

# CONFIDENTIAL

CRCTU Birmingham

A 48-WEEK PHASE II, RANDOMISED, DOUBLE BLINDED  
PLACEBO CONTROLLED, PARALLEL-GROUP,  
MULTI-CENTRE TRIAL ON LIRAGLUTIDE'S SAFETY,  
EFFICACY AND ACTION ON LIVER HISTOLOGY AND  
METABOLISM IN OVERWEIGHT PATIENTS WITH  
NON-ALCOHOLIC STEATOHEPATITIS, WITH OR WITHOUT  
TYPE II DIABETES

Liraglutide Efficacy and Action in Non-alcoholic  
steatohepatitis

The word "LEAN" is written in a large, blue, serif font. The letters have a slight 3D effect with a dark blue shadow beneath them.

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Data For Physical Measurements

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## **1 Physical Assessment Results**

Table 1.1: Systolic Blood Pressure (mmHg) by treatment and Visit Number

Liraglutide (N=170)								
	1 (N=26)	3 (N=26)	4 (N=25)	5 (N=23)	6 (N=24)	7 (N=23)	8 (N=23)	Overall (N=170)
<b>Systolic Blood Pressure (mmHg)</b>								
N	26	26	25	23	24	23	23	170
Mean (SD)	130 (13)	129 (15)	129 (15)	128 (12)	132 (17)	125 (13)	129 (14)	129 (14)
Median	130	129	128	130	129	124	128	129
IQR	121, 137	121, 139	123, 138	118, 140	120, 145	114, 135	117, 138	119, 138
Range	105, 156	86, 152	97, 162	103, 147	97, 169	99, 153	109, 165	86, 169

Placebo (N=164)								
	1 (N=26)	3 (N=25)	4 (N=24)	5 (N=23)	6 (N=22)	7 (N=22)	8 (N=22)	Overall (N=164)
<b>Systolic Blood Pressure (mmHg)</b>								
N	26	25	24	23	22	22	20	162
Mean (SD)	133 (12)	132 (14)	133 (13)	132 (12)	136 (12)	131 (14)	129 (13)	132 (13)
Median	136	130	132	129	134	132	131	132
IQR	128, 141	127, 137	126, 137	124, 140	126, 145	120, 136	120, 139	124, 139
Range	109, 162	100, 168	113, 175	112, 158	118, 159	110, 172	99, 150	99, 175

