

SSAT 058: Final locked data analysis

Version 4.0: 22nd May 2018

Sleep Questionnaire

Missing data coded as none while patients who dropped out were coded as having no results

		Baseline	Week 4	Week 12	Week 24	p-value
	Attended	41	40	39	39	Using Friedman' s test
	DNA	0	0	0	0	
	Drop out	0	1	2	2	
Total 4 items sleep score <i>Max possible=100 (severe)</i> <i>Min possible=0 (none)</i>	Median(IQR)	17(8 to 25) Range: 0 to 58	8(8 to 21) Range: 0 to 58	8(8 to 25) Range: 0 to 42	17(8 to 25) Range: 0 to 42	0.011
			Baseline to week 4	Baseline to week 12	Baseline to week 24	
% improvement in total 4 items sleep score from Baseline <i>(-ve values indicate deterioration)</i>	Median change(IQR)		0(0 to 13) Range: -42 to 33 P=0.005 <i>Using Wilcoxon signed rank test</i>	8(0 to 17) Range: -25 to 33 P=0.002 <i>Using Wilcoxon signed rank test</i>	0(0 to 8) Range: -25 to 33 P=0.027 <i>Using Wilcoxon signed rank test</i>	
		N=41	N=40	N=39	N=39	
<i>During the past month how would you rate your sleep quality overall?</i> <i>0=Very good</i> <i>1=fairly good</i> <i>2=fairly bad</i> <i>3=very bad</i>	-9=Missing 0=Very good 1=fairly good 2=fairly bad 3=very bad	0(0.0) 3(7.3) 33(80.5) 5(12.2) 0(0.0)	0(0.0) 11(27.5) 25(62.5) 4(10.0) 0(0.0)	1(2.6) 13(33.3) 21(53.9) 4(10.3) 0(0.0)	0(0.0) 8(20.5) 23(59.0) 8(20.5) 0(0.0)	

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		Baseline	Week 4	Week 12	Week 24
	Attended	41	40	39	39
	DNA	0	0	0	0
	Drop out	0	1	2	2
During the past month how much of a problem has it been for you to keep up enough enthusiasm to get things done? <i>0=No problem at all 1=only a very slight problem 2=somewhat of a problem 3=a very big problem</i>	Missing	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	No problem at all	17(41.5)	23(57.5)	19(48.7)	18(46.2)
	only a very slight problem	18(43.9)	12(30.0)	18(46.2)	19(48.7)
	somewhat of a problem	5(12.2)	5(12.5)	2(5.1)	1(2.6)
	a very big problem	1(2.4)	0(0.0)	0(0.0)	1(2.6)
During the past month, how often have you taken medicine to help you sleep? <i>0=not during the past month 1=less than once a week 2=once or twice a week 3=three or more times a week</i>	Missing	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	not during the past month	34(82.9)	36(90.0)	35(89.7)	36(89.7)
	less than once a week	3(7.3)	2(5.0)	0(0.0)	1(2.6)
	once or twice a week	1(2.4)	1(2.5)	1(2.6)	1(2.6)
	three or more times a week	3(7.3)	1(2.5)	3(7.7)	1(2.6)
During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity? <i>0=not during the past month 1=less than once a week 2=once or twice a week 3=three or more times a week</i>	Missing	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	not during the past month	34(82.9)	33(82.5)	36(92.3)	33(84.6)
	less than once a week	5(12.2)	5(12.5)	1(2.6)	5(12.8)
	once or twice a week	2(4.9)	1(2.5)	2(5.1)	1(2.6)
	three or more times a week	0(0.0)	1(2.5)	0(0.0)	0(0.0)

