Secondary efficacy outcome 4: Change in BMI SDS

Table 6.6-16: Change in BMI SDS – Completeness of data (ITT)

Time-point	BMI	CSII	MDI	Total
BMI (0m)	N	144	149	293
	Measured	124 (86.1%)	132 (88.6%)	256 (87.4%)
	Missing data	20 (13.9%)	17 (11.4%)	37 (12.6%)
BMI (12m)	N	144	149	293
	Measured	142 (98.6%)	138 (92.6%)	280 (95.6%)
	Missing data	1 (0.7%)	6 (4%)	7 (2.4%)
	WD from study prior to 12 months	1 (0.7%)	5 (3.4%)	6 (2%)
BMI (at both 0m and 12m)	N	144	149	293
	Measured	122 (84.7%)	122 (81.9%)	244 (83.3%)
	Missing data	21 (14.6%)	22 (14.8%)	43 (14.7%)
	WD from study prior to 12 months	1 (0.7%)	5 (3.4%)	6 (2%)

Table 6.6-17: Change in BMI SDS – Results (ITT)

Time-point	BMI	CSII	MDI	Total	Mean Difference (95% CI)	P-value
BMI (0m)	N	124	132	256	0.1 (0, 0.3)*	0.13*
	Mean (SD)	0.2 (1.3)	0.1 (1.3)	0.1 (1.3)		
	Median (IQR)	0.2 (-0.7, 0.9)	0.1 (-0.8, 1)	0.2 (-0.8, 1)		
	(Min, Max)	(-2.9, 4.2)	(-4, 3.5)	(-4, 4.2)		
BMI (12m)	N	142	138	280		
	Mean (SD)	0.8 (1.1)	0.7 (1)	0.7 (1.1)		
	Median (IQR)	0.8 (0.1, 1.5)	0.6 (0, 1.4)	0.6 (0, 1.4)		
	(Min, Max)	(-1.8, 4.1)	(-2.7, 3)	(-2.7, 4.1)		
BMI (12m - 0m)	N	122	122	244		
	Mean (SD)	0.6 (0.8)	0.5 (0.8)	0.5 (0.8)		
	Median (IQR)	0.5 (0.1, 1)	0.4 (-0.1, 0.9)	0.5 (0, 0.9)		
	(Min, Max)	(-1.4, 3.4)	(-1.1, 5.3)	(-1.4, 5.3)		

* Primary analysis used (12m BMI SDS – baseline BMI SDS) as the outcome variable with baseline BMI SDS, age strata, treatment and centre (random effect) as covariates. A secondary analysis uses 12m BMI SDS as the outcome with the same covariates. Both analyses give the same treatment difference, 95% confidence interval and p-value.