Figure 1.1: Systolic BP Charts

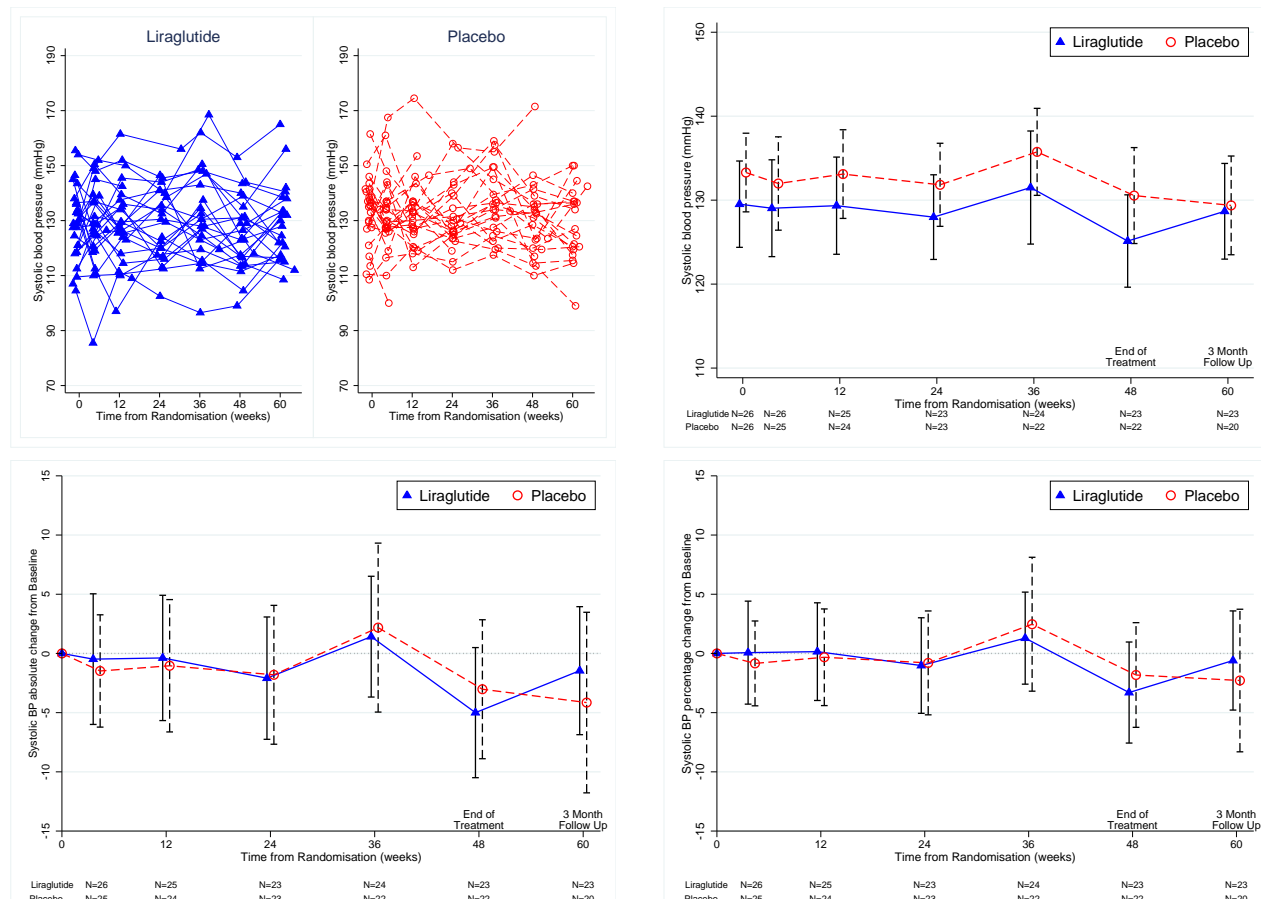


Table 1.2: Diastolic Blood Pressure (mmHg) by treatment and Visit Number

Liraglutide (N=170)								
	1 (N=26)	3 (N=26)	4 (N=25)	5 (N=23)	6 (N=24)	7 (N=23)	8 (N=23)	Overall (N=170)
Diastolic Blood Pressure (mmHg)								
N	26	26	25	23	24	23	23	170
Mean (SD)	79 (11)	81 (11)	81 (11)	80 (9)	79 (10)	80 (8)	79 (10)	80 (10)
Median	79	83	82	80	81	77	80	81
IQR	70, 86	74, 90	76, 85	74, 84	71, 83	75, 84	74, 83	74, 85
Range	60, 113	61, 101	64, 111	63, 104	64, 105	66, 95	58, 107	58, 113

Placebo (N=164)								
	1 (N=26)	3 (N=25)	4 (N=24)	5 (N=23)	6 (N=22)	7 (N=22)	8 (N=22)	Overall (N=164)
Diastolic Blood Pressure (mmHg)								
N	26	25	24	23	22	22	20	162
Mean (SD)	78 (9)	80 (10)	78 (9)	82 (9)	82 (10)	81 (8)	80 (10)	80 (9)
Median	78	81	78	82	84	83	81	81
IQR	72, 88	71, 87	71, 83	77, 88	76, 89	76, 86	74, 86	75, 87
Range	57, 95	58, 99	64, 96	66, 100	64, 101	60, 94	61, 105	57, 105

