0.9	382.5 (300 to 459)	32	14.7 (–5.7 to 35.1)	0.15

GAI, Geriatric Anxiety Index; GDS, Geriatric Depression Score; SGRQ, St. Georges Respiratory Questionnaire; 6MWT, 6-minute walk test.

Table 3 Changes in GAI, GDS and SGRQ scores: comparisons between Intervention and Control groups

End point (n=14)	Intervention group: difference from baseline, median (IQR)	Number of patients	Control group: difference from baseline, median (IQR)	Number of patients	Intervention difference - control difference (95% CI)	Between group comparison P value
GDS end of rehabilitation	−3 (−5 to 0)	19	−1 (−3 to 0)	37	−1.7 (−3.45 to 0.13)	0.053
GDS 3 months follow-up	−1 (−2.5 to 0)	12	−0 (−3 to 0)	35	−0.7 (−2.2 to −0.68)	0.29
GDS 12 months follow-up	−1 (-4 to 1)	11	−0.5 (−2 to 1)	26	−1.2 (3.01 to 0.66)	0.2
GAI end of rehabilitation	0 (-7 to 1)	19	−1.5 (−6 to 0)	38	−0.1 (−2.5 to 2.55)	0.98
GAI 3 months follow-up	0 (−5.5 to 1.5)	12	0 (−3 to 2)	37	−0.8 (−3.43 to 1.93)	0.59
GAI 12 months follow-up	−2 (−5 to 3)	11	−2.5 (−4 to 1)	26	0.1 (−4.21 to 4.47)	0.74
SGRQ end of rehabilitation	−6.8 (−21.2 to 14.3)	19	−5.6 (−26.9 to 13.3)	35	0.3 (−14.51 to 13.8)	0.96
SGRQ 3 months follow-up	−0.29 (−16.0 to 13.4)	12	−11.7 (−28.8 to 4.9)	29	−4 (−13.5 to 21.5)	0.64
SGRQ 12 months follow-up	5 (−21.1 to 19.3)	10	−7.9 (−19.8 to 12.6)	24	−8.7 (12.54 to 30.1)	0.06

GAI, Geriatric Anxiety Index; GDS, Geriatric Depression Score; SGRQ, St. Georges Respiratory Questionnaire.

GDS was 3.1 in the Intervention group (P=0.0001), while in the Control group, the mean decrease was 1.3 (P=0.01). For GAI, there was a mean decrease of 2.6 in both the Intervention and Control groups (*Table 2*). There was no statistically significant difference in the changes in GDS or GAI scores between the Intervention and Control groups (*Table 3*). The waterfall plot demonstrates that almost all patients that completed the CBT program improved their GDS, while the same was not seen in the Control group. GAI showed the same improvement pattern in both Intervention and Control groups (*Figure 2*). SGRQ and 6-minute walk test did not demonstrate a significant improvement in either the Intervention or Control groups (*Table 2*).

For those patients with symptoms of depression at baseline (GDS score ≥4/15), there was a significant improvement in GDS by the end of rehabilitation, within each of the Intervention and Control groups (P=0.0002) and (P=0.01), respectively (*Table 4*), which was not statistically different between these groups (P=0.16). By the end of pulmonary rehabilitation, 55.5% in the Intervention group and 33% in the Control group achieved no demonstrable symptoms of depression based on a normal GDS, although the difference was not significant between groups (P=0.1) (*Table 5*). Patients with symptoms of anxiety at baseline (GAI score ≥3/20) there was an improvement in GAI in both the Intervention and Control groups, which was not statistically different between these groups (P=0.32). CBT did not lead to significant increase of GAI normalization (37.5% *vs.* 24%; P=0.27) (*Table 5*).

The Intervention group showed a significant increase in the number of pulmonary rehabilitation sessions attended, with the mean number of attended sessions of 14.0 (±1.7) in the Intervention group and in 12.4 (±2.6) in the Control group, out of the maximum number of 16 sessions (P=0.03).

