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

2 Aims and objectives The Clinical PROactive Physical Activity in COPD (C-PPAC) 3 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 4 5 assess patients' experiences of PA. The C-PPAC instrument is responsive to pharmacological 6 and non-pharmacological interventions and to changes in clinically relevant variables. We 7 compared the effect of PA behavioural modification interventions alongside pulmonary 8 rehabilitation (PR) to PR alone on the C-PPAC scores in COPD patients with low baseline PA 9 levels.

Methods: In this randomised controlled trial, 48 patients (means±SD: FEV₁: 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).

21 **Conclusion:** PA behavioural modification interventions alongside PR improve the experiences

of PA in patients with advanced COPD and low baseline PA levels. (NCT03749655).

23 Key words:

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

1 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].

14 PA behavioural modification interventions have been employed to address the complex 15 behaviour of PA, with the majority of previous studies demonstrating promising results in 16 patients with COPD [10-16]. This is accomplished by stimulating patients to increase their PA 17 levels by incorporating lifestyle activities into daily life in conjunction with patient monitoring 18 and feedback of their daily steps alongside frequently adjusted goal setting [17]. A recently 19 published systematic review and meta-analysis [18] reported that pedometer-based PA 20 behavioural modification standalone interventions or alongside PR in patients with COPD 21 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 22 23 improve following PA behavioural modification interventions alongside PR [18], especially in 24 those with poor baseline exercise capacity [8, 15, 16].

1 Studies investigating patients with advanced COPD and low baseline exercise capacity and PA 2 levels [8, 15, 16] have focused primarily on the frequency, intensity, duration and type of PA, 3 which are quantified by means of activity monitors validated in patients with COPD [20]. This 4 method of assessment, however, fails to fully capture patients' experiences of PA [21]. 5 Qualitative research has indicated that while patients engage in daily physical activities, they 6 experience symptoms which adversely impact on their lifestyle [22]. Such patient centred 7 concepts are only quantifiable through a patient-reported outcome (PRO) questionnaire [23]. 8 However, implementing a PRO questionnaire alone removes the ability to assess the frequency, 9 intensity and type of PA objectively [21].

10 In order to combine these features, the Clinical PROactive physical activity in COPD (C-11 PPAC) instrument was developed, and recently validated in patients with COPD [21]. The 12 instrument provides a comprehensive measure of patients' experiences of PA, merging 13 subjective questions regarding the amount and difficulty of PA alongside objective measures 14 of PA, encompassing average steps per day and vector magnitude units (VMU), which refers 15 to intensity rather than quantity of PA [21]. The instrument measures amount of PA, difficulty 16 of PA and total PA experiences. A recent study [24] reported the effect of PA behavioural 17 modification interventions or PR alone on patients' experiences of PA using the C-PPAC 18 instrument, indicating clinically important improvements. The effect of adding PA behavioural 19 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 20 21 modification interventions alongside PR on the PA experiences of COPD patients with low 22 baseline PA and exercise capacity levels. It was hypothesised that PA behavioural modification 23 interventions including motivational interviewing, goal setting, step count monitoring and 24 feedback, alongside PR aiming to improve functional capacity, would be superior to PR alone 25 in improving all dimensions of the C-PPAC instrument.

1 Methods

2 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).

9 Participants

10 Patients were recruited from Newcastle upon Tyne Foundation Health Care Trust (NuTH) 11 Chest Clinic and PR waiting lists. Respiratory nurses and physiotherapists informed eligible 12 patients about the study and asked their willingness to participate in the study. Patients 13 inclusion criteria included: (i) COPD confirmed by obstructive spirometry (post-14 bronchodilator forced expiratory volume in the first second [FEV₁] to forced vital capacity 15 [FVC] ratio <0.70); (ii) clinically stable male or female COPD patients aged 40 years or older; 16 (iii) optimised medical therapy; (iv) able to provide informed consent. Patients exclusion 17 criteria included: (i) orthopaedic, neurological or other concomitant disease that significantly 18 impaired normal biomechanical movement patterns, as judged by the investigator; (ii) 19 moderate or severe COPD exacerbation (ECOPD) within 4 weeks prior to study enrolment; 20 (iii) unstable ischaemic heart disease, including myocardial infarction within 6 weeks prior to 21 study enrolment; (iv) moderate or severe aortic stenosis or hypertrophic obstructive 22 cardiomyopathy; (v) uncontrolled hypertension and another condition likely to limit life 23 expectancy to less than one year (principally metastatic malignancy). Upon meeting the study 24 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.

