Early responders to oral semaglutide 25 mg: A *post hoc* analysis of the OASIS 4 trial

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Introduction

In the **OASIS 4** trial (NCT05564117), after 64 weeks, participants with a BMI of ≥30 kg/m^2 (or ≥27 kg/m^2 with ≥1 obesity-related complication) without diabetes, who received once-daily oral semaglutide 25 mg, had a mean body weight change of −13.6%, compared with −2.2% with placebo.[1]

To date, there are limited data characterising the early response to oral semaglutide in terms of the degree and rate of body weight reduction.

This secondary analysis of the OASIS 4 trial investigated body weight reductions of early responders (defined as participants who achieved ≥10%, ≥7.5% and ≥5% body weight reduction by week 16) and responders.

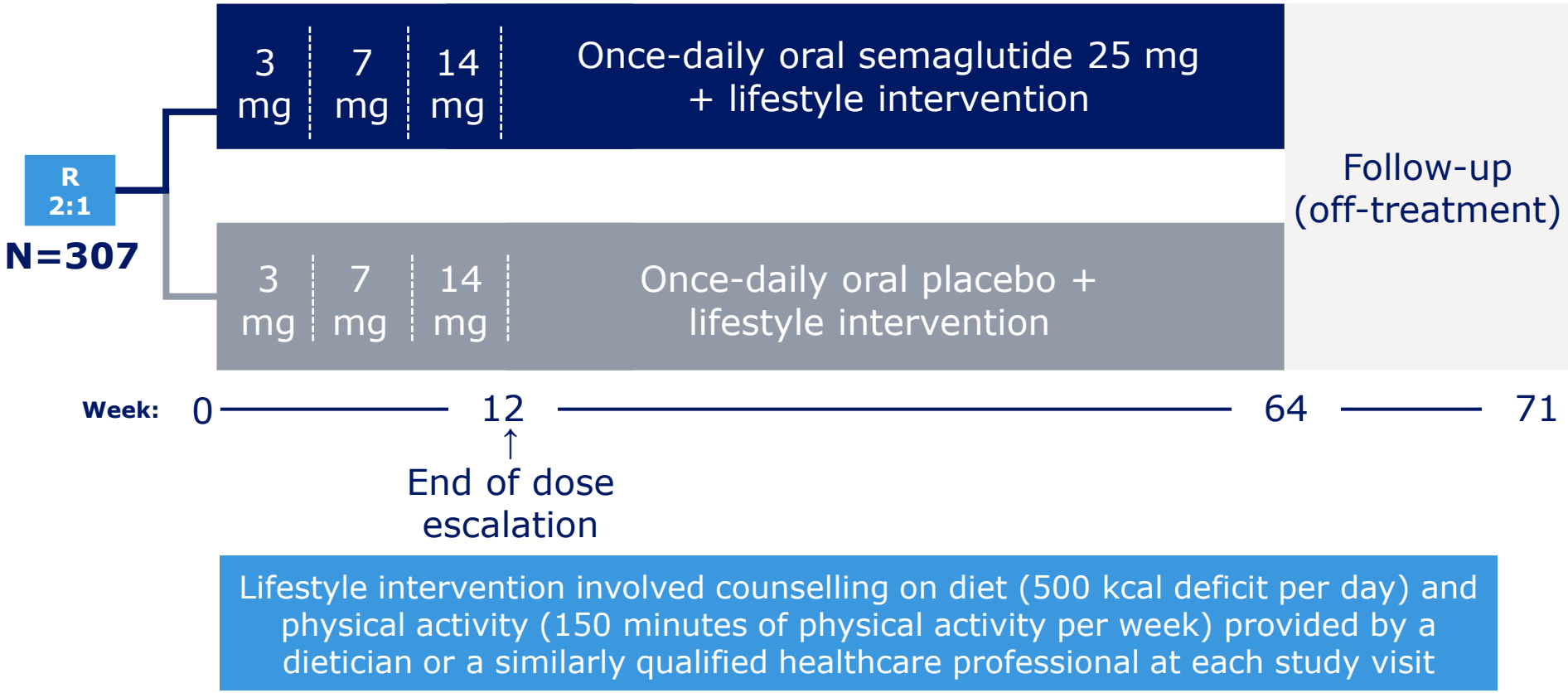
- Also assessed were the median times to achieve sustained categorical body weight reduction thresholds and the proportion of participants who maintained these reductions.

