

Table 8A. Mean change in HRQoL as measured by SGRQ from baseline to 6 and 9 months post-enrollment

	Average difference from baseline (sd)		Adjusted for baseline score, site and setting ^a		Full set of adjustors ^c	
	HCP + Peer Support	HCP	Difference between arms [95% CI]	p*	Difference between arms [95% CI]	p*
Total Score						
At 6 months N=220; HCP + Peer Support n=107; HCP Only n=113	-0.52 (18.32)	-1.78 (19.66)	1.46 [-2.47, 5.38] ^b	0.467	1.82 [-1.76, 5.40]	0.319 ^d
At 9 months N=155; HCP + Peer Support n=79; HCP Only n=76	4.61 (20.83)	2.27 (23.29)	1.71 [-2.30, 5.72]	0.404	2.06 [-1.22, 5.35]	0.219
Symptom Score			Overall p-value = 0.441^e		Overall p-value = 0.687^e	
At 6 months N=223; HCP + Peer Support n=109; HCP Only n=114	-3.11 (23.03)	-3.16 (23.46)	-0.70 [-1.80, 0.39]	-	-0.41 [-3.77, 2.95]	-
At 9 months N=161; HCP + Peer Support n=81; HCP Only n=80	4.47 (26.08)	1.05 (24.50)	0.67 [-4.25, 5.59]	-	1.87 [-3.32, 7.06]	-
Activity Score			Overall p-value < 0.001		Overall p-value < 0.001	
At 6 months N=220; HCP + Peer Support n=107; HCP n=113	0.60 (16.87)	-2.31 (23.15)	4.37 [0.65, 8.08]	0.021	5.44 [2.29, 8.58]	0.001
At 9 months N=155; HCP + Peer Support n=79; HCP Only n=76	3.14 (16.29)	0.06 (23.59)	3.69 [1.50, 5.88]	0.001	5.27 [4.15, 6.39]	<0.001
Impact Score			Overall p-value = 0.696		Overall p-value = 0.389	
At 6 months N=221; HCP + Peer Support n=107; HCP n=114	-0.57 (24.00)	-0.82 (23.34)	1.07 [-1.72, 3.85]	-	2.36 [-1.88, 6.60]	-
At 9 months N=159; HCP + Peer Support n=79; HCP Only n=80	5.31 (26.65)	4.29 (27.73)	-0.42 [-3.39, 2.55]	-	1.35 [-2.65, 5.35]	-

Notes: Randomization is stratified by enrollment site/setting. Standard errors for all analyses clustered at the site/setting level. Normality of residuals is good.

a Mixed effects linear model adjusted for baseline score, and site and setting fixed effects.

b In addition to the set of adjustors described in [a] the model for total score is adjusted additionally for the three SGRQ domain scores at baseline, but not for total score at baseline

c Mixed effects linear model adjusted for age, gender, continuous oxygen use, ever hospitalized in the previous year, Charlson comorbidity index, CHF diagnosis, annual income, education, smoking status, self-reported general and emotional health, post-enrollment disposition, SGRQ's baseline total and domain scores, and site and setting fixed effects.

d In addition to the set of adjustors described in [d] the model for total score is adjusted additionally for all three SGRQ domain scores at baseline, but not for total score at baseline

e Overall p-values test the overall interaction between the three time points and study arm; when overall p-value is <0.05, differences between study arms at the individual time points were assessed with a Bonferroni-adjusted significance level of 0.05/3 = 0.0167 to account for multiple comparisons.

Notes on Table 8A:

We compared the SGRQ Symptoms, Activity, and Impact domain scores between the two study arms. At baseline, domain scores were similar between the study arms except for higher activity scores in HCP Plus Peer arm compared to HCP arm (mean activity scores 74.1[sd 20.9] and 71[sd 23.9], respectively). Table 8A shows the changes in these domain scores from baseline by study arm at the study time points (6 months, 9 months). There were no significant interactions between timepoint and study arm for the Symptoms and Impact domain scores. There was a significant interaction between timepoint and study arm for the Activity domain score after adjustment for baseline score, hospital site, and enrollment setting ($p < 0.001$), and this interaction remained significant after additional adjustment for baseline patient characteristics ($p < 0.001$). Looking at the individual timepoints (with Bonferroni-adjusted significance level of $0.05/3 = 0.0167$), there was a significant difference in the change from baseline for the activity domain score at 6 and 9 months between the treatment groups (adjusted difference 5.44 points with 95% CI: 2.29 to 8.58 at 6 months; and 5.27 points with 95% CI: 4.15 to 6.39). Of note is that this difference between study arms in change of Activity scores was not significant in the unadjusted model ($p = 0.131$ and 0.415 at 6 and 9 months, respectively).