

Secondary efficacy outcome 7: Paediatric Quality of Life (PedsQL)

Table 6.6-22: Paediatric Quality of Life (PedsQL) – Completeness of data (ITT)

Note: 1 CSII patient that DNA 6-month visit provided a completed child PedsQL questionnaire; The parents/carers of 1 CSII patient and 1 MDI patient that DNA their 6-month visit provided a completed parent/carer PedsQL questionnaire

	6 months			12 months		
	CSII	MDI	Total	CSII	MDI	Total
Child (Diabetes)						
N	144	149	293	144	149	293
Included	100 (69.4%)	108 (72.5%)	208 (71%)	108 (75%)	107 (71.8%)	215 (73.4%)
DNA 6 months	7 (4.9%)	7 (4.7%)	14 (4.8%)	0 (0%)	0 (0%)	0 (0%)
No questionnaire completed	6 (4.2%)	6 (4%)	12 (4.1%)	7 (4.9%)	8 (5.4%)	15 (5.1%)
Only 5/11 questions answered	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	0 (0%)	1 (0.3%)
Questionnaire section not completed	1 (0.7%)	1 (0.7%)	2 (0.7%)	1 (0.7%)	3 (2%)	4 (1.4%)
Too young for questionnaire	30 (20.8%)	27 (18.1%)	57 (19.5%)	26 (18.1%)	26 (17.4%)	52 (17.7%)
WD from study prior to 12 months	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	5 (3.4%)	6 (2%)
Child (Treatment I)						
N	144	149	293	144	149	293
Included	100 (69.4%)	107 (71.8%)	207 (70.6%)	109 (75.7%)	107 (71.8%)	216 (73.7%)
DNA 6 months	7 (4.9%)	7 (4.7%)	14 (4.8%)	0 (0%)	0 (0%)	0 (0%)
No questionnaire completed	6 (4.2%)	6 (4%)	12 (4.1%)	7 (4.9%)	8 (5.4%)	15 (5.1%)
Questionnaire section not completed	1 (0.7%)	2 (1.3%)	3 (1%)	1 (0.7%)	3 (2%)	4 (1.4%)
Too young for questionnaire	30 (20.8%)	27 (18.1%)	57 (19.5%)	26 (18.1%)	26 (17.4%)	52 (17.7%)
WD from study prior to 12 months	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	5 (3.4%)	6 (2%)
Child (Treatment II)						
N	144	149	293	144	149	293
Included	100 (69.4%)	107 (71.8%)	207 (70.6%)	108 (75%)	107 (71.8%)	215 (73.4%)
DNA 6 months	7 (4.9%)	7 (4.7%)	14 (4.8%)	0 (0%)	0 (0%)	0 (0%)
No questionnaire completed	6 (4.2%)	6 (4%)	12 (4.1%)	7 (4.9%)	8 (5.4%)	15 (5.1%)

	6 months			12 months		
	CSII	MDI	Total	CSII	MDI	Total
Only 3/7 questions answered	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	0 (0%)	1 (0.3%)
Questionnaire section not completed	1 (0.7%)	2 (1.3%)	3 (1%)	1 (0.7%)	3 (2%)	4 (1.4%)
Too young for questionnaire	30 (20.8%)	27 (18.1%)	57 (19.5%)	26 (18.1%)	26 (17.4%)	52 (17.7%)
WD from study prior to 12 months	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	5 (3.4%)	6 (2%)
Child (Worry)						
N	144	149	293	144	149	293
Included	99 (68.8%)	106 (71.1%)	205 (70%)	109 (75.7%)	105 (70.5%)	214 (73%)
DNA 6 months	7 (4.9%)	7 (4.7%)	14 (4.8%)	0 (0%)	0 (0%)	0 (0%)
No questionnaire completed	6 (4.2%)	6 (4%)	12 (4.1%)	7 (4.9%)	8 (5.4%)	15 (5.1%)
Only 1/3 questions answered	1 (0.7%)	1 (0.7%)	2 (0.7%)	0 (0%)	0 (0%)	0 (0%)
Questionnaire section not completed	1 (0.7%)	2 (1.3%)	3 (1%)	1 (0.7%)	5 (3.4%)	6 (2%)
Too young for questionnaire	30 (20.8%)	27 (18.1%)	57 (19.5%)	26 (18.1%)	26 (17.4%)	52 (17.7%)
WD from study prior to 12 months	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	5 (3.4%)	6 (2%)
Child (Communication)						
N	144	149	293	144	149	293
Included	98 (68.1%)	106 (71.1%)	204 (69.6%)	106 (73.6%)	105 (70.5%)	211 (72%)
DNA 6 months	7 (4.9%)	7 (4.7%)	14 (4.8%)	0 (0%)	0 (0%)	0 (0%)
No questionnaire completed	6 (4.2%)	6 (4%)	12 (4.1%)	7 (4.9%)	8 (5.4%)	15 (5.1%)
Only 1/3 questions answered	1 (0.7%)	0 (0%)	1 (0.3%)	0 (0%)	0 (0%)	0 (0%)
Questionnaire section not completed	2 (1.4%)	3 (2%)	5 (1.7%)	4 (2.8%)	5 (3.4%)	9 (3.1%)
Too young for questionnaire	30 (20.8%)	27 (18.1%)	57 (19.5%)	26 (18.1%)	26 (17.4%)	52 (17.7%)
WD from study prior to 12 months	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	5 (3.4%)	6 (2%)
Child (Overall)						
N	144	149	293	144	149	293
Included	98 (68.1%)	104 (69.8%)	202 (68.9%)	104 (72.2%)	104 (69.8%)	208 (71%)

	6 months			12 months		
	CSII	MDI	Total	CSII	MDI	Total
1/5 incomplete sections	1 (0.7%)	3 (2%)	4 (1.4%)	5 (3.5%)	2 (1.3%)	7 (2.4%)
2/5 incomplete sections	1 (0.7%)	0 (0%)	1 (0.3%)	0 (0%)	1 (0.7%)	1 (0.3%)
3/5 incomplete sections	0 (0%)	1 (0.7%)	1 (0.3%)	0 (0%)	0 (0%)	0 (0%)
DNA 6 months	7 (4.9%)	7 (4.7%)	14 (4.8%)	0 (0%)	0 (0%)	0 (0%)
No questionnaire completed	6 (4.2%)	6 (4%)	12 (4.1%)	7 (4.9%)	8 (5.4%)	15 (5.1%)
Questionnaire section not completed	1 (0.7%)	1 (0.7%)	2 (0.7%)	1 (0.7%)	3 (2%)	4 (1.4%)
Too young for questionnaire	30 (20.8%)	27 (18.1%)	57 (19.5%)	26 (18.1%)	26 (17.4%)	52 (17.7%)
WD from study prior to 12 months	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	5 (3.4%)	6 (2%)
Parent (Diabetes)						
N	144	149	293	144	149	293
Included	127 (88.2%)	128 (85.9%)	255 (87%)	132 (91.7%)	125 (83.9%)	257 (87.7%)
DNA 6 months	7 (4.9%)	6 (4%)	13 (4.4%)	0 (0%)	0 (0%)	0 (0%)
No questionnaire completed	10 (6.9%)	14 (9.4%)	24 (8.2%)	11 (7.6%)	17 (11.4%)	28 (9.6%)
Questionnaire section not completed	0 (0%)	1 (0.7%)	1 (0.3%)	0 (0%)	2 (1.3%)	2 (0.7%)
WD from study prior to 12 months	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	5 (3.4%)	6 (2%)
Parent (Treatment I)						
N	144	149	293	144	149	293
Included	127 (88.2%)	127 (85.2%)	254 (86.7%)	131 (91%)	125 (83.9%)	256 (87.4%)
DNA 6 months	7 (4.9%)	6 (4%)	13 (4.4%)	0 (0%)	0 (0%)	0 (0%)
No questionnaire completed	10 (6.9%)	14 (9.4%)	24 (8.2%)	11 (7.6%)	17 (11.4%)	28 (9.6%)
Only 1/4 questions answered	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	0 (0%)	1 (0.3%)
Questionnaire section not completed	0 (0%)	2 (1.3%)	2 (0.7%)	0 (0%)	2 (1.3%)	2 (0.7%)
WD from study prior to 12 months	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	5 (3.4%)	6 (2%)
Parent (Treatment II)						
N	144	149	293	144	149	293

