A self-management programme for COPD: a randomised controlled trial

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ABSTRACT Studies of programmes of self-management support for chronic obstructive pulmonary disease (COPD) have been inconclusive. The Self-Management Programme of Activity, Coping and Education (SPACE) FOR COPD is a 6-week self-management intervention for COPD, and this study aimed to evaluate the effectiveness of this intervention in primary care.

A single-blind randomised controlled trial recruited people with COPD from primary care and randomised participants to receive usual care or SPACE FOR COPD. Outcome measures were performed at baseline, 6 weeks and 6 months. The primary outcome was symptom burden, measured by the self-reported Chronic Respiratory Questionnaire (CRQ-SR) dyspnoea domain. Secondary outcomes included other domains of the CRQ-SR, shuttle walking tests, disease knowledge, anxiety, depression, self-efficacy, smoking status and healthcare utilisation.

184 people with COPD were recruited and randomised. At 6 weeks, there were significant differences between groups in CRQ-SR dyspnoea, fatigue and emotion scores, exercise performance, anxiety, and disease knowledge. At 6 months, there was no between-group difference in change in CRQ-SR dyspnoea. Exercise performance, anxiety and smoking status were significantly different between groups at 6 months, in favour of the intervention.

This brief self-management intervention did not improve dyspnoea over and above usual care at 6 months; however, there were gains in anxiety, exercise performance, and disease knowledge.

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Introduction

There is a growing, yet inconclusive, literature on self-management interventions for chronic obstructive pulmonary disease (COPD). A broad scope of interventions has been described within the umbrella of self-management. Action plans are the most basic level of self-management support; however, when used in isolation, they have had little impact [1–3]. More comprehensive self-management programmes provide structured and supervised education and exercise to varying degrees [4, 5], and have had some success in reducing healthcare utilisation and improving exercise performance. However, the required infrastructure and resources are costly and may potentially restrict their ability to be delivered to the wider COPD population. A brief, ''light touch'' self-management intervention is required that can be delivered to more patients; however, it is not yet known whether such an intervention can reduce symptom burden.

The timing of the self-management intervention within the course of the disease may be critical for its success. Some self-management programmes have been directed towards patients who have been recently hospitalised with an acute exacerbation of COPD, with limited or no clinical effect [6, 7]. Patients who are clinically stable, and managed in primary care within the community, may find new skills and disease knowledge easier to learn than people who are further entrenched within the spiral of disability associated with hospitalisation. However, the efficacy of self-management support within primary care is not yet known.

The Self-Management Programme of Activity, Coping and Education (SPACE) FOR COPD aims to support people with COPD in managing day-to-day tasks, minimising symptom burden, provoking health-enhancing behaviour change and enhancing emotional well-being. It is anticipated that improving disease knowledge and self-efficacy may be fundamental to achieving these results. The programme is structured around the SPACE FOR COPD manual, which has been designed to develop both generic self-management skills and disease-specific tasks. It is a self-directed programme, which patients can follow independently at home. The development and pilot testing of the programme has previously been described [8]. We conducted a randomised controlled trial with the aim of establishing the short- and medium-term effectiveness of SPACE FOR COPD on patient outcomes, compared with usual care alone. Our hypothesis was that a brief self-management intervention delivered in primary care (SPACE FOR COPD) would reduce symptom burden at 6 months (assessed by the dyspnoea domain of the self-reported Chronic Respiratory Questionnaire (CRQ-SR)). We also investigated the effect of SPACE FOR COPD on other outcomes and health behaviours, including exercise performance, psychological morbidity, self-efficacy, disease knowledge, healthcare utilisation and smoking prevalence.

Methods

Design

This was a single-centre, investigator-blinded, randomised controlled trial conducted with 6 months follow-up, which took place from December 2009 to April 2012. Participants were randomised to SPACE FOR COPD or usual care. All participants gave written informed consent and ethical approval for the study was granted by Leicestershire, Northamptonshire and Rutland Regional Ethics Committee (reference 07/H0408/114).