Outcomes at 3 and 12 months follow-up

There was a sustained improvement in depression symptoms measured by GDS at 3 (P=0.008) and 12 months (P=0.04) in the Intervention group, that was not demonstrated in the Control group (*Table 2*). These changes at 3 and 12 months were not significantly different between the Intervention and Control groups (*Table 3*). For anxiety symptoms

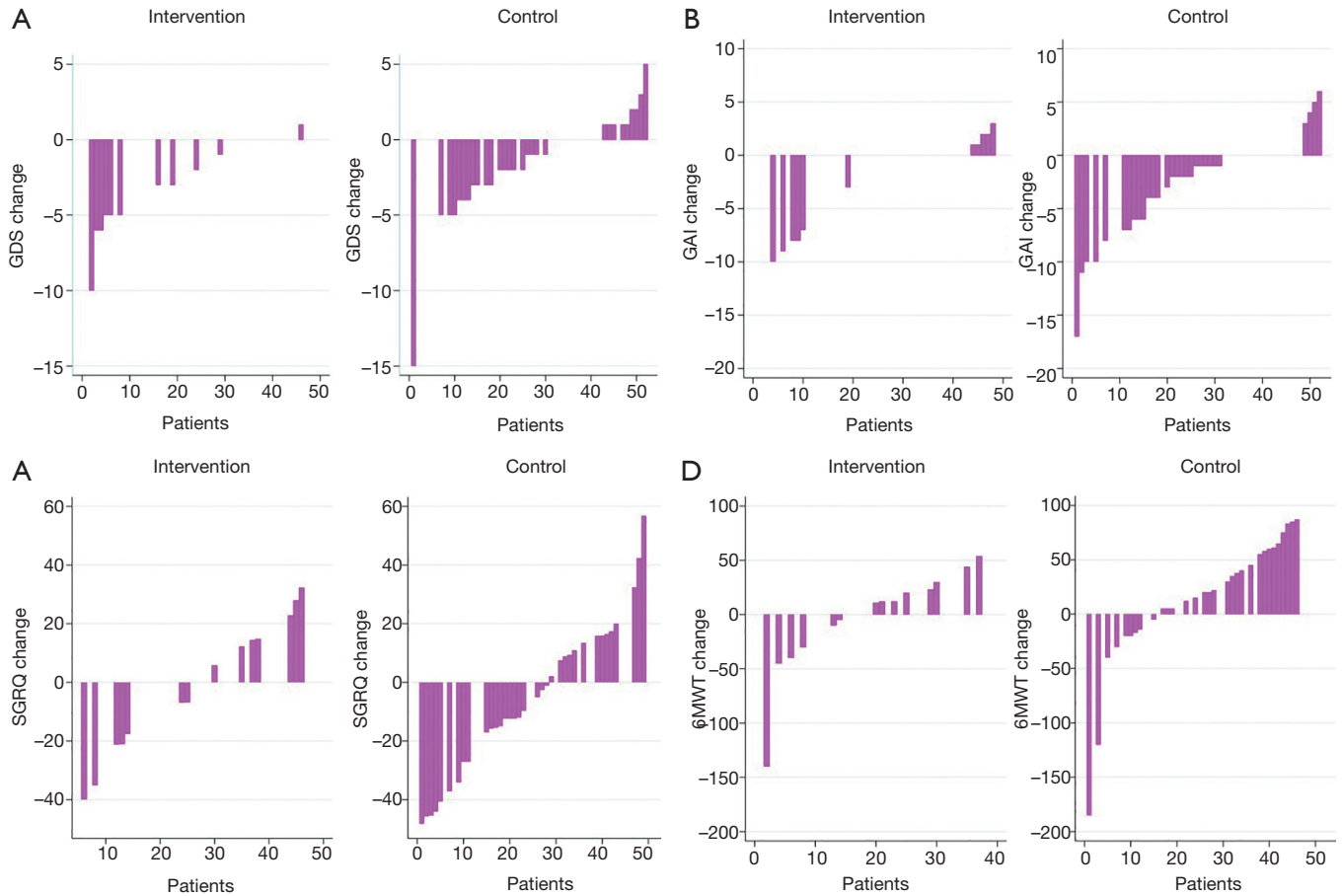

Figure 2 Waterfall charts demonstrating changes of GAI, GDS, SGRQ and 6MWT before and after pulmonary rehabilitation. Graph A demonstrates changes in GDS of each patient grouped in control and patients that completed cognitive behavioural therapy session (Intervention). Graph B demonstrates changes in GAI of each patient grouped in control and patients that completed cognitive behavioural therapy session (Intervention). Graph C demonstrates changes in SGRQ of each patient grouped in control and patients that completed cognitive behavioural therapy session (Intervention). Graph D demonstrates changes in 6MWT each patient grouped in control and patients that completed cognitive behavioural therapy session (Intervention). GAI, Geriatric Anxiety Index; GDS, Geriatric Depression Score; SGRQ, St. George's Respiratory Questionnaire; 6MWT, 6-minute walk test.

measured by GAI, there was no difference from baseline or between groups at the 3- and 12-month follow-up for the Intervention and Control groups (*Tables 2,3*). Similar to anxiety symptoms, health-related quality of life showed no significant difference from baseline in both groups, and there was no significant difference between the groups at 3 and 12 months (*Table 3*).

