Behavioural modification interventions alongside pulmonary rehabilitation improve COPD patients' experiences of physical activity

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Abstract

Aims and objectives The Clinical PROactive Physical Activity in COPD (C-PPAC) instrument, combines a questionnaire assessing the domains of amount and difficulty of physical activity (PA) with activity monitor data (steps/day and vector magnitude units) to assess patients' experiences of PA. The C-PPAC instrument is responsive to pharmacological and non-pharmacological interventions and to changes in clinically relevant variables. We compared the effect of PA behavioural modification interventions alongside pulmonary rehabilitation (PR) to PR alone on the C-PPAC scores in COPD patients with low baseline PA levels.

Methods: In this randomised controlled trial, 48 patients (means±SD: FEV_1: 50±19%, baseline steps/day: 3450±2342) were assigned 1:1 to receive PR alone, twice weekly for 8 weeks, or PA behavioural modification interventions (comprising motivational interviews, monitoring and feedback using a pedometer and goal setting) alongside PR (PR+PA). The C-PPAC instrument was used to assess PA experience, including a perspective of the amount and difficulty of PA.

Results: There were clinically important improvements in favour of the PR+PA interventions compared to PR alone in: 1) the C-PPAC total score (mean [95% CI] difference: 8 [4 to 12] points, p=0.001), the difficulty (mean [95% CI] difference: 8 [3 to 13] points, p=0.002) and the amount (mean [95% CI] difference 8 [3 to 16] points, p=0.005) domains and 2) the CAT score (mean [95% CI] difference: -2.1 [-3.8 to -0.3] points, p=0.025).

Conclusion: PA behavioural modification interventions alongside PR improve the experiences of PA in patients with advanced COPD and low baseline PA levels. (NCT03749655).

Key words:

COPD, Physical Activity, Behavioural Modification, Physical Activity Experiences, Pulmonary Rehabilitation.

Introduction

Patients with Chronic Obstructive Pulmonary Disease (COPD) have lower levels of daily physical activity (PA) than their healthy age-matched peers [1-4]. It is recognised that reduced levels of PA in patients with COPD are associated with a faster rate of disease progression, greater risk for exacerbation of COPD (ECOPD), leading to increased rates of hospital admissions and mortality [5].

Pulmonary rehabilitation (PR) is an integral non-pharmacological component in COPD management [6]. However, while PR programs improve exercise capacity and health-related quality of life in people with COPD [6], these findings have not consistently progressed into improvements in daily PA [7], particularly in patients with advanced COPD and low baseline exercise capacity [8]. This is likely due to the complexity of PA as a health behaviour in COPD [9], with those patients exhibiting low baseline exercise capacity being less capable of increasing their PA levels due to a low functional reserve [8].

PA behavioural modification interventions have been employed to address the complex behaviour of PA, with the majority of previous studies demonstrating promising results in patients with COPD [10-16]. This is accomplished by stimulating patients to increase their PA levels by incorporating lifestyle activities into daily life in conjunction with patient monitoring and feedback of their daily steps alongside frequently adjusted goal setting [17]. A recently published systematic review and meta-analysis [18] reported that pedometer-based PA behavioural modification standalone interventions or alongside PR in patients with COPD improved accelerometer derived steps per day by clinically important margins [18, 19]. However, in patients with advanced COPD and low baseline PA levels, PA was less likely to improve following PA behavioural modification interventions alongside PR [18], especially in those with poor baseline exercise capacity [8, 15, 16].

Studies investigating patients with advanced COPD and low baseline exercise capacity and PA levels [8, 15, 16] have focused primarily on the frequency, intensity, duration and type of PA, which are quantified by means of activity monitors validated in patients with COPD [20]. This method of assessment, however, fails to fully capture patients' experiences of PA [21]. Qualitative research has indicated that while patients engage in daily physical activities, they experience symptoms which adversely impact on their lifestyle [22]. Such patient centred concepts are only quantifiable through a patient-reported outcome (PRO) questionnaire [23]. However, implementing a PRO questionnaire alone removes the ability to assess the frequency, intensity and type of PA objectively [21].

In order to combine these features, the Clinical PROactive physical activity in COPD (C-PPAC) instrument was developed, and recently validated in patients with COPD [21]. The instrument provides a comprehensive measure of patients' experiences of PA, merging subjective questions regarding the amount and difficulty of PA alongside objective measures of PA, encompassing average steps per day and vector magnitude units (VMU), which refers to intensity rather than quantity of PA [21]. The instrument measures amount of PA, difficulty of PA and total PA experiences. A recent study [24] reported the effect of PA behavioural modification interventions or PR alone on patients' experiences of PA using the C-PPAC instrument, indicating clinically important improvements. The effect of adding PA behavioural modification interventions to PR as compared to PR alone on patient PA experiences was, however, not reported in that study [24]. We, therefore, evaluated the effect of PA behavioural modification interventions alongside PR on the PA experiences of COPD patients with low baseline PA and exercise capacity levels. It was hypothesised that PA behavioural modification interventions including motivational interviewing, goal setting, step count monitoring and feedback, alongside PR aiming to improve functional capacity, would be superior to PR alone in improving all dimensions of the C-PPAC instrument.

Methods

Study design

This is a single centre, two parallel-groups, randomised controlled trial (RCT) with 1:1 individual allocation looking into patient compliance to PA behavioural modification interventions alongside PR (PR+PA) and its efficacy in comparison to PR alone in patients with COPD. The design of the study and flow of patients is presented in Figure 1. This study complies with NIHR HRA requirements (Ref: 18/YH/0376) and was prospectively registered at clinicaltrials.gov online database (NCT03749655).