Setting and participants

Study participants were recruited from 30 primary care COPD registers from Leicester, Leicestershire, Rutland and Coventry, UK. Practices screened patient registers to identify eligible candidates. To be included, participants were required to: 1) have a diagnosis of COPD confirmed by spirometry, with a forced expiratory volume in 1 s (FEV_1)/forced vital capacity ratio <0.7; 2) be grade 2–5 on the Medical Research Council dyspnoea scale; and 3) have been clinically stable for 4 weeks. Individuals were excluded if they: 1) were unable to undertake an exercise regime due to neurological, musculoskeletal or cognitive comorbidities; 2) were unable to read English to the reading age of an 8-year-old; and 3) had completed pulmonary rehabilitation within the previous 12 months.

Randomisation and interventions

Participants were assigned to either usual care or SPACE FOR COPD *via* a web-based, concealed allocation programme, using simple randomisation codes prepared by the trial statistician (J. Bankart). Randomisation was conducted by the trial investigator responsible for administering the intervention (K.E. Mitchell).

All study participants continued to receive usual care for their COPD management. Within primary care, all participants were managed under a general practitioner and practice team. No participants received pulmonary rehabilitation during the study period.

In addition to usual care, participants randomised to SPACE FOR COPD received the self-management programme. The comprehensive programme is structured around the SPACE FOR COPD manual, which is

a 176-page workbook that individuals can follow independently at home. The manual, divided into four discreet sections, contains educational material and a home exercise programme (see online supplement 1 for contents page). Acquisition of skills is promoted through goal-setting strategies, coping planning and case studies (see online supplement 2 for manual structure). It incorporates an exercise regime that consists of a daily walking programme, and resistance training of the upper and lower limbs using free weights three times per week. The manual advises on training progression and includes an action plan for exacerbation management. All content of the manual was approved by the Plain English Campaign (New Mills, UK) and awarded the Crystal Mark.

Participants randomised to SPACE FOR COPD were introduced to the programme by a physiotherapist during a 30–45-min consultation. Motivational interviewing techniques were used to underpin the consultation in order to explore the patients' readiness to change and to enhance motivation for adopting new lifestyle behaviours. Participants' needs were discussed and goal setting strategies were introduced. Participants were advised how to use the manual at home and the exercise regime was described by the physiotherapist in detail. It was anticipated that participants would work through the manual in approximately 6 weeks; however, participants were advised the manual was theirs to keep, as it could be used as a resource for the future, and that the lifestyle changes it suggested should be lifelong. Participants received two telephone calls from the physiotherapist at 2 and 4 weeks into the programme, with the aim of reinforcing skills and providing encouragement to progress (see online supplement 3 for telephone contact schedule). There was no further contact between the physiotherapist and the participant after the telephone call at 4 weeks.

Outcome measures and follow-up

The primary pre-specified outcome was the change in the CRQ-SR dyspnoea domain from baseline to 6 months [9]. Secondary outcomes were the fatigue, emotion and mastery domains of the CRQ-SR, the Bristol COPD Knowledge Questionnaire (BCKQ) [10], the Hospital Anxiety and Depression Scale (HADS) [11], the incremental shuttle walk test (ISWT) [12], the endurance shuttle walk test (ESWT) [13], the Pulmonary Rehabilitation Adapted Index of Self-Efficacy (PRAISE) [14], and self-reported smoking status. All outcomes were measured at baseline, then at 6 weeks and 6 months after commencing the programme. The assessments at 6 weeks and 6 months were conducted by a member of the research team who was blind to randomisation allocation (V. Johnson-Warrington). Healthcare utilisation data were collected for the 6-month study period, which was retrieved directly from patients' records kept on both primary and secondary care databases. Self-reported smoking status data were collected at baseline and 6 months.

Sample size calculation and statistical analysis

The power calculation was based on the primary outcome at 6 months. To detect a mean$\pm$SD between-group difference of 0.5 ± 1.0 in the change in CRQ-SR dyspnoea domain with 80% power, 63 people per group were required ($\alpha=0.05$, two-sided). In anticipation of a possible 30% attrition rate from the study, we increased the total sample size to 92 per group (184 in total).