	6 months			12 months		
	CSII	MDI	Total	CSII	MDI	Total
Included	126 (87.5%)	128 (85.9%)	254 (86.7%)	131 (91%)	125 (83.9%)	256 (87.4%)
DNA 6 months	7 (4.9%)	6 (4%)	13 (4.4%)	0 (0%)	0 (0%)	0 (0%)
No questionnaire completed	10 (6.9%)	14 (9.4%)	24 (8.2%)	11 (7.6%)	17 (11.4%)	28 (9.6%)
Only 3/7 questions answered	1 (0.7%)	0 (0%)	1 (0.3%)	1 (0.7%)	0 (0%)	1 (0.3%)
Questionnaire section not completed	0 (0%)	1 (0.7%)	1 (0.3%)	0 (0%)	2 (1.3%)	2 (0.7%)
WD from study prior to 12 months	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	5 (3.4%)	6 (2%)
Parent (Worry)						
N	144	149	293	144	149	293
Included	127 (88.2%)	128 (85.9%)	255 (87%)	131 (91%)	125 (83.9%)	256 (87.4%)
DNA 6 months	7 (4.9%)	6 (4%)	13 (4.4%)	0 (0%)	0 (0%)	0 (0%)
No questionnaire completed	10 (6.9%)	14 (9.4%)	24 (8.2%)	11 (7.6%)	17 (11.4%)	28 (9.6%)
Only 1/3 questions answered	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	0 (0%)	1 (0.3%)
Questionnaire section not completed	0 (0%)	1 (0.7%)	1 (0.3%)	0 (0%)	2 (1.3%)	2 (0.7%)
WD from study prior to 12 months	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	5 (3.4%)	6 (2%)
Parent (Communication)						
N	144	149	293	144	149	293
Included	124 (86.1%)	127 (85.2%)	251 (85.7%)	130 (90.3%)	123 (82.6%)	253 (86.3%)
DNA 6 months	7 (4.9%)	6 (4%)	13 (4.4%)	0 (0%)	0 (0%)	0 (0%)
No questionnaire completed	10 (6.9%)	14 (9.4%)	24 (8.2%)	11 (7.6%)	17 (11.4%)	28 (9.6%)
Questionnaire section not completed	3 (2.1%)	2 (1.3%)	5 (1.7%)	2 (1.4%)	4 (2.7%)	6 (2%)
WD from study prior to 12 months	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	5 (3.4%)	6 (2%)
Parent (Overall)						
N	144	149	293	144	149	293
Included	124 (86.1%)	125 (83.9%)	249 (85%)	128 (88.9%)	123 (82.6%)	251 (85.7%)
1/5 incomplete sections	2 (1.4%)	3 (2%)	5 (1.7%)	3 (2.1%)	2 (1.3%)	5 (1.7%)

	6 months			12 months		
	CSII	MDI	Total	CSII	MDI	Total
2/5 incomplete sections	1 (0.7%)	0 (0%)	1 (0.3%)	1 (0.7%)	0 (0%)	1 (0.3%)
4/5 incomplete sections	0 (0%)	1 (0.7%)	1 (0.3%)	0 (0%)	0 (0%)	0 (0%)
DNA 6 months	7 (4.9%)	6 (4%)	13 (4.4%)	0 (0%)	0 (0%)	0 (0%)
No questionnaire completed	10 (6.9%)	14 (9.4%)	24 (8.2%)	11 (7.6%)	17 (11.4%)	28 (9.6%)
Questionnaire section not completed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (1.3%)	2 (0.7%)
WD from study prior to 12 months	0 (0%)	0 (0%)	0 (0%)	1 (0.7%)	5 (3.4%)	6 (2%)

Table 6.6-23: Paediatric Quality of Life (PedsQL) – Results summary at 6m and 12m (ITT)

Questionnaire age-group Summary		6 months			12 months		
		CSII	MDI	Total	CSII	MDI	Total
Children 5-7 years old (6 & 12 month follow-up)	Child (Diabetes)						
	N	12	22	34	14	19	33
	Mean (SD)	56.8 (13.4)	61 (10.4)	59.5 (11.5)	66.7 (16.9)	59.6 (16)	62.6 (16.5)
	Median (IQR) (Min, Max)	54.5 (50, 63.6) (31.8, 81.8)	59.1 (50, 72.7) (40.9, 77.3)	56.8 (50, 68.2) (31.8, 81.8)	68.2 (63.6, 79.3) (27.3, 90.9)	63.6 (50, 72.7) (22.7, 77.3)	63.6 (54.5, 72.7) (22.7, 90.9)
Children 8-12 years old (6 & 12 month follow-up)	Child (Diabetes)						
	N	59	55	114	57	55	112
	Mean (SD)	63 (16.9)	62.3 (15)	62.7 (15.9)	68.7 (15.8)	63.9 (16.1)	66.4 (16.1)
	Median (IQR) (Min, Max)	65.9 (49.6, 77.3) (25, 100)	63.6 (50, 74.4) (29.5, 100)	63.6 (50, 75) (25, 100)	70.5 (54.5, 79.5) (36.4, 100)	61.4 (50, 77.3) (37.2, 93.2)	65.9 (52.3, 79.5) (36.4, 100)
Children 13-16 years old (6 & 12 month follow-up)	Child (Diabetes)						
	N	29	31	60	37	33	70
	Mean (SD)	68.2 (16.4)	64.3 (15.3)	66.2 (15.8)	62.9 (16.8)	61.6 (17.3)	62.3 (16.9)
	Median (IQR) (Min, Max)	65.9 (56.8, 75) (40.9, 100)	61.4 (56.8, 72.7) (40.9, 100)	63.6 (56.8, 73.9) (40.9, 100)	61.4 (54.5, 71.9) (27.3, 100)	59.1 (52.3, 72.7) (29.5, 90.9)	61.1 (52.3, 72.7) (27.3, 100)

Questionnaire age-group Summary		6 months			12 months		
		CSII	MDI	Total	CSII	MDI	Total
Children 5-7 years old (6 & 12 month follow-up)	Child (Treatment I)						
	N	12	22	34	14	19	33
	Mean (SD)	77.3 (18.3)	79.8 (16.1)	79 (16.7)	81.3 (16.8)	75.7 (22.2)	78 (20)
	Median (IQR) (Min, Max)	76.6 (62.5, 93.8) (50, 100)	82.8 (75, 87.5) (37.5, 100)	78.1 (75, 87.5) (37.5, 100)	75 (75, 100) (50, 100)	75 (62.5, 87.5) (12.5, 100)	75 (62.5, 100) (12.5, 100)
Children 8-12 years old (6 & 12 month follow-up)	Child (Treatment I)						
	N	59	54	113	57	55	112
	Mean (SD)	79.3 (17.9)	74.7 (19.6)	77.1 (18.8)	83.7 (15.5)	77.2 (20.5)	80.5 (18.3)
	Median (IQR) (Min, Max)	87.5 (68.8, 93.8) (31.3, 100)	75 (68.8, 87.5) (12.5, 100)	81.3 (68.8, 93.8) (12.5, 100)	87.5 (75, 93.8) (25, 100)	81.3 (62.5, 93.8) (18.8, 100)	81.3 (75, 93.8) (18.8, 100)
Children 13-16 years old (6 & 12 month follow-up)	Child (Treatment I)						
	N	29	31	60	38	33	71
	Mean (SD)	79.7 (21.2)	79.5 (14.2)	79.6 (17.8)	76.6 (21.2)	74.8 (15.3)	75.8 (18.6)
	Median (IQR) (Min, Max)	87.5 (75, 93.8) (6.3, 100)	81.3 (75, 87.5) (43.8, 100)	81.3 (75, 93.8) (6.3, 100)	81.3 (68.8, 93.8) (25, 100)	75 (62.5, 87.5) (31.3, 100)	75 (68.8, 87.5) (25, 100)
Children 5-7 years old (6 & 12 month follow-up)	Child (Treatment II)						
	N	12	22	34	13	19	32
	Mean (SD)	80.1 (19.3)	83.2 (12.9)	82.1 (15.3)	82.3 (18.1)	79.9 (15.3)	80.9 (16.3)
	Median (IQR) (Min, Max)	85.7 (67.9, 95.4) (42.9, 100)	83.7 (73.5, 92.9) (57.1, 100)	85.7 (71.4, 92.9) (42.9, 100)	85.7 (73.5, 100) (35.7, 100)	78.6 (71.4, 92.9) (55.1, 100)	80.1 (72.4, 95.4) (35.7, 100)
Children 8-12 years old (6 & 12 month follow-up)	Child (Treatment II)						
	N	59	54	113	57	55	112
	Mean (SD)	87.9 (11.9)	83.7 (14.5)	85.9 (13.3)	89.6 (11.6)	84.8 (17.6)	87.2 (15)
	Median (IQR) (Min, Max)	92.9 (82.1, 96.4) (45.9, 100)	85.7 (77.6, 96.4) (39.3, 100)	89.3 (78.6, 96.4) (39.3, 100)	92.9 (82.1, 100) (53.1, 100)	92.9 (75, 100) (16.3, 100)	92.9 (82.1, 100) (16.3, 100)
Children 13-16 years old (6 & 12 month follow-up)	Child (Treatment II)						
	N	29	31	60	38	33	71