Participants

Patients were recruited from Newcastle upon Tyne Foundation Health Care Trust (NuTH) Chest Clinic and PR waiting lists. Respiratory nurses and physiotherapists informed eligible patients about the study and asked their willingness to participate in the study. Patients inclusion criteria included: (i) COPD confirmed by obstructive spirometry (post-bronchodilator forced expiratory volume in the first second [FEV_1] to forced vital capacity [FVC] ratio <0.70); (ii) clinically stable male or female COPD patients aged 40 years or older; (iii) optimised medical therapy; (iv) able to provide informed consent. Patients exclusion criteria included: (i) orthopaedic, neurological or other concomitant disease that significantly impaired normal biomechanical movement patterns, as judged by the investigator; (ii) moderate or severe COPD exacerbation (ECOPD) within 4 weeks prior to study enrolment; (iii) unstable ischaemic heart disease, including myocardial infarction within 6 weeks prior to study enrolment; (iv) moderate or severe aortic stenosis or hypertrophic obstructive cardiomyopathy; (v) uncontrolled hypertension and another condition likely to limit life expectancy to less than one year (principally metastatic malignancy). Upon meeting the study entry criteria, patients who agreed to participate were contacted by the research team. Detailed

information regarding the study was provided and written informed consent was obtained prior to the study.

Pulmonary Rehabilitation

The 8-week PR programme was delivered according to the BTS guidelines on PR [25], comprising two 60-minute sessions of exercise training and one 30-minute education session per week between November 2018 to November 2020. Due to the pandemic 6 patients (n=3 in the PR intervention and n=3 in the PR+PA intervention) completed one exercise session under supervision and one unsupervised at home. Each supervised exercise session was delivered by a respiratory physiotherapist and involved progressive, individualised tailored aerobic and resistance training in accordance with the BTS guidelines on PR [25]. A multidisciplinary team comprising physiotherapists, psychologists, dieticians, respiratory nurses and occupational therapists, delivered the education component of the PR programme. As per the BTS guidelines on PR [25], the educational component of PR aims to support aspects of lifestyle and behaviour change and assist the promotion of self-management to support patients decision making and self-efficacy. Specific educational talks across the 8-week PR programme included guidance and support on dyspnea/symptom management, chest clearance/breathing techniques, nutritional advice, and advice on improving PA. Regardless of group allocation in the study, generic advice on improving PA was provided with an emphasis on barriers and facilitators to improving levels of PA. Furthermore, each patient received a British Lung Foundation exercise handbook which provided added support regarding the educational sessions as well as resources to record exercise and PA conducted outside of the weekly PR sessions. Patients in both groups with a baseline hospital anxiety and/or depression score (HADS) $\geq$8 (either for anxiety or depression) received up to three sessions of Cognitive Behavioural Therapy (CBT) by a specialist respiratory nurse lasting for 30 minutes. The number of CBT sessions suggested and timescale for such sessions were co-developed with the patients depending on the patients'

individual response to treatment to manage symptoms based on their subjective feedback, HADS questionnaire results and patient preference [26]. CBT focused on understanding how experiences were interpreted, and made up of four elements: behaviour, cognition/thoughts, feelings/emotions, and physical sensations [27].

PA behavioural modification interventions

Prior to the initiation of the PA behavioural modification interventions, patients received a one-to-one semi-structured motivational interview with the researcher discussing motivational issues, favourite activities, facilitators and barriers to PA and strategies to become more physically active [28]. Throughout the interview, patients were questioned about their self-efficacy and motivational levels. On completion of the interview, each patient created a plan with the researcher consisting of three concrete actions, which could be used to increase PA levels. This plan consisted of favourite activities and was implemented throughout the PA behavioural modification interventions to stimulate patient's self-motivation. Following this, the PA behavioural modification interventions involved the provision of a pedometer (Fitbug, Camden, London), an individualised daily step-count target (reviewed twice weekly for 8 weeks), and a step-count diary that was brought to every PR session (twice weekly). Patients were encouraged to achieve the agreed target each day and to record the attained pedometer step count in their step count diary each evening. Patients were asked to attend each PR session with their step count diary, enabling the researcher to frequently observe their activity levels, assess overall compliance to the intervention and provide the appropriate level of support based on their recorded activity levels. Based on the feedback from step count diaries, the researcher calculated a daily step-count target based on an increase of 10% from the preceding week's average daily step-count, with the first week's target derived from baseline accelerometer step count data (Actigraph wGT3X, Actigraph LLC, Pensacola, FL, USA) [29] and during subsequent weeks from the pedometer (Fitbug) step count data. During the weekly step-count

review, education on the importance of PA and advice on how to increase PA levels were provided, including a focus on the barriers and facilitators to PA, whilst taking into consideration the three concrete actions that were outlined in the motivational interview [29].

Outcome measures

The Clinical PROactive C-PPAC instrument, which was previously validated for use in patients with COPD [22], required both questionnaire and accelerometer-derived PA data (Actigraph wGT3X, Actigraph LLC, Pensacola, FL, USA) and was implemented one week prior to the onset of the PR programme and one week following completion of the PR programme. The C-PPAC questionnaire included 12-items with a 7-day recall and was completed using paper and pen as shown in the online supplementary materials (Table S1). Patients were also instructed to wear an accelerometer previously validated to be part of the C-PPAC tool (Actigraph wGT3X, Actigraph LLC, Pensacola, FL, USA) [21] during waking hours for seven consecutive days prior to the onset of the PR programme [30]. A valid assessment of patient's PA was considered if patients recorded more than 8 hours of wear time on at least 4 weekdays within the 7-day period [21]. C-PPAC scores were calculated by combining questionnaire items with two objective variables from the activity monitor (steps/day and VMU). Three scores were generated (amount of PA, difficulty of PA and total PA experience) ranging from 0 to 100, where higher numbers indicated a better score [21].