Analysis was carried out on an intention-to-treat basis. Missing data were imputed in Stata (version 12; StataCorp, College Station, TX, USA) using multiple imputed chained equations. 20 imputed datasets were created using age, sex, FEV_1, body mass index, smoking status, baseline exacerbation frequency, number of comorbidities, baseline dyspnoea, fatigue, emotion, mastery, ISWT, ESWT, BCKQ, PRAISE and HADS as predictors. Analyses on imputed datasets were carried out using the micombine command in Stata, which analyses each dataset separately and combines the results. Predicted datasets were checked for similarity to the original data. All other statistical analyses were conducted using Predictive Analytics Software (version 18; IBM, Portsmouth, UK). Independent t-tests were performed on baseline and 6-week data for primary and secondary outcomes, and ANCOVA was used to correct for baseline differences. Tobit models were used in the analysis of the change in ESWT to account for the ceiling effect observed in this measure. For the CRQ-SR, HADS, ISWT and ESWT, the data were dichotomised for achievement of the established minimally important differences (MIDs) of 0.5 points [15], -1.5 points [16], 48 m [17] and 186 s [18], respectively. A Fisher's exact test was used to evaluate change in self-reported smoking status. Healthcare utilisation data were analysed using negative binomial regression. Statistical significance was accepted if the p-value was <0.05.

Results

Participants were recruited between December 2009 and September 2011. Figure 1 shows the Consolidated Standards of Reporting Trials flow diagram of participant enrolment, allocation, follow-up and analysis. There were no significant differences in demographics or baseline variables between those who completed and those who did not complete the study. Patient demographics for both groups are displayed in table 1.

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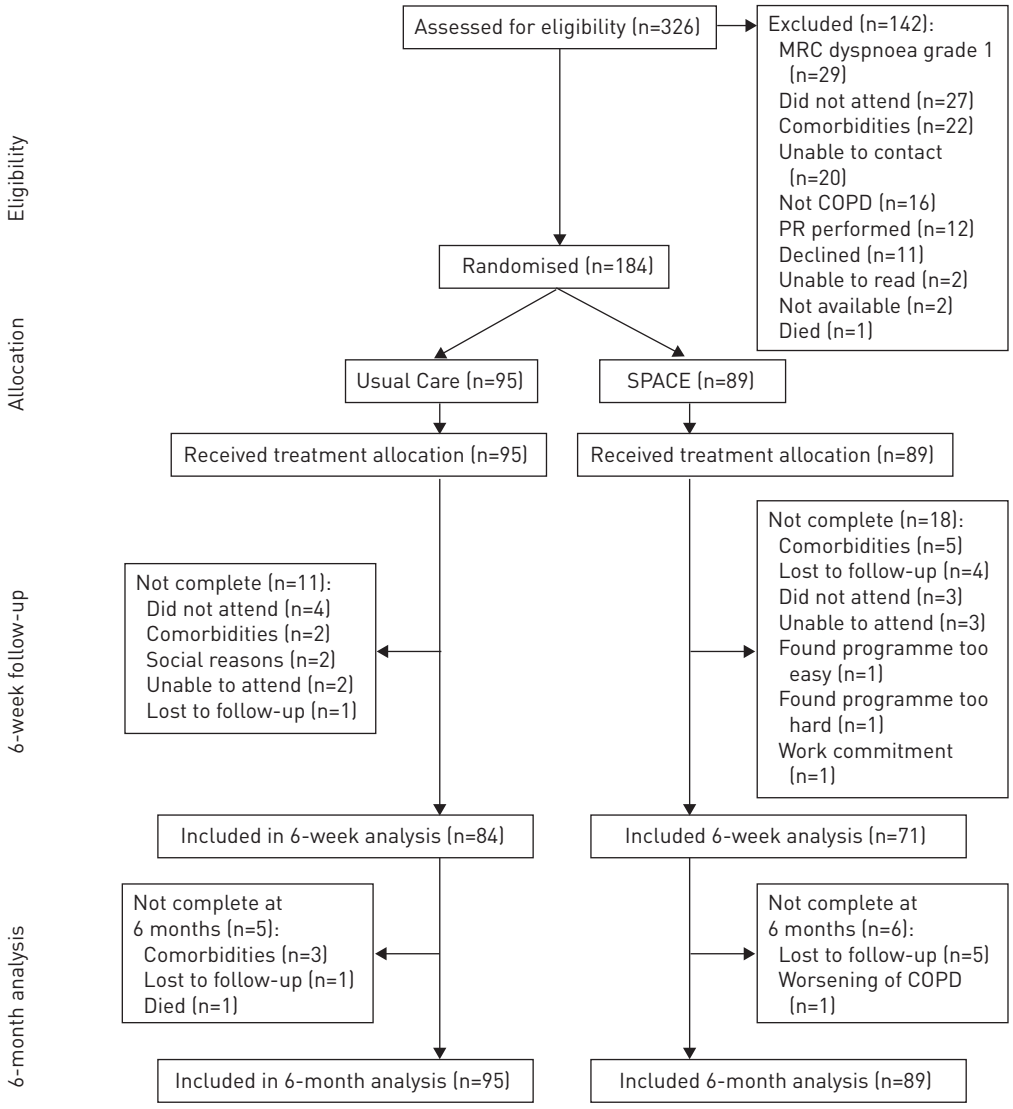