BMI, body mass index.

1. Wharton S et al. N Engl J Med 2025;393:1077–1087.

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OASIS 4 trial design



R, randomisation.

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Trial design

Population



- **Key inclusion criteria included:** aged ≥18 years; BMI ≥30 kg/m^2 (or ≥27 kg/m^2 with ≥1 obesity related complication; ≥1 self-reported unsuccessful dietary effort to lose weight.
- **Key exclusion criteria included:** HbA_{1c} ≥48 mmol/mol (≥6.5%) or history of diabetes; treatment with any medication indicated for weight management or any glucose-lowering agent within 90 days prior to screening; history of MI, stroke, hospitalisation for unstable angina, TIA or HF; presence of acute pancreatitis within 180 days prior to screening; history or presence of chronic pancreatitis.

Outcomes



- **Body weight change** of early responders (categorised as participants who achieved ≥10%, ≥7.5% and ≥5% body weight reduction by week 16, encompassing 4 weeks of maximal dosing) and responders who did not meet these thresholds (<10%, <7.5% and <5% body weight reduction) by week 16.
- The **median time to achieve sustained body weight reduction** thresholds of ≥5%, ≥10%, ≥15% and ≥20%, and the duration that these thresholds were sustained during the trial,
- The **proportion of participants maintaining body weight reduction** thresholds from achievement until the end of the trial.

BMI, body mass index; HbA_{1c}, glycated haemoglobin; HF, heart failure; MI, myocardial infarction; TIA, transient ischaemic attack.