Other outcome measures taken prior to the onset of PR and immediately following completion of PR included: the 6 minute walking distance (6MWD) [31]; leg muscle strength and endurance (one leg extension repetition maximum using a calibrated Myometer (MIE Medical Research Ltd, Leeds, UK) and 30 second sit to stand repetitions), respectively [32, 33]; handgrip strength [34]; health-related quality of life (COPD assessment test [CAT]) [35], the clinical COPD questionnaire [CCQ] [36]); and anxiety and depression (Hospital Anxiety and Depression Scale [HADS] [37]); [38].

Patient acceptability and compliance

Patient acceptability of the PA behavioural modification interventions was assessed through a project-tailored questionnaire modified from another study [39]. During the final visit of the study, patients filled in a self-administered, project tailored, multiple choice questionnaire about their experiences with the intervention and the usefulness of its components on a 10-point Likert scale as previously described [39] and shown in Table S2 of the online supplementary material. Data from the project-tailored questionnaire were scored as categorical variables and reported as frequencies and percentages (number of patients indicating each answer), except for the usefulness ratings of the components, which were expressed as median [P25-P75]. Patient compliance to components of the behavioural modification interventions was assessed via the following means: i) fractional number of weekly goal setting targets met; ii) fractional number of weekly completions of PA diaries and iii) average weekly wear time of the pedometer. Data on patient compliance were reported as percentages and median (P25-P75) and as mean ± SD depending on the variable assessed.

Data analysis

Verification of the sample size was based on the study by Louvaris et al [40] comparing PR to usual care (UC). Based on the mean difference in the C-PPAC total score (7.4 units) between PR and UC and observed SD (8.5 units), an alpha significance level of 0.05 (2-sided) and 80% power, a minimum sample of 24 patients per group was considered to be sufficient to detect significant differences in the total C-PPAC score between PR+PA and PR. Based on previous studies on similar PR programmes in the UK [15], considering an attrition rate of 20% the total sample size was increased to 58 patients. Randomisation was stratified by the 6MWD (<350 meters or ≥ 350 metres), and the average HADS score for anxiety and depression (<8 points or ≥8 points) using a block size of 4 at the onset of the PR programme.

Patient characteristics and outcome data at baseline and following PR are reported as means±SD unless otherwise stated. Within and between group differences pre- to post interventions are reported as mean, 95% confidence intervals (CI). Independent samples *t* tests were implemented to compare baseline group characteristics. A two-way repeated measures ANOVA was implemented for all outcome variables to identify differences between the two interventions. Statistical significance was set at $p < 0.05$ for all analyses.