3 Pulmonary Rehabilitation

4 The 8-week PR programme was delivered according to the BTS guidelines on PR [25], 5 comprising two 60-minute sessions of exercise training and one 30-minute education session 6 per week between November 2018 to November 2020. Due to the pandemic 6 patients (n=3 in 7 the PR intervention and n=3 in the PR+PA intervention) completed one exercise session under 8 supervision and one unsupervised at home. Each supervised exercise session was delivered by 9 a respiratory physiotherapist and involved progressive, individualised tailored aerobic and 10 resistance training in accordance with the BTS guidelines on PR [25]. A multidisciplinary team 11 comprising physiotherapists, psychologists, dieticians, respiratory nurses and occupational 12 therapists, delivered the education component of the PR programme. As per the BTS guidelines 13 on PR [25], the educational component of PR aims to support aspects of lifestyle and behaviour 14 change and assist the promotion of self-management to support patients decision making and 15 self-efficacy. Specific educational talks across the 8-week PR programme included guidance 16 and support on dyspnea/symptom management, chest clearance/breathing techniques, 17 nutritional advice, and advice on improving PA. Regardless of group allocation in the study, 18 generic advice on improving PA was provided with an emphasis on barriers and facilitators to 19 improving levels of PA. Furthermore, each patient received a British Lung Foundation exercise 20 handbook which provided added support regarding the educational sessions as well as 21 resources to record exercise and PA conducted outside of the weekly PR sessions. Patients in 22 both groups with a baseline hospital anxiety and/or depression score (HADS) ≥ 8 (either for 23 anxiety or depression) received up to three sessions of Cognitive Behavioural Therapy (CBT) 24 by a specialist respiratory nurse lasting for 30 minutes. The number of CBT sessions suggested 25 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].

5 PA behavioural modification interventions

6 Prior to the initiation of the PA behavioural modification interventions, patients received a one-7 to-one semi-structured motivational interview with the researcher discussing motivational 8 issues, favourite activities, facilitators and barriers to PA and strategies to become more 9 physically active [28]. Throughout the interview, patients were questioned about their self-10 efficacy and motivational levels. On completion of the interview, each patient created a plan 11 with the researcher consisting of three concrete actions, which could be used to increase PA 12 levels. This plan consisted of favourite activities and was implemented throughout the PA 13 behavioural modification interventions to stimulate patient's self-motivation. Following this, 14 the PA behavioural modification interventions involved the provision of a pedometer (Fitbug, 15 Camden, London), an individualised daily step-count target (reviewed twice weekly for 8 16 weeks), and a step-count diary that was brought to every PR session (twice weekly). Patients 17 were encouraged to achieve the agreed target each day and to record the attained pedometer 18 step count in their step count diary each evening. Patients were asked to attend each PR session 19 with their step count diary, enabling the researcher to frequently observe their activity levels, 20 assess overall compliance to the intervention and provide the appropriate level of support based 21 on their recorded activity levels. Based on the feedback from step count diaries, the researcher 22 calculated a daily step-count target based on an increase of 10% from the preceding week's 23 average daily step-count, with the first week's target derived from baseline accelerometer step 24 count data (Actigraph wGT3X, Actigraph LLC, Pensacola, FL, USA) [29] and during 25 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].