FIGURE 1 Consolidated Standards of Reporting Trials flow diagram of participation. MRC: Medical Research Council; COPD: chronic obstructive pulmonary disease; PR: pulmonary rehabilitation; SPACE: Self-Management Programme of Activity, Coping and Education.

The only significant baseline difference between treatment groups was the CRQ-SR dyspnoea score; therefore, this was corrected for in subsequent analyses. Age, sex, FEV_1, smoking history and pack-years, oxygen use, and all baseline outcome measures were entered into Rod Little's test for data missing completely at random [19]. This was not significant for the primary outcome ($p=0.8$), providing insufficient evidence, from the data collected, that the data were not missing completely at random.

The primary outcome

Baseline and change in CRQ-SR dyspnoea scores are presented in table 2. Compared with usual care, the change in CRQ-SR dyspnoea domain in the SPACE FOR COPD group was statistically significantly greater at 6 weeks ($p=0.049$). This level of significance was not maintained at 6 months ($p=0.17$). Both groups improved CRQ-SR dyspnoea over time ($p<0.001$) (fig. 2) and only the SPACE group maintained within-group changes that exceeded the MID of 0.5.

Secondary outcomes

Changes in secondary outcomes are presented in table 2. There was a significant difference in the change in the fatigue and emotion domains of the CRQ-SR between groups at 6 weeks but no difference in mastery. These differences were diminished at 6 months. There was a significant between-group difference in the change in distance walked on the ISWT at 6 weeks; however, this was no longer significant at 6 months

TABLE 1 Baseline characteristics and demographics

	SPACE	Usual care
Patients	89	95
Age years	69±8.0	69±10.1
Males/females	54/35	47/48
FEV1 L	1.45±0.57	1.45±0.55
FEV1 % predicted	56.04±16.76	59.60±17.42
GOLD stage I/II/III/IV	7/51/22/9	8/60/20/7
GOLD 2011 classification A/B/C/D	33/25/15/16	41/27/9/18
BMI kg·m^{-2}	28.05±5.6	27.09±4.9
Under respiratory consultant	6	7
MRC dyspnoea grade 2/3/4/5	48/24/13/4	50/22/14/9
Oxygen LTOT/ambulatory/both/none	0/1/0	3/0/1
Smoking history		
Current/ex-/never-smokers	18/67/4	21/68/6
Exposure pack-years	43±31.7	36±22.4
Comorbidities		
Hypertension	32	37
Type II diabetes	13	8
Heart failure	2	1
Arthritis	35	34
Other	49	48
Number of comorbidities 0/1/2/3/⩾4	17/31/24/12/5	16/39/30/8/2
Medication		
SABA	71	87
LABA	5	3
LABA + ICS	45	63
LAMA	42	46
Time since diagnosis years	7±6.7	6±6.2
Number of exacerbations in previous 6 months 0/1/2/3/4/⩾5	46/31/7/3/1/1	45/33/10/5/1/1
Age on leaving education years	15±1.2	16±1.7
Ethnicity		
White British	87	93
Irish	1	2
Indian	1	0
Lives with		
Alone	19	21
Spouse	54	58
Family	11	8
Other	5	8

Data are presented as n or mean±SD. SPACE: Self-Management Programme of Activity, Coping and Education; FEV1: forced expiratory volume in 1 s; GOLD: Global Initiative for Chronic Obstructive Lung Disease; BMI: body mass index; MRC: Medical Research Council; LTOT: long-term oxygen therapy; SABA: short-acting β-agonist; LABA: long-acting β-agonist; ICS: inhaled corticosteroid; LAMA: long-acting muscarinic antagonist.