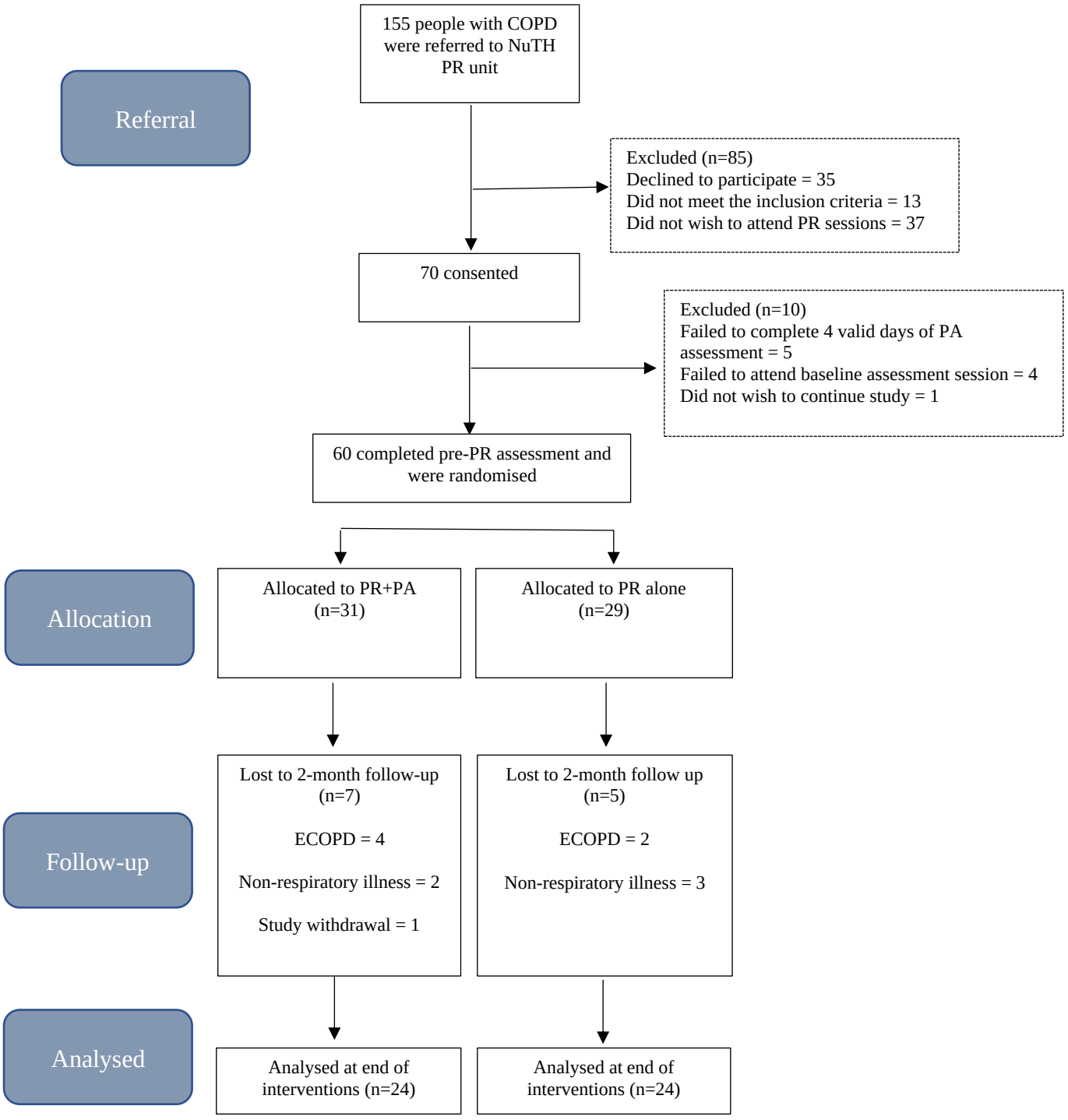

Figure 1: Consolidation Standards of Reporting Trials diagram of the study. COPD = Chronic Obstructive Pulmonary Disease, NuTH = Newcastle upon Tyne Healthcare trust, PR = Pulmonary Rehabilitation, n = number, PA = Physical Activity, ECOPD = exacerbation of COPD

Results

Participants

In total, 70 patients provided consent for the study at visit 1, while 60 patients were randomised at visit 2 to PR+PA (n=31) and PR alone (n=29) (Figure 1). Reasons for withdrawal following consent are provided in Figure 1. There were no significant between-group differences in any of the baseline characteristics (Table 1). Throughout the study, 12 patients were lost due to: ECOPD (n=6), non-respiratory illness' (n=5) and inability to attend the PR programme (n=1). Therefore, 48 patients completed the post-PR assessment visit, with 24 patients completing PR+PA and 24 completing PR alone.

Table 1: Baseline Characteristics

Variable	PR alone (n=24)	PR+PA (n=24)	p value
Gender (male/female)	9/15	9/15	n/a
Age (years)	73±9	71±9	0.395
BMI (kg/m^2)	25.5±2.9	28.8±7.4	0.084
FEV_1 (L)	1.21±0.5	1.27±0.5	0.733
FEV_1 (% predicted)	50±17	51±19	0.425
FEV_1/FVC (% predicted)	51±15	51±15	0.894
Step/day	3446±2342	3450±2168	0.608
6MWD (m)	276±92	285±92	0.240
mMRC	3±1	3±1	0.667
HADS (A)	7±4	7±4	0.678
HADS (D)	7±4	6±6	0.567

Definition of abbreviations: PR = Pulmonary Rehabilitation, PA = Physical Activity, BMI = Body Mass Index, FEV_1 = Forced Expiratory Volume in the 1st second, L = Litres, FVC = Forced Vital Capacity, 6MWD = Six Minute Walk Distance, m = metres, HADS = Hospital Anxiety and Depression Scale, A = Anxiety, D = Depression, n/a = not available. Values are mean±SD.

Patient experience of PA

The effect of PR+PA compared to PR alone on all dimensions of the C-PPAC instrument for each patient is shown in Figure 2. Post-interventions, the *total score* of the C-PPAC instrument was improved by a clinically important margin (>4 points) [21] in the PR+PA group compared

with the PR alone group, with a between group difference of 8 points (95% CI 4 to 12 points; *p*=0.001) (Table 2). In regard to the *difficulty score* of the C-PPAC instrument, clinically important (>6 points) [21] improvements were reported in the PR+PA group compared with the PR alone group, with a between group difference of 8 points (95% CI 3 to 13 points; *p*=0.002) (Table 2). Finally, clinically important (>6 points) [21] improvements in the *amount score* of the C-PPAC tool were reported in the PR+PA group compared to the PR alone group, with a between group difference of 8 points; (95% CI 3 to 16 points, *p*=0.005) (Table 2).

