SUPPLEMENTARY DATA

Efficacy and safety of liraglutide 3.0 mg in individuals with overweight or obesity and type 2 diabetes treated with basal insulin: The SCALE Insulin randomized controlled trial

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SUPPLEMENTARY DATA

Online-Only Supplementary Material

Supplementary statistics

The trial product estimand for the primary and confirmatory secondary endpoints was assessed using a mixed model for repeated measurements (MMRM). The MMRM for percentage weight change was done using assessments only from individuals who were taking the randomized treatment until end of trial or at first discontinuation of trial product. The MMRM was fitted using percentage weight change with factors treatment, sex and BMI, and baseline body weight as a covariate, all nested within visits. An unstructured covariance matrix was used to account for the variability for measurements within the same individual. The MMRM for ≥5% responders was performed using individually predicted values for percentage weight change at week 56 that were used to classify each individual as ≥5% responder or not. This classification was then analyzed using a logistic regression model with treatment as the only factor.

American Diabetes Association (ADA)'s hypoglycemia classification

- Severe hypoglycemia was defined as an episode requiring assistance of another person to actively administer carbohydrate/glucagon or take other corrective actions.
- Documented symptomatic and asymptomatic hypoglycemia were defined as a plasma glucose concentration ≤70 mg/dL (3.9 mmol/L) with and without typical symptoms of hypoglycemia, respectively.
- Severe or blood glucose (BG)-confirmed symptomatic hypoglycemia: an episode that is severe according to the ADA classification or BG confirmed by a plasma glucose value <3.1 mmol/L (56 mg/dL) with symptoms consistent with hypoglycemia.
- Pseudo-hypoglycemia was defined as a report of any of the typical symptoms of hypoglycemia with a plasma glucose concentration >70 mg/dL (3.9 mmol/L).
- Probable symptomatic hypoglycemia was defined as having the symptoms of hypoglycemia, without a plasma glucose determination, but presumably caused by a plasma glucose concentration ≤70 mg/dL (3.9 mmol/L).
- Symptomatic BG-confirmed hypoglycemia: an episode that is BG-confirmed by plasma glucose value <3.1 mmol/L (56 mg/dL) with symptoms consistent with hypoglycemia.

Novo Nordisk's hypoglycemia classification

- Severe hypoglycemia according to the ADA classification.
- Symptomatic BG-confirmed hypoglycemia: an episode that is BG-confirmed by plasma glucose value <3.1 mmol/L (56 mg/dL) with symptoms consistent with hypoglycemia.
- Asymptomatic BG-confirmed hypoglycemia: an episode that is BG-confirmed by plasma glucose value <3.1 mmol/L (56 mg/dL) without symptoms consistent with hypoglycemia.
- Severe or BG-confirmed symptomatic hypoglycemia: an episode that is severe according to the ADA classification or BG-confirmed by a plasma glucose value <3.1 mmol/L (56 mg/dL) with symptoms consistent with hypoglycemia.
- BG-confirmed hypoglycemia: an episode that is BG-confirmed by a plasma glucose value <3.1 mmol/L (56 mg/dL) with or without symptoms consistent with hypoglycemia.
- Severe or BG-confirmed hypoglycemia: an episode that is severe according to the ADA classification or BG-confirmed by a plasma glucose value <3.1 mmol/L (56 mg/dL) with or without symptoms consistent with hypoglycemia.

Recurrent hypoglycemia

Recurrent hypoglycemia is referred to as repeated episodes of hypoglycemia within the last year. The evaluation of whether episodes of hypoglycemia could be considered 'recurrent' was at the discretion of individual investigators.

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Intensive behavioral therapy

Intensive behavioral therapy consisted of physical activity, reduced energy intake and behavioral counseling, and was based on an abbreviated version of the Diabetes Prevention Program counseling. Behavioral counseling comprised 23 individual or group sessions of approximately 15 minutes over 56 weeks. Increased physical activity was of moderate intensity, starting at 100 min/week, and increasing by 25 minutes every 4 weeks to a recommended 250 min/week. Energy intake was reduced to 1200 kcal in individuals <200 lb; to the sum of body weight (lb) x 6 (kcal/lb) in individuals 200–300 lbs in weight; or to 1800 kcal for those >300 lb.

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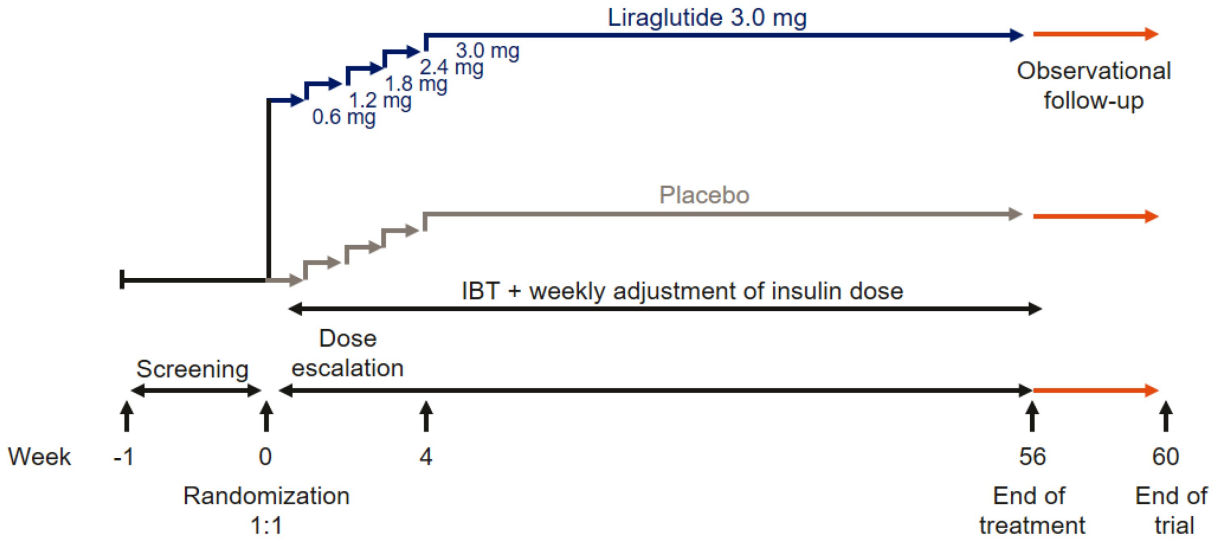
SUPPLEMENTARY DATA

