

FFIT FOLLOW UP

Final Report

Version 3.2

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Executive Summary

Title

FFIT FU: Football Fans in Training Follow Up

Description

FFIT FU is a longitudinal, follow-up study of men who were aged 35-65 with BMI at least 28kg/m² at the start of the FFIT randomised controlled trial. Follow up visit is approximately 3.5 years post randomisation in the RCT

Primary objective

The primary objective is to investigate long term weight loss trajectories from baseline to 3.5 years in 35-65 year old men with BMI at least 28kg/m².

Note

* beside p-values indicate Wilcoxon-Mann-Whitney tests for continuous variables and Fisher's exact test for categorical variables, ** indicate Wilcoxon signed rank tests.

* For mediator analysis, if mediator is measured at baseline, then the change in mediator is modelled. If the mediator is only measured once, the mediator level at the single time is modelled.

Table 1
Summary of Subject Disposition, Overall and by Group

	All	Intervention	Control
RCT Population			
Numbers randomised	747	374	373
In the consented population	665 (89.0%)	316 (84.5%)	349 (93.6%)
In the analysis population	488 (65.3%)	233 (62.3%)	255 (68.4%)
In the not-followed-up population	259 (34.7%)	141 (37.7%)	118 (31.6%)
Consented Population			
Numbers consented to follow-up	665	316	349
In the analysis population	488 (73.4%)	233 (73.7%)	255 (73.1%)
In the not-followed-up population	177 (26.6%)	83 (26.3%)	94 (26.9%)

Table 2.1.1
Summary of Demographic Characteristics I, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)
Age (years)	n (missing)	747 (0)	374 (0)	373 (0)
	Mean (SD)	47.1 (7.98)	47.0 (8.07)	47.2 (7.89)
	Median (IQR)	46 [40 , 53]	46 [40 , 53]	46 [40 , 53]
	Min - Max	33 , 65	33 , 65	34 , 65
Ethnicity	n (missing)	742 (5)	372 (2)	370 (3)
	White	735 (99.1%)	367 (98.7%)	368 (99.5%)
	Other	7 (0.9%)	5 (1.3%)	2 (0.5%)
SIMD (quintiles)	n (missing)	737 (10)	367 (7)	370 (3)
	1 (most deprived)	131 (17.8%)	65 (17.7%)	66 (17.8%)
	2	131 (17.8%)	69 (18.8%)	62 (16.8%)
	3	122 (16.6%)	62 (16.9%)	60 (16.2%)
	4	165 (22.4%)	82 (22.3%)	83 (22.4%)
	5	188 (25.5%)	89 (24.3%)	99 (26.8%)
Employment Status	n (missing)	745 (2)	373 (1)	372 (1)
	Paid work	626 (84.0%)	322 (86.3%)	304 (81.7%)
	Education or training	8 (1.1%)	3 (0.8%)	5 (1.3%)
	Unemployed	27 (3.6%)	9 (2.4%)	18 (4.8%)
	Not working due to long-term sickness or disability	16 (2.1%)	8 (2.1%)	8 (2.2%)
	Retired	32 (4.3%)	14 (3.8%)	18 (4.8%)
	Other	36 (4.8%)	17 (4.6%)	19 (5.1%)

Table 2.1.1
Summary of Demographic Characteristics II, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)
Education	n (missing)	747 (0)	374 (0)	373 (0)
	No qualifications	71 (9.5%)	37 (9.9%)	34 (9.1%)
	Standard grades/Highers	241 (32.3%)	115 (30.7%)	126 (33.8%)
	Vocational or HNC/HND	240 (32.1%)	133 (35.6%)	107 (28.7%)
	University Education	156 (20.9%)	75 (20.1%)	81 (21.7%)
	Others	39 (5.2%)	14 (3.7%)	25 (6.7%)
Housing tenure	Other	184 (24.6%)	94 (25.1%)	90 (24.1%)
	Owner-Occupied	563 (75.4%)	280 (74.9%)	283 (75.9%)
Marital status	Living with partner	95 (12.7%)	55 (14.7%)	40 (10.7%)
	Married	518 (69.3%)	249 (66.6%)	269 (72.1%)
	Other	134 (17.9%)	70 (18.7%)	64 (17.2%)

Table 2.1.2
Summary of Clinical Characteristics, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)
Weight (kg)	n (missing)	747 (0)	374 (0)	373 (0)
	Mean (SD)	109.5 (17.3)	110.3 (17.9)	108.7 (16.6)
	Median (IQR)	107 [98 , 119]	108 [98 , 121]	107 [97 , 116]
	Min - Max	71 , 180	71 , 180	73 , 180
Waist circumference (cm)	n (missing)	747 (0)	374 (0)	373 (0)
	Mean (SD)	118.4 (11.7)	118.7 (12.3)	118.0 (11.1)
	Median (IQR)	117 [110 , 125]	118 [110 , 126]	117 [110 , 123]
	Min - Max	90 , 166	90 , 159	96 , 166
BMI (kg/m ²) (manual calculation)	n (missing)	747 (0)	374 (0)	373 (0)
	Mean (SD)	35.4 (5.0)	35.6 (5.1)	35.2 (4.9)
	Median (IQR)	34 [32 , 38]	34 [32 , 38]	34 [32 , 38]
	Min - Max	28 , 56	28 , 56	28 , 55
Body fat (% total weight)	n (missing)	737 (10)	367 (7)	370 (3)
	Mean (SD)	31.7 (5.5)	31.8 (5.7)	31.5 (5.2)
	Median (IQR)	31 [28 , 35]	31 [28 , 35]	31 [28 , 35]
	Min - Max	18 , 60	18 , 59	20 , 60
Systolic blood pressure	n (missing)	745 (2)	374 (0)	371 (2)
	Mean (SD)	140.3 (16.3)	139.4 (17.5)	141.2 (14.9)
	Median (IQR)	138 [130 , 150]	138 [129 , 149]	139 [131 , 151]
	Min - Max	83 , 232	83 , 232	101 , 202
Diastolic blood pressure	n (missing)	745 (2)	374 (0)	371 (2)
	Mean (SD)	88.8 (10.2)	88.2 (10.3)	89.5 (10.1)
	Median (IQR)	88 [82 , 95]	88 [82 , 95]	89 [83 , 96]
	Min - Max	50 , 134	50 , 134	53 , 124

Table 2.1.3
Summary of Self Reported Physical Activity I, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)
MET TOTAL (min/week)	n (missing)	742 (5)	371 (3)	371 (2)
	Mean (SD)	2373.0 (3999.5)	2389.8 (4182.6)	2356.2 (3813.2)
	Median (IQR)	1188 [396 , 2628]	1188 [396 , 2739]	1173 [396 , 2559]
	Min - Max	0 , 40719	0 , 40719	0 , 28097
Vigorous (MET-min/week)	n (missing)	742 (5)	371 (3)	371 (2)
	Mean (SD)	930.6 (2838.7)	961.8 (3074.3)	899.3 (2585.6)
	Median (IQR)	0 [0 , 720]	0 [0 , 720]	0 [0 , 720]
	Min - Max	0 , 30720	0 , 30720	0 , 27800
Moderate (min/week)	n (missing)	742 (5)	371 (3)	371 (2)
	Mean (SD)	505.0 (1382.3)	477.0 (1350.0)	532.9 (1415.2)
	Median (IQR)	0 [0 , 360]	0 [0 , 360]	0 [0 , 360]
	Min - Max	0 , 11760	0 , 11760	0 , 9600
Walking (min/week)	n (missing)	742 (5)	371 (3)	371 (2)
	Mean (SD)	937.5 (1402.8)	951.0 (1400.0)	923.9 (1407.3)
	Median (IQR)	446 [99 , 1188]	462 [116 , 1188]	396 [99 , 1040]
	Min - Max	0 , 11088	0 , 11088	0 , 9504

Table 2.1.3
Summary of Self Reported Physical Activity II, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)
Truncated MET TOTAL (min/week)	n (missing)	742 (5)	371 (3)	371 (2)
	Mean (SD)	1881.6 (2334.5)	1890.8 (2344.6)	1872.4 (2327.5)
	Median (IQR)	1188 [396 , 2559]	1188 [396 , 2559]	1173 [396 , 2559]
	Min - Max	0 , 17199	0 , 17199	0 , 15120
Truncated Vigorous (min/week)	n (missing)	742 (5)	371 (3)	371 (2)
	Mean (SD)	671.3 (1410.5)	689.7 (1440.3)	652.9 (1381.7)
	Median (IQR)	0 [0 , 720]	0 [0 , 720]	0 [0 , 720]
	Min - Max	0 , 10080	0 , 10080	0 , 10080
Truncated Moderate (min/week)	n (missing)	742 (5)	371 (3)	371 (2)
	Mean (SD)	390.4 (872.9)	365.1 (810.0)	415.6 (932.0)
	Median (IQR)	0 [0 , 360]	0 [0 , 360]	0 [0 , 360]
	Min - Max	0 , 5040	0 , 5040	0 , 5040
Truncated Walking (min/week)	n (missing)	742 (5)	371 (3)	371 (2)
	Mean (SD)	819.9 (1001.6)	836.0 (1001.4)	803.9 (1002.8)
	Median (IQR)	446 [99 , 1188]	462 [116 , 1188]	396 [99 , 1040]
	Min - Max	0 , 4158	0 , 4158	0 , 4158
Time spent sitting on a week day in last 7 days	n (missing)	601 (146)	299 (75)	302 (71)
	Mean (SD)	465.4 (210.7)	478.3 (206.4)	452.5 (214.5)
	Median (IQR)	450 [300 , 600]	480 [300 , 600]	420 [300 , 600]
	Min - Max	0 , 960	20 , 960	0 , 960

Table 2.1.4
Summary of DINE Measures, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)
Fatty Food Score	n (missing)	747 (0)	374 (0)	373 (0)
	Mean (SD)	23.6 (7.2)	23.5 (7.2)	23.6 (7.2)
	Median (IQR)	23 [19 , 28]	23 [19 , 28]	23 [18 , 27]
	Min - Max	8 , 58	8 , 58	11 , 51
Sugary Food Score	n (missing)	747 (0)	374 (0)	373 (0)
	Mean (SD)	6.1 (2.8)	6.0 (2.7)	6.2 (2.9)
	Median (IQR)	5 [4 , 7]	5 [4 , 7]	6 [4 , 7]
	Min - Max	3 , 16	3 , 16	3 , 16
Fruits and Vegetable Score	n (missing)	747 (0)	374 (0)	373 (0)
	Mean (SD)	2.3 (1.7)	2.3 (1.7)	2.3 (1.7)
	Median (IQR)	2 [2 , 4]	2 [2 , 4]	2 [2 , 4]
	Min - Max	1 , 6	1 , 6	1 , 6

Table 2.1.5
Summary of Portion Sizes, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)
Cheese	n (missing)	708 (39)	354 (20)	354 (19)
	Mean (SD)	4.3 (2.0)	4.3 (2.0)	4.4 (2.0)
	Median (IQR)	4 [3 , 6]	4 [3 , 6]	4 [3 , 6]
	Min - Max	1 , 8	1 , 8	1 , 8
Meat	n (missing)	738 (9)	368 (6)	370 (3)
	Mean (SD)	5.6 (1.3)	5.6 (1.3)	5.6 (1.4)
	Median (IQR)	6 [5 , 6]	6 [5 , 6]	6 [5 , 6]
	Min - Max	1 , 8	1 , 8	1 , 8
Pasta	n (missing)	726 (21)	361 (13)	365 (8)
	Mean (SD)	5.1 (1.7)	5.2 (1.7)	5.0 (1.7)
	Median (IQR)	5 [4 , 6]	5 [4 , 6]	5 [4 , 6]
	Min - Max	1 , 8	1 , 8	1 , 8
Chips	n (missing)	712 (35)	351 (23)	361 (12)
	Mean (SD)	4.1 (1.8)	4.1 (1.8)	4.0 (1.7)
	Median (IQR)	4 [3 , 5]	4 [3 , 5]	4 [3 , 5]
	Min - Max	1 , 8	1 , 8	1 , 8

Table 2.1.6
Summary of Other Diet or Health Measures, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)
Eating breakfast (times per week)	n (missing)	747 (0)	374 (0)	373 (0)
	No times	63 (8.4%)	34 (9.1%)	29 (7.8%)
	1-2 times	158 (21.2%)	86 (23.0%)	72 (19.3%)
	3-5 times	162 (21.7%)	77 (20.6%)	85 (22.8%)
	6 or more times	364 (48.7%)	177 (47.3%)	187 (50.1%)
Total alcohol consumption (units per week)	n (missing)	747 (0)	374 (0)	373 (0)
	Mean (SD)	16.7 (17.4)	16.5 (17.4)	17.0 (17.4)
	Median (IQR)	13 [2 , 26]	12 [1 , 26]	14 [2 , 26]
	Min - Max	0 , 102	0 , 102	0 , 91
Ever smoked cigarettes	n (missing)	747 (0)	374 (0)	373 (0)
	No, I have never smoked	469 (62.8%)	234 (62.6%)	235 (63.0%)
	No, I have quit	209 (28.0%)	102 (27.3%)	107 (28.7%)
	Yes, I smoke now	69 (9.2%)	38 (10.2%)	31 (8.3%)
Number of longstanding illnesses	n (missing)	747 (0)	374 (0)	373 (0)
	Mean (SD)	0.5 (0.8)	0.5 (0.8)	0.5 (0.8)
	Median (IQR)	0 [0 , 1]	0 [0 , 1]	0 [0 , 1]
	Min - Max	0 , 6	0 , 4	0 , 6

Table 2.1.7
Summary of Psychological Characteristics, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)
Negative affect PANAS [normalized]	n (missing)	747 (0)	374 (0)	373 (0)
	Mean (SD)	1.7 (0.6)	1.7 (0.6)	1.7 (0.6)
	Median (IQR)	2 [1 , 2]	2 [1 , 2]	2 [1 , 2]
	Min - Max	1 , 4	1 , 4	1 , 4
Positive affect PANAS [normalized]	n (missing)	747 (0)	374 (0)	373 (0)
	Mean (SD)	3.2 (0.7)	3.2 (0.7)	3.2 (0.7)
	Median (IQR)	3 [3 , 4]	3 [3 , 4]	3 [3 , 4]
	Min - Max	1 , 5	1 , 5	1 , 5
Rosenberg Self-Esteem Scale [normalized]	n (missing)	747 (0)	374 (0)	373 (0)
	Mean (SD)	1.9 (0.5)	1.9 (0.5)	1.9 (0.5)
	Median (IQR)	2 [2 , 2]	2 [2 , 2]	2 [2 , 2]
	Min - Max	0 , 3	0 , 3	0 , 3
SF12 physical HRQoL	n (missing)	746 (1)	373 (1)	373 (0)
	Mean (SD)	47.4 (7.7)	47.0 (7.9)	47.7 (7.5)
	Median (IQR)	49 [43 , 53]	49 [42 , 53]	49 [43 , 53]
	Min - Max	19 , 62	19 , 62	20 , 62
SF12 mental HRQoL	n (missing)	746 (1)	373 (1)	373 (0)
	Mean (SD)	48.6 (9.7)	48.9 (10.1)	48.3 (9.2)
	Median (IQR)	51 [43 , 55]	52 [43 , 56]	50 [43 , 55]
	Min - Max	10 , 71	12 , 71	10 , 67
Conformity to masculine norms [normalized]	n (missing)	746 (1)	374 (0)	372 (1)
	Mean (SD)	1.1 (0.3)	1.2 (0.3)	1.1 (0.3)
	Median (IQR)	1 [1 , 1]	1 [1 , 1]	1 [1 , 1]
	Min - Max	0 , 2	0 , 2	0 , 2

Table 2.2.1
Summary of Demographic Characteristics I, Overall and by Group

		All Subjects (N = 747)	Analysis (N = 488)	Not Followed Up (N = 259)
Age (years)	n (missing)	747 (0)	488 (0)	259 (0)
	Mean (SD)	47.1 (7.98)	47.5 (8.03)	46.2 (7.81)
	Median (IQR)	46 [40 , 53]	47 [41 , 54]	46 [40 , 52]
	Min - Max	33 , 65	33 , 65	34 , 64
	P-value			0.0273
Ethnicity	n (missing)	742 (5)	484 (4)	258 (1)
	White	735 (99.1%)	479 (99.0%)	256 (99.2%)
	Other	7 (0.9%)	5 (1.0%)	2 (0.8%)
	P-value			1.0000*
SIMD (quintiles)	n (missing)	737 (10)	483 (5)	254 (5)
	1 (most deprived)	131 (17.8%)	86 (17.8%)	45 (17.7%)
	2	131 (17.8%)	79 (16.4%)	52 (20.5%)
	3	122 (16.6%)	80 (16.6%)	42 (16.5%)
	4	165 (22.4%)	113 (23.4%)	52 (20.5%)
	5	188 (25.5%)	125 (25.9%)	63 (24.8%)
	P-value			0.6810
Employment status	n (missing)	745 (2)	487 (1)	258 (1)
	Paid work	626 (84.0%)	416 (85.4%)	210 (81.4%)
	Education or training	8 (1.1%)	0 (0.0%)	8 (3.1%)
	Unemployed	27 (3.6%)	14 (2.9%)	13 (5.0%)
	Not working due to long-term sickness or disability	16 (2.1%)	13 (2.7%)	3 (1.2%)
	Retired	32 (4.3%)	23 (4.7%)	9 (3.5%)
	Other	36 (4.8%)	21 (4.3%)	15 (5.8%)
	P-value			0.0009*

Table 2.2.1
Summary of Demographic Characteristics II, Overall and by Group

		All Subjects (N = 747)	Analysis (N = 488)	Not Followed Up (N = 259)
Education	n (missing)	747 (0)	488 (0)	259 (0)
	No qualifications	71 (9.5%)	39 (8.0%)	32 (12.4%)
	Standard grades/Highers	241 (32.3%)	158 (32.4%)	83 (32.0%)
	Vocational or HNC/HND	240 (32.1%)	158 (32.4%)	82 (31.7%)
	University Education	156 (20.9%)	103 (21.1%)	53 (20.5%)
	Others	39 (5.2%)	30 (6.1%)	9 (3.5%)
	P-value			0.2170
Housing tenure	Other	184 (24.6%)	104 (21.3%)	80 (30.9%)
	Owner-Occupied	563 (75.4%)	384 (78.7%)	179 (69.1%)
	P-value			0.0038
Marital status	Living with partner	95 (12.7%)	64 (13.1%)	31 (12.0%)
	Married	518 (69.3%)	337 (69.1%)	181 (69.9%)
	Other	134 (17.9%)	87 (17.8%)	47 (18.1%)
	P-value			0.9044

Table 2.2.2
Summary of Clinical Characteristics I, Overall and by Group

		All Subjects (N = 747)	Analysis (N = 488)	Not Followed Up (N = 259)
Weight (kg)	n (missing)	747 (0)	488 (0)	259 (0)
	Mean (SD)	109.5 (17.3)	107.8 (17.1)	112.6 (17.2)
	Median (IQR)	107 [98 , 119]	106 [96 , 116]	110 [101 , 123]
	Min - Max	71 , 180	71 , 180	78 , 174
	P-value			0.0003
Waist circumference (cm)	n (missing)	747 (0)	488 (0)	259 (0)
	Mean (SD)	118.4 (11.7)	117.1 (11.6)	120.7 (11.7)
	Median (IQR)	117 [110 , 125]	116 [109 , 123]	119 [113 , 127]
	Min - Max	90 , 166	90 , 166	95 , 160
	P-value			<0.0001
BMI (kg/m ²) (manual calculation)	n (missing)	747 (0)	488 (0)	259 (0)
	Mean (SD)	35.4 (5.0)	34.9 (4.9)	36.3 (5.0)
	Median (IQR)	34 [32 , 38]	34 [31 , 37]	35 [33 , 39]
	Min - Max	28 , 56	28 , 56	28 , 53
	P-value			0.0002
Body fat (% total weight)	n (missing)	737 (10)	481 (7)	256 (3)
	Mean (SD)	31.7 (5.5)	31.2 (5.6)	32.5 (5.0)
	Median (IQR)	31 [28 , 35]	31 [28 , 34]	33 [29 , 36]
	Min - Max	18 , 60	18 , 60	21 , 46
	P-value			0.0015

Table 2.2.2
Summary of Clinical Characteristics II, Overall and by Group

		All Subjects (N = 747)	Analysis (N = 488)	Not Followed Up (N = 259)
Systolic blood pressure	n (missing)	745 (2)	488 (0)	257 (2)
	Mean (SD)	140.3 (16.3)	139.1 (15.8)	142.5 (17.0)
	Median (IQR)	138 [130 , 150]	137 [129 , 148]	141 [132 , 152]
	Min - Max	83 , 232	83 , 222	102 , 232
	P-value			0.0079
Diastolic blood pressure	n (missing)	745 (2)	488 (0)	257 (2)
	Mean (SD)	88.8 (10.2)	88.1 (9.9)	90.2 (10.7)
	Median (IQR)	88 [82 , 95]	87 [82 , 95]	90 [84 , 97]
	Min - Max	50 , 134	50 , 131	53 , 134
	P-value			0.0097

Table 2.2.3
Summary of Self Reported Physical Activity I, Overall and by Group

		All Subjects (N = 747)	Analysis (N = 488)	Not Followed Up (N = 259)
MET TOTAL (min/week)	n (missing)	742 (5)	485 (3)	257 (2)
	Mean (SD)	2373.0 (3999.5)	2469.4 (4375.4)	2191.1 (3170.9)
	Median (IQR)	1188 [396 , 2628]	1188 [396 , 2556]	1173 [396 , 2772]
	Min - Max	0 , 40719	0 , 40719	0 , 22308
	P-value			0.9872*
Vigorous (MET-min/week)	n (missing)	742 (5)	485 (3)	257 (2)
	Mean (SD)	930.6 (2838.7)	994.2 (3155.0)	810.4 (2117.5)
	Median (IQR)	0 [0 , 720]	0 [0 , 720]	0 [0 , 720]
	Min - Max	0 , 30720	0 , 30720	0 , 19200
	P-value			0.9706*
Moderate (min/week)	n (missing)	742 (5)	485 (3)	257 (2)
	Mean (SD)	505.0 (1382.3)	524.6 (1429.3)	467.9 (1291.0)
	Median (IQR)	0 [0 , 360]	0 [0 , 360]	0 [0 , 360]
	Min - Max	0 , 11760	0 , 11760	0 , 9600
	P-value			0.6719*
Walking (min/week)	n (missing)	742 (5)	485 (3)	257 (2)
	Mean (SD)	937.5 (1402.8)	950.6 (1426.9)	912.8 (1358.4)
	Median (IQR)	446 [99 , 1188]	396 [99 , 1188]	495 [99 , 1040]
	Min - Max	0 , 11088	0 , 9504	0 , 11088
	P-value			0.8025*

Table 2.2.3
Summary of Self Reported Physical Activity II, Overall and by Group

		All Subjects (N = 747)	Analysis (N = 488)	Not Followed Up (N = 259)
Truncated MET TOTAL (min/week)	n (missing)	742 (5)	485 (3)	257 (2)
	Mean (SD)	1881.6 (2334.5)	1921.4 (2439.4)	1806.5 (2125.1)
	Median (IQR)	1188 [396 , 2559]	1188 [396 , 2460]	1173 [396 , 2739]
	Min - Max	0 , 17199	0 , 17199	0 , 14220
	P-value			0.9178*
Truncated Vigorous (min/week)	n (missing)	742 (5)	485 (3)	257 (2)
	Mean (SD)	671.3 (1410.5)	679.1 (1458.3)	656.7 (1318.2)
	Median (IQR)	0 [0 , 720]	0 [0 , 720]	0 [0 , 720]
	Min - Max	0 , 10080	0 , 10080	0 , 7200
	P-value			0.9635*
Truncated Moderate (min/week)	n (missing)	742 (5)	485 (3)	257 (2)
	Mean (SD)	390.4 (872.9)	407.7 (923.8)	357.7 (768.5)
	Median (IQR)	0 [0 , 360]	0 [0 , 360]	0 [0 , 360]
	Min - Max	0 , 5040	0 , 5040	0 , 5040
	P-value			0.6638*
Truncated Walking (min/week)	n (missing)	742 (5)	485 (3)	257 (2)
	Mean (SD)	819.9 (1001.6)	834.6 (1030.3)	792.2 (946.2)
	Median (IQR)	446 [99 , 1188]	396 [99 , 1188]	495 [99 , 1040]
	Min - Max	0 , 4158	0 , 4158	0 , 4158
	P-value			0.8381*
Sitting (min/day)	n (missing)	601 (146)	406 (82)	195 (64)
	Mean (SD)	465.4 (210.7)	463.1 (210.2)	470.1 (212.2)
	Median (IQR)	450 [300 , 600]	465 [300 , 600]	435 [300 , 600]
	Min - Max	0 , 960	0 , 960	0 , 960
	P-value			0.7044

Table 2.2.4
Summary of DINE Measures, Overall and by Group

		All Subjects (N = 747)	Analysis (N = 488)	Not Followed Up (N = 259)
Fatty Food Score	n (missing)	747 (0)	488 (0)	259 (0)
	Mean (SD)	23.6 (7.2)	23.9 (7.2)	22.9 (7.2)
	Median (IQR)	23 [19 , 28]	23 [19 , 28]	22 [18 , 27]
	Min - Max	8 , 58	8 , 58	11 , 50
	P-value			0.0587
Sugary Food Score	n (missing)	747 (0)	488 (0)	259 (0)
	Mean (SD)	6.1 (2.8)	6.2 (2.9)	5.9 (2.7)
	Median (IQR)	5 [4 , 7]	5 [4 , 7]	5 [4 , 7]
	Min - Max	3 , 16	3 , 16	3 , 16
	P-value			0.2626
Fruits and Vegetable Score	n (missing)	747 (0)	488 (0)	259 (0)
	Mean (SD)	2.3 (1.7)	2.3 (1.7)	2.2 (1.6)
	Median (IQR)	2 [2 , 4]	2 [2 , 4]	2 [2 , 4]
	Min - Max	1 , 6	1 , 6	1 , 6
	P-value			0.2957

Table 2.2.5
Summary of Portion Sizes, Overall and by Group

		All Subjects (N = 747)	Analysis (N = 488)	Not Followed Up (N = 259)
Cheese	n (missing)	708 (39)	463 (25)	245 (14)
	Mean (SD)	4.3 (2.0)	4.4 (2.0)	4.2 (2.0)
	Median (IQR)	4 [3 , 6]	4 [3 , 6]	4 [3 , 6]
	Min - Max	1 , 8	1 , 8	1 , 8
	P-value			0.1723
Meat	n (missing)	738 (9)	482 (6)	256 (3)
	Mean (SD)	5.6 (1.3)	5.7 (1.3)	5.5 (1.4)
	Median (IQR)	6 [5 , 6]	6 [5 , 6]	6 [5 , 6]
	Min - Max	1 , 8	1 , 8	2 , 8
	P-value			0.1040
Pasta	n (missing)	726 (21)	472 (16)	254 (5)
	Mean (SD)	5.1 (1.7)	5.2 (1.7)	5.0 (1.8)
	Median (IQR)	5 [4 , 6]	5 [4 , 6]	5 [4 , 6]
	Min - Max	1 , 8	1 , 8	1 , 8
	P-value			0.3738
Chips	n (missing)	712 (35)	463 (25)	249 (10)
	Mean (SD)	4.1 (1.8)	4.1 (1.8)	4.0 (1.7)
	Median (IQR)	4 [3 , 5]	4 [3 , 5]	4 [3 , 5]
	Min - Max	1 , 8	1 , 8	1 , 8
	P-value			0.5731

Table 2.2.6
Summary of Other Diet or Health Measures, Overall and by Group

		All Subjects (N = 747)	Analysis (N = 488)	Not Followed Up (N = 259)
Eating breakfast (times per week)	n (missing)	747 (0)	488 (0)	259 (0)
	No times	63 (8.4%)	40 (8.2%)	23 (8.9%)
	1-2 times	158 (21.2%)	97 (19.9%)	61 (23.6%)
	3-5 times	162 (21.7%)	88 (18.0%)	74 (28.6%)
	6 or more times	364 (48.7%)	263 (53.9%)	101 (39.0%)
	P-value			0.0005
Total alcohol consumption (units per week)	n (missing)	747 (0)	488 (0)	259 (0)
	Mean (SD)	16.7 (17.4)	16.9 (17.4)	16.5 (17.4)
	Median (IQR)	13 [2 , 26]	12 [2 , 27]	13 [1 , 24]
	Min - Max	0 , 102	0 , 91	0 , 102
	P-value			0.7521
Ever smoked cigarettes	n (missing)	747 (0)	488 (0)	259 (0)
	No, I have never smoked	469 (62.8%)	309 (63.3%)	160 (61.8%)
	No, I have quit	209 (28.0%)	142 (29.1%)	67 (25.9%)
	Yes, I smoke now	69 (9.2%)	37 (7.6%)	32 (12.4%)
	P-value			0.0877
Number of longstanding illnesses	n (missing)	747 (0)	488 (0)	259 (0)
	Mean (SD)	0.5 (0.8)	0.5 (0.9)	0.5 (0.7)
	Median (IQR)	0 [0 , 1]	0 [0 , 1]	0 [0 , 1]
	Min - Max	0 , 6	0 , 6	0 , 4
	P-value			0.3742

Table 2.2.7
Summary of Psychological Characteristics I, Overall and by Group

		All Subjects (N = 747)	Analysis (N = 488)	Not Followed Up (N = 259)
Negative affect PANAS [normalized]	n (missing)	747 (0)	488 (0)	259 (0)
	Mean (SD)	1.7 (0.6)	1.7 (0.6)	1.7 (0.6)
	Median (IQR)	2 [1 , 2]	2 [1 , 2]	2 [1 , 2]
	Min - Max	1 , 4	1 , 4	1 , 4
	P-value			0.5360
Positive affect PANAS [normalized]	n (missing)	747 (0)	488 (0)	259 (0)
	Mean (SD)	3.2 (0.7)	3.2 (0.7)	3.2 (0.7)
	Median (IQR)	3 [3 , 4]	3 [3 , 4]	3 [3 , 4]
	Min - Max	1 , 5	1 , 5	1 , 5
	P-value			0.9519
Rosenberg Self-Esteem Scale [normalized]	n (missing)	747 (0)	488 (0)	259 (0)
	Mean (SD)	1.9 (0.5)	1.9 (0.5)	1.9 (0.5)
	Median (IQR)	2 [2 , 2]	2 [2 , 2]	2 [2 , 2]
	Min - Max	0 , 3	0 , 3	0 , 3
	P-value			0.0620
SF12 physical HRQoL	n (missing)	746 (1)	487 (1)	259 (0)
	Mean (SD)	47.4 (7.7)	47.7 (7.8)	46.6 (7.5)
	Median (IQR)	49 [43 , 53]	49 [44 , 53]	49 [42 , 53]
	Min - Max	19 , 62	20 , 62	19 , 62
	P-value			0.0550

Table 2.2.7
Summary of Psychological Characteristics II, Overall and by Group

		All Subjects (N = 747)	Analysis (N = 488)	Not Followed Up (N = 259)
SF12 mental HRQoL	n (missing)	746 (1)	487 (1)	259 (0)
	Mean (SD)	48.6 (9.7)	48.6 (9.8)	48.5 (9.4)
	Median (IQR)	51 [43 , 55]	52 [43 , 55]	51 [44 , 55]
	Min - Max	10 , 71	10 , 71	17 , 69
	P-value			0.8378
Conformity to masculine norms [normalized]	n (missing)	746 (1)	488 (0)	258 (1)
	Mean (SD)	1.1 (0.3)	1.2 (0.2)	1.1 (0.3)
	Median (IQR)	1 [1 , 1]	1 [1 , 1]	1 [1 , 1]
	Min - Max	0 , 2	0 , 2	0 , 2
	P-value			0.6663

Table 2.3.1
Summary of Demographic Characteristics I, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Age (years)	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	47.5 (8.03)	47.3 (8.16)	47.7 (7.92)
	Median (IQR)	47 [41 , 54]	47 [41 , 54]	47 [41 , 53]
	Min - Max	33 , 65	33 , 65	34 , 65
Ethnicity	n (missing)	484 (4)	231 (2)	253 (2)
	White	479 (99.0%)	228 (98.7%)	251 (99.2%)
	Other	5 (1.0%)	3 (1.3%)	2 (0.8%)
SIMD (quintiles)	n (missing)	483 (5)	231 (2)	252 (3)
	1 (most deprived)	86 (17.8%)	40 (17.3%)	46 (18.3%)
	2	79 (16.4%)	35 (15.2%)	44 (17.5%)
	3	80 (16.6%)	43 (18.6%)	37 (14.7%)
	4	113 (23.4%)	58 (25.1%)	55 (21.8%)
	5	125 (25.9%)	55 (23.8%)	70 (27.8%)
Employment Status	n (missing)	487 (1)	232 (1)	255 (0)
	Paid work	416 (85.4%)	201 (86.6%)	215 (84.3%)
	Unemployed	14 (2.9%)	3 (1.3%)	11 (4.3%)
	Not working due to long-term sickness or disability	13 (2.7%)	8 (3.4%)	5 (2.0%)
	Retired	23 (4.7%)	10 (4.3%)	13 (5.1%)
	Other	21 (4.3%)	10 (4.3%)	11 (4.3%)

Table 2.3.1
Summary of Demographic Characteristics II, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Education	n (missing)	488 (0)	233 (0)	255 (0)
	No qualifications	39 (8.0%)	17 (7.3%)	22 (8.6%)
	Standard grades/Highers	158 (32.4%)	73 (31.3%)	85 (33.3%)
	Vocational or HNC/HND	158 (32.4%)	84 (36.1%)	74 (29.0%)
	University Education	103 (21.1%)	48 (20.6%)	55 (21.6%)
	Others	30 (6.1%)	11 (4.7%)	19 (7.5%)
Housing tenure	Other	104 (21.3%)	51 (21.9%)	53 (20.8%)
	Owner-Occupied	384 (78.7%)	182 (78.1%)	202 (79.2%)
Marital status	Living with partner	64 (13.1%)	39 (16.7%)	25 (9.8%)
	Married	337 (69.1%)	149 (63.9%)	188 (73.7%)
	Other	87 (17.8%)	45 (19.3%)	42 (16.5%)

Table 2.3.2
Summary of Clinical Characteristics, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Weight (kg)	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	107.8 (17.1)	108.3 (17.9)	107.4 (16.3)
	Median (IQR)	106 [96 , 116]	106 [96 , 117]	106 [96 , 116]
	Min - Max	71 , 180	71 , 180	73 , 180
Waist circumference (cm)	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	117.1 (11.6)	117.5 (12.3)	116.8 (10.8)
	Median (IQR)	116 [109 , 123]	115 [109 , 124]	116 [110 , 123]
	Min - Max	90 , 166	90 , 159	96 , 166
BMI (kg/m2) (manual calculation)	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	34.9 (4.9)	35.0 (5.1)	34.8 (4.7)
	Median (IQR)	34 [31 , 37]	34 [31 , 38]	34 [31 , 37]
	Min - Max	28 , 56	28 , 56	28 , 55
Body fat (% total weight)	n (missing)	481 (7)	229 (4)	252 (3)
	Mean (SD)	31.2 (5.6)	31.3 (6.0)	31.2 (5.3)
	Median (IQR)	31 [28 , 34]	31 [28 , 34]	31 [28 , 34]
	Min - Max	18 , 60	18 , 59	20 , 60
Systolic blood pressure	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	139.1 (15.8)	137.5 (16.7)	140.7 (14.9)
	Median (IQR)	137 [129 , 148]	136 [128 , 145]	138 [131 , 150]
	Min - Max	83 , 222	83 , 222	101 , 185
Diastolic blood pressure	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	88.1 (9.9)	87.4 (10.0)	88.8 (9.8)
	Median (IQR)	87 [82 , 95]	87 [82 , 94]	88 [83 , 95]
	Min - Max	50 , 131	50 , 131	62 , 119

Table 2.3.3
Summary of Self Reported Physical Activity I, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
MET TOTAL (min/week)	n (missing)	485 (3)	232 (1)	253 (2)
	Mean (SD)	2469.4 (4375.4)	2488.6 (4590.8)	2451.9 (4177.2)
	Median (IQR)	1188 [396 , 2556]	1251 [396 , 2606]	1155 [396 , 2445]
	Min - Max	0 , 40719	0 , 40719	0 , 28097
Vigorous (MET-min/week)	n (missing)	485 (3)	232 (1)	253 (2)
	Mean (SD)	994.2 (3155.0)	1036.6 (3413.7)	955.4 (2904.0)
	Median (IQR)	0 [0 , 720]	0 [0 , 720]	0 [0 , 640]
	Min - Max	0 , 30720	0 , 30720	0 , 27800
Moderate (min/week)	n (missing)	485 (3)	232 (1)	253 (2)
	Mean (SD)	524.6 (1429.3)	481.6 (1404.0)	564.0 (1453.8)
	Median (IQR)	0 [0 , 360]	0 [0 , 320]	0 [0 , 360]
	Min - Max	0 , 11760	0 , 11760	0 , 9600
Walking (min/week)	n (missing)	485 (3)	232 (1)	253 (2)
	Mean (SD)	950.6 (1426.9)	970.4 (1413.7)	932.4 (1441.5)
	Median (IQR)	396 [99 , 1188]	454 [99 , 1386]	396 [99 , 1188]
	Min - Max	0 , 9504	0 , 8316	0 , 9504

Table 2.3.3
Summary of Self Reported Physical Activity II, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Truncated MET TOTAL (min/week)	n (missing)	485 (3)	232 (1)	253 (2)
	Mean (SD)	1921.4 (2439.4)	1943.0 (2432.6)	1901.6 (2450.2)
	Median (IQR)	1188 [396 , 2460]	1230 [396 , 2460]	1155 [396 , 2445]
	Min - Max	0 , 17199	0 , 17199	0 , 15120
Truncated Vigorous (min/week)	n (missing)	485 (3)	232 (1)	253 (2)
	Mean (SD)	679.1 (1458.3)	713.8 (1472.1)	647.3 (1447.7)
	Median (IQR)	0 [0 , 720]	0 [0 , 720]	0 [0 , 640]
	Min - Max	0 , 10080	0 , 10080	0 , 10080
Truncated Moderate (min/week)	n (missing)	485 (3)	232 (1)	253 (2)
	Mean (SD)	407.7 (923.8)	366.8 (854.8)	445.2 (983.0)
	Median (IQR)	0 [0 , 360]	0 [0 , 320]	0 [0 , 360]
	Min - Max	0 , 5040	0 , 5040	0 , 5040
Truncated Walking (min/week)	n (missing)	485 (3)	232 (1)	253 (2)
	Mean (SD)	834.6 (1030.3)	862.4 (1047.6)	809.1 (1015.7)
	Median (IQR)	396 [99 , 1188]	454 [99 , 1386]	396 [99 , 1188]
	Min - Max	0 , 4158	0 , 4158	0 , 4158
Time spent sitting on a week day in last 7 days	n (missing)	406 (82)	193 (40)	213 (42)
	Mean (SD)	463.1 (210.2)	476.3 (202.2)	451.2 (216.9)
	Median (IQR)	465 [300 , 600]	480 [300 , 600]	420 [300 , 600]
	Min - Max	0 , 960	20 , 960	0 , 960

Table 2.3.4
Summary of DINE Measures, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Fatty Food Score	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	23.9 (7.2)	24.1 (7.1)	23.8 (7.3)
	Median (IQR)	23 [19 , 28]	24 [19 , 29]	23 [19 , 28]
	Min - Max	8 , 58	8 , 58	11 , 51
Sugary Food Score	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	6.2 (2.9)	6.0 (2.7)	6.3 (3.0)
	Median (IQR)	5 [4 , 7]	5 [4 , 7]	5 [4 , 7]
	Min - Max	3 , 16	3 , 16	3 , 16
Fruits and Vegetable Score	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	2.3 (1.7)	2.3 (1.7)	2.3 (1.7)
	Median (IQR)	2 [2 , 4]	2 [2 , 4]	2 [2 , 4]
	Min - Max	1 , 6	1 , 6	1 , 6

Table 2.3.5
Summary of Portion Sizes, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Cheese	n (missing)	463 (25)	224 (9)	239 (16)
	Mean (SD)	4.4 (2.0)	4.4 (2.0)	4.4 (1.9)
	Median (IQR)	4 [3 , 6]	4 [3 , 6]	4 [3 , 6]
	Min - Max	1 , 8	1 , 8	1 , 8
Meat	n (missing)	482 (6)	228 (5)	254 (1)
	Mean (SD)	5.7 (1.3)	5.7 (1.3)	5.7 (1.3)
	Median (IQR)	6 [5 , 6]	6 [5 , 6]	6 [5 , 6]
	Min - Max	1 , 8	1 , 8	1 , 8
Pasta	n (missing)	472 (16)	222 (11)	250 (5)
	Mean (SD)	5.2 (1.7)	5.3 (1.6)	5.1 (1.7)
	Median (IQR)	5 [4 , 6]	5 [4 , 6]	5 [4 , 6]
	Min - Max	1 , 8	1 , 8	1 , 8
Chips	n (missing)	463 (25)	216 (17)	247 (8)
	Mean (SD)	4.1 (1.8)	4.1 (1.9)	4.0 (1.7)
	Median (IQR)	4 [3 , 5]	4 [3 , 5]	4 [3 , 5]
	Min - Max	1 , 8	1 , 8	1 , 8

Table 2.3.6
Summary of Other Diet or Health Measures, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Eating breakfast (times per week)	n (missing)	488 (0)	233 (0)	255 (0)
	No times	40 (8.2%)	23 (9.9%)	17 (6.7%)
	1-2 times	97 (19.9%)	47 (20.2%)	50 (19.6%)
	3-5 times	88 (18.0%)	40 (17.2%)	48 (18.8%)
	6 or more times	263 (53.9%)	123 (52.8%)	140 (54.9%)
Total alcohol consumption (units per week)	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	16.9 (17.4)	15.9 (16.9)	17.8 (17.8)
	Median (IQR)	12 [2 , 27]	11 [0 , 26]	14 [2 , 29]
	Min - Max	0 , 91	0 , 90	0 , 91
Ever smoked cigarettes	n (missing)	488 (0)	233 (0)	255 (0)
	No, I have never smoked	309 (63.3%)	145 (62.2%)	164 (64.3%)
	No, I have quit	142 (29.1%)	68 (29.2%)	74 (29.0%)
	Yes, I smoke now	37 (7.6%)	20 (8.6%)	17 (6.7%)
Number of longstanding illnesses	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	0.5 (0.9)	0.5 (0.8)	0.5 (0.9)
	Median (IQR)	0 [0 , 1]	0 [0 , 1]	0 [0 , 1]
	Min - Max	0 , 6	0 , 4	0 , 6

Table 2.3.7
Summary of Psychological Characteristics, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Negative affect PANAS [normalized]	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	1.7 (0.6)	1.7 (0.6)	1.6 (0.6)
	Median (IQR)	2 [1 , 2]	2 [1 , 2]	1 [1 , 2]
	Min - Max	1 , 4	1 , 4	1 , 4
Positive affect PANAS [normalized]	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	3.2 (0.7)	3.3 (0.7)	3.2 (0.6)
	Median (IQR)	3 [3 , 4]	3 [3 , 4]	3 [3 , 4]
	Min - Max	1 , 5	1 , 5	1 , 5
Rosenberg Self-Esteem Scale [normalized]	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	1.9 (0.5)	1.9 (0.5)	2.0 (0.5)
	Median (IQR)	2 [2 , 2]	2 [2 , 2]	2 [2 , 2]
	Min - Max	0 , 3	0 , 3	1 , 3
SF12 physical HRQoL	n (missing)	487 (1)	232 (1)	255 (0)
	Mean (SD)	47.7 (7.8)	47.3 (7.9)	48.2 (7.6)
	Median (IQR)	49 [44 , 53]	49 [43 , 53]	50 [44 , 53]
	Min - Max	20 , 62	21 , 62	20 , 62
SF12 mental HRQoL	n (missing)	487 (1)	232 (1)	255 (0)
	Mean (SD)	48.6 (9.8)	48.9 (10.1)	48.4 (9.5)
	Median (IQR)	52 [43 , 55]	52 [43 , 55]	50 [43 , 55]
	Min - Max	10 , 71	12 , 71	10 , 67
Conformity to masculine norms [normalized]	n (missing)	488 (0)	233 (0)	255 (0)
	Mean (SD)	1.2 (0.2)	1.2 (0.3)	1.1 (0.2)
	Median (IQR)	1 [1 , 1]	1 [1 , 1]	1 [1 , 1]
	Min - Max	0 , 2	0 , 2	0 , 2

Table 3.1
Weight at 12 Month and Change From Baseline, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)	P-Value
Weight(kg) 12 Month					
Baseline	N (missing)	688 (59)	333 (41)	355 (18)	
	Mean (sd)	109.26 (17.28)	109.71 (17.96)	108.84 (16.63)	
	(95% CI)	(107.96, 110.55)	(107.77, 111.64)	(107.10, 110.57)	
	Median (IQR)	107.2 (97.6, 117.9)	107.0 (97.7, 120.5)	107.3 (97.5, 116.8)	
	[Min, Max]	[71, 180]	[71, 180]	[73, 180]	
Follow up	N (missing)	688 (59)	333 (41)	355 (18)	-4.11 (-1.47, -6.75),
	Mean (sd)	106.27 (17.73)	104.14 (17.97)	108.26 (17.30)	0.0023
	(95% CI)	(104.94, 107.59)	(102.21, 106.08)	(106.45, 110.06)	
	Median (IQR)	103.7 (93.9, 116.1)	101.4 (91.6, 113.2)	106.8 (96.1, 116.8)	
	[Min, Max]	[58, 183]	[58, 164]	[71, 183]	
Change from baseline	N (missing)	688 (59)	333 (41)	355 (18)	-4.98 (-3.96, -6.01),
	Mean (sd)	-2.99 (7.17)	-5.56 (8.05)	-0.58 (5.18)	<0.0001*
	(95% CI)	(-3.53, -2.46)	(-6.43, -4.70)	(-1.12, -0.04)	
	Median (IQR)	-1.6 (-5.4, 1.3)	-3.7 (-9.6, -0.5)	0.1 (-2.6, 2.2)	
	[Min, Max]	[-39, 17]	[-37, 12]	[-39, 17]	
	P-Value	<0.0001**	<0.0001**	0.2762**	
Percent change from baseline (%)	N (missing)	688 (59)	333 (41)	355 (18)	-4.44 (-3.54, -5.33),
	Mean (sd)	-2.67 (6.30)	-4.96 (7.00)	-0.52 (4.64)	<0.0001*
	(95% CI)	(-3.14, -2.19)	(-5.71, -4.20)	(-1.00, -0.03)	
	Median (IQR)	-1.4 (-4.9, 1.3)	-3.4 (-8.8, -0.4)	0.1 (-2.4, 2.0)	
	[Min, Max]	[-31, 15]	[-31, 10]	[-31, 15]	
	P-Value	<0.0001**	<0.0001**	0.2738**	