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Baseline characteristics

Participants randomised to semaglutide 25 mg

n=205

Participants randomised to placebo

n=102



Sex
Male | Female

21.2% | 78.8%



Mean age

48 years



Mean body weight

105.9 kg

Mean BMI

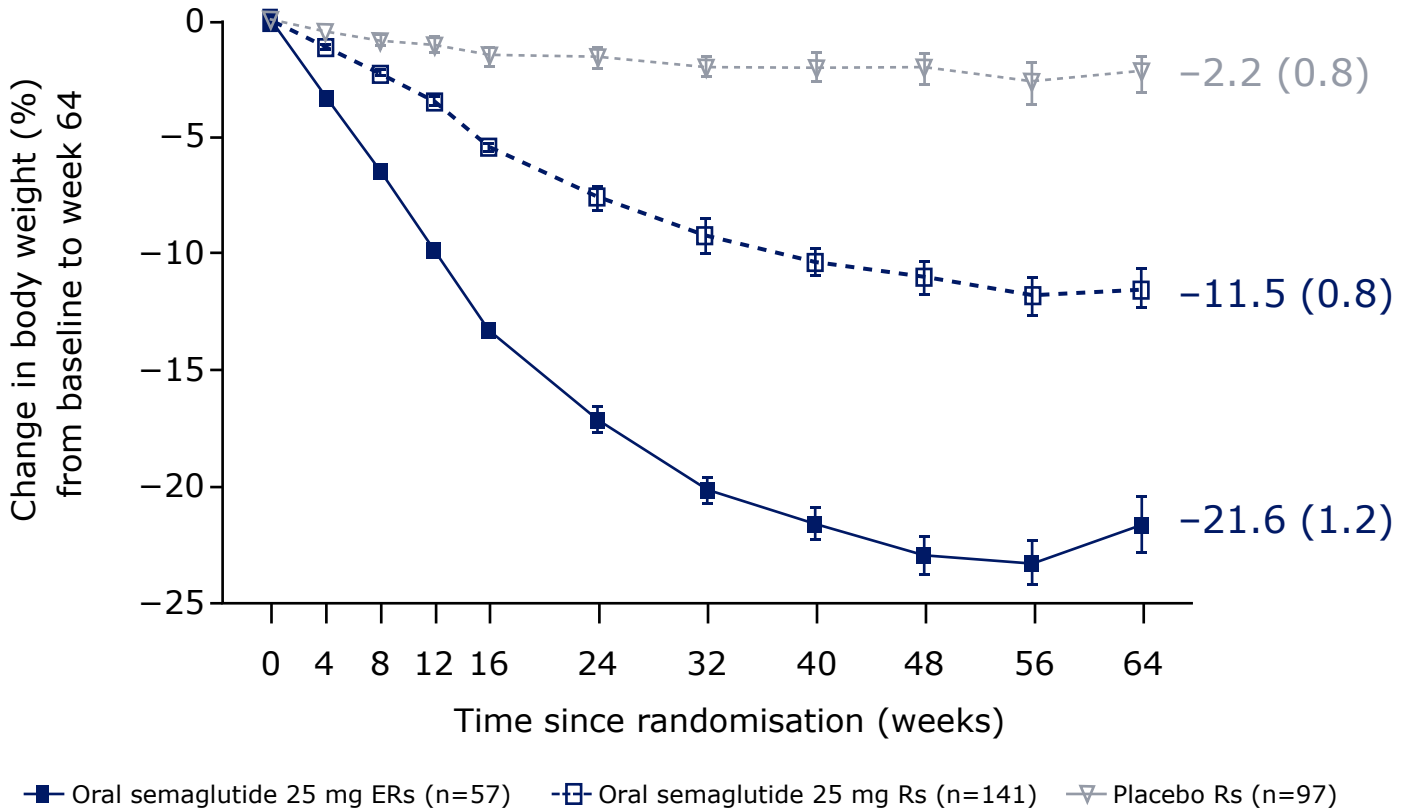
37.6 kg/m^2

BMI, body mass index.

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Progressive and overall weight reduction in early responders versus responders: ≥10% ERs