Median(IQR), p-values using Wilcoxon sign rank test

Missing data coded as none while not applicable were coded as having no results

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		Baseline	Week 4	Week 12	Week 24	p-value
		N=41	N=40	N=39	N=39	
Do you have a bed partner or a roommate?	Missing	1(2.4)	4(10.0)	5(12.8)	4(10.3)	Using Friedman's test
	No bed partner or roommate	24(58.5)	26(65.0)	23(59.0)	24(61.5)	
	Partner/roommate in other room	3(7.3)	0(0.0)	2(5.1)	0(0.0)	
	Partner/roommate in room but not same bed	0(0.0)	0(0.0)	0(0.0)	2(5.1)	
	Partner in same bed	13(31.7)	10(25.0)	9(23.1)	9(23.1)	
Total 5 items sleep score <i>Max possible=100 (severe)</i> <i>Min possible=0 none</i>	Median(IQR)	N=17 30(30 to 45) Range: 20 to 60	N=14 33(25 to 50) Range: 25 to 80	N=15 30(25 to 50) Range: 0 to 60	N=15 30(25 to 45) Range: 20 to 90	0.791
% improvement in total 5 items sleep score from Baseline <i>(-ve values indicate deterioration)</i>	Median change(IQR)		N=14 3(-5 to 5) Range: -20 to 15 P=0.949 <i>Using Wilcoxon signed rank test</i>	N=14 0(-5 to 5) Range: -20 to 25 P=0.992 <i>Using Wilcoxon signed rank test</i>	N=14 3(0 to 5) Range: -30 to 40 P=0.545 <i>Using Wilcoxon signed rank test</i>	
If you have a roommate or bed partner How often in the past month have you had..... 1=Not during the past month 2=less than once a week 3=once or twice a week 4=three or more times a week						
Loud snoring	Not applicable	24	26	24	25	
	Missing	0(0.0)	0(0.0)	1(6.3)	0(6.3)	
	1=Not during the past month	8(47.1)	7(50.0)	6(37.5)	8(53.3)	
	2=less than once a week	3(17.7)	1(7.1)	6(37.5)	5(33.3)	
	3=once or twice a week	2(11.8)	3(21.4)	2(12.5)	1(6.7)	
	4=three or more times a week	4(23.5)	3(21.4)	0(0.0)	1(6.7)	

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Long pauses between breadths while asleep	Not applicable	24	26	24	25
	Missing	1(5.9)	1(7.1)	1(6.3)	0(0.0)
	1=Not during the past month	12(70.6)	9(64.3)	11(68.8)	12(80.0)
	2=less than once a week	2(11.8)	0(0.0)	2(12.5)	1(6.7)
	3=once or twice a week	1(5.9)	3(21.4)	1(6.3)	1(6.7)
4=three or more times a week	1(5.9)	1(7.1)	0(0.0)	1(6.7)	
Legs twitching or jerking while sleeping	Not applicable	24	26	24	25
	Missing	0(0.0)	0(0.0)	2(6.3)	0(0.0)
	1=Not during the past month	12(70.6)	8(57.1)	8(50.0)	10(66.7)
	2=less than once a week	4(23.5)	4(28.6)	1(6.3)	4(26.7)
	3=once or twice a week	0(0.0)	1(7.1)	3(18.8)	0(0.0)
4=three or more times a week	1(5.9)	1(7.1)	1(6.3)	1(6.7)	
Episodes of disorientation or confusion during sleep	Not applicable	24	26	24	25
	Missing	0(0.0)	0(0.0)	1(6.3)	0(0.0)
	1=Not during the past month	16(94.1)	11(78.6)	12(75.5)	13(86.7)
	2=less than once a week	1(5.9)	3(21.4)	2(12.5)	1(6.7)
	3=once or twice a week	0(0.0)	0(0.0)	0(0.0)	1(6.7)
4=three or more times a week	0(0.0)	0(0.0)	0(0.0)	0(0.0)	
Other restlessness while you sleep	Not applicable	26	26	26	25
	Missing	2(11.8)	0(0.0)	2(12.5)	1(6.7)
	1=Not during the past month	8(47.1)	12(85.7)	10(62.5)	9(60.0)
	2=less than once a week	5(29.4)	1(7.1)	1(6.3)	1(6.7)
	3=once or twice a week	1(5.9)	1(7.1)	1(6.3)	3(20.0)
4=three or more times a week	1(5.9)	0(0.0)	1(6.3)	1(6.7)	

Median(IQR), p-values using Wilcoxon sign rank test

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Missing data coded as none while not applicable were coded as having no results