Table 3.2
Weight at 12 Month and Change From Baseline, Overall and by Group

		All Subjects (N = 747)	Analysis (N = 488)	Not Followed Up (N = 259)	P-Value
Weight(kg) 12 Month					
Baseline	N (missing)	688 (59)	488 (0)	200 (59)	
	Mean (sd)	109.26 (17.28)	107.80 (17.07)	112.82 (17.30)	
	(95% CI)	(107.96, 110.55)	(106.28, 109.31)	(110.41, 115.24)	
	Median (IQR)	107.2 (97.6, 117.9)	106.2 (96.0, 116.1)	110.0 (101.4, 122.6)	
	[Min, Max]	[71, 180]	[71, 180]	[78, 174]	
Follow up	N (missing)	688 (59)	488 (0)	200 (59)	-4.97 (-2.07, -7.87),
	Mean (sd)	106.27 (17.73)	104.82 (17.30)	109.79 (18.31)	0.0008
	(95% CI)	(104.94, 107.59)	(103.28, 106.36)	(107.24, 112.34)	
	Median (IQR)	103.7 (93.9, 116.1)	102.1 (92.9, 114.3)	105.8 (99.1, 119.3)	
	[Min, Max]	[58, 183]	[58, 183]	[69, 178]	
Change from baseline	N (missing)	688 (59)	488 (0)	200 (59)	0.06 (1.24, -1.12),
	Mean (sd)	-2.99 (7.17)	-2.98 (7.05)	-3.03 (7.46)	0.8891*
	(95% CI)	(-3.53, -2.46)	(-3.60, -2.35)	(-4.07, -1.99)	
	Median (IQR)	-1.6 (-5.4, 1.3)	-1.5 (-5.2, 1.2)	-1.6 (-5.9, 1.7)	
	[Min, Max]	[-39, 17]	[-39, 17]	[-35, 16]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	
Percent change from baseline (%)	N (missing)	688 (59)	488 (0)	200 (59)	-0.01 (1.03, -1.05),
	Mean (sd)	-2.67 (6.30)	-2.67 (6.23)	-2.66 (6.48)	0.8605*
	(95% CI)	(-3.14, -2.19)	(-3.22, -2.11)	(-3.56, -1.75)	
	Median (IQR)	-1.4 (-4.9, 1.3)	-1.4 (-4.8, 1.2)	-1.5 (-5.2, 1.5)	
	[Min, Max]	[-31, 15]	[-31, 15]	[-31, 10]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 3.3
Weight at 12 Month and Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Weight(kg) 12 Month					
Baseline	N (missing)	488 (0)	233 (0)	255 (0)	
	Mean (sd)	107.80 (17.07)	108.28 (17.94)	107.36 (16.26)	
	(95% CI)	(106.28, 109.31)	(105.96, 110.59)	(105.35, 109.36)	
	Median (IQR)	106.2 (96.0, 116.1)	106.4 (96.2, 116.8)	105.5 (95.8, 116.0)	
	[Min, Max]	[71, 180]	[71, 180]	[73, 180]	
Follow up	N (missing)	488 (0)	233 (0)	255 (0)	-3.89 (-0.83, -6.96),
	Mean (sd)	104.82 (17.30)	102.79 (17.86)	106.68 (16.60)	0.0129
	(95% CI)	(103.28, 106.36)	(100.48, 105.09)	(104.63, 108.73)	
	Median (IQR)	102.1 (92.9, 114.3)	99.8 (90.3, 112.1)	105.4 (94.9, 115.6)	
	[Min, Max]	[58, 183]	[58, 164]	[71, 183]	
Change from baseline	N (missing)	488 (0)	233 (0)	255 (0)	-4.81 (-3.61, -6.02),
	Mean (sd)	-2.98 (7.05)	-5.49 (7.91)	-0.68 (5.20)	<0.0001*
	(95% CI)	(-3.60, -2.35)	(-6.51, -4.47)	(-1.32, -0.03)	
	Median (IQR)	-1.5 (-5.2, 1.2)	-3.5 (-10.3, -0.3)	-0.1 (-2.7, 1.9)	
	[Min, Max]	[-39, 17]	[-37, 10]	[-39, 17]	
	P-Value	<0.0001**	<0.0001**	0.1244**	
Percent change from baseline (%)	N (missing)	488 (0)	233 (0)	255 (0)	-4.39 (-3.33, -5.44),
	Mean (sd)	-2.67 (6.23)	-4.96 (6.90)	-0.57 (4.66)	<0.0001*
	(95% CI)	(-3.22, -2.11)	(-5.85, -4.07)	(-1.15, -0.00)	
	Median (IQR)	-1.4 (-4.8, 1.2)	-3.3 (-9.2, -0.4)	-0.1 (-2.5, 1.8)	
	[Min, Max]	[-31, 15]	[-27, 10]	[-31, 15]	
	P-Value	<0.0001**	<0.0001**	0.1425**	

Table 3.4
Weight at 12 Month and Change From Baseline, Overall and by Group

		All Subjects (N = 260)	Intervention (N = 141)	Control (N = 119)	P-Value
Weight(kg) 12 Month					
Baseline	N (missing)	200 (59)	100 (41)	100 (18)	
	Mean (sd)	112.82 (17.30)	113.04 (17.63)	112.61 (17.05)	
	(95% CI)	(110.41, 115.24)	(109.54, 116.54)	(109.22, 115.99)	
	Median (IQR)	110.0 (101.4, 122.6)	110.8 (101.6, 123.1)	108.9 (101.4, 121.2)	
	[Min, Max]	[78, 174]	[78, 163]	[82, 174]	
Follow up	N (missing)	200 (59)	100 (41)	100 (18)	-4.97 (0.10, -10.04),
	Mean (sd)	109.79 (18.31)	107.30 (17.92)	112.28 (18.45)	0.0547
	(95% CI)	(107.24, 112.34)	(103.75, 110.86)	(108.61, 115.94)	
	Median (IQR)	105.8 (99.1, 119.3)	104.0 (96.4, 118.2)	109.3 (101.1, 120.5)	
	[Min, Max]	[69, 178]	[69, 159]	[79, 178]	
Change from baseline	N (missing)	200 (59)	100 (41)	100 (18)	-5.40 (-3.46, -7.35),
	Mean (sd)	-3.03 (7.46)	-5.74 (8.40)	-0.33 (5.16)	<0.0001*
	(95% CI)	(-4.07, -1.99)	(-7.40, -4.07)	(-1.36, 0.69)	
	Median (IQR)	-1.6 (-5.9, 1.7)	-4.1 (-8.7, -0.7)	0.6 (-2.4, 2.5)	
	[Min, Max]	[-35, 16]	[-35, 12]	[-16, 16]	
	P-Value	<0.0001**	<0.0001**	0.7031**	
Percent change from baseline (%)	N (missing)	200 (59)	100 (41)	100 (18)	-4.57 (-2.88, -6.27),
	Mean (sd)	-2.66 (6.48)	-4.94 (7.26)	-0.37 (4.61)	<0.0001*
	(95% CI)	(-3.56, -1.75)	(-6.38, -3.50)	(-1.29, 0.54)	
	Median (IQR)	-1.5 (-5.2, 1.5)	-3.8 (-7.0, -0.7)	0.5 (-2.2, 2.2)	
	[Min, Max]	[-31, 10]	[-31, 8]	[-14, 10]	
	P-Value	<0.0001**	<0.0001**	0.8191**	

Table 4.1.1
Weight at 12 Month - Change and Percent Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Weight(kg) 12 Month					
Baseline	N (missing)	488 (0)	233 (0)	255 (0)	
	Mean (sd)	107.80 (17.07)	108.28 (17.94)	107.36 (16.26)	
	(95% CI)	(106.28, 109.31)	(105.96, 110.59)	(105.35, 109.36)	
	Median (IQR)	106.2 (96.0, 116.1)	106.4 (96.2, 116.8)	105.5 (95.8, 116.0)	
	[Min, Max]	[71, 180]	[71, 180]	[73, 180]	
Follow up	N (missing)	488 (0)	233 (0)	255 (0)	-3.89 (-0.83, -6.96),
	Mean (sd)	104.82 (17.30)	102.79 (17.86)	106.68 (16.60)	0.0129
	(95% CI)	(103.28, 106.36)	(100.48, 105.09)	(104.63, 108.73)	
	Median (IQR)	102.1 (92.9, 114.3)	99.8 (90.3, 112.1)	105.4 (94.9, 115.6)	
	[Min, Max]	[58, 183]	[58, 164]	[71, 183]	
Change from baseline	N (missing)	488 (0)	233 (0)	255 (0)	-4.81 (-3.61, -6.02),
	Mean (sd)	-2.98 (7.05)	-5.49 (7.91)	-0.68 (5.20)	<0.0001*
	(95% CI)	(-3.60, -2.35)	(-6.51, -4.47)	(-1.32, -0.03)	
	Median (IQR)	-1.5 (-5.2, 1.2)	-3.5 (-10.3, -0.3)	-0.1 (-2.7, 1.9)	
	[Min, Max]	[-39, 17]	[-37, 10]	[-39, 17]	
	P-Value	<0.0001**	<0.0001**	0.1244**	
Percent change from baseline (%)	N (missing)	488 (0)	233 (0)	255 (0)	-4.39 (-3.33, -5.44),
	Mean (sd)	-2.67 (6.23)	-4.96 (6.90)	-0.57 (4.66)	<0.0001*
	(95% CI)	(-3.22, -2.11)	(-5.85, -4.07)	(-1.15, -0.00)	
	Median (IQR)	-1.4 (-4.8, 1.2)	-3.3 (-9.2, -0.4)	-0.1 (-2.5, 1.8)	
	[Min, Max]	[-31, 15]	[-27, 10]	[-31, 15]	
	P-Value	<0.0001**	<0.0001**	0.1425**	

Table 4.1.2
Weight at FU - Change and Percent Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Weight(kg) FU					
Baseline	N (missing)	488 (0)	233 (0)	255 (0)	
	Mean (sd)	107.80 (17.07)	108.28 (17.94)	107.36 (16.26)	
	(95% CI)	(106.28, 109.31)	(105.96, 110.59)	(105.35, 109.36)	
	Median (IQR)	106.2 (96.0, 116.1)	106.4 (96.2, 116.8)	105.5 (95.8, 116.0)	
	[Min, Max]	[71, 180]	[71, 180]	[73, 180]	
Follow up	N (missing)	488 (0)	233 (0)	255 (0)	0.73 (3.86, -2.40),
	Mean (sd)	105.00 (17.56)	105.38 (18.18)	104.65 (17.00)	0.6470
	(95% CI)	(103.44, 106.56)	(103.03, 107.73)	(102.55, 106.75)	
	Median (IQR)	102.6 (92.6, 114.5)	102.6 (92.9, 114.1)	102.4 (92.0, 114.7)	
	[Min, Max]	[65, 193]	[65, 166]	[70, 193]	
Change from baseline	N (missing)	488 (0)	233 (0)	255 (0)	-0.19 (1.35, -1.73),
	Mean (sd)	-2.80 (8.64)	-2.90 (8.70)	-2.71 (8.60)	0.7421*
	(95% CI)	(-3.57, -2.03)	(-4.02, -1.78)	(-3.77, -1.65)	
	Median (IQR)	-1.9 (-7.3, 2.3)	-2.3 (-7.2, 2.3)	-1.4 (-7.5, 2.2)	
	[Min, Max]	[-62, 24]	[-62, 20]	[-43, 24]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	
Percent change from baseline (%)	N (missing)	488 (0)	233 (0)	255 (0)	-0.16 (1.17, -1.49),
	Mean (sd)	-2.44 (7.44)	-2.52 (7.16)	-2.36 (7.69)	0.7266*
	(95% CI)	(-3.10, -1.78)	(-3.45, -1.60)	(-3.31, -1.41)	
	Median (IQR)	-1.7 (-6.6, 2.1)	-2.1 (-6.6, 2.1)	-1.3 (-6.7, 2.1)	
	[Min, Max]	[-35, 23]	[-35, 17]	[-34, 23]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Figure 4.1.1
Mean Weight by Treatment and Visit

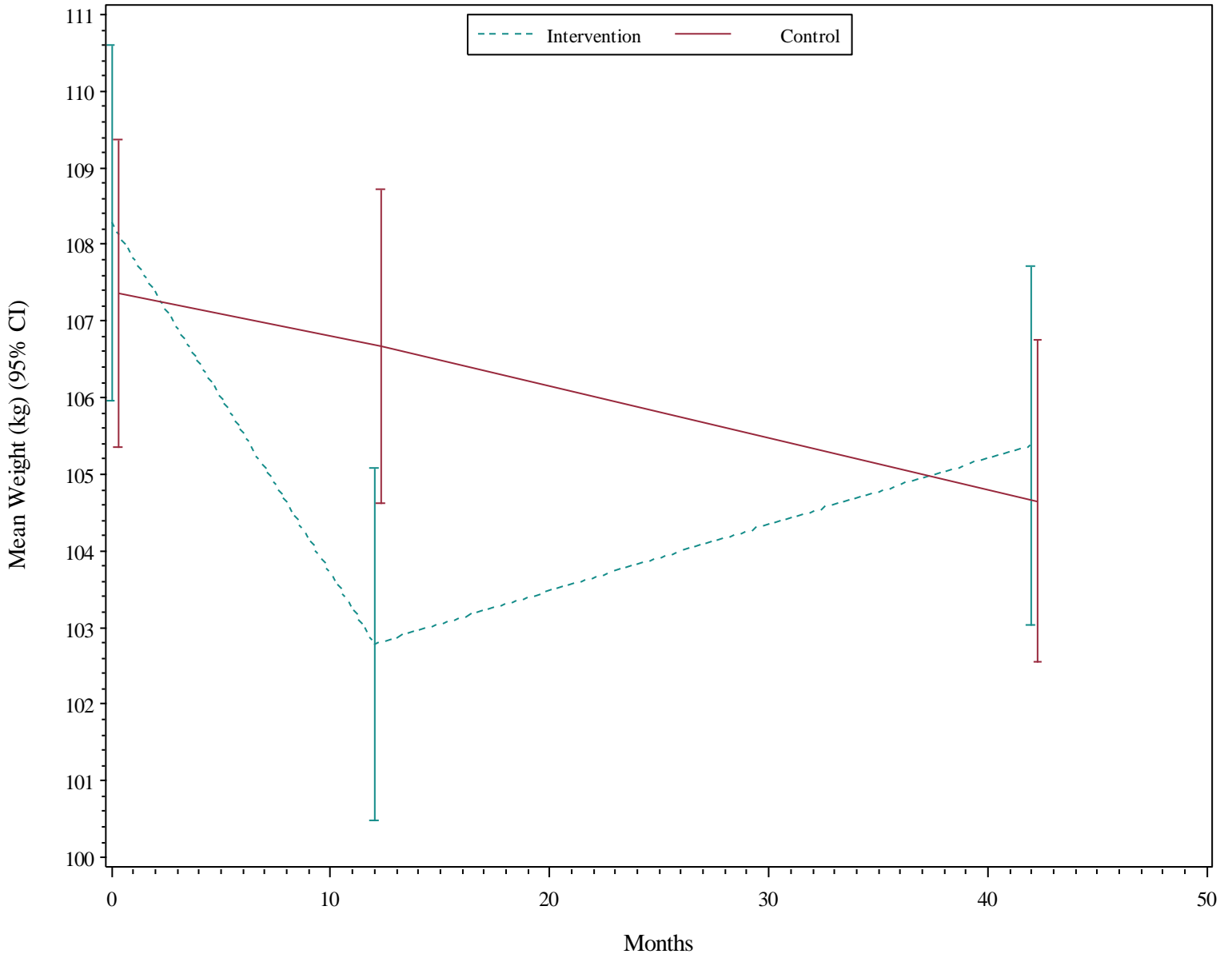


Figure 4.1.2
Mean Change in Weight by Treatment and Visit

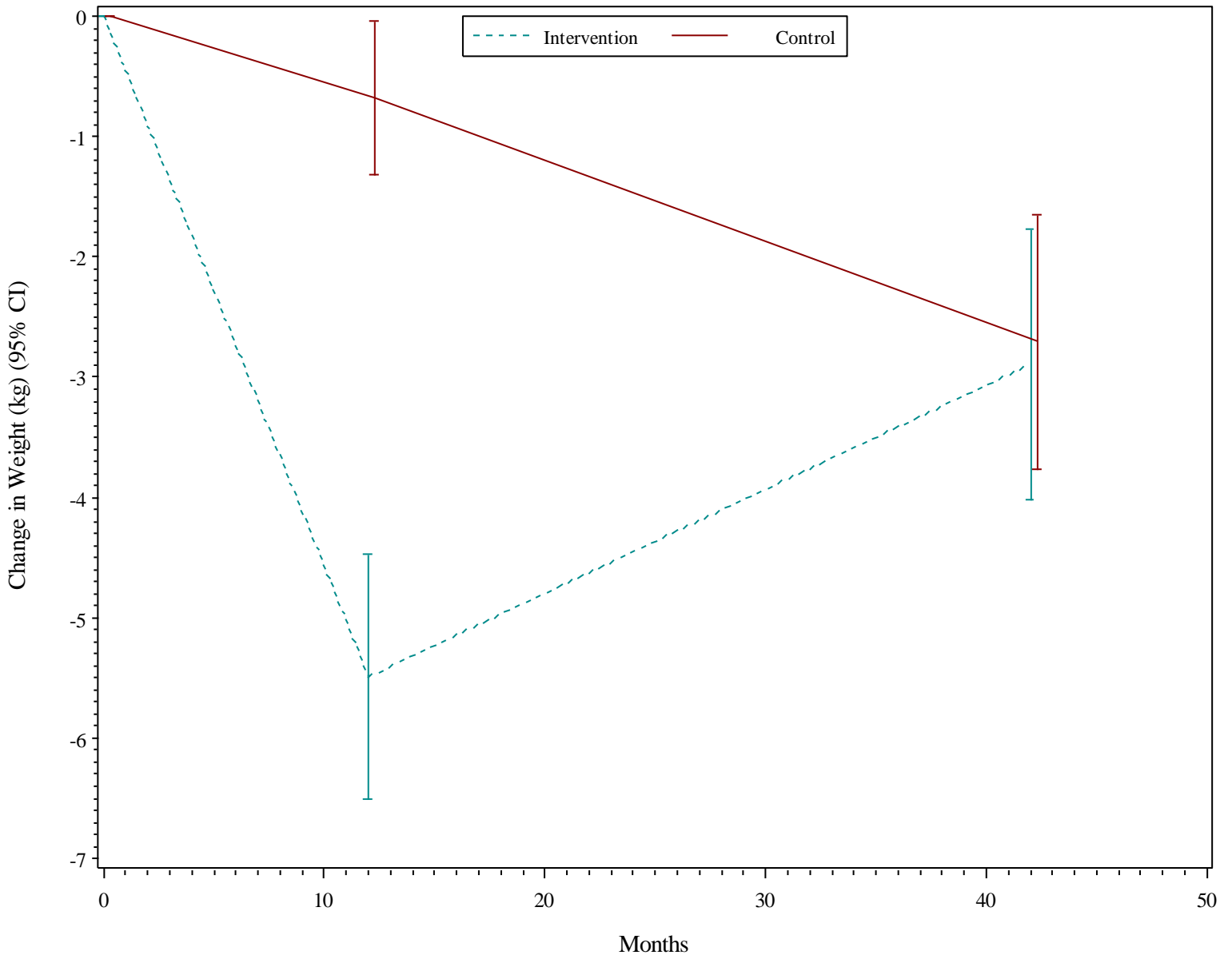


Table 4.2.1
Weight at 12 Month - Change and Percent Change From Baseline, Overall and by Group

		All Subjects (N = 451)	Intervention (N = 214)	Control (N = 237)	P-Value
Weight(kg) 12 Month (Measured)					
Baseline	N (missing)	451 (0)	214 (0)	237 (0)	
	Mean (sd)	107.60 (17.04)	108.09 (18.24)	107.16 (15.90)	
	(95% CI)	(106.02, 109.18)	(105.63, 110.55)	(105.13, 109.20)	
	Median (IQR)	105.5 (96.0, 116.0)	105.7 (96.2, 116.5)	105.5 (95.9, 115.9)	
	[Min, Max]	[71, 180]	[71, 180]	[73, 180]	
Follow up	N (missing)	451 (0)	214 (0)	237 (0)	-3.96 (-0.80, -7.12),
	Mean (sd)	104.58 (17.15)	102.50 (18.13)	106.46 (16.01)	0.0143
	(95% CI)	(103.00, 106.17)	(100.06, 104.95)	(104.41, 108.51)	
	Median (IQR)	101.9 (92.9, 113.8)	99.5 (90.3, 111.4)	105.5 (95.1, 115.4)	
	[Min, Max]	[58, 183]	[58, 164]	[71, 183]	
Change from baseline	N (missing)	451 (0)	214 (0)	237 (0)	-4.88 (-3.63, -6.14),
	Mean (sd)	-3.02 (7.05)	-5.59 (7.91)	-0.70 (5.18)	<0.0001*
	(95% CI)	(-3.67, -2.37)	(-6.65, -4.52)	(-1.36, -0.04)	
	Median (IQR)	-1.5 (-5.2, 1.2)	-3.5 (-9.7, -0.4)	-0.1 (-2.6, 1.9)	
	[Min, Max]	[-39, 17]	[-37, 10]	[-39, 17]	
	P-Value	<0.0001**	<0.0001**	0.1546**	
Percent change from baseline (%)	N (missing)	451 (0)	214 (0)	237 (0)	-4.49 (-3.39, -5.58),
	Mean (sd)	-2.70 (6.20)	-5.06 (6.86)	-0.57 (4.62)	<0.0001*
	(95% CI)	(-3.28, -2.13)	(-5.98, -4.14)	(-1.16, 0.02)	
	Median (IQR)	-1.4 (-4.8, 1.0)	-3.4 (-9.0, -0.4)	-0.1 (-2.4, 1.8)	
	[Min, Max]	[-31, 15]	[-27, 10]	[-31, 15]	
	P-Value	<0.0001**	<0.0001**	0.1865**	

Table 4.2.2
Weight at FU - Change and Percent Change From Baseline, Overall and by Group

		All Subjects (N = 451)	Intervention (N = 214)	Control (N = 237)	P-Value
Weight(kg) FU (Measured)					
Baseline	N (missing)	451 (0)	214 (0)	237 (0)	
	Mean (sd)	107.60 (17.04)	108.09 (18.24)	107.16 (15.90)	
	(95% CI)	(106.02, 109.18)	(105.63, 110.55)	(105.13, 109.20)	
	Median (IQR)	105.5 (96.0, 116.0)	105.7 (96.2, 116.5)	105.5 (95.9, 115.9)	
	[Min, Max]	[71, 180]	[71, 180]	[73, 180]	
Follow up	N (missing)	451 (0)	214 (0)	237 (0)	0.71 (3.93, -2.52),
	Mean (sd)	104.70 (17.39)	105.07 (18.29)	104.36 (16.56)	0.6662
	(95% CI)	(103.09, 106.31)	(102.60, 107.53)	(102.24, 106.48)	
	Median (IQR)	102.3 (92.6, 114.5)	102.5 (92.9, 114.1)	102.2 (92.1, 114.6)	
	[Min, Max]	[65, 193]	[65, 166]	[70, 193]	
Change from baseline	N (missing)	451 (0)	214 (0)	237 (0)	-0.22 (1.38, -1.82),
	Mean (sd)	-2.90 (8.60)	-3.02 (8.62)	-2.80 (8.61)	0.7224*
	(95% CI)	(-3.70, -2.11)	(-4.18, -1.86)	(-3.90, -1.70)	
	Median (IQR)	-1.8 (-7.3, 2.2)	-2.2 (-7.2, 2.2)	-1.3 (-7.4, 2.1)	
	[Min, Max]	[-62, 24]	[-62, 20]	[-43, 24]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	
Percent change from baseline (%)	N (missing)	451 (0)	214 (0)	237 (0)	-0.19 (1.18, -1.56),
	Mean (sd)	-2.53 (7.38)	-2.63 (7.07)	-2.44 (7.66)	0.7189*
	(95% CI)	(-3.21, -1.85)	(-3.58, -1.67)	(-3.42, -1.46)	
	Median (IQR)	-1.6 (-6.6, 2.0)	-2.1 (-6.6, 2.0)	-1.2 (-6.5, 2.0)	
	[Min, Max]	[-35, 23]	[-35, 16]	[-34, 23]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Figure 4.2.1
Mean Weight by Treatment and Visit

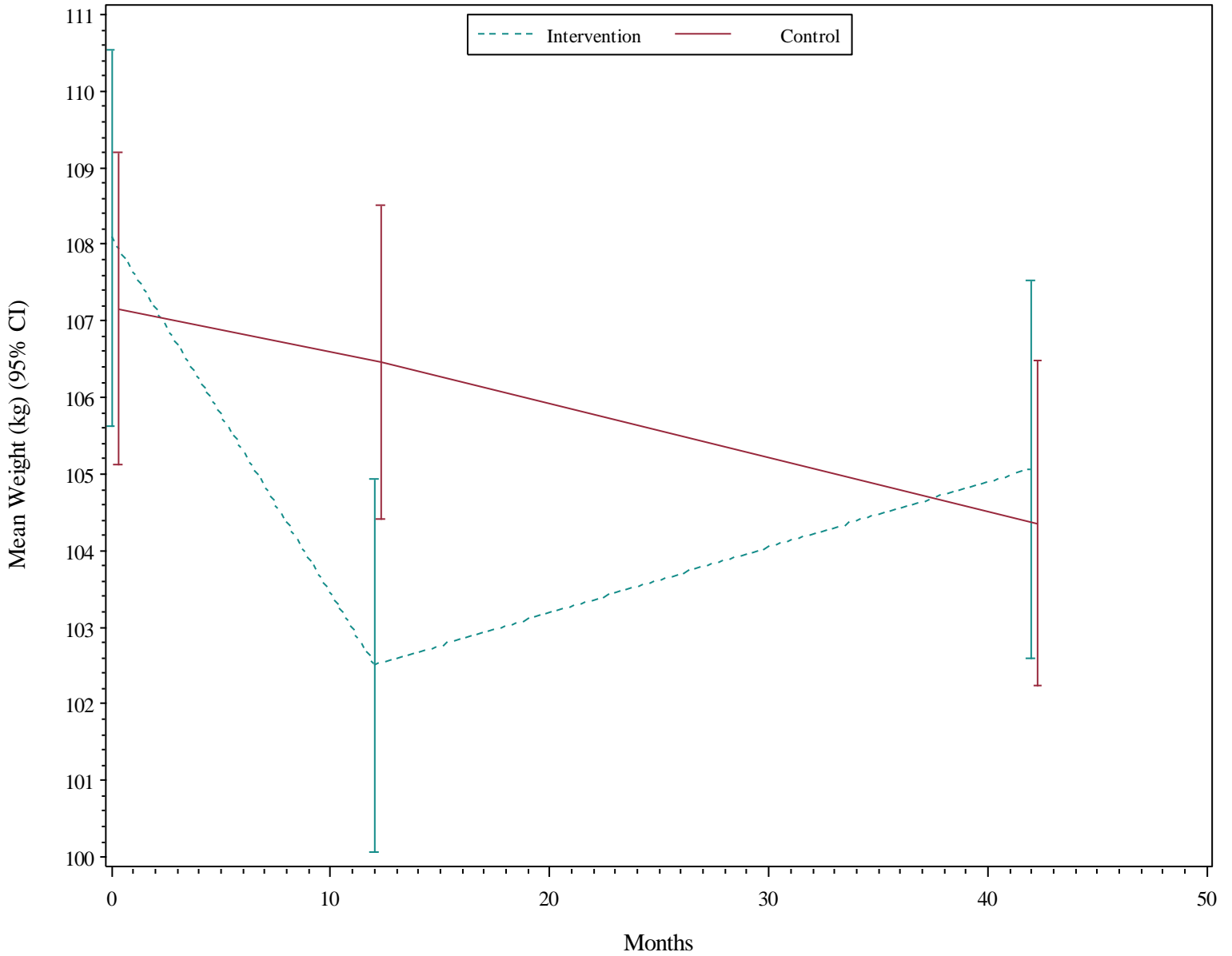


Figure 4.2.2
Mean Change in Weight by Treatment and Visit

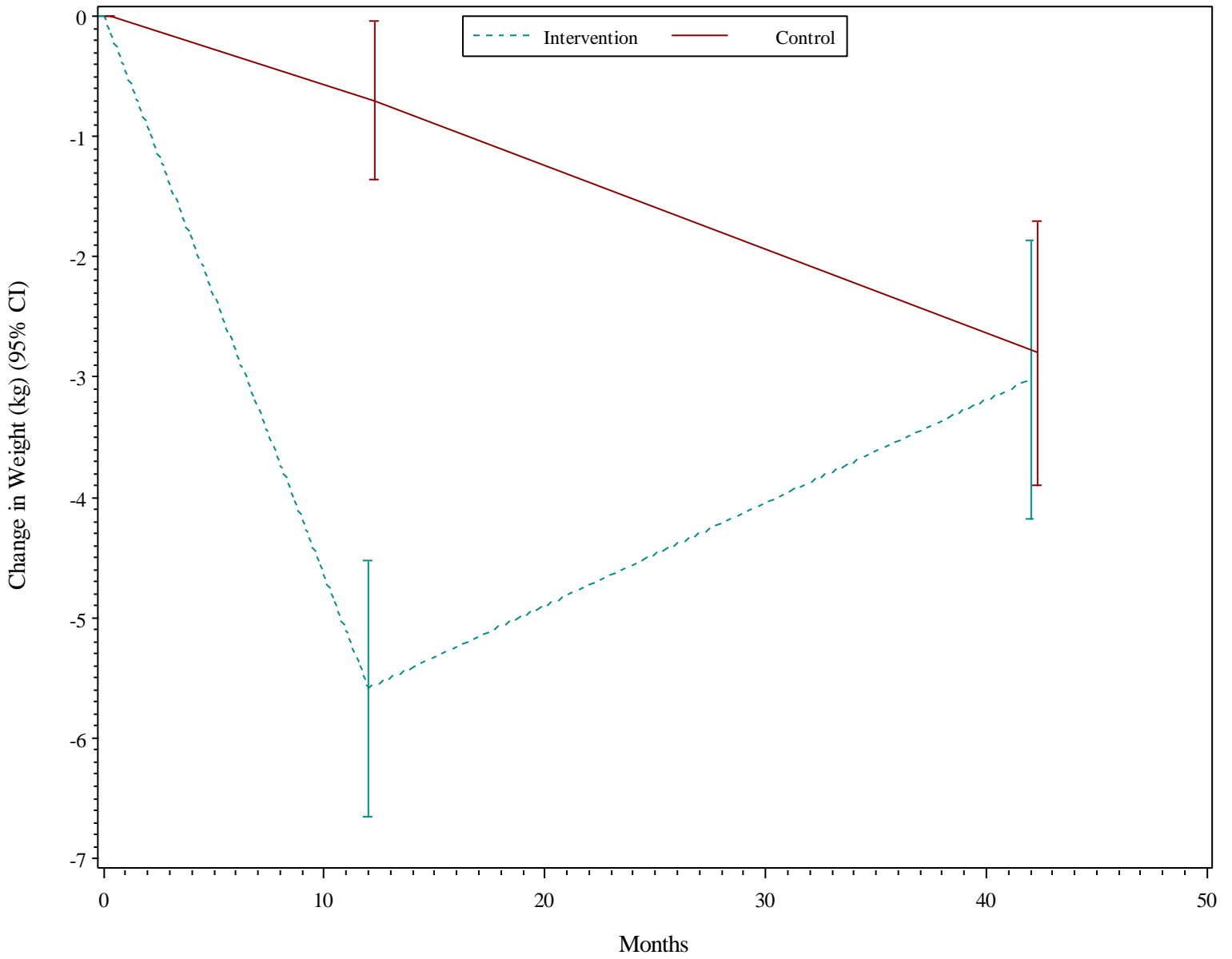


Table 4.3.1
Weight at 12 Month - Change and Percent Change From Baseline, Overall and by Group

		All Subjects (N = 37)	Intervention (N = 19)	Control (N = 18)	P-Value
Weight(kg) 12 Month (Self Report)					
Baseline	N (missing)	37 (0)	19 (0)	18 (0)	
	Mean (sd)	110.16 (17.48)	110.39 (14.33)	109.93 (20.73)	
	(95% CI)	(104.34, 115.99)	(103.48, 117.30)	(99.62, 120.23)	
	Median (IQR)	107.3 (94.2, 122.5)	109.4 (94.2, 126.0)	106.3 (93.1, 122.3)	
	[Min, Max]	[85, 157]	[89, 131]	[85, 157]	
Follow up	N (missing)	37 (0)	19 (0)	18 (0)	-3.61 (9.27, -16.49),
	Mean (sd)	107.72 (19.11)	105.97 (14.45)	109.58 (23.35)	0.5732
	(95% CI)	(101.35, 114.10)	(99.00, 112.93)	(97.97, 121.19)	
	Median (IQR)	103.9 (91.9, 118.3)	111.6 (91.0, 118.3)	103.2 (91.9, 124.1)	
	[Min, Max]	[81, 166]	[81, 128]	[82, 166]	
Change from baseline	N (missing)	37 (0)	19 (0)	18 (0)	-4.07 (0.57, -8.72),
	Mean (sd)	-2.44 (7.16)	-4.42 (7.97)	-0.35 (5.69)	0.1862*
	(95% CI)	(-4.83, -0.05)	(-8.26, -0.58)	(-3.18, 2.48)	
	Median (IQR)	-1.8 (-5.7, 1.9)	-2.7 (-12.3, 1.9)	-0.6 (-4.5, 2.4)	
	[Min, Max]	[-18, 11]	[-18, 8]	[-11, 11]	
	P-Value	0.0676**	0.0446**	0.6862**	
Percent change from baseline (%)	N (missing)	37 (0)	19 (0)	18 (0)	-3.23 (1.09, -7.55),
	Mean (sd)	-2.26 (6.59)	-3.83 (7.44)	-0.60 (5.26)	0.2945*
	(95% CI)	(-4.46, -0.06)	(-7.42, -0.24)	(-3.22, 2.01)	
	Median (IQR)	-1.5 (-4.8, 1.6)	-2.1 (-10.8, 1.9)	-0.7 (-4.6, 1.6)	
	[Min, Max]	[-16, 10]	[-16, 8]	[-12, 10]	
	P-Value	0.0781**	0.0663**	0.7467**	

Table 4.3.2
Weight at FU - Change and Percent Change From Baseline, Overall and by Group

		All Subjects (N = 37)	Intervention (N = 19)	Control (N = 18)	P-Value
Weight(kg) FU (Self Report)					
Baseline	N (missing)	37 (0)	19 (0)	18 (0)	
	Mean (sd)	110.16 (17.48)	110.39 (14.33)	109.93 (20.73)	
	(95% CI)	(104.34, 115.99)	(103.48, 117.30)	(99.62, 120.23)	
	Median (IQR)	107.3 (94.2, 122.5)	109.4 (94.2, 126.0)	106.3 (93.1, 122.3)	
	[Min, Max]	[85, 157]	[89, 131]	[85, 157]	
Follow up	N (missing)	37 (0)	19 (0)	18 (0)	0.42 (13.54, -12.70),
	Mean (sd)	108.67 (19.37)	108.87 (16.87)	108.46 (22.21)	0.9488
	(95% CI)	(102.21, 115.13)	(100.74, 117.00)	(97.41, 119.50)	
	Median (IQR)	106.1 (93.9, 115.2)	108.4 (95.0, 115.2)	105.7 (89.8, 117.5)	
	[Min, Max]	[80, 157]	[84, 146]	[80, 157]	
Change from baseline	N (missing)	37 (0)	19 (0)	18 (0)	-0.04 (6.10, -6.19),
	Mean (sd)	-1.49 (9.07)	-1.52 (9.68)	-1.47 (8.66)	0.9394*
	(95% CI)	(-4.52, 1.53)	(-6.18, 3.15)	(-5.78, 2.83)	
	Median (IQR)	-2.6 (-8.6, 4.0)	-2.5 (-8.8, 5.3)	-2.8 (-8.6, 4.0)	
	[Min, Max]	[-18, 19]	[-18, 19]	[-16, 16]	
	P-Value	0.2539**	0.4413**	0.3927**	
Percent change from baseline (%)	N (missing)	37 (0)	19 (0)	18 (0)	-0.01 (5.50, -5.51),
	Mean (sd)	-1.33 (8.12)	-1.33 (8.26)	-1.33 (8.22)	0.9879*
	(95% CI)	(-4.04, 1.38)	(-5.31, 2.65)	(-5.41, 2.76)	
	Median (IQR)	-2.4 (-7.7, 3.8)	-2.7 (-8.7, 4.7)	-2.2 (-7.7, 3.8)	
	[Min, Max]	[-14, 17]	[-14, 17]	[-14, 14]	
	P-Value	0.2476**	0.4180**	0.4423**	

Figure 4.3.1
Mean Weight by Treatment and Visit

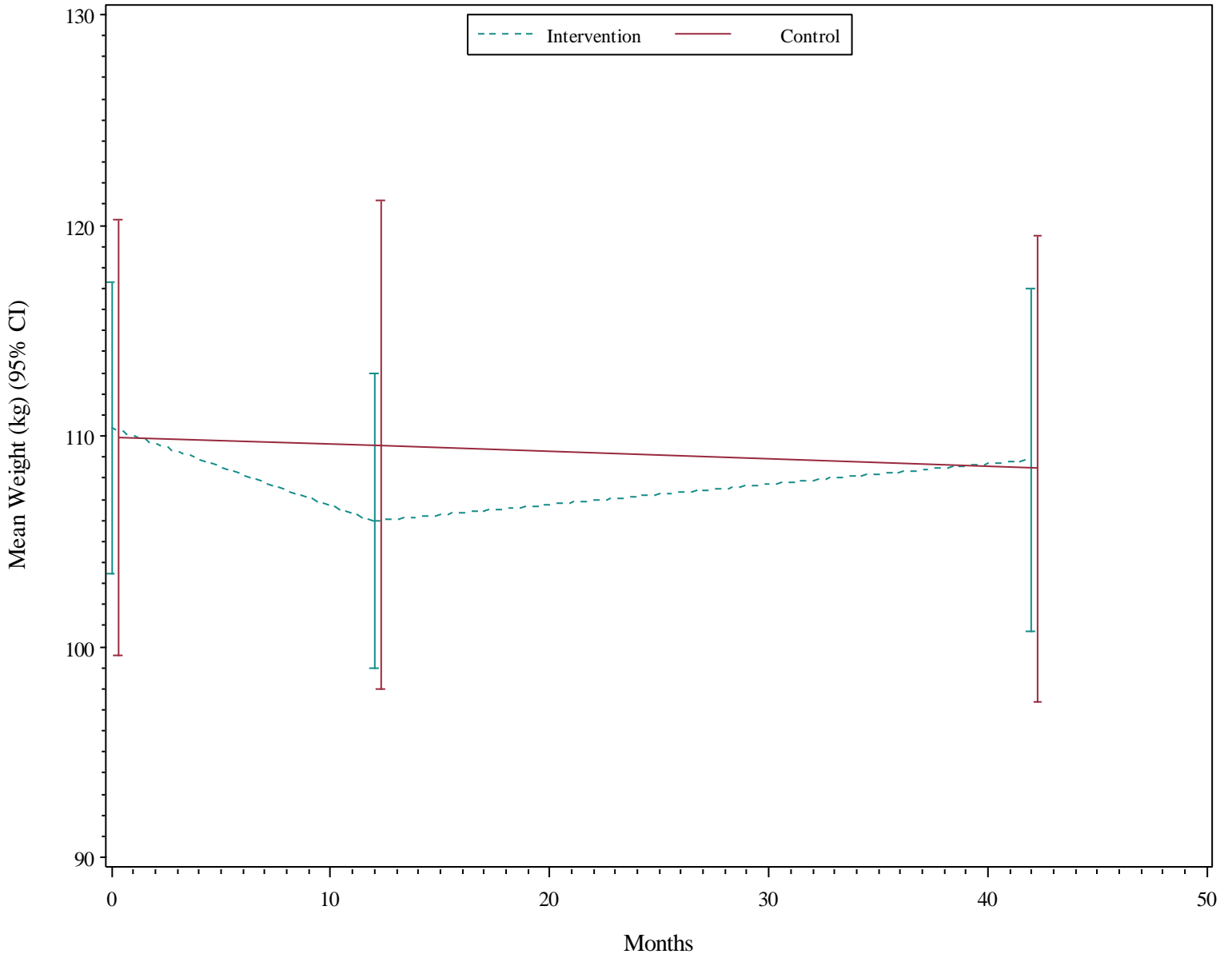


Figure 4.3.2
Mean Change in Weight by Treatment and Visit

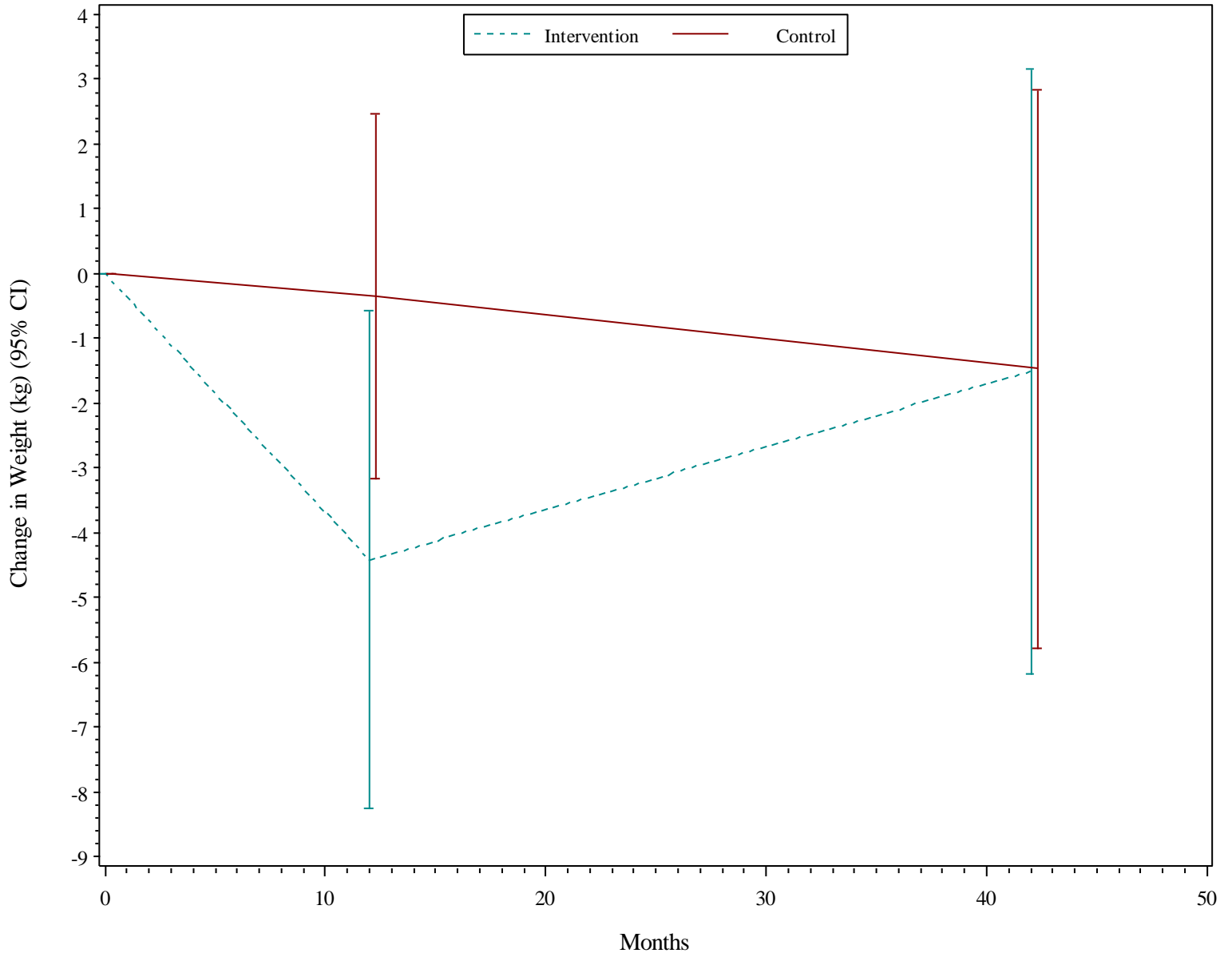


Table 4.4.1
Mixed Effects Repeated Linear Regression Model and Adjusted Mean Change in Weight, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Weight (1 kg)	-0.103 (-0.154, -0.051)	<0.001
	Follow-Up vs End-of-RCT	2.594 (1.607, 3.580)	<0.001
	Visit	Mean Change in Weight (kg)	
	End-of-RCT	-5.491 (-6.536, -4.446)	<0.001
	Follow-Up	-2.897 (-3.942, -1.852)	<0.001
	Difference	2.594 (1.607, 3.580)	<0.001
Control	Fixed Effects		
	Baseline Weight (1 kg)	-0.062 (-0.106, -0.017)	0.007
	Follow-Up vs End-of-RCT	-2.030 (-2.979, -1.080)	<0.001
	Visit	Mean Change in Weight (kg)	
	End-of-RCT	-0.676 (-1.543, 0.190)	0.126
	Follow-Up	-2.706 (-3.573, -1.839)	<0.001
	Difference	-2.030 (-2.979, -1.080)	<0.001
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.085 (-0.120, -0.051)	<0.001
	Follow-Up vs End-of-RCT	0.178 (-0.535, 0.890)	0.625
	Interaction Effect		
	Treatment * Visit	4.623 (3.256, 5.991)	<0.001

Note: Intervention and control groups are analysed separately, then combined to estimate the interaction effect and overall visit effect (two separate models).

