Abstract S47 Table 1

	Controls (n = 50)	Mild OSAS [ODI 5 –15] (n = 44)	Moderate OSAS [ODI 16 – 30] (n = 41)	Severe OSAS [ODI >30] (n = 48)	One way ANOVA Is p<0.05?	Bonferroni's Multiple comparison test					
					P value	Control vs Mild	Control vs Moderate	Control vs Severe	Mild vs Moderate	Mild Vs Severe	Moderate vs Severe
Coping Strategy Score	3.5(2.5)	6.9(4.1)	6.8(4.4)	6.6(5.2)	<0.0001	Yes	Yes	Yes	No	No	No
ESS	3(2)	12(5)	10(5)	11(6)	<0.0001	Yes	Yes	Yes	No	No	Yes

have a rest, but some may use various strategies to try to stay alert. We devised a questionnaire that assessed various commonly used coping strategies and explored whether there is a difference between patients with OSAS and normal controls. We also hypothesised that patients might admit to utilising such strategies more readily than to sleepiness while driving and asked about sleepiness while driving in various situations.

Method 133 (52±10 yrs, ESS 12±6, ODI 31± 24) untreated OSAS patients and 49 healthy controls (45±17 yrs, ESS 3±2) were included in the study. The coping strategy section included ten questions about various strategies they adapt in order to stay awake. They were asked to rate on a 3-point scale, from "never" to "frequently". The questionnaire was scored by adding up the ratings for the ten questions, and the highest possible score was 30. Comparisons were made using one way ANOVA.

Results There was a significant difference in the total coping strategy score between the patients of different severities (mild, moderate, severe, as per ODI) and the healthy controls. However there was no difference when different severities of OSAS were compared against each other (Table 1). There was strong correlation between the coping strategy score & ESS (Spearman r=0.53, p<0.0001). 81% (38/47) of patients and 77% (23/30) of controls who did not admit to feeling sleepy while driving admitted using coping strategies.

Conclusion OSAS patients report using significantly higher number of coping strategies compared to healthy individuals irrespective of the severity of disease. It also correlated strongly with marker of day time sleepiness (ESS). Asking about such coping strategies may be a better way identifying who are at risk of an accident than asking directly about problems with sleepiness while driving.

Randomised clinical trials in COPD

S48 THE EFFECT OF ANGIOTENSIN-CONVERTING ENZYME INHIBITION ON SKELETAL MUSCLE DYSFUNCTION IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE: A RANDOMISED CONTROLLED TRIAL

doi:10.1136/thoraxjnl-2012-202678.054

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Introduction Skeletal muscle impairment is a well recognised complication of COPD, predicting mortality in severe disease.[1] Evidence from animal models, genetic studies and observational cohorts suggest a role for the renin-angiotensin system in control of muscle phenotype.[2] We hypothesised that angiotensin-converting enzyme (ACE) inhibition would have a beneficial effect on quadriceps function in patients with COPD.

Methods A single-centre, double-blind randomised controlled parallel-group trial investigating the effect of fosinopril versus placebo on quadriceps muscle dysfunction in COPD patients with quadriceps weakness. Muscle weakness was defined as a quadriceps maximum voluntary contraction (QMVC) less than 120% of the body mass index.[1]

Measurements The primary outcome was change in non-volitional quadriceps endurance at 3 months, measured using repetitive magnetic stimulation. QMVC, mid-thigh CT cross-sectional area (MT_{CSA}), incremental shuttle walk distance (ISWD) and serum inflammatory markers were secondary outcomes.