10-item sleep scores was derived where 0 was given for 'Not during the past month' response, 100 is indicative of response of 3 or more times a week for all 10 items

		Baseline	Week 4	Week 12	Week 24	p-value Using Friedman' s test
Total 10 items sleep score <i>Max possible=100 (severe)</i> <i>Min possible=0 (not during the past month)</i>	Median(IQR)	40(33 to 48) Range: 3 to 65	35(29 to 44) Range: 23 to 68	35(28 to 45) Range: 25 to 63	38(23 to 43) Range: 0 to 65	0.057
% improvement in total 10 items sleep score from Baseline <i>(-ve values indicate deterioration)</i>	Median change(IQR)		3(-3 to 10) Range: -20 to 23 P=0.204 <i>Using Wilcoxon signed rank test</i>	3(-3 to 8) Range: -20 to 23 P=0.013 <i>Using Wilcoxon signed rank test</i>	3(-3 to 13) Range: -18 to 43 P=0.090 <i>Using Wilcoxon signed rank test</i>	
	During the past month, how often have you had trouble sleeping because you..... 1=Not during the past month 2=less than once a week 3=once or twice a week 4=three or more times a week					
Could not go to sleep within 30 minutes	-88=N/A -9=Missing 1=Not during the past month 2=less than once a week 3=once or twice a week 4=three or more times a week	0(0.0) 1(2.4) 17(41.5) 15(36.6) 4(9.8) 4(9.8)	0(0.0) 0(0.0) 19(47.5) 13(32.5) 7(17.5) 1(2.5)	0(0.0) 1(2.6) 22(56.4) 8(20.5) 6(15.4) 2(5.1)	0(0.0) 1(2.6) 16(41.0) 16(41.0) 5(12.8) 1(2.6)	
Woke up in the middle of the night or early in the morning	-88=N/A -9=Missing 1=Not during the past month 2=less than once a week 3=once or twice a week 4=three or more times a week	0(0.0) 1(2.4) 7(17.1) 11(26.8) 14(34.2) 8(19.5)	0(0.0) 0(0.0) 8(20.0) 10(25.0) 11(27.5) 11(27.5)	0(0.0) 2(5.1) 14(35.9) 7(18.0) 5(12.8) 11(28.2)	0(0.0) 1(2.6) 6(15.4) 13(33.3) 13(33.3) 6(15.4)	