Outcomes in patients with significant symptoms of GDS or GAI at baseline

For patients with an elevated GDS score at baseline, there was a sustained improvement in GDS scores at 3 months (P=0.007) but not at 12 months (P=0.08) follow-up in the Intervention group, which was not demonstrated in the Control group at 3 and 12 months (*Table 4*); and there was no significant difference between groups at both 3 months (P=0.3) and 12 months (P=0.48). CBT did not lead to a significant improvement in patients achieving a normal GDS, with 53% of patients in the Intervention group achieving a normal GDS at 3 months and 40% achieving a normal GDS at 12 months follow-up; while the Control group 39% and 24% of patients achieved a normal GDS at 3 and 12 months, respectively (*Table 5*).

For patients with an elevated GAI score at baseline, there was no significant improvement in GAI in the Intervention

Table 4 Changes in GDS and GAI scores for patients with elevated GDS or GAI at baseline

End point	Intervention (n=14), median (IQR)	Difference (95% CI) compared to baseline	P value	Control (n=37), median (IQR)	Difference (95% CI) compared to baseline	P value
Elevated GDS at baseline (patients with GDS ≥4)						
Baseline	6 (4 to 10)			6 (4 to 10)		
End of rehabilitation (n=62)	4 (2 to 5)	−3.3 (−4.74 to −1.84)	0.0002	5 (2 to 8)	−1.7 (−3.0 to −0.3)	0.01
3 months (n=44)	4 (3 to 5)	−2.6 (−4.4 to −0.83)	0.007	5.5 (3 to 8)	−0.8 (−1.76 to 0.15)	0.09
12 months (n=32)	4 (3 to 5)	−1.7 (−3.66 to 0.26)	0.08	7 (4 to 8)	−0.5 (−1.75 to 0.70)	0.38
Elevated GAI at baseline (patients with GAI ≥3)						
Baseline	7.0 (3.5 to 8.5)			9 (5 to 15)		
End of rehabilitation (n=62)	4.0 (0.5 to 7)	−3.3 (−5.86 to −0.79)	0.01	5 (3 to 11)	−3.4 (−5.29 to −1.46)	0.001
3 months (n=44)	5.5 (3.0 to 8.5)	−2.7 (−5.9 to 0.37)	0.07	6.5 (4 to 11)	−1.6 (−3.31 to 0.04)	0.06
12 months (n=32)	5.0 (1 to 13)	−1.6 (−7.36 to 4.03)	0.51	6 (2 to 12)	−1.5 (−4.03 to 1.08)	0.24

GAI, Geriatric Anxiety Index; GDS, Geriatric Depression Score

Table 5 Normalization of GDS and GAI in patients over time

End point	No. normalized/no. of participants (%)		Odds ratio (95% CI)	P value
	Intervention	Control		
Patients achieving normal GDS				
End of rehabilitation (n=43)	10/18 (55.5)	10/30 (33.3)	2.5 (0.64 to 9.82)	0.1
3 months (n=43)	9/17(52.9)	9/31 (29.0)	2.7 (0.67 to 11.16)	0.09
12 months (n=43)	4/10 (40.0)	5/21 (23.8)	2.1 (0.30 to 13.97)	0.30
Patients achieving normal GAI				
End of rehabilitation (n=41)	6/16 (37.5)	7/29 (24.1)	1.9 (0.4 to 8.53)	0.27
3 months (n=42)	8/15 (53.3)	5/30 (16.6)	5.7 (1.15 to 29.2)	0.01
12 months (n=29)	2/9 (22.2)	6/23 (26.1)	0.8 (0.06 to 6.24)	0.6

GAI, Geriatric Anxiety Index; GDS, Geriatric Depression Score.

and Control groups at 3 and 12 months follow-up (*Table 4*). There was also no significant difference between the groups at 3 months (P=0.13) and 12 months (P=0.84). At 3 months there was a significant increase in the rate of GAI normalization in the Intervention groups [53% *vs.* 17%; OR −1.63 (−3.31 to 0.04); P=0.01], which was not present at 12 months (22.2% *vs.* 26.1%; P=0.6) (*Table 5*).

