npj | Primary Care Respiratory Medicine

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'The COPD breathlessness manual': a randomised controlled trial to test a cognitive-behavioural manual versus information booklets on health service use, mood and health status, in patients with chronic obstructive pulmonary disease

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BACKGROUND: Chronic obstructive pulmonary disease (COPD) is a costly long-term condition associated with frequent Accident and Emergency (A&E) and hospital admissions. Psychological difficulties and inadequate self-management can amplify this picture.
AIMS: To compare a cognitive-behavioural manual versus information booklets (IB) on health service use, mood and health status.
METHODS: Two hundred and twenty-two COPD patients were randomly allocated to receive either the COPD breathlessness manual (CM) or IB. They were instructed to work through their programme at home, over 5 weeks. Guidance from a facilitator was provided at an initial home visit plus two telephone call follow-ups.
RESULTS: After 12 months, total A&E visits had reduced by 42% in the CM group, compared with a 16% rise in the IB group. The odds of people in the IB group attending A&E 12 months post-intervention was 1.9 times higher than for the CM group (CI 1.05–3.53). Reduction in hospital admissions and bed days were greatest in the CM group. At 6 months, there were significantly greater improvements in anxiety ($F(2,198) = 5.612$, $P = 0.004$), depression ($F(1.8,176.1) = 10.697$, $P \leqslant 0.001$) and dyspnoea ($F(2,198) = 18.170$, $P \leqslant 0.001$) in the CM group. Estimated savings at 12 months were greatest in the CM group, amounting to £30k or £270 per participant.
CONCLUSION: The COPD manual, which addresses physical and mental health, is a straightforward cost-effective intervention that is worth offering to COPD patients within primary or secondary care.

npj Primary Care Respiratory Medicine (2014) **24,** 14076; doi:10.1038/npjpcrm.2014.76; published online 16 October 2014

INTRODUCTION

Living with Chronic Obstructive Pulmonary Disease (COPD) presents significant ongoing physical, psychological, emotional and lifestyle challenges for individuals, families and carers. It is a costly condition to the UK National Health Service (NHS). Mental health problems are estimated to exist in 30% of all people with a long-term condition.[1] This figure is higher in COPD (34–60%) for problems such as anxiety, panic and depression[2–5] and prevalence of panic disorder is up to 10 times higher in COPD compared with the general population.[6] Psychological comorbidity is associated with persistent smoking, greater Accident and Emergency (A&E) visits, hospital admissions and readmissions, longer stays and increased NHS spending.[7–12] Furthermore, individuals suffer worse quality of life, functioning and disease outcomes, which is unrelated to level of disease severity.[4,13–15]

Breathlessness can be distressing and difficult to understand and control.[16] It is a defining feature of both COPD and panic attacks and can develop through a complex interaction between physical, psychological, emotional and behavioural factors. The cognitive-behavioural model[17] explains panic via a vicious cycle of catastrophic appraisals of breathlessness, escalating fear and heightened sympathetic arousal. This pattern may be emphasised further through the reactions of observers, who may feel equally frightened and helpless. The culmination can often be an overreliance on medications, over-monitoring of symptoms and inappropriate presentation at emergency services. Individuals may start to mistakenly avoid activities due to fearful beliefs about the consequences of becoming breathless,[18] leading to isolation, depression, continued smoking and a lack of motivation and energy for self-management.[6] This could have a knock-on effect on participation in pulmonary rehabilitation (PR), despite the demonstrated benefits of these programmes on dyspnoea, fatigue and control over the disease.[19] Patients often value group support; however, in reality, encouraging attendance and adherence to PR/breathlessness groups can be an issue.[20,21]

There is promising evidence for the effectiveness of cognitive-behaviour therapy (CBT) in addressing mental health difficulties in COPD[6,18,21–26] over and above pharmacotherapy in the short term.[7] It is also important to integrate a mental health model with a framework of adjusting to a physical health condition. Applying the self-regulatory model,[27] which identifies people's idiosyncratic beliefs about their COPD, the emotional impact and their coping strategies, can help formulate and address a clients' difficulties within this physical health context. For example, in a previous study, panic symptoms were most prevalent in participants with low perceived control over symptoms and the disease, negative beliefs about the life-limiting consequences of unpredictable breathlessness attacks and by those using emotional coping strategies such as denial and avoidance.[28]

The COPD breathlessness manual (CM) was developed as a guided self-help intervention that individuals complete in their own time at home, with support from a facilitator. It applies CBT

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Received 11 May 2014; revised 18 July 2014; accepted 12 August 2014

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techniques within a self-management framework and specifically targets the cognitive-behavioural aspects of breathlessness and panic, which, it has been indicated, may facilitate greater improvements in health outcomes than PR alone.[29] A previous group cognitive-behavioural intervention targeting breathlessness and panic demonstrated a reduction in A&E and hospital admissions as well as improved mood and health status in end-stage COPD patients, resulting in NHS savings.[21] The CM was adapted from this intervention. This randomised trial compares the effectiveness of the CM versus British Lung Foundation information booklets (IB) on health service use, mood and health status.