(fig. 2). The mean change in ISWT either within or between groups did not reach the MID of 48 m [17] at either 6 weeks or 6 months. The ESWT time improved significantly in the SPACE FOR COPD group compared with usual care at 6 weeks, and was maintained between 6 weeks and 6 months (fig. 2). There was a significant difference between groups in change in anxiety scores at 6 weeks, which was maintained at 6 months. There were no significant changes in depression at 6 weeks or 6 months. Since the HADS can be analysed according to thresholds of ⩾8 indicating a possible presence of anxiety or depression [20], subgroups of those who scored ⩾8 at baseline were evaluated in *post hoc* analyses (table 2). In patients scoring ⩾8 at baseline on the HADS depression domain, there was a between-group difference in change in depression scores of 1.76, exceeding the MCID of -1.5, although this was not statistically significant. The between-group difference in change in disease knowledge was statistically significant at 6 weeks and was maintained at 6 months (fig. 2). There was no significant change in PRAISE scores at 6 weeks or 6 months. For the CRQ-SR, HADS, ISWT and ESWT, results were dichotomised according to attainment of the MID in each relevant domain. Results are presented in table 3.

At baseline, there were 18 current smokers in the SPACE group and 21 receiving usual care. At 6 months, five of those patients in the SPACE group reported having stopped smoking, while none of the 21 smokers

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TABLE 2 Baseline, and change at 6 weeks and 6 months for all outcomes

	SPACE			Usual care			Between-group difference in change at 6 weeks	Between-group difference in change at 6 months
	Baseline	Change at 6 weeks	Change at 6 months	Baseline	Change at 6 weeks	Change at 6 months		
CRQ-SR score								
Dyspnoea	3.31±1.07	0.71 (0.45–1.00)	0.66 (0.39–0.93)	2.95±1.17	0.42 (0.20–0.65)	0.49 (0.18–0.78)	0.29 (-0.12–0.56) (p=0.049)	0.17 (-0.29–0.52) (p=0.17)
Fatigue	3.93±1.23	0.49 (0.24–0.66)	0.19 (-0.08–0.47)	3.80±1.32	0.01 (-0.21–0.22)	-0.10 (-0.28–0.08)	0.48 (0.08–0.66) (p=0.013)	0.29 (-0.12–0.53) (p=0.06)
Emotion	4.86±1.27	0.34 (0.11–0.57)	0.16 (-0.14–0.46)	4.83±1.22	-0.07 (-0.27–0.11)	-0.19 (-0.39–0.01)	0.41 (0.08–0.62) (p=0.011)	0.35 (-0.08–0.6) (p=0.09)
Mastery	5.25±1.32	0.15 (-0.06–0.37)	0.04 (-0.22–0.30)	5.14±1.40	-0.11 (-0.35–0.13)	-0.23 (-0.47–0.20)	0.26 (-0.05–0.54) (p=0.10)	0.27 (-0.14–0.56) (p=0.09)
ISWT m	343.0±150.0	9.4 (-5.0–24.0)	10.2 (-7.1–27.5)	353.0±161.8	-6.7 (-17.9–4.5)	-5.7 (-17.5–6.0)	16.1 (-1.7–34.0) (p=0.017)	15.9 (-4.8–36.7) (p=0.50)
ESWT s	260.3±179.4	209.7 (122.3–297.1)	233.5 (136.0–331.0)	262.8±166.6	92.1 (32.8–151.4)	49.9 (-4.5–104.4)	117.6 (16.8–218.5) (p=0.006)	183.6 (72.8–294.4) (p=0.003)
HADS score								
Anxiety	5.98±3.94	-0.73 (-1.28– -1.17)	-0.31 (-1.06–0.45)	6.91±4.06	0.12 (-0.38–0.62)	0.09 (-0.45–0.63)	-0.85 (-1.58– -1.00) (p=0.04)	-0.40 (-1.30–0.50) (p=0.04)
Depression	5.32±3.22	-0.50 (-1.03–0.03)	-0.19 (-0.87–0.49)	5.06±3.10	0.22 (-0.30–0.75)	0.47 (-0.02–0.95)	-0.72 (-1.47–0.03) (p=0.10)	-0.66 (-1.47–0.15) (p=0.27)
Anxiety among those with baseline ⩾8[#]	10.50±2.11	-1.00 (-2.30–0.30)	-1.14 (-2.47–0.19)	10.67±2.47	-0.39 (-1.07–0.29)	-0.52 (-1.31–0.28)	-0.61 (-1.91–0.70) (p=0.35)	-0.62 (-2.04–0.80) (p=0.38)
Depression among those with baseline ⩾8[¶]	9.44±1.38	-0.89 (-2.25–0.47)	-1.44 (-2.65– -0.23)	9.94±1.77	-0.69 (-2.39–1.01)	0.31 (-1.25–1.88)	-0.20 (-2.28–1.87) (p=0.84)	-1.76 (-3.63–0.12) (p=0.06)
BCKQ score	34.41±7.60	2.79 (0.97–4.60)	3.21 (1.24–5.19)	32.99±9.37	0.44 (-1.02–1.90)	0.88 (-0.68–2.45)	2.35 (0.07–4.62) (p=0.04)	2.33 (-0.12–4.78) (p=0.04)
PRAISE score	46.00±7.03	0.90 (-0.34–2.15)	1.26 (-0.12–2.65)	45.17±8.15	-1.08 (-2.67–0.51)	-0.21 (-1.78–1.36)	1.98 (-0.09–4.05) (p=0.32)	1.47 (-0.65–3.60) (p=0.21)