Results 80 patients were enrolled (mean(SD), 65(8) years, FEV_1 43(21)% predicted, 53% male). 67 patients (31 fosinopril and 36 placebo) completed the trial, with the treatment group demonstrating a significant reduction in systolic blood pressure (Δ-10.5mmHg, 95%CI –19.9 to –1.1, p=0.03) and serum ACE activity (Δ-20.4units/L, 95%CI –31.0 to –9.8, p<0.001) compared to placebo. At 3 months, no significant difference was observed in quadriceps muscle endurance half-time (fosinopril Δ5.1s, 95%CI –4.3 to 14.5, p=0.27 vs. placebo Δ4.6s, 95%CI –5.8 to 15.1, p=0.37; between group Δ0.5s, 95%CI –13.3 to 14.3, p=0.94). QMVC improved significantly in both groups (fosinopril Δ1.1kg, 95%CI 0.03 to 2.2, p=0.045 vs. placebo Δ3.6kg, 95%CI 2.1 to 5.0, p<0.0001) with a greater increase in the placebo arm (between group Δ2.5kg, 95%CI 0.7 to 4.3, p<0.01). There was no significant change in MT_{CSA} (p=0.09), ISWD (p=0.51) or serum inflammatory markers (C-reactive protein, p=0.17) between the groups. Stratification based on ACE genotype did not influence study outcomes.

Conclusion This randomised controlled trial found that ACE-inhibition did not improve quadriceps function in a COPD population with quadriceps weakness. Study funded by the Medical Research Council. Trial registration: NCT01014338.

1. Swallow EB, *et al*. *Thorax* 2007; 62:115–20.
2. Shrikrishna D, *et al*. *Clin Sci* 2012; 123:487–98.

S49 A SELF-MANAGEMENT PROGRAMME OF ACTIVITY COPING AND EDUCATION (SPACE) FOR COPD: RESULTS FROM A RANDOMISED CONTROLLED TRIAL

doi:10.1136/thoraxjnl-2012-202678.055

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Introduction The NHS Outcomes Strategy for COPD has identified self-management as an approach targeted at reducing the impact of COPD.[1] Previous self-management programmes have either been unsupported, such as brief education or action plans, or have been of high intensity, equivalent with pulmonary rehabilitation. Furthermore, no studies have specifically tested self-management in patients managed in primary care. SPACE is a

Abstract S49 Table 1

	Space			Usual Care			Between group difference
	Baseline	6 Weeks	6 Months	Baseline	6 Weeks	6 Months	
Dyspnoea	3.31 (1.07)	4.02 (1.19)	3.97 (1.37)	2.95 (1.17)	3.38 (1.35)	3.44 (1.40)	0.17 p=0.323
Fatigue	3.93 (1.23)	4.37 (1.15)	4.12 (1.34)	3.80 (1.32)	3.80 (1.47)	3.70 (1.40)	0.31 p=0.034
Emotion	4.86 (1.27)	5.20 (1.18)	5.02 (1.32)	4.83 (1.22)	4.75 (1.32)	4.64 (1.43)	0.35 p=0.047
Mastery	5.25 (1.32)	5.40 (1.17)	5.29 (1.37)	5.14 (1.40)	5.03 (1.49)	4.91 (1.52)	0.26 p=0.287
ISWT (metres)	343 (150)	353 (161)	354 (154)	349 (161)	343 (163)	347 (163)	13 p=0.145
ESWT (seconds)	260 (179)	470 (390)	494 (413)	263 (167)	355 (308)	313 (290)	184 p=0.038
HADS anxiety	10.50 (2.11)	9.50 (3.11)	9.36 (3.81)	10.67 (2.47)	10.30 (2.98)	10.18 (3.42)	–0.62 p=0.581
HADS depression	9.44 (1.38)	8.56 (3.24)	8.00 (2.87)	9.94 (1.77)	9.25 (3.53)	10.25 (3.79)	–1.75 p=0.156

supported self-management programme that adopts a light touch approach. This study aimed to test the effectiveness of SPACE in patients with COPD in primary care.