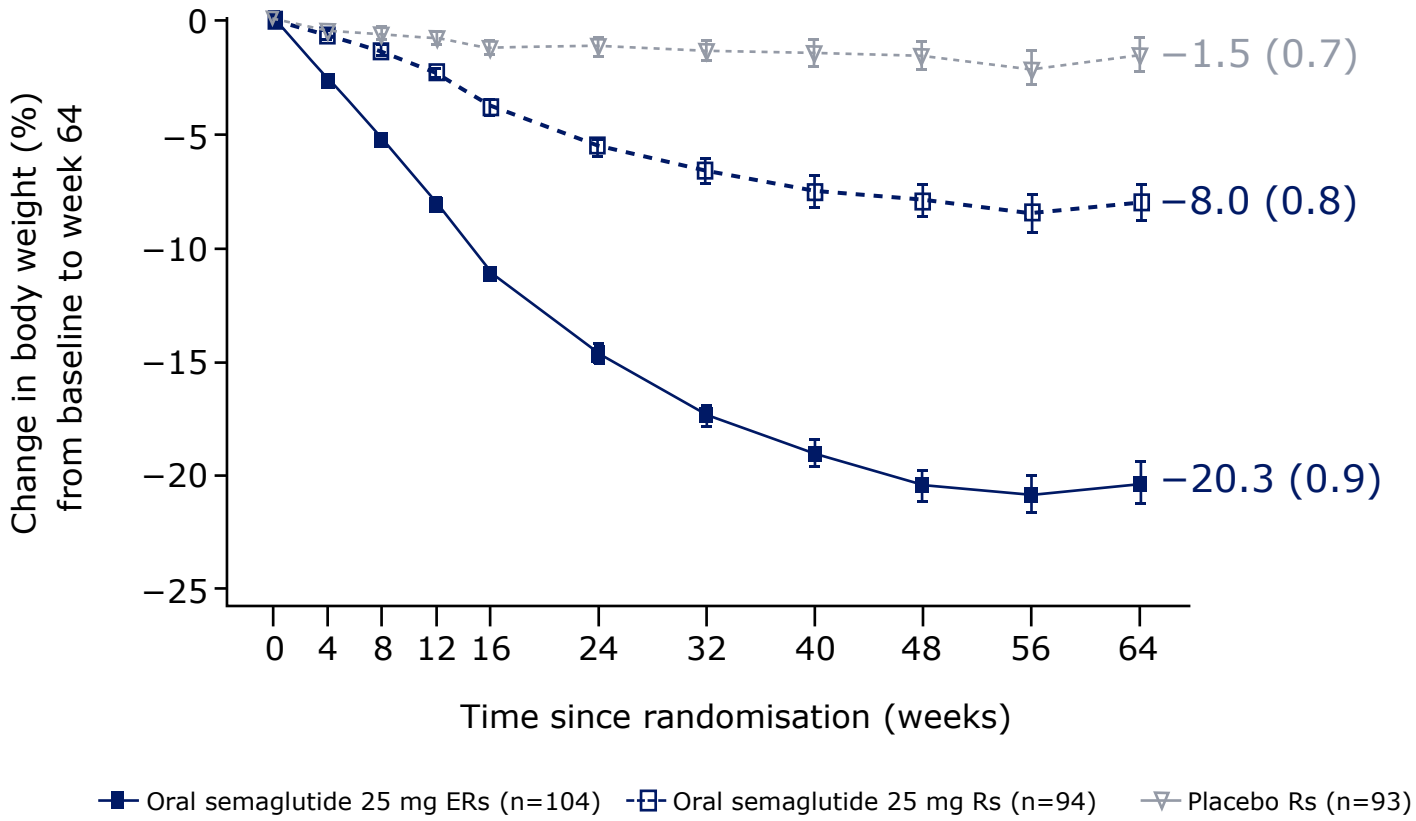
In the semaglutide 25 mg group, 28.8% (n=57) of participants were considered ≥10% body weight reduction early responders

Data are mean ± SEM from the in-trial period.
ER, early responder; R, responder; SEM, standard error of the mean.

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Progressive and overall weight reduction in early responders versus responders: ≥7.5% ERs