Data are presented as mean± SD or mean (95% CI), unless otherwise stated. SPACE: Self-Management Programme of Activity, Coping and Education; CRQ-SR: self-reported Chronic Respiratory Questionnaire; ISWT: incremental shuttle walk test; ESWT: endurance shuttle walking test; HADS: Hospital Anxiety and Depression Scale; BCKQ: Bristol COPD Knowledge Questionnaire; PRAISE: Pulmonary Rehabilitation Index of Self-Efficacy. [#]: n=55; [¶]: n=34.

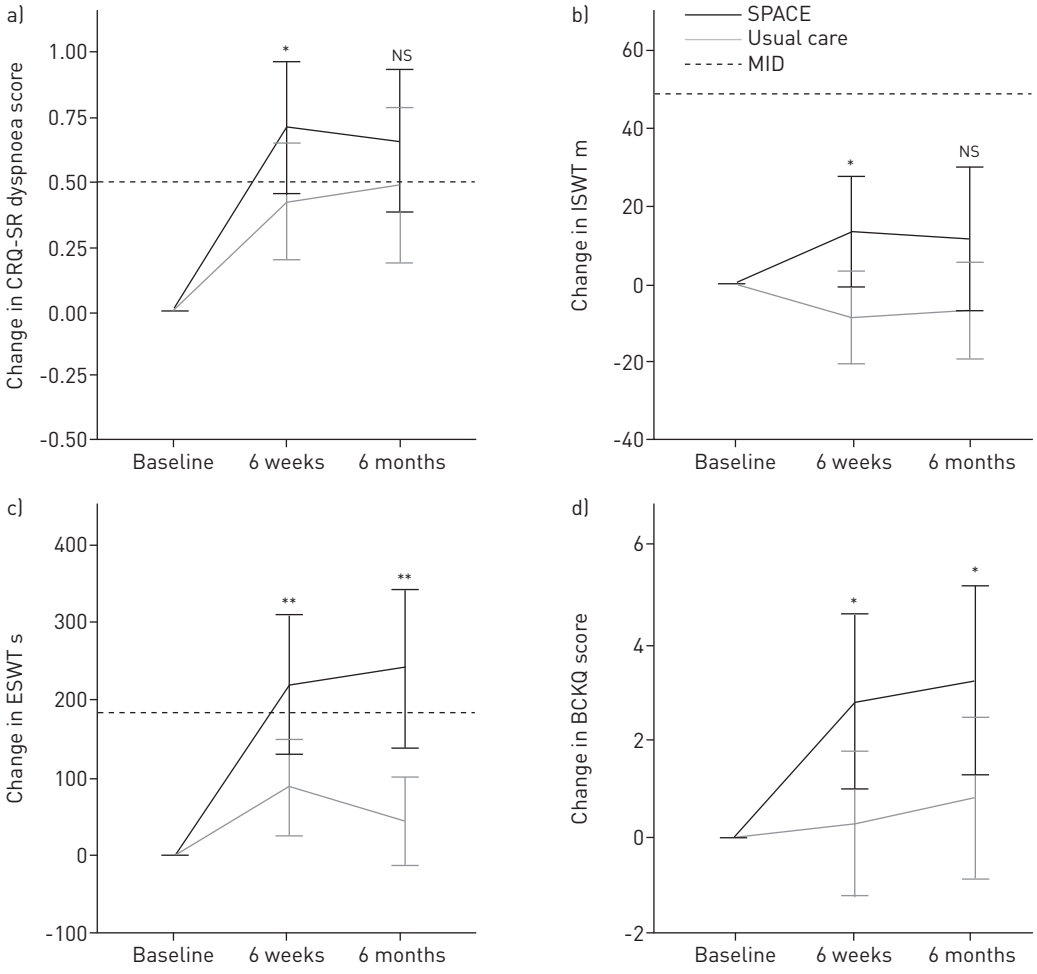

FIGURE 2 Change in outcome measures from baseline to 6 weeks and baseline to 6 months. Data are presented as mean and whiskers represent 95% confidence intervals. SPACE: Self-Management Programme of Activity, Coping and Education; MID: minimal important difference; CRQ-SR: self-reported Chronic Respiratory Questionnaire; ISWT: incremental shuttle walk test; ESWT: endurance shuttle walking test; BCKQ: Bristol COPD Knowledge Questionnaire; NS: nonsignificant. *: $p<0.05$; **: $p<0.01$.

in the usual care group reported stopping smoking. This was significantly different between groups ($p=0.015$). Two of the five smokers who reported having stopped had each received two individual smoking cessation counselling sessions (table 4).

Healthcare utilisation for the 6 months is presented in table 5. There was a statistically significant reduction in the number of nurse home visits for respiratory reasons in the SPACE FOR COPD group compared with usual care. There were no other statistically significant differences between groups in number of antibiotic courses, respiratory GP visits, respiratory nurse visits, respiratory emergency admissions, respiratory admissions or all-cause admissions. Access to other respiratory interventions is recorded in table 4.

Discussion

This brief, light-touch self-management intervention, with limited healthcare professional support delivered to patients in primary care, demonstrated clinical advantages in symptom burden, exercise performance, disease knowledge and anxiety over and above usual care in the short term (6 weeks). Some of these gains were maintained at 6 months; however, without any ongoing support, the primary outcome of dyspnoea was not significant. These findings do not support our hypothesis that this brief intervention would improve symptom burden at 6 months; however, the secondary outcomes suggest there is some efficacy of this intervention, but that more support may be required to maintain these gains.