MATERIALS AND METHODS

Study design

This was a prospective, randomised, single-blind, parallel-group trial comparing the CM with British Lung Foundation IB.

Participants

COPD patients ($n = 1,217$) were identified through 10 GP practices in North West London and invited by letter to participate in the trial. Inclusion criteria were: a diagnosis of COPD, verified by being on the COPD disease register at the GP practice (based on the NICE 2010 COPD guidelines[30]—i.e. a forced expiratory volume in the first second (FEV_1)/forced vital capacity (FVC) ratio of less than 0.7, or if FEV_1 is equal to or above 80% predicted normal with other respiratory symptoms being present such as breathlessness or cough); a self-rating breathlessness score on the Medical Research Council (MRC) dyspnoea scale[31] of 3 or more; willingness to participate; ability to provide informed consent; and ability to read and write in English or with assistance. Exclusion criteria were: known psychosis and personality disorders; receiving psychological therapy; participating in PR, or having had PR within the previous six months; cognitive impairment; dementia; and verbal and/or written communication problems.

Randomisation

Simple blocked random sampling was undertaken. Computerised random blocks of six at a time were randomised, three in each group. Participants were blind to group allocation. Primary and secondary care staff were aware of patients' participation in the trial, but were unaware of group allocation and the trial was separate to any clinical care provided. See Figure 1 for trial profile.

Procedure

Patients who had opted-in were telephoned to discuss the trial, check whether they met the criteria and arrange a home visit. Both groups received a 90-min home visit involving obtaining signed informed consent, baseline measures, a semi-structured interview and introducing the