Figure 1.2: Diastolic BP Charts

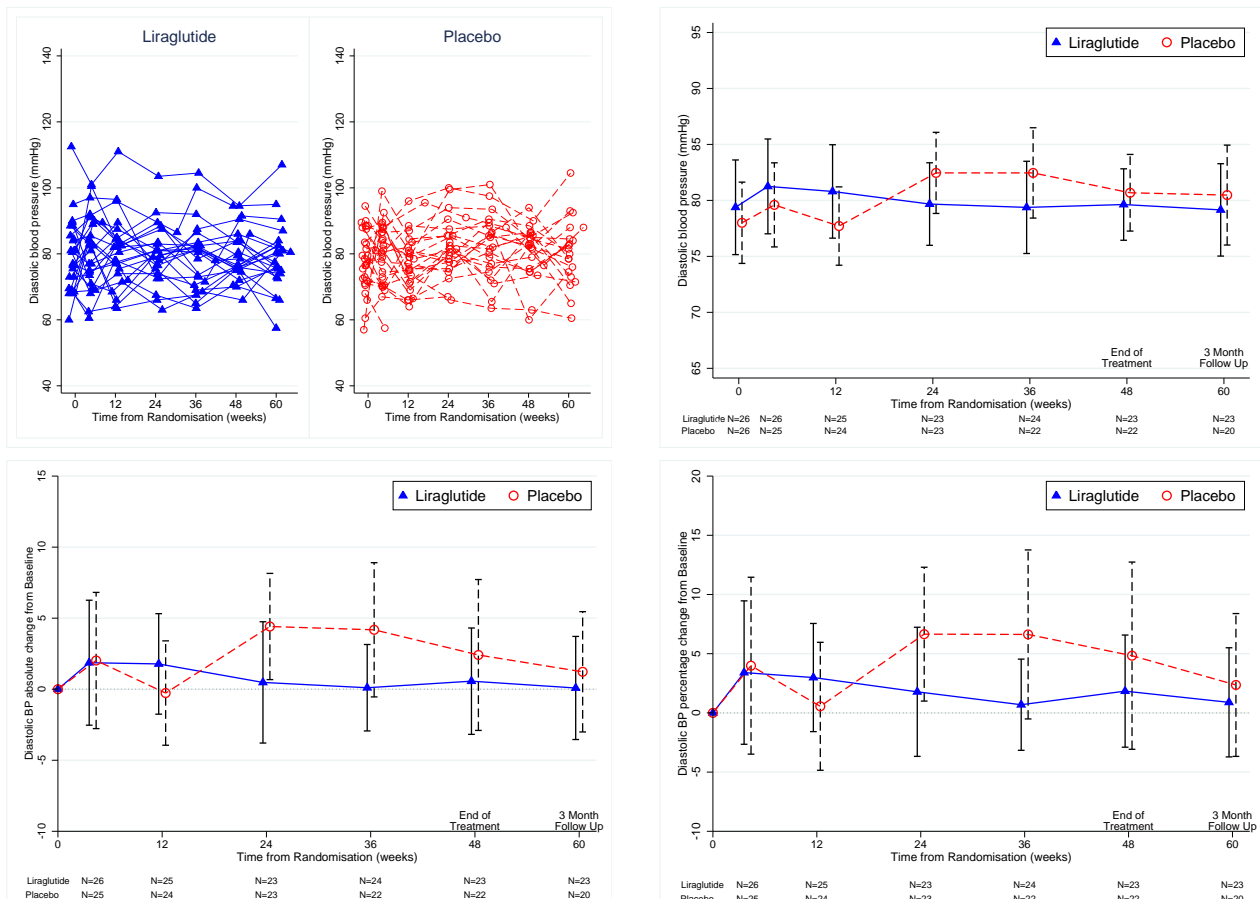


Table 1.3: Weight (kg) by treatment and Visit Number

Liraglutide (N=170)								
	1 (N=26)	3 (N=26)	4 (N=25)	5 (N=23)	6 (N=24)	7 (N=23)	8 (N=23)	Overall (N=170)
Weight (kg)								
N	26	26	25	23	24	23	23	170
Mean (SD)	101 (18)	98 (18)	95 (17)	93 (17)	94 (18)	95 (19)	97 (19)	96 (18)
Median	97	96	92	95	96	94	97	96
IQR	89, 115	86, 111	84, 107	79, 103	81, 104	80, 108	80, 109	83, 109
Range	70, 128	66, 126	66, 122	62, 123	65, 126	64, 132	64, 133	62, 133

Placebo (N=164)								
	1 (N=26)	3 (N=25)	4 (N=24)	5 (N=23)	6 (N=22)	7 (N=22)	8 (N=22)	Overall (N=164)
Weight (kg)								
N	26	25	24	23	22	22	20	162
Mean (SD)	108 (18)	107 (18)	107 (18)	106 (19)	107 (19)	108 (20)	105 (19)	107 (18)
Median	107	107	106	107	108	110	99	107
IQR	99, 120	97, 117	96, 118	95, 121	94, 122	93, 122	91, 119	96, 120
Range	72, 146	72, 146	71, 144	70, 147	72, 147	70, 147	70, 141	70, 147