Supplementary Figure 1. SCALE Insulin study design



IBT, intensive behavioral therapy

IBT, intensive behavioral therapy

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Supplementary Table 1. Insulin dose adjustment algorithm

Mean of three pre-breakfast or pre-dinner SMBGs		**Change in basal insulin dose**
mmol/L	mg/dL	U
4.0−5.0	71−90	No adjustment
5.1−7.0	91−126	+2
7.1−8.0	127−144	+4
8.1−9.0	145−162	+6
>9.0	>162	+8
Lowest of three pre-breakfast or pre-dinner SMBG		**Change in basal insulin dose**
mmol/L	mg/dL	U
<3.1	<56	-4 (or 10% if the dose >45 U)
3.1−3.9	56−70	-2 (or 5% if the dose >45 U)

SMBG, self-measured blood glucose

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Supplementary Table 2. Individual disposition

	Liraglutide 3.0 mg (n=198)	Placebo (n=198)	Total (n=396)
Exposed, n	195	197	392
On drug at week 56 visit, n (%)	166 (83.8)	168 (84.8)	334 (84.3)
Discontinued trial drug, n (%)	32 (16.2)	30 (15.2)	62 (15.7)
Retrieved, n (%)	26 (13.1)	26 (13.1)	52 (13.1)
Withdrawals, n (%)	4 (2.0)	4 (2.0)	8 (2.0)
With BW measurement, n (%)	191 (96.5)	193 (97.5)	384 (97.0)
Without BW measurement, n (%)	7 (3.5)	5 (2.5)	12 (3.0)

BW, body weight

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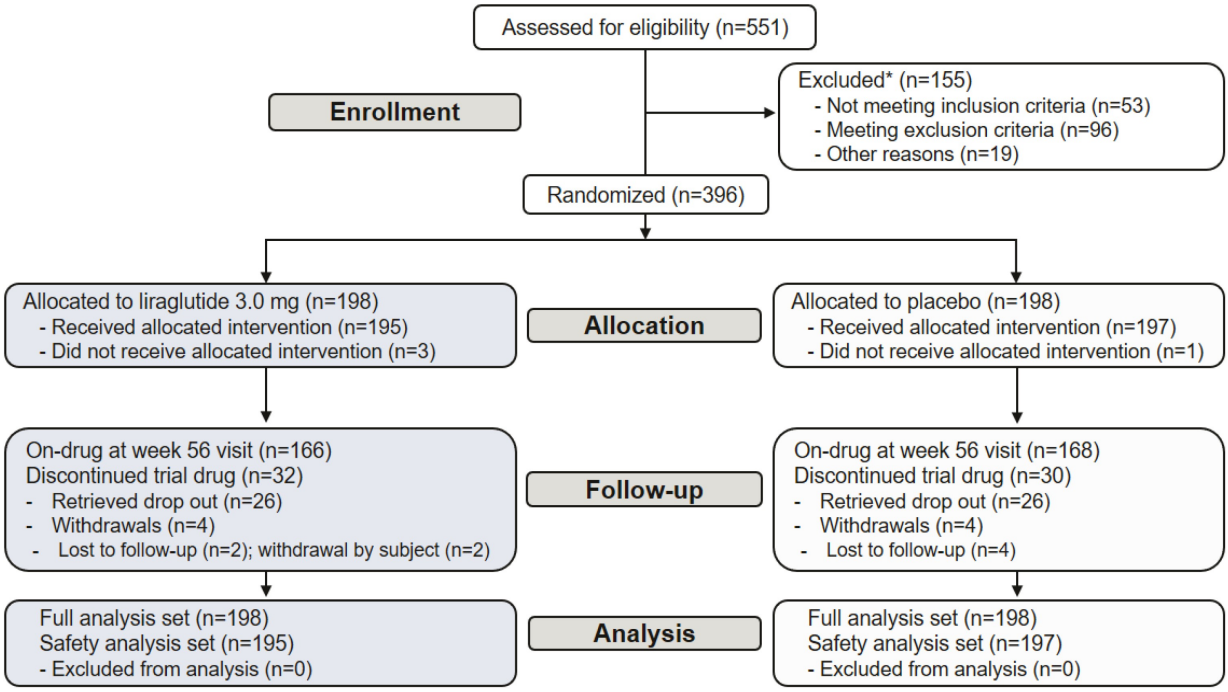
SUPPLEMENTARY DATA