Discussion

This study evaluated the effects of CBT as an addition to pulmonary rehabilitation for patients with chronic lung conditions of moderate to severe disease severity and symptoms of depression and anxiety. As demonstrated in previous studies, there was a significant reduction in symptoms of anxiety and depression in all patients by the

end of pulmonary rehabilitation. However, unlike those studies, our study did not show an improvement in health-related quality of life (as determined by SGRQ) (38-40). The study by Catalfo *et al.* (40), which evaluated patients with COPD with symptoms of anxiety and depression, employed a more intensive pulmonary rehabilitation program of 2 hours daily for 6 weeks, which was significantly more than the standard 2 hours twice a week in our pulmonary rehabilitation program. Their more intensive exercise protocol could have played a significant role in improving both quality of life and mood symptoms and highlights the link between physical capacity and quality of life. Our study showed that despite the lack of improvement in SGRQ, there was an improvement in depression and anxiety symptoms in both Intervention and Control group, which may suggest that these symptoms are more responsive to the effects of pulmonary rehabilitation.

As demonstrated in previous studies (26,28), our study showed a significant improvement in GDS by the end of rehabilitation for both the Intervention and Control groups. The Intervention group seemed to have a numerically larger reduction in mean GDS of 3.1 (almost 50% of baseline score) compared to the Control group (1.34), although this did not reach statistical significance. Interestingly, in almost all patients that undertook CBT, there was a reduction in GDS as shown in the waterfall plots, while in the Control group approximately two-thirds of the patients improved their GDS. After CBT, the level of reduction of depression scores in our study was similar to the study by Catalfo *et al.* (40) which had a more rehabilitation program sessions, which may indicate that CBT could augment the psychological benefits of pulmonary rehabilitation. A factor that could have contributed to the lack of significance observed between Intervention and Control groups by the end of rehabilitation was the overall improvement in each patient group. This improvement might have had a dampening effect, an issue that may have contributed to a reduced effect in another study that used 6 sessions of group based CBT given with a similar pulmonary rehabilitation program (28). Our study showed a sustained improvement in GDS at 3 and 12 months in the Intervention group, which was not significantly different from the Control group at both time intervals. The lack of a significant difference could be secondary to the reduced sample size analysed. It is possible that CBT could prolong pulmonary rehabilitation benefits in patients with symptoms of depression, a fact supported by the demonstration of sustained improvement of GDS between baseline and follow-up for the Intervention group but not for the Control group. When analysing only those with elevated GDS at baseline, there is also a sustained improvement at 3 months but unexpectedly not at 12 months, which may reflect smaller numbers of participants at 12 months follow up since the overall improvement was larger in those with high GDS. With regards to anxiety symptoms, by the end of pulmonary rehabilitation, the results were similar to GDS, and there was no significant sustained improvement at 3 and 12 months.

With regards to anxiety symptoms, the Intervention group failed to show significant improvement in GAI at 3 and 12 months follow-up, although there was a significant difference in reaching normal GAI at 3 months follow up. The reason for the lack of sustained improvement in GAI or the discrepancy between anxiety and depression was not clear, although similar results were demonstrated in a comparable study that used mindfulness and CBT added to pulmonary rehabilitation (49). Possible reasons for the heterogeneity of results could be due to different methods of anxiety symptoms assessment tools (28), durations of CBT, method of delivery of therapy or if CBT was aimed at panic symptoms or generalized anxiety. There have been heterogeneous results regarding therapy delivery, duration and improvement in anxiety and depression scores. A previous study by Hynninen *et al.* (22) showed sustained improvement in both depression and anxiety, although the study involved 7 sessions of 2 hours of group delivered CBT, which is significantly more than our protocol of 6 sessions of one hour duration of 2 face to face and 4 phone delivered sessions. On the other hand, a study by Farver-Vestergaard *et al.* (49) using mindfulness-based CBT provided 8 telephone sessions and 8 group sessions added to pulmonary rehabilitation and showed a reduction in depression symptoms but not anxiety. The study by Livermore *et al.* (25) which had a targeted protocol to panic-related anxiety symptoms given to post-pulmonary rehabilitation patients, showed a significant reduction in anxiety score up to 18 months post treatment, although there was no change in depression scores. This may imply that the panic-related anxiety symptoms are more significant is this group and that treatment targeted to these symptoms is more effective to improve anxiety scores.

Similar to previous studies, the presence of depression was associated with poor pulmonary rehabilitation attendance and completion (43,44,61-63). Non-attendance in pulmonary rehabilitation programs may reflect poor overall adherence to other forms of treatment, as depression

has been associated with poor medication adherence (8). The cause is unclear, but lack of energy, motivation and poor perception of self-worth could all contribute to the lack of engagement with treatment in this population. This is unfortunate since due to the negative impact of depression and the positive effects of pulmonary rehabilitation for these patients, they are a group who could possibly benefit the most from engagement with treatment. As hoped, a targeted psychological therapy such as CBT for this at-risk population of poor adherence improved attendance at pulmonary rehabilitation in our study. However, this improved attendance did not translate to improved markers such as 6MWT or improved health-related quality of life.

