

Weight loss as determined by adherence to reduced caloric diet, increased physical activity, liraglutide 3.0 mg and placebo: a sub-analysis of the SCALE IBT trial

PO2.192



qrs.ly/5b9pb5g

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Background

- SCALE IBT demonstrated superiority of liraglutide 3.0 mg for weight reduction vs. placebo as an adjunct to intensive behaviour therapy (IBT; reduced calorie intake, increased physical activity and behaviour counselling) after 56 weeks' treatment (-7.5% vs. -4.0%; estimated treatment difference [95% CI], -3.5% [-5.3, -1.6]; $p=0.0003$).¹
- Adherence to pharmacological weight-management interventions in the real world is low.¹
- To our knowledge, the benefits of adherence to pharmacotherapy, physical activity goals and reduced caloric diet have not been evaluated within the same trial before.

Aim

- The aim of this pre-specified exploratory sub-analysis of the SCALE IBT trial was to evaluate adherence to the trial product, caloric diet and physical activity interventions, and their individual contribution to weight change.

Methods

- SCALE IBT was a randomised, controlled, double-blind trial of liraglutide 3.0 mg vs. placebo, both combined with IBT in individuals with obesity (body mass index ≥ 30 kg/m²).
- Adherence was measured as described in Figure 1.
- The effect of adherence on body weight was evaluated through an analysis of variance model that was reduced by removing nonsignificant interactions with the randomised drug ($p>0.05$), rendering the effect of adherence to diet, physical activity and study medication independent of each other.

Figure 1: Adherence definitions

Individuals adherent at given week if individual has:

At least one administration of trial product per week
Recorded on a weekly basis by individuals' self-reports

At least one food diary entry for 5 days per week
Assessed via the individuals' completion of food diaries

At least 50% of the target time of physical activity per week
Assessed using electronic activity trackers

Results

- 282 individuals were randomised: 142 to liraglutide 3.0 mg + IBT (16% male; mean age 45 years; mean weight 109 kg; mean BMI 39 kg/m²) and 140 to placebo + IBT (17% male; mean age 49 years; mean weight 107 kg; mean BMI 39 kg/m²).
- The proportion of individuals adherent to trial product, dietary self-monitoring and physical activity decreased over the course of the trial in both treatment groups (Figure 2).

- There were no statistically significant differences in the liraglutide 3.0 mg vs. placebo ratios for adherent weeks for caloric diet (odds ratio: 1.07 [95% CI: 0.94;1.22]; $p=0.2762$), physical activity (odds ratio: 0.99 [95% CI: 0.84;1.16]; $p=0.8827$) or trial product (odds ratio: 1.06 [95% CI: 0.95;1.17]; $p=0.3029$).
- Adherence to physical activity recommendations provided an estimated reduction of 2.0% in initial body weight (95% CI: -3.2;-0.8; $p=0.0009$) and adherence to dietary recommendations provided an estimated 7.2% reduction (95% CI: -10.4;-4.0; $p<0.0001$) (Figure 3).
- Adherence to liraglutide 3.0 mg provided an additional loss of 6.5% (95% CI: -10.2;-2.9; $p=0.0005$), while adherence to placebo did not have a statistically significant effect on weight loss (mean contribution of -1.9% [95% CI: -5.6;1.9]; $p=0.33$) (Figure 3).
- Expressed additively, adherence to all components of treatment would result in mean weight loss of 15.7% (95% CI: -19.5;-11.9) with liraglutide 3.0 mg and 11.1% (95% CI: -14.9;-7.2) with placebo (Figure 3).

Discussion

- In this analysis, higher adherence to liraglutide 3.0 mg, physical activity and reduced caloric diet were each associated with increased weight loss.
- These findings are similar to those of the Look AHEAD study, which also concluded that adherence to diet and physical activity was positively related to both short- and long-term weight-loss outcomes.²
- This was a pre-specified but exploratory analysis. The ways in which adherence was recorded, defined and analysed are preliminary in nature, thus it is possible that the adherence measures employed were not sufficiently sensitive to detect a difference.
- Although this study investigated whether adherence influences weight loss, conversely, weight loss may influence adherence. This analysis is unable to determine causality.