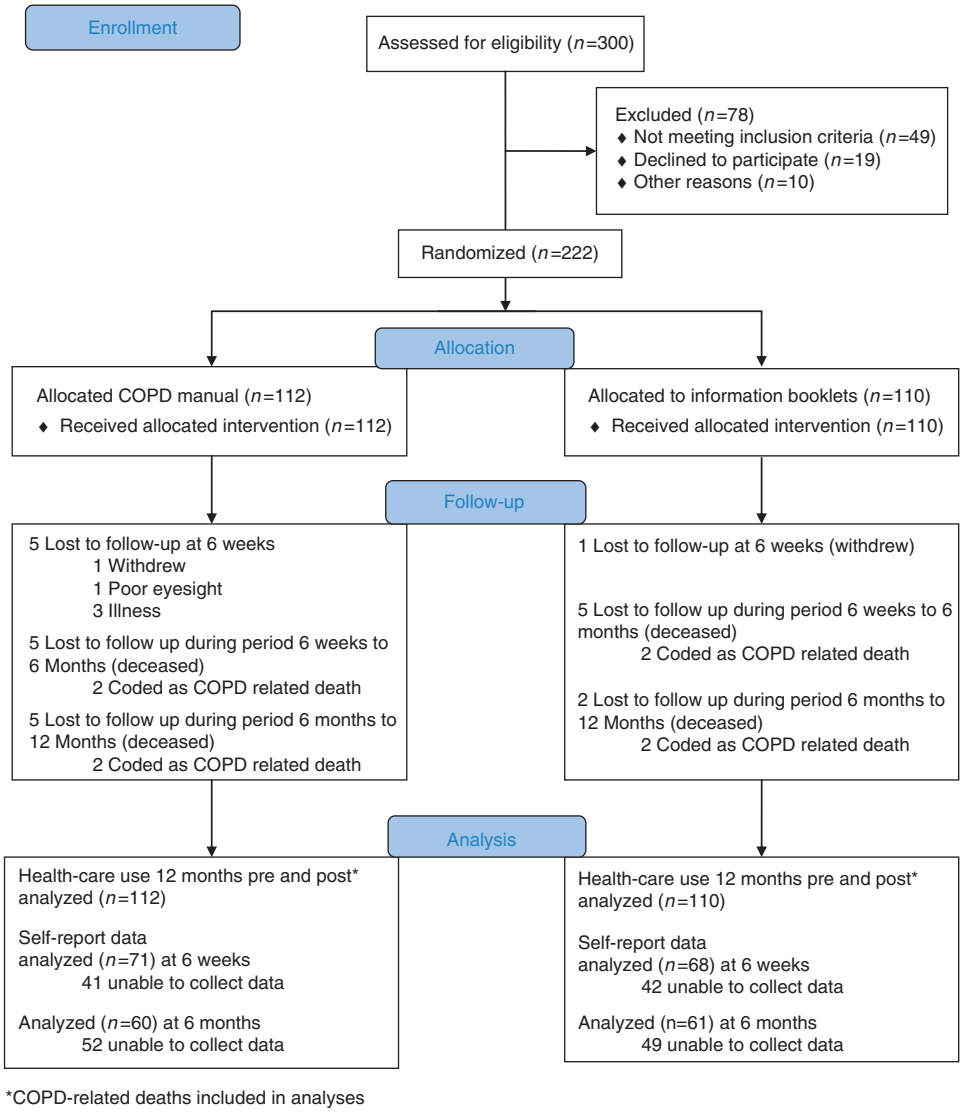

Figure 1. Trial profile.

intervention. Participants were encouraged to follow their programme for approximately 1 h per day (broken up throughout the day) over a 5-week period. For example, for the CM, this could include reading a section, writing in a question response, practising a physical exercise (e.g., walking on the spot) and listening to a track from the relaxation CD. For the IB, this involved predominantly reading, but any practical techniques in the booklets (e.g., breathing control) were reinforced. Partners/carers were encouraged to be involved. Participants received two 30-min telephone call booster sessions at weeks 3 and 6.

The CM

The CM was developed by a health psychologist, with multidisciplinary team input and piloted with small focus groups of COPD patients over 6 months. The final version consisted of a 5-week intervention, with each week divided into six sections. For example, week 1: 'Understanding COPD and the experience of breathlessness' was divided into the following six sections:

Section 1: What is COPD all about?
Section 2: Focus on breathlessness—part 1
Section 3: How to control breathlessness and panic
Section 4: Daily exercises
Section 5: Relaxation CD: Introduction and exercise 1: Breathing control
Section 6: Summary and weekly record

The main theme was breaking the cognitive-behavioural maintenance cycle of breathlessness, panic, frustration and depression, with a specific focus on ways to manage distress (for both patients and carers) to ultimately prevent inappropriate A&E attendance and hospital admissions. Education on distinguishing between a COPD exacerbation and a panic attack was provided alongside self-management guidance. Shifting unhelpful illness cognitions and encouraging adaptive behaviours using pacing and goal-setting was a central strategy. Breathing control and mobility exercises were demonstrated and trialled and participants were encouraged to practise these daily. Participants were asked to complete self-help tasks as well as a weekly mood and breathlessness rating. The manual was accompanied by a relaxation CD.

IB

Participants received a series of British Lung Foundation COPD booklets and were encouraged to work through them over 5 weeks.

Facilitator input

The facilitators (psychologists) were trained in applying CBT techniques within a physical health context to formulate common cognitive-behavioural maintenance patterns as well as utilising motivational interviewing to facilitate behaviour change. A one-day training workshop consisted of understanding the physical and psychological issues in COPD, the challenges of self-management in COPD, the theory and application of the CBT model for breathlessness, panic and prevention of A&E attendance as well as managing frustration and low mood. In addition, practical role plays were conducted for enhancing skills in assessing patients' current psychological status, explaining the interaction between emotions and COPD symptoms, motivation (and barriers) to participation, as well as demonstration of exercises and breathing techniques.

Primary outcome: health service use

Frequency of A&E attendance and frequency and duration of COPD-related hospital admissions 12 months pre- and post-intervention were recorded from a district general hospital's electronic records. Health-care resource group tariffs[32] were calculated for each activity.

Secondary outcomes

Mood and health status were measured at baseline, 6 weeks and 6 months using the following questionnaires:

– The Hospital Anxiety and Depression Scale (HADS),[33] a validated, widely used measure to screen for anxiety and depression in medical settings. Scores are categorised into: 0 to 7, normal; 8 to 10, borderline; and 11 to 21, clinical levels.

– The Self-Reported Chronic Respiratory Questionnaire (CRQ-SR),[34] a reproducible, reliable, and stable measure of health status in chronic lung disease, divided into four domains: (1) Dyspnoea (5 to 35); (2) Fatigue (4 to 28); (3) Emotional function (7 to 49); and (4) Mastery (4 to 28). Higher scores represent better function.