4 *Outcome measures*

5 The Clinical PROactive C-PPAC instrument, which was previously validated for use in 6 patients with COPD [22], required both questionnaire and accelerometer-derived PA data 7 (Actigraph wGT3X, Actigraph LLC, Pensacola, FL, USA) and was implemented one week 8 prior to the onset of the PR programme and one week following completion of the PR 9 programme. The C-PPAC questionnaire included 12-items with a 7-day recall and was 10 completed using paper and pen as shown in the online supplementary materials (Table S1). 11 Patients were also instructed to wear an accelerometer previously validated to be part of the C-12 PPAC tool (Actigraph wGT3X, Actigraph LLC, Pensacola, FL, USA) [21] during waking 13 hours for seven consecutive days prior to the onset of the PR programme [30]. A valid 14 assessment of patient's PA was considered if patients recorded more than 8 hours of wear time 15 on at least 4 weekdays within the 7-day period [21]. C-PPAC scores were calculated by 16 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 17 18 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].

1 *Patient acceptability and compliance*

2 Patient acceptability of the PA behavioural modification interventions was assessed through a 3 project-tailored questionnaire modified from another study [39]. During the final visit of the 4 study, patients filled in a self-administered, project tailored, multiple choice questionnaire 5 about their experiences with the intervention and the usefulness of its components on a 10-6 point Likert scale as previously described [39] and shown in Table S2 of the online 7 supplementary material. Data from the project-tailored questionnaire were scored as 8 categorical variables and reported as frequencies and percentages (number of patients 9 indicating each answer), except for the usefulness ratings of the components, which were 10 expressed as median [P25-P75]. Patient compliance to components of the behavioural 11 modification interventions was assessed via the following means: i) fractional number of 12 weekly goal setting targets met; ii) fractional number of weekly completions of PA diaries and 13 iii) average weekly wear time of the pedometer. Data on patient compliance were reported as percentages and median (P25-P75) and as mean \pm SD depending on the variable assessed. 14

15 Data analysis

16 Verification of the sample size was based on the study by Louvaris et al [40] comparing PR to 17 usual care (UC). Based on the mean difference in the C-PPAC total score (7.4 units) between 18 PR and UC and observed SD (8.5 units), an alpha significance level of 0.05 (2-sided) and 80% 19 power, a minimum sample of 24 patients per group was considered to be sufficient to detect 20 significant differences in the total C-PPAC score between PR+PA and PR. Based on previous 21 studies on similar PR programmes in the UK [15], considering an attrition rate of 20% the total 22 sample size was increased to 58 patients. Randomisation was stratified by the 6MWD (<350 23 meters or \geq 350 metres), and the average HADS score for anxiety and depression (<8 points or \geq 8 points) using a block size of 4 at the onset of the PR programme. 24

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.