Table 4.4.2
Mixed Effects Repeated Linear Regression Model and Adjusted Mean Percent Change in Weight, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Weight (1 kg)	-0.046 (-0.091, -0.001)	0.043
	Follow-Up vs End-of-RCT	2.438 (1.610, 3.266)	<0.001
	Visit	Mean Percent Change in Weight (%)	
	End-of-RCT	-4.952 (-5.947, -3.957)	<0.001
	Follow-Up	-2.514 (-3.509, -1.519)	<0.001
	Difference	2.438 (1.610, 3.266)	<0.001
Control	Fixed Effects		
	Baseline Weight (1 kg)	-0.044 (-0.084, -0.004)	0.031
	Follow-Up vs End-of-RCT	-1.787 (-2.654, -0.920)	<0.001
	Visit	Mean Percent Change in Weight (%)	
	End-of-RCT	-0.575 (-1.353, 0.204)	0.148
	Follow-Up	-2.362 (-3.140, -1.584)	<0.001
	Difference	-1.787 (-2.654, -0.920)	<0.001
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.046 (-0.077, -0.016)	0.003
	Follow-Up vs End-of-RCT	0.230 (-0.398, 0.859)	0.472
	Interaction Effect		
	Treatment * Visit	4.225 (3.023, 5.428)	<0.001

Note: Intervention and control groups are analysed separately, then combined to estimate the interaction effect and overall visit effect (two separate models).

Figure 4.4
Adjusted Mean Change in Weight by Treatment and Visit From Mixed Effects Model

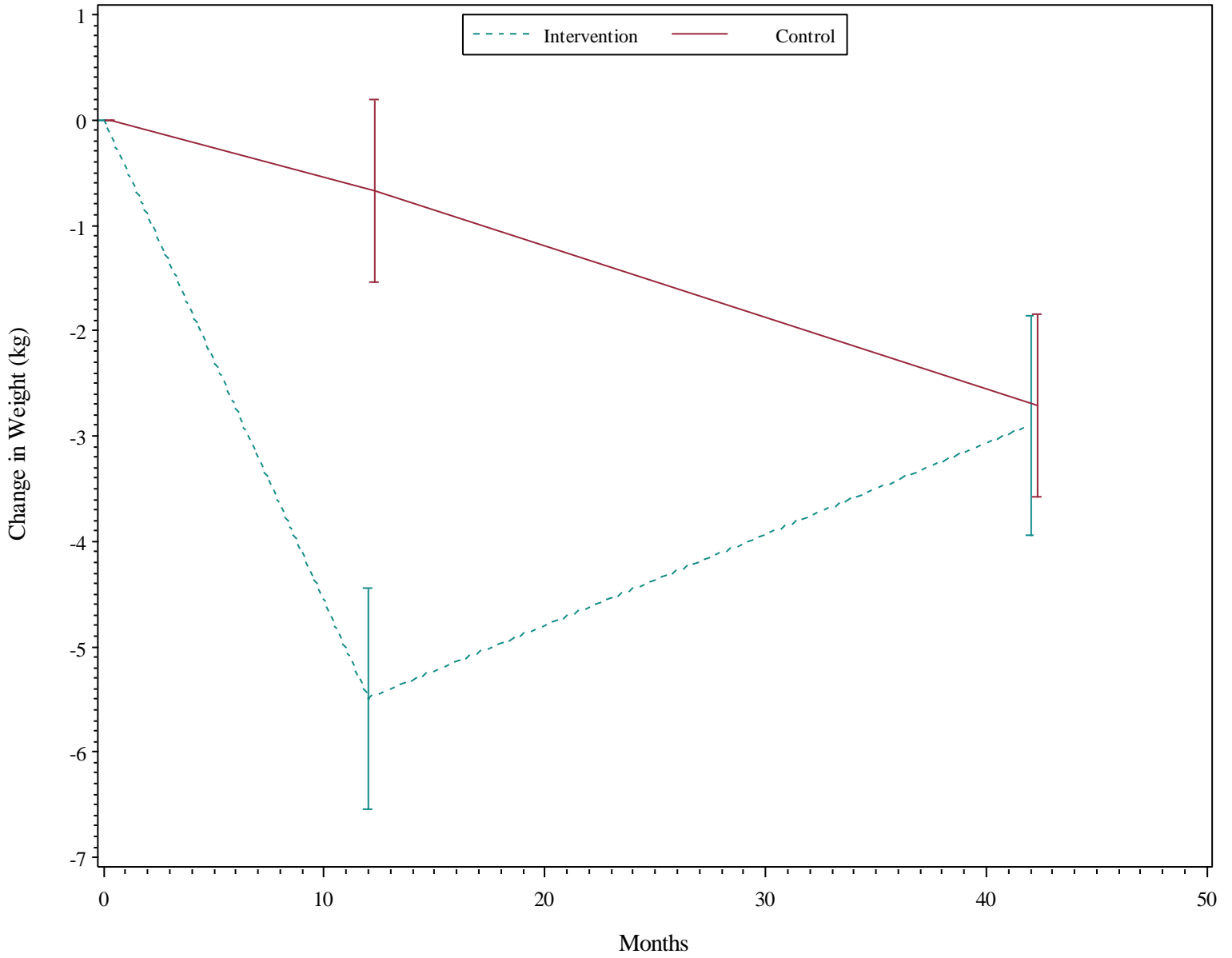


Table 4.5.1
Weight at FU - Change and Percent Change From Sensitivity Baseline 1, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Weight(kg) FU - Sensitivity 1					
Sensitivity Baseline 1	N (missing)	488 (0)	233 (0)	255 (0)	
	Mean (sd)	107.44 (17.25)	108.28 (17.94)	106.68 (16.60)	
	(95% CI)	(105.91, 108.98)	(105.96, 110.59)	(104.63, 108.73)	
	Median (IQR)	105.8 (95.7, 116.1)	106.4 (96.2, 116.8)	105.4 (94.9, 115.6)	
	[Min, Max]	[71, 183]	[71, 180]	[71, 183]	
Follow up	N (missing)	488 (0)	233 (0)	255 (0)	0.73 (3.86, -2.40),
	Mean (sd)	105.00 (17.56)	105.38 (18.18)	104.65 (17.00)	0.6470
	(95% CI)	(103.44, 106.56)	(103.03, 107.73)	(102.55, 106.75)	
	Median (IQR)	102.6 (92.6, 114.5)	102.6 (92.9, 114.1)	102.4 (92.0, 114.7)	
	[Min, Max]	[65, 193]	[65, 166]	[70, 193]	
Change from sensitivity baseline 1	N (missing)	488 (0)	233 (0)	255 (0)	-0.87 (0.59, -2.33),
	Mean (sd)	-2.44 (8.20)	-2.90 (8.70)	-2.03 (7.72)	0.2435
	(95% CI)	(-3.17, -1.71)	(-4.02, -1.78)	(-2.98, -1.08)	
	Median (IQR)	-1.9 (-6.5, 2.3)	-2.3 (-7.2, 2.3)	-1.5 (-5.7, 2.3)	
	[Min, Max]	[-62, 20]	[-62, 20]	[-30, 18]	
Percent change from sensitivity baseline 1 (%)	N (missing)	488 (0)	233 (0)	255 (0)	-0.79 (0.48, -2.06),
	Mean (sd)	-2.11 (7.14)	-2.52 (7.16)	-1.73 (7.10)	0.2241
	(95% CI)	(-2.74, -1.48)	(-3.45, -1.60)	(-2.61, -0.86)	
	Median (IQR)	-1.8 (-6.0, 2.2)	-2.1 (-6.6, 2.1)	-1.4 (-5.3, 2.4)	
	[Min, Max]	[-35, 20]	[-35, 17]	[-27, 20]	

Note: Sensitivity-baseline defined as month 0, year 0 for the FFIT RCT intervention group and as month 12, year 0 (ie. the end of the FFIT RCT) for the comparison group.

Table 4.5.2
Weight at FU - Change and Percent Change From Sensitivity Baseline 2, Overall and by Group

		All Subjects (N = 461)	Intervention (N = 233)	Control (N = 228)	P-Value
Weight(kg) FU - Sensitivity 2					
Sensitivity Baseline 2	N (missing)	461 (0)	233 (0)	228 (0)	
	Mean (sd)	107.96 (17.29)	108.28 (17.94)	107.63 (16.63)	
	(95% CI)	(106.37, 109.54)	(105.96, 110.59)	(105.46, 109.80)	
	Median (IQR)	106.5 (96.1, 116.6)	106.4 (96.2, 116.8)	106.9 (96.1, 116.2)	
	[Min, Max]	[71, 183]	[71, 180]	[71, 183]	
Follow up	N (missing)	461 (0)	233 (0)	228 (0)	0.41 (3.66, -2.84),
	Mean (sd)	105.18 (17.75)	105.38 (18.18)	104.97 (17.33)	0.8054
	(95% CI)	(103.55, 106.80)	(103.03, 107.73)	(102.71, 107.23)	
	Median (IQR)	102.7 (92.8, 114.5)	102.6 (92.9, 114.1)	103.0 (92.4, 114.7)	
	[Min, Max]	[65, 193]	[65, 166]	[70, 193]	
Change from sensitivity baseline 2	N (missing)	461 (0)	233 (0)	228 (0)	-0.24 (1.25, -1.73),
	Mean (sd)	-2.78 (8.15)	-2.90 (8.70)	-2.65 (7.56)	0.7493
	(95% CI)	(-3.52, -2.03)	(-4.02, -1.78)	(-3.64, -1.67)	
	Median (IQR)	-2.1 (-6.6, 2.0)	-2.3 (-7.2, 2.3)	-2.0 (-6.2, 2.0)	
	[Min, Max]	[-62, 20]	[-62, 20]	[-30, 18]	
Percent change from sensitivity baseline 2 (%)	N (missing)	461 (0)	233 (0)	228 (0)	-0.15 (1.13, -1.44),
	Mean (sd)	-2.45 (7.00)	-2.52 (7.16)	-2.37 (6.84)	0.8149
	(95% CI)	(-3.09, -1.81)	(-3.45, -1.60)	(-3.26, -1.48)	
	Median (IQR)	-1.9 (-6.1, 1.9)	-2.1 (-6.6, 2.1)	-1.9 (-5.5, 1.8)	
	[Min, Max]	[-35, 20]	[-35, 17]	[-27, 20]	

Note: Sensitivity-baseline defined as month 0, year 0 for the FFIT RCT intervention group and as month 12, year 0 (ie. the end of the FFIT RCT) for the comparison group. In addition, those in the comparison group who had lost at least 5% of their baseline weight by month 12, year 0 are excluded.

Table 4.5.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Weight, Overall and by Group

		Estimate (95% C.I.)	P-Value
Sensitivity 1	Fixed Effects		
	Intervention vs Control	-0.717 (-2.151, 0.717)	0.326
	Baseline Weight (1 kg)	-0.094 (-0.136, -0.053)	<0.001
	Treatment Group	Mean Change in Weight (kg)	
	Control	-2.102 (-3.092, -1.111)	<0.001
	Intervention	-2.819 (-3.855, -1.783)	<0.001
	Difference	-0.717 (-2.151, 0.717)	0.326
Sensitivity 2	Fixed Effects		
	Intervention vs Control	-0.188 (-1.659, 1.283)	0.802
	Baseline Weight (1 kg)	-0.084 (-0.127, -0.042)	<0.001
	Treatment Group	Mean Change in Weight (kg)	
	Control	-2.682 (-3.728, -1.637)	<0.001
	Intervention	-2.870 (-3.905, -1.836)	<0.001
	Difference	-0.188 (-1.659, 1.283)	0.802

Note: For sensitivity analysis 1, baseline for the control group is defined as end-of-study. For sensitivity analysis 2, the same criteria is used except those in the control group who had lost more than 5% of their baseline weight are excluded.

Table 5.1.1
BMI at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
BMI (kg/m²) 12 Month					
Baseline	N (missing)	488 (0)	233 (0)	255 (0)	
	Mean (sd)	34.93 (4.90)	35.03 (5.11)	34.84 (4.71)	
	(95% CI)	(34.49, 35.37)	(34.37, 35.69)	(34.26, 35.42)	
	Median (IQR)	33.9 (31.3, 37.5)	33.9 (31.1, 37.6)	34.0 (31.3, 36.8)	
	[Min, Max]	[28, 56]	[28, 56]	[28, 55]	
Follow up	N (missing)	488 (0)	233 (0)	255 (0)	-1.35 (-0.46, -2.24),
	Mean (sd)	33.97 (5.05)	33.26 (5.23)	34.61 (4.79)	0.0030
	(95% CI)	(33.52, 34.42)	(32.59, 33.94)	(34.02, 35.20)	
	Median (IQR)	33.2 (30.5, 36.3)	32.1 (29.8, 35.3)	34.0 (31.1, 36.8)	
	[Min, Max]	[23, 55]	[23, 55]	[26, 54]	
Change from baseline	N (missing)	488 (0)	233 (0)	255 (0)	-1.55 (-1.16, -1.94),
	Mean (sd)	-0.96 (2.28)	-1.77 (2.54)	-0.22 (1.72)	<0.0001*
	(95% CI)	(-1.17, -0.76)	(-2.10, -1.44)	(-0.43, -0.01)	
	Median (IQR)	-0.5 (-1.7, 0.4)	-1.2 (-3.3, -0.1)	-0.0 (-0.9, 0.6)	
	[Min, Max]	[-14, 5]	[-11, 3]	[-14, 5]	
	P-Value	<0.0001**	<0.0001**	0.1244**	

Table 5.1.2
BMI at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
BMI (kg/m²) FU					
Baseline	N (missing)	488 (0)	233 (0)	255 (0)	
	Mean (sd)	34.93 (4.90)	35.03 (5.11)	34.84 (4.71)	
	(95% CI)	(34.49, 35.37)	(34.37, 35.69)	(34.26, 35.42)	
	Median (IQR)	33.9 (31.3, 37.5)	33.9 (31.1, 37.6)	34.0 (31.3, 36.8)	
	[Min, Max]	[28, 56]	[28, 56]	[28, 55]	
Follow up	N (missing)	488 (0)	233 (0)	255 (0)	0.12 (1.02, -0.78),
	Mean (sd)	34.01 (5.04)	34.08 (5.14)	33.96 (4.96)	0.7923
	(95% CI)	(33.57, 34.46)	(33.41, 34.74)	(33.34, 34.57)	
	Median (IQR)	33.4 (30.6, 36.2)	33.1 (30.6, 36.1)	33.7 (30.4, 36.3)	
	[Min, Max]	[25, 56]	[25, 55]	[25, 56]	
Change from baseline	N (missing)	488 (0)	233 (0)	255 (0)	-0.08 (0.42, -0.57),
	Mean (sd)	-0.92 (2.77)	-0.96 (2.76)	-0.88 (2.79)	0.7010*
	(95% CI)	(-1.16, -0.67)	(-1.31, -0.60)	(-1.22, -0.54)	
	Median (IQR)	-0.6 (-2.4, 0.7)	-0.7 (-2.2, 0.7)	-0.5 (-2.5, 0.7)	
	[Min, Max]	[-18, 7]	[-18, 6]	[-15, 7]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.1.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in BMI, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline BMI (kg/m2)	-0.119 (-0.177, -0.062)	<0.001
	Follow-Up vs End-of-RCT	0.815 (0.501, 1.130)	<0.001
	Visit	Mean Change in BMI (kg/m2)	
	End-of-RCT	-1.771 (-2.104, -1.438)	<0.001
	Follow-Up	-0.956 (-1.289, -0.623)	<0.001
	Difference	0.815 (0.501, 1.130)	<0.001
Control	Fixed Effects		
	Baseline BMI (kg/m2)	-0.085 (-0.135, -0.035)	<0.001
	Follow-Up vs End-of-RCT	-0.657 (-0.960, -0.353)	<0.001
	Visit	Mean Change in BMI (kg/m2)	
	End-of-RCT	-0.223 (-0.504, 0.058)	0.119
	Follow-Up	-0.880 (-1.161, -0.599)	<0.001
	Difference	-0.657 (-0.960, -0.353)	<0.001
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.104 (-0.143, -0.066)	<0.001
	Follow-Up vs End-of-RCT	0.046 (-0.181, 0.274)	0.690
	Interaction Effect		
	Treatment * Visit	1.472 (1.036, 1.908)	<0.001

Table 5.2.1
Waist Circumference at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Waist Circumference (cm) 12 Month					
Baseline	N (missing)	487 (1)	232 (1)	255 (0)	
	Mean (sd)	117.12 (11.56)	117.43 (12.32)	116.84 (10.84)	
	(95% CI)	(116.09, 118.15)	(115.84, 119.02)	(115.50, 118.17)	
	Median (IQR)	115.5 (109.2, 123.1)	115.4 (108.8, 123.4)	116.0 (109.5, 122.9)	
	[Min, Max]	[90, 166]	[90, 159]	[96, 166]	
Follow up	N (missing)	487 (1)	232 (1)	255 (0)	-4.87 (-2.62, -7.11),
	Mean (sd)	112.67 (12.71)	110.13 (13.71)	114.99 (11.26)	<0.0001
	(95% CI)	(111.54, 113.81)	(108.35, 111.90)	(113.60, 116.38)	
	Median (IQR)	111.4 (103.9, 120.3)	108.2 (100.7, 117.2)	113.9 (107.7, 121.7)	
	[Min, Max]	[76, 159]	[76, 157]	[88, 159]	
Change from baseline	N (missing)	487 (1)	232 (1)	255 (0)	-5.46 (-4.27, -6.65),
	Mean (sd)	-4.45 (7.09)	-7.30 (7.66)	-1.85 (5.34)	<0.0001*
	(95% CI)	(-5.08, -3.81)	(-8.30, -6.31)	(-2.50, -1.19)	
	Median (IQR)	-3.5 (-7.8, 0.2)	-6.0 (-10.6, -2.0)	-1.5 (-4.6, 1.7)	
	[Min, Max]	[-38, 14]	[-38, 10]	[-28, 14]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.2.2
Waist Circumference at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Waist Circumference (cm) FU					
Baseline	N (missing)	451 (37)	214 (19)	237 (18)	
	Mean (sd)	117.09 (11.50)	117.37 (12.39)	116.84 (10.66)	
	(95% CI)	(116.03, 118.15)	(115.70, 119.04)	(115.48, 118.20)	
	Median (IQR)	115.9 (109.3, 123.2)	115.4 (108.6, 123.5)	116.2 (109.6, 122.9)	
	[Min, Max]	[90, 166]	[90, 159]	[96, 166]	
Follow up	N (missing)	451 (37)	214 (19)	237 (18)	0.27 (2.67, -2.12),
	Mean (sd)	114.33 (12.91)	114.47 (13.43)	114.20 (12.46)	0.8219
	(95% CI)	(113.13, 115.52)	(112.66, 116.28)	(112.60, 115.79)	
	Median (IQR)	113.3 (105.6, 121.3)	112.6 (105.8, 120.5)	114.0 (105.5, 121.5)	
	[Min, Max]	[82, 176]	[82, 157]	[87, 176]	
Change from baseline	N (missing)	451 (37)	214 (19)	237 (18)	-0.25 (1.15, -1.66),
	Mean (sd)	-2.76 (7.57)	-2.90 (7.34)	-2.64 (7.79)	0.7057*
	(95% CI)	(-3.47, -2.06)	(-3.89, -1.91)	(-3.64, -1.65)	
	Median (IQR)	-1.9 (-7.3, 2.3)	-2.3 (-6.3, 2.3)	-1.2 (-7.4, 2.3)	
	[Min, Max]	[-42, 21]	[-42, 17]	[-31, 21]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.2.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Waist Circumference, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Waist Circumference (cm)	-0.085 (-0.153, -0.016)	0.016
	Follow-Up vs End-of-RCT	4.408 (3.459, 5.357)	<0.001
	Visit	Mean Change in Waist Circumference (cm)	
	End-of-RCT	-7.166 (-8.538, -5.795)	<0.001
	Follow-Up	-2.758 (-4.148, -1.369)	<0.001
	Difference	4.408 (3.459, 5.357)	<0.001
Control	Fixed Effects		
	Baseline Waist Circumference (cm)	-0.080 (-0.142, -0.017)	0.012
	Follow-Up vs End-of-RCT	-0.833 (-1.786, 0.120)	0.086
	Visit	Mean Change in Waist Circumference (cm)	
	End-of-RCT	-1.836 (-2.668, -1.004)	<0.001
	Follow-Up	-2.669 (-3.527, -1.812)	<0.001
	Difference	-0.833 (-1.786, 0.120)	0.086
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.082 (-0.130, -0.035)	<0.001
	Follow-Up vs End-of-RCT	1.643 (0.928, 2.357)	<0.001
	Interaction Effect		
Treatment * Visit	5.259 (3.911, 6.606)	<0.001	

Table 5.3.1
Percent Body Fat at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Percent Body Fat (%) 12 Month					
Baseline	N (missing)	440 (48)	207 (26)	233 (22)	
	Mean (sd)	31.24 (5.62)	31.30 (5.97)	31.18 (5.31)	
	(95% CI)	(30.71, 31.76)	(30.48, 32.12)	(30.49, 31.86)	
	Median (IQR)	30.6 (27.6, 33.9)	30.6 (27.5, 33.5)	30.5 (27.6, 34.4)	
	[Min, Max]	[18, 60]	[18, 59]	[20, 60]	
Follow up	N (missing)	442 (46)	207 (26)	235 (20)	-2.22 (-1.07, -3.37),
	Mean (sd)	30.12 (6.18)	28.94 (6.51)	31.16 (5.69)	0.0002
	(95% CI)	(29.54, 30.70)	(28.04, 29.83)	(30.43, 31.89)	
	Median (IQR)	29.5 (26.1, 33.0)	28.0 (25.4, 32.0)	30.5 (27.7, 33.8)	
	[Min, Max]	[15, 58]	[15, 58]	[19, 56]	
Change from baseline	N (missing)	440 (48)	207 (26)	233 (22)	-2.35 (-1.42, -3.27),
	Mean (sd)	-1.12 (4.97)	-2.36 (5.64)	-0.02 (3.98)	<0.0001*
	(95% CI)	(-1.59, -0.66)	(-3.14, -1.59)	(-0.53, 0.49)	
	Median (IQR)	-1.0 (-3.1, 1.2)	-2.2 (-5.1, 0.2)	-0.2 (-2.2, 1.5)	
	[Min, Max]	[-29, 30]	[-29, 30]	[-22, 23]	
	P-Value	<0.0001**	<0.0001**	0.4371**	

Table 5.3.2
Percent Body Fat at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Percent Body Fat (%) FU					
Baseline	N (missing)	327 (161)	162 (71)	165 (90)	
	Mean (sd)	31.18 (5.61)	31.09 (6.06)	31.26 (5.14)	
	(95% CI)	(30.57, 31.79)	(30.15, 32.03)	(30.47, 32.05)	
	Median (IQR)	30.5 (27.6, 33.8)	30.4 (27.2, 33.4)	31.0 (27.8, 33.8)	
	[Min, Max]	[18, 60]	[18, 59]	[21, 60]	
Follow up	N (missing)	328 (160)	162 (71)	166 (89)	-0.71 (0.78, -2.19),
	Mean (sd)	29.51 (6.84)	29.15 (6.34)	29.86 (7.29)	0.3500
	(95% CI)	(28.77, 30.25)	(28.17, 30.13)	(28.74, 30.98)	
	Median (IQR)	28.6 (25.6, 32.7)	28.4 (25.6, 31.7)	28.8 (25.8, 33.1)	
	[Min, Max]	[12, 68]	[12, 58]	[15, 68]	
Change from baseline	N (missing)	327 (161)	162 (71)	165 (90)	-0.56 (0.72, -1.83),
	Mean (sd)	-1.66 (5.85)	-1.94 (5.66)	-1.38 (6.04)	0.3085*
	(95% CI)	(-2.29, -1.02)	(-2.81, -1.06)	(-2.31, -0.45)	
	Median (IQR)	-1.8 (-4.2, 0.8)	-2.1 (-4.3, 0.5)	-1.3 (-4.1, 1.1)	
	[Min, Max]	[-26, 30]	[-26, 30]	[-25, 27]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.3.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Percent Body Fat, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Percent Body Fat (%)	-0.362 (-0.464, -0.261)	<0.001
	Follow-Up vs End-of-RCT	0.404 (-0.437, 1.244)	0.346
	Visit	Mean Change in Percent Body Fat (%)	
	End-of-RCT	-2.306 (-3.254, -1.358)	<0.001
	Follow-Up	-1.903 (-2.906, -0.899)	<0.001
	Difference	0.404 (-0.437, 1.244)	0.346
Control	Fixed Effects		
	Baseline Percent Body Fat (%)	-0.175 (-0.267, -0.084)	<0.001
	Follow-Up vs End-of-RCT	-1.398 (-2.301, -0.495)	0.002
	Visit	Mean Change in Percent Body Fat (%)	
	End-of-RCT	-0.022 (-1.021, 0.977)	0.965
	Follow-Up	-1.420 (-2.489, -0.350)	0.009
	Difference	-1.398 (-2.301, -0.495)	0.002
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.280 (-0.349, -0.211)	<0.001
	Follow-Up vs End-of-RCT	-0.558 (-1.191, 0.074)	0.084
	Interaction Effect		
	Treatment * Visit	1.844 (0.594, 3.094)	0.004

Table 5.4.1
Systolic BP at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Systolic blood pressure 12 Month					
Baseline	N (missing)	487 (1)	232 (1)	255 (0)	
	Mean (sd)	139.10 (15.84)	137.38 (16.68)	140.66 (14.90)	
	(95% CI)	(137.69, 140.51)	(135.22, 139.54)	(138.82, 142.50)	
	Median (IQR)	137.0 (129.0, 148.0)	136.0 (128.0, 144.5)	138.0 (131.0, 150.0)	
	[Min, Max]	[83, 222]	[83, 222]	[101, 185]	
Follow up	N (missing)	487 (1)	232 (1)	255 (0)	-4.92 (-2.39, -7.46),
	Mean (sd)	132.28 (14.42)	129.70 (13.61)	134.63 (14.76)	0.0002
	(95% CI)	(131.00, 133.57)	(127.94, 131.47)	(132.81, 136.45)	
	Median (IQR)	132.0 (122.0, 141.0)	130.0 (121.0, 138.8)	134.0 (125.0, 144.0)	
	[Min, Max]	[89, 186]	[95, 186]	[89, 183]	
Change from baseline	N (missing)	487 (1)	232 (1)	255 (0)	-1.64 (0.68, -3.96),
	Mean (sd)	-6.81 (13.04)	-7.67 (13.39)	-6.03 (12.69)	0.1769*
	(95% CI)	(-7.98, -5.65)	(-9.40, -5.94)	(-7.60, -4.47)	
	Median (IQR)	-6.0 (-14.5, 1.0)	-6.8 (-15.5, 0.3)	-5.5 (-13.5, 1.5)	
	[Min, Max]	[-72, 35]	[-72, 35]	[-57, 29]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.4.2
Systolic BP at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Systolic blood pressure					
FU					
Baseline	N (missing)	449 (39)	214 (19)	235 (20)	
	Mean (sd)	139.39 (15.67)	137.81 (16.84)	140.83 (14.40)	
	(95% CI)	(137.94, 140.84)	(135.54, 140.08)	(138.98, 142.68)	
	Median (IQR)	137.0 (130.0, 148.0)	136.0 (128.0, 145.5)	138.5 (131.0, 150.0)	
	[Min, Max]	[83, 222]	[83, 222]	[101, 185]	
Follow up	N (missing)	449 (39)	214 (19)	235 (20)	-1.57 (1.14, -4.28),
	Mean (sd)	135.50 (14.60)	134.68 (14.43)	136.25 (14.74)	0.2543
	(95% CI)	(134.15, 136.85)	(132.73, 136.62)	(134.35, 138.14)	
	Median (IQR)	136.0 (124.0, 144.5)	134.0 (123.0, 144.5)	136.0 (126.0, 145.0)	
	[Min, Max]	[103, 197]	[105, 197]	[103, 183]	
Change from baseline	N (missing)	449 (39)	214 (19)	235 (20)	1.45 (4.17, -1.27),
	Mean (sd)	-3.89 (14.63)	-3.13 (14.97)	-4.58 (14.32)	0.1862*
	(95% CI)	(-5.25, -2.53)	(-5.15, -1.11)	(-6.42, -2.74)	
	Median (IQR)	-3.0 (-12.0, 6.0)	-2.0 (-10.0, 6.0)	-4.0 (-14.0, 6.0)	
	[Min, Max]	[-59, 36]	[-59, 35]	[-50, 36]	
	P-Value	<0.0001**	0.0080**	<0.0001**	

Table 5.4.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Systolic BP, Overall and by Group

		Estimate (95% C.I.)	P-Value	
Intervention	Fixed Effects			
	Baseline Systolic blood pressure (mmHg)	-0.506 (-0.580, -0.431)	<0.001	
	Follow-Up vs End-of-RCT	4.622 (2.976, 6.267)	<0.001	
	Visit	Mean Change in Systolic blood pressure (mmHg)		
	End-of-RCT	-7.842 (-9.716, -5.968)	<0.001	
	Follow-Up	-3.220 (-5.131, -1.310)	0.001	
	Difference	4.622 (2.976, 6.267)	<0.001	
	Control	Fixed Effects		
		Baseline Systolic blood pressure (mmHg)	-0.422 (-0.508, -0.336)	<0.001
Follow-Up vs End-of-RCT		1.380 (-0.248, 3.008)	0.096	
Visit		Mean Change in Systolic blood pressure (mmHg)		
End-of-RCT		-5.964 (-7.641, -4.286)	<0.001	
Follow-Up		-4.584 (-6.305, -2.863)	<0.001	
Difference		1.380 (-0.248, 3.008)	0.096	
All		Fixed Effect		
		Baseline Weight (1 kg)	-0.465 (-0.521, -0.408)	<0.001
	Follow-Up vs End-of-RCT	2.922 (1.758, 4.086)	<0.001	
	Interaction Effect			
	Treatment * Visit	3.197 (0.882, 5.512)	0.007	

Table 5.5.1
Diastolic BP at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Diastolic blood pressure 12 Month					
Baseline	N (missing)	487 (1)	232 (1)	255 (0)	
	Mean (sd)	88.10 (9.90)	87.30 (9.97)	88.82 (9.79)	
	(95% CI)	(87.22, 88.98)	(86.01, 88.59)	(87.62, 90.03)	
	Median (IQR)	87.0 (82.0, 94.5)	87.0 (81.3, 94.0)	87.5 (82.5, 94.5)	
	[Min, Max]	[50, 131]	[50, 131]	[62, 119]	
Follow up	N (missing)	487 (1)	232 (1)	255 (0)	-2.67 (-1.02, -4.32),
	Mean (sd)	84.15 (9.33)	82.75 (9.02)	85.42 (9.44)	0.0016
	(95% CI)	(83.32, 84.98)	(81.58, 83.92)	(84.25, 86.58)	
	Median (IQR)	84.0 (78.0, 89.5)	83.0 (76.0, 88.0)	85.0 (78.0, 91.5)	
	[Min, Max]	[59, 129]	[62, 118]	[59, 129]	
Change from baseline	N (missing)	487 (1)	232 (1)	255 (0)	-1.14 (0.37, -2.66),
	Mean (sd)	-3.95 (8.51)	-4.55 (8.80)	-3.41 (8.22)	0.1817*
	(95% CI)	(-4.71, -3.19)	(-5.69, -3.41)	(-4.42, -2.39)	
	Median (IQR)	-3.5 (-9.0, 2.0)	-4.0 (-9.3, 1.0)	-3.0 (-9.0, 2.0)	
	[Min, Max]	[-45, 21]	[-45, 21]	[-31, 17]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.5.2
Diastolic BP at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Diastolic blood pressure					
FU					
Baseline	N (missing)	449 (39)	214 (19)	235 (20)	
	Mean (sd)	88.28 (9.95)	87.52 (10.09)	88.97 (9.79)	
	(95% CI)	(87.35, 89.20)	(86.16, 88.88)	(87.71, 90.23)	
	Median (IQR)	87.0 (82.0, 94.5)	87.0 (81.5, 94.0)	88.0 (83.0, 94.5)	
	[Min, Max]	[50, 131]	[50, 131]	[62, 119]	
Follow up	N (missing)	449 (39)	214 (19)	235 (20)	-0.06 (1.65, -1.77),
	Mean (sd)	85.99 (9.19)	85.96 (9.07)	86.02 (9.33)	0.9459
	(95% CI)	(85.14, 86.84)	(84.74, 87.18)	(84.82, 87.22)	
	Median (IQR)	85.0 (80.0, 91.5)	85.3 (79.5, 93.0)	85.0 (80.5, 91.0)	
	[Min, Max]	[58, 121]	[65, 120]	[58, 121]	
Change from baseline	N (missing)	449 (39)	214 (19)	235 (20)	1.39 (3.18, -0.39),
	Mean (sd)	-2.29 (9.65)	-1.56 (9.20)	-2.95 (10.01)	0.0920*
	(95% CI)	(-3.18, -1.39)	(-2.80, -0.32)	(-4.24, -1.67)	
	Median (IQR)	-1.5 (-8.0, 4.0)	0.0 (-7.0, 4.5)	-2.5 (-9.5, 4.0)	
	[Min, Max]	[-38, 30]	[-38, 27]	[-30, 30]	
	P-Value	<0.0001**	0.0308**	<0.0001**	

Table 5.5.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Diastolic BP, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Diastolic blood pressure (mmHg)	-0.493 (-0.572, -0.415)	<0.001
	Follow-Up vs End-of-RCT	3.053 (1.848, 4.258)	<0.001
	Visit	Mean Change in Diastolic blood pressure (mmHg)	
	End-of-RCT	-4.616 (-5.611, -3.621)	<0.001
	Follow-Up	-1.562 (-2.593, -0.532)	0.003
	Difference	3.053 (1.848, 4.258)	<0.001
Control	Fixed Effects		
	Baseline Diastolic blood pressure (mmHg)	-0.475 (-0.558, -0.392)	<0.001
	Follow-Up vs End-of-RCT	0.477 (-0.649, 1.603)	0.406
	Visit	Mean Change in Diastolic blood pressure (mmHg)	
	End-of-RCT	-3.431 (-4.440, -2.422)	<0.001
	Follow-Up	-2.955 (-3.997, -1.912)	<0.001
	Difference	0.477 (-0.649, 1.603)	0.406
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.482 (-0.539, -0.425)	<0.001
	Follow-Up vs End-of-RCT	1.703 (0.874, 2.532)	<0.001
	Interaction Effect		
Treatment * Visit	2.548 (0.902, 4.193)	0.002	

Table 5.6.1
MET TOTAL at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
MET TOTAL (min/week) 12 Month					
Baseline	N (missing)	477 (11)	228 (5)	249 (6)	
	Mean (sd)	2364.1 (4054.8)	2374.4 (4226.2)	2354.6 (3899.9)	
	(95% CI)	(1999.3, 2728.9)	(1822.9, 2925.9)	(1867.8, 2841.4)	
	Median (IQR)	1188 (396.0, 2460)	1251 (396.0, 2582)	1140 (396.0, 2400)	
	[Min, Max]	[0, 40719]	[0, 40719]	[0, 28097]	
Follow up	N (missing)	480 (8)	229 (4)	251 (4)	1006.51 (1778.86, 234.17),
	Mean (sd)	3715.7 (4326.2)	4242.0 (4533.3)	3235.5 (4078.2)	<0.0001*
	(95% CI)	(3327.7, 4103.7)	(3651.7, 4832.3)	(2728.5, 3742.5)	
	Median (IQR)	2346 (957.0, 4888)	2742 (1575, 5634)	1836 (678.0, 3960)	
	[Min, Max]	[0, 30612]	[0, 30612]	[0, 29160]	
Change from baseline	N (missing)	477 (11)	228 (5)	249 (6)	937.55 (1833.08, 42.01),
	Mean (sd)	1340.8 (4988.9)	1830.2 (5218.7)	892.65 (4734.9)	0.0003*
	(95% CI)	(891.94, 1789.6)	(1149.2, 2511.2)	(301.65, 1483.7)	
	Median (IQR)	702.0 (-239, 2358)	1170 (0.0, 3251)	462.0 (-473, 1881)	
	[Min, Max]	[-32868, 29160]	[-32868, 28047]	[-26942, 29160]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.6.2
MET TOTAL at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
MET TOTAL (min/week) FU					
Baseline	N (missing)	445 (43)	213 (20)	232 (23)	
	Mean (sd)	2484.4 (4412.2)	2463.9 (4646.7)	2503.1 (4195.4)	
	(95% CI)	(2073.3, 2895.4)	(1836.3, 3091.5)	(1960.4, 3045.8)	
	Median (IQR)	1188 (396.0, 2559)	1188 (396.0, 2598)	1173 (427.5, 2559)	
	[Min, Max]	[0, 40719]	[0, 40719]	[0, 28097]	
Follow up	N (missing)	448 (40)	214 (19)	234 (21)	-183.04 (665.45, -1031.5),
	Mean (sd)	3955.0 (4590.9)	3859.4 (4223.7)	4042.4 (4910.1)	0.8101*
	(95% CI)	(3528.7, 4381.3)	(3290.3, 4428.5)	(3410.0, 4674.8)	
	Median (IQR)	2361 (1173, 4823)	2396 (1158, 4518)	2344 (1188, 5072)	
	[Min, Max]	[0, 38052]	[0, 19494]	[0, 38052]	
Change from baseline	N (missing)	445 (43)	213 (20)	232 (23)	-158.54 (843.23, -1160.3),
	Mean (sd)	1489.8 (5365.9)	1407.1 (5292.7)	1565.7 (5442.5)	0.5881*
	(95% CI)	(989.88, 1989.7)	(692.28, 2122.0)	(861.66, 2269.7)	
	Median (IQR)	840.0 (-201, 2919)	760.5 (-195, 2700)	937.5 (-232, 3169)	
	[Min, Max]	[-30473, 31101]	[-30473, 18180]	[-22212, 31101]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.6.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in MET TOTAL, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline MET TOTAL (min/week)	-0.719 (-0.820, -0.619)	<0.001
	Follow-Up vs End-of-RCT	-300.49 (-955.21, 354.237)	0.368
	Visit	Mean Change in MET TOTAL (min/week)	
	End-of-RCT	1795.23 (1212.74, 2377.72)	<0.001
	Follow-Up	1494.74 (896.463, 2093.02)	<0.001
	Difference	-300.49 (-955.21, 354.237)	0.368
Control	Fixed Effects		
	Baseline MET TOTAL (min/week)	-0.692 (-0.802, -0.581)	<0.001
	Follow-Up vs End-of-RCT	797.945 (194.336, 1401.55)	0.010
	Visit	Mean Change in MET TOTAL (min/week)	
	End-of-RCT	954.839 (285.127, 1624.55)	0.005
	Follow-Up	1752.78 (1070.83, 2434.73)	<0.001
	Difference	797.945 (194.336, 1401.55)	0.010
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.702 (-0.777, -0.628)	<0.001
	Follow-Up vs End-of-RCT	274.829 (-169.92, 719.582)	0.226
	Interaction Effect		
	Treatment * Visit	-1090.4 (-1976.3, -204.49)	0.016

Table 5.7.1
Truncated MET TOTAL at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Truncated MET TOTAL (min/week) 12 Month					
Baseline	N (missing)	477 (11)	228 (5)	249 (6)	
	Mean (sd)	1896.2 (2414.0)	1928.8 (2429.4)	1866.4 (2404.3)	
	(95% CI)	(1679.0, 2113.4)	(1611.7, 2245.8)	(1566.3, 2166.5)	
	Median (IQR)	1188 (396.0, 2445)	1230 (396.0, 2459)	1140 (396.0, 2376)	
	[Min, Max]	[0, 17199]	[0, 17199]	[0, 15120]	
Follow up	N (missing)	480 (8)	229 (4)	251 (4)	1015.63 (1545.69, 485.57),
	Mean (sd)	3122.7 (2992.3)	3653.8 (3134.6)	2638.1 (2774.8)	<0.0001*
	(95% CI)	(2854.3, 3391.1)	(3245.6, 4061.9)	(2293.2, 2983.1)	
	Median (IQR)	2325 (943.9, 4212)	2742 (1554, 5047)	1782 (645.0, 3588)	
	[Min, Max]	[0, 17118]	[0, 16524]	[0, 17118]	
Change from baseline	N (missing)	477 (11)	228 (5)	249 (6)	925.18 (1478.06, 372.30),
	Mean (sd)	1220.9 (3101.1)	1703.9 (3185.3)	778.67 (2959.7)	<0.0001*
	(95% CI)	(941.89, 1499.9)	(1288.2, 2119.5)	(409.25, 1148.1)	
	Median (IQR)	699.0 (-183, 2232)	1219 (45.0, 3167)	445.5 (-473, 1782)	
	[Min, Max]	[-13388, 16623]	[-9348, 15120]	[-13388, 16623]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.7.2
Truncated MET TOTAL at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Truncated MET TOTAL (min/week) FU					
Baseline	N (missing)	445 (43)	213 (20)	232 (23)	
	Mean (sd)	1931.4 (2430.9)	1939.5 (2490.5)	1923.9 (2380.3)	
	(95% CI)	(1704.9, 2157.8)	(1603.1, 2275.9)	(1615.9, 2231.8)	
	Median (IQR)	1188 (396.0, 2475)	1188 (396.0, 2457)	1173 (427.5, 2559)	
	[Min, Max]	[0, 17199]	[0, 17199]	[0, 15120]	
Follow up	N (missing)	448 (40)	214 (19)	234 (21)	-121.51 (427.33, -670.34),
	Mean (sd)	3229.8 (2949.8)	3166.3 (2811.7)	3287.8 (3075.5)	0.8528*
	(95% CI)	(2955.9, 3503.7)	(2787.5, 3545.2)	(2891.7, 3684.0)	
	Median (IQR)	2346 (1173, 4411)	2396 (1158, 4305)	2324 (1188, 4518)	
	[Min, Max]	[0, 17892]	[0, 12798]	[0, 17892]	
Change from baseline	N (missing)	445 (43)	213 (20)	232 (23)	-148.69 (427.54, -724.91),
	Mean (sd)	1312.7 (3087.1)	1235.2 (3009.5)	1383.9 (3161.5)	0.6055*
	(95% CI)	(1025.1, 1600.3)	(828.70, 1641.6)	(974.90, 1792.8)	
	Median (IQR)	840.0 (-132, 2783)	800.0 (-120, 2514)	919.0 (-186, 2909)	
	[Min, Max]	[-12798, 13896]	[-12798, 12780]	[-10134, 13896]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.7.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Truncated MET TOTAL, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Truncated MET TOTAL (min/week)	-0.558 (-0.678, -0.437)	<0.001
	Follow-Up vs End-of-RCT	-439.23 (-870.77, -7.699)	0.046
	Visit	Mean Change in Truncated MET TOTAL (min/week)	
	End-of-RCT	1700.52 (1274.00, 2127.05)	<0.001
	Follow-Up	1261.29 (825.596, 1696.98)	<0.001
	Difference	-439.23 (-870.77, -7.699)	0.046
Control	Fixed Effects		
	Baseline Truncated MET TOTAL (min/week)	-0.593 (-0.714, -0.472)	<0.001
	Follow-Up vs End-of-RCT	668.055 (291.819, 1044.29)	<0.001
	Visit	Mean Change in Truncated MET TOTAL (min/week)	
	End-of-RCT	821.609 (411.712, 1231.51)	<0.001
	Follow-Up	1489.66 (1071.78, 1907.55)	<0.001
	Difference	668.055 (291.819, 1044.29)	<0.001
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.570 (-0.656, -0.485)	<0.001
	Follow-Up vs End-of-RCT	138.065 (-150.61, 426.741)	0.348
	Interaction Effect		
Treatment * Visit	-1096.0 (-1665.7, -526.40)	<0.001	

Table 5.8.1
MET Vigorous at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Vigorous (MET-min/week) 12 Month					
Baseline	N (missing)	477 (11)	228 (5)	249 (6)	
	Mean (sd)	904.40 (2747.9)	919.30 (2819.7)	890.76 (2686.1)	
	(95% CI)	(657.18, 1151.6)	(551.34, 1287.3)	(555.49, 1226.0)	
	Median (IQR)	0.0 (0.0, 720.0)	0.0 (0.0, 720.0)	0.0 (0.0, 640.0)	
	[Min, Max]	[0, 30240]	[0, 30240]	[0, 27800]	
Follow up	N (missing)	480 (8)	229 (4)	251 (4)	783.75 (1298.15, 269.35),
	Mean (sd)	1585.9 (2868.4)	1995.7 (3062.8)	1212.0 (2629.6)	<0.0001*
	(95% CI)	(1328.6, 1843.1)	(1596.9, 2394.5)	(885.06, 1538.8)	
	Median (IQR)	580.0 (0.0, 1920)	960.0 (0.0, 2560)	0.0 (0.0, 1440)	
	[Min, Max]	[0, 25200]	[0, 24000]	[0, 25200]	
Change from baseline	N (missing)	477 (11)	228 (5)	249 (6)	748.62 (1378.27, 118.96),
	Mean (sd)	684.90 (3512.2)	1075.7 (3467.5)	327.07 (3521.6)	0.0001*
	(95% CI)	(368.91, 1000.9)	(623.18, 1528.2)	(-112.5, 766.62)	
	Median (IQR)	0.0 (0.0, 1200)	420.0 (0.0, 1920)	0.0 (0.0, 800.0)	
	[Min, Max]	[-27800, 25200]	[-23520, 23280]	[-27800, 25200]	
	P-Value	<0.0001**	<0.0001**	0.0015**	