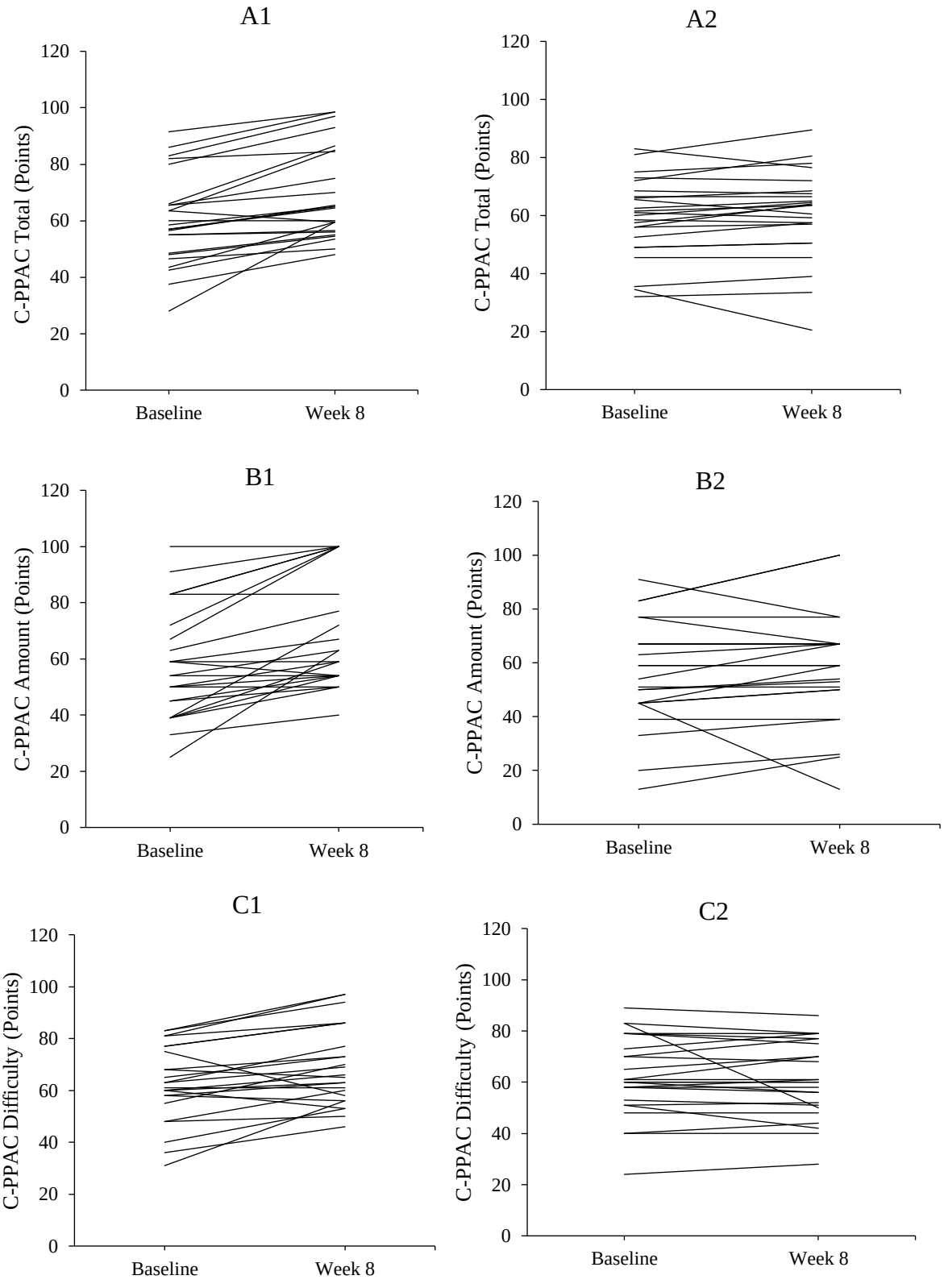

Figure 2: Individual responses to the C-PPAC instrument for A1: total score for PR+PA, A2: total score for PR alone, B1: amount score for PR+PA, B2: amount score for PR alone, C1: difficulty score for PR+PA, C2: difficulty score for PR alone.

Physical activity outcomes

Changes in accelerometer-derived PA variables are shown in Table 2. Post intervention, clinically important (600-1100 steps/day) [19] improvements in accelerometer steps/day data were found in the PR+PA intervention only, with a between group difference of 1016 steps/day (95% CI 556 to 1474 steps/day, p=0.001) (Table 2). Following the completion of the PR programme a significant improvement in accelerometer movement intensity was recorded in PR+PA group only, with a between group difference of 93 VMU (95% CI 41 to 145 VMU, p=0.001, Table 2). Finally, following completion of the PR programme, a significant improvement in time spent in light PA was recorded only in the PR+PA intervention, with a between group difference of 22 minutes (95% CI 2 to 43, p=0.030) (Table 2).

1 Table 2: Changes in PA parameters in the PR+PA and PR alone interventions.

	Group	Baseline	2 Months	Within Group Mean Difference	P value	Between Group Difference	P value
C-PPAC Total score	PR+PA	60±16	69±16	9 (6 to 12)	0.001	8 (4 to 12)	0.001
	PR alone	59±14	60±15	1 (-1 to 4)	0.369		
C-PPAC Difficulty score	PR+PA	62±15	69±15	7 (3 to 10)	0.001	8 (3 to 13)	0.002
	PR alone	62±16	61±15	-1 (-4 to 2)	0.525		
C-PPAC Amount score	PR+PA	58±20	69±20	11 (7 to 16)	0.001	8 (3 to 16)	0.005
	PR alone	56±19	59±21	3 (-2 to 7)	0.315		
Steps/day	PR+PA	3450±2168	4426±2577	976 (651 to 1300)	0.001	1016 (556 to 1474)	0.001
	PR alone	3446±2342	3406±2095	-40 (-365 to 284)	0.805		
Movement intensity (VMU)	PR+PA	337±154	410±231	73 (37 to 109)	0.001	93 (41 to 145)	0.001
	PR alone	307±170	287±133	-20 (-57 to 17)	0.281		
Sedentary time (min)	PR+PA	495±84	458±111	-37 (12 to 62)	0.005	-15 (-51 to 21)	0.406
	PR alone	541±90	519±103	-22 (-48 to 3)	0.088		
Light time (min)	PR+PA	167±56	187±73	20 (6 to 35)	0.006	22 (2 to 43)	0.030
	PR alone	135±57	133±48	-2 (-17 to 12)	0.741		
MVPA (min)	PR+PA	7±8	10±14	3 (0 to 6)	0.041	3 (-1 to 7)	0.185
	PR alone	7±10	7±8	0 (-3 to 3)	0.791		

Definition of abbreviations: C-PPAC = Clinical visit-PROactive physical activity in COPD, Min = Minutes, PA = Physical activity, PR = pulmonary rehabilitation, MVPA = moderate to vigorous physical activity. Values are mean±SD. Within and between group differences are reported with 95% confidence intervals (CI).

Other outcomes

The 6MWD improved following both PR+PA and PR alone interventions, with similar within group changes (Table 3). Significant between group improvements were reported in upper and lower body strength and clinically important differences in the CAT score in favour of the PR+PA group (Table 3).