Questionnaire age-group Summary		6 months			12 months		
		CSII	MDI	Total	CSII	MDI	Total
12 month follow-up)	Mean (SD) Median (IQR) (Min, Max)	90.1 (13.8) 96.4 (87.2, 100) (50, 100)	87.2 (10.7) 85.7 (82.1, 96.4) (60.7, 100)	88.6 (12.3) 92.9 (82.1, 98) (50, 100)	84 (16.7) 91.3 (75, 96.4) (42.9, 100)	85.3 (12.4) 85.7 (78.6, 96.4) (50, 100)	84.6 (14.8) 89.3 (75, 96.4) (42.9, 100)
Children 5-7 years old (6 & 12 month follow-up)	Child (Worry) N Mean (SD) Median (IQR) (Min, Max)	11 74.2 (26.2) 66.7 (66.7, 100) (16.7, 100)	21 77.8 (24.9) 83.3 (66.7, 100) (16.7, 100)	32 76.6 (25) 83.3 (66.7, 100) (16.7, 100)	14 77.4 (31.1) 100 (50, 100) (16.7, 100)	19 68.4 (28.8) 66.7 (50, 100) (0, 100)	33 72.2 (29.7) 83.3 (50, 100) (0, 100)
Children 8-12 years old (6 & 12 month follow-up)	Child (Worry) N Mean (SD) Median (IQR) (Min, Max)	59 81.2 (16.8) 83.3 (75, 91.7) (33.3, 100)	54 75.8 (20.7) 79.2 (58.3, 91.7) (25, 100)	113 78.6 (18.9) 83.3 (66.7, 91.7) (25, 100)	57 82.5 (17.7) 83.3 (75, 100) (16.7, 100)	53 78 (23.4) 83.3 (66.7, 100) (8.3, 100)	110 80.3 (20.6) 83.3 (66.7, 100) (8.3, 100)
Children 13-16 years old (6 & 12 month follow-up)	Child (Worry) N Mean (SD) Median (IQR) (Min, Max)	29 80.5 (22.1) 83.3 (66.7, 100) (25, 100)	31 77.2 (17.9) 83.3 (66.7, 91.7) (33.3, 100)	60 78.8 (19.9) 83.3 (66.7, 91.7) (25, 100)	38 73 (23.2) 75 (50, 100) (33.3, 100)	33 74.5 (23.3) 75 (58.3, 100) (25, 100)	71 73.7 (23.1) 75 (50, 100) (25, 100)
Children 5-7 years old (6 & 12 month follow-up)	Child (Communication) N Mean (SD) Median (IQR) (Min, Max)	11 56.1 (38.2) 50 (16.7, 100) (0, 100)	22 77.3 (23.9) 83.3 (66.7, 100) (33.3, 100)	33 70.2 (30.5) 66.7 (50, 100) (0, 100)	14 57.1 (33.1) 58.3 (33.3, 83.3) (0, 100)	18 80.6 (25.7) 83.3 (66.7, 100) (0, 100)	32 70.3 (31) 75 (50, 100) (0, 100)
Children 8-12 years old (6 & 12 month follow-up)	Child (Communication) N Mean (SD)	58 82.2 (18.3)	55 72 (25.3)	113 77.2 (22.5)	54 79.7 (23.7)	54 75.6 (26.6)	108 77.6 (25.2)

Questionnaire Summary age-group		6 months			12 months		
		CSII	MDI	Total	CSII	MDI	Total
Children 13-16 years old (6 & 12 month follow-up)	Median (IQR) (Min, Max)	83.3 (75, 100) (16.7, 100)	75 (58.3, 91.7) (0, 100)	83.3 (66.7, 100) (0, 100)	91.7 (66.7, 100) (8.3, 100)	83.3 (58.3, 100) (0, 100)	83.3 (58.3, 100) (0, 100)
	Child (Communication) N	29	29	58	38	33	71
	Mean (SD)	86.2 (15.5)	81.6 (19.7)	83.9 (17.7)	81.6 (18.1)	76.8 (26.4)	79.3 (22.3)
	Median (IQR) (Min, Max)	91.7 (75, 100) (50, 100)	83.3 (75, 100) (16.7, 100)	87.5 (75, 100) (16.7, 100)	83.3 (66.7, 100) (33.3, 100)	83.3 (66.7, 100) (0, 100)	83.3 (66.7, 100) (0, 100)
Children 5-7 years old (6 & 12 month follow-up)	Child (Overall) N	11	21	32	13	18	31
	Mean (SD)	67.3 (15.4)	73 (9)	71 (11.7)	72.6 (15.5)	70 (15.2)	71.1 (15.1)
	Median (IQR) (Min, Max)	75 (51.5, 80.4) (41.1, 83.4)	70.9 (67.9, 80.4) (55.4, 87.5)	71.4 (67, 80.4) (41.1, 87.5)	78.6 (60.7, 85.7) (39.3, 89.3)	76.4 (60.7, 81.6) (30.4, 85.7)	76.8 (60.7, 82.1) (30.4, 89.3)
Children 8-12 years old (6 & 12 month follow-up)	Child (Overall) N	58	54	112	54	53	107
	Mean (SD)	75.9 (12.6)	71.8 (13.2)	73.9 (13)	79 (12)	74.4 (14.3)	76.7 (13.3)
	Median (IQR) (Min, Max)	79.1 (66.6, 84.8) (45.5, 94.1)	71.5 (64.3, 80.4) (40.2, 99.1)	75.9 (66.3, 83.6) (40.2, 99.1)	81.7 (70.7, 88.4) (44.6, 100)	76.8 (64.3, 85.7) (39.8, 96.4)	77.7 (70.5, 87.8) (39.8, 100)
Children 13-16 years old (6 & 12 month follow-up)	Child (Overall) N	29	29	58	37	33	70
	Mean (SD)	78.6 (13)	75.9 (11.6)	77.2 (12.3)	73.7 (13.8)	72.4 (14.4)	73.1 (14)
	Median (IQR) (Min, Max)	79.5 (71.4, 87.6) (43.8, 99.1)	75.9 (67, 82.1) (50, 98.2)	76.9 (69.6, 85.7) (43.8, 99.1)	75 (63.4, 84.8) (47.3, 95.5)	73.2 (60.7, 79.3) (35.7, 94.6)	74.7 (60.7, 84.8) (35.7, 95.5)
Parents / carers 2-4 years old (6 & 12 month follow-up)	Parent (Diabetes) N	25	18	43	22	18	40
	Mean (SD)	62 (16)	58.1 (11.1)	60.4 (14.1)	62.7 (17.1)	56.2 (16.2)	59.8 (16.8)
	Median (IQR)	62 (54.5, 65.9)	58.1 (47.7, 65.9)	61.4 (47.7, 65.9)	59.1 (47.7, 75)	56.8 (43.2, 68.2)	56.8 (46.6, 72.7)

Questionnaire age-group Summary		6 months			12 months		
		CSII	MDI	Total	CSII	MDI	Total
Parents / carers 5-7 years old (6 & 12 month follow-up)	(Min, Max)	(27.3, 97.7)	(38.6, 75)	(27.3, 97.7)	(33.1, 97.7)	(27.3, 81.8)	(27.3, 97.7)
	Parent (Diabetes)						
	N	14	23	37	17	18	35
	Mean (SD)	66.2 (12)	61.4 (13.9)	63.2 (13.2)	68.3 (15.4)	60.8 (15.7)	64.5 (15.8)
	Median (IQR)	65.9 (59.1, 77.3)	59.1 (50, 72.7)	61.4 (54.5, 72.7)	65.9 (56.8, 77.3)	61.4 (53.7, 72.7)	65.9 (53.7, 75)
Parents / carers 8-12 years old (6 & 12 month follow-up)	(Min, Max)	(43.2, 84.1)	(38.6, 90.9)	(38.6, 90.9)	(45.5, 95.5)	(13.6, 81.8)	(13.6, 95.5)
	Parent (Diabetes)						
	N	58	58	116	55	55	110
	Mean (SD)	62.9 (14.9)	62.7 (15.3)	62.8 (15)	66.2 (14.6)	60.8 (16.2)	63.5 (15.6)
	Median (IQR)	63.6 (52.3, 75)	61.4 (52.3, 72.7)	61.4 (52.3, 72.7)	65.9 (52.3, 75.2)	61.4 (47.7, 74.4)	63.6 (52.3, 75)
Parents / carers 13-16 years old (6 & 12 month follow-up)	(Min, Max)	(25, 93.2)	(36.4, 95.5)	(25, 95.5)	(43.2, 100)	(29.5, 97.7)	(29.5, 100)
	Parent (Diabetes)						
	N	30	29	59	38	34	72
	Mean (SD)	63.9 (17.4)	60.3 (18.1)	62.1 (17.7)	60.3 (17.7)	61.5 (14)	60.9 (15.9)
	Median (IQR)	58 (52.3, 81.8)	61.4 (50, 72.7)	59.1 (52.1, 75)	59.1 (47.7, 68.2)	61.4 (54.5, 70.5)	61.4 (50, 70.5)
Parents / carers 2-4 years old (6 & 12 month follow-up)	(Min, Max)	(36.4, 97.7)	(24.8, 100)	(24.8, 100)	(27.3, 100)	(22.7, 90.9)	(22.7, 100)
	Parent (Treatment I)						
	N	25	18	43	21	18	39
	Mean (SD)	79.8 (20.5)	69.8 (20.7)	75.6 (20.9)	80.7 (18.9)	73.6 (20.8)	77.4 (19.9)
	Median (IQR)	87.5 (62.5, 100)	68.8 (56.3, 93.8)	75 (56.3, 100)	87.5 (68.8, 93.8)	81.3 (68.8, 87.5)	81.3 (68.8, 87.5)
Parents / carers 5-7 years old (6 & 12 month follow-up)	(Min, Max)	(37.5, 100)	(31.3, 100)	(31.3, 100)	(31.3, 100)	(18.8, 100)	(18.8, 100)
	Parent (Treatment I)						
	N	14	23	37	17	18	35
	Mean (SD)	63.8 (28.4)	69.3 (19.2)	67.2 (22.9)	72.8 (21.5)	69.8 (21.1)	71.3 (21.1)
	Median (IQR)	62.5 (50, 87.5)	68.8 (56.3, 81.3)	68.8 (56.3, 81.3)	81.3 (56.3, 87.5)	71.9 (56.3, 87.5)	75 (56.3, 87.5)
	(Min, Max)	(0, 100)	(31.3, 100)	(0, 100)	(37.5, 100)	(25, 100)	(25, 100)