Table 5.8.2
MET Vigorous at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Vigorous (MET-min/week) FU					
Baseline	N (missing)	445 (43)	213 (20)	232 (23)	
	Mean (sd)	986.52 (3161.4)	995.68 (3364.5)	978.10 (2970.0)	
	(95% CI)	(691.98, 1281.0)	(541.25, 1450.1)	(593.92, 1362.3)	
	Median (IQR)	0.0 (0.0, 720.0)	0.0 (0.0, 720.0)	0.0 (0.0, 680.0)	
	[Min, Max]	[0, 30720]	[0, 30720]	[0, 27800]	
Follow up	N (missing)	448 (40)	214 (19)	234 (21)	-173.55 (319.70, -666.81),
	Mean (sd)	1463.7 (2692.4)	1373.0 (2167.7)	1546.6 (3097.9)	0.6106*
	(95% CI)	(1213.7, 1713.7)	(1081.0, 1665.1)	(1147.6, 1945.6)	
	Median (IQR)	480.0 (0.0, 1800)	480.0 (0.0, 1920)	480.0 (0.0, 1440)	
	[Min, Max]	[0, 23520]	[0, 11520]	[0, 23520]	
Change from baseline	N (missing)	445 (43)	213 (20)	232 (23)	-198.02 (504.59, -900.62),
	Mean (sd)	487.05 (3764.4)	383.81 (3695.7)	581.83 (3831.8)	0.9157*
	(95% CI)	(136.34, 837.75)	(-115.4, 882.98)	(86.16, 1077.5)	
	Median (IQR)	0.0 (0.0, 1280)	0.0 (0.0, 1440)	0.0 (0.0, 1020)	
	[Min, Max]	[-30720, 21600]	[-30720, 11520]	[-19160, 21600]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.8.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in MET Vigorous, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Vigorous (MET-min/week)	-0.802 (-0.890, -0.714)	<0.001
	Follow-Up vs End-of-RCT	-574.00 (-973.34, -174.65)	0.005
	Visit	Mean Change in Vigorous (MET-min/week)	
	End-of-RCT	1037.15 (657.254, 1417.04)	<0.001
	Follow-Up	463.154 (74.137, 852.170)	0.020
	Difference	-574.00 (-973.34, -174.65)	0.005
Control	Fixed Effects		
	Baseline Vigorous (MET-min/week)	-0.840 (-0.941, -0.739)	<0.001
	Follow-Up vs End-of-RCT	338.893 (-87.207, 764.992)	0.119
	Visit	Mean Change in Vigorous (MET-min/week)	
	End-of-RCT	355.117 (-87.869, 798.103)	0.116
	Follow-Up	694.009 (242.458, 1145.56)	0.003
	Difference	338.893 (-87.207, 764.992)	0.119
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.816 (-0.883, -0.749)	<0.001
	Follow-Up vs End-of-RCT	-100.17 (-396.21, 195.860)	0.507
	Interaction Effect		
Treatment * Visit	-915.25 (-1502.8, -327.69)	0.002	

Table 5.9.1
Truncated MET Vigorous at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Truncated Vigorous (min/week) 12 Month					
Baseline	N (missing)	477 (11)	228 (5)	249 (6)	
	Mean (sd)	661.47 (1419.1)	700.35 (1444.6)	625.86 (1397.4)	
	(95% CI)	(533.79, 789.15)	(511.83, 888.87)	(451.45, 800.28)	
	Median (IQR)	0.0 (0.0, 720.0)	0.0 (0.0, 720.0)	0.0 (0.0, 640.0)	
	[Min, Max]	[0, 10080]	[0, 10080]	[0, 10080]	
Follow up	N (missing)	480 (8)	229 (4)	251 (4)	689.49 (1037.61, 341.36),
	Mean (sd)	1347.0 (1952.3)	1707.5 (2085.6)	1018.0 (1763.0)	<0.0001*
	(95% CI)	(1171.9, 1522.0)	(1435.9, 1979.1)	(798.84, 1237.2)	
	Median (IQR)	580.0 (0.0, 1920)	960.0 (0.0, 2560)	0.0 (0.0, 1440)	
	[Min, Max]	[0, 10080]	[0, 10080]	[0, 10080]	
Change from baseline	N (missing)	477 (11)	228 (5)	249 (6)	608.69 (980.65, 236.73),
	Mean (sd)	687.41 (2085.3)	1005.2 (2076.9)	396.47 (2054.3)	<0.0001*
	(95% CI)	(499.80, 875.03)	(734.13, 1276.2)	(140.05, 652.88)	
	Median (IQR)	0.0 (0.0, 1200)	460.0 (0.0, 1880)	0.0 (0.0, 800.0)	
	[Min, Max]	[-10080, 10080]	[-7200, 10080]	[-10080, 10080]	
	P-Value	<0.0001**	<0.0001**	0.0003**	

Table 5.9.2
Truncated MET Vigorous at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Truncated Vigorous (min/week) FU					
Baseline	N (missing)	445 (43)	213 (20)	232 (23)	
	Mean (sd)	685.12 (1478.9)	713.99 (1496.4)	658.62 (1465.4)	
	(95% CI)	(547.34, 822.90)	(511.88, 916.10)	(469.07, 848.17)	
	Median (IQR)	0.0 (0.0, 720.0)	0.0 (0.0, 720.0)	0.0 (0.0, 680.0)	
	[Min, Max]	[0, 10080]	[0, 10080]	[0, 10080]	
Follow up	N (missing)	448 (40)	214 (19)	234 (21)	-80.35 (230.65, -391.35),
	Mean (sd)	1190.3 (1688.5)	1148.3 (1479.7)	1228.6 (1861.5)	0.6520*
	(95% CI)	(1033.5, 1347.1)	(948.91, 1347.7)	(988.90, 1468.4)	
	Median (IQR)	480.0 (0.0, 1520)	480.0 (0.0, 1920)	480.0 (0.0, 1440)	
	[Min, Max]	[0, 10080]	[0, 7200]	[0, 10080]	
Change from baseline	N (missing)	445 (43)	213 (20)	232 (23)	-140.92 (235.38, -517.22),
	Mean (sd)	513.17 (2016.6)	439.70 (1949.9)	580.62 (2077.9)	0.6872*
	(95% CI)	(325.29, 701.05)	(176.33, 703.07)	(311.84, 849.41)	
	Median (IQR)	0.0 (0.0, 1280)	0.0 (0.0, 1320)	0.0 (0.0, 1140)	
	[Min, Max]	[-10080, 8640]	[-8640, 7200]	[-10080, 8640]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.9.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Truncated MET Vigorous, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Truncated Vigorous (min/week)	-0.675 (-0.801, -0.549)	<0.001
	Follow-Up vs End-of-RCT	-542.42 (-823.79, -261.04)	<0.001
	Visit	Mean Change in Truncated Vigorous (min/week)	
	End-of-RCT	994.252 (743.650, 1244.85)	<0.001
	Follow-Up	451.836 (194.711, 708.960)	<0.001
	Difference	-542.42 (-823.79, -261.04)	<0.001
Control	Fixed Effects		
	Baseline Truncated Vigorous (min/week)	-0.753 (-0.876, -0.629)	<0.001
	Follow-Up vs End-of-RCT	219.197 (-57.596, 495.990)	0.120
	Visit	Mean Change in Truncated Vigorous (min/week)	
	End-of-RCT	425.691 (135.881, 715.501)	0.004
	Follow-Up	644.888 (349.832, 939.943)	<0.001
	Difference	219.197 (-57.596, 495.990)	0.120
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.703 (-0.792, -0.614)	<0.001
	Follow-Up vs End-of-RCT	-146.17 (-346.13, 53.792)	0.152
	Interaction Effect		
	Treatment * Visit	-760.25 (-1154.9, -365.61)	<0.001

Table 5.10.1
MET Moderate at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Moderate (min/week) 12 Month					
Baseline	N (missing)	477 (11)	228 (5)	249 (6)	
	Mean (sd)	525.88 (1436.1)	487.98 (1415.2)	560.58 (1457.0)	
	(95% CI)	(396.67, 655.09)	(303.30, 672.66)	(378.72, 742.44)	
	Median (IQR)	0.0 (0.0, 360.0)	0.0 (0.0, 320.0)	0.0 (0.0, 360.0)	
	[Min, Max]	[0, 11760]	[0, 11760]	[0, 9600]	
Follow up	N (missing)	480 (8)	229 (4)	251 (4)	26.28 (310.39, -257.83),
	Mean (sd)	779.71 (1603.4)	793.45 (1320.0)	767.17 (1826.6)	0.0102*
	(95% CI)	(635.91, 923.51)	(621.58, 965.32)	(540.10, 994.24)	
	Median (IQR)	180.0 (0.0, 930.0)	240.0 (0.0, 960.0)	0.0 (0.0, 600.0)	
	[Min, Max]	[0, 16800]	[0, 9240]	[0, 16800]	
Change from baseline	N (missing)	477 (11)	228 (5)	249 (6)	79.60 (420.77, -261.56),
	Mean (sd)	242.13 (1892.6)	283.68 (1877.5)	204.08 (1909.3)	0.0226*
	(95% CI)	(71.86, 412.40)	(38.68, 528.69)	(-34.23, 442.39)	
	Median (IQR)	0.0 (0.0, 480.0)	0.0 (0.0, 720.0)	0.0 (0.0, 360.0)	
	[Min, Max]	[-9660, 11400]	[-9660, 9240]	[-8640, 11400]	
	P-Value	<0.0001**	<0.0001**	0.0101**	

Table 5.10.2
MET Moderate at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Moderate (min/week) FU					
Baseline	N (missing)	445 (43)	213 (20)	232 (23)	
	Mean (sd)	546.89 (1470.1)	509.11 (1460.0)	581.57 (1481.7)	
	(95% CI)	(409.92, 683.85)	(311.91, 706.30)	(389.91, 773.23)	
	Median (IQR)	0.0 (0.0, 360.0)	0.0 (0.0, 320.0)	0.0 (0.0, 360.0)	
	[Min, Max]	[0, 11760]	[0, 11760]	[0, 9600]	
Follow up	N (missing)	448 (40)	214 (19)	234 (21)	-237.61 (125.96, -601.17),
	Mean (sd)	1004.1 (1983.9)	880.00 (1639.3)	1117.6 (2251.0)	0.9961*
	(95% CI)	(819.90, 1188.3)	(659.11, 1100.9)	(827.68, 1407.5)	
	Median (IQR)	240.0 (0.0, 960.0)	240.0 (0.0, 960.0)	170.0 (0.0, 960.0)	
	[Min, Max]	[0, 16920]	[0, 11760]	[0, 16920]	
Change from baseline	N (missing)	445 (43)	213 (20)	232 (23)	-166.51 (234.06, -567.08),
	Mean (sd)	461.83 (2166.3)	375.02 (1916.8)	541.53 (2373.8)	0.9443*
	(95% CI)	(260.01, 663.66)	(116.13, 633.92)	(234.47, 848.60)	
	Median (IQR)	0.0 (0.0, 680.0)	0.0 (0.0, 700.0)	0.0 (0.0, 670.0)	
	[Min, Max]	[-9600, 13320]	[-7920, 11680]	[-9600, 13320]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.10.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in MET Moderate, Overall and by Group

		Estimate (95% C.I.)	P-Value	
Intervention	Fixed Effects			
	Baseline Moderate (min/week)	-0.843 (-0.946, -0.740)	<0.001	
	Follow-Up vs End-of-RCT	113.519 (-127.44, 354.478)	0.355	
	Visit	Mean Change in Moderate (min/week)		
	End-of-RCT	280.249 (24.803, 535.696)	0.032	
	Follow-Up	393.768 (134.028, 653.507)	0.003	
	Difference	113.519 (-127.44, 354.478)	0.355	
	Control	Fixed Effects		
		Baseline Moderate (min/week)	-0.603 (-0.734, -0.472)	<0.001
Follow-Up vs End-of-RCT		341.363 (25.025, 657.701)	0.034	
Visit		Mean Change in Moderate (min/week)		
End-of-RCT		227.036 (-48.603, 502.675)	0.106	
Follow-Up		568.400 (285.576, 851.223)	<0.001	
Difference		341.363 (25.025, 657.701)	0.034	
All		Fixed Effect		
		Baseline Weight (1 kg)	-0.711 (-0.795, -0.627)	<0.001
	Follow-Up vs End-of-RCT	231.217 (30.167, 432.266)	0.024	
	Interaction Effect			
	Treatment * Visit	-229.44 (-631.84, 172.952)	0.263	

Table 5.11.1
Truncated MET Moderate at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Truncated Moderate (min/week) 12 Month					
Baseline	N (missing)	477 (11)	228 (5)	249 (6)	
	Mean (sd)	408.48 (927.05)	371.14 (861.18)	442.67 (984.00)	
	(95% CI)	(325.07, 491.88)	(258.76, 483.52)	(319.85, 565.49)	
	Median (IQR)	0.0 (0.0, 360.0)	0.0 (0.0, 320.0)	0.0 (0.0, 360.0)	
	[Min, Max]	[0, 5040]	[0, 5040]	[0, 5040]	
Follow up	N (missing)	480 (8)	229 (4)	251 (4)	102.79 (287.92, -82.34),
	Mean (sd)	632.63 (1031.2)	686.38 (978.54)	583.59 (1076.7)	0.0083*
	(95% CI)	(540.14, 725.11)	(558.96, 813.79)	(449.74, 717.43)	
	Median (IQR)	180.0 (0.0, 720.0)	240.0 (0.0, 960.0)	0.0 (0.0, 600.0)	
	[Min, Max]	[0, 5040]	[0, 5040]	[0, 5040]	
Change from baseline	N (missing)	477 (11)	228 (5)	249 (6)	171.84 (395.08, -51.40),
	Mean (sd)	219.07 (1241.1)	308.77 (1261.9)	136.93 (1218.6)	0.0192*
	(95% CI)	(107.41, 330.73)	(144.10, 473.44)	(-15.17, 289.03)	
	Median (IQR)	0.0 (0.0, 480.0)	0.0 (0.0, 720.0)	0.0 (0.0, 360.0)	
	[Min, Max]	[-5040, 5040]	[-4800, 5040]	[-5040, 5040]	
	P-Value	<0.0001**	<0.0001**	0.0153**	

Table 5.11.2
Truncated MET Moderate at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Truncated Moderate (min/week) FU					
Baseline	N (missing)	445 (43)	213 (20)	232 (23)	
	Mean (sd)	419.42 (932.17)	384.04 (886.29)	451.91 (973.17)	
	(95% CI)	(332.58, 506.27)	(264.33, 503.74)	(326.03, 577.80)	
	Median (IQR)	0.0 (0.0, 360.0)	0.0 (0.0, 320.0)	0.0 (0.0, 360.0)	
	[Min, Max]	[0, 5040]	[0, 5040]	[0, 5040]	
Follow up	N (missing)	448 (40)	214 (19)	234 (21)	-75.21 (137.84, - 288.27),
	Mean (sd)	756.29 (1145.5)	717.01 (1086.4)	792.22 (1198.1)	0.9548*
	(95% CI)	(649.93, 862.65)	(570.62, 863.40)	(637.91, 946.54)	
	Median (IQR)	240.0 (0.0, 960.0)	240.0 (0.0, 960.0)	170.0 (0.0, 960.0)	
	[Min, Max]	[0, 5040]	[0, 5040]	[0, 5040]	
Change from baseline	N (missing)	445 (43)	213 (20)	232 (23)	-6.66 (229.39, - 242.72),
	Mean (sd)	339.81 (1264.3)	336.34 (1198.8)	343.00 (1324.1)	0.8298*
	(95% CI)	(222.02, 457.60)	(174.42, 498.26)	(171.72, 514.28)	
	Median (IQR)	0.0 (0.0, 660.0)	0.0 (0.0, 700.0)	0.0 (0.0, 630.0)	
	[Min, Max]	[-5040, 4960]	[-4400, 4960]	[-5040, 4320]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.11.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Truncated MET Moderate, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Truncated Moderate (min/week)	-0.791 (-0.912, -0.670)	<0.001
	Follow-Up vs End-of-RCT	45.194 (-117.94, 208.325)	0.586
	Visit	Mean Change in Truncated Moderate (min/week)	
	End-of-RCT	306.606 (120.374, 492.837)	0.001
	Follow-Up	351.799 (162.767, 540.831)	<0.001
	Difference	45.194 (-117.94, 208.325)	0.586
Control	Fixed Effects		
	Baseline Truncated Moderate (min/week)	-0.675 (-0.789, -0.561)	<0.001
	Follow-Up vs End-of-RCT	209.985 (45.971, 374.000)	0.012
	Visit	Mean Change in Truncated Moderate (min/week)	
	End-of-RCT	140.817 (2.910, 278.725)	0.045
	Follow-Up	350.803 (208.539, 493.066)	<0.001
	Difference	209.985 (45.971, 374.000)	0.012
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.725 (-0.807, -0.642)	<0.001
	Follow-Up vs End-of-RCT	130.533 (14.750, 246.316)	0.027
	Interaction Effect		
Treatment * Visit	-161.28 (-392.93, 70.372)	0.172	

Table 5.12.1
MET Walking at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Walking (min/week) 12 Month					
Baseline	N (missing)	477 (11)	228 (5)	249 (6)	
	Mean (sd)	933.78 (1391.3)	967.13 (1406.9)	903.25 (1379.0)	
	(95% CI)	(808.61, 1059.0)	(783.53, 1150.7)	(731.12, 1075.4)	
	Median (IQR)	396.0 (99.0, 1188)	453.8 (107.3, 1386)	396.0 (99.0, 1040)	
	[Min, Max]	[0, 9504]	[0, 8316]	[0, 9504]	
Follow up	N (missing)	480 (8)	229 (4)	251 (4)	196.48 (512.18, -119.21),
	Mean (sd)	1350.1 (1759.1)	1452.9 (1746.7)	1256.4 (1768.6)	0.0092*
	(95% CI)	(1192.4, 1507.9)	(1225.4, 1680.3)	(1036.5, 1476.2)	
	Median (IQR)	693.0 (330.0, 1733)	891.0 (396.0, 2079)	594.0 (297.0, 1386)	
	[Min, Max]	[0, 12474]	[0, 12474]	[0, 10395]	
Change from baseline	N (missing)	477 (11)	228 (5)	249 (6)	109.33 (449.42, -230.77),
	Mean (sd)	413.76 (1887.0)	470.83 (1953.7)	361.50 (1826.2)	0.0930*
	(95% CI)	(243.99, 583.53)	(215.88, 725.78)	(133.56, 589.45)	
	Median (IQR)	165.0 (-165, 792.0)	231.0 (-99.0, 932.3)	99.0 (-181, 693.0)	
	[Min, Max]	[-9009, 12227]	[-7920, 12227]	[-9009, 9009]	
	P-Value	<0.0001**	<0.0001**	0.0002**	

Table 5.12.2
MET Walking at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Walking (min/week) FU					
Baseline	N (missing)	445 (43)	213 (20)	232 (23)	
	Mean (sd)	950.95 (1448.5)	959.09 (1432.6)	943.47 (1466.0)	
	(95% CI)	(816.00, 1085.9)	(765.59, 1152.6)	(753.83, 1133.1)	
	Median (IQR)	396.0 (99.0, 1188)	396.0 (99.0, 1188)	396.0 (66.0, 1188)	
	[Min, Max]	[0, 9504]	[0, 8316]	[0, 9504]	
Follow up	N (missing)	448 (40)	214 (19)	234 (21)	228.12 (559.30, -103.07),
	Mean (sd)	1487.2 (1753.0)	1606.4 (2068.4)	1378.2 (1399.9)	0.8786*
	(95% CI)	(1324.4, 1650.0)	(1327.7, 1885.1)	(1197.9, 1558.5)	
	Median (IQR)	990.0 (396.0, 1848)	990.0 (396.0, 1848)	924.0 (396.0, 1848)	
	[Min, Max]	[0, 12474]	[0, 12474]	[0, 7425]	
Change from baseline	N (missing)	445 (43)	213 (20)	232 (23)	205.99 (581.90, -169.93),
	Mean (sd)	540.91 (1995.2)	648.30 (2229.1)	442.31 (1752.4)	0.7639*
	(95% CI)	(355.03, 726.79)	(347.23, 949.38)	(215.63, 669.00)	
	Median (IQR)	297.0 (-132, 1188)	297.0 (-132, 1089)	297.0 (-173, 1370)	
	[Min, Max]	[-8910, 12227]	[-6930, 12227]	[-8910, 7425]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.12.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in MET Walking, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Walking (min/week)	-0.682 (-0.818, -0.546)	<0.001
	Follow-Up vs End-of-RCT	166.460 (-135.82, 468.736)	0.280
	Visit	Mean Change in Walking (min/week)	
	End-of-RCT	474.377 (233.229, 715.526)	<0.001
	Follow-Up	640.837 (391.855, 889.820)	<0.001
	Difference	166.460 (-135.82, 468.736)	0.280
Control	Fixed Effects		
	Baseline Walking (min/week)	-0.661 (-0.769, -0.553)	<0.001
	Follow-Up vs End-of-RCT	119.879 (-117.18, 356.935)	0.321
	Visit	Mean Change in Walking (min/week)	
	End-of-RCT	344.867 (154.152, 535.582)	<0.001
	Follow-Up	464.746 (267.628, 661.864)	<0.001
	Difference	119.879 (-117.18, 356.935)	0.321
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.670 (-0.756, -0.584)	<0.001
	Follow-Up vs End-of-RCT	142.198 (-47.534, 331.929)	0.142
	Interaction Effect		
	Treatment * Visit	46.641 (-333.67, 426.950)	0.810

Table 5.13.1
Truncated MET Walking at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Truncated Walking (min/week) 12 Month					
Baseline	N (missing)	477 (11)	228 (5)	249 (6)	
	Mean (sd)	826.27 (1018.3)	857.28 (1030.4)	797.88 (1008.3)	
	(95% CI)	(734.66, 917.89)	(722.81, 991.74)	(672.03, 923.74)	
	Median (IQR)	396.0 (99.0, 1188)	453.8 (107.3, 1386)	396.0 (99.0, 1040)	
	[Min, Max]	[0, 4158]	[0, 4158]	[0, 4158]	
Follow up	N (missing)	480 (8)	229 (4)	251 (4)	223.35 (423.53, 23.18),
	Mean (sd)	1143.1 (1119.2)	1259.9 (1106.3)	1036.6 (1122.5)	0.0068*
	(95% CI)	(1042.7, 1243.5)	(1115.9, 1404.0)	(897.01, 1176.1)	
	Median (IQR)	693.0 (330.0, 1691)	891.0 (396.0, 2079)	594.0 (297.0, 1386)	
	[Min, Max]	[0, 4158]	[0, 4158]	[0, 4158]	
Change from baseline	N (missing)	477 (11)	228 (5)	249 (6)	144.65 (358.75, -69.46),
	Mean (sd)	314.41 (1189.7)	389.92 (1227.7)	245.27 (1151.9)	0.0618*
	(95% CI)	(207.38, 421.45)	(229.71, 550.13)	(101.50, 389.05)	
	Median (IQR)	165.0 (-149, 742.5)	231.0 (-99.0, 932.3)	99.0 (-165, 594.0)	
	[Min, Max]	[-3663, 4158]	[-3663, 4158]	[-3069, 4158]	
	P-Value	<0.0001**	<0.0001**	0.0002**	

Table 5.13.2
Truncated MET Walking at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Truncated Walking (min/week) FU					
Baseline	N (missing)	445 (43)	213 (20)	232 (23)	
	Mean (sd)	826.81 (1023.0)	841.50 (1032.9)	813.32 (1015.8)	
	(95% CI)	(731.50, 922.11)	(701.99, 981.01)	(681.92, 944.72)	
	Median (IQR)	396.0 (99.0, 1188)	396.0 (99.0, 1188)	396.0 (66.0, 1188)	
	[Min, Max]	[0, 4158]	[0, 4158]	[0, 4158]	
Follow up	N (missing)	448 (40)	214 (19)	234 (21)	34.06 (244.12, -176.01),
	Mean (sd)	1283.2 (1128.9)	1301.0 (1166.3)	1267.0 (1095.9)	0.9644*
	(95% CI)	(1178.4, 1388.1)	(1143.9, 1458.2)	(1125.8, 1408.1)	
	Median (IQR)	990.0 (396.0, 1848)	990.0 (396.0, 1848)	924.0 (396.0, 1848)	
	[Min, Max]	[0, 4158]	[0, 4158]	[0, 4158]	
Change from baseline	N (missing)	445 (43)	213 (20)	232 (23)	-1.10 (237.60, -239.80),
	Mean (sd)	459.71 (1278.4)	459.13 (1284.6)	460.24 (1275.5)	0.8652*
	(95% CI)	(340.60, 578.81)	(285.63, 632.64)	(295.24, 625.23)	
	Median (IQR)	297.0 (-132, 1155)	297.0 (-66.0, 1040)	297.0 (-132, 1287)	
	[Min, Max]	[-4158, 4158]	[-4158, 4158]	[-3366, 4158]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.13.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Truncated MET Walking, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Truncated Walking (min/week)	-0.642 (-0.750, -0.533)	<0.001
	Follow-Up vs End-of-RCT	55.498 (-115.24, 226.238)	0.523
	Visit	Mean Change in Truncated Walking (min/week)	
	End-of-RCT	398.149 (252.696, 543.603)	<0.001
	Follow-Up	453.647 (304.012, 603.283)	<0.001
	Difference	55.498 (-115.24, 226.238)	0.523
Control	Fixed Effects		
	Baseline Truncated Walking (min/week)	-0.617 (-0.719, -0.516)	<0.001
	Follow-Up vs End-of-RCT	232.331 (67.069, 397.593)	0.006
	Visit	Mean Change in Truncated Walking (min/week)	
	End-of-RCT	243.632 (108.411, 378.853)	<0.001
	Follow-Up	475.963 (336.546, 615.380)	<0.001
	Difference	232.331 (67.069, 397.593)	0.006
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.630 (-0.704, -0.556)	<0.001
	Follow-Up vs End-of-RCT	147.838 (29.060, 266.617)	0.015
	Interaction Effect		
Treatment * Visit	-175.63 (-413.00, 61.751)	0.147	

Table 5.14.1
Sitting Time at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Time spent sitting on a week day in last 7 days - 12 Month					
Baseline	N (missing)	370 (118)	177 (56)	193 (62)	
	Mean (sd)	471.43 (208.76)	482.74 (200.77)	461.06 (215.82)	
	(95% CI)	(450.09, 492.77)	(452.96, 512.52)	(430.42, 491.70)	
	Median (IQR)	480.0 (300.0, 600.0)	480.0 (300.0, 600.0)	420.0 (300.0, 600.0)	
	[Min, Max]	[0, 960]	[20, 960]	[0, 960]	
Follow up	N (missing)	431 (57)	208 (25)	223 (32)	-6.53 (31.28, -44.33),
	Mean (sd)	417.29 (199.34)	413.92 (202.10)	420.44 (197.13)	0.7346
	(95% CI)	(398.42, 436.17)	(386.29, 441.55)	(394.43, 446.46)	
	Median (IQR)	360.0 (270.0, 540.0)	360.0 (240.0, 540.0)	360.0 (300.0, 540.0)	
	[Min, Max]	[45, 960]	[60, 960]	[45, 960]	
Change from baseline	N (missing)	370 (118)	177 (56)	193 (62)	-26.05 (14.49, -66.58),
	Mean (sd)	-47.15 (198.25)	-60.73 (201.65)	-34.69 (194.77)	0.1613*
	(95% CI)	(-67.42, -26.88)	(-90.65, -30.82)	(-62.34, -7.04)	
	Median (IQR)	-60.0 (-150, 60.0)	-60.0 (-180, 30.0)	-30.0 (-120, 60.0)	
	[Min, Max]	[-780, 900]	[-780, 660]	[-780, 900]	
	P-Value	<0.0001**	<0.0001**	0.0062**	

Table 5.14.2
Sitting Time at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Time spent sitting on a week day in last 7 days - FU					
Baseline	N (missing)	360 (128)	171 (62)	189 (66)	
	Mean (sd)	465.21 (209.41)	475.12 (204.09)	456.24 (214.25)	
	(95% CI)	(443.50, 486.91)	(444.31, 505.93)	(425.50, 486.99)	
	Median (IQR)	450.0 (300.0, 600.0)	480.0 (300.0, 600.0)	420.0 (300.0, 600.0)	
	[Min, Max]	[0, 960]	[20, 960]	[0, 960]	
Follow up	N (missing)	421 (67)	204 (29)	217 (38)	23.10 (62.36, -16.16),
	Mean (sd)	418.73 (204.88)	430.64 (210.92)	407.53 (198.88)	0.2480
	(95% CI)	(399.10, 438.36)	(401.52, 459.75)	(380.92, 434.14)	
	Median (IQR)	390.0 (270.0, 540.0)	420.0 (300.0, 540.0)	360.0 (240.0, 510.0)	
	[Min, Max]	[0, 960]	[30, 960]	[0, 960]	
Change from baseline	N (missing)	360 (128)	171 (62)	189 (66)	12.39 (60.95, -36.17),
	Mean (sd)	-43.08 (233.72)	-36.58 (239.20)	-48.97 (229.12)	0.6121*
	(95% CI)	(-67.31, -18.86)	(-72.69, -0.47)	(-81.84, -16.09)	
	Median (IQR)	-30.0 (-180, 67.5)	-30.0 (-180, 120.0)	-30.0 (-180, 60.0)	
	[Min, Max]	[-810, 720]	[-780, 720]	[-810, 720]	
	P-Value	0.0002**	0.0389**	0.0011**	

Table 5.14.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Sitting Time, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Time spent sitting (min/day)	-0.554 (-0.670, -0.439)	<0.001
	Follow-Up vs End-of-RCT	24.217 (-7.399, 55.834)	0.133
	Visit	Mean Change in Time spent sitting (min/day)	
	End-of-RCT	-58.742 (-89.342, -28.143)	<0.001
	Follow-Up	-34.525 (-65.412, -3.638)	0.029
	Difference	24.217 (-7.399, 55.834)	0.133
Control	Fixed Effects		
	Baseline Time spent sitting (min/day)	-0.578 (-0.672, -0.485)	<0.001
	Follow-Up vs End-of-RCT	-15.842 (-43.287, 11.603)	0.257
	Visit	Mean Change in Time spent sitting (min/day)	
	End-of-RCT	-36.697 (-61.004, -12.390)	0.003
	Follow-Up	-52.539 (-77.067, -28.011)	<0.001
	Difference	-15.842 (-43.287, 11.603)	0.257
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.567 (-0.640, -0.495)	<0.001
	Follow-Up vs End-of-RCT	3.430 (-17.456, 24.316)	0.747
	Interaction Effect		
Treatment * Visit	40.368 (-1.236, 81.972)	0.057	

Table 5.15.1
Fatty Food Score at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Fatty Food Score 12 Month					
Baseline	N (missing)	488 (0)	233 (0)	255 (0)	
	Mean (sd)	23.95 (7.17)	24.06 (7.07)	23.85 (7.28)	
	(95% CI)	(23.31, 24.59)	(23.14, 24.97)	(22.95, 24.75)	
	Median (IQR)	23.0 (18.5, 28.0)	23.5 (18.5, 28.5)	23.0 (18.5, 28.0)	
	[Min, Max]	[8, 58]	[8, 58]	[11, 51]	
Follow up	N (missing)	488 (0)	233 (0)	255 (0)	-2.54 (-1.42, -3.66),
	Mean (sd)	20.65 (6.39)	19.32 (5.88)	21.86 (6.61)	<0.0001
	(95% CI)	(20.08, 21.21)	(18.56, 20.08)	(21.04, 22.67)	
	Median (IQR)	19.5 (16.0, 24.0)	18.0 (15.5, 22.5)	21.0 (17.0, 26.0)	
	[Min, Max]	[8, 47]	[8, 47]	[9, 44]	
Change from baseline	N (missing)	488 (0)	233 (0)	255 (0)	-2.75 (-1.60, -3.90),
	Mean (sd)	-3.30 (6.51)	-4.74 (7.18)	-1.99 (5.53)	<0.0001*
	(95% CI)	(-3.88, -2.72)	(-5.67, -3.81)	(-2.67, -1.31)	
	Median (IQR)	-2.5 (-7.0, 0.8)	-4.0 (-9.0, 0.0)	-2.0 (-5.0, 1.0)	
	[Min, Max]	[-33, 26]	[-33, 26]	[-19, 14]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.15.2
Fatty Food Score at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Fatty Food Score FU					
Baseline	N (missing)	450 (38)	214 (19)	236 (19)	
	Mean (sd)	23.84 (7.19)	23.88 (7.15)	23.80 (7.25)	
	(95% CI)	(23.17, 24.50)	(22.91, 24.84)	(22.87, 24.73)	
	Median (IQR)	23.0 (18.5, 28.0)	23.3 (18.5, 28.0)	23.0 (18.8, 27.8)	
	[Min, Max]	[8, 58]	[8, 58]	[11, 51]	
Follow up	N (missing)	450 (38)	214 (19)	236 (19)	-0.63 (0.49, -1.74),
	Mean (sd)	20.34 (6.02)	20.02 (5.90)	20.64 (6.12)	0.2714
	(95% CI)	(19.79, 20.90)	(19.22, 20.81)	(19.86, 21.43)	
	Median (IQR)	19.5 (16.5, 24.0)	19.0 (16.0, 23.0)	19.5 (16.5, 24.0)	
	[Min, Max]	[8, 47]	[8, 46]	[9, 47]	
Change from baseline	N (missing)	450 (38)	214 (19)	236 (19)	-0.70 (0.57, -1.97),
	Mean (sd)	-3.49 (6.83)	-3.86 (7.18)	-3.16 (6.50)	0.3289*
	(95% CI)	(-4.13, -2.86)	(-4.83, -2.89)	(-3.99, -2.33)	
	Median (IQR)	-3.0 (-7.0, 0.5)	-3.5 (-7.5, 0.5)	-3.0 (-6.5, 1.0)	
	[Min, Max]	[-29, 17]	[-29, 17]	[-25, 14]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.15.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Fatty Food Score, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Fatty Food Score	-0.672 (-0.754, -0.590)	<0.001
	Follow-Up vs End-of-RCT	0.713 (-0.101, 1.526)	0.086
	Visit	Mean Change in Fatty Food Score	
	End-of-RCT	-4.680 (-5.375, -3.985)	<0.001
	Follow-Up	-3.967 (-4.689, -3.246)	<0.001
	Difference	0.713 (-0.101, 1.526)	0.086
Control	Fixed Effects		
	Baseline Fatty Food Score	-0.453 (-0.523, -0.383)	<0.001
	Follow-Up vs End-of-RCT	-1.149 (-1.895, -0.404)	0.003
	Visit	Mean Change in Fatty Food Score	
	End-of-RCT	-1.980 (-2.598, -1.362)	<0.001
	Follow-Up	-3.130 (-3.770, -2.490)	<0.001
	Difference	-1.149 (-1.895, -0.404)	0.003
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.556 (-0.611, -0.501)	<0.001
	Follow-Up vs End-of-RCT	-0.253 (-0.809, 0.304)	0.373
	Interaction Effect		
	Treatment * Visit	1.876 (0.774, 2.977)	<0.001

Table 5.16.1
Sugary Food Score at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Sugary Food Score 12 Month					
Baseline	N (missing)	488 (0)	233 (0)	255 (0)	
	Mean (sd)	6.16 (2.88)	6.04 (2.71)	6.26 (3.03)	
	(95% CI)	(5.90, 6.41)	(5.69, 6.39)	(5.89, 6.64)	
	Median (IQR)	5.0 (4.0, 7.0)	5.0 (4.0, 7.0)	5.0 (4.0, 7.0)	
	[Min, Max]	[3, 16]	[3, 16]	[3, 16]	
Follow up	N (missing)	488 (0)	233 (0)	255 (0)	-1.00 (-0.55, -1.45),
	Mean (sd)	5.20 (2.61)	4.67 (2.09)	5.67 (2.94)	<0.0001
	(95% CI)	(4.96, 5.43)	(4.40, 4.94)	(5.31, 6.04)	
	Median (IQR)	4.0 (3.0, 6.0)	4.0 (3.0, 5.0)	5.0 (4.0, 6.0)	
	[Min, Max]	[3, 16]	[3, 16]	[3, 16]	
Change from baseline	N (missing)	488 (0)	233 (0)	255 (0)	-0.78 (-0.26, -1.30),
	Mean (sd)	-0.96 (2.94)	-1.37 (3.04)	-0.59 (2.80)	0.0034*
	(95% CI)	(-1.22, -0.70)	(-1.76, -0.98)	(-0.93, -0.24)	
	Median (IQR)	-1.0 (-2.0, 0.0)	-1.0 (-3.0, 0.0)	0.0 (-2.0, 1.0)	
	[Min, Max]	[-12, 9]	[-12, 8]	[-11, 9]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.16.2
Sugary Food Score at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Sugary Food Score FU					
Baseline	N (missing)	450 (38)	214 (19)	236 (19)	
	Mean (sd)	6.08 (2.80)	5.97 (2.66)	6.18 (2.92)	
	(95% CI)	(5.82, 6.34)	(5.61, 6.33)	(5.80, 6.55)	
	Median (IQR)	5.0 (4.0, 7.0)	5.0 (4.0, 7.0)	5.0 (4.0, 7.0)	
	[Min, Max]	[3, 16]	[3, 16]	[3, 16]	
Follow up	N (missing)	450 (38)	214 (19)	236 (19)	-0.46 (-0.09, -0.83),
	Mean (sd)	4.89 (2.02)	4.65 (1.73)	5.11 (2.24)	0.0154
	(95% CI)	(4.70, 5.08)	(4.42, 4.88)	(4.82, 5.39)	
	Median (IQR)	4.0 (3.0, 6.0)	4.0 (3.0, 5.0)	5.0 (4.0, 6.0)	
	[Min, Max]	[3, 14]	[3, 11]	[3, 14]	
Change from baseline	N (missing)	450 (38)	214 (19)	236 (19)	-0.25 (0.25, -0.75),
	Mean (sd)	-1.19 (2.69)	-1.32 (2.74)	-1.07 (2.64)	0.4264*
	(95% CI)	(-1.44, -0.94)	(-1.69, -0.95)	(-1.41, -0.73)	
	Median (IQR)	-1.0 (-2.0, 0.0)	-1.0 (-2.0, 0.0)	-1.0 (-2.0, 0.0)	
	[Min, Max]	[-13, 7]	[-12, 7]	[-13, 7]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.16.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Sugary Food Score, Overall and by Group

		Estimate (95% C.I.)	P-Value	
Intervention	Fixed Effects			
	Baseline Sugary Food Score	-0.826 (-0.898, -0.754)	<0.001	
	Follow-Up vs End-of-RCT	-0.016 (-0.321, 0.288)	0.917	
	Visit	Mean Change in Sugary Food Score		
	End-of-RCT	-1.340 (-1.590, -1.090)	<0.001	
	Follow-Up	-1.356 (-1.616, -1.097)	<0.001	
	Difference	-0.016 (-0.321, 0.288)	0.917	
	Control	Fixed Effects		
		Baseline Sugary Food Score	-0.538 (-0.614, -0.462)	<0.001
Follow-Up vs End-of-RCT		-0.540 (-0.863, -0.216)	0.001	
Visit		Mean Change in Sugary Food Score		
End-of-RCT		-0.566 (-0.840, -0.293)	<0.001	
Follow-Up		-1.106 (-1.389, -0.822)	<0.001	
Difference		-0.540 (-0.863, -0.216)	0.001	
All		Fixed Effect		
		Baseline Weight (1 kg)	-0.655 (-0.710, -0.600)	<0.001
	Follow-Up vs End-of-RCT	-0.291 (-0.514, -0.067)	0.011	
	Interaction Effect			
	Treatment * Visit	0.535 (0.090, 0.980)	0.018	

Table 5.17.1
Fruits and Vegetable Score at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Fruits and Vegetable Score 12 Month					
Baseline	N (missing)	488 (0)	233 (0)	255 (0)	
	Mean (sd)	2.33 (1.71)	2.30 (1.70)	2.35 (1.72)	
	(95% CI)	(2.17, 2.48)	(2.08, 2.52)	(2.14, 2.56)	
	Median (IQR)	1.5 (1.5, 4.0)	1.5 (1.5, 4.0)	1.5 (1.5, 4.0)	
	[Min, Max]	[1, 6]	[1, 6]	[1, 6]	
Follow up	N (missing)	488 (0)	233 (0)	255 (0)	0.65 (0.97, 0.32),
	Mean (sd)	2.87 (1.86)	3.21 (1.92)	2.56 (1.75)	0.0001
	(95% CI)	(2.70, 3.03)	(2.96, 3.45)	(2.35, 2.78)	
	Median (IQR)	1.5 (1.5, 4.0)	4.0 (1.5, 4.0)	1.5 (1.5, 4.0)	
	[Min, Max]	[1, 6]	[1, 6]	[1, 6]	
Change from baseline	N (missing)	488 (0)	233 (0)	255 (0)	0.69 (1.04, 0.34),
	Mean (sd)	0.54 (1.96)	0.90 (2.07)	0.21 (1.81)	0.0002*
	(95% CI)	(0.37, 0.72)	(0.64, 1.17)	(-0.01, 0.43)	
	Median (IQR)	0.0 (0.0, 2.0)	0.0 (0.0, 2.5)	0.0 (0.0, 1.0)	
	[Min, Max]	[-6, 6]	[-6, 6]	[-6, 6]	
	P-Value	<0.0001**	<0.0001**	0.0872**	

Table 5.17.2
Fruits and Vegetable Score at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Fruits and Vegetable Score FU					
Baseline	N (missing)	450 (38)	214 (19)	236 (19)	
	Mean (sd)	2.33 (1.70)	2.31 (1.69)	2.35 (1.71)	
	(95% CI)	(2.17, 2.49)	(2.08, 2.54)	(2.13, 2.57)	
	Median (IQR)	1.5 (1.5, 4.0)	1.5 (1.5, 4.0)	1.5 (1.5, 4.0)	
	[Min, Max]	[1, 6]	[1, 6]	[1, 6]	
Follow up	N (missing)	450 (38)	214 (19)	236 (19)	0.06 (0.39, -0.27),
	Mean (sd)	2.78 (1.78)	2.81 (1.77)	2.75 (1.79)	0.7298
	(95% CI)	(2.61, 2.94)	(2.57, 3.05)	(2.52, 2.98)	
	Median (IQR)	1.5 (1.5, 4.0)	1.5 (1.5, 4.0)	1.5 (1.5, 4.0)	
	[Min, Max]	[1, 6]	[1, 6]	[1, 6]	
Change from baseline	N (missing)	450 (38)	214 (19)	236 (19)	0.10 (0.47, -0.27),
	Mean (sd)	0.44 (1.98)	0.50 (1.98)	0.40 (1.99)	0.5596*
	(95% CI)	(0.26, 0.63)	(0.23, 0.76)	(0.14, 0.65)	
	Median (IQR)	0.0 (0.0, 2.0)	0.0 (0.0, 2.0)	0.0 (0.0, 2.0)	
	[Min, Max]	[-6, 6]	[-5, 6]	[-6, 6]	
	P-Value	<0.0001**	0.0007**	0.0038**	

Table 5.17.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Fruits and Vegetable Score, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Fruits and Vegetable Score	-0.610 (-0.722, -0.497)	<0.001
	Follow-Up vs End-of-RCT	-0.417 (-0.669, -0.166)	0.001
	Visit	Mean Change in Fruits and Vegetable Score	
	End-of-RCT	0.902 (0.676, 1.127)	<0.001
	Follow-Up	0.485 (0.251, 0.718)	<0.001
	Difference	-0.417 (-0.669, -0.166)	0.001
Control	Fixed Effects		
	Baseline Fruits and Vegetable Score	-0.575 (-0.670, -0.480)	<0.001
	Follow-Up vs End-of-RCT	0.185 (-0.055, 0.426)	0.130
	Visit	Mean Change in Fruits and Vegetable Score	
	End-of-RCT	0.211 (0.012, 0.410)	0.038
	Follow-Up	0.396 (0.190, 0.603)	<0.001
	Difference	0.185 (-0.055, 0.426)	0.130
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.593 (-0.666, -0.520)	<0.001
	Follow-Up vs End-of-RCT	-0.101 (-0.277, 0.075)	0.259
	Interaction Effect		
Treatment * Visit	-0.601 (-0.949, -0.253)	<0.001	

Table 5.18.1
Cheese Portion at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Cheese 12 Month					
Baseline	N (missing)	434 (54)	201 (32)	233 (22)	
	Mean (sd)	4.49 (1.93)	4.56 (1.93)	4.42 (1.94)	
	(95% CI)	(4.31, 4.67)	(4.29, 4.83)	(4.17, 4.67)	
	Median (IQR)	4.0 (3.0, 6.0)	5.0 (3.0, 6.0)	4.0 (3.0, 6.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Follow up	N (missing)	440 (48)	204 (29)	236 (19)	-0.59 (-0.28, -0.91),
	Mean (sd)	3.43 (1.70)	3.11 (1.68)	3.70 (1.68)	0.0003
	(95% CI)	(3.27, 3.58)	(2.88, 3.34)	(3.48, 3.91)	
	Median (IQR)	3.0 (2.0, 4.0)	3.0 (2.0, 4.0)	4.0 (2.0, 5.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Change from baseline	N (missing)	434 (54)	201 (32)	233 (22)	-0.72 (-0.36, -1.08),
	Mean (sd)	-1.04 (1.94)	-1.42 (2.00)	-0.70 (1.83)	0.0001*
	(95% CI)	(-1.22, -0.85)	(-1.70, -1.14)	(-0.94, -0.47)	
	Median (IQR)	-1.0 (-2.0, 0.0)	-1.0 (-3.0, 0.0)	-1.0 (-2.0, 1.0)	
	[Min, Max]	[-7, 5]	[-6, 4]	[-7, 5]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.18.2
Cheese Portion at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Cheese FU					
Baseline	N (missing)	411 (77)	198 (35)	213 (42)	
	Mean (sd)	4.46 (1.95)	4.45 (1.97)	4.47 (1.93)	
	(95% CI)	(4.27, 4.65)	(4.17, 4.73)	(4.21, 4.74)	
	Median (IQR)	4.0 (3.0, 6.0)	4.0 (3.0, 6.0)	4.0 (3.0, 6.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Follow up	N (missing)	420 (68)	202 (31)	218 (37)	-0.02 (0.30, -0.34),
	Mean (sd)	3.32 (1.66)	3.31 (1.67)	3.33 (1.64)	0.9096
	(95% CI)	(3.16, 3.48)	(3.08, 3.54)	(3.11, 3.55)	
	Median (IQR)	3.0 (2.0, 4.0)	3.0 (2.0, 4.0)	3.0 (2.0, 4.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Change from baseline	N (missing)	411 (77)	198 (35)	213 (42)	0.00 (0.41, -0.41),
	Mean (sd)	-1.12 (2.09)	-1.12 (2.05)	-1.12 (2.13)	0.9393*
	(95% CI)	(-1.32, -0.92)	(-1.41, -0.83)	(-1.41, -0.83)	
	Median (IQR)	-1.0 (-2.0, 0.0)	-1.0 (-2.0, 0.0)	-1.0 (-2.0, 0.0)	
	[Min, Max]	[-7, 7]	[-7, 7]	[-7, 6]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.18.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Cheese Portion, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Cheese Portion	-0.660 (-0.748, -0.571)	<0.001
	Follow-Up vs End-of-RCT	0.222 (-0.035, 0.479)	0.090
	Visit	Mean Change in Cheese Portion	
	End-of-RCT	-1.393 (-1.608, -1.179)	<0.001
	Follow-Up	-1.171 (-1.387, -0.955)	<0.001
	Difference	0.222 (-0.035, 0.479)	0.090
Control	Fixed Effects		
	Baseline Cheese Portion	-0.655 (-0.737, -0.572)	<0.001
	Follow-Up vs End-of-RCT	-0.387 (-0.627, -0.146)	0.002
	Visit	Mean Change in Cheese Portion	
	End-of-RCT	-0.719 (-0.925, -0.512)	<0.001
	Follow-Up	-1.105 (-1.319, -0.891)	<0.001
	Difference	-0.387 (-0.627, -0.146)	0.002
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.661 (-0.721, -0.600)	<0.001
	Follow-Up vs End-of-RCT	-0.105 (-0.283, 0.072)	0.245
	Interaction Effect		
	Treatment * Visit	0.607 (0.256, 0.959)	<0.001