Feedback

Participants were invited to provide feedback using a 1 to 5 Likert scale to various statements such as 'How would you rate your confidence in managing your COPD after using the programme?' Open comments were also invited.

Clinical information

Spirometry was obtained at baseline using a portable spirometer. The percent-predicted forced expiratory volume in the first second (FEV_1%) was used as an indicator of disease severity. Participants reported on length of diagnosis, details of co-existing medical conditions, current prescribed medication(s) and smoking status.

Sample size

A sample size of 186 was calculated (93 per group) for a 5% significance level and 80% power. This was based on a previous study suggesting that the number of admissions varied by a mean of 0.7 between control and intervention groups. It also indicated that the s.d. of the change in number of admissions was 1.7.[21]

Statistical analyses

Statistical methods were employed using SPSS for windows version 17.0. Unpaired *t*-tests on the mean change scores were conducted for A&E visits, hospital admissions and length of stay. Logistic regression was used to predict A&E attendance (attendance versus non-attendance) and hospital admissions (admission versus non-admission). Mixed model analysis of variance was conducted to analyse changes in mood and health status. Data were analysed on an intention to treat basis. Any health service use period culminating in patient fatality was investigated and if coded as COPD-related, was included in subsequent analyses.

Ethics

Ethical approval was obtained from NHS Central REC 3.

RESULTS

Sample characteristics

Eight to 10 participants per week were entered into the trial between January and August 2011. Baseline comparisons with unpaired *t*-tests and X^2-tests showed no major differences between groups on demographic measures, FEV_1%, mood and health status. More people in the CM group attended A&E (X^2 (1) = 7.893, $P = 0.005$) and were hospitalised (X^2 (1) = 4.833, $P = 0.03$) 12 months pre-study, compared with the IB group (Table 1).

A&E visits

Table 2 shows that in the 12 months post-intervention, total A&E visits in the CM group had fallen by 42%, indicating a cost saving of £6,934.12, whereas A&E visits had increased by 16% in the IB group. Despite this increase in A&E visits, the cost did not rise substantially due to 73% of participants being discharged and a lower A&E tariff being charged. Unpaired *t*-test on the mean change scores in A&E visits just failed to reach significance (CM group mean change = − 0.30, (s.e. 0.09), IB group mean change = 0.06, (s.e. 0.16), *t* (220) = 1.994, $P = 0.047$, CI 0.01–0.73, $r = 0.13$).

Thirty-eight percent fewer participants in the CM group visited A&E 12 months post-intervention, compared with a 24% increase in the IB group. A logistic regression model based on entering the variables 'pre-intervention A&E activity' and 'group' was significant in predicting whether or not participants attended A&E in the 12 months following study participation (X^2 (2) = 16.387, $P < 0.001$). 'Pre-intervention A&E attendance' ($\beta = 1.160$, (s.e. 0.311), $P < 0.001$) and group ($\beta = 0.654$, (s.e. 0.309), $P = 0.034$) were significant in predicting 'post-intervention A&E attendance'. The odds of people in the IB group attending A&E 12 months post was 1.9 times higher than for the CM group (CI 1.05–3.53).

Hospital admissions and bed days

All hospital admissions were emergency admissions (via A&E). Table 2 shows that in 12 months, the total number of admissions had fallen by 54 and 23% in the CM and IB group, respectively. Total number of bed days reduced by 61% in the CM group (cost saving £23,263.00) but had increased by 18% in the IB group (cost saving £7,439.00 due to bed days falling under the 'reduced short stay emergency tariff'[32]). Unpaired *t*-tests showed no significant difference between groups on the mean change scores in hospital admissions (CM group mean change = −0.22 (s.e. 0.07), IB group mean change = −0.09, (s.e. 0.13), t (220) = 0.927, P = 0.36, CI −0.15–0.41, r = 0.06) or bed days (CM group mean change = −0.92 (s.e. 0.40), IB group mean change = −0.16 (s.e. 0.62), t (220) = 1.033, P = 0.30, CI −0.69–2.20, r = 0.07).

A logistic regression model based on entering the variables 'pre-intervention hospital admissions' and 'group' was not significant in predicting whether or not participants were admitted to hospital in the 12 months post-intervention (X^2 (2) = 2.799, P = 0.247). See Supplementary Table 1 for logistic regression summary table.

The total savings from the CM at 12 months amounted to £30,197.12, or £269.62 per participant, compared with a £50 cost of delivering the programme.