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		Baseline	Week 4	Week 12	Week 24	p-value Using Friedman' s test
Had to get up to use the bathroom	-88=N/A	0(0.0)	0(0.0)	0(0.0)	0(0.0)	
	-9=Missing	0(0.0)	0(0.0)	0(0.0)	2(0.0)	
	1=Not during the past month	12(29.3)	13(32.5)	12(30.8)	12(30.8)	
	2=less than once a week	9(22.0)	10(25.0)	10(25.6)	9(23.1)	
	3=once or twice a week	9(22.0)	9(22.5)	7(18.0)	8(20.5)	
4=three or more times a week	11(26.8)	8(20.0)	10(25.6)	8(20.5)		
Could not breathe comfortably	-88=N/A	0(0.0)	0(0.0)	0(0.0)	0(0.0)	
	-9=Missing	1(2.4)	1(2.5)	0(0.0)	1(2.6)	
	1=Not during the past month	36(87.8)	36(90.0)	34(87.2)	35(89.7)	
	2=less than once a week	2(4.9)	3(7.5)	2(5.1)	3(7.7)	
	3=once or twice a week	2(4.9)	0(0.0)	1(2.6)	0(0.0)	
4=three or more times a week	0(0.0)	0(0.0)	2(5.1)	0(0.0)		
Coughed and snored	-88=N/A	0(0.0)	0(0.0)	0(0.0)	0(0.0)	
	-9=Missing	1(2.4)	1(2.5)	0(0.0)	1(2.6)	
	1=Not during the past month	30(73.2)	30(75.0)	30(76.9)	28(71.8)	
	2=less than once a week	3(7.3)	2(5.0)	4(10.3)	5(12.8)	
	3=once or twice a week	3(7.3)	5(12.5)	2(5.1)	2(5.1)	
4=three or more times a week	4(9.8)	2(5.0)	3(7.7)	3(7.7)		
Felt too cold	-88=N/A	0(0.0)	0(0.0)	0(0.0)	0(0.0)	
	-9=Missing	1(2.4)	1(2.5)	1(2.6)	1(2.6)	
	1=Not during the past month	35(85.4)	32(80.0)	35(89.7)	34(87.2)	
	2=less than once a week	4(9.8)	5(12.5)	2(5.1)	2(5.1)	
	3=once or twice a week	1(2.4)	2(5.0)	0(0.0)	1(2.6)	
4=three or more times a week	0(0.0)	0(0.0)	1(2.6)	1(2.6)		
Felt too hot	-88=N/A	0(0.0)	0(0.0)	0(0.0)	0(0.0)	
	-9=Missing	1(2.5)	0(0.0)	0(0.0)	1(2.6)	
	1=Not during the past month	21(30.0)	26(65.0)	24(61.5)	20(51.3)	
	2=less than once a week	11(22.5)	9(22.5)	8(20.5)	10(25.6)	
	3=once or twice a week	5(32.5)	4(10.0)	6(15.4)	6(15.4)	
4=three or more times a week	3(12.5)	1(2.5)	1(2.6)	2(5.1)		
Had bad dreams	-88=N/A	0(0.0)	0(0.0)	0(0.0)	0(0.0)	
	-9=Missing	1(2.4)	1(2.6)	0(0.0)	1(2.6)	
	1=Not during the past month	26(63.4)	29(74.4)	33(84.6)	30(76.9)	
	2=less than once a week	6(14.6)	6(15.4)	5(12.8)	6(15.4)	
	3=once or twice a week	6(14.6)	4(10.0)	1(2.6)	1(2.6)	
4=three or more times a week	2(4.9)	0(0.0)	0(0.0)	1(2.6)		

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		Baseline	Week 4	Week 12	Week 24	p-value Using Friedman' s test
Had pain	-88=N/A -9=Missing 1=Not during the past month 2=less than once a week 3=once or twice a week 4=three or more times a week	0(0.0) 1(2.4) 34(82.9) 2(4.9) 2(4.9) 2(4.9)	0(0.0) 1(2.5) 31(77.5) 3(7.5) 4(10.0) 1(2.5)	0(0.0) 0(0.0) 35(89.7) 2(5.1) 2(5.1) 0(0.0)	0(0.0) 1(2.6) 34(87.2) 3(7.7) 0(0.0) 1(2.6)	
Other reasons	-88=N/A -9=Missing 1=Not during the past month 2=less than once a week 3=once or twice a week 4=three or more times a week	0(0.0) 16(40.0) 24(58.5) 0(0.0) 0(0.0) 1(2.4)	0(0.0) 23(57.5) 16(40.0) 0(0.0) 0(0.0) 1(2.5)	0(0.0) 15(38.5) 21(53.9) 0(0.0) 1(2.6) 2(5.1)	0(0.0) 24(61.5) 14(35.9) 0(0.0) 0(0.0) 1(2.6)	
Overall total of 4, 5 & 10 items sleep score <i>Max possible=100 (severe)</i> <i>Min possible=0 (none)</i>	Median(IQR) <i>These figures are affected by individual grouped items with either low or high scores so need to be interpreted with caution</i>	22(20 to 32) Range: 4 to 50	20(14 to 29) Range: 8 to 58	19(14 to 27) Range: 8 to 46	20(14 to 26) Range: 8 to 66	0.030
% improvement in Overall total of 4, 5 & 10 items sleep score from Baseline <i>(-ve values indicate deterioration)</i>	Median change(IQR) <i>These figures are affected by individual grouped items with either low or high scores so need to be interpreted with caution</i>		2(-1 to 8) Range: -20 to 29 P=0.008 <i>Using Wilcoxon signed rank test</i>	4(-1 to 10) Range: -16 to 21 P=0.004 <i>Using Wilcoxon signed rank test</i>	3(-2 to 10) Range: -16 to 26 P=0.009 <i>Using Wilcoxon signed rank test</i>	

Median(IQR)