Supplementary Figure 2. Patient disposition



*A given individual may be excluded for more than one reason

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SUPPLEMENTARY DATA

Supplementary Table 3. Change in primary and secondary confirmatory endpoints from baseline to week 56: trial product

	Liraglutide 3.0 mg (n=198)	Placebo (n=198)	ETD/OR* [95% CI]	*p*-value
Primary endpoints				
Change in body weight from baseline (%)	-6.4	-1.3	-5.1 [-6.3; -3.9]	<0.0001
Proportion of individuals achieving ≥5% weight loss* (%)	56.9	21.8	4.7 [3.0; 7.4]	<0.0001
Secondary confirmatory endpoints				
Proportion of individuals achieving >10% weight loss* (%)	22.6	5.6	4.9 [2.5; 9.9]	<0.0001
Change in waist circumference from baseline (cm)	-5.6	-2.3	-3.4 [-4.6; -2.1]	<0.0001
Change in HbA_{1c} from baseline % mmol/mol	 -1.3 -13.8	 -0.7 -7.6	 -0.6 [-0.8; -0.4] -6.2 [-8.5; -3.9]	 <0.0001 <0.0001
Change in fasting plasma glucose from baseline mmol/L mg/dL	 -1.2 -22.1	 -0.9 -15.7	 -0.4 [-0.9; 0.2] -6.5 [-16.1; 3.2]	 0.1909 0.1909
Change in SF-36 Physical Functioning score from baseline	2.8	2.2	0.6 [-0.8; 2.0]	0.3831
Change in IWQOL-Lite-CT Physical Function domain score from baseline	8.8	5.4	3.4 [-0.7; 7.4]	0.1028

estimand

*The endpoint is analyzed in a logistic regression model. Statistical analysis is MMRM. ETD, estimated treatment difference; HbA_{1c}, glycated hemoglobin; IWQOL-Lite-CT, Impact of Weight on Quality of Life-Lite Clinical Trial version; MMRM, mixed model for repeated measurements; OR, odds ratio; SF-36, short-form 36

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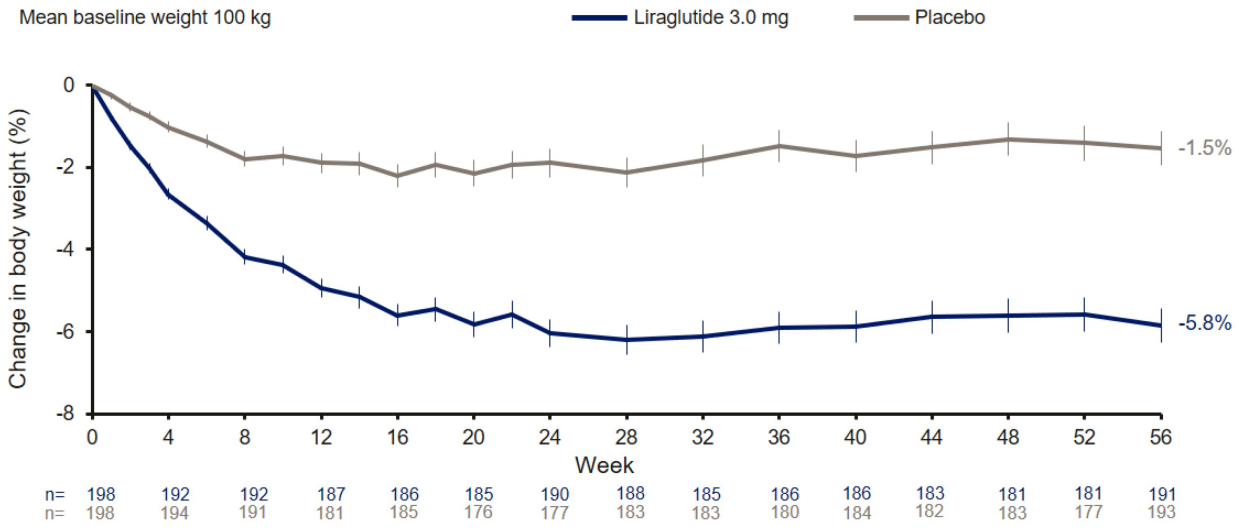
SUPPLEMENTARY DATA

Supplementary Figure 3A. Estimated change in body weight over time: treatment policy estimand



Graph is estimated mean data ±SEM based on the in-trial observation period (ANCOVA; J2R-MI). The estimand aims to reflect the placebo-adjusted effect of initiating treatment with liraglutide, as an adjunct to IBT, even if trial product is discontinued. IBT, intensive behavior therapy; J2R-MI, jump to reference-multiple imputation; SEM, standard error of the mean