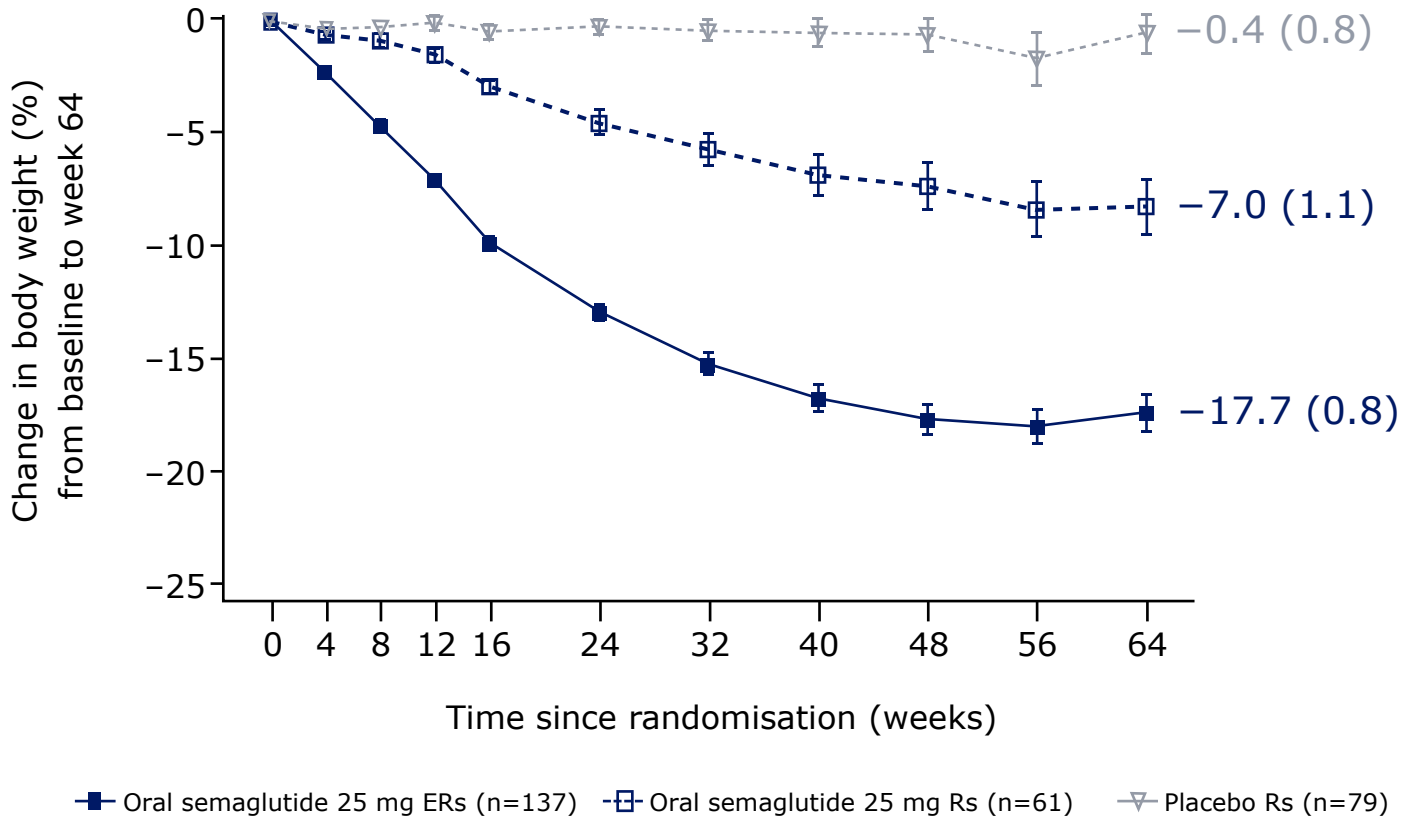
In the semaglutide 25 mg group, 52.5% (n=104) of participants were considered ≥7.5% body weight reduction early responders

Data are mean ± SEM from the in-trial period.
ER, early responder; R, responder; SEM, standard error of the mean.

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Progressive and overall weight reduction in early responders versus responders: ≥5% ERs