The aim of this intervention was to provide a brief, light-touch approach to self-management that requires limited resources and healthcare professional input, and could therefore be delivered to the wider COPD

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TABLE 3 Proportion of patients achieving the minimal important difference in various outcomes

	SPACE	Usual care	Between-group p-value
6 weeks			
CRQ-SR			
Dyspnoea	63	45	0.187
Fatigue	47	33	0.085
Emotion	32	25	0.317
Mastery	35	29	0.468
HADS			
Anxiety	33	20	0.242
Depression	28	20	0.195
ISWT	20	10	0.073
ESWT	35	17	0.011
6 months			
CRQ-SR			
Dyspnoea	56	44	0.143
Fatigue	46	25	0.010
Emotion	31	26	0.533
Mastery	34	23	0.129
HADS			
Anxiety	28	27	0.847
Depression	25	18	0.286
ISWT	20	10	0.116
ESWT	42	16	0.001

Data are presented as % unless otherwise stated. Minimal important differences: self-reported Chronic Respiratory Questionnaire (CRQ-SR) dyspnoea, fatigue, emotion and mastery domains, 0.5 points; Hospital Anxiety and Depression Scale, -1.5 points; incremental shuttle walk test (ISWT), 48 m; endurance shuttle walk test (ESWT), 186 s. SPACE: Self-Management Programme of Activity, Coping and Education.

population. The intervention was introduced during a single consultation and was supported by telephone calls at 2 and 4 weeks, after which no further support was provided. With such a limited amount of support, the immediate advantages in symptom burden, exercise performance, anxiety and knowledge over such a short period of time were remarkable. This is the first self-management programme with such a brief intervention that has demonstrated improvements in such a range of outcomes over such a short time-frame. Other self-management programmes have provided significant ongoing support, either face-to-face or *via* telephone, and have demonstrated some longer-term benefits in healthcare utilisation and exercise

TABLE 4 Patients who had access to other pulmonary interventions during the 6-month study period

	SPACE	Usual care
Smoking cessation support	3	0
Self-reported successful cessation	2	0
Pulmonary rehabilitation	0	0
Supplementary oxygen assessment	6	2
Change in oxygen prescription	1	0
Respiratory physiotherapy	0	0
NIV assessment	0	0
CPAP assessment	1	0
Change in CPAP treatment	0	0
Nebuliser assessment	0	1

Data are presented as n. SPACE: Self-Management Programme of Activity, Coping and Education; NIV: noninvasive ventilation; CPAP: continuous positive airway pressure.