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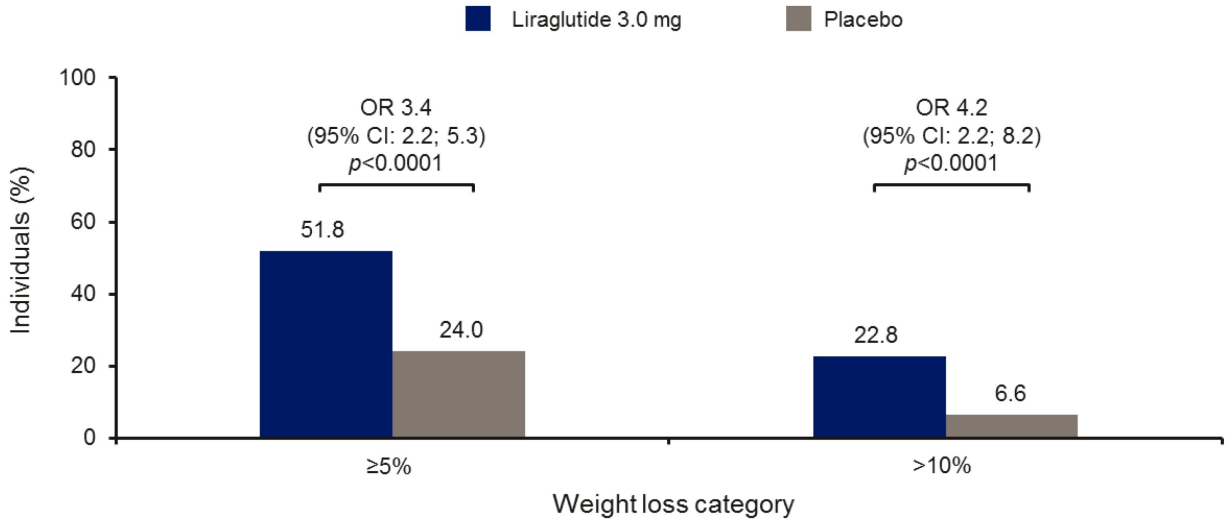
SUPPLEMENTARY DATA

Supplementary Figure 3B. Estimated change in body weight over time: trial product estimand



Graph is estimated mean data ±SEM based on the on-drug observation period (MMRM). The estimand aims to reflect the effect of liraglutide, as an adjunct to IBT. IBT, intensive behavior therapy MMRM, mixed model for repeated measurements; SEM, standard error of the mean

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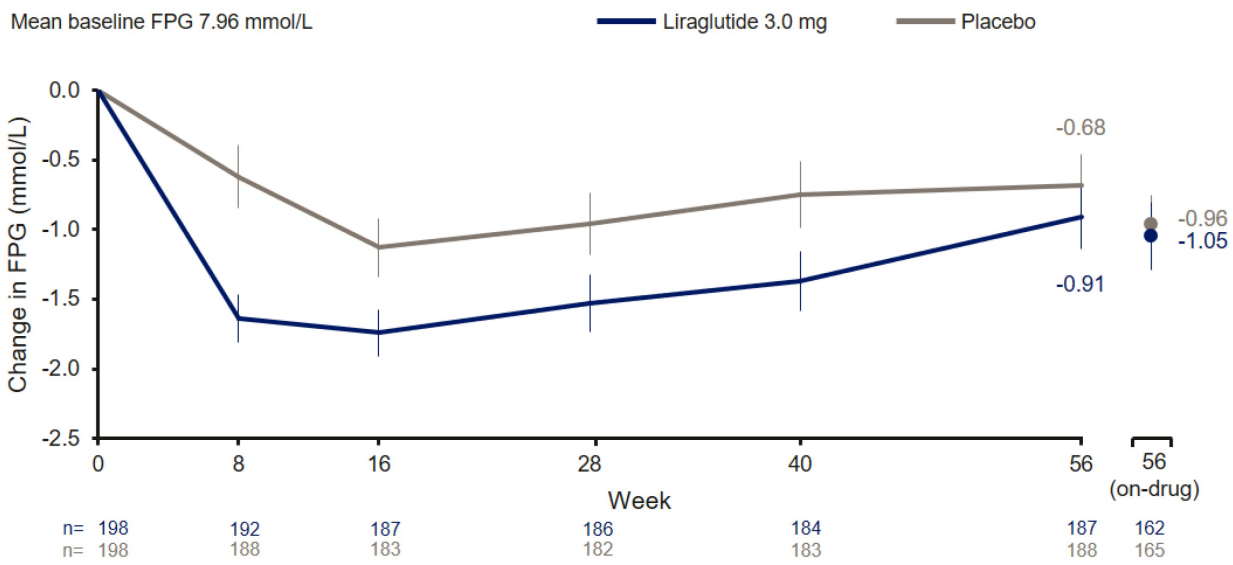
SUPPLEMENTARY DATA

Supplementary Figure 4. Proportion of individuals reaching ≥5% and >10% weight loss at week 56



Data are estimated proportions. Statistical analysis is logistic regression with J2R-MI. J2R-MI, jump to reference-multiple imputation; OR, odds ratio

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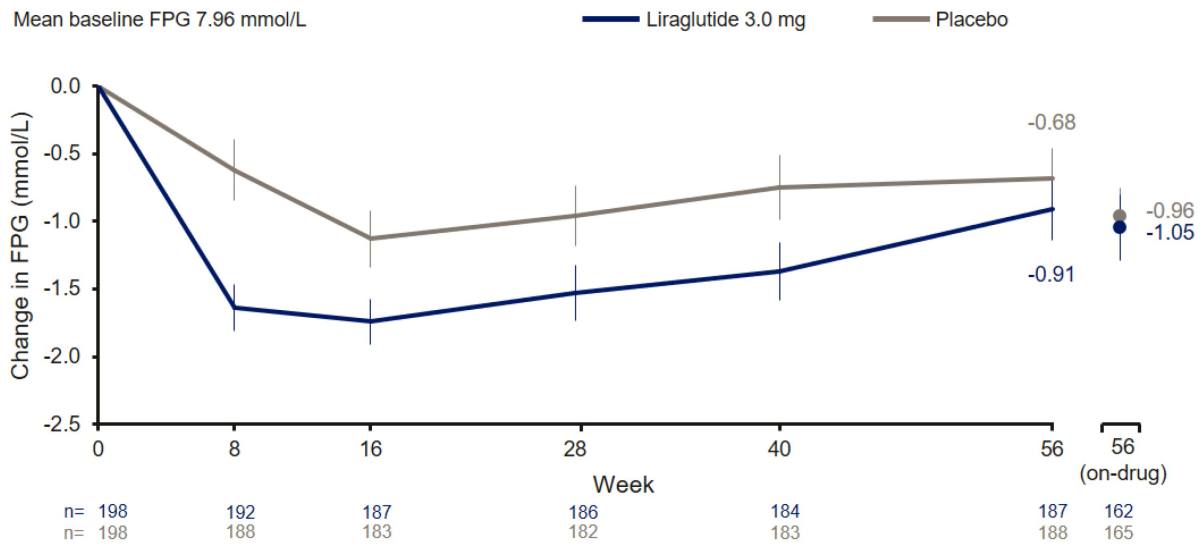
SUPPLEMENTARY DATA