Table 1. Baseline data

Variable	*CM*, n = *112 (%)*	*IB*, n = *110 (%)*
Sociodemographic		
Male/female	44/56	41/59
Age (years)[a]	71.2 (s.d.10.4)	73.2 (s.d. 11.4)
Married/partner/widowed/ divorced/single	44/5/24/15/12	39/6/33/14/8
Living alone/with another	36/64	45/55
Has carer/does not have carer	53/47	45/55
Has/does not have community matron	10/90	6/94
Ever/never smoked (number of pack years)[a]	94/6 (38.2 s.d. 18.2)	94/6 (37.1, s.d. 18.3)
Number of years quit[a]	8.6 (s.d. 12.0)	9.2 (s.d. 13.0)
Current smoker at baseline (no. per day)[a]	27 (3.6 s.d. 6.9)	30 (3.5 s.d. 6.9)
Medical		
FEV_1%[a]	55.9 (s.d. 15.7) (n = 93)	59.6 (s.d. 15.9) (n = 93)
Years COPD (self-report)[a]	9.6 (s.d. 9.4)	9.5 (s.d. 11.8)
MRC dyspnoea score (self-rating)—median	4	4
Self-reported comorbidities		
Baseline clinical anxiety (HADS score ⩾ 11)	33 (8.4 s.d. 4.6)	25 (7.7 s.d. 4.3)
Baseline clinical depression (HADS score ⩾ 11)	32 (8.8 s.d. 3.7)	29 (8.6 s.d. 3.5)
Arthritis	50	49
Chronic back pain	56	48
Angina	14	14
Coronary heart disease	13	16
Diabetes	17	16
Hypertension	51	50
Previous cancer	13	14
Previous stroke	6	6
Self-reported medications		
Short-acting $beta_2$ agonist	92	79
Long-acting $beta_2$ agonist	59	50
Long-acting anticholinergic	69	61
Inhaled corticosteroid	21	19
Antisecretory	45	39
Oxygen	2	1
Analygesic	36	34
Antidepressant	16	12
Anxiolytic	4	5
Antibacterial	4	4
Drugs for rheumatic disease and gout	3	2
Calcium channel blocker	31	26
Diuretic	20	23
Angiotensin-converting enzyme inhibitor	27	22
Antiplatelet	33	31
Statin	49	40
Beta-blocker	6	5
Antidiabetic	13	14
Antihypertensive	4	1

Abbreviations: CM, COPD breathlessness manual; COPD, chronic obstructive pulmonary disease; FEV_1, forced expired volume in the first second; HADS, Hospital Anxiety and Depression Scale; IB, information booklets; MRC, Medical Research Council.
[a]Figures represent the mean (s.d.).

Mood and health status

All participants completed questionnaires at baseline. Six-week response rate was 63 (n = 71) and 62% (n = 68) in the CM and IB group, respectively, and at 6 months, 59 (n = 60) and 57% (n = 61) in the CM and IB group, respectively. See Table 3 for mean scores and s.d. on self-report measures.

Anxiety. At 6 months, 3% remained clinically anxious in the CM group, compared with 23% in the IB group. Mixed model analysis of variance showed a significant main effect of anxiety and time (F (2,198) = 3.870 P = 0.022) and a significant interaction between anxiety and group (F (2,198) = 5.612, P = 0.004) (see Figure 2). The contrast between group and anxiety at baseline versus six months was significant (F (1,99) = 7.948, P = 0.006, r = 0.3) as well as at 6 weeks versus 6 months (F (1,99) = 7.863, P = 0.006, r = 0.3).

When selecting participants with borderline to clinically significant anxiety at baseline (HADS ⩾ 8), there was a significant main effect of clinical anxiety and time (F (2,92) = 12.658, P = 0.001), but the interaction between clinical anxiety and group over time just failed to reach significance (F (2,92) = 3.181, P = 0.046). The contrast between group and clinical anxiety at baseline versus 6 months was significant (F (1,46) = 5.247, P = 0.027, r = 0.3) (see Figure 3).

Depression. At 6 months, 7% in the CM group remained clinically depressed, compared with 15% in the IB group. Greenhouse–Geisser estimates showed a significant main effect of depression and time (F (1.8,176.0) = 14.179, P ⩽ 0.001) and a significant interaction between depression and group (F (1.8,176.0) = 10.697, P ⩽ 0.001) (see Figure 4). The contrast between group and depression at baseline versus 6 months was significant (F (1,99) = 10.341, P = 0.002, r = 0.3) with lower depression levels in the CM group, but not at 6 weeks versus 6 months (F (1,99) = 0.378, P = 0.540, r = 0.1).