Questionnaire age-group Summary		6 months			12 months		
		CSII	MDI	Total	CSII	MDI	Total
Parents / carers 8-12 years old (6 & 12 month follow-up) Parents / carers 13-16 years old (6 & 12 month follow-up)	Parent (Treatment I)						
	N	58	57	115	55	55	110
	Mean (SD)	71.3 (20.3)	67.9 (20.8)	69.6 (20.5)	69.1 (18.7)	66.9 (19.6)	68 (19.1)
	Median (IQR)	75 (56.3, 87.5)	68.8 (56.3, 87.5)	68.8 (56.3, 87.5)	68.8 (56.3, 81.3)	62.5 (56.3, 81.3)	68.8 (56.3, 81.3)
	(Min, Max)	(25, 100)	(12.5, 100)	(12.5, 100)	(25, 100)	(25, 100)	(25, 100)
	Parent (Treatment I)						
	N	30	29	59	38	34	72
	Mean (SD)	65.2 (22.3)	61.3 (18.1)	63.3 (20.3)	67.3 (22.1)	62.3 (21.9)	64.9 (22)
Parents / carers 2-4 years old (6 & 12 month follow-up) Parents / carers 5-7 years old (6 & 12 month follow-up) Parents / carers 8-12 years old (6 & 12 month follow-up)	Median (IQR)	68.8 (43.8, 81.3)	62.5 (50, 75)	62.5 (50, 81.3)	68.8 (50, 81.3)	62.5 (43.8, 81.3)	68.8 (50, 81.3)
	(Min, Max)	(25, 100)	(31.3, 100)	(25, 100)	(25, 100)	(12.5, 100)	(12.5, 100)
	Parent (Treatment II)						
	N	25	18	43	22	18	40
	Mean (SD)	85.4 (13.6)	74.2 (16.6)	80.8 (15.7)	88.6 (10.9)	82.7 (14.8)	85.9 (13)
	Median (IQR)	91.8 (82.1, 96.4)	73.2 (61.2, 85.7)	82.1 (69.4, 96.4)	92.3 (85.7, 92.9)	87.8 (75, 93.9)	90.8 (80.4, 93.4)
	(Min, Max)	(49, 100)	(40.8, 100)	(40.8, 100)	(59.7, 100)	(45.9, 100)	(45.9, 100)
	Parent (Treatment II)						
	N	14	23	37	16	18	34
	Mean (SD)	84.2 (14.4)	82.8 (9.8)	83.3 (11.6)	84.8 (14.3)	77.6 (15.3)	81 (15.1)
	Median (IQR)	91.3 (75, 96.4)	82.1 (75, 92.9)	85.7 (75, 93.9)	85.7 (70.2, 100)	76.8 (64.3, 92.9)	82.1 (65.3, 96.4)
	(Min, Max)	(57.1, 98)	(64.3, 100)	(57.1, 100)	(64.3, 100)	(50, 98)	(50, 100)
	Parent (Treatment II)						
	N	58	58	116	55	55	110
	Mean (SD)	86.4 (12.7)	80.9 (15.3)	83.7 (14.3)	86.8 (13.5)	81.1 (16.6)	83.9 (15.3)
	Median (IQR)	87.2 (77.6, 98)	82.1 (71.4, 92.9)	85.7 (73.5, 96.4)	89.3 (81.6, 100)	85.7 (67.9, 92.9)	89.3 (75, 96.4)

Questionnaire age-group Summary		6 months			12 months		
		CSII	MDI	Total	CSII	MDI	Total
Parents / carers 13-16 years old (6 & 12 month follow-up)	(Min, Max)	(50, 100)	(39.3, 100)	(39.3, 100)	(44.9, 100)	(16.3, 100)	(16.3, 100)
	Parent (Treatment II)						
	N	29	29	58	38	34	72
	Mean (SD)	84.6 (15.1)	79.4 (15)	82 (15.1)	80.7 (16.4)	77.7 (19.6)	79.3 (17.9)
	Median (IQR)	85.7 (77.6, 98)	82.1 (64.3, 92.9)	85.7 (73.5, 93.9)	81.9 (64.3, 96.4)	78.6 (67.9, 92.9)	81.6 (67.9, 96.4)
	(Min, Max)	(42.9, 100)	(55.1, 100)	(42.9, 100)	(39.3, 100)	(32.1, 100)	(32.1, 100)
Parents / carers 2-4 years old (6 & 12 month follow-up)	Parent (Worry)						
	N	25	18	43	21	18	39
	Mean (SD)	63 (29.5)	45.4 (28.6)	55.6 (30.1)	47.9 (28.1)	48.6 (31.9)	48.2 (29.5)
	Median (IQR)	58.3 (33.3, 91.7)	41.7 (25, 58.3)	50 (33.3, 83.3)	41.7 (33.3, 75)	54.2 (25, 66.7)	50 (25, 75)
Parents / carers 5-7 years old (6 & 12 month follow-up)	(Min, Max)	(8.3, 100)	(0, 100)	(0, 100)	(0, 100)	(0, 100)	(0, 100)
	Parent (Worry)						
	N	14	23	37	17	18	35
	Mean (SD)	61.3 (26.7)	75.4 (22)	70 (24.5)	61.3 (29.3)	67.1 (25.2)	64.3 (27)
Parents / carers 8-12 years old (6 & 12 month follow-up)	Median (IQR)	58.3 (33.3, 83.3)	83.3 (58.3, 91.7)	75 (50, 91.7)	66.7 (33.3, 83.3)	75 (50, 83.3)	75 (41.7, 83.3)
	(Min, Max)	(25, 100)	(25, 100)	(25, 100)	(16.7, 100)	(0, 100)	(0, 100)
	Parent (Worry)						
	N	58	58	116	55	55	110
Parents / carers 13-16 years old (6 & 12 month follow-up)	Mean (SD)	72.1 (20.1)	64.4 (21.3)	68.2 (21)	68.2 (24.3)	67.7 (25.3)	68 (24.7)
	Median (IQR)	75 (58.3, 83.3)	66.7 (50, 83.3)	66.7 (50, 83.3)	75 (50, 91.7)	66.7 (50, 91.7)	70.8 (50, 91.7)
	(Min, Max)	(25, 100)	(25, 100)	(25, 100)	(8.3, 100)	(0, 100)	(0, 100)
	Parent (Worry)						
Parents / carers 13-16 years old (6 & 12 month follow-up)	N	30	29	59	38	34	72
	Mean (SD)	69.2 (24.4)	65.2 (23.5)	67.2 (23.8)	71.9 (21)	66.9 (23.6)	69.6 (22.3)
	Median (IQR)	75 (50, 91.7)	66.7 (50, 83.3)	66.7 (50, 83.3)	75 (50, 83.3)	75 (50, 83.3)	75 (50, 83.3)
	(Min, Max)	(8.3, 100)	(16.7, 100)	(8.3, 100)	(33.3, 100)	(8.3, 100)	(8.3, 100)