Supplementary Figure 5. Change in fasting plasma glucose



Graph is observed mean data ± SEM. n-values refer to all individuals who attended visit regardless of treatment status; on drug n-values refer to individuals who are still on active treatment at time of visit. FPG, fasting plasma glucose; SEM, standard error of the mean

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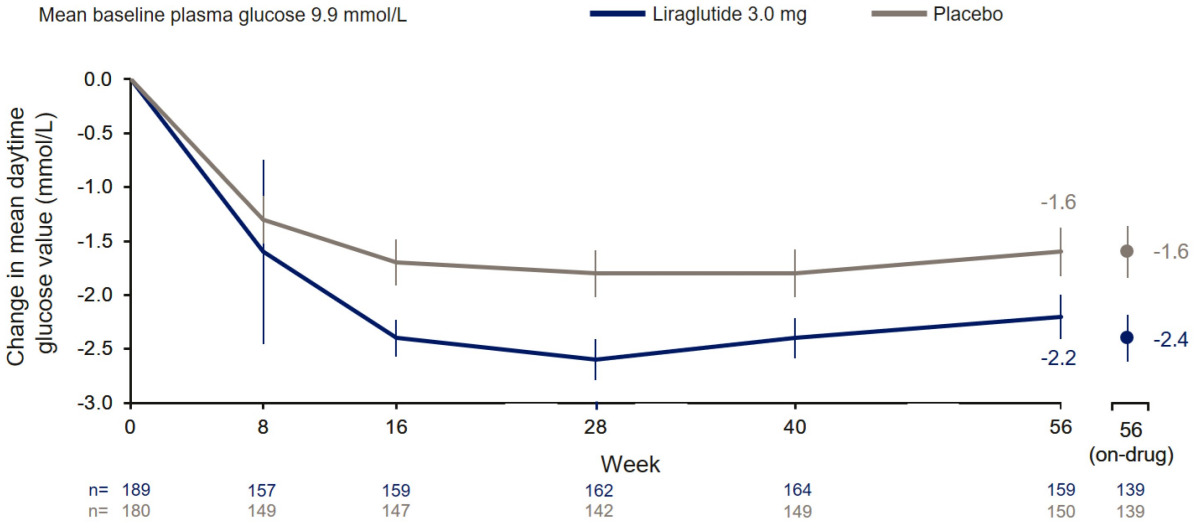
SUPPLEMENTARY DATA

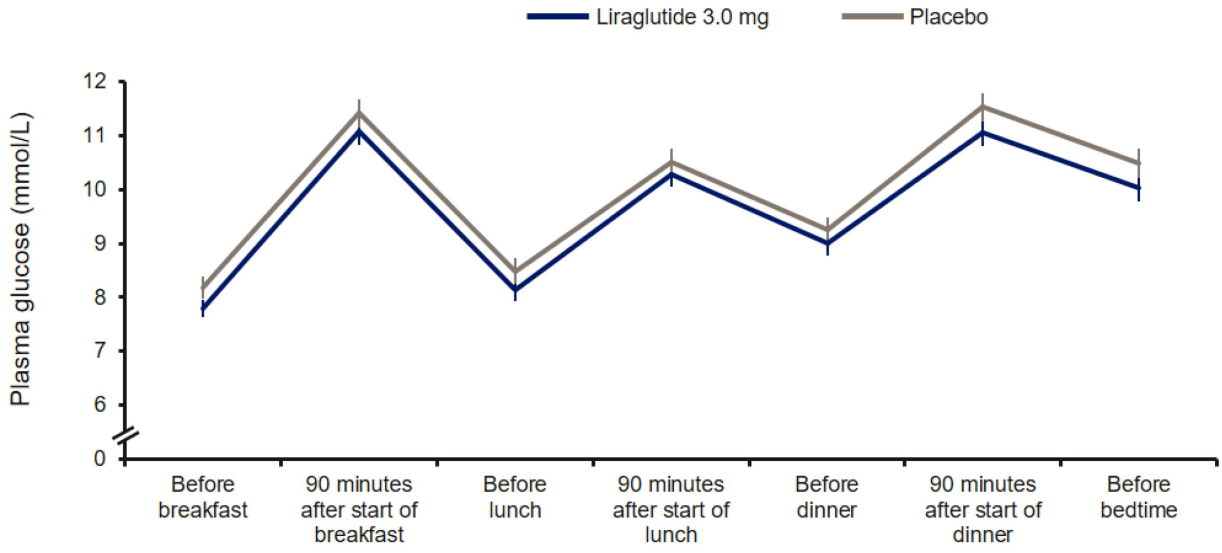
Supplementary Figure 6. Change in mean daytime glucose value and 7-point self-measured blood glucose