Figure 2: Proportion of individuals adhering to the caloric diet, physical activity and trial product over the trial period

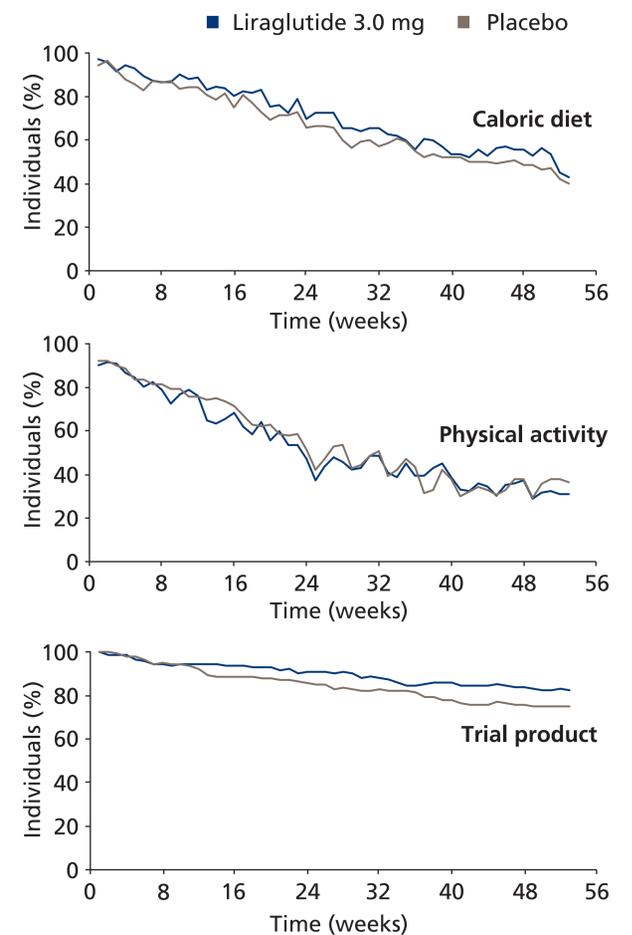
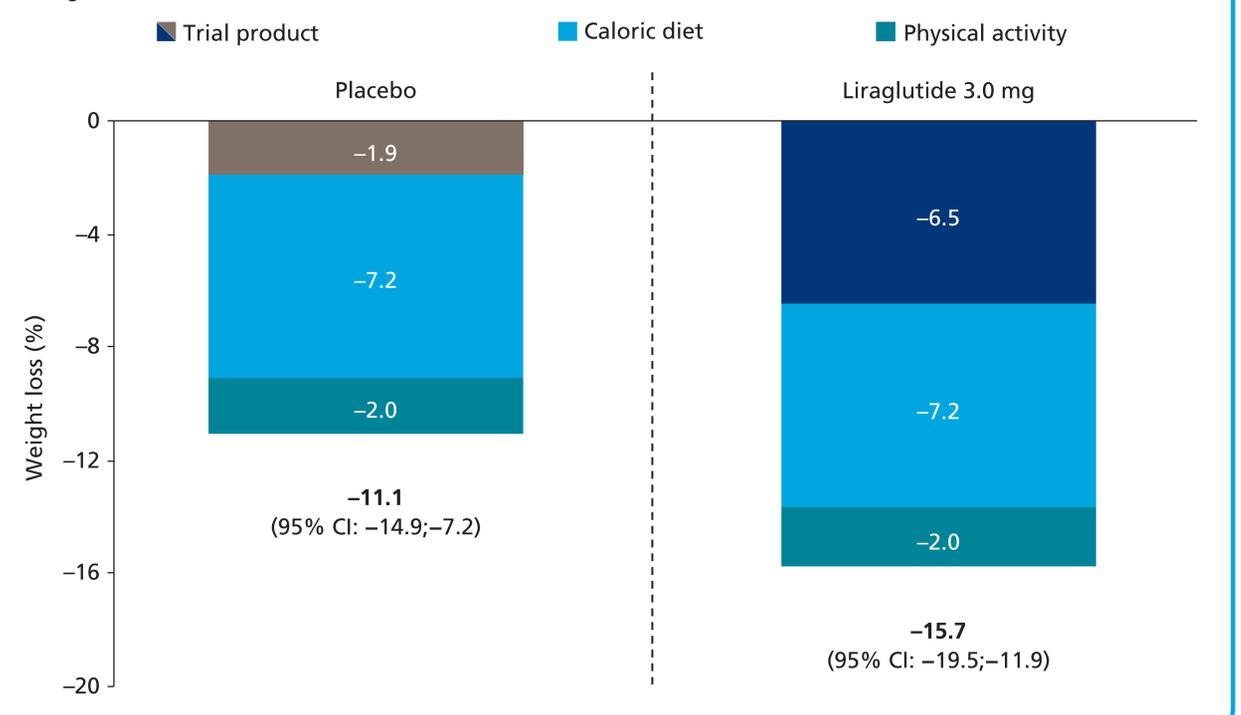


Figure 3: Combined and individual component effects on body weight if all individuals had been adherent throughout the trial



Key result

Conclusion

- This sub-analysis indicated that the majority of individuals in both treatment groups were adherent to trial product, but adherence to all treatment components decreased over time.
- Adherence to dietary recommendations and treatment with liraglutide 3.0 mg provided clinically relevant weight loss, whereas the effect of physical activity was more modest in size.