Figure 1.3: Weight Charts

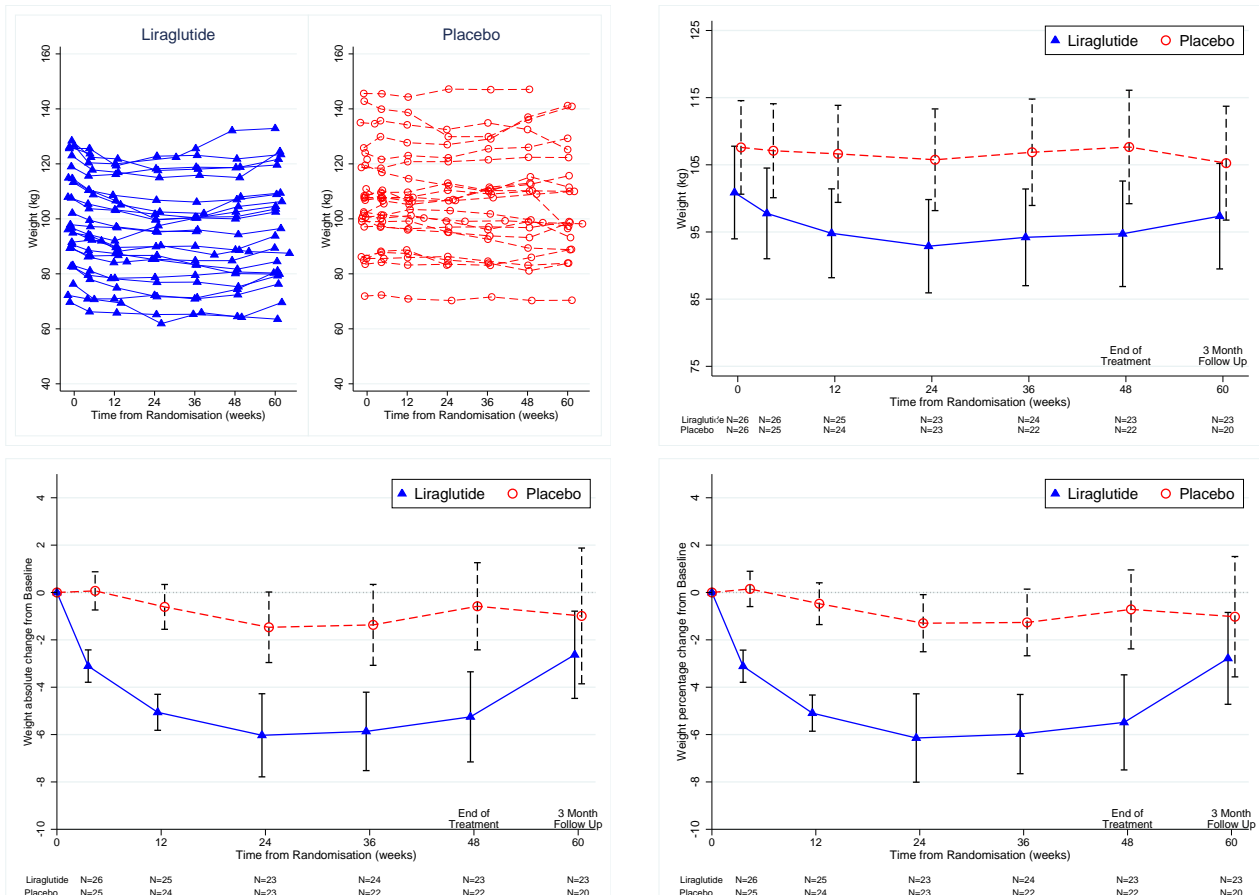


Table 1.4: Body Mass Index ( $\text{kg}/\text{m}^2$ ) by treatment and Visit Number

Liraglutide (N=170)								
	1 (N=26)	3 (N=26)	4 (N=25)	5 (N=23)	6 (N=24)	7 (N=23)	8 (N=23)	Overall (N=170)
<b>Body Mass Index (<math>\text{kg}/\text{m}^2</math>)</b>								
N	26	26	25	23	24	23	23	170
Mean (SD)	34.2 (4.7)	33.1 (4.5)	32.3 (4.5)	32.1 (4.7)	32.4 (4.7)	32.5 (5.2)	33.5 (5.2)	32.9 (4.8)
Median	33.8	33.3	32.5	32.2	31.8	32.3	32.7	32.6
IQR	30.0, 37.1	29.0, 35.8	28.8, 35.3	28.2, 37.1	28.1, 36.9	28.5, 37.9	29.1, 38.8	28.8, 37.0
Range	26.8, 44.3	26.2, 42.5	25.3, 41.0	24.8, 40.0	24.9, 39.8	24.3, 42.2	25.6, 42.7	24.3, 44.3