Intervention acceptability and compliance

Overall, the PR+PA intervention was well received by patients, with 75% indicating they "liked taking part in the intervention a lot". Furthermore, 58% of patients claimed the intervention "helped them a lot" regarding completing more PA outside of PR. The majority of patients (79%) experienced the proposed weekly increases in step goals as "reasonable", whereas 21% of patients experienced these increases as "a little too high" or "a little too low". The usability of the pedometer was deemed "very easy" in 96% of patients. Patients rated the usefulness of components of the PR+PA intervention with scores based on a satisfaction scale (0 terrible to 10- perfect) with the step counter (median [P25-P75]; 9 [8-10]), daily step goals (8 [8-9]) and feedback from researcher (9 [8-10]) all deemed useful parts of the intervention. Regarding patient compliance, the average weekly wear time of the Fitbug pedometer was high equivalent to 6.6±0.2 days worn. Compliance with the PA diary to self-reported daily step counts was also high (91±18%), with a median number of 55 [49-56] recorded days over the 8 weeks. Finally, compliance with step goal targets throughout the 8 weeks was high, with an average 68±12% of step goals achieved. In terms of pedometer (Fitbug) steps/day (PR+PA patients only), significant improvements were reported from baseline to end of the intervention (by 1566 steps/day: 95% CI 681 to 2357, p=0.001).

1 Table 3: Changes in functional capacity, muscular strength/endurance, health-related quality of life and anxiety and depression parameters in the

2 PR+PA and PR alone interventions.

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	Group	Baseline	2 Months	Within Group Mean Difference	P value	Between Group Difference	P value
6MWD (m)	PR+PA	285±92	339±90	54 (36 to 72)	0.001	16 (-10 to 41)	0.236
	PR alone	276±92	314±99	38 (20 to 57)	0.001		
HG (kg)	PR+PA	22.7±8.9	26.0±9.2	3.3 (2.1 to 4.5)	0.001	2.1 (0.3 to 3.9)	0.022
	PR alone	18.3±6	19.5±7	1.2 (0.2 to 2.5)	0.083		
QMVC (kg)	PR+PA	24.6±8.7	29.6±9.7	5.0 (3.4 to 6.8)	0.001	2.5 (0.2 to 4.9)	0.033
	PR alone	21.0±10.2	23.5±10.7	2.5 (0.8 to 4.20	0.005		
Sit to Stand (reps)	PR+PA	10±3	13±4	3 (2 to 4)	0.001	1 (-1 to 2)	0.446
	PR alone	11±4	13±5	2 (1 to 3)	0.001		
CCQ (T)	PR+PA	2.5±1.1	2.2±1.1	-0.3 (-0.6 to 0.02)	0.068	-0.2 (-0.7 to 0.2)	0.349
	PR alone	2.5±1.3	2.4±1.3	-0.1 (-0.4 to 0.2)	0.599		
CCQ (S)	PR+PA	2.5±1.2	2.2±1.1	-0.3 (-0.7 to 0.1)	0.169	-0.2 (-0.9 to 0.4)	0.435
	PR alone	2.7±1.2	2.6±1.4	-0.1 (-0.5 to 0.4)	0.805		
CCQ (F)	PR+PA	2.4±1.2	2.1±1.3	-0.3 (-0.7 to 0.1)	0.134	-0.1 (-0.7 to 0.5)	0.722
	PR alone	2.4±1.4	2.2±1.4	-0.2 (-0.6 to 0.2)	0.326		
CCQ (M)	PR+PA	1.8±1.5	1.7±1.6	-0.1 (-0.5 to 0.8)	0.677	-0.1 (-1.0 to 0.8)	0.869
	PR alone	1.9±1.5	1.9±1.5	-0 (-0.7 to 0.6)	0.859		
CAT	PR+PA	25.9±6.4	21.7±6.1	-4.2 (-5.4 to -2.9)	0.001	-2.1 (-3.8 to -0.3)	0.025
	PR alone	27.0±6.4	24.9±7.1	-2.1 (-3.4 to -0.8)	0.002		
HADS (A)	PR+PA	7±6	6±4	-1 (-2 to 0)	0.065	-1 (-2 to 1)	0.421
	PR alone	7±4	7±4	0 (-2 to 1)	0.461		
HADS (D)	PR+PA	6±6	5±4	-1 (-2 to 0)	0.004	0 (-2 to 1)	0.527
	PR alone	7±4	6±3	-1 (-2 to -1)	0.036		

Definition of abbreviations: 6MWD = Six Minute Walk Distance, HG = Hand grip strength, QMVC = Quadriceps Muscle Voluntary Capacity, CCQ = Clinical COPD Questionnaire, T = Total, S = Symptoms, F = Functional, M = Mental, CAT = COPD Assessment Test, HADS = Hospital Anxiety and Depression Scale, A = Anxiety, D = Depression, m = Metres, PA = Physical activity, PR = Pulmonary Rehabilitation. Values are mean±SD. Within and between group differences are reported with 95% confidence intervals (CI).

Discussion

The novel finding of this study is the clinically important improvements in COPD patients' experiences of PA following PR+PA compared to PR alone in patients with advanced COPD exhibiting low baseline PA levels. Improvements in the 6MWD were similar for both interventions, however the magnitude of improvement in upper and lower muscle strength was greater in the PR+PA intervention. Collectively these findings suggest that PA behavioural modification interventions alongside PR provide insightful support to patients with low baseline levels of PA to translate PR-induced improvements in functional capacity into improvements in patients' experiences of PA.