TABLE 5 Healthcare utilisation

	SPACE	Usual care	OR (95% CI)
12 months preceding randomisation			
Respiratory admissions	4	5	0.865 (0.225–3.327)
Nonrespiratory admissions	6	11	0.590 (0.209–1.664)
6 months post-randomisation			
Antibiotic course	82	70	1.199 (0.774–1.856)
Respiratory GP visits	78	73	1.153 (0.749–1.775)
Respiratory GP home visits	1	7	0.154 (0.019–1.279)
Respiratory nurse visits	48	53	0.978 (0.601–1.590)
Respiratory specialist nurse home visits	10	26	0.415 (0.189–0.910)*
Respiratory emergency department visits	1	2	0.540 (0.048–6.058)
Respiratory admissions	2	5	0.432 (0.082–2.283)
All cause admissions	17	26	0.706 (0.359–1.389)

Data are presented as n unless otherwise stated. GP: general practitioner. *: $p<0.05$.

performance at 12 months [4, 21]. While a light-touch approach is desirable to meet the demand for self-management support that has been identified in international guidelines, SPACE FOR COPD delivered in this trial was possibly too light-touch for successful outcomes to be maintained. Benefits might be better preserved if some ongoing support, such as regular telephone contact, face-to-face appointments, and group-based or lay-led support networks is provided.

Other explanations for the study's negative findings might be that aspects of the intervention were not comprehensive enough to sustain prolonged change. The lack of any kind of group support, supervised exercise training and healthcare professional-led education may have limited the effectiveness of this intervention for maintaining outcomes.

The aim of this intervention was to provide self-management support to people with COPD who were being managed primarily under their family physician. This was in contrast to programmes that have specifically targeted treatment at populations who have been hospitalised with their COPD, where outcomes were less successful [6, 7]. We hypothesised that people with COPD who had not yet required the help of specialist respiratory services might be more able to change their health behaviours. The patients recruited to this study were less disabled with respect to their exercise capacity and dyspnoea, and were much lower users of healthcare compared with several other self-management studies [6, 21]. Although the primary outcome was not significant, the short-term improvements suggest that it is possible to provoke a significant response from this intervention in this population, and targeting patients at an earlier stage of their disease management pathway may be more fruitful than initiating self-management support post-exacerbation.

Limitations

Due to the nature of the intervention, there was no method of reliably establishing how well participants followed and complied with the self-management strategies in the SPACE FOR COPD manual. Level of adherence is important for understanding whether there is an exposure response to the intervention. Additionally, understanding how patients used the programme would allow us to ascertain which aspects of the manual were well used and which were less so, and therefore inform future re-development of the intervention.

The findings from this study are limited due to lack of a placebo or attention control group, particularly given the subjective nature of the primary outcome. Lack of participant blinding may have increased motivation when receiving the treatment and attempts to satisfy the researchers might have increased the observed treatment effect in the intervention arm. We cannot, therefore, rule out the possible impact of attention. However, the intervention itself consisted of minimal attention, with a 30-min consultation and two telephone calls. Attention during the study assessments may have been more important. A specialist respiratory assessment and conduct of exercise tests may have increased confidence to undertake physical activity or training [22, 23] and to seek information about self-management of COPD. This may help to explain why such a significant improvement in dyspnoea was observed in the control arm.

Smoking status was only captured by self-report data. This data may not be reliable, and some of those who were successful in cessation had accessed additional smoking cessation counselling. However, smoking

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cessation was not the primary behaviour targeted by this intervention and this was an incidental secondary finding. Future work should objectively measure smoking and other methods of cessation support should be recorded.

Conclusions

This study has found that SPACE FOR COPD, delivered and supported during a 6-week period in primary care, did not confer any significant improvement in dyspnoea at 6 months compared with usual care alone. The short-term improvements in secondary outcomes suggest that there may be some clinical effect of this intervention, but that modification, such as longer-term support, peer support and supervision, may be required to preserve these benefits.

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