Placebo (N=164)								
	1 (N=26)	3 (N=25)	4 (N=24)	5 (N=23)	6 (N=22)	7 (N=22)	8 (N=22)	Overall (N=164)
<b>Body Mass Index (<math>\text{kg}/\text{m}^2</math>)</b>								
N	26	25	24	23	22	22	20	162
Mean (SD)	37.7 (6.2)	37.8 (6.1)	37.7 (6.0)	37.2 (6.0)	37.7 (5.9)	38.0 (6.3)	37.3 (6.3)	37.6 (6.0)
Median	37.9	37.7	37.9	37.4	38.1	37.8	36.6	37.7
IQR	33.1, 41.0	33.1, 41.1	32.6, 41.0	32.4, 40.4	33.6, 40.6	32.5, 40.9	32.2, 41.3	32.9, 40.9
Range	27.7, 51.0	28.8, 50.9	28.9, 50.5	27.2, 51.5	28.9, 51.5	28.4, 51.5	28.7, 49.9	27.2, 51.5

Figure 1.4: BMI Charts

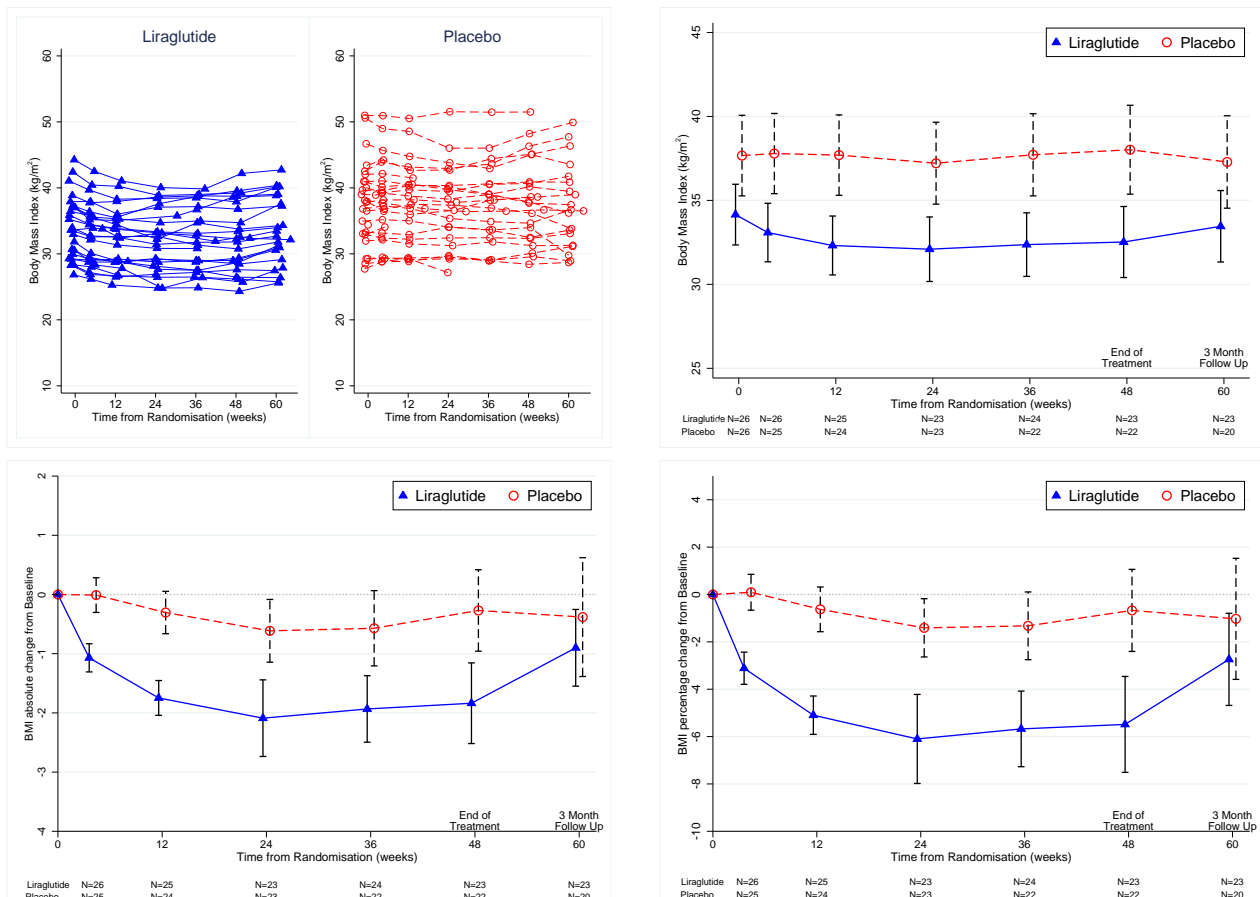


Table 1.5: Waist Size (cm) by treatment and Visit Number

Liraglutide (N=170)							
	1 (N=26)	3 (N=26)	4 (N=25)	5 (N=23)	6 (N=24)	7 (N=23)	8 (N=23)
Overall (N=170)							
Waist Size (cm)							
N	26	25	25	23	23	23	22
Mean (SD)	110 (11)	108 (9)	106 (8)	106 (9)	105 (9)	107 (11)	108 (11)
Median	110	109	104	107	106	109	112
IQR	101, 120	100, 116	100, 112	97, 114	95, 113	97, 116	98, 117
Range	85, 126	91, 123	89, 121	92, 122	90, 119	86, 128	86, 126

Placebo (N=164)							
	1 (N=26)	3 (N=25)	4 (N=24)	5 (N=23)	6 (N=22)	7 (N=22)	8 (N=22)
Overall (N=164)							
Waist Size (cm)							
N	26	25	24	23	22	22	19
Mean (SD)	120 (15)	120 (16)	119 (14)	117 (13)	118 (14)	118 (16)	118 (15)
Median	121	122	121	121	119	122	118
IQR	107, 131	109, 133	109, 127	106, 125	107, 125	105, 132	105, 131
Range	90, 145	93, 144	93, 140	93, 146	96, 152	87, 148	85, 146