Table 5.19.1
Meat Portion at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Meat 12 Month					
Baseline	N (missing)	478 (10)	225 (8)	253 (2)	
	Mean (sd)	5.70 (1.25)	5.70 (1.24)	5.70 (1.26)	
	(95% CI)	(5.59, 5.81)	(5.54, 5.87)	(5.54, 5.86)	
	Median (IQR)	6.0 (5.0, 6.0)	6.0 (5.0, 6.0)	6.0 (5.0, 6.0)	
	[Min, Max]	[1, 8]	[1, 8]	[2, 8]	
Follow up	N (missing)	479 (9)	226 (7)	253 (2)	-0.54 (-0.29, -0.79),
	Mean (sd)	4.92 (1.41)	4.63 (1.38)	5.17 (1.39)	<0.0001
	(95% CI)	(4.79, 5.05)	(4.45, 4.81)	(5.00, 5.35)	
	Median (IQR)	5.0 (4.0, 6.0)	5.0 (4.0, 5.0)	5.0 (5.0, 6.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Change from baseline	N (missing)	478 (10)	225 (8)	253 (2)	-0.55 (-0.29, -0.80),
	Mean (sd)	-0.78 (1.44)	-1.07 (1.51)	-0.53 (1.34)	<0.0001*
	(95% CI)	(-0.91, -0.65)	(-1.27, -0.87)	(-0.69, -0.36)	
	Median (IQR)	-1.0 (-2.0, 0.0)	-1.0 (-2.0, 0.0)	0.0 (-1.0, 0.0)	
	[Min, Max]	[-7, 3]	[-7, 3]	[-7, 3]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.19.2
Meat Portion at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Meat FU					
Baseline	N (missing)	437 (51)	205 (28)	232 (23)	
	Mean (sd)	5.69 (1.27)	5.68 (1.27)	5.70 (1.27)	
	(95% CI)	(5.57, 5.81)	(5.50, 5.85)	(5.53, 5.86)	
	Median (IQR)	6.0 (5.0, 6.0)	6.0 (5.0, 6.0)	6.0 (5.0, 6.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Follow up	N (missing)	439 (49)	207 (26)	232 (23)	-0.18 (0.09, -0.45),
	Mean (sd)	4.78 (1.44)	4.69 (1.41)	4.87 (1.47)	0.1911
	(95% CI)	(4.65, 4.92)	(4.49, 4.88)	(4.68, 5.06)	
	Median (IQR)	5.0 (4.0, 6.0)	5.0 (4.0, 6.0)	5.0 (4.0, 6.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Change from baseline	N (missing)	437 (51)	205 (28)	232 (23)	-0.14 (0.14, -0.43),
	Mean (sd)	-0.90 (1.51)	-0.98 (1.51)	-0.83 (1.51)	0.2017*
	(95% CI)	(-1.04, -0.76)	(-1.18, -0.77)	(-1.03, -0.64)	
	Median (IQR)	-1.0 (-2.0, 0.0)	-1.0 (-2.0, 0.0)	-1.0 (-2.0, 0.0)	
	[Min, Max]	[-6, 4]	[-5, 4]	[-6, 4]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.19.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Meat Portion, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Meat Portion	-0.609 (-0.723, -0.496)	<0.001
	Follow-Up vs End-of-RCT	0.090 (-0.108, 0.288)	0.374
	Visit	Mean Change in Meat Portion	
	End-of-RCT	-1.057 (-1.227, -0.886)	<0.001
	Follow-Up	-0.967 (-1.145, -0.790)	<0.001
	Difference	0.090 (-0.108, 0.288)	0.374
Control	Fixed Effects		
	Baseline Meat Portion	-0.491 (-0.591, -0.390)	<0.001
	Follow-Up vs End-of-RCT	-0.312 (-0.508, -0.116)	0.002
	Visit	Mean Change in Meat Portion	
	End-of-RCT	-0.527 (-0.685, -0.369)	<0.001
	Follow-Up	-0.839 (-1.003, -0.674)	<0.001
	Difference	-0.312 (-0.508, -0.116)	0.002
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.546 (-0.622, -0.470)	<0.001
	Follow-Up vs End-of-RCT	-0.124 (-0.264, 0.017)	0.084
	Interaction Effect		
	Treatment * Visit	0.402 (0.123, 0.682)	0.005

Table 5.20.1
Pasta Portion at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Pasta 12 Month					
Baseline	N (missing)	456 (32)	213 (20)	243 (12)	
	Mean (sd)	5.21 (1.63)	5.30 (1.58)	5.13 (1.68)	
	(95% CI)	(5.06, 5.36)	(5.09, 5.51)	(4.92, 5.34)	
	Median (IQR)	5.0 (4.0, 6.0)	5.0 (4.0, 6.0)	5.0 (4.0, 6.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Follow up	N (missing)	460 (28)	217 (16)	243 (12)	-0.77 (-0.47, -1.06),
	Mean (sd)	4.10 (1.65)	3.69 (1.58)	4.46 (1.63)	<0.0001
	(95% CI)	(3.94, 4.25)	(3.48, 3.90)	(4.25, 4.66)	
	Median (IQR)	4.0 (3.0, 5.0)	4.0 (3.0, 5.0)	4.0 (3.0, 6.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Change from baseline	N (missing)	456 (32)	213 (20)	243 (12)	-0.90 (-0.60, -1.20),
	Mean (sd)	-1.09 (1.66)	-1.57 (1.78)	-0.67 (1.43)	<0.0001*
	(95% CI)	(-1.24, -0.94)	(-1.81, -1.33)	(-0.85, -0.49)	
	Median (IQR)	-1.0 (-2.0, 0.0)	-2.0 (-3.0, 0.0)	-1.0 (-2.0, 0.0)	
	[Min, Max]	[-6, 4]	[-6, 3]	[-5, 4]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.20.2
Pasta Portion at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Pasta FU					
Baseline	N (missing)	424 (64)	198 (35)	226 (29)	
	Mean (sd)	5.20 (1.64)	5.25 (1.60)	5.16 (1.67)	
	(95% CI)	(5.05, 5.36)	(5.03, 5.48)	(4.94, 5.38)	
	Median (IQR)	5.0 (4.0, 6.0)	5.0 (4.0, 6.0)	5.0 (4.0, 6.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Follow up	N (missing)	429 (59)	203 (30)	226 (29)	-0.05 (0.24, -0.34),
	Mean (sd)	4.03 (1.53)	4.00 (1.48)	4.05 (1.57)	0.7450
	(95% CI)	(3.89, 4.18)	(3.80, 4.21)	(3.85, 4.26)	
	Median (IQR)	4.0 (3.0, 5.0)	4.0 (3.0, 5.0)	4.0 (3.0, 5.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Change from baseline	N (missing)	424 (64)	198 (35)	226 (29)	-0.11 (0.22, -0.43),
	Mean (sd)	-1.16 (1.68)	-1.21 (1.65)	-1.11 (1.71)	0.6339*
	(95% CI)	(-1.32, -1.00)	(-1.44, -0.98)	(-1.33, -0.88)	
	Median (IQR)	-1.0 (-2.0, 0.0)	-1.0 (-2.0, 0.0)	-1.0 (-2.0, 0.0)	
	[Min, Max]	[-6, 5]	[-5, 3]	[-6, 5]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.20.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Pasta Portion, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Pasta Portion	-0.629 (-0.731, -0.526)	<0.001
	Follow-Up vs End-of-RCT	0.317 (0.117, 0.516)	0.002
	Visit	Mean Change in Pasta Portion	
	End-of-RCT	-1.548 (-1.737, -1.360)	<0.001
	Follow-Up	-1.232 (-1.426, -1.038)	<0.001
	Difference	0.317 (0.117, 0.516)	0.002
Control	Fixed Effects		
	Baseline Pasta Portion	-0.477 (-0.560, -0.394)	<0.001
	Follow-Up vs End-of-RCT	-0.433 (-0.639, -0.227)	<0.001
	Visit	Mean Change in Pasta Portion	
	End-of-RCT	-0.673 (-0.843, -0.503)	<0.001
	Follow-Up	-1.106 (-1.282, -0.931)	<0.001
	Difference	-0.433 (-0.639, -0.227)	<0.001
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.552 (-0.618, -0.486)	<0.001
	Follow-Up vs End-of-RCT	-0.082 (-0.230, 0.067)	0.279
	Interaction Effect		
	Treatment * Visit	0.757 (0.468, 1.046)	<0.001

Table 5.21.1
Chips Portion at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Chips 12 Month					
Baseline	N (missing)	425 (63)	194 (39)	231 (24)	
	Mean (sd)	4.10 (1.78)	4.18 (1.88)	4.03 (1.70)	
	(95% CI)	(3.93, 4.27)	(3.91, 4.45)	(3.81, 4.25)	
	Median (IQR)	4.0 (3.0, 5.0)	4.0 (3.0, 5.0)	4.0 (3.0, 5.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Follow up	N (missing)	435 (53)	199 (34)	236 (19)	-0.67 (-0.40, -0.94),
	Mean (sd)	3.11 (1.48)	2.75 (1.36)	3.42 (1.51)	<0.0001
	(95% CI)	(2.97, 3.25)	(2.56, 2.94)	(3.23, 3.61)	
	Median (IQR)	3.0 (2.0, 4.0)	2.0 (2.0, 4.0)	3.0 (2.0, 4.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Change from baseline	N (missing)	425 (63)	194 (39)	231 (24)	-0.83 (-0.51, -1.15),
	Mean (sd)	-0.98 (1.69)	-1.43 (1.82)	-0.60 (1.48)	<0.0001*
	(95% CI)	(-1.14, -0.82)	(-1.69, -1.17)	(-0.79, -0.41)	
	Median (IQR)	-1.0 (-2.0, 0.0)	-1.0 (-3.0, 0.0)	0.0 (-1.0, 0.0)	
	[Min, Max]	[-7, 4]	[-7, 3]	[-5, 4]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.21.2
Chips Portion at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Chips FU					
Baseline	N (missing)	400 (88)	183 (50)	217 (38)	
	Mean (sd)	4.11 (1.76)	4.20 (1.84)	4.03 (1.70)	
	(95% CI)	(3.93, 4.28)	(3.93, 4.46)	(3.80, 4.26)	
	Median (IQR)	4.0 (3.0, 5.0)	4.0 (3.0, 5.0)	4.0 (3.0, 5.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Follow up	N (missing)	415 (73)	194 (39)	221 (34)	-0.12 (0.17, -0.41),
	Mean (sd)	3.12 (1.50)	3.06 (1.48)	3.18 (1.51)	0.4173
	(95% CI)	(2.98, 3.27)	(2.85, 3.27)	(2.98, 3.38)	
	Median (IQR)	3.0 (2.0, 4.0)	3.0 (2.0, 4.0)	3.0 (2.0, 4.0)	
	[Min, Max]	[1, 8]	[1, 8]	[1, 8]	
Change from baseline	N (missing)	400 (88)	183 (50)	217 (38)	-0.24 (0.09, -0.58),
	Mean (sd)	-0.95 (1.69)	-1.08 (1.65)	-0.84 (1.72)	0.0911*
	(95% CI)	(-1.12, -0.78)	(-1.32, -0.84)	(-1.07, -0.61)	
	Median (IQR)	-1.0 (-2.0, 0.0)	-1.0 (-2.0, 0.0)	-1.0 (-2.0, 0.0)	
	[Min, Max]	[-6, 5]	[-6, 3]	[-6, 5]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.21.3

Mixed Effects Linear Regression Model and Adjusted Mean Change in Chips Portion, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Chips Portion	-0.638 (-0.721, -0.554)	<0.001
	Follow-Up vs End-of-RCT	0.344 (0.160, 0.528)	<0.001
	Visit	Mean Change in Chips Portion	
	End-of-RCT	-1.409 (-1.606, -1.211)	<0.001
	Follow-Up	-1.064 (-1.265, -0.863)	<0.001
	Difference	0.344 (0.160, 0.528)	<0.001
Control	Fixed Effects		
	Baseline Chips Portion	-0.537 (-0.619, -0.455)	<0.001
	Follow-Up vs End-of-RCT	-0.259 (-0.453, -0.064)	0.009
	Visit	Mean Change in Chips Portion	
	End-of-RCT	-0.594 (-0.775, -0.413)	<0.001
	Follow-Up	-0.852 (-1.038, -0.667)	<0.001
	Difference	-0.259 (-0.453, -0.064)	0.009
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.592 (-0.652, -0.532)	<0.001
	Follow-Up vs End-of-RCT	0.015 (-0.124, 0.153)	0.833
	Interaction Effect		
	Treatment * Visit	0.608 (0.336, 0.880)	<0.001

Table 5.22.1
Alcohol Consumption at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Total alcohol consumption (units per week) 12 Month					
Baseline	N (missing)	488 (0)	233 (0)	255 (0)	
	Mean (sd)	16.90 (17.40)	15.88 (16.95)	17.83 (17.78)	
	(95% CI)	(15.35, 18.44)	(13.69, 18.06)	(15.63, 20.02)	
	Median (IQR)	12.3 (1.5, 27.0)	10.5 (0.0, 26.0)	14.0 (2.0, 29.0)	
	[Min, Max]	[0, 91]	[0, 90]	[0, 91]	
Follow up	N (missing)	488 (0)	233 (0)	255 (0)	-3.35 (-0.66, -6.04),
	Mean (sd)	13.76 (15.31)	12.01 (13.65)	15.36 (16.55)	0.0148
	(95% CI)	(12.40, 15.12)	(10.25, 13.77)	(13.32, 17.40)	
	Median (IQR)	10.0 (0.0, 21.0)	8.5 (0.0, 19.0)	11.0 (0.0, 24.5)	
	[Min, Max]	[0, 98]	[0, 98]	[0, 93]	
Change from baseline	N (missing)	488 (0)	233 (0)	255 (0)	-1.40 (0.65, -3.44),
	Mean (sd)	-3.13 (11.38)	-3.86 (12.48)	-2.47 (10.26)	0.5136*
	(95% CI)	(-4.15, -2.12)	(-5.47, -2.25)	(-3.73, -1.20)	
	Median (IQR)	0.0 (-8.0, 2.0)	-0.5 (-8.0, 1.0)	0.0 (-8.0, 2.0)	
	[Min, Max]	[-62, 36]	[-62, 30]	[-34, 36]	
	P-Value	<0.0001**	<0.0001**	0.0001**	

Table 5.22.2
Alcohol Consumption at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Total alcohol consumption (units per week) FU					
Baseline	N (missing)	440 (48)	207 (26)	233 (22)	
	Mean (sd)	16.78 (16.85)	15.07 (15.31)	18.30 (18.00)	
	(95% CI)	(15.20, 18.36)	(12.97, 17.17)	(15.98, 20.62)	
	Median (IQR)	12.8 (2.0, 27.1)	10.5 (0.0, 25.3)	14.0 (2.8, 29.5)	
	[Min, Max]	[0, 91]	[0, 68]	[0, 91]	
Follow up	N (missing)	440 (48)	207 (26)	233 (22)	-1.62 (0.93, -4.18),
	Mean (sd)	13.25 (13.63)	12.39 (13.34)	14.02 (13.87)	0.2128
	(95% CI)	(11.98, 14.53)	(10.57, 14.22)	(12.23, 15.81)	
	Median (IQR)	10.0 (0.0, 22.0)	9.0 (0.0, 19.0)	11.0 (1.0, 23.0)	
	[Min, Max]	[0, 68]	[0, 68]	[0, 61]	
Change from baseline	N (missing)	440 (48)	207 (26)	233 (22)	1.61 (4.16, -0.95),
	Mean (sd)	-3.53 (13.63)	-2.68 (13.45)	-4.28 (13.78)	0.2945*
	(95% CI)	(-4.80, -2.25)	(-4.52, -0.83)	(-6.06, -2.50)	
	Median (IQR)	-0.2 (-8.0, 2.0)	0.0 (-7.0, 2.9)	-2.0 (-9.5, 2.0)	
	[Min, Max]	[-78, 50]	[-56, 50]	[-78, 30]	
	P-Value	<0.0001**	0.0070**	<0.0001**	

Table 5.22.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Alcohol Consumption, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Alcohol Consumption (units/week)	-0.473 (-0.541, -0.405)	<0.001
	Follow-Up vs End-of-RCT	0.691 (-0.950, 2.332)	0.408
	Visit	Mean Change in Alcohol Consumption (units/week)	
	End-of-RCT	-3.664 (-5.042, -2.287)	<0.001
	Follow-Up	-2.973 (-4.423, -1.523)	<0.001
	Difference	0.691 (-0.950, 2.332)	0.408
Control	Fixed Effects		
	Baseline Alcohol Consumption (units/week)	-0.361 (-0.417, -0.306)	<0.001
	Follow-Up vs End-of-RCT	-1.675 (-3.312, -0.038)	0.045
	Visit	Mean Change in Alcohol Consumption (units/week)	
	End-of-RCT	-2.548 (-3.805, -1.291)	<0.001
	Follow-Up	-4.223 (-5.536, -2.910)	<0.001
	Difference	-1.675 (-3.312, -0.038)	0.045
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.409 (-0.452, -0.365)	<0.001
	Follow-Up vs End-of-RCT	-0.517 (-1.680, 0.646)	0.383
	Interaction Effect		
	Treatment * Visit	2.420 (0.098, 4.742)	0.041

Table 5.23.1
Number of longstanding illnesses at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Number of longstanding illnesses 12 Month					
Baseline	N (missing)	488 (0)	233 (0)	255 (0)	
	Mean (sd)	0.51 (0.85)	0.50 (0.79)	0.53 (0.90)	
	(95% CI)	(0.44, 0.59)	(0.40, 0.60)	(0.41, 0.64)	
	Median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	
	[Min, Max]	[0, 6]	[0, 4]	[0, 6]	
Follow up	N (missing)	488 (0)	233 (0)	255 (0)	-0.02 (0.16, -0.19),
	Mean (sd)	0.64 (0.97)	0.63 (0.85)	0.65 (1.08)	0.4405*
	(95% CI)	(0.55, 0.73)	(0.52, 0.74)	(0.51, 0.78)	
	Median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	
	[Min, Max]	[0, 8]	[0, 4]	[0, 8]	
Change from baseline	N (missing)	488 (0)	233 (0)	255 (0)	0.01 (0.15, -0.13),
	Mean (sd)	0.13 (0.79)	0.13 (0.76)	0.12 (0.81)	0.5821*
	(95% CI)	(0.06, 0.20)	(0.03, 0.23)	(0.02, 0.22)	
	Median (IQR)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	
	[Min, Max]	[-3, 4]	[-3, 3]	[-3, 4]	
	P-Value	0.0002**	0.0084**	0.0110**	

Table 5.23.2
Number of longstanding illnesses at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Number of longstanding illnesses FU					
Baseline	N (missing)	450 (38)	214 (19)	236 (19)	
	Mean (sd)	0.53 (0.83)	0.52 (0.78)	0.54 (0.88)	
	(95% CI)	(0.45, 0.61)	(0.41, 0.62)	(0.43, 0.65)	
	Median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	
	[Min, Max]	[0, 6]	[0, 4]	[0, 6]	
Follow up	N (missing)	450 (38)	214 (19)	236 (19)	-0.07 (0.12, -0.27),
	Mean (sd)	0.80 (1.03)	0.76 (0.98)	0.83 (1.08)	0.5614*
	(95% CI)	(0.70, 0.89)	(0.62, 0.89)	(0.69, 0.97)	
	Median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	1.0 (0.0, 1.0)	
	[Min, Max]	[0, 6]	[0, 5]	[0, 6]	
Change from baseline	N (missing)	450 (38)	214 (19)	236 (19)	-0.05 (0.11, -0.22),
	Mean (sd)	0.27 (0.90)	0.24 (0.93)	0.29 (0.88)	0.5553*
	(95% CI)	(0.18, 0.35)	(0.11, 0.36)	(0.18, 0.41)	
	Median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	
	[Min, Max]	[-4, 4]	[-4, 4]	[-3, 4]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.23.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Number of longstanding illnesses, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Number of longstanding illnesses	-0.407 (-0.516, -0.297)	<0.001
	Follow-Up vs End-of-RCT	0.111 (-0.000, 0.222)	0.050
	Visit	Mean Change in Number of longstanding illnesses	
	End-of-RCT	0.129 (0.028, 0.230)	0.012
	Follow-Up	0.240 (0.135, 0.345)	<0.001
	Difference	0.111 (-0.000, 0.222)	0.050
Control	Fixed Effects		
	Baseline Number of longstanding illnesses	-0.218 (-0.314, -0.122)	<0.001
	Follow-Up vs End-of-RCT	0.168 (0.058, 0.278)	0.003
	Visit	Mean Change in Number of longstanding illnesses	
	End-of-RCT	0.120 (0.019, 0.221)	0.019
	Follow-Up	0.288 (0.184, 0.392)	<0.001
	Difference	0.168 (0.058, 0.278)	0.003
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.296 (-0.368, -0.223)	<0.001
	Follow-Up vs End-of-RCT	0.141 (0.063, 0.219)	<0.001
	Interaction Effect		
Treatment * Visit	-0.059 (-0.215, 0.097)	0.460	

Table 5.24.1
SF12 physical HRQoL at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
SF12 physical HRQoL 12 Month					
Baseline	N (missing)	483 (5)	230 (3)	253 (2)	
	Mean (sd)	47.80 (7.77)	47.32 (7.92)	48.25 (7.62)	
	(95% CI)	(47.11, 48.50)	(46.29, 48.35)	(47.30, 49.19)	
	Median (IQR)	49.5 (43.6, 53.5)	49.1 (42.7, 53.2)	49.8 (44.8, 53.5)	
	[Min, Max]	[20, 62]	[21, 62]	[20, 62]	
Follow up	N (missing)	484 (4)	231 (2)	253 (2)	0.90 (2.44, -0.63),
	Mean (sd)	48.96 (8.60)	49.44 (8.93)	48.53 (8.28)	0.2480
	(95% CI)	(48.20, 49.73)	(48.28, 50.59)	(47.51, 49.56)	
	Median (IQR)	51.7 (44.2, 55.2)	52.9 (44.3, 56.2)	50.9 (44.1, 54.5)	
	[Min, Max]	[19, 68]	[19, 68]	[21, 65]	
Change from baseline	N (missing)	483 (5)	230 (3)	253 (2)	1.83 (3.18, 0.49),
	Mean (sd)	1.16 (7.57)	2.12 (7.61)	0.28 (7.44)	0.0019*
	(95% CI)	(0.48, 1.83)	(1.13, 3.11)	(-0.64, 1.21)	
	Median (IQR)	1.0 (-2.4, 5.9)	2.0 (-1.9, 6.7)	0.2 (-3.6, 4.5)	
	[Min, Max]	[-25, 31]	[-24, 23]	[-25, 31]	
	P-Value	0.0001**	<0.0001**	0.4793**	

Table 5.24.2
SF12 physical HRQoL at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
SF12 physical HRQoL					
FU					
Baseline	N (missing)	448 (40)	213 (20)	235 (20)	
	Mean (sd)	47.92 (7.70)	47.50 (7.85)	48.31 (7.57)	
	(95% CI)	(47.21, 48.64)	(46.44, 48.56)	(47.34, 49.28)	
	Median (IQR)	49.4 (43.7, 53.5)	49.2 (42.7, 53.4)	49.7 (44.9, 53.8)	
	[Min, Max]	[20, 62]	[21, 62]	[20, 62]	
Follow up	N (missing)	449 (39)	214 (19)	235 (20)	0.11 (1.81, -1.59),
	Mean (sd)	49.45 (9.15)	49.51 (9.31)	49.39 (9.02)	0.8972
	(95% CI)	(48.60, 50.30)	(48.25, 50.76)	(48.24, 50.55)	
	Median (IQR)	52.2 (45.2, 55.9)	52.7 (45.2, 55.9)	52.2 (45.5, 55.9)	
	[Min, Max]	[12, 71]	[20, 71]	[12, 64]	
Change from baseline	N (missing)	448 (40)	213 (20)	235 (20)	0.90 (2.55, -0.76),
	Mean (sd)	1.51 (8.91)	1.98 (8.73)	1.09 (9.07)	0.1008*
	(95% CI)	(0.69, 2.34)	(0.81, 3.16)	(-0.08, 2.25)	
	Median (IQR)	1.9 (-3.2, 7.0)	3.0 (-3.4, 8.1)	1.3 (-3.2, 5.7)	
	[Min, Max]	[-32, 34]	[-30, 25]	[-32, 34]	
	P-Value	<0.0001**	<0.0001**	0.0218**	

Table 5.24.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in SF12 physical HRQoL, Overall and by Group

		Estimate (95% C.I.)	P-Value	
Intervention	Fixed Effects			
	Baseline SF12 physical HRQoL	-0.365 (-0.471, -0.259)	<0.001	
	Follow-Up vs End-of-RCT	-0.073 (-1.187, 1.041)	0.897	
	Visit	Mean Change in SF12 physical HRQoL		
	End-of-RCT	2.067 (1.033, 3.100)	<0.001	
	Follow-Up	1.993 (0.929, 3.057)	<0.001	
	Difference	-0.073 (-1.187, 1.041)	0.897	
	Control	Fixed Effects		
		Baseline SF12 physical HRQoL	-0.446 (-0.550, -0.342)	<0.001
Follow-Up vs End-of-RCT		0.814 (-0.225, 1.853)	0.124	
Visit		Mean Change in SF12 physical HRQoL		
End-of-RCT		0.321 (-0.740, 1.381)	0.553	
Follow-Up		1.135 (0.050, 2.220)	0.040	
Difference		0.814 (-0.225, 1.853)	0.124	
All		Fixed Effect		
		Baseline Weight (1 kg)	-0.412 (-0.486, -0.338)	<0.001
	Follow-Up vs End-of-RCT	0.393 (-0.366, 1.152)	0.310	
	Interaction Effect			
	Treatment * Visit	-0.894 (-2.413, 0.625)	0.249	

Table 5.25.1
SF12 mental HRQoL at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
SF12 mental HRQoL 12 Month					
Baseline	N (missing)	483 (5)	230 (3)	253 (2)	
	Mean (sd)	48.62 (9.81)	48.92 (10.15)	48.35 (9.51)	
	(95% CI)	(47.74, 49.49)	(47.60, 50.23)	(47.17, 49.52)	
	Median (IQR)	51.6 (42.9, 55.4)	52.0 (42.9, 55.5)	49.6 (43.2, 55.3)	
	[Min, Max]	[10, 71]	[12, 71]	[10, 67]	
Follow up	N (missing)	484 (4)	231 (2)	253 (2)	1.29 (3.02, -0.44),
	Mean (sd)	50.55 (9.68)	51.23 (9.51)	49.94 (9.81)	0.1425
	(95% CI)	(49.69, 51.42)	(50.00, 52.46)	(48.72, 51.15)	
	Median (IQR)	53.6 (46.6, 57.2)	54.2 (47.4, 57.2)	53.2 (46.3, 57.1)	
	[Min, Max]	[10, 69]	[13, 69]	[10, 64]	
Change from baseline	N (missing)	483 (5)	230 (3)	253 (2)	0.71 (2.13, -0.72),
	Mean (sd)	1.93 (7.96)	2.30 (8.37)	1.59 (7.56)	0.5952*
	(95% CI)	(1.22, 2.64)	(1.21, 3.38)	(0.65, 2.53)	
	Median (IQR)	1.9 (-3.0, 6.0)	1.9 (-2.8, 6.2)	1.6 (-3.0, 5.9)	
	[Min, Max]	[-24, 33]	[-24, 33]	[-24, 27]	
	P-Value	<0.0001**	<0.0001**	0.0004**	

Table 5.25.2
SF12 mental HRQoL at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
SF12 mental HRQoL FU					
Baseline	N (missing)	448 (40)	213 (20)	235 (20)	
	Mean (sd)	48.72 (9.75)	48.90 (10.08)	48.56 (9.45)	
	(95% CI)	(47.82, 49.63)	(47.54, 50.27)	(47.34, 49.77)	
	Median (IQR)	51.3 (42.9, 55.4)	52.0 (42.9, 55.7)	50.2 (43.2, 55.4)	
	[Min, Max]	[10, 71]	[12, 71]	[10, 67]	
Follow up	N (missing)	449 (39)	214 (19)	235 (20)	-1.20 (0.66, -3.06),
	Mean (sd)	50.61 (9.94)	49.98 (10.85)	51.19 (9.01)	0.2038
	(95% CI)	(49.69, 51.54)	(48.52, 51.45)	(50.03, 52.35)	
	Median (IQR)	54.0 (46.9, 57.2)	53.8 (46.1, 57.2)	54.0 (47.8, 57.2)	
	[Min, Max]	[7, 66]	[7, 66]	[18, 66]	
Change from baseline	N (missing)	448 (40)	213 (20)	235 (20)	-1.51 (0.17, -3.19),
	Mean (sd)	1.91 (8.99)	1.12 (9.69)	2.63 (8.26)	0.1619*
	(95% CI)	(1.08, 2.75)	(-0.19, 2.43)	(1.57, 3.69)	
	Median (IQR)	1.8 (-3.0, 7.3)	1.3 (-3.8, 6.6)	2.1 (-2.5, 7.6)	
	[Min, Max]	[-42, 33]	[-42, 33]	[-21, 30]	
	P-Value	<0.0001**	0.0145**	<0.0001**	

Table 5.25.3

Mixed Effects Linear Regression Model and Adjusted Mean Change in SF12 mental HRQoL, Overall and by Group

		Estimate (95% C.I.)	P-Value	
Intervention	Fixed Effects			
	Baseline SF12 mental HRQoL	-0.387 (-0.476, -0.299)	<0.001	
	Follow-Up vs End-of-RCT	-1.197 (-2.357, -0.037)	0.043	
	Visit	Mean Change in SF12 mental HRQoL		
	End-of-RCT	2.272 (1.221, 3.323)	<0.001	
	Follow-Up	1.075 (-0.010, 2.160)	0.052	
	Difference	-1.197 (-2.357, -0.037)	0.043	
	Control	Fixed Effects		
		Baseline SF12 mental HRQoL	-0.345 (-0.425, -0.265)	<0.001
Follow-Up vs End-of-RCT		1.021 (0.056, 1.986)	0.038	
Visit		Mean Change in SF12 mental HRQoL		
End-of-RCT		1.554 (0.667, 2.441)	<0.001	
Follow-Up		2.575 (1.661, 3.489)	<0.001	
Difference		1.021 (0.056, 1.986)	0.038	
All		Fixed Effect		
		Baseline Weight (1 kg)	-0.367 (-0.426, -0.307)	<0.001
	Follow-Up vs End-of-RCT	-0.031 (-0.784, 0.723)	0.937	
	Interaction Effect			
	Treatment * Visit	-2.223 (-3.720, -0.726)	0.004	

Table 5.26.1
Negative affect PANAS at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Negative affect PANAS [normalized] 12 Month					
Baseline	N (missing)	484 (4)	231 (2)	253 (2)	
	Mean (sd)	1.66 (0.61)	1.69 (0.64)	1.64 (0.57)	
	(95% CI)	(1.61, 1.72)	(1.61, 1.77)	(1.57, 1.71)	
	Median (IQR)	1.6 (1.2, 2.0)	1.6 (1.2, 2.0)	1.4 (1.2, 1.8)	
	[Min, Max]	[1, 4]	[1, 4]	[1, 4]	
Follow up	N (missing)	484 (4)	231 (2)	253 (2)	-0.06 (0.04, -0.16),
	Mean (sd)	1.52 (0.56)	1.49 (0.55)	1.55 (0.57)	0.2484
	(95% CI)	(1.47, 1.57)	(1.42, 1.56)	(1.48, 1.62)	
	Median (IQR)	1.4 (1.0, 1.8)	1.4 (1.0, 1.8)	1.4 (1.2, 1.8)	
	[Min, Max]	[1, 4]	[1, 4]	[1, 4]	
Change from baseline	N (missing)	484 (4)	231 (2)	253 (2)	-0.11 (-0.03, -0.20),
	Mean (sd)	-0.14 (0.47)	-0.20 (0.51)	-0.09 (0.43)	0.0106*
	(95% CI)	(-0.18, -0.10)	(-0.27, -0.13)	(-0.14, -0.03)	
	Median (IQR)	0.0 (-0.4, 0.0)	-0.2 (-0.4, 0.0)	0.0 (-0.2, 0.2)	
	[Min, Max]	[-3, 2]	[-3, 2]	[-2, 2]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.26.2
Negative affect PANAS at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Negative affect PANAS [normalized] FU					
Baseline	N (missing)	451 (37)	214 (19)	237 (18)	
	Mean (sd)	1.66 (0.60)	1.70 (0.65)	1.62 (0.55)	
	(95% CI)	(1.60, 1.71)	(1.61, 1.79)	(1.55, 1.69)	
	Median (IQR)	1.4 (1.2, 2.0)	1.6 (1.2, 2.0)	1.4 (1.2, 1.8)	
	[Min, Max]	[1, 4]	[1, 4]	[1, 4]	
Follow up	N (missing)	451 (37)	214 (19)	237 (18)	0.02 (0.12, -0.08),
	Mean (sd)	1.52 (0.54)	1.53 (0.57)	1.51 (0.51)	0.7295
	(95% CI)	(1.47, 1.57)	(1.45, 1.61)	(1.45, 1.58)	
	Median (IQR)	1.4 (1.2, 1.8)	1.4 (1.2, 1.8)	1.4 (1.2, 1.8)	
	[Min, Max]	[1, 4]	[1, 4]	[1, 4]	
Change from baseline	N (missing)	451 (37)	214 (19)	237 (18)	-0.06 (0.03, -0.15),
	Mean (sd)	-0.14 (0.49)	-0.17 (0.50)	-0.11 (0.48)	0.2429*
	(95% CI)	(-0.18, -0.09)	(-0.24, -0.11)	(-0.17, -0.05)	
	Median (IQR)	0.0 (-0.4, 0.0)	0.0 (-0.4, 0.0)	0.0 (-0.4, 0.2)	
	[Min, Max]	[-2, 2]	[-2, 2]	[-2, 2]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.26.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Negative affect PANAS, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Negative affect PANAS [normalized]	-0.418 (-0.488, -0.348)	<0.001
	Follow-Up vs End-of-RCT	0.036 (-0.028, 0.100)	0.273
	Visit	Mean Change in Negative affect PANAS [normalized]	
	End-of-RCT	-0.198 (-0.261, -0.136)	<0.001
	Follow-Up	-0.162 (-0.226, -0.099)	<0.001
	Difference	0.036 (-0.028, 0.100)	0.273
Control	Fixed Effects		
	Baseline Negative affect PANAS [normalized]	-0.342 (-0.421, -0.263)	<0.001
	Follow-Up vs End-of-RCT	-0.020 (-0.069, 0.029)	0.427
	Visit	Mean Change in Negative affect PANAS [normalized]	
	End-of-RCT	-0.084 (-0.134, -0.034)	0.001
	Follow-Up	-0.104 (-0.156, -0.053)	<0.001
	Difference	-0.020 (-0.069, 0.029)	0.427
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.390 (-0.443, -0.337)	<0.001
	Follow-Up vs End-of-RCT	0.006 (-0.034, 0.046)	0.756
	Interaction Effect		
Treatment * Visit	0.059 (-0.021, 0.139)	0.149	

Table 5.27.1
Positive affect PANAS at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Positive affect PANAS [normalized] 12 Month					
Baseline	N (missing)	484 (4)	231 (2)	253 (2)	
	Mean (sd)	3.21 (0.68)	3.25 (0.71)	3.18 (0.64)	
	(95% CI)	(3.15, 3.27)	(3.16, 3.35)	(3.10, 3.26)	
	Median (IQR)	3.2 (2.8, 3.6)	3.4 (2.8, 3.8)	3.2 (2.8, 3.6)	
	[Min, Max]	[1, 5]	[1, 5]	[1, 5]	
Follow up	N (missing)	484 (4)	231 (2)	253 (2)	0.34 (0.47, 0.21),
	Mean (sd)	3.41 (0.73)	3.59 (0.72)	3.25 (0.71)	<0.0001
	(95% CI)	(3.34, 3.47)	(3.49, 3.68)	(3.16, 3.33)	
	Median (IQR)	3.5 (3.0, 4.0)	3.6 (3.2, 4.0)	3.2 (2.8, 3.8)	
	[Min, Max]	[1, 5]	[1, 5]	[1, 5]	
Change from baseline	N (missing)	484 (4)	231 (2)	253 (2)	0.27 (0.38, 0.15),
	Mean (sd)	0.19 (0.66)	0.33 (0.66)	0.07 (0.63)	<0.0001*
	(95% CI)	(0.14, 0.25)	(0.25, 0.42)	(-0.01, 0.15)	
	Median (IQR)	0.2 (-0.2, 0.6)	0.4 (0.0, 0.6)	0.0 (-0.2, 0.4)	
	[Min, Max]	[-4, 4]	[-1, 4]	[-4, 2]	
	P-Value	<0.0001**	<0.0001**	0.0106**	

Table 5.27.2
Positive affect PANAS at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Positive affect PANAS [normalized] FU					
Baseline	N (missing)	451 (37)	214 (19)	237 (18)	
	Mean (sd)	3.22 (0.68)	3.26 (0.71)	3.19 (0.65)	
	(95% CI)	(3.16, 3.28)	(3.16, 3.35)	(3.11, 3.27)	
	Median (IQR)	3.2 (2.8, 3.6)	3.4 (2.8, 3.8)	3.2 (2.8, 3.6)	
	[Min, Max]	[1, 5]	[1, 5]	[1, 5]	
Follow up	N (missing)	451 (37)	214 (19)	237 (18)	0.10 (0.23, -0.02),
	Mean (sd)	3.48 (0.69)	3.53 (0.72)	3.43 (0.67)	0.1090
	(95% CI)	(3.41, 3.54)	(3.43, 3.63)	(3.34, 3.51)	
	Median (IQR)	3.6 (3.0, 4.0)	3.6 (3.2, 4.0)	3.4 (3.0, 3.8)	
	[Min, Max]	[1, 5]	[1, 5]	[1, 5]	
Change from baseline	N (missing)	451 (37)	214 (19)	237 (18)	0.04 (0.17, -0.09),
	Mean (sd)	0.26 (0.69)	0.27 (0.75)	0.24 (0.64)	0.8715*
	(95% CI)	(0.19, 0.32)	(0.17, 0.38)	(0.16, 0.32)	
	Median (IQR)	0.2 (-0.2, 0.6)	0.2 (-0.2, 0.6)	0.2 (-0.2, 0.6)	
	[Min, Max]	[-3, 4]	[-2, 4]	[-3, 2]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.27.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Positive affect PANAS, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Positive affect PANAS [normalized]	-0.465 (-0.564, -0.365)	<0.001
	Follow-Up vs End-of-RCT	-0.058 (-0.136, 0.021)	0.148
	Visit	Mean Change in Positive affect PANAS [normalized]	
	End-of-RCT	0.332 (0.242, 0.421)	<0.001
	Follow-Up	0.274 (0.183, 0.365)	<0.001
	Difference	-0.058 (-0.136, 0.021)	0.148
Control	Fixed Effects		
	Baseline Positive affect PANAS [normalized]	-0.413 (-0.507, -0.319)	<0.001
	Follow-Up vs End-of-RCT	0.172 (0.095, 0.248)	<0.001
	Visit	Mean Change in Positive affect PANAS [normalized]	
	End-of-RCT	0.069 (-0.006, 0.144)	0.073
	Follow-Up	0.241 (0.164, 0.318)	<0.001
	Difference	0.172 (0.095, 0.248)	<0.001
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.435 (-0.505, -0.366)	<0.001
	Follow-Up vs End-of-RCT	0.062 (0.007, 0.118)	0.029
	Interaction Effect		
	Treatment * Visit	-0.229 (-0.339, -0.120)	<0.001

Table 5.28.1
Rosenberg Self-Esteem Score at 12 Month - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Rosenberg Self-Esteem Scale [normalized] 12 Month					
Baseline	N (missing)	484 (4)	231 (2)	253 (2)	
	Mean (sd)	1.95 (0.49)	1.94 (0.53)	1.95 (0.47)	
	(95% CI)	(1.90, 1.99)	(1.87, 2.01)	(1.89, 2.01)	
	Median (IQR)	2.0 (1.6, 2.3)	1.9 (1.6, 2.3)	2.0 (1.7, 2.3)	
	[Min, Max]	[0, 3]	[0, 3]	[1, 3]	
Follow up	N (missing)	484 (4)	231 (2)	253 (2)	0.12 (0.21, 0.03),
	Mean (sd)	2.14 (0.51)	2.20 (0.52)	2.08 (0.49)	0.0115
	(95% CI)	(2.09, 2.18)	(2.13, 2.26)	(2.02, 2.14)	
	Median (IQR)	2.2 (1.8, 2.5)	2.3 (1.9, 2.6)	2.1 (1.8, 2.5)	
	[Min, Max]	[0, 3]	[0, 3]	[0, 3]	
Change from baseline	N (missing)	484 (4)	231 (2)	253 (2)	0.13 (0.19, 0.06),
	Mean (sd)	0.19 (0.36)	0.25 (0.37)	0.13 (0.33)	0.0002*
	(95% CI)	(0.16, 0.22)	(0.21, 0.30)	(0.09, 0.17)	
	Median (IQR)	0.2 (0.0, 0.4)	0.2 (0.0, 0.5)	0.1 (-0.1, 0.3)	
	[Min, Max]	[-1, 2]	[-1, 2]	[-1, 1]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.28.2
Rosenberg Self-Esteem Score at FU - Change From Baseline, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)	P-Value
Rosenberg Self-Esteem Scale [normalized] FU					
Baseline	N (missing)	451 (37)	214 (19)	237 (18)	
	Mean (sd)	1.95 (0.49)	1.94 (0.52)	1.96 (0.46)	
	(95% CI)	(1.91, 2.00)	(1.87, 2.01)	(1.91, 2.02)	
	Median (IQR)	2.0 (1.6, 2.3)	1.9 (1.6, 2.3)	2.0 (1.7, 2.3)	
	[Min, Max]	[0, 3]	[0, 3]	[1, 3]	
Follow up	N (missing)	451 (37)	214 (19)	237 (18)	-0.04 (0.06, -0.13),
	Mean (sd)	2.19 (0.51)	2.18 (0.53)	2.21 (0.50)	0.4677
	(95% CI)	(2.15, 2.24)	(2.10, 2.25)	(2.15, 2.27)	
	Median (IQR)	2.3 (1.9, 2.6)	2.3 (1.9, 2.6)	2.3 (1.9, 2.5)	
	[Min, Max]	[0, 3]	[0, 3]	[0, 3]	
Change from baseline	N (missing)	451 (37)	214 (19)	237 (18)	-0.01 (0.06, -0.09),
	Mean (sd)	0.24 (0.41)	0.23 (0.42)	0.25 (0.40)	0.5507*
	(95% CI)	(0.20, 0.28)	(0.18, 0.29)	(0.20, 0.30)	
	Median (IQR)	0.2 (0.0, 0.5)	0.2 (0.0, 0.5)	0.2 (0.0, 0.5)	
	[Min, Max]	[-1, 2]	[-1, 1]	[-1, 2]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Table 5.28.3
Mixed Effects Linear Regression Model and Adjusted Mean Change in Rosenberg Self-Esteem Score, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Rosenberg Self-Esteem Score [normalized]	-0.282 (-0.363, -0.201)	<0.001
	Follow-Up vs End-of-RCT	-0.014 (-0.058, 0.030)	0.544
	Visit	Mean Change in Rosenberg Self-Esteem Score [normalized]	
	End-of-RCT	0.253 (0.206, 0.301)	<0.001
	Follow-Up	0.240 (0.191, 0.288)	<0.001
	Difference	-0.014 (-0.058, 0.030)	0.544
Control	Fixed Effects		
	Baseline Rosenberg Self-Esteem Score [normalized]	-0.225 (-0.304, -0.145)	<0.001
	Follow-Up vs End-of-RCT	0.117 (0.071, 0.163)	<0.001
	Visit	Mean Change in Rosenberg Self-Esteem Score [normalized]	
	End-of-RCT	0.133 (0.082, 0.184)	<0.001
	Follow-Up	0.250 (0.198, 0.302)	<0.001
	Difference	0.117 (0.071, 0.163)	<0.001
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.256 (-0.313, -0.199)	<0.001
	Follow-Up vs End-of-RCT	0.054 (0.022, 0.087)	0.001
	Interaction Effect		
Treatment * Visit	-0.131 (-0.195, -0.067)	<0.001	

Table 6
Summary of Newly Diagnosed Medical Conditions Related to FFIT, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Number of Medical Conditions related to FFIT Programme	n (missing)	450 (38)	214 (19)	236 (19)
	None	414 (92.0%)	193 (90.2%)	221 (93.6%)
	One	30 (6.7%)	16 (7.5%)	14 (5.9%)
	Two	5 (1.1%)	4 (1.9%)	1 (0.4%)
	Four	1 (0.2%)	1 (0.5%)	0 (0.0%)

Listing 6A

Listing of injuries, joint problems or newly diagnosed medical conditions related to participation in a FFIT programme for Control Group