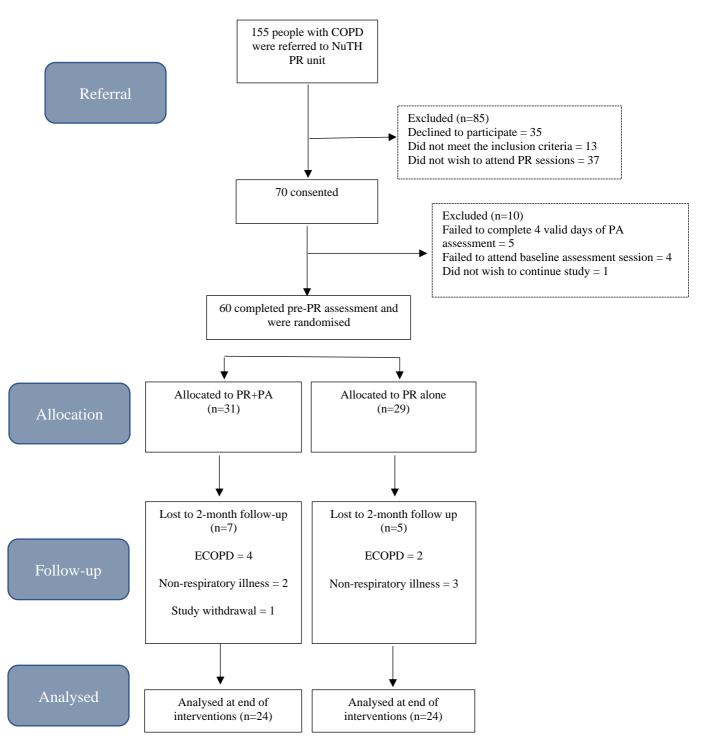


Figure 1: Consolidation Standards of Reporting Trials diagram of the study. COPD = Chronic
Obstructive Pulmonary Disease, NuTH = Newcastle upon Tyne Healthcare trust, PR =
Pulmonary Rehabilitation, n = number, PA = Physical Activity, ECOPD = exacerbation of
COPD

1 **Results**

2 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.

10

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, FEV₁ = 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 \pm SD.

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12 Patient experience of PA

13 The effect of PR+PA compared to PR alone on all dimensions of the C-PPAC instrument for

14 each patient is shown in Figure 2. Post-interventions, the *total score* of the C-PPAC instrument

15 was improved by a clinically important margin (>4 points) [21] in the PR+PA group compared

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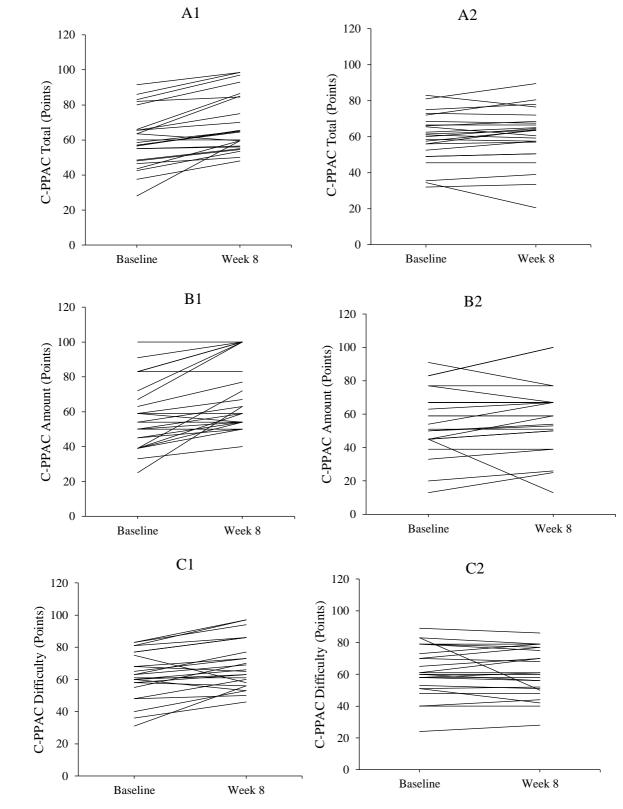


Figure 2: Individual responses to the C-PPAC instrument for A1: total score for PR+PA, A2:
total score for PR alone, B1: amount score for PR+PA, B2: amount score for PR alone, C1:
difficulty score for PR+PA, C2: difficulty score for PR alone.

1 Physical activity outcomes

2 Changes in accelerometer-derived PA variables are shown in Table 2. Post intervention, 3 clinically important (600-1100 steps/day) [19] improvements in accelerometer steps/day data 4 were found in the PR+PA intervention only, with a between group difference of 1016 steps/day 5 (95% CI 556 to 1474 steps/day, p=0.001) (Table 2). Following the completion of the PR 6 programme a significant improvement in accelerometer movement intensity was recorded in 7 PR+PA group only, with a between group difference of 93 VMU (95% CI 41 to 145 VMU, 8 p=0.001, Table 2). Finally, following completion of the PR programme, a significant 9 improvement in time spent in light PA was recorded only in the PR+PA intervention, with a 10 between group difference of 22 minutes (95% CI 2 to 43, p=0.030) (Table 2). 11 12