A. Change in mean daytime glucose value



Graph is observed mean data ± SEM. Mean daytime glucose value was calculated from the 7 -point SMBG profile as area under the curve (AUC) divided by length of time-interval. n-values refer to all individuals who attended visit regardless of treatment status; on drug n-values refer to individuals who are still on active treatment at time of visit. SEM, standard error of the mean; SMBG, self-measured blood glucose

B. Daily 7-point self-measured blood glucose profiles at baseline



Graph is observed mean data ± SEM. SEM, standard error of the mean

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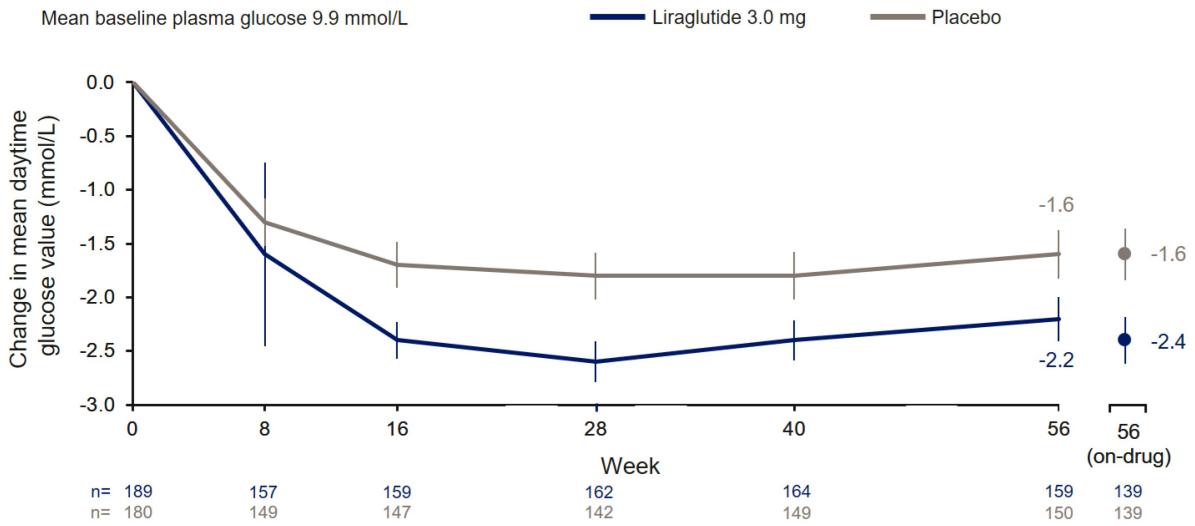
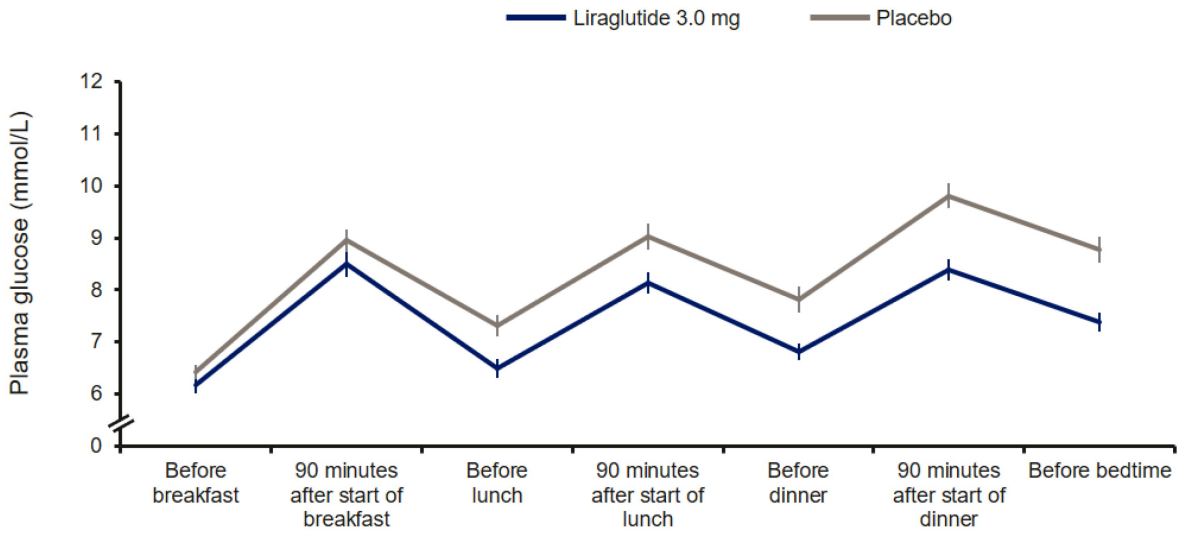
C. Daily 7-point self-measured blood glucose profiles at week 16