Subject ID	Date of Event	Event
11058R	JUN14	PROBLEMS WITH KNEE JOINT
12074Q	MAR15	JOINT PROBLEMS
12094J	OCT12	ACHILES DAMAGE
13086E	FEB14	TORN CALF MUSCLE
14004K	DEC12	RUPTURED ACHILLES PLAYING FIVE-A-SIDES
14010T	NOV14	MEDIAL KNEE LIGAMENT INJURY
14026B	JUN13	ANKLE INJURY WHILST PLAYING FOOTBALL AGAINST ANOTHER FFIT TEAM
16029C	APR14	TORN CALF MUSCLE (DIDNT HAPPEN DURING 12 WEEK PROG)
16100H	NOV12	FOOTBALL MATCH BROKEN WRIST
17006M	OCT14	KNEE PROBLEM - TOTAL KNEE REPLACEMENT
19007V	JUN13	KNESS
	JAN13	SHOULDERS
20044J	JAN15	BOTH SHOULDERS WEAR & TEAR OF JOINTS
20085T	SEP13	SHOULDER JOINT INJURY
21007H	FEB14	KNEE SURGERY
21014G	NOV12	LEFT KNEE INJURY - CARTLIDGE DAMAGE (WEEK 2 OF PROGRAM)

Listing 6B

Listing of injuries, joint problems or newly diagnosed medical conditions related to participation in a FFIT programme for Intervention Group

Subject ID	Date of Event	Event
11047V	SEP12	HURT RIGHT KNEE PLAYING FOOTBALL
11055W	OCT13	DAMAGED KNEE LIGAMENTS/SOFT TISSUE LEFT KNEE
	FEB14	BROKE LEFT LEG & ANKLE DAMAGED LIGAMENTS
12001X	OCT14	ANKLE FRACTURE
12012L	APR14	TORN LIGAMENTS IN UPPER RIGHT LEG AND KNEE
12072C	JAN15	HURT RIGHT KNEE PLAYING FOOTBALL BUT GETTING SLOWLY BETTER
14064Q	OCT12	LEFT KNEE/LIGAMENT/CARTILEDGE DAMAGE (RECURRENCE)
14076Z	JUN13	KNEE INJURY
	JAN14	ANKLE INJURY
15032X	APR15	INJURY FRACTURE TO METATARSIL
16013Y	DEC14	BACK
	DEC14	KNEES
17007F	JAN13	BROKEN HAND (RT)
	MAY15	TENDON INJURY (RT FOOT)
17032N	.	DIAGNOSED LEFT FOOT PLANTOFASITUS IT HAS NOW RECURRED BUT STILL PLAY FIVES ONCE A WEEK + TAI CHI FOR PAST 2 YEARS WHICH IS EXCELLENT ALL ROUND FOR ME
17035K	AUG13	I FELL WHEN RUNNING BUT I WAS OUT RUNNING
18039G	NOV14	TRAINING ISSUE - DAMAGED BOTH ANKLES
18061E	FEB14	KNEE
	APR14	ANKLE
	DEC12	ELBOW
	DEC12	NECK & SHOULDER
20001Q	MAY14	ACUTE KIDNEY FAILURE
20069W	JAN13	FELL OFF A HORSE
21092F	JUN13	TWISTED RIGHT KNEE PLAYING GOLF - 2 YEARS AGO
22022B	JUL14	ACHILLES TENDON INJURY
22044L	JUL13	SCIATICA
23035M	JAN14	WEAR + TEAR ON BOTH KNEE JOINTS RESULTING IN SURGERY
23074X	SEP14	BROKEN METATARSEL LEFT FOOT

Table 7.1
Age as Predictor of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
	Predictor Effect		
Intervention	Baseline Age (years)	-0.026 (-0.142, 0.089)	0.655
Control	Baseline Age (years)	-0.015 (-0.108, 0.078)	0.748
	Interaction Effect		
All	Treatment * Age	0.005 (-0.140, 0.150)	0.948

Note: Model also includes baseline weight and visit as fixed effects

Table 7.2
BMI as Predictor of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
	Predictor Effect		
Intervention	Baseline BMI (kg/m ²)	-0.301 (-0.680, 0.078)	0.119
Control	Baseline BMI (kg/m ²)	-0.234 (-0.511, 0.043)	0.098
	Interaction Effect		
All	Treatment * BMI	-0.133 (-0.370, 0.103)	0.269

Note: Model also includes baseline weight and visit as fixed effects

Table 7.3

Education as Predictor of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value	
Intervention	Predictor Effects			
	Others vs. No qualifications	1.536 (-3.927, 7.000)	0.581	
	Standard grades/Highers vs. No qualifications	-1.459 (-5.253, 2.335)	0.450	
	University Education vs. No qualifications	-2.365 (-6.339, 1.609)	0.243	
	Vocational or HNC/HND vs. No qualifications	-1.609 (-5.358, 2.140)	0.399	
	Education	Mean Change in Weight (kg)		
	Others	-1.206 (-5.461, 3.049)	0.578	
	Standard grades/Highers	-4.201 (-5.849, -2.553)	<0.001	
	University Education	-5.107 (-7.142, -3.073)	<0.001	
	Vocational or HNC/HND	-4.352 (-5.889, -2.814)	<0.001	
	No qualifications	-2.742 (-6.160, 0.675)	0.115	
	Control	Predictor Effects		
		Others vs. No qualifications	-1.260 (-4.896, 2.376)	0.496
		Standard grades/Highers vs. No qualifications	-2.172 (-4.961, 0.617)	0.127
University Education vs. No qualifications		-1.076 (-4.007, 1.855)	0.471	
Vocational or HNC/HND vs. No qualifications		-2.180 (-5.017, 0.657)	0.132	
Education		Mean Change in Weight (kg)		
Others		-1.269 (-3.929, 1.391)	0.349	
Standard grades/Highers		-2.181 (-3.439, -0.923)	<0.001	
University Education		-1.085 (-2.649, 0.479)	0.174	
Vocational or HNC/HND		-2.189 (-3.540, -0.838)	0.002	
No qualifications		-0.009 (-2.494, 2.476)	0.994	

Note: Model also includes baseline weight and visit as fixed effects

Figure 7.3
Effect of Treatment on Change in Weight by Education

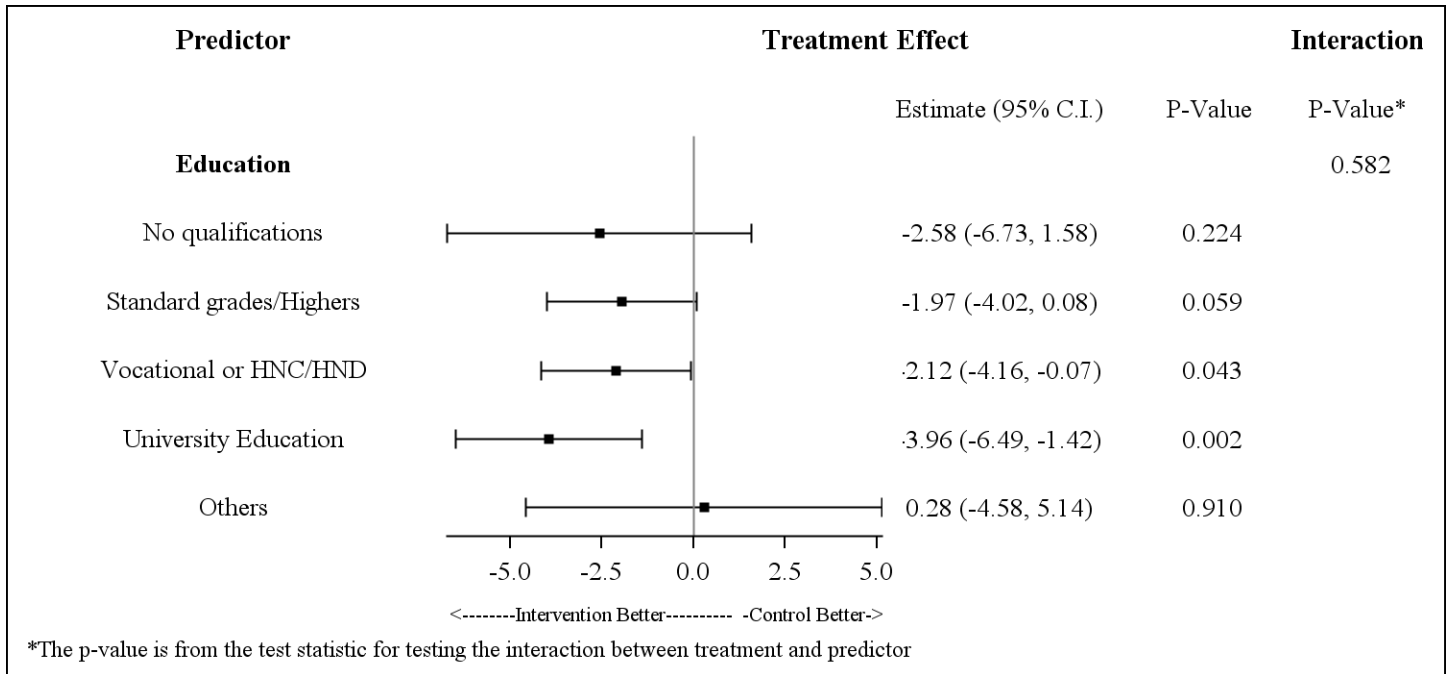


Table 7.4
SIMD as Predictor of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Predictor Effects		
	2 vs. 1 (most deprived)	-1.856 (-5.179, 1.468)	0.273
	3 vs. 1 (most deprived)	1.091 (-1.972, 4.153)	0.484
	4 vs. 1 (most deprived)	-0.625 (-3.490, 2.239)	0.668
	5 vs. 1 (most deprived)	-0.346 (-3.244, 2.551)	0.814
	SIMD	Mean Change in Weight (kg)	
	2	-5.752 (-8.198, -3.307)	<0.001
	3	-2.806 (-4.934, -0.678)	0.010
	4	-4.522 (-6.359, -2.686)	<0.001
	5	-4.243 (-6.124, -2.362)	<0.001
	1 (most deprived)	-3.897 (-6.105, -1.688)	<0.001
Control	Predictor Effects		
	2 vs. 1 (most deprived)	0.313 (-2.132, 2.758)	0.801
	3 vs. 1 (most deprived)	0.714 (-1.851, 3.279)	0.585
	4 vs. 1 (most deprived)	-0.391 (-2.704, 1.922)	0.740
	5 vs. 1 (most deprived)	-1.458 (-3.655, 0.739)	0.193
	SIMD	Mean Change in Weight (kg)	
	2	-1.091 (-2.837, 0.655)	0.220
	3	-0.690 (-2.598, 1.218)	0.478
	4	-1.795 (-3.357, -0.234)	0.024
	5	-2.863 (-4.246, -1.479)	<0.001
	1 (most deprived)	-1.404 (-3.113, 0.304)	0.107

Note: Model also includes baseline weight and visit as fixed effects

Figure 7.4
Effect of Treatment on Change in Weight by SIMD (Quintiles)

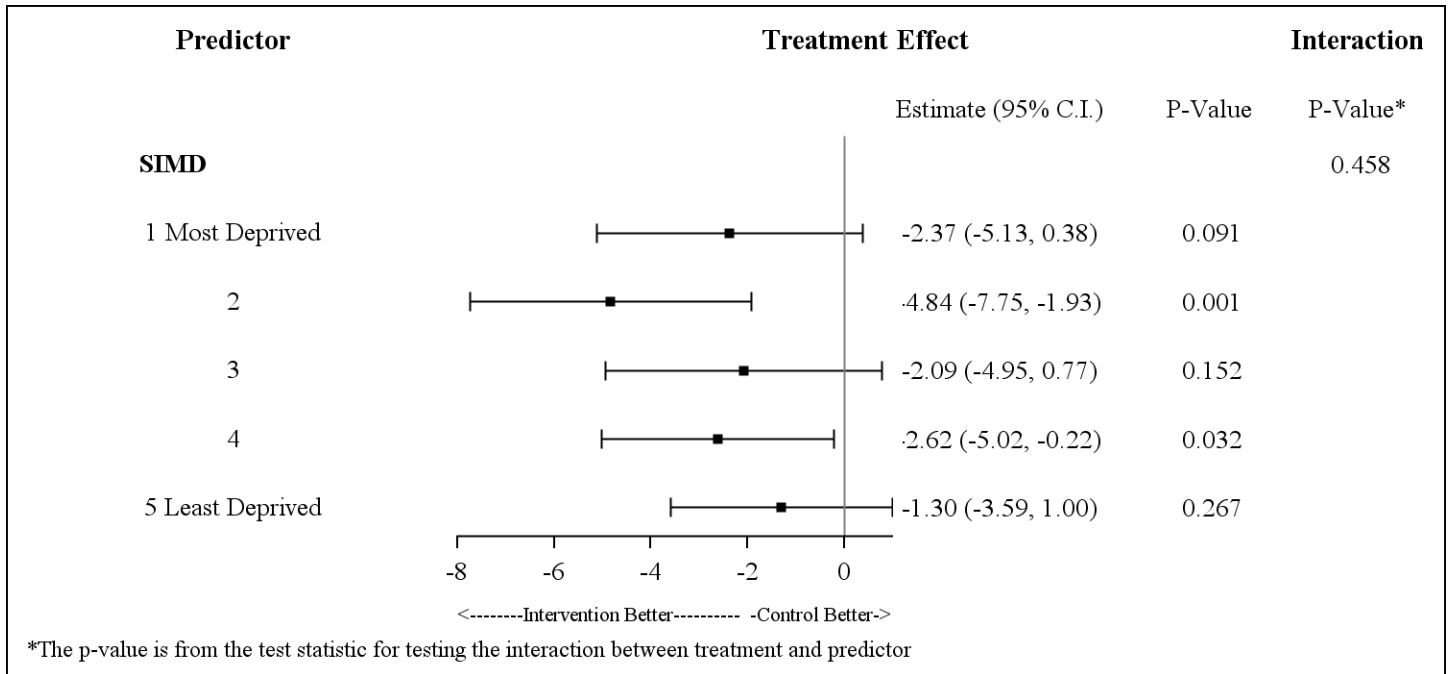


Table 7.5

Marital Status as Predictor of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Predictor Effects		
	Living with partner vs. Other	0.183 (-2.883, 3.249)	0.907
	Married vs. Other	-2.007 (-4.386, 0.371)	0.098
	Marital Status	Mean Change in Weight (kg)	
	Living with partner	-2.758 (-5.003, -0.513)	0.016
	Married	-4.948 (-6.094, -3.802)	<0.001
	Other	-2.941 (-5.026, -0.857)	0.006
Control	Predictor Effects		
	Living with partner vs. Other	0.226 (-2.728, 3.179)	0.881
	Married vs. Other	-0.539 (-2.529, 1.452)	0.595
	Marital Status	Mean Change in Weight (kg)	
	Living with partner	-1.091 (-3.420, 1.239)	0.358
	Married	-1.855 (-2.702, -1.008)	<0.001
	Other	-1.316 (-3.116, 0.483)	0.151

Note: Model also includes baseline weight and visit as fixed effects

Figure 7.5
Effect of Treatment on Change in Weight by Marital Status

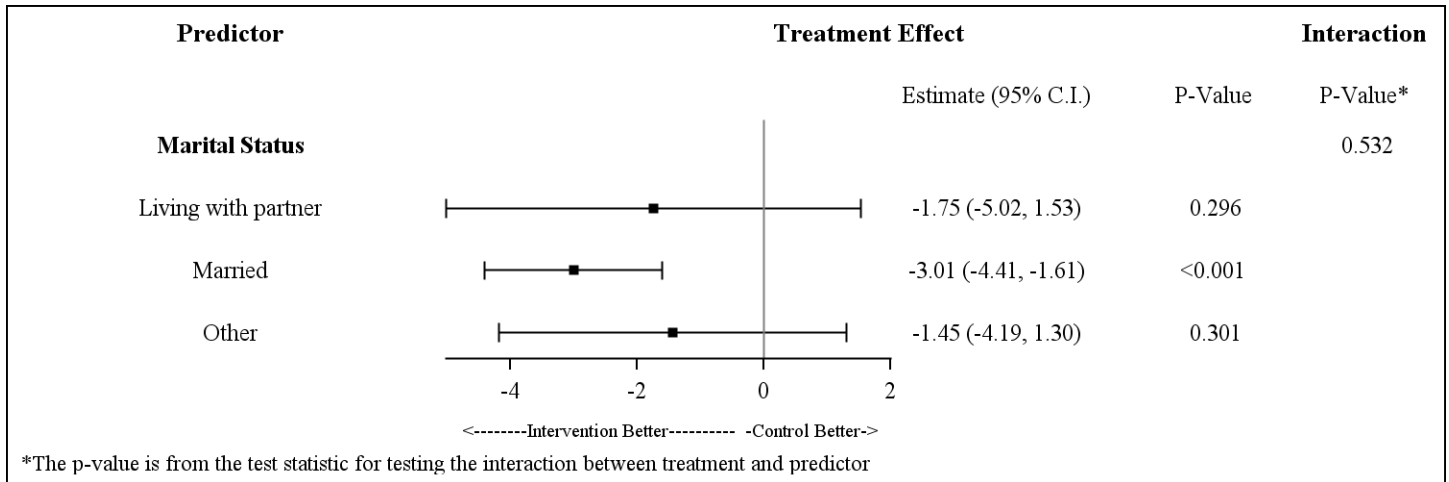


Table 7.6
Orientation to masculine norms as Predictor of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Predictor Effect			
Intervention	Baseline Conformity to masculine norms [normalized]	-0.308 (-3.931, 3.316)	0.867
Control	Baseline Conformity to masculine norms [normalized]	2.334 (-0.707, 5.375)	0.132
Interaction Effect			
All	Treatment * Orientation to Masculine Norms	-2.807 (-7.514, 1.900)	0.242

Note: Model also includes baseline weight and visit as fixed effects

Table 7.7
Number of Longstanding Illnesses as Predictor of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
	Predictor Effect		
Intervention	Baseline Number of longstanding illnesses	0.772 (-0.389, 1.934)	0.192
Control	Baseline Number of longstanding illnesses	0.361 (-0.450, 1.172)	0.382
	Interaction Effect		
All	Treatment * Illness Number	0.352 (-1.032, 1.735)	0.618

Note: Model also includes baseline weight and visit as fixed effects

Table 7.8
Employment Status as Predictor of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Predictor Effects		
	Not working due to long-term sickness or disability vs. Paid work	6.363 (1.298, 11.427)	0.014
	Other vs. Paid work	0.969 (-3.583, 5.520)	0.676
	Retired vs. Paid work	-1.370 (-5.909, 3.169)	0.553
	Unemployed vs. Paid work	-1.375 (-9.528, 6.778)	0.740
	Employment Status	Mean Change in Weight (kg)	
	Not working due to long-term sickness or disability	1.988 (-2.982, 6.957)	0.432
	Other	-3.406 (-7.851, 1.038)	0.133
	Retired	-5.746 (-10.178, -1.313)	0.011
	Unemployed	-5.750 (-13.845, 2.345)	0.163
	Paid work	-4.375 (-5.378, -3.372)	<0.001
Control	Predictor Effects		
	Not working due to long-term sickness or disability vs. Paid work	6.042 (0.815, 11.269)	0.024
	Other vs. Paid work	-0.424 (-3.997, 3.150)	0.816
	Retired vs. Paid work	-0.072 (-3.380, 3.236)	0.966
	Unemployed vs. Paid work	-0.041 (-3.613, 3.530)	0.982
	Employment Status	Mean Change in Weight (kg)	
	Not working due to long-term sickness or disability	4.256 (-0.911, 9.423)	0.106
	Other	-2.210 (-5.695, 1.275)	0.213
	Retired	-1.858 (-5.069, 1.354)	0.256
	Unemployed	-1.827 (-5.311, 1.656)	0.303
	Paid work	-1.786 (-2.574, -0.998)	<0.001

Note: Model also includes baseline weight and visit as fixed effects

Figure 7.8
Effect of Treatment on Change in Weight by Employment Status

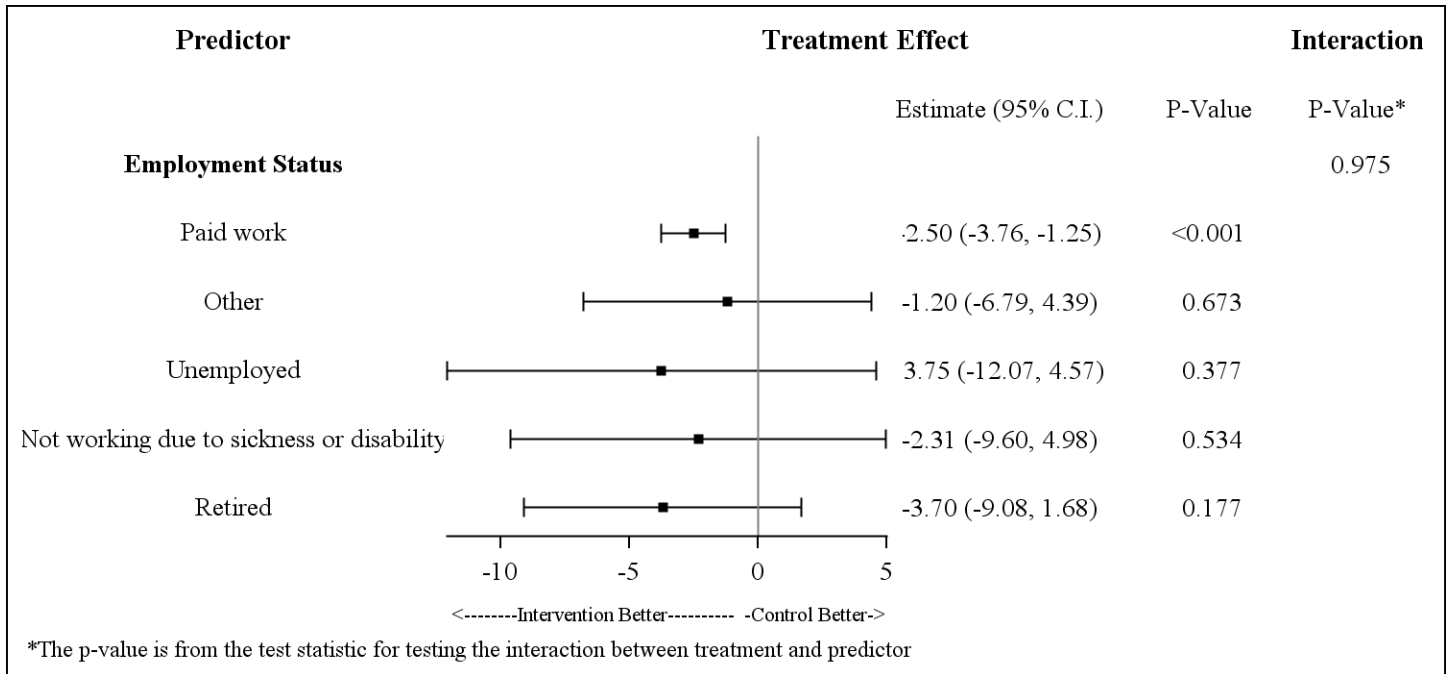


Table 7.9.1
Backwards Selection - Independent Predictors of Change in Weight in Intervention Group

There are no independent predictors in the intervention group. The selected model is the same as the referent model.

Reference model is the primary outcome model with baseline weight and visit as fixed effects.

Table 7.9.2
Backwards Selection - Independent Predictors of Change in Weight in Control Group

There are no independent predictors in the control group. The selected model is the same as the referent model.

Reference model is the primary outcome model with baseline weight and visit as fixed effects.

Table 8.1
Self-Reported Total Physical Activity as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	MET TOTAL (min/week)	-0.0002 (-0.0003, -0.0001)	<0.001
Control	MET TOTAL (min/week)	-0.0001 (-0.0002, -0.0000)	0.003
Interaction Effect			
All	Treatment * MET TOTAL	-0.0000 (-0.0002, 0.0001)	0.815

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.2
Self-Reported Vigorous Physical Activity as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
	Mediator Effect		
Intervention	MET Vigorous (min/week)	-0.0002 (-0.0004, -0.0001)	0.003
Control	MET Vigorous (min/week)	-0.0001 (-0.0003, 0.0000)	0.117
	Interaction Effect		
All	Treatment * MET Vigorous	-0.0001 (-0.0003, 0.0001)	0.242

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.3
Self-Reported Moderate Physical Activity as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	MET Moderate (min/week)	-0.0003 (-0.0006, 0.0000)	0.092
Control	MET Moderate (min/week)	-0.0001 (-0.0003, 0.0001)	0.364
Interaction Effect			
All	Treatment * MET Moderate	-0.0001 (-0.0004, 0.0003)	0.736

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

**Table 8.4
Self-Reported Walking as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group**

		Estimate (95% C.I.)	P-Value
	Mediator Effect		
Intervention	MET Walking (min/week)	-0.0003 (-0.0006, -0.0000)	0.026
Control	MET Walking (min/week)	-0.0005 (-0.0008, -0.0003)	<0.001
	Interaction Effect		
All	Treatment * MET Walking	0.0003 (-0.0001, 0.0007)	0.112

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.5
Truncated Self-Reported Total Physical Activity as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
	Mediator Effect		
Intervention	Truncated MET TOTAL (min/week)	-0.0004 (-0.0005, -0.0002)	<0.001
Control	Truncated MET TOTAL (min/week)	-0.0003 (-0.0005, -0.0002)	<0.001
	Interaction Effect		
All	Treatment * Truncated MET TOTAL	-0.0000 (-0.0002, 0.0002)	0.948

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.6
Truncated Self-Reported Vigorous Physical Activity as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	Truncated MET Vigorous (min/week)	-0.0005 (-0.0007, -0.0002)	<0.001
Control	Truncated MET Vigorous (min/week)	-0.0003 (-0.0005, -0.0001)	0.018
Interaction Effect			
All	Treatment * Truncated MET Vigorous	-0.0002 (-0.0006, 0.0001)	0.224

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.7
Truncated Self-Reported Moderate Physical Activity as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
	Mediator Effect		
Intervention	Truncated MET Moderate (min/week)	-0.0005 (-0.0009, -0.0001)	0.029
Control	Truncated MET Moderate (min/week)	-0.0003 (-0.0007, 0.0001)	0.133
	Interaction Effect		
All	Treatment * Truncated MET Moderate	-0.0000 (-0.0006, 0.0005)	0.881

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.8
Truncated Self-Reported Walking as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	Truncated MET Walking (min/week)	-0.0006 (-0.0010, -0.0002)	0.006
Control	Truncated MET Walking (min/week)	-0.0009 (-0.0013, -0.0005)	<0.001
Interaction Effect			
All	Treatment * Truncated MET Walking	0.0004 (-0.0002, 0.0010)	0.161

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.9
Self reported Sitting Time as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
	Mediator Effect		
Intervention	Sitting Time (min/day)	0.0026 (-0.0003, 0.0056)	0.083
Control	Sitting Time (min/day)	0.0032 (0.0007, 0.0056)	0.011
	Interaction Effect		
All	Treatment * Sit Time	0.0003 (-0.0036, 0.0043)	0.868

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.10
DINE Fatty Food Score as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	DINE Fatty Food Score	0.1785 (0.0990, 0.2580)	<0.001
Control	DINE Fatty Food Score	0.1502 (0.0738, 0.2266)	<0.001
Interaction Effect			
All	Treatment * Fatty Food Score	0.0215 (-0.0908, 0.1339)	0.707

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.11
DINE Sugary Food Score as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	DINE Sugary Food Score	0.4453 (0.2311, 0.6594)	<0.001
Control	DINE Sugary Food Score	0.4150 (0.2467, 0.5832)	<0.001
Interaction Effect			
All	Treatment * Sugary Food Score	0.0142 (-0.2574, 0.2859)	0.918

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.12
DINE Fruits and Vegetable Score as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	DINE Fruits and Vegetable Score	-0.8106 (-1.0805, -0.5407)	<0.001
Control	DINE Fruits and Vegetable Score	-0.3850 (-0.6296, -0.1404)	0.002
Interaction Effect			
All	Treatment * Fruits and Vegetable Score	-0.5199 (-0.8881, -0.1517)	0.006

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.13
Cheese Portion Size as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	Cheese Portion Size	0.5288 (0.2489, 0.8087)	<0.001
Control	Cheese Portion Size	0.4542 (0.2035, 0.7049)	<0.001
Interaction Effect			
All	Treatment * Cheese Portion Size	0.0427 (-0.3397, 0.4251)	0.827

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.14
Meat Portion Size as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
	Mediator Effect		
Intervention	Meat Portion Size	0.6543 (0.2873, 1.0213)	<0.001
Control	Meat Portion Size	0.7391 (0.4124, 1.0659)	<0.001
	Interaction Effect		
All	Treatment * Meat Portion Size	-0.1089 (-0.6099, 0.3920)	0.670

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.15
Pasta Portion Size as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	Pasta Portion Size	0.6527 (0.3060, 0.9993)	<0.001
Control	Pasta Portion Size	0.8321 (0.5253, 1.1390)	<0.001
Interaction Effect			
All	Treatment * Pasta Portion Size	-0.1617 (-0.6302, 0.3068)	0.499

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.16
Chips Portion Size as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	Chips Portion Size	0.5834 (0.2148, 0.9521)	0.002
Control	Chips Portion Size	0.6551 (0.3477, 0.9626)	<0.001
Interaction Effect			
All	Treatment * Chips Portion Size	-0.0395 (-0.5204, 0.4415)	0.872

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.17

Eating breakfast as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	Eating breakfast	-0.8985 (-1.5527, -0.2443)	0.007
Control	Eating breakfast	-0.8586 (-1.4306, -0.2865)	0.003
Interaction Effect			
All	Treatment * Eating breakfast	0.2339 (-0.6451, 1.1129)	0.602

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.18
Alcohol consumption as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	Total alcohol consumption (units/week)	0.0105 (-0.0333, 0.0542)	0.638
Control	Total alcohol consumption (units/week)	0.0329 (-0.0025, 0.0683)	0.068
Interaction Effect			
All	Treatment * Alcohol consumption	-0.0207 (-0.0774, 0.0361)	0.475

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.19
Negative affect PANAS as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	Negative affect PANAS [normalized]	0.3881 (-0.7673, 1.5435)	0.510
Control	Negative affect PANAS [normalized]	-0.0974 (-1.1162, 0.9215)	0.851
Interaction Effect			
All	Treatment * Negative PANAS	0.3940 (-1.1770, 1.9650)	0.623

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.20
Positive affect PANAS as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	Positive affect PANAS [normalized]	-2.2212 (-3.0284, -1.4141)	<0.001
Control	Positive affect PANAS [normalized]	-1.7552 (-2.5005, -1.0099)	<0.001
Interaction Effect			
All	Treatment * Positive PANAS	-0.4576 (-1.5687, 0.6535)	0.419

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.21
Rosenberg Self-Esteem Scale as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	Rosenberg Self-Esteem Scale [normalized]	-3.6581 (-5.1263, -2.1900)	<0.001
Control	Rosenberg Self-Esteem Scale [normalized]	-3.7295 (-4.9987, -2.4602)	<0.001
Interaction Effect			
All	Treatment * Rosenberg Score	0.8344 (-1.1136, 2.7823)	0.401

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.22
SF12 physical HRQoL as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	SF12 physical HRQoL	-0.1940 (-0.2618, -0.1262)	<0.001
Control	SF12 physical HRQoL	-0.1853 (-0.2421, -0.1286)	<0.001
Interaction Effect			
All	Treatment * SF12 Physical	-0.0094 (-0.0996, 0.0809)	0.838

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.23
SF12 mental HRQoL as Mediator of Change in Weight - Mixed Effects Linear Regression Model, Overall and by Group

		Estimate (95% C.I.)	P-Value
Mediator Effect			
Intervention	SF12 mental HRQoL	-0.0072 (-0.0708, 0.0564)	0.823
Control	SF12 mental HRQoL	-0.0111 (-0.0679, 0.0458)	0.702
Interaction Effect			
All	Treatment * SF12 Mental	-0.0095 (-0.0967, 0.0777)	0.830

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.24
Diet Relative Autonomous Motivation Index as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
TSRQ diet relative autonomous motivation index	n (missing)	446 (42)	212 (21)	234 (21)
	Mean (SD)	2.3 (1.34)	2.3 (1.26)	2.2 (1.41)
	Median (IQR)	2 [1 , 3]	2 [2 , 3]	2 [1 , 3]
	Min - Max	-1 , 6	-0 , 6	-1 , 6
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	TSRQ diet relative autonomous motivation index		-0.5323 (-1.1708, 0.1062)	0.102
Control	TSRQ diet relative autonomous motivation index		-0.5524 (-0.9650, -0.1399)	0.009
	Interaction Effect			
All	Treatment * TSRQ Diet Index		0.1412 (-0.5869, 0.8692)	0.704

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.25
Diet Autonomous as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
TSRQ diet autonomous scale	n (missing)	446 (42)	212 (21)	234 (21)
	Mean (SD)	5.6 (1.12)	5.7 (1.07)	5.5 (1.16)
	Median (IQR)	6 [5 , 7]	6 [5 , 7]	6 [5 , 6]
	Min - Max	1 , 7	2 , 7	1 , 7
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	TSRQ diet autonomous scale		-1.2352 (-1.9687, -0.5017)	<0.001
Control	TSRQ diet autonomous scale		-0.9783 (-1.4708, -0.4859)	<0.001
	Interaction Effect			
All	Treatment * TSRQ Diet Autonomous		-0.1471 (-1.0065, 0.7122)	0.737

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.26
Diet Control as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
TSRQ diet controlled scale	n (missing)	446 (42)	212 (21)	234 (21)
	Mean (SD)	3.3 (1.25)	3.3 (1.25)	3.3 (1.25)
	Median (IQR)	3 [2 , 4]	3 [3 , 4]	3 [2 , 4]
	Min - Max	1 , 7	1 , 7	1 , 6
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	TSRQ diet controlled scale		-0.3731 (-1.0044, 0.2583)	0.246
Control	TSRQ diet controlled scale		-0.1398 (-0.6131, 0.3335)	0.562
	Interaction Effect			
All	Treatment * TSRQ Diet Control		-0.2809 (-1.0588, 0.4970)	0.479

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.27
Diet Amotivation as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
TSRQ diet amotivation scale	n (missing)	446 (42)	212 (21)	234 (21)
	Mean (SD)	2.2 (1.12)	2.2 (1.19)	2.3 (1.07)
	Median (IQR)	2 [1 , 3]	2 [1 , 3]	2 [1 , 3]
	Min - Max	1 , 7	1 , 7	1 , 6
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	TSRQ diet amotivation scale		0.4721 (-0.1931, 1.1372)	0.164
Control	TSRQ diet amotivation scale		0.3942 (-0.1555, 0.9439)	0.160
	Interaction Effect			
All	Treatment * TSRQ Diet Amotivation		0.0203 (-0.8407, 0.8814)	0.963

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.28
Physical Activity Index as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
TSRQ exercise relative autonomous motivation index	n (missing)	446 (42)	212 (21)	234 (21)
	Mean (SD)	2.6 (1.48)	2.7 (1.47)	2.5 (1.49)
	Median (IQR)	3 [2 , 4]	3 [2 , 4]	3 [2 , 4]
	Min - Max	-1 , 6	-1 , 6	-1 , 6
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	TSRQ physical activity relative autonomous motivation index		-0.4890 (-1.0375, 0.0594)	0.080
Control	TSRQ physical activity relative autonomous motivation index		-0.5141 (-0.9035, -0.1247)	0.010
	Interaction Effect			
All	Treatment * TSRQ PA Index		0.1197 (-0.5355, 0.7750)	0.720

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.29

Physical Activity Autonomous as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
TSRQ exercise autonomous scale	n (missing)	446 (42)	212 (21)	234 (21)
	Mean (SD)	5.6 (1.14)	5.7 (1.09)	5.5 (1.17)
	Median (IQR)	6 [5 , 7]	6 [5 , 7]	6 [5 , 6]
	Min - Max	2 , 7	2 , 7	2 , 7
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	TSRQ physical activity autonomous scale		-1.2053 (-1.9249, -0.4857)	0.001
Control	TSRQ physical activity autonomous scale		-0.6790 (-1.1753, -0.1826)	0.007
	Interaction Effect			
All	Treatment * TSRQ PA Autonomous		-0.4256 (-1.2786, 0.4274)	0.328

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.30
Physical Activity Control as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
TSRQ exercise controlled scale	n (missing)	446 (42)	212 (21)	234 (21)
	Mean (SD)	3.0 (1.26)	3.0 (1.29)	3.0 (1.25)
	Median (IQR)	3 [2 , 4]	3 [2 , 4]	3 [2 , 4]
	Min - Max	1 , 7	1 , 7	1 , 7
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	TSRQ physical activity controlled scale		-0.2592 (-0.8739, 0.3555)	0.408
Control	TSRQ physical activity controlled scale		0.1464 (-0.3245, 0.6174)	0.542
	Interaction Effect			
All	Treatment * TSRQ PA Control		-0.4355 (-1.2023, 0.3313)	0.265

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.31
Physical Activity Amotivation as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
TSRQ exercise amotivation scale	n (missing)	446 (42)	212 (21)	234 (21)
	Mean (SD)	2.0 (1.08)	2.0 (1.13)	2.0 (1.04)
	Median (IQR)	2 [1 , 3]	2 [1 , 3]	2 [1 , 3]
	Min - Max	1 , 6	1 , 6	1 , 6
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	TSRQ physical activity amotivation scale		0.5909 (-0.1157, 1.2974)	0.101
Control	TSRQ physical activity amotivation scale		0.4491 (-0.1137, 1.0119)	0.118
	Interaction Effect			
All	Treatment * TSRQ PA Amotivation		0.0383 (-0.8542, 0.9309)	0.933

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.32
LoC Diet as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Locus of causality for diet	n (missing)	446 (42)	212 (21)	234 (21)
	Mean (SD)	4.4 (1.34)	4.4 (1.36)	4.4 (1.32)
	Median (IQR)	4 [3 , 5]	4 [3 , 5]	4 [3 , 5]
	Min - Max	1 , 7	1 , 7	1 , 7
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Locus of causality for diet		-0.7182 (-1.2920, -0.1443)	0.014
Control	Locus of causality for diet		-0.7169 (-1.1562, -0.2776)	0.001
	Interaction Effect			
All	Treatment * LoC Diet		0.0541 (-0.6582, 0.7665)	0.882

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.33
LoC Physical Activity as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Locus of causality for exercise	n (missing)	446 (42)	212 (21)	234 (21)
	Mean (SD)	5.0 (1.40)	5.1 (1.38)	4.9 (1.41)
	Median (IQR)	5 [4 , 6]	5 [4 , 6]	5 [4 , 6]
	Min - Max	1 , 7	2 , 7	1 , 7
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Locus of causality for exercise		-0.5489 (-1.1208, 0.0230)	0.060
Control	Locus of causality for exercise		-0.5311 (-0.9432, -0.1191)	0.012
	Interaction Effect			
All	Treatment * LoC PA		0.0430 (-0.6486, 0.7345)	0.903

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.34
PC Diet as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Perceived competence - maintaining a healthy diet	n (missing)	446 (42)	212 (21)	234 (21)
	Mean (SD)	4.5 (1.45)	4.5 (1.43)	4.5 (1.46)
	Median (IQR)	5 [4 , 6]	5 [4 , 6]	5 [4 , 6]
	Min - Max	1 , 7	1 , 7	1 , 7
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Perceived competence - maintaining a healthy diet		-1.3760 (-1.9014, -0.8506)	<0.001
Control	Perceived competence - maintaining a healthy diet		-1.0822 (-1.4584, -0.7060)	<0.001
	Interaction Effect			
All	Treatment * PC Diet		-0.2367 (-0.8716, 0.3982)	0.465

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.35
PC Physical Activity as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Perceived competence - exercising regularly	n (missing)	446 (42)	212 (21)	234 (21)
	Mean (SD)	5.2 (1.47)	5.2 (1.52)	5.1 (1.41)
	Median (IQR)	6 [4 , 6]	6 [4 , 6]	5 [4 , 6]
	Min - Max	1 , 7	1 , 7	1 , 7
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Perceived competence - exercising regularly		-1.1960 (-1.6936, -0.6984)	<0.001
Control	Perceived competence - exercising regularly		-0.6574 (-1.0663, -0.2486)	0.002
	Interaction Effect			
All	Treatment * PC PA		-0.4660 (-1.1043, 0.1724)	0.152

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.36
Peers Intimacy as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Need for relatedness scale - peers intimacy	n (missing)	403 (85)	205 (28)	198 (57)
	Mean (SD)	3.2 (1.84)	3.4 (1.86)	3.0 (1.80)
	Median (IQR)	3 [1 , 5]	3 [1 , 5]	3 [1 , 4]
	Min - Max	1 , 7	1 , 7	1 , 7
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Need for relatedness scale - peers intimacy		-0.1508 (-0.5759, 0.2744)	0.486
Control	Need for relatedness scale - peers intimacy		-0.5057 (-0.8585, -0.1529)	0.005
	Interaction Effect			
All	Treatment * Peers Intimacy		0.3406 (-0.2158, 0.8971)	0.230

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.37
Family Intimacy as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Need for relatedness scale - family intimacy	n (missing)	442 (46)	209 (24)	233 (22)
	Mean (SD)	6.2 (1.00)	6.2 (1.03)	6.2 (0.98)
	Median (IQR)	7 [6 , 7]	7 [6 , 7]	7 [6 , 7]
	Min - Max	1 , 7	1 , 7	2 , 7
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Need for relatedness scale - family intimacy		-0.1499 (-0.9238, 0.6239)	0.704
Control	Need for relatedness scale - family intimacy		-0.0122 (-0.6160, 0.5915)	0.968
	Interaction Effect			
All	Treatment * Family Intimacy		-0.1470 (-1.1221, 0.8280)	0.767

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.38
Peers Acceptance as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Need for relatedness scale - peers acceptance	n (missing)	404 (84)	205 (28)	199 (56)
	Mean (SD)	3.9 (1.91)	4.0 (1.92)	3.8 (1.90)
	Median (IQR)	4 [2 , 5]	4 [2 , 6]	4 [2 , 5]
	Min - Max	1 , 7	1 , 7	1 , 7
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Need for relatedness scale - peers acceptance		-0.2036 (-0.6169, 0.2097)	0.334
Control	Need for relatedness scale - peers acceptance		-0.2637 (-0.6019, 0.0744)	0.126
	Interaction Effect			
All	Treatment * Peers Acceptance		0.0460 (-0.4888, 0.5807)	0.866

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.39
Family Acceptance as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Need for relatedness scale - family acceptance	n (missing)	442 (46)	209 (24)	233 (22)
	Mean (SD)	5.9 (1.04)	5.9 (1.05)	5.9 (1.03)
	Median (IQR)	6 [5 , 7]	6 [6 , 7]	6 [5 , 7]
	Min - Max	1 , 7	1 , 7	2 , 7
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Need for relatedness scale - family acceptance		-0.5157 (-1.2770, 0.2456)	0.184
Control	Need for relatedness scale - family acceptance		-0.3333 (-0.9031, 0.2365)	0.251
	Interaction Effect			
All	Treatment * Family Acceptance		-0.1700 (-1.1098, 0.7697)	0.723

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.40
Change in Diet Immediate Satisfaction as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Satisfaction following changes to diet just after FFIT programme	n (missing)	413 (75)	205 (28)	208 (47)
	Others	74 (17.9%)	31 (15.1%)	43 (20.7%)
	Very satisfied	339 (82.1%)	174 (84.9%)	165 (79.3%)
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Satisfaction following changes to diet just after FFIT programme		-1.0869 (-3.2926, 1.1188)	0.334
Control	Satisfaction following changes to diet just after FFIT programme		-0.8439 (-2.3722, 0.6844)	0.279
	Interaction Effect			
All	Treatment * Change in Diet Immediate Satisfaction		-0.3692 (-3.0096, 2.2711)	0.784

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.41
Change in PA Immediate Satisfaction as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Satisfaction following changes to physical activity just after FFIT pr	n (missing)	413 (75)	205 (28)	208 (47)
	Others	69 (16.7%)	28 (13.7%)	41 (19.7%)
	Very satisfied	344 (83.3%)	177 (86.3%)	167 (80.3%)
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Satisfaction following changes to physical activity just after FFIT pr		-2.0805 (-4.3647, 0.2037)	0.074
Control	Satisfaction following changes to physical activity just after FFIT pr		-0.8250 (-2.3845, 0.7345)	0.299
	Interaction Effect			
All	Treatment * Change in PA Immediate Satisfaction		-1.2170 (-3.9365, 1.5026)	0.380

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.42
Change in Weight Immediate Satisfaction as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Satisfaction following changes to weight just after FFIT programme	n (missing)	412 (76)	205 (28)	207 (48)
	Others	90 (21.8%)	40 (19.5%)	50 (24.2%)
	Very satisfied	322 (78.2%)	165 (80.5%)	157 (75.8%)
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Satisfaction following changes to weight just after FFIT programme		-2.5560 (-4.5173, -0.5948)	0.011
Control	Satisfaction following changes to weight just after FFIT programme		-1.2741 (-2.7209, 0.1728)	0.084
	Interaction Effect			
All	Treatment * Change in Weight Immediate Satisfaction		-1.3083 (-3.7234, 1.1068)	0.288

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.43
Change in Diet FU Satisfaction as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Satisfaction following changes to diet at fu	n (missing)	414 (74)	205 (28)	209 (46)
	Others	208 (50.2%)	105 (51.2%)	103 (49.3%)
	Very satisfied	206 (49.8%)	100 (48.8%)	106 (50.7%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Satisfaction following changes to diet at fu		-3.3411 (-4.8446, -1.8377)	<0.001
Control	Satisfaction following changes to diet at fu		-3.0939 (-4.2601, -1.9276)	<0.001
	Interaction Effect			
All	Treatment * Change in Diet FU Satisfaction		-0.1680 (-2.0641, 1.7282)	0.862

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.44
Change in PA FU Satisfaction as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Satisfaction following changes to physical activity at fu	n (missing)	414 (74)	205 (28)	209 (46)
	Others	199 (48.1%)	104 (50.7%)	95 (45.5%)
	Very satisfied	215 (51.9%)	101 (49.3%)	114 (54.5%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Satisfaction following changes to physical activity at fu		-3.7922 (-5.2759, -2.3084)	<0.001
Control	Satisfaction following changes to physical activity at fu		-2.0978 (-3.3052, -0.8905)	<0.001
All	Interaction Effect Treatment * Change in PA FU Satisfaction		-1.6203 (-3.5316, 0.2910)	0.097

