Primary endpoint

Efficacy - VAS primary endpoint of >/= 2 point improvement in dyspnoea

Analysed as per ITT population i.e. all randomised patients fulfilling the eligibility criteria (63 patients).

Patients are classed as responders if their VAS dyspnoea measurement at 4 weeks is recorded as a >/= 2 point reduction compared to baseline.
Patients whose score is not recorded or withdrawn before the 4 week assessment for any reason are considered to be non-responders.

25 patients out of 63 (40%) had a response at 4 weeks.

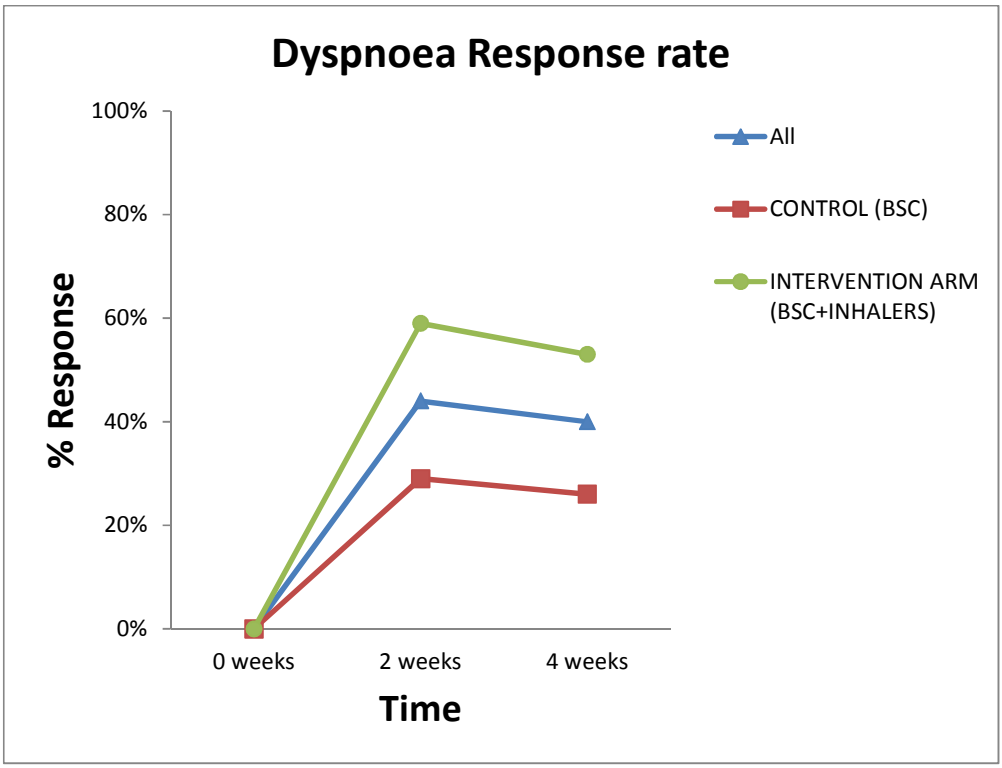
Table 1: VAS Dyspnoea response at 4 weeks by treatment

	Intervention (BSC + Inhalers)	**Control (BSC)**	**All patients**
Response	17	8	25
Non-response	13	20	33
Withdrawn / No data (i.e. Non-response)	2	3	5
Total	32	31	63
Response rate (95% CI)	53% (95% CI: 35% to 71%)	26% (95% CI: 12% to 45%)	40% (95% CI: 28% to 53%)

Significance: Intervention (BSC + Inhalers) vs. Control (BSC)→ p-value = 0.027 (Chi-squared)

There is a statistically significant difference between responders and non-responders of 2-points (or more) reduction in VAS dyspnoea at 4 weeks compared to baseline, when compared between the two treatment groups.

44% of patients maintained a response to 2 weeks and 40% to 4 weeks.


Dyspnoea Response rate
100%
80%
60%
40%
20%
0%
% Response
0 weeks
2 weeks
4 weeks
Time
All
CONTROL (BSC)
INTERVENTION ARM (BSC+INHALERS)