Graph is observed mean data ± SEM. SEM, standard error of the mean

D. Daily 7-point self-measured blood glucose profiles at week 56



Graph is observed mean data ± SEM. SEM, standard error of the mean

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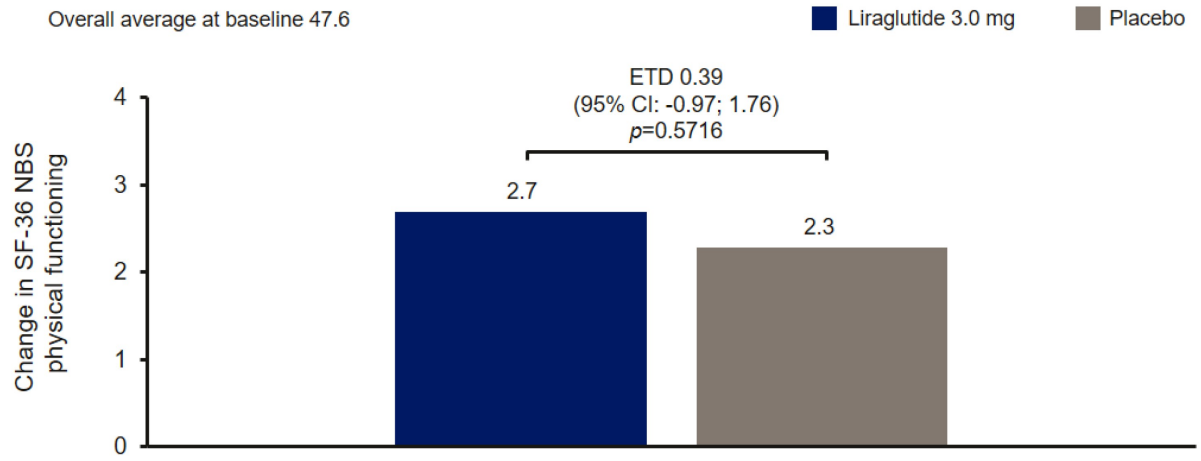
SUPPLEMENTARY DATA

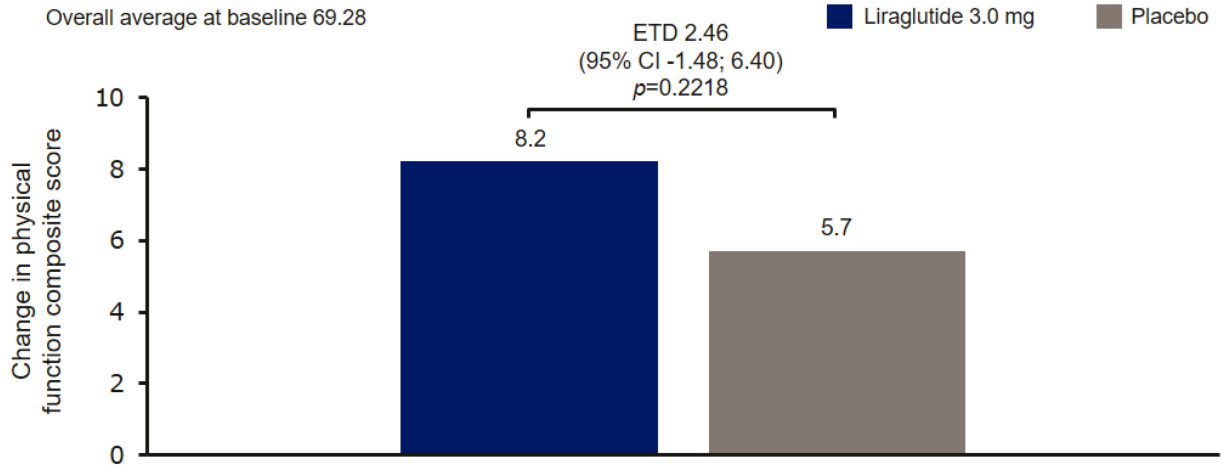
Supplementary Figure 7. Change in physical functioning

A. Change in SF-36 physical functioning score



Graph is estimated mean data ±SEM. Statistical analysis is ANCOVA with J2R-MI. ETD, estimated treatment difference; J2R-MI, jump to reference-multiple imputation; NBS, norm-based score; SEM, standard error of the mean; SF-36, Short Form-36 v2® Health Survey

B. Change in IWQOL-Lite-CT physical function score



Graph is estimated mean data ±SEM. Statistical analysis is ANCOVA with J2R-MI. ETD, estimated treatment difference; IWQOL-Lite-CT, Impact of Weight on Quality of Life-Lite Clinical Trial version; J2R-MI, jump to reference-multiple imputation; SEM, standard error of the mean

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Supplementary Table 4. Adverse events in ≥5% of individuals

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	Liraglutide 3.0 mg (n=198)			Placebo (n=198)		
	%	E	R	%	E	R
Adverse events in ≥5% of participants	83.6	624	316.8	72.1	477	240.6
Nausea	29.7	105	53.3	11.7	27	13.6
Nasopharyngitis	21.5	48	24.4	18.3	49	24.7
Diarrhea	23.1	77	39.1	15.2	54	27.2
Headache	14.9	36	18.3	14.7	47	23.7
Upper respiratory tract infection	12.3	32	16.2	14.7	37	18.7
Constipation	14.4	36	18.3	8.6	21	10.6
Vomiting	16.4	53	26.9	6.1	13	6.6
Arthralgia	6.2	14	7.1	12.2	37	18.7
Pain in extremity	8.2	17	8.6	9.6	21	10.6
Influenza	6.2	14	7.1	11.2	26	13.1
Urinary tract infection	3.6	12	6.1	10.2	23	11.6
Back pain	6.7	13	6.6	6.1	17	8.6
Decreased appetite	9.7	24	12.2	2.5	5	2.5
Fatigue	7.2	18	9.1	5.1	11	5.5
Abdominal pain upper	6.2	17	8.6	4.1	9	4.5
Dizziness	6.7	18	9.1	3.6	7	3.5

