

Table 14.2.8.1 Summary of Leiter Scale (Total Equivalence Age VR) - by timepoint - FAS

Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	Change from baseline	t-Test results		
					t-value (df)	p-value	95% CI
Total Equivalence Age VR (Years)							
Baseline							
n	33						
Mean (SD)	5.879(1.565)						
Median	5.833						
Min; Max	3.00; 8.67						
Month 6							
n	24	24	24	Absolute change	1.031 (23)	0.313	(-.122,0.365)
Mean (SD)	5.840(1.380)	0.122(0.577)	3.447(10.28)				
Median	5.833	0.208	4.002	% Change	1.643 (23)	0.114	(-.894,7.787)
Min; Max	3.08; 8.25	-1.33; 1.33	-15.4;26.67				
Month 12							
n	31	31	31	Absolute change	2.484 (30)	0.019	(0.057,0.583)
Mean (SD)	6.296(1.541)	0.320(0.717)	6.695(12.17)				
Median	6.083	0.333	5.208	% Change	3.063 (30)	0.005	(2.232,11.16)
Min; Max	3.58; 9.58	-1.00; 1.92	-15.2;30.00				
Month 18							
n	11	11	11	Absolute change	1.884 (10)	0.089	(-.061,0.728)
Mean (SD)	5.788(1.574)	0.333(0.587)	6.251(10.75)				
Median	5.750	0.333	9.302	% Change	1.928 (10)	0.083	(-.973,13.47)
Min; Max	3.58; 8.67	-0.83; 1.33	-16.1;20.00				
Month 24							
n	10	10	10	Absolute change	2.238 (9)	0.052	(-.003,0.620)
Mean (SD)	6.292(1.317)	0.308(0.436)	6.724(8.951)				
Median	6.208	0.458	7.777	% Change	2.375 (9)	0.042	(0.321,13.13)
Min; Max	4.00; 8.42	-0.50; 0.83	-7.59;20.00				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data.

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Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	t-Test results			
				Change from baseline	t-value (df)	p-value	95% CI
Total Equivalence Age VR (Years)							
Month 36							
n	7	7	7	Absolute change	2.567 (6)	0.043	(0.016,0.651)
Mean (SD)	5.131(1.584)	0.333(0.344)	9.037(10.77)				
Median	5.417	0.167	5.000	% Change	2.221 (6)	0.068	(-.921,19.00)
Min; Max	3.50; 8.00	-0.08; 0.92	-1.39;30.56				
Month 48							
n	9	9	9	Absolute change	0.967 (8)	0.362	(-.282,0.690)
Mean (SD)	5.898(1.437)	0.204(0.632)	4.140(11.24)				
Median	5.583	0.000	0.000	% Change	1.105 (8)	0.301	(-4.50,12.78)
Min; Max	3.58; 8.25	-0.50; 1.58	-8.96;23.75				
Last Observation							
n	33	33	33	Absolute change	2.393 (32)	0.023	(0.039,0.491)
Mean (SD)	6.144(1.612)	0.265(0.637)	5.338(10.45)				
Median	5.917	0.333	5.208	% Change	2.935 (32)	0.006	(1.633,9.043)
Min; Max	3.50; 9.58	-1.00; 1.92	-16.1;25.00				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data.