Methods 184 patients [101 male; mean (SD) age 69 (9) yrs; FEV_1 1.44 (0.56) l; BMI 27.56 (5.26) kg/m^2] with COPD were recruited and randomised to either SPACE or usual care. Patients who received SPACE were introduced to a manual by a healthcare professional and received two telephone calls at 2 and 4 weeks. Measures were taken at baseline, 6 weeks and 6 months. The primary outcome was the Chronic Respiratory Questionnaire (CRQ) dyspnoea. Secondary outcomes were CRQ fatigue, emotion and mastery, Incremental Shuttle Walk Test (ISWT), Endurance Shuttle Walk Test (ESWT) and Hospital Anxiety and Depression Scale (HADS). HADS was analysed on a subgroup of those scoring ≥8 at baseline. Repeated measures ANOVA was conducted to test the effect of time and intervention. Results

Results are displayed in table 1.

Conclusions SPACE can bring about gains in HRQoL, endurance capacity and reduced depression for those at risk, that are maintained over 6 months. These are important patient outcomes which suggest self-management skills of emotional and medical management have been gained.

Reference

1. Department of Health. 'An Outcomes Strategy for COPD and Asthma: NHS Companion Document.' May 2012.

S50 ONCE-DAILY GLYCOPYRRONIUM IMPROVES LUNG FUNCTION IN COPD PATIENTS: POOLED RESULTS OF THE GLOW1 AND GLOW2 STUDIES

doi:10.1136/thoraxjnl-2012-202678.056

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Introduction NVA237 (glycopyrronium) is a safe and effective once-daily inhaled long-acting muscarinic antagonist for the maintenance treatment of COPD.

Methods This pooled analysis of the Glycopyrronium Bromide in COPD Airways Clinical Studies (GLOW1 and 2) assessed the efficacy of glycopyrronium 50μg once daily versus placebo and open-label tiotropium 18μg once daily over 26 to 52 weeks in patients with moderate-to-severe COPD. Glycopyrronium and placebo were delivered via the Breezhaler® device and tiotropium was delivered via the Handihaler® device, in the morning between 8:00–11:00 hours. Analyses included trough forced expiratory volume in 1 second (FEV_1) and forced vital capacity (FVC) at Day 1 and Weeks 12, 26 and 52; 24hour (h) serial spirometry in a subset of patients, and FEV_1 area under the curve (AUC).

Results 1888 subjects were randomised, 98.2% analysed (glycopyrronium=1059, tiotropium=267, placebo=528); male: 71.5%, mean age: 63.9 years, mean post-bronchodilator FEV_1: 55.5% predicted. All trough FEV_1 and FVC values for glycopyrronium and tiotropium were significantly greater than placebo ($p<0.001$) and glycopyrronium was numerically higher than tiotropium at all time-points (table).

The improvement in FEV_1 with glycopyrronium was seen immediately after the first dose on Day 1 (90mL at 5min and 144mL at 15min versus placebo, $p<0.001$) and sustained throughout the 52 Week period. FEV_1 AUC for 0–4h, 0–12h, 0–24h and 12–24h for glycopyrronium was significantly greater than placebo ($p<0.05$). AUC 0–4h for glycopyrronium was significantly greater than tiotropium on Day 1 and Weeks 12 and 26; all other AUC values for glycoprrronium were numerically higher than tiotropium.

Conclusion Once-daily glycopyrronium provided rapid, sustained and clinically meaningful bronchodilation over 52 weeks with efficacy similar to tiotropium in patients with COPD.

Abstract S50 Table 1 Trough FEV_1 and FVC least square mean treatment difference (SE) from placebo (mL)

	FEV_1		FVC	
	Glycopyrronium	Tiotropium	Glycopyrronium	Tiotropium
Day 1	98 (7.7)	88 (11.5)	187 (15.1)	178 (22.7)
Week 12	103 (11.2)	88 (16.7)	190 (21.5)	172 (32.0)
Week 26	125 (12.6)	78 (18.6)	205 (22.7)	133 (33.9)
Week 52	108 (19.5)	89 (22.3)	179 (34.4)	180 (39.4)

S51 EFFICACY OF ACLIDINIUM BROMIDE COMPARED WITH TIOTROPIUM AND PLACEBO IN PATIENTS WITH MODERATE TO SEVERE COPD: A PHASE IIIB STUDY

doi:10.1136/thoraxjnl-2012-202678.057

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