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	Group	Baseline	2 Months	Within Group Mean Difference	P value	Between Group Difference	P value
C-PPAC	PR+PA	60±16	69±16	9 (6 to 12)	0.001	8 (4 to 12)	0.001
Total score	PR alone	59±14	60±15	1 (-1 to 4)	0.369		
C-PPAC Difficulty	PR+PA	62±15	69±15	7 (3 to 10)	0.001	8 (3 to 13)	0.002
score	PR alone	62±16	61±15	-1 (-4 to 2)	0.525		
C-PPAC	PR+PA	58±20	69±20	11 (7 to 16)	0.001	8 (3 to 16)	0.005
Amount score	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	PR+PA	337±154	410±231	73 (37 to 109)	0.001	93 (41 to 145)	0.001
(VMU)	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		

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

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).

1 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).

6 Intervention acceptability and compliance

7 Overall, the PR+PA intervention was well received by patients, with 75% indicating they 8 "liked taking part in the intervention a lot". Furthermore, 58% of patients claimed the 9 intervention "helped them a lot" regarding completing more PA outside of PR. The majority 10 of patients (79%) experienced the proposed weekly increases in step goals as "reasonable", 11 whereas 21% of patients experienced these increases as "a little too high" or "a little too low". 12 The usability of the pedometer was deemed "very easy" in 96% of patients. Patients rated the 13 usefulness of components of the PR+PA intervention with scores based on a satisfaction scale 14 (0 terrible to 10- perfect) with the step counter (median [P25-P75]; 9 [8-10]), daily step goals 15 (8 [8-9]) and feedback from researcher (9 [8-10]) all deemed useful parts of the intervention. 16 Regarding patient compliance, the average weekly wear time of the Fitbug pedometer was high 17 equivalent to 6.6±0.2 days worn. Compliance with the PA diary to self-reported daily step 18 counts was also high (91±18%), with a median number of 55 [49-56] recorded days over the 8 19 weeks. Finally, compliance with step goal targets throughout the 8 weeks was high, with an 20 average 68±12% of step goals achieved. In terms of pedometer (Fitbug) steps/day (PR+PA

21 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).

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

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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	$1.9{\pm}1.5$	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 \pm SD. Within and between group differences are reported with 95% confidence intervals (CI).

1 **Discussion**

2 The novel finding of this study is the clinically important improvements in COPD patients' 3 experiences of PA following PR+PA compared to PR alone in patients with advanced COPD 4 exhibiting low baseline PA levels. Improvements in the 6MWD were similar for both 5 interventions, however the magnitude of improvement in upper and lower muscle strength was 6 greater in the PR+PA intervention. Collectively these findings suggest that PA behavioural 7 modification interventions alongside PR provide insightful support to patients with low 8 baseline levels of PA to translate PR-induced improvements in functional capacity into 9 improvements in patients' experiences of PA.

10 Previous literature has documented the response of the C-PPAC instrument in two behavioural 11 modification interventions [29, 41]. Demeyer and colleagues [29] found a significant between 12 group difference in both the total and amount dimensions of the C-PPAC instrument following 13 12 weeks of semi-automated PA tele-coaching delivered via a smartphone app. It should be 14 noted that the usual care group reported a large decrease in C-PPAC scores following a 12-15 week period, with only small improvements in C-PPAC scores reported following the tele-16 coaching intervention, thereby suggesting that the tele-coaching intervention only had marginal 17 effects on the C-PPAC tool [29]. Furthermore, Demeyer and colleagues were unable to 18 demonstrate an improvement in the difficulty dimension of the C-PPAC instrument [29]. The 19 difficulty dimension has demonstrated a moderate-strong correlation with health status, chronic 20 dyspnea and exercise capacity [21], which is not captured by the amount dimension. The study 21 by Demeyer et al [29] did not include any specific exercise training and as a result was 22 unsuccessful in demonstrating improvements in exercise capacity, which may be the reason for 23 not reporting an improvement in the difficulty domain following 12-weeks of tele-coaching 24 [29].