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Gastroenteritis	7.7	15	7.6	2.5	5	2.5
Osteoarthritis	4.1	11	5.6	6.1	13	6.6
Abdominal discomfort	5.6	17	8.6	4.1	11	5.5
Sinusitis	4.6	11	5.6	5.1	11	5.5
Dyspepsia	6.2	13	6.6	2.5	5	2.5
Oropharyngeal pain	3.6	7	3.6	5.1	12	6.1
Hypertension	2.1	4	2	6.1	14	7.1
Gastroesophageal reflux disease	5.1	12	6.1	1.0	2	1

%, percentage of individuals experiencing at least one event; E, number of events; R, episode rate per 100 years of observation

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Supplementary Table 5. Hypoglycemic episodes (Novo Nordisk criteria)

	Liraglutide 3.0 mg (n=198)			Placebo (n=198)		
	n (%)	**E**	**R**	**n (%)**	**E**	**R**
Hypoglycemic episodes	140 (71.8)	1462	742.3	140 (71.1)	1859	937.9
Novo Nordisk-classified						
Severe	3 (1.5)	3	1.5	2 (1.0)	2	1.0
Symptomatic BG-confirmed	51 (26.2)	161	81.7	59 (29.9)	249	125.6
Asymptomatic BG-confirmed	26 (13.3)	42	21.3	35 (17.8)	89	44.9
Unclassifiable	138 (70.8)	1256	637.7	139 (70.6)	1519	766.3

n, number of individuals experiencing at least one event; %, percentage of individuals experiencing at least one event; E, number of events; R, episode rate per 100 years of observation; BG, blood glucose

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Supplementary Table 6. Hypoglycemic episodes by sulfonylurea status at baseline

	Individuals on SUs at baseline						Individuals not on SUs at baseline					
	Liraglutide 3.0 mg			Placebo			Liraglutide 3.0 mg			Placebo		
	n (%)	E	R	n (%)	E	R	n (%)	E	R	n (%)	E	R
Episodes	52 (81.3)	596	892.5	52 (74.3)	662	927.8	88 (67.2)	866	665.2	88 (69.3)	1197	943.5
ADA-classified												
Severe	2 (3.1)	2	3	1 (1.4)	1	1.4	1 (0.8)	1	0.8	1 (0.8)	1	0.8
Asymptomatic	41 (64.1)	288	431.3	41 (58.6)	424	594.3	75 (57.3)	454	348.7	75 (59.1)	564	444.6
Documented symptomatic	39 (60.9)	284	425.3	42 (60)	213	298.5	53 (40.5)	378	290.4	60 (47.2)	603	475.3
Pseudo-hypoglycemia	3 (4.7)	19	28.5	7 (10)	20	28	14 (10.7)	23	17.7	7 (5.5)	11	8.7
Probable symptomatic	2 (3.1)	2	3	3 (4.3)	4	5.6	6 (4.6)	8	6.1	15 (11.8)	18	14.2
Unclassifiable	1 (1.6)	1	1.5	0 (0)	0	0	1 (0.8)	2	1.5	0 (0)	0	0
Novo Nordisk-classified												
Severe	2 (3.1)	2	3	1 (1.4)	1	1.4	1 (0.8)	1	0.8	1 (0.8)	1	0.8
Symptomatic BG-confirmed	23 (35.9)	72	107.8	24 (34.3)	55	77.1	28 (21.4)	89	68.4	35 (27.6)	194	152.9
Asymptomatic BG-confirmed	15 (23.4)	24	35.9	18 (25.7)	52	72.9	11 (8.4)	18	13.8	17 (13.4)	37	29.2

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Unclassifiable	52 (81.3)	498	745.7	51 (72.9)	554	776.5	86 (65.6)	758	582.2	88 (69.3)	965	760.6

ADA, American Diabetes Association; BG, blood glucose, E, number of events; n, number of individuals experiencing at least one episode; R, episode rate per 100 years of observation; SU, sulfonylurea

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Supplementary Table 7. Serious neoplasm events

	Liraglutide 3.0 mg			Placebo		
	N (%)	**E**	**R**	**N (%)**	**E**	**R**
Events	6 (3.1)	6	2.7	2 (1.0)	2	0.9
Thyroid adenoma	1 (0.5)	1	0.4	0 (0.0)	0	0
Papillary thyroid cancer*	1 (0.5)	1	0.4	0 (0.0)	0	0
Adenocarcinoma pancreas	1 (0.5)	1	0.4	0 (0.0)	0	0
Renal cell carcinoma	1 (0.5)	1	0.4	0 (0.0)	0	0
Lung squamous cell carcinoma metastatic	1 (0.5)	1	0.4	0 (0.0)	0	0
Invasive lobular breast carcinoma	0 (0.0)	0	0	1 (0.5)	1	0.4
Malignant melanoma	0 (0.0)	0	0	1 (0.5)	1	0.4
Endometrial hyperplasia	1 (0.5)	1	0.4	0 (0.0)	0	0

*Identified before treatment initiation. N, number of individuals experiencing at least one event; %, percentage of individuals experiencing at least one event; E, number of events; R, episode rate per 100 years of observation

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SUPPLEMENTARY DATA

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