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.45
Routinisation of Walking as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Routinisation of PA - walking	n (missing)	416 (72)	205 (28)	211 (44)
	Never/ Rarely/ Sometimes	123 (29.6%)	58 (28.3%)	65 (30.8%)
	Frequently/ Always	293 (70.4%)	147 (71.7%)	146 (69.2%)
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Routinisation of PA - walking		-1.0855 (-2.8286, 0.6576)	0.222
Control	Routinisation of PA - walking		-1.0619 (-2.3890, 0.2651)	0.117
	Interaction Effect			
All	Treatment * Routinisation of Walking		0.1144 (-2.0538, 2.2825)	0.918

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.46
Routinisation of Attending Gym as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Routinisation of PA - attending gym	n (missing)	414 (74)	203 (30)	211 (44)
	Never/ Rarely/ Sometimes	346 (83.6%)	170 (83.7%)	176 (83.4%)
	Frequently/ Always	68 (16.4%)	33 (16.3%)	35 (16.6%)
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Routinisation of PA - attending gym		-2.4327 (-4.5591, -0.3063)	0.025
Control	Routinisation of PA - attending gym		-0.9504 (-2.5939, 0.6931)	0.257
	Interaction Effect			
All	Treatment * Routinisation of Attending Gym		-1.3482 (-4.0162, 1.3197)	0.322

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.47
Routinisation of Indp Exercise as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Routinisation of PA - other forms of exercise	n (missing)	415 (73)	204 (29)	211 (44)
	Never/ Rarely/ Sometimes	270 (65.1%)	132 (64.7%)	138 (65.4%)
	Frequently/ Always	145 (34.9%)	72 (35.3%)	73 (34.6%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Routinisation of PA - other forms of exercise		-0.7609 (-2.4107, 0.8889)	0.365
Control	Routinisation of PA - other forms of exercise		-1.4772 (-2.7564, -0.1979)	0.024
	Interaction Effect			
All	Treatment * Routinisation of Indp Exercise		0.8335 (-1.2420, 2.9091)	0.431

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.48
Routinisation of Exercise Programme as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Routinisation of PA - group exercise programme	n (missing)	412 (76)	203 (30)	209 (46)
	Never/ Rarely/ Sometimes	352 (85.4%)	163 (80.3%)	189 (90.4%)
	Frequently/ Always	60 (14.6%)	40 (19.7%)	20 (9.6%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Routinisation of PA - group exercise programme		-2.9490 (-4.9021, -0.9958)	0.003
Control	Routinisation of PA - group exercise programme		0.0432 (-2.0515, 2.1379)	0.968
	Interaction Effect			
All	Treatment * Routinisation of Exercise Programme		-2.9945 (-5.9464, -0.0425)	0.047

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.49
Regular Meals as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Routinisation of diet - regular meals	n (missing)	415 (73)	204 (29)	211 (44)
	Never/ Rarely/ Sometimes	84 (20.2%)	48 (23.5%)	36 (17.1%)
	Frequently/ Always	331 (79.8%)	156 (76.5%)	175 (82.9%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Routinisation of diet - regular meals		-1.4436 (-3.3185, 0.4314)	0.131
Control	Routinisation of diet - regular meals		-1.3127 (-2.9309, 0.3055)	0.112
	Interaction Effect			
All	Treatment * Regular Meals		0.0535 (-2.4331, 2.5400)	0.966

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.50
Limit Portion Size as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Routinisation of diet - limit portion size	n (missing)	415 (73)	204 (29)	211 (44)
	Never/ Rarely/ Sometimes	219 (52.8%)	107 (52.5%)	112 (53.1%)
	Frequently/ Always	196 (47.2%)	97 (47.5%)	99 (46.9%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Routinisation of diet - limit portion size		-2.3090 (-3.8577, -0.7602)	0.004
Control	Routinisation of diet - limit portion size		-2.1152 (-3.3150, -0.9154)	<0.001
	Interaction Effect			
All	Treatment * Limit Portion Size		-0.2240 (-2.1759, 1.7278)	0.822

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.51
Limit Food as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Routinisation of diet - limit fatty/ sugary food	n (missing)	416 (72)	205 (28)	211 (44)
	Never/ Rarely/ Sometimes	185 (44.5%)	93 (45.4%)	92 (43.6%)
	Frequently/ Always	231 (55.5%)	112 (54.6%)	119 (56.4%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Routinisation of diet - limit fatty/ sugary food		-1.6829 (-3.2447, -0.1212)	0.035
Control	Routinisation of diet - limit fatty/ sugary food		-1.8791 (-3.0933, -0.6650)	0.002
	Interaction Effect			
All	Treatment * Limit Food		0.2041 (-1.7718, 2.1800)	0.839

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.52
Limit Calories as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Routinisation of diet - limit calories	n (missing)	416 (72)	205 (28)	211 (44)
	Never/ Rarely/ Sometimes	312 (75.0%)	152 (74.1%)	160 (75.8%)
	Frequently/ Always	104 (25.0%)	53 (25.9%)	51 (24.2%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Routinisation of diet - limit calories		-2.6786 (-4.4366, -0.9206)	0.003
Control	Routinisation of diet - limit calories		-3.0719 (-4.4441, -1.6997)	<0.001
All	Interaction Effect Treatment * Limit Calories		0.3004 (-1.9263, 2.5270)	0.791

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.53
Limit Sugary Drinks as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Routinisation of diet - limit sugary drinks	n (missing)	416 (72)	205 (28)	211 (44)
	Never/ Rarely/ Sometimes	120 (28.8%)	57 (27.8%)	63 (29.9%)
	Frequently/ Always	296 (71.2%)	148 (72.2%)	148 (70.1%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Routinisation of diet - limit sugary drinks		-1.1103 (-2.8590, 0.6384)	0.213
Control	Routinisation of diet - limit sugary drinks		-0.9873 (-2.3233, 0.3486)	0.147
All	Interaction Effect Treatment * Limit Sugary Drinks		-0.0958 (-2.2829, 2.0913)	0.932

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.54
Limit Alcohol as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Routinisation of diet - limit alcohol	n (missing)	416 (72)	205 (28)	211 (44)
	Never/ Rarely/ Sometimes	179 (43.0%)	88 (42.9%)	91 (43.1%)
	Frequently/ Always	237 (57.0%)	117 (57.1%)	120 (56.9%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Routinisation of diet - limit alcohol		-0.1956 (-1.7866, 1.3954)	0.809
Control	Routinisation of diet - limit alcohol		0.5207 (-0.7190, 1.7604)	0.410
All	Interaction Effect Treatment * Limit Alcohol		-0.8183 (-2.8238, 1.1872)	0.424

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.55
Eat Slowly as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Routinisation of diet - eat slowly	n (missing)	414 (74)	205 (28)	209 (46)
	Never/ Rarely/ Sometimes	348 (84.1%)	169 (82.4%)	179 (85.6%)
	Frequently/ Always	66 (15.9%)	36 (17.6%)	30 (14.4%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Routinisation of diet - eat slowly		1.1894 (-0.8726, 3.2515)	0.258
Control	Routinisation of diet - eat slowly		0.0120 (-1.7464, 1.7703)	0.989
All	Interaction Effect Treatment * Eat Slowly		1.2183 (-1.5097, 3.9463)	0.381

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.56
Read Food Labels as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Routinisation of diet - read food labels	n (missing)	415 (73)	204 (29)	211 (44)
	Never/ Rarely/ Sometimes	233 (56.1%)	113 (55.4%)	120 (56.9%)
	Frequently/ Always	182 (43.9%)	91 (44.6%)	91 (43.1%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Routinisation of diet - read food labels		-1.6131 (-3.1833, -0.0429)	0.044
Control	Routinisation of diet - read food labels		-1.1645 (-2.4019, 0.0728)	0.065
All	Interaction Effect Treatment * Read Food Labels		-0.5486 (-2.5369, 1.4397)	0.588

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.57
Pedometer as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Ongoing use of BCT - pedometer	n (missing)	414 (74)	205 (28)	209 (46)
	Never/ Rarely	198 (47.8%)	95 (46.3%)	103 (49.3%)
	Sometimes/ Frequently/ Always	216 (52.2%)	110 (53.7%)	106 (50.7%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Ongoing use of BCT - pedometer		0.3489 (-1.2290, 1.9267)	0.664
Control	Ongoing use of BCT - pedometer		-0.2990 (-1.5383, 0.9403)	0.636
All	Interaction Effect Treatment * Pedometer		0.6624 (-1.3386, 2.6633)	0.516

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.58
Monitor Weight as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Ongoing use of BCT - monitor weight	n (missing)	413 (75)	204 (29)	209 (46)
	Never/ Rarely	104 (25.2%)	47 (23.0%)	57 (27.3%)
	Sometimes/ Frequently/ Always	309 (74.8%)	157 (77.0%)	152 (72.7%)
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Ongoing use of BCT - monitor weight		-1.5991 (-3.4903, 0.2921)	0.097
Control	Ongoing use of BCT - monitor weight		-1.5704 (-2.9404, -0.2004)	0.025
	Interaction Effect			
All	Treatment * Monitor Weight		0.1394 (-2.1623, 2.4412)	0.905

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.59
SMART Foals as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Ongoing use of BCT - SMART goals	n (missing)	414 (74)	205 (28)	209 (46)
	Never/ Rarely	232 (56.0%)	109 (53.2%)	123 (58.9%)
	Sometimes/ Frequently/ Always	182 (44.0%)	96 (46.8%)	86 (41.1%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Ongoing use of BCT - SMART goals		-0.3437 (-1.9200, 1.2326)	0.669
Control	Ongoing use of BCT - SMART goals		-0.4192 (-1.6779, 0.8396)	0.513
	Interaction Effect			
All	Treatment * SMART Foals		0.0941 (-1.9195, 2.1077)	0.927

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.60
Tips to Overcome Setbacks as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Ongoing use of BCT - tips	n (missing)	411 (77)	204 (29)	207 (48)
	Never/ Rarely	229 (55.7%)	102 (50.0%)	127 (61.4%)
	Sometimes/ Frequently/ Always	182 (44.3%)	102 (50.0%)	80 (38.6%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Ongoing use of BCT - tips		-1.9675 (-3.5326, - 0.4024)	0.014
Control	Ongoing use of BCT - tips		-0.1553 (-1.4371, 1.1265)	0.812
	Interaction Effect			
All	Treatment * Tips		-1.8369 (-3.8616, 0.1878)	0.075

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.61
Exercise Support as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Ongoing use of BCT - support in more exercise	n (missing)	414 (74)	205 (28)	209 (46)
	Never/ Rarely	143 (34.5%)	57 (27.8%)	86 (41.1%)
	Sometimes/ Frequently/ Always	271 (65.5%)	148 (72.2%)	123 (58.9%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Ongoing use of BCT - support in more exercise		-0.7772 (-2.5298, 0.9755)	0.384
Control	Ongoing use of BCT - support in more exercise		-0.4598 (-1.7210, 0.8015)	0.474
All	Interaction Effect Treatment * Exercise Support		-0.2450 (-2.3725, 1.8825)	0.821

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.62
Healthy Diet Support as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Ongoing use of BCT - support for eating healthier	n (missing)	414 (74)	205 (28)	209 (46)
	Never/ Rarely	98 (23.7%)	37 (18.0%)	61 (29.2%)
	Sometimes/ Frequently/ Always	316 (76.3%)	168 (82.0%)	148 (70.8%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Ongoing use of BCT - support for eating healthier		0.2099 (-1.8357, 2.2555)	0.840
Control	Ongoing use of BCT - support for eating healthier		-1.4591 (-2.7982, -0.1201)	0.033
	Interaction Effect			
All	Treatment * Healthy Diet Support		1.7077 (-0.6863, 4.1018)	0.162

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.63
Ongoing Contact with Other FFIT Participants as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Ongoing contact with other FFIT participants	n (missing)	420 (68)	209 (24)	211 (44)
	Never	144 (34.3%)	56 (26.8%)	88 (41.7%)
	Very frequently/ Frequently/ Occasionally /Rarely	276 (65.7%)	153 (73.2%)	123 (58.3%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Ongoing contact with other FFIT participants		-3.6387 (-5.3749, -1.9025)	<0.001
Control	Ongoing contact with other FFIT participants		-0.7749 (-2.0253, 0.4754)	0.224
All	Interaction Effect Treatment * Contact w/ Participants		-2.9084 (-5.0110, -0.8058)	0.007

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.64
Ongoing Contact with FFIT Coaches as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Ongoing contact with FFIT coaches	n (missing)	421 (67)	209 (24)	212 (43)
	Never	202 (48.0%)	83 (39.7%)	119 (56.1%)
	Very frequently/ Frequently/ Occasionally /Rarely	219 (52.0%)	126 (60.3%)	93 (43.9%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Ongoing contact with FFIT coaches		-2.2090 (-3.8221, -0.5958)	0.007
Control	Ongoing contact with FFIT coaches		-0.8024 (-2.0364, 0.4317)	0.202
All	Interaction Effect Treatment * Contact w/ Coaches		-1.4262 (-3.4458, 0.5934)	0.166

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.65

Ongoing Contact with Other Weight Management Initiatives as Mediator - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Ongoing contact with club-based and other health promotion/weight mana	n (missing)	421 (67)	209 (24)	212 (43)
	Never	290 (68.9%)	143 (68.4%)	147 (69.3%)
	Very frequently/ Frequently/ Occasionally /Rarely	131 (31.1%)	66 (31.6%)	65 (30.7%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Ongoing contact with club-based and other health promotion/weight mana		-0.7416 (-2.4611, 0.9780)	0.397
Control	Ongoing contact with club-based and other health promotion/weight mana		0.0562 (-1.2756, 1.3880)	0.934
	Interaction Effect			
All	Treatment * Contact w/ Clubs		-0.7992 (-2.9665, 1.3682)	0.470

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.66
Number of Major Changes to Own Health as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Number of major changes in life circumstances - own health	n (missing)	447 (41)	213 (20)	234 (21)
	0	370 (82.8%)	176 (82.6%)	194 (82.9%)
	1	72 (16.1%)	35 (16.4%)	37 (15.8%)
	2	5 (1.1%)	2 (0.9%)	3 (1.3%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Number of major changes in life circumstances - own health		2.5410 (0.6652, 4.4169)	0.008
Control	Number of major changes in life circumstances - own health		0.3814 (-0.9804, 1.7432)	0.583
	Interaction Effect			
All	Treatment * Own Health		2.2031 (-0.0777, 4.4840)	0.058

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.67

Number of Major Changes to Personal Circumstances as Mediator - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Number of major changes in life circumstances - personal circumstances	n (missing)	446 (42)	211 (22)	235 (20)
	0	342 (76.7%)	166 (78.7%)	176 (74.9%)
	1	82 (18.4%)	34 (16.1%)	48 (20.4%)
	2	13 (2.9%)	7 (3.3%)	6 (2.6%)
	3	7 (1.6%)	4 (1.9%)	3 (1.3%)
	4	2 (0.4%)		2 (0.9%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Number of major changes in life circumstances - personal circumstances		0.4125 (-0.8742, 1.6991)	0.529
Control	Number of major changes in life circumstances - personal circumstances		-0.0971 (-0.9353, 0.7410)	0.820
All	Interaction Effect Treatment * Personal Circumstances		0.4317 (-1.0580, 1.9214)	0.570

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.68

Number of Major Changes to Family Health as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Number of major changes in life circumstances - family health	n (missing)	448 (40)	212 (21)	236 (19)
	0	233 (52.0%)	100 (47.2%)	133 (56.4%)
	1	139 (31.0%)	68 (32.1%)	71 (30.1%)
	2	65 (14.5%)	36 (17.0%)	29 (12.3%)
	3	11 (2.5%)	8 (3.8%)	3 (1.3%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Number of major changes in life circumstances - family health		-0.0567 (-0.9636, 0.8502)	0.902
Control	Number of major changes in life circumstances - family health		0.3146 (-0.4571, 1.0863)	0.424
	Interaction Effect			
All	Treatment * Family Health		-0.3605 (-1.5525, 0.8316)	0.553

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.69
Number of Major Changes to Work as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Number of major changes in life circumstances - work	n (missing)	447 (41)	212 (21)	235 (20)
	0	280 (62.6%)	131 (61.8%)	149 (63.4%)
	1	108 (24.2%)	51 (24.1%)	57 (24.3%)
	2	47 (10.5%)	25 (11.8%)	22 (9.4%)
	3	10 (2.2%)	4 (1.9%)	6 (2.6%)
	4	2 (0.4%)	1 (0.5%)	1 (0.4%)
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Number of major changes in life circumstances -work		0.3434 (-0.6230, 1.3099)	0.486
Control	Number of major changes in life circumstances -work		0.1569 (-0.5518, 0.8656)	0.664
	Interaction Effect			
All	Treatment * Work		0.1240 (-1.0605, 1.3084)	0.837

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.70

Total Number of Major Changes in life circumstances as Mediator - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Number of major changes in life circumstances - total	n (missing)	450 (38)	214 (19)	236 (19)
	0	98 (21.8%)	45 (21.0%)	53 (22.5%)
	1	128 (28.4%)	57 (26.6%)	71 (30.1%)
	2	102 (22.7%)	55 (25.7%)	47 (19.9%)
	3	70 (15.6%)	27 (12.6%)	43 (18.2%)
	4	27 (6.0%)	15 (7.0%)	12 (5.1%)
	5	15 (3.3%)	7 (3.3%)	8 (3.4%)
	6	7 (1.6%)	6 (2.8%)	1 (0.4%)
	7	2 (0.4%)	1 (0.5%)	1 (0.4%)
	9	1 (0.2%)	1 (0.5%)	
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Number of major changes in life circumstances - total		0.2469 (-0.2422, 0.7360)	0.322
Control	Number of major changes in life circumstances - total		0.1686 (-0.2463, 0.5834)	0.425
	Interaction Effect			
All	Treatment * Total Changes		0.0566 (-0.5865, 0.6998)	0.863

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.71
12 month Upper Limb Joint Pain Frequency as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
12 month Joint Pain Frequency - Upper (includes neck and back)	n (missing)	488 (0)	233 (0)	255 (0)
	Other	464 (95.1%)	222 (95.3%)	242 (94.9%)
	All the time	24 (4.9%)	11 (4.7%)	13 (5.1%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect 12 month Upper Limb Joint Pain Frequency (All the time)		-1.4459 (-5.0100, 2.1181)	0.426
Control	12 month Upper Limb Joint Pain Frequency (All the time)		0.2355 (-2.3190, 2.7900)	0.856
All	Interaction Effect Treatment * Upper Limb Frequency		-1.6657 (-5.9926, 2.6611)	0.450

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.72

12 month Lower Limb Joint Pain Frequency as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
12 month Joint Pain Frequency - Lower	n (missing)	488 (0)	233 (0)	255 (0)
	Other	450 (92.2%)	212 (91.0%)	238 (93.3%)
	All the time	38 (7.8%)	21 (9.0%)	17 (6.7%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect 12 month Lower Limb Joint Pain Frequency (All the time)		0.2793 (-2.3676, 2.9261)	0.836
Control	12 month Lower Limb Joint Pain Frequency (All the time)		2.1366 (-0.1105, 4.3838)	0.062
	Interaction Effect			
All	Treatment * Lower Limb Frequency		-2.1174 (-5.6041, 1.3694)	0.234

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.73
12 month Upper Limb Limiting JP as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
12 month Limiting Pain - Upper (includes neck and back)	n (missing)	488 (0)	233 (0)	255 (0)
	Others	474 (97.1%)	225 (96.6%)	249 (97.6%)
	To a moderate degree and above	14 (2.9%)	8 (3.4%)	6 (2.4%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect 12 month Upper Limb Limiting JP (To a moderate degree and above)		0.7707 (-3.4062, 4.9475)	0.717
Control	12 month Upper Limb Limiting JP (To a moderate degree and above)		-0.1611 (-3.8493, 3.5272)	0.932
	Interaction Effect			
All	Treatment * Upper Limb Limiting JP		0.9270 (-4.7166, 6.5705)	0.747

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.74
12 month Lower Limb Limiting JP as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
12 month Limiting Pain - Lower	n (missing)	488 (0)	233 (0)	255 (0)
	Others	457 (93.6%)	216 (92.7%)	241 (94.5%)
	To a moderate degree and above	31 (6.4%)	17 (7.3%)	14 (5.5%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect 12 month Lower Limb Limiting JP (To a moderate degree and above)		1.2564 (-1.6608, 4.1737)	0.398
Control	12 month Lower Limb Limiting JP (To a moderate degree and above)		2.3683 (-0.0644, 4.8010)	0.056
	Interaction Effect			
All	Treatment * Lower Limb Limiting JP		-1.2126 (-5.0338, 2.6086)	0.534

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.75

FU Upper Limb Joint Pain Frequency as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
FU Joint Pain Frequency - Upper (includes neck and back)	n (missing)	450 (38)	214 (19)	236 (19)
	Other	401 (89.1%)	191 (89.3%)	210 (89.0%)
	All the time	49 (10.9%)	23 (10.7%)	26 (11.0%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect FU Upper Limb Joint Pain Frequency (All the time vs Others)		2.5348 (0.0112, 5.0584)	0.049
Control	FU Upper Limb Joint Pain Frequency (All the time vs Others)		0.5307 (-1.3266, 2.3880)	0.575
	Interaction Effect			
All	Treatment * Upper Limb Frequency		1.8860 (-1.2034, 4.9754)	0.231

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.76

FU Lower Limb Joint Pain Frequency as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
FU Joint Pain Frequency - Lower	n (missing)	450 (38)	214 (19)	236 (19)
	Other	403 (89.6%)	186 (86.9%)	217 (91.9%)
	All the time	47 (10.4%)	28 (13.1%)	19 (8.1%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect FU Lower Limb Joint Pain Frequency (All the time vs Others)		1.0005 (-1.3395, 3.3404)	0.401
Control	FU Lower Limb Joint Pain Frequency (All the time vs Others)		1.6788 (-0.4548, 3.8124)	0.123
	Interaction Effect			
All	Treatment * Lower Limb Frequency		-0.8543 (-4.0534, 2.3448)	0.600

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.77

FU Upper Limb Limiting JP as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
FU Limiting Pain - Upper(includes neck and back)	n (missing)	450 (38)	214 (19)	236 (19)
	Others	400 (88.9%)	191 (89.3%)	209 (88.6%)
	To a moderate degree and above	50 (11.1%)	23 (10.7%)	27 (11.4%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect FU Upper Limb Limiting JP (To a moderate degree and above)		2.6442 (0.0632, 5.2253)	0.045
Control	FU Upper Limb Limiting JP (To a moderate degree and above)		1.1501 (-0.6784, 2.9786)	0.217
All	Interaction Effect Treatment * Upper Limb Limiting JP		1.1479 (-1.9291, 4.2249)	0.464

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.78

FU Lower Limb Limiting JP as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
FU Limiting Pain - Lower	n (missing)	450 (38)	214 (19)	236 (19)
	Others	402 (89.3%)	188 (87.9%)	214 (90.7%)
	To a moderate degree and above	48 (10.7%)	26 (12.1%)	22 (9.3%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect FU Lower Limb Limiting JP (To a moderate degree and above)		1.3389 (-1.0672, 3.7449)	0.275
Control	FU Lower Limb Limiting JP (To a moderate degree and above)		1.8376 (-0.1563, 3.8314)	0.071
	Interaction Effect			
All	Treatment * Lower Limb Limiting JP		-0.6620 (-3.7808, 2.4567)	0.677

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.79
Any Upper Limb Pain at 12 Months as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Any Upper Limb Pain at 12 Months	n (missing)	488 (0)	233 (0)	255 (0)
	Never/ Don't know	297 (60.9%)	148 (63.5%)	149 (58.4%)
	Any	191 (39.1%)	85 (36.5%)	106 (41.6%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Any Upper Limb Pain at 12 Months		-0.5071 (-2.0827, 1.0685)	0.528
Control	Any Upper Limb Pain at 12 Months		-0.4881 (-1.6218, 0.6456)	0.398
	Interaction Effect			
All	Treatment * Upper Limb Pain		-0.1077 (-2.0231, 1.8077)	0.912

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.80
Any Lower Limb Pain at 12 Months as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Any Lower Limb Pain at 12 Months	n (missing)	488 (0)	233 (0)	255 (0)
	Never/ Don't know	320 (65.6%)	147 (63.1%)	173 (67.8%)
	Any	168 (34.4%)	86 (36.9%)	82 (32.2%)
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Any Lower Limb Pain at 12 Months		-0.3814 (-1.9599, 1.1972)	0.635
Control	Any Lower Limb Pain at 12 Months		0.5844 (-0.6108, 1.7796)	0.337
	Interaction Effect			
All	Treatment * Lower Limb Pain		-1.0780 (-3.0418, 0.8857)	0.282

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.81
Any Joint Pain at 12 Months as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Any Joint Pain at 12 Months	n (missing)	488 (0)	233 (0)	255 (0)
	Never/ Don't know	211 (43.2%)	99 (42.5%)	112 (43.9%)
	Any	277 (56.8%)	134 (57.5%)	143 (56.1%)
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Any Joint Pain at 12 Months		-0.7545 (-2.2913, 0.7824)	0.335
Control	Any Joint Pain at 12 Months		-0.2627 (-1.3946, 0.8692)	0.649
	Interaction Effect			
All	Treatment * Any Joint Pain		-0.6573 (-2.5405, 1.2259)	0.494

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.82
Any Upper Limb Pain at FU as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Any Upper Limb Pain at FU	n (missing)	450 (38)	214 (19)	236 (19)
	Never/ Don't know	243 (54.0%)	124 (57.9%)	119 (50.4%)
	Any	207 (46.0%)	90 (42.1%)	117 (49.6%)
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Any Upper Limb Pain at FU		0.6892 (-0.9242, 2.3025)	0.402
Control	Any Upper Limb Pain at FU		-0.1106 (-1.2786, 1.0574)	0.853
	Interaction Effect			
All	Treatment * Upper Limb Pain		0.6775 (-1.2789, 2.6338)	0.497

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.83
Any Lower Limb Pain at FU as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Any Lower Limb Pain at FU	n (missing)	450 (38)	214 (19)	236 (19)
	Never/ Don't know	264 (58.7%)	120 (56.1%)	144 (61.0%)
	Any	186 (41.3%)	94 (43.9%)	92 (39.0%)
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Any Lower Limb Pain at FU		0.6923 (-0.9012, 2.2859)	0.394
Control	Any Lower Limb Pain at FU		0.1267 (-1.0654, 1.3188)	0.835
	Interaction Effect			
All	Treatment * Lower Limb Pain		0.4370 (-1.5239, 2.3979)	0.662

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.84
Any Joint Pain at FU as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Any Joint Pain at FU	n (missing)	450 (38)	214 (19)	236 (19)
	Never/ Don't know	162 (36.0%)	80 (37.4%)	82 (34.7%)
	Any	288 (64.0%)	134 (62.6%)	154 (65.3%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Any Joint Pain at FU		0.6276 (-1.0202, 2.2754)	0.455
Control	Any Joint Pain at FU		0.2072 (-1.0198, 1.4342)	0.740
	Interaction Effect			
All	Treatment * Any Joint Pain		0.2284 (-1.7916, 2.2484)	0.824

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.85
Number of Lower Limb Injuries at 12 Months as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Number of Lower Limb Injuries at 12 Months	n (missing)	487 (1)	232 (1)	255 (0)
	0	414 (85.0%)	183 (78.9%)	231 (90.6%)
	1	67 (13.8%)	43 (18.5%)	24 (9.4%)
	2	6 (1.2%)	6 (2.6%)	
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Number of Lower Limb Injuries at 12 Months		0.5296 (-1.0397, 2.0989)	0.508
Control	Number of Lower Limb Injuries at 12 Months		-0.9285 (-2.8420, 0.9849)	0.341
	Interaction Effect			
All	Treatment * Number of Lower Limb Injuries		1.3854 (-1.2259, 3.9968)	0.298

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.86
Number of Torso/Upper Body Injuries at 12 Months as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Number of Torso/Upper Body Injuries at 12 Months	n (missing)	487 (1)	232 (1)	255 (0)
	0	455 (93.4%)	210 (90.5%)	245 (96.1%)
	1	31 (6.4%)	21 (9.1%)	10 (3.9%)
	2	1 (0.2%)	1 (0.4%)	
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Number of Torso/Upper Body Injuries at 12 Months		0.4048 (-2.0200, 2.8296)	0.743
Control	Number of Torso/Upper Body Injuries at 12 Months		0.6937 (-2.1803, 3.5677)	0.636
	Interaction Effect			
All	Treatment * Number of Torso/Upper Body Injuries		-0.3697 (-4.3249, 3.5854)	0.855

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.87
Any Injuries at 12 Months that Limit Walking as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Any Injuries at 12 Months that Limit Walking	n (missing)	487 (1)	232 (1)	255 (0)
	No	463 (95.1%)	214 (92.2%)	249 (97.6%)
	Yes	24 (4.9%)	18 (7.8%)	6 (2.4%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Any Injuries at 12 Months that Limit Walking		3.4505 (0.6397, 6.2613)	0.016
Control	Any Injuries at 12 Months that Limit Walking		-0.4339 (-4.1145, 3.2467)	0.817
	Interaction Effect			
All	Treatment * Injuries that Limit Walking		3.8047 (-1.1066, 8.7160)	0.129

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.88

Any Injuries at 12 Months that Limit Using Stairs as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Any Injuries at 12 Months that Limit Using Stairs	n (missing)	487 (1)	232 (1)	255 (0)
	No	462 (94.9%)	216 (93.1%)	246 (96.5%)
	Yes	25 (5.1%)	16 (6.9%)	9 (3.5%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Any Injuries at 12 Months that Limit Using Stairs		2.8332 (-0.1591, 5.8255)	0.063
Control	Any Injuries at 12 Months that Limit Using Stairs		-0.7812 (-3.8036, 2.2411)	0.612
	Interaction Effect			
All	Treatment * Injuries that Limit Using Stairs		3.3272 (-1.0524, 7.7068)	0.136

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.89
Any Injuries at 12 Months that Limit PA as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Any Injuries at 12 Months that Limit PA	n (missing)	487 (1)	232 (1)	255 (0)
	No	444 (91.2%)	201 (86.6%)	243 (95.3%)
	Yes	43 (8.8%)	31 (13.4%)	12 (4.7%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Any Injuries at 12 Months that Limit PA		2.0934 (-0.1210, 4.3079)	0.064
Control	Any Injuries at 12 Months that Limit PA		0.6795 (-1.9546, 3.3137)	0.613
	Interaction Effect			
All	Treatment * Any Injuries that Limit PA		1.4518 (-2.1600, 5.0637)	0.431

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.90
Total Types of Limitations due to Injury at 12 Months as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Total Types of Limitations due to Injury at 12 Months	n (missing)	487 (1)	232 (1)	255 (0)
	0	439 (90.1%)	200 (86.2%)	239 (93.7%)
	1	21 (4.3%)	13 (5.6%)	8 (3.1%)
	2	10 (2.1%)	5 (2.2%)	5 (2.0%)
	3	17 (3.5%)	14 (6.0%)	3 (1.2%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Total Types of Limitations due to Injury at 12 Months		1.1027 (0.1367, 2.0686)	0.025
Control	Total Types of Limitations due to Injury at 12 Months		-0.0299 (-1.2638, 1.2041)	0.962
	Interaction Effect			
All	Treatment * Total Types of Limitations		1.1045 (-0.5531, 2.7621)	0.191

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.91

Number of Lower Limb Injuries at FU as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Number of Lower Limb Injuries at FU	n (missing)	450 (38)	214 (19)	236 (19)
	0	373 (82.9%)	174 (81.3%)	199 (84.3%)
	1	66 (14.7%)	32 (15.0%)	34 (14.4%)
	2	11 (2.4%)	8 (3.7%)	3 (1.3%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Number of Lower Limb Injuries at FU		1.3839 (-0.1813, 2.9490)	0.083
Control	Number of Lower Limb Injuries at FU		-0.2223 (-1.6500, 1.2053)	0.760
	Interaction Effect			
All	Treatment * Number of Lower Limb Injuries		1.5196 (-0.6196, 3.6589)	0.164

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.92
Number of Torso/Upper Body Injuries at FU as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Number of Torso/Upper Body Injuries at FU	n (missing)	450 (38)	214 (19)	236 (19)
	0	414 (92.0%)	191 (89.3%)	223 (94.5%)
	1	36 (8.0%)	23 (10.7%)	13 (5.5%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Number of Torso/Upper Body Injuries at FU		0.6721 (-1.8950, 3.2393)	0.607
Control	Number of Torso/Upper Body Injuries at FU		0.3942 (-2.1498, 2.9382)	0.761
	Interaction Effect			
All	Treatment * Number of Torso/Upper Body Injuries		0.0288 (-3.6616, 3.7192)	0.988

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.93

Any Injuries at FU that Limit Walking as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Any Injuries at FU that Limit Walking	n (missing)	450 (38)	214 (19)	236 (19)
	No	425 (94.4%)	201 (93.9%)	224 (94.9%)
	Yes	25 (5.6%)	13 (6.1%)	12 (5.1%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Any Injuries at FU that Limit Walking		1.8669 (-1.4121, 5.1460)	0.264
Control	Any Injuries at FU that Limit Walking		3.3164 (0.6809, 5.9519)	0.014
	Interaction Effect			
All	Treatment * Injuries that Limit Walking		-1.5993 (-5.7803, 2.5817)	0.453

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.94
Any Injuries at FU that Limit Using Stairs as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Any Injuries at FU that Limit Using Stairs	n (missing)	450 (38)	214 (19)	236 (19)
	No	426 (94.7%)	204 (95.3%)	222 (94.1%)
	Yes	24 (5.3%)	10 (4.7%)	14 (5.9%)
			Estimate (95% C.I.)	P-Value
Mediator Effect				
Intervention	Any Injuries at FU that Limit Using Stairs	3.2590 (-0.4255, 6.9436)		0.083
Control	Any Injuries at FU that Limit Using Stairs	2.5869 (0.1434, 5.0305)		0.038
Interaction Effect				
All	Treatment * Injuries that Limit Using Stairs	0.6234 (-3.6755, 4.9223)		0.776

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.95
Any Injuries at FU that Limit PA as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Any Injuries at FU that Limit PA	n (missing)	450 (38)	214 (19)	236 (19)
	No	402 (89.3%)	194 (90.7%)	208 (88.1%)
	Yes	48 (10.7%)	20 (9.3%)	28 (11.9%)
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Any Injuries at FU that Limit PA		1.2833 (-1.4183, 3.9850)	0.351
Control	Any Injuries at FU that Limit PA		1.2520 (-0.5422, 3.0462)	0.171
	Interaction Effect			
All	Treatment * Any Injuries that Limit PA		-0.0196 (-3.1774, 3.1382)	0.990

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.96
Total Types of Limitations due to Injury at FU as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Total Types of Limitations due to Injury at FU	n (missing)	450 (38)	214 (19)	236 (19)
	0	398 (88.4%)	190 (88.8%)	208 (88.1%)
	1	25 (5.6%)	12 (5.6%)	13 (5.5%)
	2	9 (2.0%)	5 (2.3%)	4 (1.7%)
	3	18 (4.0%)	7 (3.3%)	11 (4.7%)
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Total Types of Limitations due to Injury at FU		0.8933 (-0.3371, 2.1237)	0.154
Control	Total Types of Limitations due to Injury at FU		0.8930 (0.0672, 1.7187)	0.034
	Interaction Effect			
All	Treatment * Total Types of Limitations		-0.0310 (-1.4729, 1.4109)	0.966

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.97

Attendance at FFIT sessions for Comparison Group as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Never attended FFIT programme for comparison group	n (missing)	236 (252)	0 (233)	236 (19)
	No	206 (87.3%)		206 (87.3%)
	Yes	30 (12.7%)		30 (12.7%)
			Estimate (95% C.I.)	P-Value
Control	Mediator Effect Never attended FFIT programme		0.0733 (-1.6820, 1.8286)	0.935

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.98
Attendance at FFIT sessions for Intervention Group as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Number of sessions attended ≥ 6 for intervention group	n (missing)	221 (267)	221 (12)	0 (255)
	No	32 (14.5%)	32 (14.5%)	
	Yes	189 (85.5%)	189 (85.5%)	
			Estimate (95% C.I.)	P-Value
Intervention	Mediator Effect Number of sessions attended ≥ 6		-4.1993 (-6.3789, -2.0198)	<0.001

Note: Model also includes baseline weight and visit as fixed effects. 12 weeks data also incorporated.

Table 8.99.1

Backwards Selection - Independent Mediators of Change in Weight in Intervention Group, Overall and by Group

	Estimate (95% C.I.)	P-Value
Change in DINE Sugary Food Score	0.3811 (0.1674, 0.5947)	<0.001
Change in DINE Fruits and Veg Score	-0.7070 (-0.9795, -0.4345)	<0.001
Change in cheese portion size	0.2931 (0.0213, 0.5648)	0.035
Perceived Competence - maintaining a healthy diet	-0.9281 (-1.5488, -0.3075)	0.003
Satisfaction following changes to physical activity at FU	-2.8064 (-4.4504, -1.1623)	<0.001
Routinisation of Diet - Eat Slowly	2.6436 (0.7085, 4.5786)	0.008
Lower Limb Joint Pain Limit Activities to a Moderate Degree and Above at 12 months	3.8765 (0.7031, 7.0499)	0.017
FU Limiting Pain - Upper	3.5237 (1.1363, 5.9110)	0.004

Note backwards selection was performed in GLM, the selected variables were then entered in the Mixed Model

Reference model is the primary outcome model with baseline weight and visit as fixed effects. 12 weeks data also incorporated.

The following were selected out from the GLM, but were no longer significant in the Mixed Model: Number of Torso/Upper Body Injuries at 12 Months, routinisation of PA - walking, Number of major changes in life circumstances - work, total and own health, Perceived competence - exercising regularly, Ongoing contact with FFIT coaches, Satisfaction following changes to physical activity and weight just after FFIT programme, TSRQ exercise amotivation scale, Any Injuries at FU that Limit Walking.

Table 8.99.2

Backwards Selection - Independent Mediators of Change in Weight in Control Group, Overall and by Group

	Estimate (95% C.I.)	P-Value
Change in DINE Sugary Food Score	0.4145 (0.2347, 0.5943)	<0.001
Change in DINE Fruits and Veg Score	-0.3016 (-0.5547, -0.0485)	0.020
Change in Meat Portion Size	0.4865 (0.1384, 0.8345)	0.006
Change in Pasta Portion Size	0.6548 (0.3368, 0.9727)	<0.001
Change in Having Breakfast (1 Category Increase)	-0.8314 (-1.4313, -0.2316)	0.007
Change in Rosenberg Self Esteem Scale	-2.5358 (-3.8475, -1.2240)	<0.001
Change in SF12 Physical HRQoL	-0.1882 (-0.2497, -0.1266)	<0.001
Satisfaction Following Changes to Diet at FU	-1.8479 (-2.9490, -0.7468)	0.001
Ongoing Use of BCT - Monitor Weight	-1.4684 (-2.6640, -0.2728)	0.016
Never attended FFIT programme for comparison group	5.7305 (1.3697, 10.0912)	0.010

Note backwards selection was performed in GLM, the selected variables were then entered in the Mixed Model

Reference model is the primary outcome model with baseline weight and visit as fixed effects. 12 weeks data also incorporated.

The following were selected out from the GLM, but were no longer significant in the Mixed Model: Satisfaction following changes to physical activity at fu.

Table 8.100
Post Intervention Weight Change as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Post intervention weight change	n (missing)	426 (62)	223 (10)	203 (52)
	Did not lose weight	44 (10.3%)	20 (9.0%)	24 (11.8%)
	Lost up to 5%	182 (42.7%)	100 (44.8%)	82 (40.4%)
	Lost 5-10%	148 (34.7%)	75 (33.6%)	73 (36.0%)
	Lost more than 10%	52 (12.2%)	28 (12.6%)	24 (11.8%)
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Intervention	Post Intervention Weight Change (1 category up)		-3.4385 (-4.6934, -2.1837)	<0.001
Control	Post Intervention Weight Change (1 category up)		-2.6105 (-3.9803, -1.2408)	<0.001
	Interaction Effect			
All	Treatment * Post Intervention Weight Change		-0.7564 (-2.5951, 1.0824)	0.419

Note: Model also includes baseline weight as fixed effect. The dependent variable is the change in weight at follow up, i.e. no 12 week or 12 months change in weight, therefore post intervention weight change as a mediator was not incorporated in the backwards selection model.

Table 8.101

Pre-Intervention Weight Change in Control Group as Mediator of Change in Weight - Mixed Effects Linear Regression Model and Summary, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Pre-intervention weight change in comparison group	n (missing)	251 (237)	0 (233)	251 (4)
	Mean (SD)	-0.5 (2.83)	. (.)	-0.5 (2.83)
	Median (IQR)	0 [-1 , 1]	. [. , .]	0 [-1 , 1]
	Min - Max	-15 , 6	. , .	-15 , 6
			Estimate (95% C.I.)	P-Value
	Mediator Effect			
Control	Pre-Intervention Weight Change (1 kg)		0.9425 (0.5813, 1.3038)	<0.001

Note: Model also includes baseline weight as fixed effect. The dependent variable is the change in weight at follow up, i.e. no 12 week or 12 months change in weight, therefore pre-intervention weight change as a mediator was not incorporated in the backwards selection model.