Dyspnoea. There was a significant main effect of dyspnoea and time (F (2,188) = 18.283, P ⩽ 0.001) and a significant interaction between dyspnoea and group (F (2,198) = 18.170, P ⩽ 0.001). The contrast between group and dyspnoea at baseline versus 6 months was significant (F (1,94) = 32.835, P ⩽ 0.001, r = 0.5) as well as at 6 weeks versus 6 months (F (1,94) = 19.953, P ⩽ 0.001, r = 0.4) with improved dyspnoea ratings in the CM group.

Fatigue. There was no significant main effect of fatigue and time (F (2,194) = 2.574, P = 0.079) but a significant interaction between fatigue and group (F (2,194) = 9.457, P ⩽ 0.001). The contrast

Table 2. Health service use and costs

Activity	*COPD Manual*, n = *112*		*Information booklets*, n = *110*	
	12 months pre	*12 months post*	*12 months pre*	*12 months post*
Total visits to A&E	90 (52 people)	52 (32 people)	68[a] (31 people)	81 (41 people)
Mean visits (s.d.)	1.69 (s.d. 0.90)	1.59 (s.d. 0.95)	2.19 (s.d. 2.17)	1.98 (s.d. 1.75)
Total A&E cost	£12,788.63	£5,854.51	£9,372.70	£9,853.30
Number of A&E visits resulting in discharge home or to GP	44 (29 people)	31 (20 people)	29 (18 people)	50 (30 people)
Number of A&E visits resulting in a hospital admission	46 (37 people)	21 (15 people) (4 deaths due to COPD)	40 (22 people)	31 (16 people) (3 deaths due to COPD)
Total bed days	227	89	163	198
Mean days hospital admission	6.14 (s.d. 9.91)	5.93 (s.d. 5.65)	7.41 (s.d. 9.97)	12.38 (s.d. 10.84)
Total admission cost	£36,446	£13,183	£27,880	£20,441

NB Some people visited A&E more than once with a different outcome at each visit, i.e., admitted at one visit, but discharged at another visit.
Abbreviations: A&E, Accident and Emergency; COPD, chronic obstructive pulmonary disease.
[a]One participant admitted as an emergency via GP.

Table 3. Mean scores (standard deviation) on self-report measures

	CM group			*IB group*		
	Baseline	*6 weeks*	*6 months*	*Baseline*	*6 weeks*	*6 months*
Anxiety (HADS)	8.4 (4.5)	6.8 (3.7)	6.7 (3.9)	7.8 (4.2)	6.8 (3.8)	7.8 (3.7)
Depression (HADS)	8.8 (3.7)	6.0 (3.5)	5.3 (3.1)	8.6 (3.5)	7.8 (3.3)	7.2 (3.2)
Dyspnoea (CRQ)	12.0 (4.7)	14.9 (6.1)	16.4 (6.7)	12.5 (4.3)	14.4 (5.4)	12.8 (4.8)
Fatigue (CRQ)	12.3 (5.4)	33.2 (8.3)	15.0 (5.1)	13.6 (5.1)	14.3 (4.6)	12.9 (4.4)
Emotional functioning (CRQ)	28.5 (9.1)	33.2 (8.3)	31.9 (7.8)	30.1 (9.6)	32.3 (8.1)	27.1 (7.0)
Mastery (CRQ)	16.2 (5.2)	20.4 (4.4)	19.0 (5.7)	17.6 (5.7)	19.1 (5.0)	16.4 (3.7)

Abbreviations: CM, COPD breathlessness manual; CRQ-SR, The Self-Reported Chronic Respiratory Questionnaire; HADS, Hospital Anxiety and Depression Scale; IB, information booklets.

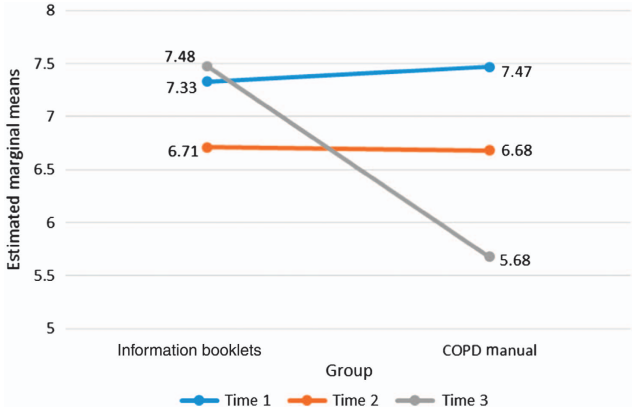

Figure 2. Estimated marginal means of anxiety over time.