Figure 1.5: Waist Size Charts

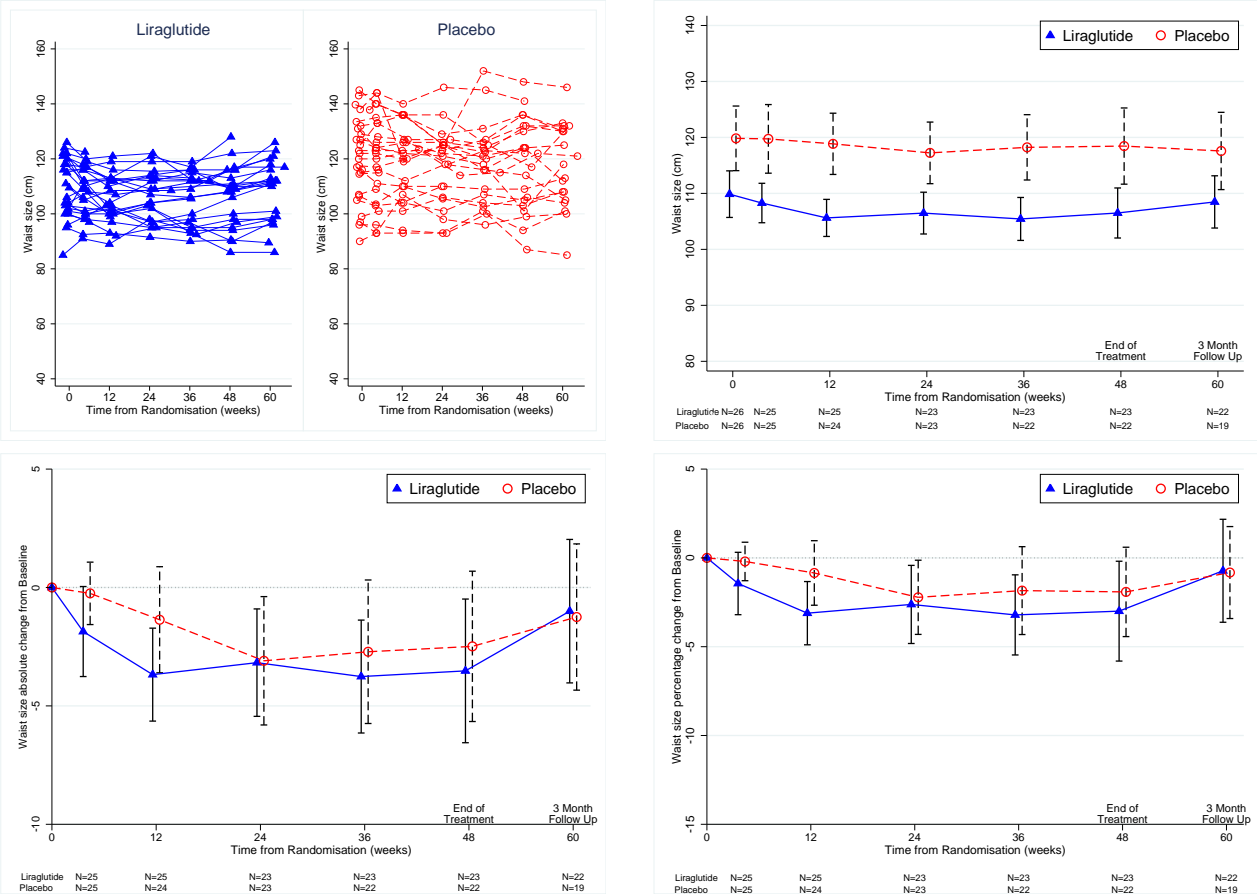


Table 1.6: Hip Size (cm) by treatment and Visit Number

Liraglutide (N=170)								
	1 (N=26)	3 (N=26)	4 (N=25)	5 (N=23)	6 (N=24)	7 (N=23)	8 (N=23)	Overall (N=170)
Hip Size (cm)								
N	26	26	25	23	23	23	22	168
Mean (SD)	112 (9)	111 (8)	109 (9)	110 (9)	110 (10)	110 (11)	112 (10)	111 (9)
Median	113	110	108	109	110	110	112	110
IQR	106, 117	106, 114	105, 112	106, 116	101, 118	103, 118	105, 116	105, 116
Range	93, 139	96, 132	94, 130	93, 128	93, 128	88, 131	92, 133	88, 139
Placebo (N=164)								
	1 (N=26)	3 (N=25)	4 (N=24)	5 (N=23)	6 (N=22)	7 (N=22)	8 (N=22)	Overall (N=164)
Hip Size (cm)								
N	26	25	24	23	22	22	19	161
Mean (SD)	119 (13)	121 (14)	121 (12)	121 (13)	122 (15)	124 (14)	121 (14)	121 (14)
Median	119	122	123	120	120	119	115	120
IQR	106, 132	107, 129	110, 130	108, 133	108, 133	112, 134	109, 138	109, 132
Range	102, 143	102, 148	101, 146	100, 141	104, 152	105, 151	102, 143	100, 152