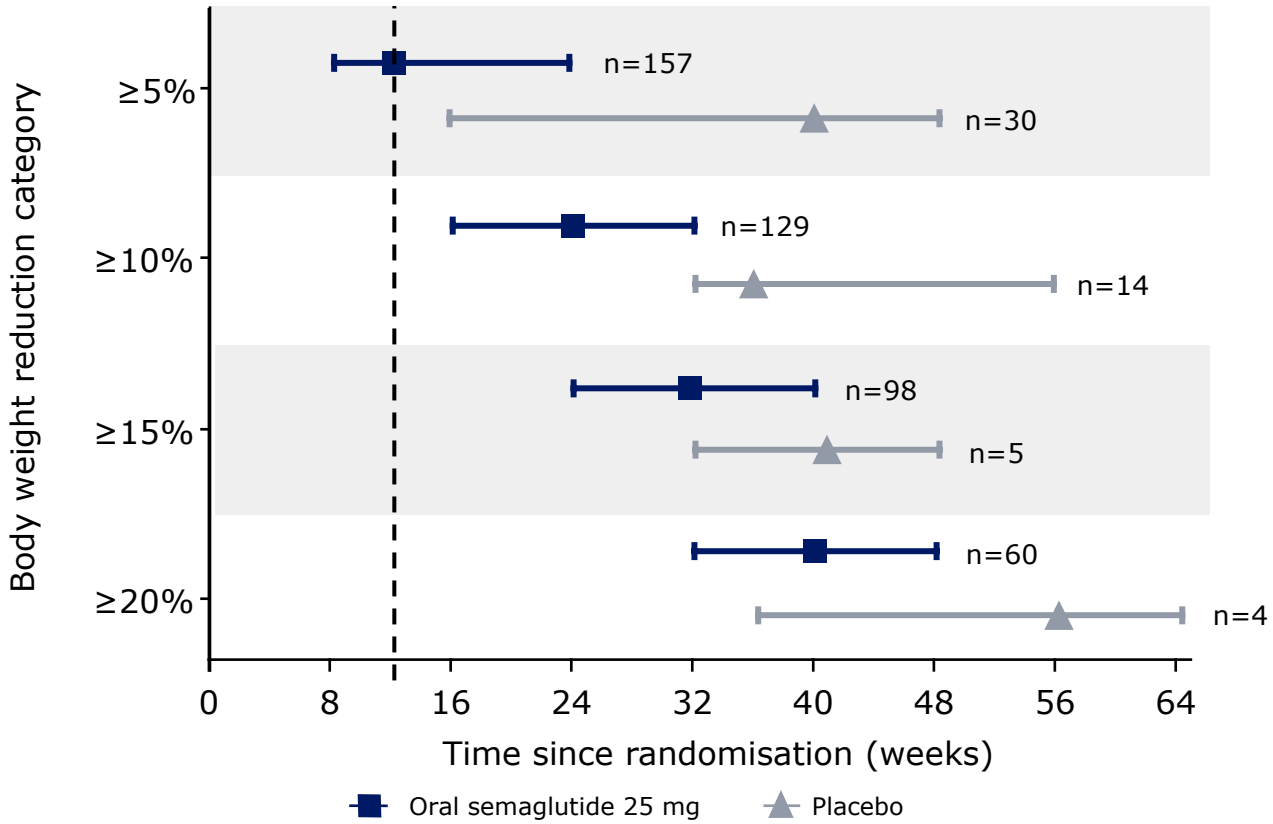
In the semaglutide 25 mg group, 69.2% (n=137) of participants were considered ≥5% body weight reduction early responders

Data are mean ± SEM from the in-trial period.
ER, early responder; R, responder; SEM, standard error of the mean.

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Median time to achieve categorical body weight reduction thresholds



In the semaglutide 25 mg group, categorical body weight reductions were maintained by 81.8%, 67.2%, 51.0% and 31.3% of participants for the ≥5%, ≥10%, ≥15% and ≥20% body weight reduction thresholds , respectively.

In the placebo group, these values were 33.3%, 15.6%, 5.6%, and 4.4%, respectively.

Data are median (IQR) from the in-trial period. The dashed vertical line indicates end of dose escalation. Sustained weight loss is achieved if meeting weight loss target at a post-baseline visit and at all subsequent visits, with 3% fluctuation allowed at subsequent visits.
IQR, interquartile range.

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Conclusions

Overall, 69.2%, 52.5% and 28.8% of participants in the semaglutide 25 mg group met body weight reduction thresholds of ≥5%, ≥7.5% and ≥10% at 16 weeks, respectively, and achieved –17.7%, –20.3% and –21.6% mean body weight change at 64 weeks.

Treatment with semaglutide 25 mg provided faster body weight reductions than with placebo (e.g. median time to achieve ≥5% body weight reduction was 12 weeks with semaglutide vs 40 weeks with placebo).

When body weight reduction thresholds of ≥5%, ≥10% and ≥15% were achieved, they were maintained until the end of the trial by most participants in the semaglutide group, with approximately one third maintaining ≥20% body weight reduction. In the placebo group, maintenance of these body weight reduction thresholds was achieved by fewer participants.

These data could be useful to clinicians in predicting longer term weight loss efficacy of semaglutide 25 mg based on early weight loss response at 16 week.

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