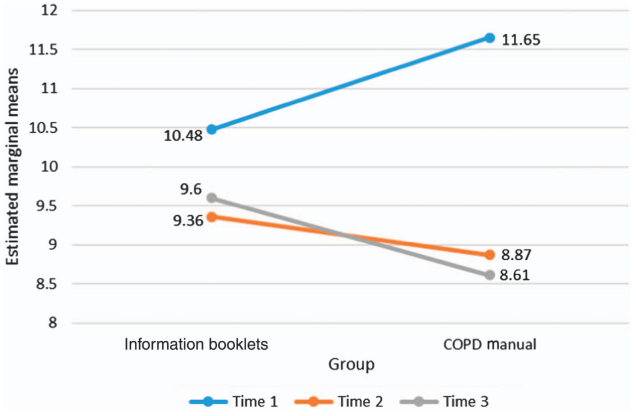

Figure 3. Estimated marginal means of clinical anxiety over time.

between group and fatigue at baseline versus 6 months was significant (F (1,97) = 15.945, $P \leqslant 0.001$, $r = 0.4$) as well as at 6 weeks versus 6 months (F (1,97) = 6.910, $P = 0.010$, $r = 0.3$) with less fatigue reported in the CM group.

Emotional function. Greenhouse–Geisser estimates showed a significant main effect of emotional function and time (F (1.8,175.7) = 13.595 $P \leqslant 0.001$) and a significant interaction between emotional function and group (F (1.8,175.7) = 11.453, $P \leqslant 0.001$). The contrast between group and emotional function at baseline versus 6 months was significant (F (1,96) = 17.503, $P \leqslant 0.001$, $r = 0.4$) as well as at 6 weeks versus 6 months (F (1,96) = 13.079, $P \leqslant 0.001$, $r = 0.3$) with improved emotional function reported in the CM group.

Mastery (control). There was a significant main effect of mastery and time (F (2,200) = 18.241 $P \leqslant 0.001$) and a significant interaction between mastery and group (F (2,200) = 11.212, $P \leqslant 0.001$). The contrast between group and mastery at baseline versus six months was significant with improved mastery in the CM group

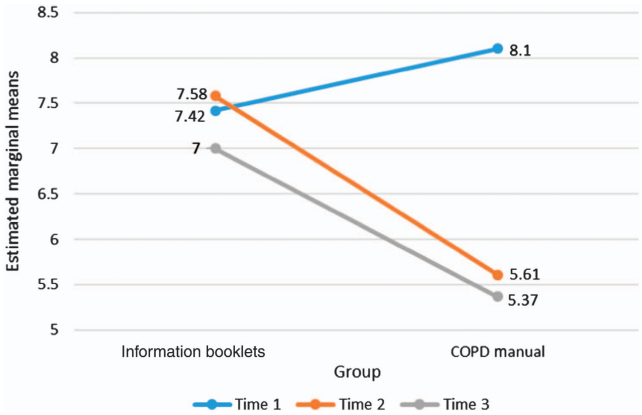

Figure 4. Estimated marginal means of depression over time.

(F (1,100) = 17.704, $P \leqslant 0.001$, $r = 0.4$) but not at 6 weeks versus 6 months (F (1,100) = 2.081, $P = 0.152$, $r = 0.1$).

Participant feedback

Seventy-eight percent reported that the CM was very useful, 92% reported more confidence in managing COPD, and 79% reported a great improvement to their quality of life. Most useful aspects were discussions on the phone, managing breathlessness and panic, distinguishing anxiety and a flare up, pacing, breathing and relaxation. Improvements included increasing the programme length as well as combining it with group sessions to increase motivation and social contact.

Thirty-seven percent reported that the information booklets were useful and 28% reported an improvement in their quality of life. Participants appreciated the facilitator input, although as a programme, they generally wanted more practical elements in addition to reading information.

DISCUSSION

Main findings

The COPD breathlessness manual (CM) resulted in greater improvements in health-care use, mood and health status, with greater NHS savings, compared to IB. It appears that the latter plus facilitator input is beneficial up to a point, but does not result in long term sustained changes compared to the CBT component underpinning the CM. This is in keeping with previous evidence that providing information is important, but in itself does not lead to significant behaviour change.[35]

Participants in the IB group were almost twice as likely to attend A&E in the 12 months post intervention, compared to participants in the CM group. At 12 months, A&E visits in the IB group had increased by 16%. Furthermore, the majority of IB participants were discharged from A&E in the 12-month follow-up period, indicating potentially avoidable visits, perhaps due to almost a quarter remaining clinically anxious and reporting greater dyspnoea. In comparison, A&E visits in the CM group had fallen by 42% along with a greater reduction in anxiety and depression.