Limitations

The main limitation in our study was slower than expected enrolment and high rates of withdrawal or failure to attend therapy, leading to a relatively small number of patients completing the Intervention group. In the Intervention group, 10 of 24 patients (42%) withdrew or did not attend pulmonary rehabilitation and CBT. Compared to another study that had only employed telephone-based CBT (27), this was a lower than expected completion rate. 17% of eligible patients declined to participate and most patients that declined therapy did this before receiving any CBT sessions, which could reflect negative preconceptions of what CBT entails and its effectiveness, or the stigma associated with psychological conditions. Our study did not randomize patients based on pharmacotherapy treatment which resulted in a non-significant difference in use between the Intervention and Control group and may have impacted the efficacy of CBT. However the impact of pharmacotherapy is likely minimal as there is some controversy regarding the benefit of pharmacotherapy as a monotherapy for depression or anxiety (64), and the likely minimal effects when added to CBT (65). The addition of CBT to pulmonary rehabilitation treatment could be seen by some patients as too time-consuming, as many patients who did not wish to attend CBT still attended pulmonary rehabilitation. It is possible that solely telephone-based therapy would have fewer withdrawals, as all patients that withdrew or failed to attend CBT did so during the face-to-face period of therapy; possibly making telephone-based a more attractive method of additional CBT therapy. A more individualised case-formulation approach to CBT may have also improved compliance and yielded better outcomes. Although there was a significant withdrawal rate that may have led a reduced effect size and which would make the analysis more susceptible to type 2 error, this was mitigated by the intention to treat analysis. The high withdrawal rate could also have led to a selection bias in the study. CBT seems to improve depression scores, but possibly only for patients already predisposed to engage in treatment. Independent of this matter, offering CBT to patients with depression during pulmonary rehabilitation could be beneficial, even if only for those willing to participate.

The study used a pragmatic approach of the same type of CBT intervention for all patients, independent of their underlying respiratory condition. This approach was chosen based on the hypothesis that an integrated pulmonary rehabilitation program with psychological treatment would benefit all types of patients. Although there was ultimately no difference in major outcomes between groups, it is possible that psychological comorbidities are different between respiratory conditions and consequently require different approaches, an aspect that was not assessed in our study.

Future considerations

Improvement in depression scores in the CBT group indicates the possible benefit in adding this treatment to patients with depressive symptoms attending pulmonary rehabilitation. Patients have the opportunity to learn strategies to manage depressive symptoms like cognitive restructuring and have opportunities to practice those techniques during safe and supervised exposures that cause dyspnoea. The pulmonary rehabilitation sessions can create positive experiences for patients and has the potential for desensitization of the symptoms of dyspnoea. How much teaching or how many sessions are sufficient to achieve proficiency in deploying these strategies is not clear; however, more sessions are likely to improve the likelihood of success (22,24,26). The target of therapy could play an essential role in the improvement of anxiety symptoms, as possibly the addition of therapy more directed at panic attack-related anxiety be more beneficial to those with anxiety symptoms (25). More intensive pulmonary rehabilitation programs are also likely to be more effective to improve mood symptoms (40), and in this context, the addition of CBT can lead to more opportunities to employ learnt strategies and possibly be a more effective treatment. Other options for rehabilitation such as home rehabilitation (66) are possibly as effective as usual pulmonary rehabilitation, making telephone-based CBT an ideal additional therapy for this form of rehabilitation. Another aspect that needs

clarification is which method of delivery is the most efficient and cost-effective; as face-to-face may be more effective for anxiety symptoms (25), while telephone-based therapy may have better patient compliance (27).

Conclusions

This study did not find evidence that the addition of CBT in a mixed face-to-face and telephone approach to pulmonary rehabilitation was more effective in improving depression, anxiety and quality of life symptoms, compared to pulmonary rehabilitation alone. There was an associated sustained improvement in depression scores in the Intervention group at 3- and 12-month follow-up that was not significantly different from the Control group. The addition of CBT to pulmonary rehabilitation did not improve anxiety symptoms or quality of life compared to pulmonary rehabilitation alone. The use of CBT did improve pulmonary rehabilitation attendance, although this did not translate into an improvement in psychological or physical outcomes. A number of factors—slower than anticipated recruitment rate, high withdrawal rate from the Intervention (CBT) group and limited resources available—resulted in the premature cessation of this study at two-thirds of the planned sample size, which could have limited the effectiveness of the intervention in this study. Future studies should better determine the effect of targeted therapy against panic attack-related anxiety for those with anxiety symptoms and assess the difference in effectiveness and adherence to face-to-face therapy, telephone-based or group CBT in this population.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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