Questionnaire age-group Summary		6 months			12 months		
		CSII	MDI	Total	CSII	MDI	Total
Parents / carers 2-4 years old (6 & 12 month follow-up)	Parent (Communication)						
	N	24	19	43	21	17	38
	Mean (SD)	83.7 (25.2)	74.1 (28.7)	79.5 (26.9)	81.3 (25.7)	70.6 (34)	76.5 (29.8)
	Median (IQR)	100 (75, 100)	75 (58.3, 100)	91.7 (66.7, 100)	91.7 (75, 100)	83.3 (50, 100)	91.7 (50, 100)
	(Min, Max)	(0, 100)	(0, 100)	(0, 100)	(25, 100)	(0, 100)	(0, 100)
Parents / carers 5-7 years old (6 & 12 month follow-up)	Parent (Communication)						
	N	13	23	36	17	17	34
	Mean (SD)	82.7 (22.4)	84.1 (22.5)	83.6 (22.1)	72.5 (32.1)	80.9 (18.8)	76.7 (26.3)
	Median (IQR)	100 (66.7, 100)	91.7 (75, 100)	95.8 (75, 100)	83.3 (50, 100)	83.3 (66.7, 100)	83.3 (66.7, 100)
	(Min, Max)	(41.7, 100)	(16.7, 100)	(16.7, 100)	(0, 100)	(41.7, 100)	(0, 100)
Parents / carers 8-12 years old (6 & 12 month follow-up)	Parent (Communication)						
	N	58	57	115	54	55	109
	Mean (SD)	78.7 (22.4)	75.7 (26.2)	77.2 (24.3)	80.1 (22.8)	67.2 (26.3)	73.6 (25.4)
	Median (IQR)	83.3 (66.7, 100)	83.3 (58.3, 100)	83.3 (58.3, 100)	87.5 (75, 100)	75 (50, 91.7)	75 (58.3, 100)
	(Min, Max)	(16.7, 100)	(0, 100)	(0, 100)	(0, 100)	(0, 100)	(0, 100)
Parents / carers 13-16 years old (6 & 12 month follow-up)	Parent (Communication)						
	N	29	28	57	38	34	72
	Mean (SD)	77 (28.9)	67.3 (24.1)	72.2 (26.9)	73.2 (26.1)	72.8 (30.7)	73 (28.2)
	Median (IQR)	83.3 (75, 100)	66.7 (50, 91.7)	83.3 (50, 100)	75 (50, 100)	79.2 (58.3, 100)	75 (58.3, 100)
	(Min, Max)	(0, 100)	(25, 100)	(0, 100)	(0, 100)	(0, 100)	(0, 100)
Parents / carers 2-4 years old (6 & 12 month follow-up)	Parent (Overall)						
	N	24	18	42	20	17	37
	Mean (SD)	72.5 (13)	64 (11.5)	68.9 (12.9)	73 (12.7)	67 (15.7)	70.2 (14.3)
	Median (IQR)	72.8 (62.9, 77.2)	61.8 (55.5, 74.1)	68.8 (57, 76.8)	75 (62.1, 82.1)	70.5 (54.7, 79.5)	73.2 (60.7, 80.4)
	(Min, Max)	(54.5, 98.6)	(46.7, 81.6)	(46.7, 98.6)	(52.4, 99.1)	(40.2, 90.2)	(40.2, 99.1)

Questionnaire age-group	Summary	6 months			12 months		
		CSII	MDI	Total	CSII	MDI	Total
Parents / carers 5-7 years old (6 & 12 month follow-up)	Parent (Overall)						
	N	13	23	36	16	17	33
	Mean (SD)	72.5 (12.8)	71.8 (8.6)	72 (10.1)	73.1 (15.8)	71 (9.3)	72 (12.7)
	Median (IQR) (Min, Max)	70.5 (63.5, 85.7) (51.8, 90.2)	69.6 (65.2, 80.4) (54.7, 84.4)	69.8 (65.1, 80.8) (51.8, 90.2)	75.6 (60.4, 86.6) (45.5, 94.6)	72.3 (64.7, 76) (49.1, 86.6)	73.2 (63.4, 81.3) (45.5, 94.6)
Parents / carers 8-12 years old (6 & 12 month follow-up)	Parent (Overall)						
	N	58	56	114	54	55	109
	Mean (SD)	72.7 (12.7)	69.9 (13)	71.3 (12.8)	73.9 (11.9)	68.2 (14.9)	71 (13.8)
	Median (IQR) (Min, Max)	73.2 (65.2, 84.2) (31.3, 94.6)	68.8 (63.4, 78.8) (34.8, 95.8)	70.5 (64.3, 81.5) (31.3, 95.8)	74.5 (65.9, 81.3) (39.5, 100)	67.9 (57.1, 77.7) (34.2, 99.1)	70.5 (61.6, 80.4) (34.2, 100)
Parents / carers 13-16 years old (6 & 12 month follow-up)	Parent (Overall)						
	N	29	28	57	38	34	72
	Mean (SD)	71.7 (15.4)	66.7 (16.1)	69.3 (15.8)	69 (14.5)	67.5 (15.7)	68.3 (15)
	Median (IQR) (Min, Max)	73.2 (59.8, 84.3) (42, 99.1)	67.6 (55.6, 74.9) (35.1, 98.2)	69.6 (58.9, 80.4) (35.1, 99.1)	67.3 (58, 80.7) (41.1, 96.4)	67.4 (59.8, 79.5) (19.6, 91.1)	67.3 (58.9, 80.1) (19.6, 96.4)

Table 6.6-24: Paediatric Quality of Life (PedsQL) – Modelling results at 6m and 12m (ITT)

Type	Least Squares Mean Difference between treatment groups (CSII-MDI) across all questionnaire age-groups	p-value
Child Self-Report	3.1 (-0.6, 6.8)	0.10
Parent/Carer Proxy*	4.1 (0.6, 7.6)	0.02

* The Estimated G matrix was not positive definite which indicates that the variance component in the RANDOM statement (site) are estimated to be zero so were removed from the model.

Table 6.6-25: Paediatric Quality of Life (PedsQL) – Mean profile plot inclusion status (ITT)

Note: Only Patients that completed the same questionnaire age-group at both 6m and 12m are included in the mean profile plots

	Mean profile plot inclusion status	6-month questionnaire status	12-month questionnaire status	CSII	MDI	Total
Child	Included	Children 13-16 years old	Children 13-16 years old	27 (18.8%)	25 (16.8%)	52 (17.7%)
		Children 5-7 years old	Children 5-7 years old	8 (5.6%)	14 (9.4%)	22 (7.5%)
		Children 8-12 years old	Children 8-12 years old	46 (31.9%)	45 (30.2%)	91 (31.1%)
	Excluded	1/5 incomplete sections	1/5 incomplete sections	1 (0.7%)	1 (0.7%)	2 (0.7%)
		1/5 incomplete sections	Included	0 (0%)	2 (1.3%)	2 (0.7%)
		2/5 incomplete sections	Included	1 (0.7%)	0 (0%)	1 (0.3%)
		3/5 incomplete sections	Included	0 (0%)	1 (0.7%)	1 (0.3%)
		DNA 6 months	1/5 incomplete sections	1 (0.7%)	0 (0%)	1 (0.3%)
		DNA 6 months	Included	6 (4.2%)	3 (2%)	9 (3.1%)
		DNA 6 months	No questionnaire completed	0 (0%)	2 (1.3%)	2 (0.7%)
		DNA 6 months	WD from study prior to 12 months	0 (0%)	2 (1.3%)	2 (0.7%)
		Included	1/5 incomplete sections	2 (1.4%)	1 (0.7%)	3 (1%)
		Included	2/5 incomplete sections	0 (0%)	1 (0.7%)	1 (0.3%)
		Included	No questionnaire completed	4 (2.8%)	5 (3.4%)	9 (3.1%)
		Included	Questionnaire section not completed	0 (0%)	3 (2%)	3 (1%)
		Included	WD from study prior to 12 months	0 (0%)	3 (2%)	3 (1%)
		No questionnaire completed	Included	3 (2.1%)	5 (3.4%)	8 (2.7%)
		No questionnaire completed	No questionnaire completed	1 (0.7%)	1 (0.7%)	2 (0.7%)
		No questionnaire completed	Questionnaire section not completed	1 (0.7%)	0 (0%)	1 (0.3%)
		No questionnaire completed	WD from study prior to 12 months	1 (0.7%)	0 (0%)	1 (0.3%)
		Questionnaire completed but different age questionnaires at 6m and at 12m	Questionnaire completed but different age questionnaires at 6m and at 12m	11 (7.6%)	7 (4.7%)	18 (6.1%)
		Questionnaire section not completed	Included	1 (0.7%)	1 (0.7%)	2 (0.7%)

	Mean profile plot inclusion status	6-month questionnaire status	12-month questionnaire status	CSII	MDI	Total
		Too young for questionnaire	Now old enough and included	1 (0.7%)	1 (0.7%)	2 (0.7%)
		Too young for questionnaire	Now old enough but: 1/5 incomplete sections	1 (0.7%)	0 (0%)	1 (0.3%)
		Too young for questionnaire	Now old enough but: No questionnaire completed	2 (1.4%)	0 (0%)	2 (0.7%)
		Too young for questionnaire	Too young for questionnaire	26 (18.1%)	26 (17.4%)	52 (17.7%)
Parent / Carer	Included	Parents / carers 13-16 years old (6 & 12 month follow-up)	Parents / carers 13-16 years old (6 & 12 month follow-up)	28 (19.4%)	26 (17.4%)	54 (18.4%)
		Parents / carers 2-4 years old (6 & 12 month follow-up)	Parents / carers 2-4 years old (6 & 12 month follow-up)	18 (12.5%)	13 (8.7%)	31 (10.6%)
		Parents / carers 5-7 years old (6 & 12 month follow-up)	Parents / carers 5-7 years old (6 & 12 month follow-up)	10 (6.9%)	15 (10.1%)	25 (8.5%)
		Parents / carers 8-12 years old (6 & 12 month follow-up)	Parents / carers 8-12 years old (6 & 12 month follow-up)	45 (31.3%)	47 (31.5%)	92 (31.4%)
	Excluded	1/5 incomplete sections	2/5 incomplete sections	1 (0.7%)	0 (0%)	1 (0.3%)
		1/5 incomplete sections	Included	1 (0.7%)	1 (0.7%)	2 (0.7%)
		1/5 incomplete sections	No questionnaire completed	0 (0%)	1 (0.7%)	1 (0.3%)
		1/5 incomplete sections	Questionnaire section not completed	0 (0%)	1 (0.7%)	1 (0.3%)
		2/5 incomplete sections	Included	1 (0.7%)	0 (0%)	1 (0.3%)
		4/5 incomplete sections	No questionnaire completed	0 (0%)	1 (0.7%)	1 (0.3%)
		DNA 6 months	Included	6 (4.2%)	3 (2%)	9 (3.1%)
		DNA 6 months	No questionnaire completed	1 (0.7%)	2 (1.3%)	3 (1%)
		DNA 6 months	WD from study prior to 12 months	0 (0%)	1 (0.7%)	1 (0.3%)
		Included	1/5 incomplete sections	2 (1.4%)	1 (0.7%)	3 (1%)
		Included	No questionnaire completed	8 (5.6%)	10 (6.7%)	18 (6.1%)
		Included	Questionnaire section not completed	0 (0%)	1 (0.7%)	1 (0.3%)
		Included	WD from study prior to 12 months	0 (0%)	4 (2.7%)	4 (1.4%)
		No questionnaire completed	1/5 incomplete sections	1 (0.7%)	1 (0.7%)	2 (0.7%)