Interpretation of findings in relation to previously published work

The results of this study replicate the findings from a previous breathlessness group CBT intervention[21] and highlight the comparable benefits of delivering CBT in both group and home-based settings. The CM was a targeted intervention and not part of a wider PR or other exercise/education programme. The findings correspond to a recent meta-analysis,[36] which showed a small effect of CBT for anxiety and highlighted the need for adequately powered RCT's disentangling the contributions of exercise training, education and CBT.

This study highlights that providing no CBT intervention leaves potential for psychological problems to escalate and can lead to inappropriate health-care use and increasing NHS costs. It raises the importance of intervening early in COPD with brief targeted CBT interventions, to prevent the development and worsening of anxiety, panic attacks and panic disorder and associated hospital admissions, which has equally been emphasised in previous studies.[6,37]

The delivery of the CM intervention, i.e., brief with minimal telephone-based support appears feasible and relates to a similar study,[25] which found that six weekly sessions and three telephone booster sessions of CBT improved anxiety, depression, mastery and fatigue in COPD. Furthermore, a recent RCT[38] provided evidence that a self-managed programme in primary care offering minimal telephone support can lead to health benefits similar to PR.

Strengths and limitations of this study

The CM is the first known 'manualised' psychological intervention, targeting breathlessness, panic and prevention of hospital use in COPD. This programme demonstrated clinical and cost-effectiveness, was acceptable to participants, and has the potential to be used in both primary and secondary care.

A number of study limitations should be noted. The response rate to the mailed letters for recruitment was low (25%), making it a small study. A larger study would have enhanced the representativeness and generalisability of the sample to a wider COPD population. Hospital data were collected from a single hospital database, and hence did not account for attendance at hospitals elsewhere. Self-report measures were not collected beyond 6 months, and the moderate follow-up rates may have biased results. Anxious and depressed individuals were not selected *per se;* rather, COPD was considered to be an innately psychologically challenging condition and research has shown that psychological issues can often go unrecognised and remain untreated in COPD patients.[39] It should be noted that a small proportion of participants were taking medication for depression and anxiety, which may have confounded the results, although these percentages were comparable in both groups (16 and 12% reported taking antidepressants from the CM and IB group, respectively; for anxiolytics, this was 4 and 5%).

It is appreciated that motivation and commitment are a prerequisite for patients engaging in guided self-help interventions; likewise, facilitator skills make a huge difference. Both groups received equal facilitator guidance, which in itself may have positively influenced results. The facilitators in the study were psychologists; however, this is not an integral requirement, and a facilitator training workshop has been developed and delivered. This is in keeping with the current emphasis on providing CBT skills training for respiratory nurses and community matrons to help address psychological issues in COPD.[40,41] It is recognised that levels of participation in the CM programme would have varied. Fidelity to completing the intervention was discussed during follow-ups, although was not recorded objectively and level of adherence rate would have enhanced the study rigour. Furthermore, it is not possible to state which particular aspect of the CM was most effective, which is necessary for future research.

Implications for future research, policy and practice

The CM is cost-effective and easy to deliver in different settings. It could be particularly beneficial for anxious/depressed individuals, frequent GP or A&E attenders, post exacerbation or as an 'add-on' to PR to increase adherence. It could also be implemented within

a respiratory service or an Improving Access to Psychological Therapies service in accordance with government policy on addressing mental health in long-term conditions.[12] Future research intends to explore the delivery of the CM in different formats such as Telemedicine as well as interventions for carers.

Conclusions

Results show that the CM provided psychological benefit, improved self-management and reduced costs to the NHS in an unselected group. It is emphasised that it should be considered as an option for the majority of COPD patients as a preventative measure, to help them cope better.

ACKNOWLEDGEMENTS

Thanks to Mr Paul Bassett and Dr Gordon Taylor for advice on statistical analysis.

CONTRIBUTIONS

CH contributed to the design and implementation of the study, enrolment and follow-up of participants, data collection, statistical analysis and interpretation of results and writing of the report. SD contributed to the study conception and design. SD acted as the guarantor for the study.

COMPETING INTERESTS

The authors declare no conflict of interest.

FUNDING

Central and North West London NHS Foundation Trust innovations department funded this research. The funding source had no involvement in undertaking any aspect of the study.

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Supplemental Information accompanies the paper on the *npj Primary Care Respiratory Medicine* website (http://www.nature.com/npjpcrm)