1 Arbillaga and colleagues [41] implemented a 12-month urban training programme that 2 incorporated behavioural and community-based exercise interventions in patients with COPD. 3 The C-PPAC instrument was able to detect a significant improvement from baseline to 12 4 months in both the amount and difficulty C-PPAC scores, however improvements were not 5 significant between the intervention and the usual care groups [41]. Considering the magnitude 6 of change in the C-PPAC total scores between the intervention and control groups in the studies 7 of Arbillaga-Extarri [41] (4.5 units) and Demeyer [29] (4.5 units) and that of the current study 8 (8 units), it is clear that PA behavioural techniques added to PR are superior to PA behavioural 9 interventions alone in improving the total score of the C-PPAC instrument.

10 Louvaris and colleagues [40] presented significant and clinically important improvements in 11 the total score of the C-PPAC instrument following PR (5.6 units), which was not found in the 12 PR alone group (1 unit) in the current study. Louvaris and colleagues [40] provided a different 13 type of PR, with their programme consisting of 3 sessions per week for a total of 10 weeks, 14 whilst the current study consisted of 2 sessions per week for 8 weeks. Secondly, Louvaris and 15 colleagues [40] prescribed high-intensity interval exercise, whereas the current study 16 implemented moderate intensity exercise. Furthermore, COPD patients in the Louvaris et al. 17 study [40] presented greater baseline levels of PA and 6MWD than the current study, which 18 has previously been documented to influence the effectiveness of interventions to improve PA 19 [18]. With this in mind, it is plausible that the incorporation of PA behavioural modification 20 interventions, in conjunction with improved functional capacity through PR exercise training, 21 yielded clinically important improvements in all C-PPAC dimensions in patients with very low 22 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

1 empowered and motivated patients to engage in more daily activity. Such behavioural 2 modification components have been shown to benefit COPD patients' readiness, motivation 3 and confidence to engage in PA and were associated with significant improvements in PA 4 behaviour [42]. Furthermore, the initial motivation interview stimulated a discussion between 5 patient and researcher regarding preferred and non-preferred activities, allowing the researcher 6 to tailor weekly PA goals around activities that the patient enjoyed, encouraging self-7 motivation within the patient [12]. Finally, attending each PR session with a step count diary 8 and twice-weekly face-to-face consultations gave the research team an insight into the 9 compliance of each patient, and enabled researchers to intervene if patients were unable to cope 10 with the present goals.

11 Study limitations

12 There are several limitations that must be considered in this study. Our inability to blind 13 patients to the study allocation may have impacted on the overall quality of evidence and 14 increased the risk of bias towards the intervention. Our failure to blind patients was based on 15 several reasons. Firstly, it would require a pedometer being issued to the PR alone group. 16 Although the simple addition of a pedometer alongside generic advice on PA provided during 17 PR doesn't necessary provide any form of PA counselling, the stimulus and incentive to self-18 manage and increase steps/day with the availability of a pedometer may impact upon the 19 steps/day of the PR alone group. Secondly, in order to remain comparable with previous 20 literature, we followed the procedure of several previous studies that implemented PA 21 counselling alongside standard care PR [10, 12, 13, 15], of which pedometers were not 22 provided to the control group. In future studies however, studies may wish to follow the 23 blinding procedure of two recent studies in COPD [16, 41]. Varas and colleagues [16] blinded 24 patients by allocating a pedometer to both intervention and control groups, but provided no 25 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.

5 Due to all measures being administered in a face-to-face manner by a single researcher, bias 6 related to the researcher providing the PA behavioural modification interventions couldn't be 7 avoided and blinding of assessor was not possible.

8 This was a small-scale study, therefore, generalisability of the results to clinical practice may 9 be limited. Finally, the present behavioral modification interventions alongside PR were well 10 received by the vast majority of patients showing high compliance, however such behavioral 11 interventions may require significant health care resources as they are more time consuming 12 compared to PA tele-coaching [38].

