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

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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

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Introduction and Objective Aclidinium bromide is a novel, long-acting, muscarinic antagonist indicated as a maintenance treatment for chronic obstructive pulmonary disease (COPD). Maintaining significant bronchodilation throughout the 24-hour day is important to improve outcomes for patients with COPD. This study evaluated daily bronchodilatory symptom control with twice-daily (BID) aclidinium in patients with stable, moderate-to-severe COPD.
Methods In this 6-week, randomised, double-blind, Phase IIIb study, patients received aclidinium 400 μg (metered dose; equivalent to aclidinium 322 μg delivered dose) BID, tiotropium bromide 18 μg once daily or placebo. Change from baseline in normalised forced expiratory volume in 1 second (FEV_1) area under the curve over the 24-hour period immediately following morning treatment ($AUC_{0–24}$) at Week 6 was the primary endpoint. Other endpoints included change from baseline in normalised FEV_1 $AUC_{12–24}$ and $AUC_{0–12}$, pre-dose (trough) FEV_1 and peak FEV_1. Daily symptoms were recorded each evening using the 11-item EXAcerbations of Chronic pulmonary disease Tool-Respiratory Symptoms (EXACT-RS) and a total score was calculated (range 0-40: more severe symptoms indicated by higher score). Additional daily symptoms, including presence of morning symptoms and night-time symptom severity (5-point scale: 0=none; 4=very severe), were recorded using electronic diaries.
Results In total, 414 patients were randomised: mean age was 62.3±8.1 years (mean±SD); 54.1% were current smokers; baseline FEV_1 was 1.484±0.51 L At Week 6, aclidinium 400 μg BID and tiotropium 18 μg QD significantly improved lung function from baseline compared with placebo (Table). Compared with placebo, aclidinium and tiotropium significantly reduced EXACT-RS total scores from baseline (–2.1 and –1.3 versus –0.1; $p<0.0001$ and $p<0.05$, respectively), and increased percentage of days without morning symptoms from baseline (6.7% and 3.4%, respectively, versus -2.2%; $p<0.05$ for both) at Week 6. Night-time symptom severity scores were significantly reduced from baseline with aclidinium (–0.16) versus placebo (–0.02) at Week 6 ($p<0.05$) but improvements with tiotropium (–0.09) did not reach statistical significance.
Conclusions Aclidinium 400 μg BID provided significant 24-hour bronchodilation and daily symptom improvement throughout the study. The bronchodilatory effect of aclidinium was similar to tiotropium, with numerically greater improvement in morning and night-time symptoms among aclidinium-treated patients.

Abstract S51 Table 1 Spirometric variables at Week 6

Change from baseline vs placebo, mL	Aclidinium 400 μg	Tiotropium 18 μg	Difference
Normalized FEV_1 $AUC_{0–24}$	150†	140†	10
Normalized FEV_1 $AUC_{12–24}$	160†	123†	37
Normalized FEV_1 $AUC_{0–12}$	138†	156†	–18
Morning pre-dose (trough) FEV_1	141†	102*	39
Peak FEV_1	180†	172†	8

*$p<0.05$; †$p<0.0001$.

S52 CLINICAL EFFECTIVENESS OF TELEMONITORING FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD): RANDOMISED CONTROLLED TRIAL

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Introduction Previous trials of telehealthcare for COPD have included enhanced clinical care compared with controls. It is therefore unclear if telehealthcare alone improves clinical outcomes and reduces hospital admissions.

Aim To determine if telemetrically supported self-monitoring of COPD postpones hospital admissions when both intervention and control groups receive optimised care.
Trial design 1-year, researcher-blind RCT in UK primary care.
Methods Patients with a COPD admission in the previous year were randomised centrally to telemetric or traditional modes of monitoring: both groups received the same clinical care. The primary outcome, assessed by a researcher blinded to allocation, was time to first hospital admission caused by a COPD exacerbation over the trial year. Other outcomes included number of admissions, bed days, deaths and health-related quality of life (St George's Respiratory Questionnaire (SGRQ)).
Results We randomised 256 patients (128 telemonitoring): baseline characteristics were similar. Using an intention-to-treat analysis, there was no difference in time to admission between the groups (adjusted hazard ratio for admission (reference=tele-group) 1.03 (95%CI 0.70 to 1.50). 61 patients in each group had an admission. There was no significant difference in the mean number of admissions/person (tele-group: 1.2 (SD 1.9), control: 1.1 (SD 1.6) p=0.51); bed days (tele-group: 9.4 (SD 19.1) vs control 8.8 (SD 15.9) p=0.66); or deaths (tele-group: 16, control 21. p=0.38). Quality of life at 1 year was similar in both groups (SGRQ tele-group: 68.2 (16.3) vs usual: 67.3 (17.3), mean difference: 1.5 (95% CI –1.5 to 4.5)).
Conclusion When both groups received optimised care, telemonitoring did not appear to reduce the time to a hospital admission, duration of hospital admissions or increase quality of life. The place of telemonitoring in clinical care may depend upon whether it offers efficiency savings by enabling professionals to monitor and support the care of more patients than using traditional means of communication.
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S53 OUTCOMES OF THE REPNEU ENDOBRONCHIAL COILS FOR THE TREATMENT OF SEVERE EMPHYSEMA WITH HYPERINFLATION (RESET) TRIAL

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Background The predominant pathophysiology in severe emphysema with gas trapping and hyperinflation is that of dynamic airway collapse on minimal expiratory effort. This limits the benefit from drug therapy. Safer and cheaper alternatives to lung volume reduction surgery (LVRS), which has success in selected patients with low exercise capacity and upper lobe-predominant emphysema, are being developed. Endobronchial valve treatment has been shown to be beneficial to patients with heterogenous disease in the absence of collateral ventilation. RePneu Lung Volume Reduction Coils (LVRCs) are self-actuating implantable devices composed of nitinol. They are implanted bronchoscopically using conscious sedation. The LVRC is delivered into targeted airways using fluoroscopic guidance, and when its sheath is removed recoils to it original pre-determined shape.
Methods In a prospective randomised study of LVRCs on patients with severe emphysema and hyperinflation, 63 patients were screened at 3 centres in the United Kingdom with 23 randomised to treatment with LVRCs and 24 to best medical care (control). LVRC patients were initially treated in one lung, with the contralateral lung treated after one month if appropriate. The primary end point was the difference between treatment and control groups in the St. George's Respiratory Questionnaire (SGRQ) 90 days post-final treatment. The trial is registered with ClinicalTrials.gov (NCT01334307).