	Mean profile plot inclusion status	6-month questionnaire status	12-month questionnaire status	CSII	MDI	Total
		No questionnaire completed	Included	6 (4.2%)	10 (6.7%)	16 (5.5%)
		No questionnaire completed	No questionnaire completed	2 (1.4%)	3 (2%)	5 (1.7%)
		No questionnaire completed	WD from study prior to 12 months	1 (0.7%)	0 (0%)	1 (0.3%)
		Questionnaire completed but different age questionnaires at 6m and at 12m	Questionnaire completed but different age questionnaires at 6m and at 12m	13 (9%)	8 (5.4%)	21 (7.2%)

Figure 6.6-5: Paediatric Quality of Life (PedsQL) – Child mean profile plots (5-7 years old) (ITT)

PedsQL Overall Score Mean Profile Plots For Children That Completed a 5-7 Years Old questionnaire at both 6m and 12m
PedsQL Overall Score

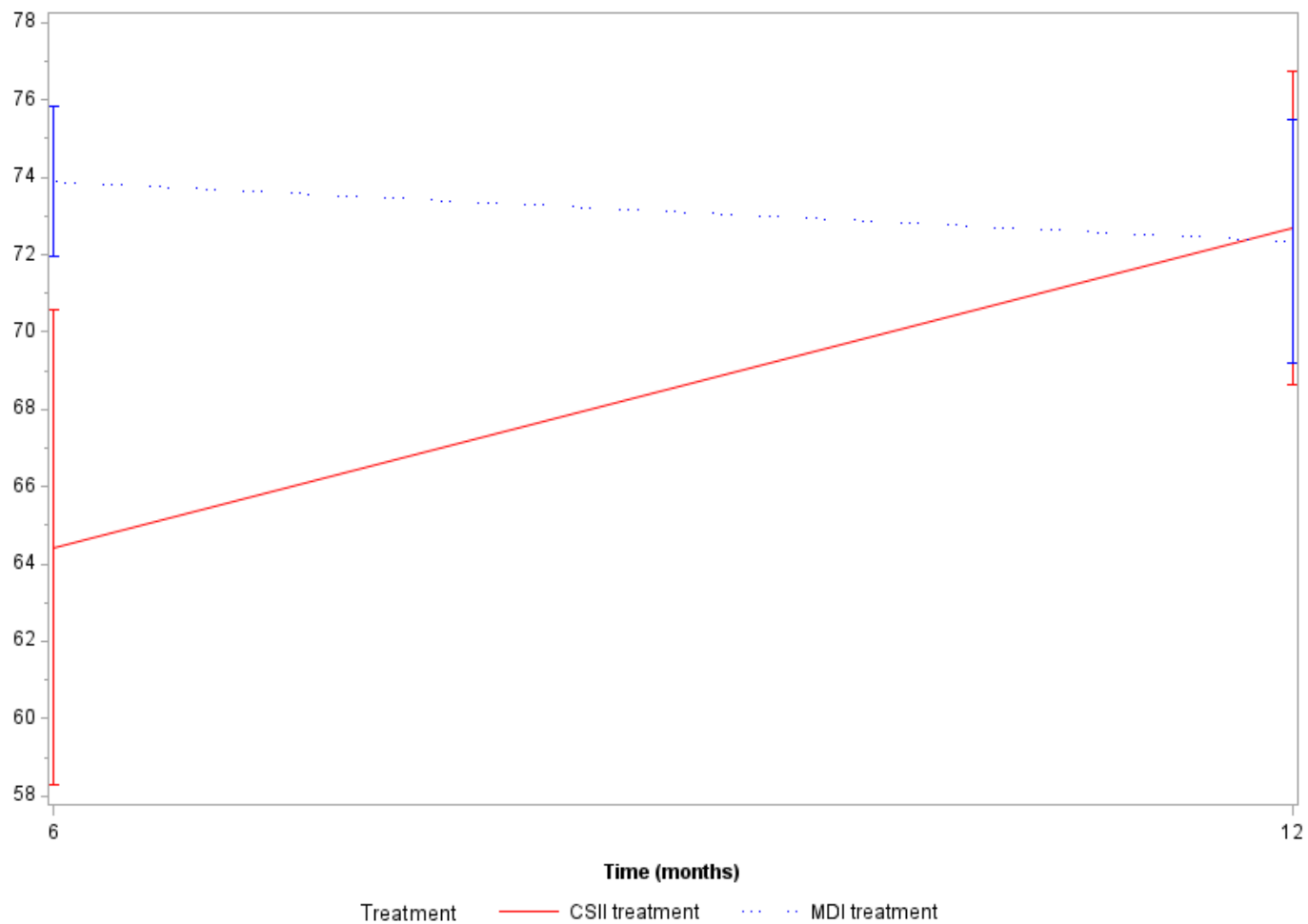


Figure 6.6-6: Paediatric Quality of Life (PedsQL) – Child mean profile plots (8-12 years old) (ITT)
PedsQL Overall Score Mean Profile Plots For Children That Completed a 8-12 Years Old questionnaire at both 6m and 12m
PedsQL Overall Score