13

14 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.

18

19 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.

1	Graham Burns: conceptualization, methodology, supervision, writing- review & editing.
2	Karen Heslop Marshall: conceptualization, methodology, investigation, supervision, writing-
3	review & editing, writing- review & editing. Ioannis Vogiatzis: conceptualization, funding
4	acquisition, investigation, supervision, writing- review & editing.
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1 Appendices

2 A1: The C-PPAC instrument



Northumbria University NEWCASTLE

The Newcastle upon Tyne Hospitals MHS

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.

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? 3 Some examples are gardening, taking the rubbish out, or doing small errands. 0 None at all 0 A few 1 Some 2 A lot 3 A lot 3 A large amount 4 In the past 7 days, how much difficulty did you have getting dressed? 4 In the past 7 days, how much difficulty did you have getting out and 4 In the past 7 days, how much difficulty did you have getting out and 4		Difficult	Amount
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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	dressed?		
Some 2 A lot 1 A great deal 0 In the past 7 days, how much difficulty did you have getting out and about? 4 None at all 4 A little bit 3 Some 2 A lot 1	None at all	4	
A lot 1 A great deal 0 In the past 7 days, how much difficulty did you have getting out and about? 4 None at all 4 A little bit 3 Some 2 A lot 1	A little bit	3	
A great deal 0 In the past 7 days, how much difficulty did you have getting out and about? 4 None at all 4 A little bit 3 Some 2 A lot 1		2	
In the past 7 days, how much difficulty did you have getting out and about? None at all A little bit Some A lot A	A lot	1	
about? 4 None at all 4 A little bit 3 Some 2 A lot 1	A great deal	0	
None at all 4 A little bit 3 Some 2 A lot 1	In the past 7 days, how much difficulty did you have getting o	ut and	
A little bit 3 Some 2 A lot 1	about?		
□ Some 2 □ A lot 1	None at all	4	
A lot 1		3	
A lot 1	Some	2	
A great deal 0	A lot	1	
	A great deal	0	



The	Newcastle	upon	Tyne	Hospitals	NHS
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NHS Foundation Trust

In the past 7 days, how often did you avoid doing activities because of your lung problems? Not at all Rarely Sometimes Frequently All the time	4 3 2 1 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	
U Very	1	
	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	



Northumbria University NEWCASTLE

The Newcastle upon Tyne Hospitals

In the past 7	days, how breathless were you when walking on level	
ground indo	ors 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 acti	vities?	
	None at all	4
	A little bit	3
B	Some	2
	A lot	1
	A great deal	0
In the past	7 days, did you need to consider your lung problems	
when you p	anned your activities because of your lung problems?	
Examples a	re 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	Measured by	Measured by	
score	Actigraph	Dynaport	
🗖 0	<1000	<1500	0
🗖 1	1000-2000	1500-2500	1
D 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
D 2	200-300	130-210	2
🔲 3	300-500	210-370	3
□ 4	>500	>370	4
	Amo	ount scores (sum above):	
	Diffi	culty scores (sum above):	F
	Tota	I scores (sum above):	

1 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?

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?



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

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.....

- 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?

1 2 3



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

1)	The step	count	er									
	C)	1	2	3	4	5	6	7	8	9	10
2)	The step	count	diary p	rovided	i i							
	0)	1	2	3	4	5	6	7	8	9	10
3)	Daily ste	p goal	s displa	yed on y	your ste	p coun	t diary e	ach we	ek			
	0)	1	2	3	4	5	6	7	8	9	10
41	Activity	leedha	ek durir	ng each	of the	aulmon	anv reha	abilitativ	n sessi	ons		
-,				-				6		8	9	10
5)	If your H	ADS le	vels we	re >8, y	our ses	sions of	СВТ					
	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

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:
	Would you like to add a comment?
	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
$\leq$	Thank you for your time throughout this research study and I hope the benefits you have received taking part will continue!
$\subseteq$	

2