Table 9.1.1
Number of NHS Service Use Over Previous 3 Months I, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
GP	n (missing)	438 (50)	207 (26)	231 (24)
	Mean (SD)	0.8 (1.16)	0.7 (1.11)	0.8 (1.20)
	Median (IQR)	0 [0 , 1]	0 [0 , 1]	0 [0 , 1]
	Min - Max	0 , 8	0 , 7	0 , 8
GP	n (missing)	438 (50)	207 (26)	231 (24)
	0	233 (53.2%)	114 (55.1%)	119 (51.5%)
	1	132 (30.1%)	59 (28.5%)	73 (31.6%)
	2	41 (9.4%)	22 (10.6%)	19 (8.2%)
	3	17 (3.9%)	5 (2.4%)	12 (5.2%)
	4	8 (1.8%)	4 (1.9%)	4 (1.7%)
	5	2 (0.5%)	1 (0.5%)	1 (0.4%)
	6	3 (0.7%)	1 (0.5%)	2 (0.9%)
	7	1 (0.2%)	1 (0.5%)	0 (0.0%)
	8	1 (0.2%)	0 (0.0%)	1 (0.4%)
Nurse	n (missing)	435 (53)	205 (28)	230 (25)
	Mean (SD)	0.5 (2.17)	0.6 (3.00)	0.4 (0.93)
	Median (IQR)	0 [0 , 1]	0 [0 , 0]	0 [0 , 1]
	Min - Max	0 , 42	0 , 42	0 , 10
Nurse	n (missing)	435 (53)	205 (28)	230 (25)
	0	326 (74.9%)	157 (76.6%)	169 (73.5%)
	1	70 (16.1%)	28 (13.7%)	42 (18.3%)
	2	27 (6.2%)	13 (6.3%)	14 (6.1%)
	3	10 (2.3%)	6 (2.9%)	4 (1.7%)
	10	1 (0.2%)	0 (0.0%)	1 (0.4%)
	42	1 (0.2%)	1 (0.5%)	0 (0.0%)

Table 9.1.2
Number of NHS Service Use Over Previous 3 Months II, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Physiotherapist	n (missing)	439 (49)	205 (28)	234 (21)
	Mean (SD)	0.2 (1.06)	0.2 (1.14)	0.2 (0.98)
	Median (IQR)	0 [0 , 0]	0 [0 , 0]	0 [0 , 0]
	Min - Max	0 , 12	0 , 12	0 , 8
Physiotherapist	n (missing)	439 (49)	205 (28)	234 (21)
	0	402 (91.6%)	190 (92.7%)	212 (90.6%)
	1	17 (3.9%)	5 (2.4%)	12 (5.1%)
	2	7 (1.6%)	4 (2.0%)	3 (1.3%)
	3	3 (0.7%)	1 (0.5%)	2 (0.9%)
	4	4 (0.9%)	2 (1.0%)	2 (0.9%)
	6	3 (0.7%)	2 (1.0%)	1 (0.4%)
	8	2 (0.5%)	0 (0.0%)	2 (0.9%)
	12	1 (0.2%)	1 (0.5%)	0 (0.0%)
Emergency	n (missing)	440 (48)	206 (27)	234 (21)
	Mean (SD)	0.1 (0.32)	0.1 (0.33)	0.1 (0.30)
	Median (IQR)	0 [0 , 0]	0 [0 , 0]	0 [0 , 0]
	Min - Max	0 , 3	0 , 3	0 , 2
Emergency	n (missing)	440 (48)	206 (27)	234 (21)
	0	407 (92.5%)	190 (92.2%)	217 (92.7%)
	1	30 (6.8%)	15 (7.3%)	15 (6.4%)
	2	2 (0.5%)	0 (0.0%)	2 (0.9%)
	3	1 (0.2%)	1 (0.5%)	0 (0.0%)

Table 9.1.3
Number of NHS Service Use Over Previous 3 Months III, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Outpatient	n (missing)	443 (45)	208 (25)	235 (20)
	Mean (SD)	0.4 (1.28)	0.4 (1.26)	0.5 (1.30)
	Median (IQR)	0 [0 , 0]	0 [0 , 0]	0 [0 , 0]
	Min - Max	0 , 12	0 , 12	0 , 9
Outpatient	n (missing)	443 (45)	208 (25)	235 (20)
	0	358 (80.8%)	172 (82.7%)	186 (79.1%)
	1	48 (10.8%)	22 (10.6%)	26 (11.1%)
	2	20 (4.5%)	9 (4.3%)	11 (4.7%)
	3	5 (1.1%)	2 (1.0%)	3 (1.3%)
	4	1 (0.2%)	0 (0.0%)	1 (0.4%)
	5	1 (0.2%)	0 (0.0%)	1 (0.4%)
	6	6 (1.4%)	1 (0.5%)	5 (2.1%)
	7	1 (0.2%)	0 (0.0%)	1 (0.4%)
	9	1 (0.2%)	0 (0.0%)	1 (0.4%)
	10	1 (0.2%)	1 (0.5%)	0 (0.0%)
	12	1 (0.2%)	1 (0.5%)	0 (0.0%)
	Inpatient	n (missing)	434 (54)	203 (30)
Mean (SD)		0.1 (1.48)	0.0 (0.37)	0.2 (2.00)
Median (IQR)		0 [0 , 0]	0 [0 , 0]	0 [0 , 0]
Min - Max		0 , 30	0 , 4	0 , 30
Inpatient	n (missing)	434 (54)	203 (30)	231 (24)
	0	424 (97.7%)	198 (97.5%)	226 (97.8%)
	1	6 (1.4%)	3 (1.5%)	3 (1.3%)
	3	1 (0.2%)	1 (0.5%)	0 (0.0%)
	4	1 (0.2%)	1 (0.5%)	0 (0.0%)
	5	1 (0.2%)	0 (0.0%)	1 (0.4%)
	30	1 (0.2%)	0 (0.0%)	1 (0.4%)

Table 9.1.4
Number of NHS Service Use Over Previous 3 Months IV, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Other NHS	n (missing)	437 (51)	205 (28)	232 (23)
	Mean (SD)	0.2 (0.81)	0.2 (0.78)	0.3 (0.84)
	Median (IQR)	0 [0 , 0]	0 [0 , 0]	0 [0 , 0]
	Min - Max	0 , 8	0 , 8	0 , 6
Other NHS	n (missing)	437 (51)	205 (28)	232 (23)
	0	380 (87.0%)	180 (87.8%)	200 (86.2%)
	1	31 (7.1%)	15 (7.3%)	16 (6.9%)
	2	14 (3.2%)	7 (3.4%)	7 (3.0%)
	3	5 (1.1%)	1 (0.5%)	4 (1.7%)
	4	5 (1.1%)	1 (0.5%)	4 (1.7%)
	6	1 (0.2%)	0 (0.0%)	1 (0.4%)
	8	1 (0.2%)	1 (0.5%)	0 (0.0%)

Table 9.2.1
Number of Prescriptions/ Times Bought Without Prescriptions Over Previous 3 Months I, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Prescribed medicines of interest	n (missing)	448 (40)	214 (19)	234 (21)
	Mean (SD)	1.1 (1.77)	1.0 (1.83)	1.1 (1.71)
	Median (IQR)	0 [0 , 2]	0 [0 , 2]	0 [0 , 2]
	Min - Max	0 , 12	0 , 10	0 , 12
Prescribed medicines of interest	n (missing)	448 (40)	214 (19)	234 (21)
	0	262 (58.5%)	134 (62.6%)	128 (54.7%)
	1	58 (12.9%)	25 (11.7%)	33 (14.1%)
	2	50 (11.2%)	21 (9.8%)	29 (12.4%)
	3	41 (9.2%)	14 (6.5%)	27 (11.5%)
	4	17 (3.8%)	7 (3.3%)	10 (4.3%)
	5	7 (1.6%)	6 (2.8%)	1 (0.4%)
	6	4 (0.9%)	2 (0.9%)	2 (0.9%)
	7	1 (0.2%)	1 (0.5%)	0 (0.0%)
	8	4 (0.9%)	1 (0.5%)	3 (1.3%)
	9	2 (0.4%)	2 (0.9%)	0 (0.0%)
	10	1 (0.2%)	1 (0.5%)	0 (0.0%)
	12	1 (0.2%)	0 (0.0%)	1 (0.4%)

Table 9.2.2

Number of Prescriptions/ Times Bought Without Prescriptions Over Previous 3 Months II, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Not prescribed medicines of interest	n (missing)	395 (93)	187 (46)	208 (47)
	Mean (SD)	1.9 (4.51)	1.9 (3.35)	2.0 (5.34)
	Median (IQR)	1 [0 , 2]	1 [0 , 3]	1 [0 , 2]
	Min - Max	0 , 66	0 , 26	0 , 66
Not prescribed medicines of interest	n (missing)	395 (93)	187 (46)	208 (47)
	0	190 (48.1%)	90 (48.1%)	100 (48.1%)
	1	62 (15.7%)	27 (14.4%)	35 (16.8%)
	2	47 (11.9%)	23 (12.3%)	24 (11.5%)
	3	27 (6.8%)	11 (5.9%)	16 (7.7%)
	4	28 (7.1%)	16 (8.6%)	12 (5.8%)
	5	11 (2.8%)	6 (3.2%)	5 (2.4%)
	6	9 (2.3%)	5 (2.7%)	4 (1.9%)
	7	5 (1.3%)	2 (1.1%)	3 (1.4%)
	8	5 (1.3%)	2 (1.1%)	3 (1.4%)
	9	3 (0.8%)	1 (0.5%)	2 (1.0%)
	10	1 (0.3%)	0 (0.0%)	1 (0.5%)
	11	1 (0.3%)	0 (0.0%)	1 (0.5%)
	12	1 (0.3%)	1 (0.5%)	0 (0.0%)
	15	1 (0.3%)	1 (0.5%)	0 (0.0%)
	24	1 (0.3%)	1 (0.5%)	0 (0.0%)
	26	1 (0.3%)	1 (0.5%)	0 (0.0%)
30	1 (0.3%)	0 (0.0%)	1 (0.5%)	
66	1 (0.3%)	0 (0.0%)	1 (0.5%)	

Table 9.2.3

Number of Prescriptions/ Times Bought Without Prescriptions Over Previous 3 Months III, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Other prescribed medicine	n (missing)	444 (44)	212 (21)	232 (23)
	Mean (SD)	2.6 (5.69)	2.2 (3.54)	3.0 (7.10)
	Median (IQR)	0 [0 , 3]	0 [0 , 3]	1 [0 , 4]
	Min - Max	0 , 72	0 , 18	0 , 72
Other prescribed medicine	n (missing)	444 (44)	212 (21)	232 (23)
	0	232 (52.3%)	119 (56.1%)	113 (48.7%)
	1	30 (6.8%)	9 (4.2%)	21 (9.1%)
	2	43 (9.7%)	21 (9.9%)	22 (9.5%)
	3	32 (7.2%)	14 (6.6%)	18 (7.8%)
	4	22 (5.0%)	10 (4.7%)	12 (5.2%)
	5	9 (2.0%)	5 (2.4%)	4 (1.7%)
	6	23 (5.2%)	12 (5.7%)	11 (4.7%)
	7	4 (0.9%)	2 (0.9%)	2 (0.9%)
	8	12 (2.7%)	6 (2.8%)	6 (2.6%)
	9	9 (2.0%)	4 (1.9%)	5 (2.2%)
	10	5 (1.1%)	1 (0.5%)	4 (1.7%)
	12	8 (1.8%)	5 (2.4%)	3 (1.3%)
	13	1 (0.2%)	0 (0.0%)	1 (0.4%)
	14	1 (0.2%)	0 (0.0%)	1 (0.4%)
	15	9 (2.0%)	2 (0.9%)	7 (3.0%)
	18	2 (0.5%)	2 (0.9%)	0 (0.0%)
	63	1 (0.2%)	0 (0.0%)	1 (0.4%)
	72	1 (0.2%)	0 (0.0%)	1 (0.4%)

Table 9.2.4

Number of Prescriptions/ Times Bought Without Prescriptions Over Previous 3 Months IV, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Other not prescribed medicine	n (missing)	444 (44)	212 (21)	232 (23)
	Mean (SD)	0.1 (0.46)	0.1 (0.62)	0.0 (0.24)
	Median (IQR)	0 [0 , 0]	0 [0 , 0]	0 [0 , 0]
	Min - Max	0 , 6	0 , 6	0 , 3
Other not prescribed medicine	n (missing)	444 (44)	212 (21)	232 (23)
	0	431 (97.1%)	205 (96.7%)	226 (97.4%)
	1	6 (1.4%)	1 (0.5%)	5 (2.2%)
	2	3 (0.7%)	3 (1.4%)	0 (0.0%)
	3	2 (0.5%)	1 (0.5%)	1 (0.4%)
	5	1 (0.2%)	1 (0.5%)	0 (0.0%)
	6	1 (0.2%)	1 (0.5%)	0 (0.0%)

Table 9.2.5
Number of Prescriptions/ Times Bought Without Prescriptions Over Previous 3 Months V, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Total number of prescribed medicine	n (missing)	450 (38)	214 (19)	236 (19)
	Mean (SD)	3.7 (6.33)	3.2 (4.38)	4.1 (7.67)
	Median (IQR)	2 [0 , 5]	2 [0 , 5]	2 [0 , 6]
	Min - Max	0 , 76	0 , 26	0 , 76
Total number of prescribed medicine	n (missing)	450 (38)	214 (19)	236 (19)
	0	161 (35.8%)	88 (41.1%)	73 (30.9%)
	1	38 (8.4%)	13 (6.1%)	25 (10.6%)
	2	62 (13.8%)	30 (14.0%)	32 (13.6%)
	3	44 (9.8%)	18 (8.4%)	26 (11.0%)
	4	21 (4.7%)	9 (4.2%)	12 (5.1%)
	5	12 (2.7%)	4 (1.9%)	8 (3.4%)
	6	31 (6.9%)	13 (6.1%)	18 (7.6%)
	7	9 (2.0%)	5 (2.3%)	4 (1.7%)
	8	14 (3.1%)	7 (3.3%)	7 (3.0%)
	9	15 (3.3%)	10 (4.7%)	5 (2.1%)
	10	8 (1.8%)	2 (0.9%)	6 (2.5%)
	11	3 (0.7%)	2 (0.9%)	1 (0.4%)
	12	10 (2.2%)	4 (1.9%)	6 (2.5%)
	13	5 (1.1%)	2 (0.9%)	3 (1.3%)
	15	1 (0.2%)	0 (0.0%)	1 (0.4%)
	16	4 (0.9%)	2 (0.9%)	2 (0.8%)
	17	2 (0.4%)	2 (0.9%)	0 (0.0%)
	18	4 (0.9%)	2 (0.9%)	2 (0.8%)
	19	1 (0.2%)	0 (0.0%)	1 (0.4%)
	22	1 (0.2%)	0 (0.0%)	1 (0.4%)
	26	1 (0.2%)	1 (0.5%)	0 (0.0%)
	27	1 (0.2%)	0 (0.0%)	1 (0.4%)
	67	1 (0.2%)	0 (0.0%)	1 (0.4%)
	76	1 (0.2%)	0 (0.0%)	1 (0.4%)

Table 9.2.6

Number of Prescriptions/ Times Bought Without Prescriptions Over Previous 3 Months VI, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
Total number of not prescribed medicine	n (missing)	446 (42)	213 (20)	233 (22)
	Mean (SD)	1.8 (4.33)	1.7 (3.31)	1.8 (5.09)
	Median (IQR)	0 [0 , 2]	0 [0 , 2]	0 [0 , 2]
	Min - Max	0 , 66	0 , 26	0 , 66
Total number of not prescribed medicine	n (missing)	446 (42)	213 (20)	233 (22)
	0	239 (53.6%)	115 (54.0%)	124 (53.2%)
	1	59 (13.2%)	26 (12.2%)	33 (14.2%)
	2	49 (11.0%)	23 (10.8%)	26 (11.2%)
	3	26 (5.8%)	11 (5.2%)	15 (6.4%)
	4	27 (6.1%)	14 (6.6%)	13 (5.6%)
	5	12 (2.7%)	6 (2.8%)	6 (2.6%)
	6	12 (2.7%)	8 (3.8%)	4 (1.7%)
	7	6 (1.3%)	3 (1.4%)	3 (1.3%)
	8	4 (0.9%)	1 (0.5%)	3 (1.3%)
	9	3 (0.7%)	1 (0.5%)	2 (0.9%)
	10	1 (0.2%)	0 (0.0%)	1 (0.4%)
	11	1 (0.2%)	0 (0.0%)	1 (0.4%)
	12	1 (0.2%)	1 (0.5%)	0 (0.0%)
	13	1 (0.2%)	1 (0.5%)	0 (0.0%)
	15	1 (0.2%)	1 (0.5%)	0 (0.0%)
	24	1 (0.2%)	1 (0.5%)	0 (0.0%)
	26	1 (0.2%)	1 (0.5%)	0 (0.0%)
	30	1 (0.2%)	0 (0.0%)	1 (0.4%)
66	1 (0.2%)	0 (0.0%)	1 (0.4%)	

Table 9.3
SF6D, Overall and by Group

		All Subjects (N = 488)	Intervention (N = 233)	Control (N = 255)
SF6D	n (missing)	451 (37)	214 (19)	237 (18)
	Mean (SD)	0.80 (0.13)	0.79 (0.14)	0.81 (0.13)
	Median (IQR)	0.9 [0.7 , 0.9]	0.8 [0.7 , 0.9]	0.9 [0.7 , 0.9]
	Min - Max	0.3 , 1.0	0.3 , 1.0	0.4 , 1.0

Table 10.1.1
Weight at 12 Month - Change and Percent Change From Baseline, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)	P-Value
Weight(kg) 12 Month					
Baseline	N (missing)	747 (0)	374 (0)	373 (0)	
	Mean (sd)	109.46 (17.26)	110.26 (17.85)	108.65 (16.63)	
	(95% CI)	(108.22, 110.70)	(108.45, 112.08)	(106.96, 110.35)	
	Median (IQR)	107.3 (97.6, 118.6)	107.9 (98.2, 121.4)	107.2 (97.2, 116.4)	
	[Min, Max]	[71, 180]	[71, 180]	[73, 180]	
Follow up	N (missing)	747 (0)	374 (0)	373 (0)	-2.79 (-0.25, -5.34),
	Mean (sd)	106.70 (17.73)	105.31 (18.11)	108.10 (17.26)	0.0312
	(95% CI)	(105.43, 107.98)	(103.47, 107.15)	(106.34, 109.86)	
	Median (IQR)	104.2 (94.4, 116.6)	102.0 (92.6, 116.0)	105.9 (96.1, 116.6)	
	[Min, Max]	[58, 183]	[58, 164]	[71, 183]	
Change from baseline	N (missing)	747 (0)	374 (0)	373 (0)	-4.40 (-3.46, -5.35),
	Mean (sd)	-2.76 (6.92)	-4.95 (7.79)	-0.55 (5.06)	<0.0001*
	(95% CI)	(-3.25, -2.26)	(-5.75, -4.16)	(-1.07, -0.04)	
	Median (IQR)	-1.0 (-4.9, 1.1)	-2.7 (-8.6, 0.0)	0.0 (-2.5, 2.1)	
	[Min, Max]	[-39, 17]	[-37, 12]	[-39, 17]	
	P-Value	<0.0001**	<0.0001**	0.2762**	
Percent change from baseline (%)	N (missing)	747 (0)	374 (0)	373 (0)	-3.92 (-3.09, -4.75),
	Mean (sd)	-2.45 (6.09)	-4.41 (6.78)	-0.49 (4.53)	<0.0001*
	(95% CI)	(-2.89, -2.02)	(-5.10, -3.72)	(-0.95, -0.03)	
	Median (IQR)	-1.0 (-4.6, 1.0)	-2.4 (-7.0, 0.0)	0.0 (-2.3, 1.9)	
	[Min, Max]	[-31, 15]	[-31, 10]	[-31, 15]	
	P-Value	<0.0001**	<0.0001**	0.2738**	

Table 10.1.2
Weight at FU - Change and Percent Change From Baseline, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)	P-Value
Weight(kg) FU					
Baseline	N (missing)	747 (0)	374 (0)	373 (0)	
	Mean (sd)	109.46 (17.26)	110.26 (17.85)	108.65 (16.63)	
	(95% CI)	(108.22, 110.70)	(108.45, 112.08)	(106.96, 110.35)	
	Median (IQR)	107.3 (97.6, 118.6)	107.9 (98.2, 121.4)	107.2 (97.2, 116.4)	
	[Min, Max]	[71, 180]	[71, 180]	[73, 180]	
Follow up	N (missing)	747 (0)	374 (0)	373 (0)	1.65 (4.21, -0.90),
	Mean (sd)	107.63 (17.80)	108.46 (18.26)	106.80 (17.32)	0.2045
	(95% CI)	(106.35, 108.91)	(106.60, 110.31)	(105.04, 108.57)	
	Median (IQR)	105.0 (95.4, 117.5)	105.1 (96.4, 118.9)	104.5 (94.2, 116.1)	
	[Min, Max]	[65, 193]	[65, 166]	[70, 193]	
Change from baseline	N (missing)	747 (0)	374 (0)	373 (0)	0.05 (1.07, -0.98),
	Mean (sd)	-1.83 (7.10)	-1.81 (7.00)	-1.85 (7.22)	0.7984*
	(95% CI)	(-2.34, -1.32)	(-2.52, -1.09)	(-2.58, -1.12)	
	Median (IQR)	0.0 (-4.0, 0.4)	0.0 (-3.7, 0.0)	0.0 (-4.5, 0.6)	
	[Min, Max]	[-62, 24]	[-62, 20]	[-43, 24]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	
Percent change from baseline (%)	N (missing)	747 (0)	374 (0)	373 (0)	0.04 (0.92, -0.84),
	Mean (sd)	-1.59 (6.12)	-1.57 (5.78)	-1.61 (6.45)	0.7898*
	(95% CI)	(-2.03, -1.15)	(-2.16, -0.98)	(-2.27, -0.96)	
	Median (IQR)	0.0 (-3.9, 0.4)	0.0 (-3.6, 0.0)	0.0 (-4.2, 0.7)	
	[Min, Max]	[-35, 23]	[-35, 17]	[-34, 23]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Figure 10.1.1
Mean Weight by Treatment and Visit

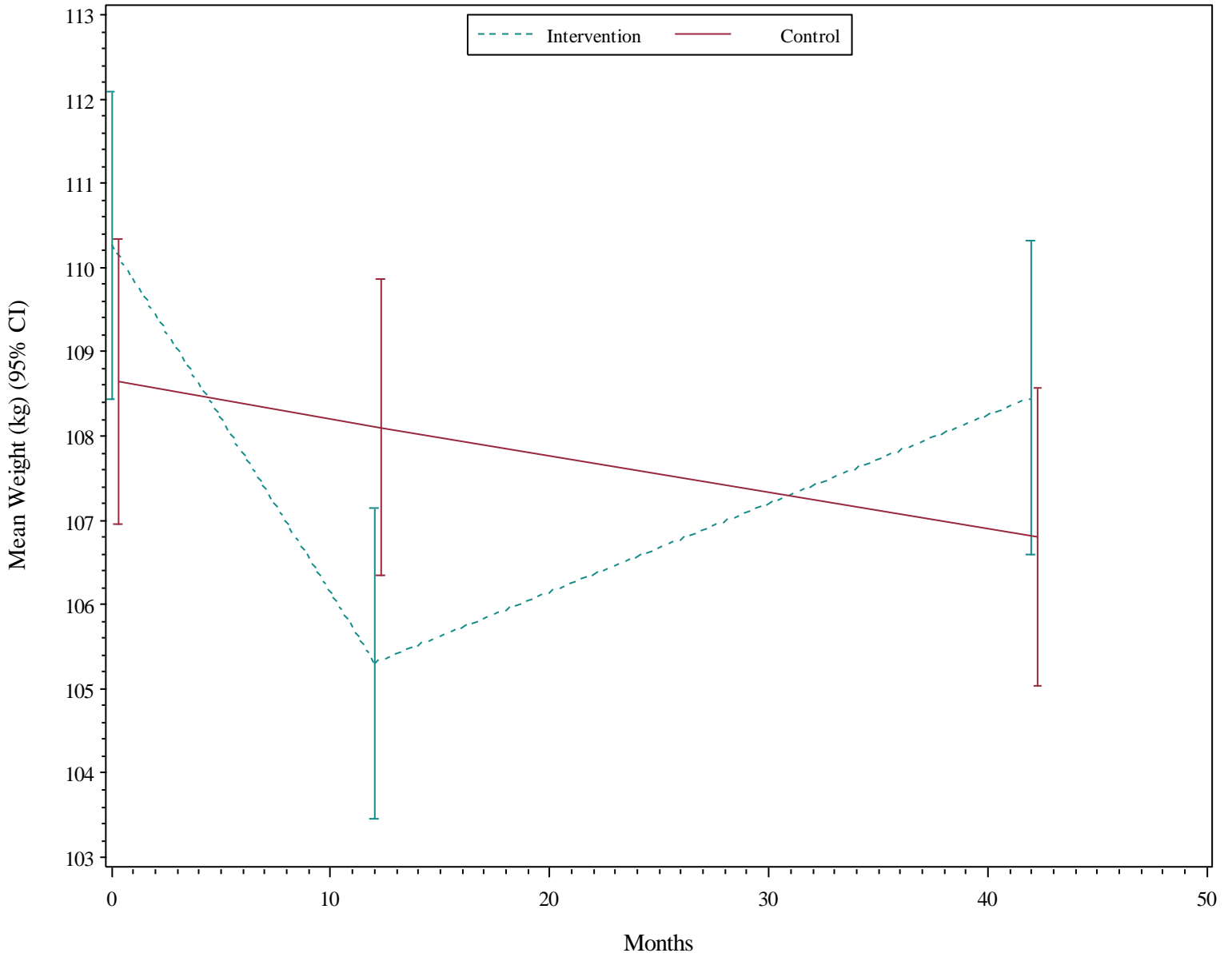


Figure 10.1.2
Mean Change in Weight by Treatment and Visit

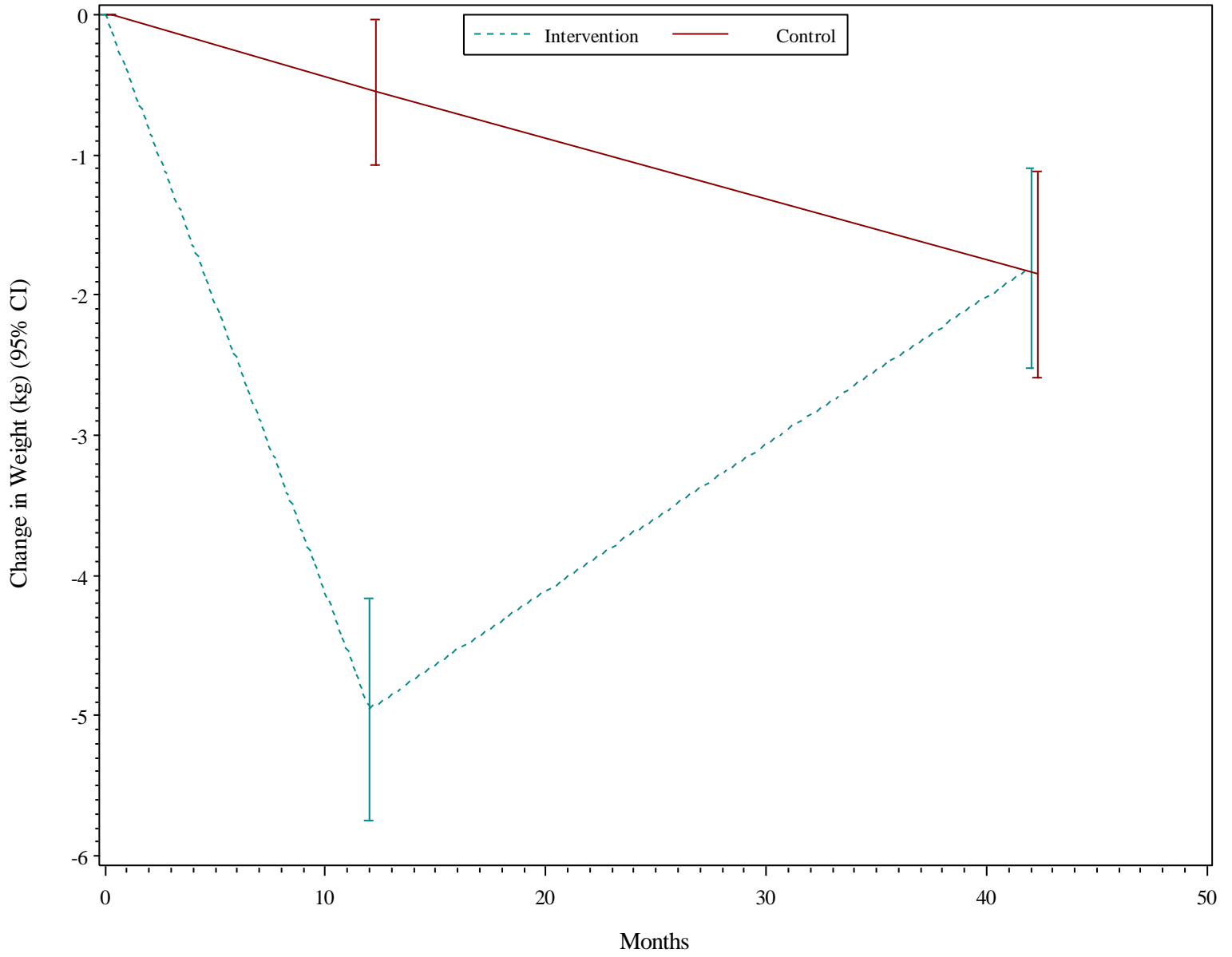


Table 10.1.3

Mixed Effects Repeated Linear Regression Model and Adjusted Mean Change in Weight, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Weight (1 kg)	-0.068 (-0.103, -0.032)	<0.001
	Follow-Up vs End-of-RCT	3.149 (2.374, 3.924)	<0.001
	Visit	Adjusted Change	
	End-of-RCT	-4.954 (-5.697, -4.212)	<0.001
	Follow-Up	-1.805 (-2.547, -1.063)	<0.001
	Difference	3.149 (2.374, 3.924)	<0.001
Control	Fixed Effects		
	Baseline Weight (1 kg)	-0.030 (-0.061, 0.002)	0.063
	Follow-Up vs End-of-RCT	-1.298 (-2.009, -0.587)	<0.001
	Visit	Adjusted Change	
	End-of-RCT	-0.546 (-1.193, 0.102)	0.099
	Follow-Up	-1.844 (-2.492, -1.196)	<0.001
	Difference	-1.298 (-2.009, -0.587)	<0.001
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.053 (-0.077, -0.029)	<0.001
	Follow-Up vs End-of-RCT	0.928 (0.379, 1.477)	<0.001
	Interaction Effect		
	Treatment * Visit	4.448 (3.397, 5.499)	<0.001

Note: Intervention and control groups are analysed separately, then combined to estimate the interaction effect and overall visit effect (two separate models).

Table 10.1.4
Mixed Effects Repeated Linear Regression Model and Adjusted Mean Percent Change in Weight, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Weight (1 kg)	-0.026 (-0.056, 0.005)	0.102
	Follow-Up vs End-of-RCT	2.841 (2.184, 3.498)	<0.001
	Visit	Adjusted Change	
	End-of-RCT	-4.412 (-5.050, -3.773)	<0.001
	Follow-Up	-1.571 (-2.209, -0.932)	<0.001
	Difference	2.841 (2.184, 3.498)	<0.001
Control	Fixed Effects		
	Baseline Weight (1 kg)	-0.020 (-0.048, 0.008)	0.154
	Follow-Up vs End-of-RCT	-1.122 (-1.769, -0.475)	<0.001
	Visit	Adjusted Change	
	End-of-RCT	-0.488 (-1.066, 0.091)	0.099
	Follow-Up	-1.610 (-2.188, -1.031)	<0.001
	Difference	-1.122 (-1.769, -0.475)	<0.001
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.026 (-0.047, -0.005)	0.017
	Follow-Up vs End-of-RCT	0.862 (0.380, 1.344)	<0.001
	Interaction Effect		
	Treatment * Visit	3.963 (3.042, 4.884)	<0.001

Note: Intervention and control groups are analysed separately, then combined to estimate the interaction effect and overall visit effect (two separate models).

Figure 10.1.4
Adjusted Mean Change in Weight by Treatment and Visit From Mixed Effects Model

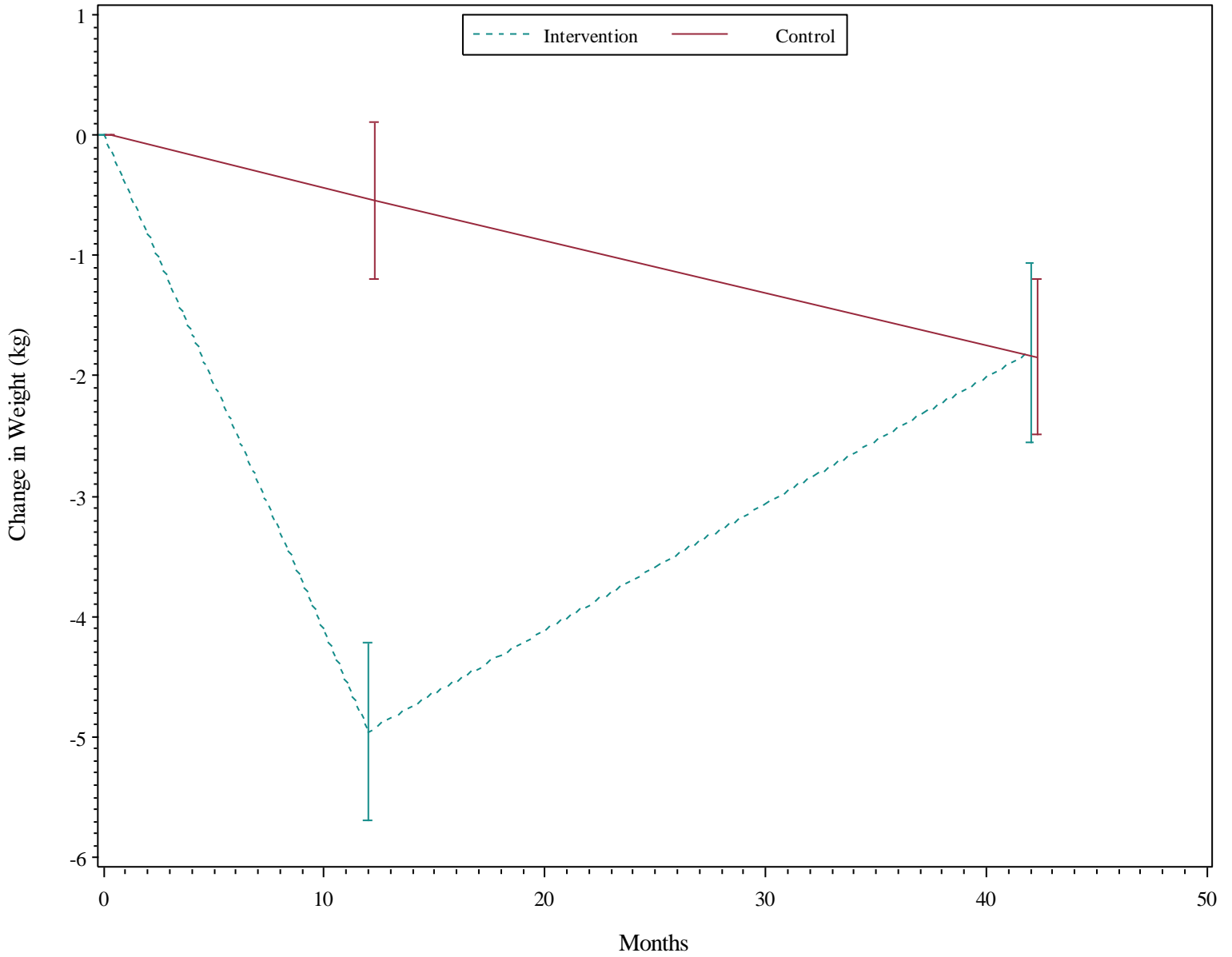


Table 10.2.1
Weight at 12 Month - Change and Percent Change From Baseline, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)	P-Value
Weight(kg) 12 Month					
Baseline	N (missing)	747 (0)	374 (0)	373 (0)	
	Mean (sd)	109.46 (17.26)	110.26 (17.85)	108.65 (16.63)	
	(95% CI)	(108.22, 110.70)	(108.45, 112.08)	(106.96, 110.35)	
	Median (IQR)	107.3 (97.6, 118.6)	107.9 (98.2, 121.4)	107.2 (97.2, 116.4)	
	[Min, Max]	[71, 180]	[71, 180]	[73, 180]	
Follow up	N (missing)	747 (0)	374 (0)	373 (0)	-3.01 (-0.47, -5.54),
	Mean (sd)	106.56 (17.71)	105.06 (18.02)	108.07 (17.29)	0.0202
	(95% CI)	(105.29, 107.83)	(103.23, 106.89)	(106.31, 109.83)	
	Median (IQR)	104.1 (94.2, 116.6)	101.9 (92.5, 116.0)	105.9 (96.1, 116.6)	
	[Min, Max]	[58, 183]	[58, 164]	[71, 183]	
Change from baseline	N (missing)	747 (0)	374 (0)	373 (0)	-4.62 (-3.68, -5.56),
	Mean (sd)	-2.90 (6.93)	-5.20 (7.73)	-0.59 (5.07)	<0.0001*
	(95% CI)	(-3.40, -2.40)	(-5.99, -4.42)	(-1.10, -0.07)	
	Median (IQR)	-1.4 (-5.1, 1.1)	-3.2 (-8.8, 0.0)	0.0 (-2.6, 2.1)	
	[Min, Max]	[-39, 17]	[-37, 12]	[-39, 17]	
	P-Value	<0.0001**	<0.0001**	0.1978**	
Percent change from baseline (%)	N (missing)	747 (0)	374 (0)	373 (0)	-4.10 (-3.28, -4.93),
	Mean (sd)	-2.58 (6.10)	-4.63 (6.73)	-0.53 (4.54)	<0.0001*
	(95% CI)	(-3.02, -2.14)	(-5.32, -3.95)	(-0.99, -0.07)	
	Median (IQR)	-1.4 (-4.6, 1.0)	-2.9 (-7.3, 0.0)	0.0 (-2.4, 1.9)	
	[Min, Max]	[-31, 15]	[-31, 10]	[-31, 15]	
	P-Value	<0.0001**	<0.0001**	0.1877**	

Table 10.2.2
Weight at FU - Change and Percent Change From Baseline, Overall and by Group

		All Subjects (N = 747)	Intervention (N = 374)	Control (N = 373)	P-Value
Weight(kg) FU					
Baseline	N (missing)	747 (0)	374 (0)	373 (0)	
	Mean (sd)	109.46 (17.26)	110.26 (17.85)	108.65 (16.63)	
	(95% CI)	(108.22, 110.70)	(108.45, 112.08)	(106.96, 110.35)	
	Median (IQR)	107.3 (97.6, 118.6)	107.9 (98.2, 121.4)	107.2 (97.2, 116.4)	
	[Min, Max]	[71, 180]	[71, 180]	[73, 180]	
Follow up	N (missing)	747 (0)	374 (0)	373 (0)	-0.00 (2.56, -2.57),
	Mean (sd)	106.68 (17.86)	106.68 (18.05)	106.68 (17.69)	0.9976
	(95% CI)	(105.39, 107.96)	(104.84, 108.51)	(104.88, 108.48)	
	Median (IQR)	104.2 (94.0, 117.2)	103.8 (94.4, 117.5)	104.5 (94.0, 116.8)	
	[Min, Max]	[65, 193]	[65, 166]	[70, 193]	
Change from baseline	N (missing)	747 (0)	374 (0)	373 (0)	-1.61 (-0.47, -2.76),
	Mean (sd)	-2.78 (8.02)	-3.59 (8.28)	-1.97 (7.67)	0.0008*
	(95% CI)	(-3.36, -2.21)	(-4.43, -2.75)	(-2.76, -1.19)	
	Median (IQR)	-1.5 (-6.5, 1.7)	-2.5 (-7.2, 0.8)	-0.5 (-5.5, 2.2)	
	[Min, Max]	[-62, 24]	[-62, 20]	[-43, 24]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	
Percent change from baseline (%)	N (missing)	747 (0)	374 (0)	373 (0)	-1.36 (-0.37, -2.35),
	Mean (sd)	-2.43 (6.92)	-3.11 (6.93)	-1.75 (6.85)	0.0013*
	(95% CI)	(-2.93, -1.93)	(-3.82, -2.41)	(-2.45, -1.05)	
	Median (IQR)	-1.5 (-5.9, 1.7)	-2.4 (-6.5, 0.8)	-0.5 (-5.0, 2.1)	
	[Min, Max]	[-35, 23]	[-35, 17]	[-34, 23]	
	P-Value	<0.0001**	<0.0001**	<0.0001**	

Figure 10.2.1
Mean Weight by Treatment and Visit

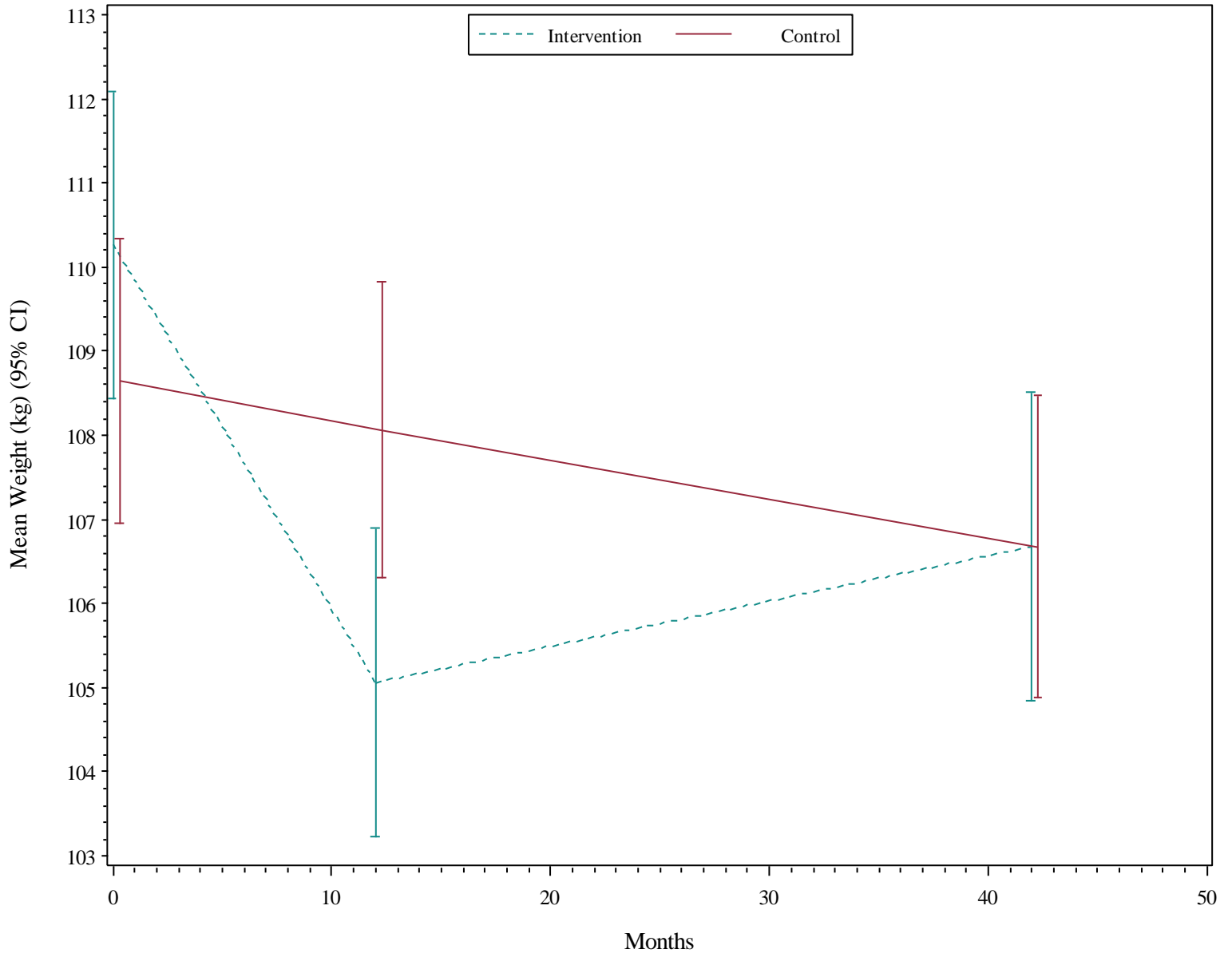


Figure 10.2.2
Mean Change in Weight by Treatment and Visit

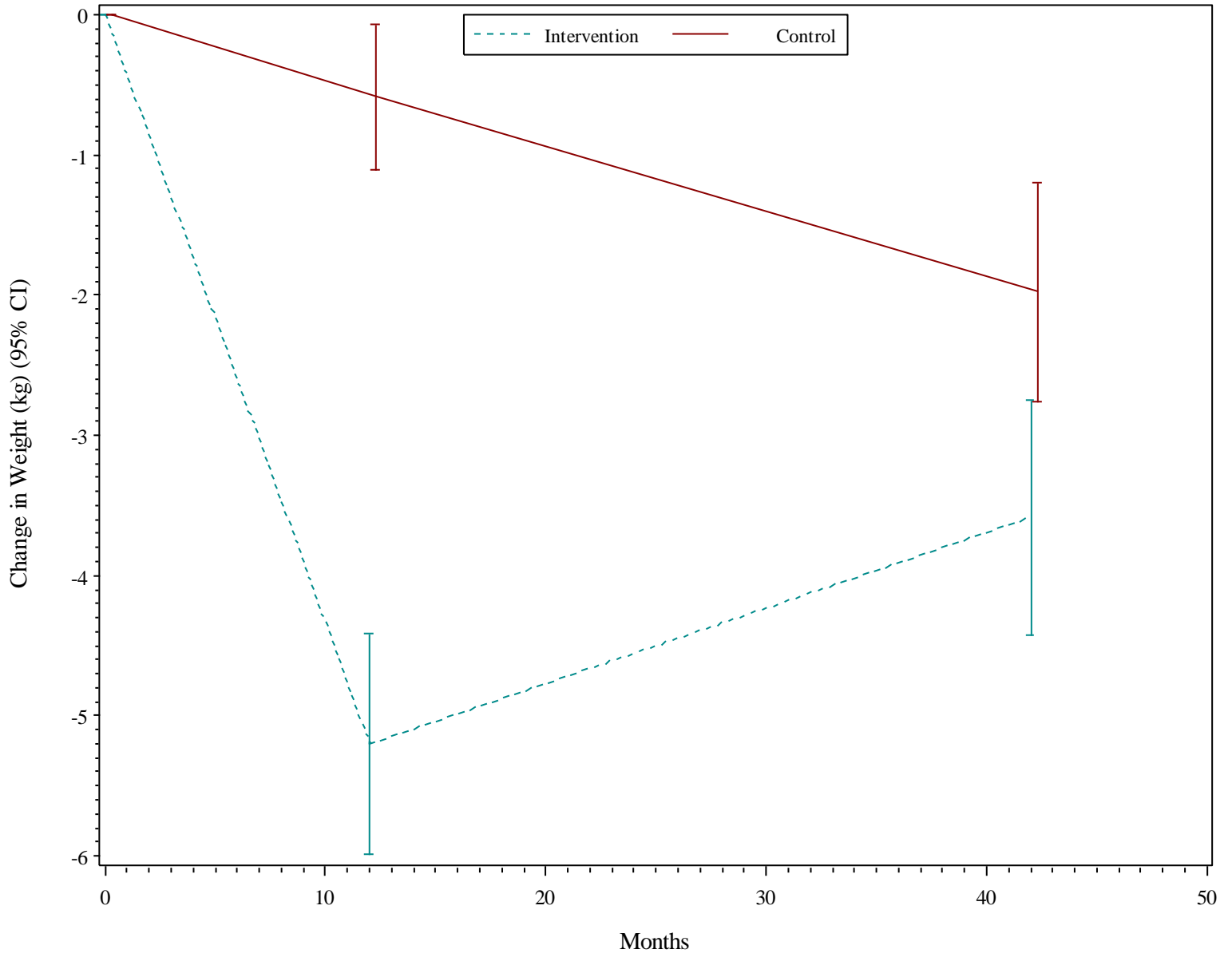


Table 10.2.3
Mixed Effects Repeated Linear Regression Model and Adjusted Mean Change in Weight, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Weight (1 kg)	-0.091 (-0.132, -0.049)	<0.001
	Follow-Up vs End-of-RCT	1.616 (0.989, 2.242)	<0.001
	Visit	Adjusted Change	
	End-of-RCT	-5.203 (-6.000, -4.405)	<0.001
	Follow-Up	-3.587 (-4.385, -2.790)	<0.001
	Difference	1.616 (0.989, 2.242)	<0.001
Control	Fixed Effects		
	Baseline Weight (1 kg)	-0.023 (-0.058, 0.011)	0.188
	Follow-Up vs End-of-RCT	-1.388 (-2.043, -0.732)	<0.001
	Visit	Adjusted Change	
	End-of-RCT	-0.563 (-1.291, 0.164)	0.129
	Follow-Up	-1.951 (-2.679, -1.223)	<0.001
	Difference	-1.388 (-2.043, -0.732)	<0.001
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.063 (-0.091, -0.036)	<0.001
	Follow-Up vs End-of-RCT	0.116 (-0.349, 0.581)	0.625
	Interaction Effect		
	Treatment * Visit	3.003 (2.098, 3.909)	<0.001

Note: Intervention and control groups are analysed separately, then combined to estimate the interaction effect and overall visit effect (two separate models).

Table 10.2.4
Mixed Effects Repeated Linear Regression Model and Adjusted Mean Percent Change in Weight, Overall and by Group

		Estimate (95% C.I.)	P-Value
Intervention	Fixed Effects		
	Baseline Weight (1 kg)	-0.040 (-0.076, -0.004)	0.030
	Follow-Up vs End-of-RCT	1.519 (0.990, 2.048)	<0.001
	Visit	Adjusted Change	
	End-of-RCT	-4.631 (-5.322, -3.940)	<0.001
	Follow-Up	-3.112 (-3.803, -2.421)	<0.001
	Difference	1.519 (0.990, 2.048)	<0.001
Control	Fixed Effects		
	Baseline Weight (1 kg)	-0.015 (-0.046, 0.015)	0.330
	Follow-Up vs End-of-RCT	-1.222 (-1.820, -0.624)	<0.001
	Visit	Adjusted Change	
	End-of-RCT	-0.505 (-1.163, 0.152)	0.132
	Follow-Up	-1.727 (-2.385, -1.069)	<0.001
	Difference	-1.222 (-1.820, -0.624)	<0.001
All	Fixed Effect		
	Baseline Weight (1 kg)	-0.032 (-0.056, -0.008)	0.010
	Follow-Up vs End-of-RCT	0.150 (-0.260, 0.561)	0.472
	Interaction Effect		
	Treatment * Visit	2.741 (1.943, 3.538)	<0.001

Note: Intervention and control groups are analysed separately, then combined to estimate the interaction effect and overall visit effect (two separate models).

Figure 10.2.4
Adjusted Mean Change in Weight by Treatment and Visit From Mixed Effects Model