Previous literature has documented the response of the C-PPAC instrument in two behavioural modification interventions [29, 41]. Demeyer and colleagues [29] found a significant between group difference in both the total and amount dimensions of the C-PPAC instrument following 12 weeks of semi-automated PA tele-coaching delivered via a smartphone app. It should be noted that the usual care group reported a large decrease in C-PPAC scores following a 12-week period, with only small improvements in C-PPAC scores reported following the tele-coaching intervention, thereby suggesting that the tele-coaching intervention only had marginal effects on the C-PPAC tool [29]. Furthermore, Demeyer and colleagues were unable to demonstrate an improvement in the difficulty dimension of the C-PPAC instrument [29]. The difficulty dimension has demonstrated a moderate-strong correlation with health status, chronic dyspnea and exercise capacity [21], which is not captured by the amount dimension. The study by Demeyer et al [29] did not include any specific exercise training and as a result was unsuccessful in demonstrating improvements in exercise capacity, which may be the reason for not reporting an improvement in the difficulty domain following 12-weeks of tele-coaching [29].

Arbillaga and colleagues [41] implemented a 12-month urban training programme that incorporated behavioural and community-based exercise interventions in patients with COPD. The C-PPAC instrument was able to detect a significant improvement from baseline to 12 months in both the amount and difficulty C-PPAC scores, however improvements were not significant between the intervention and the usual care groups [41]. Considering the magnitude of change in the C-PPAC total scores between the intervention and control groups in the studies of Arbillaga-Extarri [41] (4.5 units) and Demeyer [29] (4.5 units) and that of the current study (8 units), it is clear that PA behavioural techniques added to PR are superior to PA behavioural interventions alone in improving the total score of the C-PPAC instrument.

Louvaris and colleagues [40] presented significant and clinically important improvements in the total score of the C-PPAC instrument following PR (5.6 units), which was not found in the PR alone group (1 unit) in the current study. Louvaris and colleagues [40] provided a different type of PR, with their programme consisting of 3 sessions per week for a total of 10 weeks, whilst the current study consisted of 2 sessions per week for 8 weeks. Secondly, Louvaris and colleagues [40] prescribed high-intensity interval exercise, whereas the current study implemented moderate intensity exercise. Furthermore, COPD patients in the Louvaris et al. study [40] presented greater baseline levels of PA and 6MWD than the current study, which has previously been documented to influence the effectiveness of interventions to improve PA [18]. With this in mind, it is plausible that the incorporation of PA behavioural modification interventions, in conjunction with improved functional capacity through PR exercise training, yielded clinically important improvements in all C-PPAC dimensions in patients with very low levels of PA at baseline (approximately 3000 steps/day) [21].

Importantly, several components of the PA behavioural modification interventions used in the current study, including patient education on the benefits of PA and incorporating behaviour change techniques such as goal setting, action planning and self-monitoring, may have

empowered and motivated patients to engage in more daily activity. Such behavioural modification components have been shown to benefit COPD patients' readiness, motivation and confidence to engage in PA and were associated with significant improvements in PA behaviour [42]. Furthermore, the initial motivation interview stimulated a discussion between patient and researcher regarding preferred and non-preferred activities, allowing the researcher to tailor weekly PA goals around activities that the patient enjoyed, encouraging self-motivation within the patient [12]. Finally, attending each PR session with a step count diary and twice-weekly face-to-face consultations gave the research team an insight into the compliance of each patient, and enabled researchers to intervene if patients were unable to cope with the present goals.

Study limitations

There are several limitations that must be considered in this study. Our inability to blind patients to the study allocation may have impacted on the overall quality of evidence and increased the risk of bias towards the intervention. Our failure to blind patients was based on several reasons. Firstly, it would require a pedometer being issued to the PR alone group. Although the simple addition of a pedometer alongside generic advice on PA provided during PR doesn't necessary provide any form of PA counselling, the stimulus and incentive to self-manage and increase steps/day with the availability of a pedometer may impact upon the steps/day of the PR alone group. Secondly, in order to remain comparable with previous literature, we followed the procedure of several previous studies that implemented PA counselling alongside standard care PR [10, 12, 13, 15], of which pedometers were not provided to the control group. In future studies however, studies may wish to follow the blinding procedure of two recent studies in COPD [16, 41]. Varas and colleagues [16] blinded patients by allocating a pedometer to both intervention and control groups, but provided no pedometer specific instructions to the control group. Meanwhile, Arbillaga and colleagues [41]

took a different approach by refraining the existence of an alternative group to patients. The latter would be difficult to incorporate into the current study due to the lack of resources available to run two separate PR programmes simultaneously, in order to refrain the existence of groups from one another.

Due to all measures being administered in a face-to-face manner by a single researcher, bias related to the researcher providing the PA behavioural modification interventions couldn't be avoided and blinding of assessor was not possible.

This was a small-scale study, therefore, generalisability of the results to clinical practice may be limited. Finally, the present behavioral modification interventions alongside PR were well received by the vast majority of patients showing high compliance, however such behavioral interventions may require significant health care resources as they are more time consuming compared to PA tele-coaching [38].

Conclusions

Incorporating PA behavioural modification interventions alongside a PR programme conveys improvements in functional capacity into improved experiences of PA in COPD patients with low baseline PA and exercise capacity levels.

CRediT authorship contribution

Matthew Armstrong: conceptualization, data curation, formal analysis, investigation, methodology, writing- original draft, project administration. **Emily Hume**: Data curation, formal analysis, investigation, writing- review & editing. **Laura McNeillie**: Project administration, resources, investigation, writing – Review & Editing. **Francesca Chambers**: Project administration, resources, investigation, writing – Review & Editing. **Lynsey Wakenshaw:** Project administration, resources, investigation, writing – Review & Editing.

Graham Burns: conceptualization, methodology, supervision, writing- review & editing. **Karen Heslop Marshall:** conceptualization, methodology, investigation, supervision, writing- review & editing, writing- review & editing. **Ioannis Vogiatzis:** conceptualization, funding acquisition, investigation, supervision, writing- review & editing.