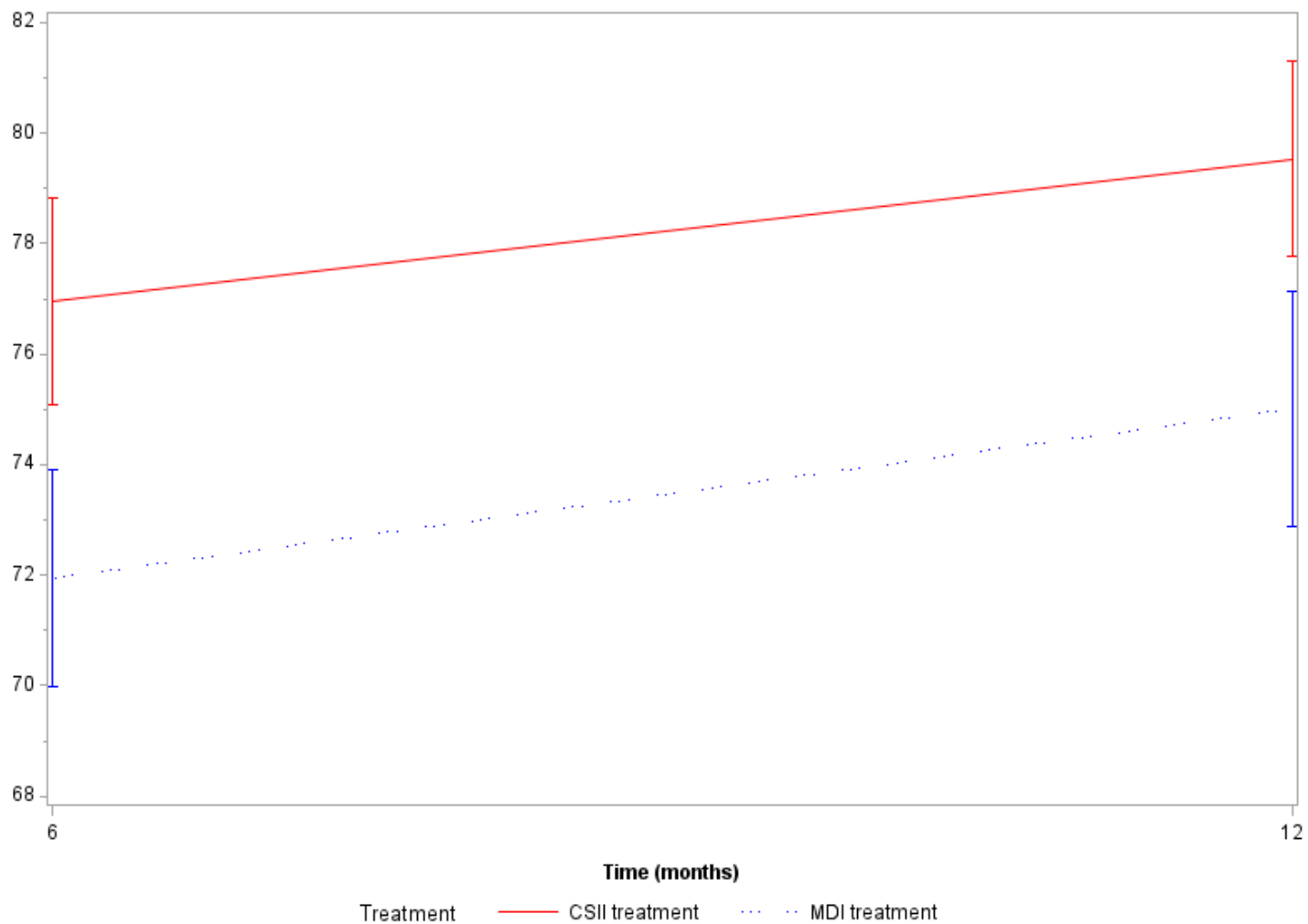


Figure 6.6-7: Paediatric Quality of Life (PedsQL) – Child mean profile plots (13-16 years old) (ITT)
PedsQL Overall Score Mean Profile Plots For Children That Completed a 13-16 Years Old questionnaire at both 6m and 12m
PedsQL Overall Score

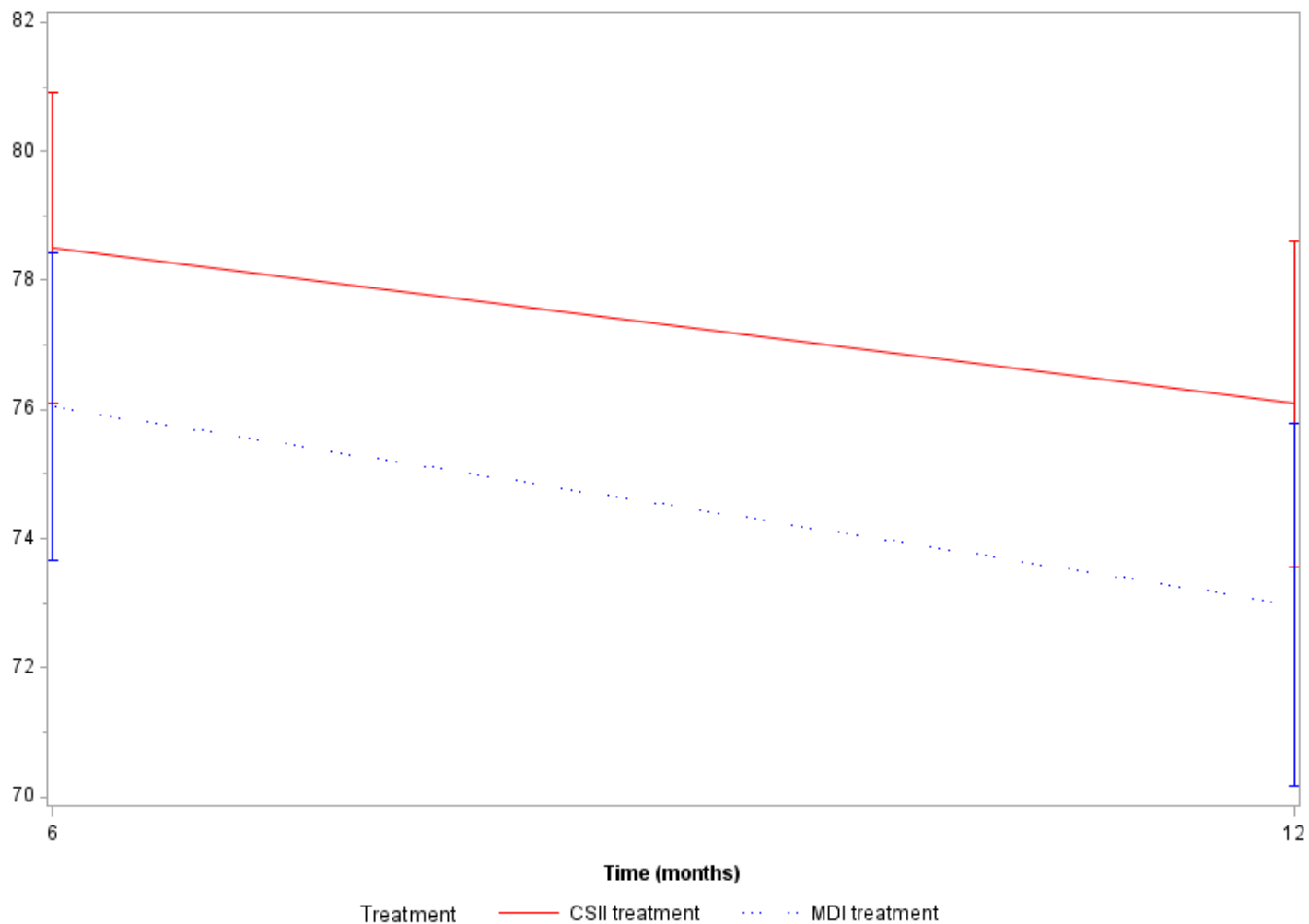


Figure 6.6-8: Paediatric Quality of Life (PedsQL) – Parent/carer mean profile plots (2-4 years old) (ITT)
PedsQL Overall Score Mean Profile Plots For Parents/Carers Of Children That Completed a 2-4 Years Old questionnaire at both 6m and 12m
PedsQL Overall Score

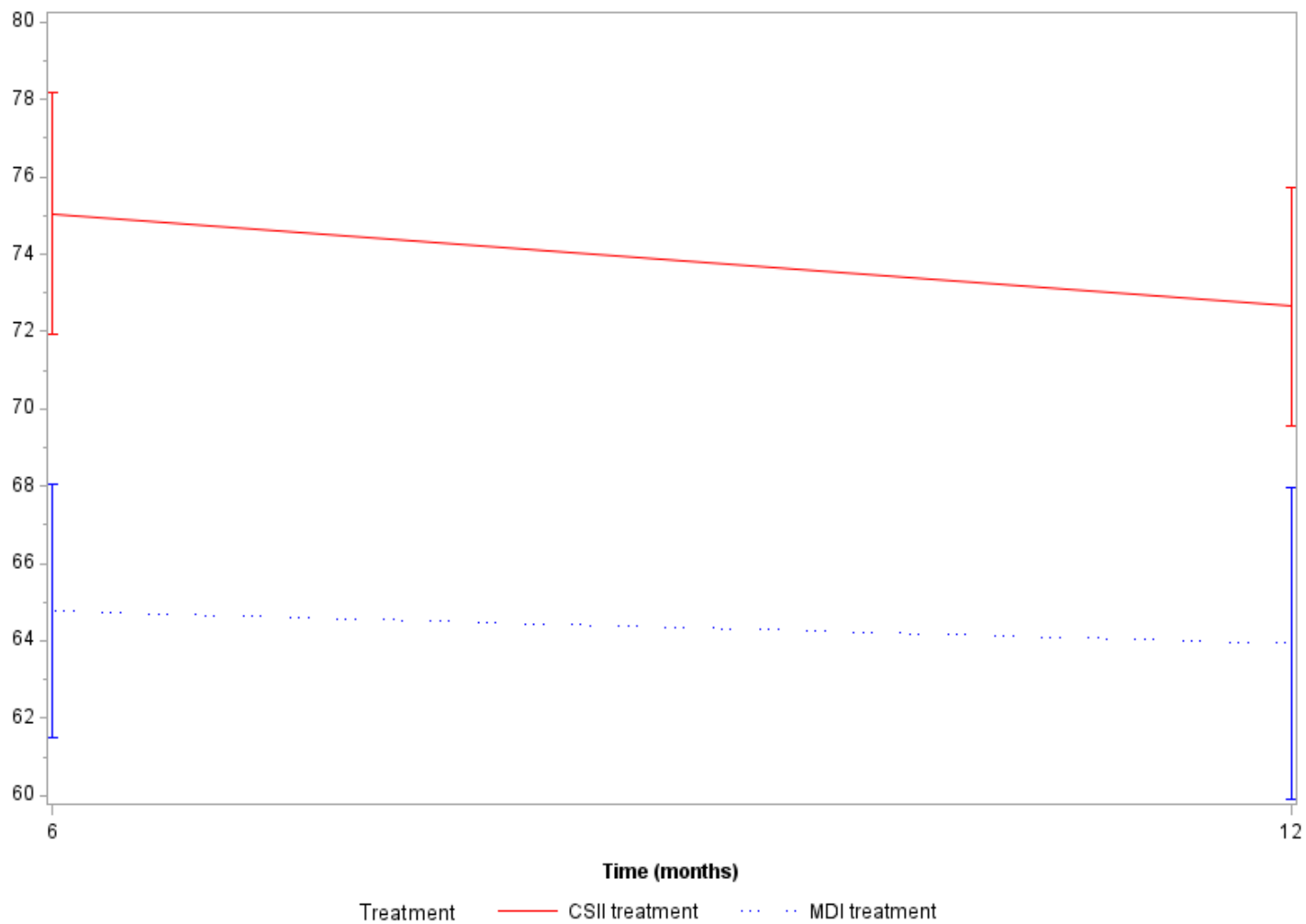


Figure 6.6-9: Paediatric Quality of Life (PedsQL) – Parent/carer mean profile plots (5-7 years old) (ITT)
PedsQL Overall Score Mean Profile Plots For Parents/Carers Of Children That Completed a 5-7 Years Old questionnaire at both 6m and 12m
PedsQL Overall Score