Figure 1.6: Hip Size Charts

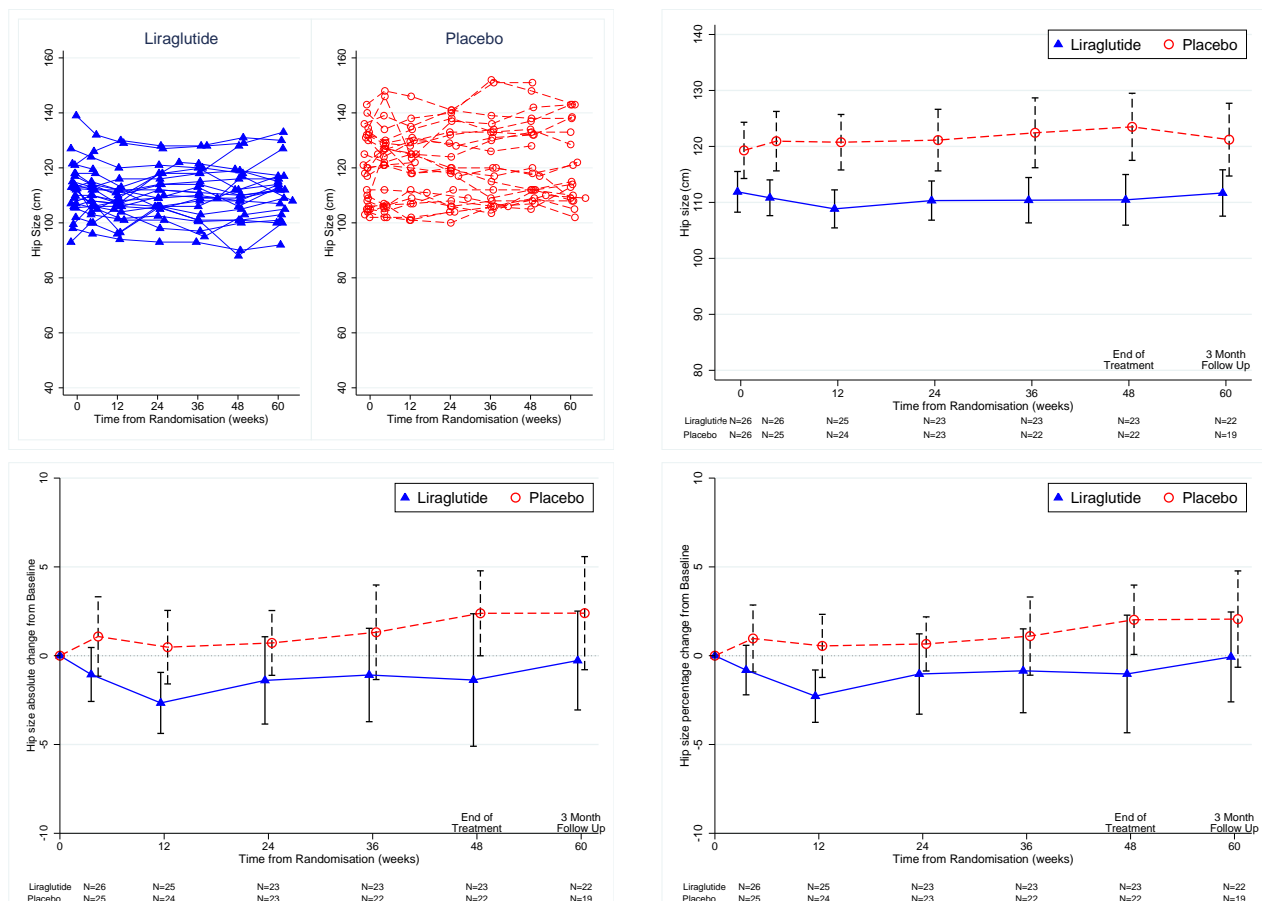


Table 1.7: Waist Hip Ratio by treatment and Visit Number

Liraglutide (N=170)								
	1 (N=26)	3 (N=26)	4 (N=25)	5 (N=23)	6 (N=24)	7 (N=23)	8 (N=23)	Overall (N=170)
<b>Waist Hip Ratio</b>								
N	26	25	25	23	23	23	22	167
Mean (SD)	0.98 (0.08)	0.98 (0.06)	0.97 (0.06)	0.97 (0.05)	0.96 (0.05)	0.96 (0.05)	0.97 (0.06)	0.97 (0.06)
Median	1.00	0.98	0.97	0.97	0.96	0.98	0.97	0.97
IQR	0.93, 1.03	0.94, 1.02	0.93, 1.03	0.93, 1.00	0.92, 1.00	0.94, 1.00	0.93, 1.00	0.93, 1.02
Range	0.75, 1.13	0.82, 1.07	0.83, 1.06	0.86, 1.05	0.88, 1.04	0.84, 1.03	0.84, 1.08	0.75, 1.13

Placebo (N=164)								
	1 (N=26)	3 (N=25)	4 (N=24)	5 (N=23)	6 (N=22)	7 (N=22)	8 (N=22)	Overall (N=164)
<b>Waist Hip Ratio</b>								
N	26	25	24	23	22	22	19	161
Mean (SD)	1.01 (0.08)	0.99 (0.07)	0.98 (0.06)	0.97 (0.07)	0.97 (0.05)	0.96 (0.07)	0.97 (0.07)	0.98 (0.07)
Median	1.00	0.99	0.98	0.96	0.96	0.97	0.96	0.98
IQR	0.98, 1.04	0.97, 1.02	0.96, 1.01	0.91, 1.05	0.93, 1.00	0.92, 1.00	0.92, 1.02	0.94, 1.02
Range	0.80, 1.15	0.79, 1.11	0.78, 1.11	0.79, 1.09	0.85, 1.08	0.81, 1.11	0.83, 1.11	0.78, 1.15

Figure 1.7: Hip Ratio Charts