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Appendices

A1: The C-PPAC instrument

Northumbria University NEWCASTLE

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

Clinical Visit Of Proactive Physical Activity In COPD (C-PPAC)

INSTRUCTIONS TO PATIENTS:

Patients with chronic lung disease like you often report that they have problems during physical activity. By physical activity, we mean all activities that require movement of your body. Examples are household activities, walking, going to work, or getting dressed. However, please consider all activities you do, and not only these examples. We would like to know how you experienced your physical activity IN THE PAST 7 DAYS.

Please select the box next to the response that best applies to you IN THE PAST 7 DAYS.

There are no wrong answers. We very much value your response.

	Difficulty score	Amount score
In the past 7 days, how much walking did you do outside?		
☐ None at all		0
☐ A little bit (about 10 minutes every day)		1
☐ Some (about 30 minutes every day)		2
☐ A lot (about 1 hour every day)		3
☐ A great deal (more than 1 hour every day)		3
In the past 7 days, how many chores did you do outside the house? Some examples are gardening, taking the rubbish out, or doing small errands.		
☐ None at all		0
☐ A few		1
☐ Some		2
☐ A lot		3
☐ A large amount		4
In the past 7 days, how much difficulty did you have getting dressed?		
☐ None at all	4	
☐ A little bit	3	
☐ Some	2	
☐ A lot	1	
☐ A great deal	0	
In the past 7 days, how much difficulty did you have getting out and about?		
☐ None at all	4	
☐ A little bit	3	
☐ Some	2	
☐ A lot	1	
☐ A great deal	0	

In the past 7 days, how often did you avoid doing activities because of your lung problems?

☐ Not at all	4
☐ Rarely	3
☐ Sometimes	2
☐ Frequently	1
☐ All the time	0

In the past 7 days, how breathless were you in general during your activities?

☐ Not at all	4
☐ A little bit	3
☐ Moderately	2
☐ Very	1
☐ Extremely	0

In the past 7 days, how often did you lack physical strength to do things because of your lung problems?

☐ Not at all	4
☐ Rarely	3
☐ Sometimes	2
☐ Frequently	1
☐ All the time	0

In the past 7 days, how tired were you in general during your activities?

☐ Not at all	4
☐ A little bit	3
☐ Moderately	2
☐ Very	1
☐ Extremely	0

In the past 7 days, how often did you have to take breaks during your physical activities?

☐ Not at all	4
☐ Rarely	3
☐ Sometimes	2
☐ Frequently	1
☐ All the time	0

1

In the past 7 days, how breathless were you when walking on level ground indoors and outdoors?		
☐	Not at all	4
☐	A little bit	3
☐	Moderately	2
☐	Very	1
☐	Extremely	0
In the past 7 days, how much time did you need to recover from your physical activities?		
☐	None at all	4
☐	A little bit	3
☐	Some	2
☐	A lot	1
☐	A great deal	0
In the past 7 days, did you need to consider your lung problems when you planned your activities because of your lung problems? Examples are a trip out, an appointment or expecting visitors.		
☐	No	4
☐	A little bit	3
☐	Sometimes	2
☐	A lot	1
☐	A great deal	0

Weekly steps score		Measured by Actigraph	Measured by Dynaport	
☐	0	<1000	<1500	0
☐	1	1000-2000	1500-2500	1
☐	2	2000-4000	2500-4500	2
☐	3	4000-6000	4500-6500	3
☐	4	>6000	>6500	4
Weekly VMU score		Measured by Actigraph	Measured by Dynaport	
☐	0	<100	<60	0
☐	1	100-200	60-130	1
☐	2	200-300	130-210	2
☐	3	300-500	210-370	3
☐	4	>500	>370	4

Amount scores (sum above):		
Difficulty scores (sum above):		
Total scores (sum above):		

1

2

3

A2: Project tailored patient satisfaction questionnaire.

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How much did you **enjoy taking part** in this activity program?

- I liked it a lot
- I liked it
- Neutral
- I did not like it
- No opinion

Explain why? .....

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.....

Did the intervention **coach you in increasing** your physical activity outside of pulmonary rehabilitation?

- Yes, it helped me a lot
- Yes, a little bit
- Not noticeable
- No, not at all
- No, it rather discouraged me

Explain why? .....

.....

.....

How did you **experience the weekly increases** proposed during the intervention?

- Much too low
- A little bit too low
- Reasonable
- A little bit to high
- Much too high

Explain why? .....

.....

.....

How was it for you to work with the **pedometer** provided?

- Very easy
- Easy
- Not easy, but I managed
- Difficult
- Very difficult

Explain why? .....

.....

.....

How useful did you find the following parts of the intervention for increasing physical activity?

1) The **step counter**

0 1 2 3 4 5 6 7 8 9 10

2) The **step count diary** provided

0 1 2 3 4 5 6 7 8 9 10

3) Daily **step goals** displayed on your step count diary each week

0 1 2 3 4 5 6 7 8 9 10

4) Activity **feedback** during each of the pulmonary rehabilitation sessions

0 1 2 3 4 5 6 7 8 9 10

5) If your HADS levels were >8, **your sessions of CBT**

0 1 2 3 4 5 6 7 8 9 10

How often did you (in general) perform the following actions?

	Several times per day	Once per day	Sometimes, but not every day	Once or twice per week	Never
Look at your step counter during the day					
Look and use your daily step diary					

Which part of the intervention would you be willing to use further in the future?

1

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Which part of the intervention would you be willing to use further in the future?

- Nothing
- The step counter
- The step counter and daily step diary
- CBT (HADS >8 patients)
- Pulmonary rehabilitation alone
- All of the above interventions together

What component of the intervention would you like to change in the future?

Explain:

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.....

.....

Would you like to add a comment?

.....

.....

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.....

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Thank you for your time throughout this research study and I hope the benefits you have received taking part will continue!