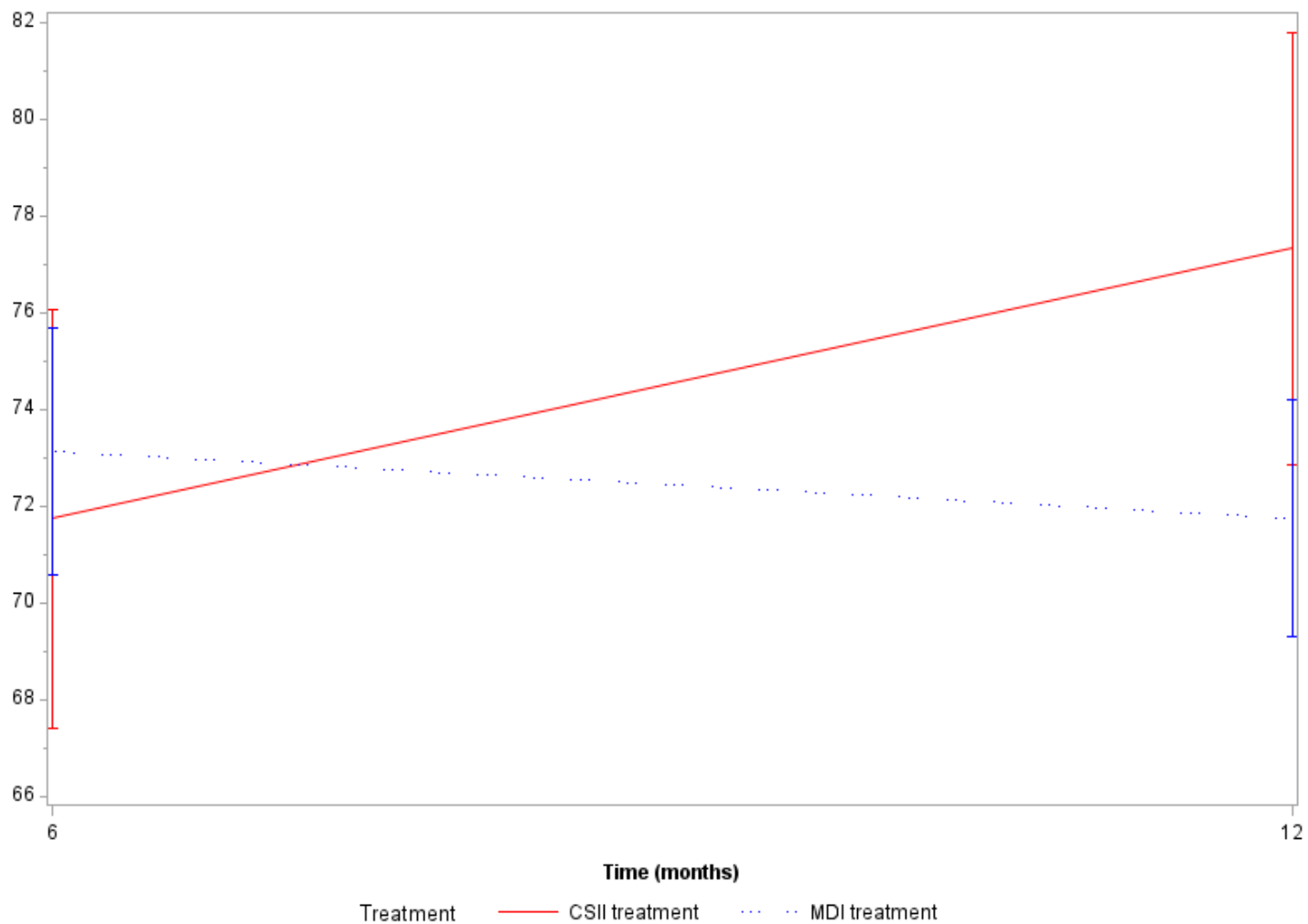


Figure 6.6-10: Paediatric Quality of Life (PedsQL) – Parent/carer mean profile plots (8-12 years old) (ITT)
PedsQL Overall Score Mean Profile Plots For Parents/Carers Of Children That Completed a 8-12 Years Old questionnaire at both 6m and 12m
PedsQL Overall Score

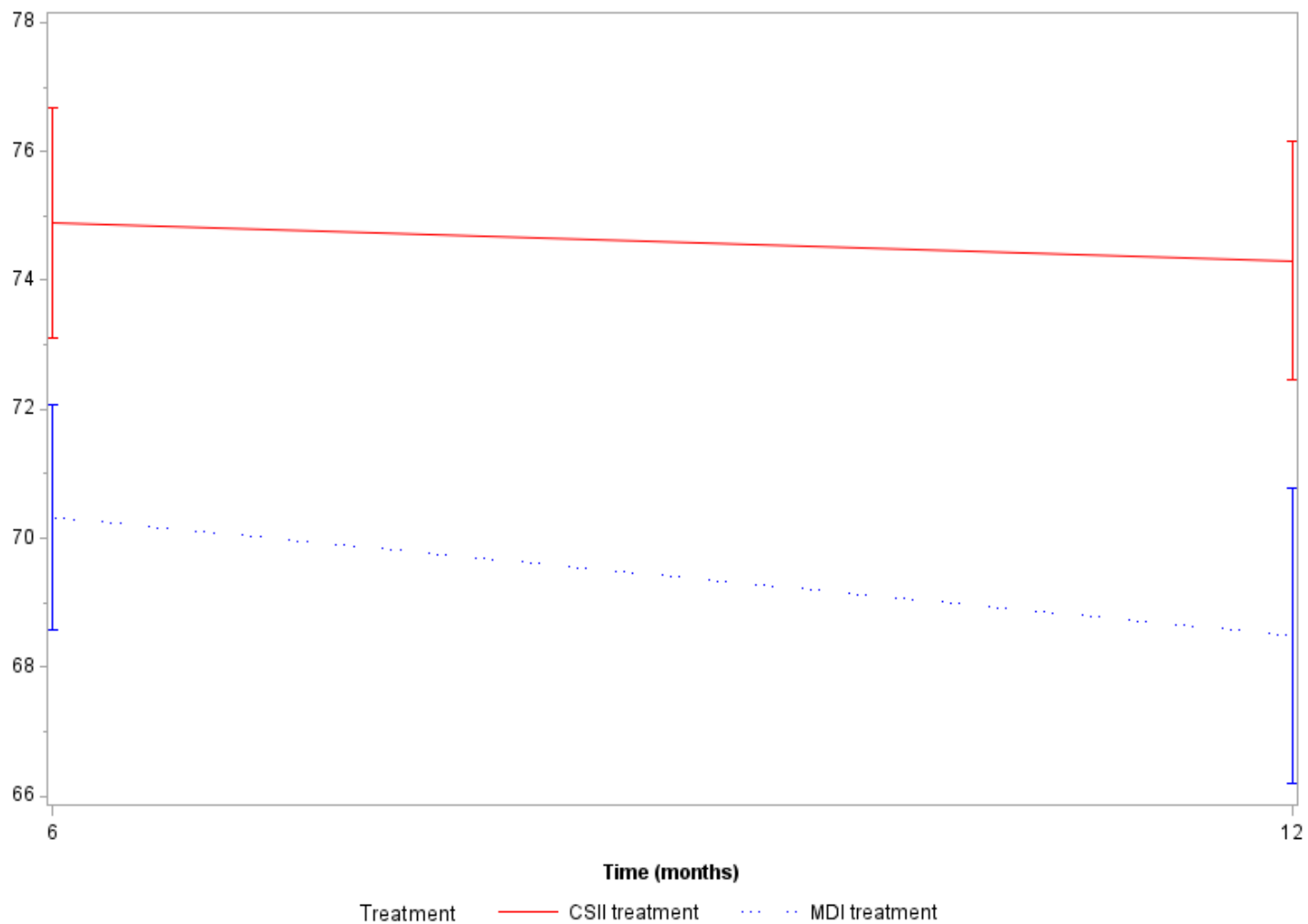


Figure 6.6-11: Paediatric Quality of Life (PedsQL) – Parent/carer mean profile plots (13-16 years old) (ITT)

PedsQL Overall Score Mean Profile Plots For Parents/Carers Of Children That Completed a 13-16 Years Old questionnaire at both 6m and 12m

PedsQL Overall Score

