Efficacy of a digital health application (DiGA) in obesity management: 6-months results from the AMODA randomized controlled trial on Oviva Direkt for obesity

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Background

Oviva Direkt for Obesity is a digital health application (DiGA) reimbursed in German statutory health care. It is a guideline-based, multimodal, app-based intervention supporting adults with obesity to achieve sustainable weight loss. A previous randomized, controlled trial has demonstrated its clinical efficacy at 3 months (1). The AMODA trial evaluated the efficacy of Oviva Direkt for Obesity at 6 months.

Methods

164 participants with obesity (BMI 30-45 kg/m2) were randomized into an intervention group using Oviva Direkt for Obesity together with usual care or a control group only receiving usual care. Outcomes were assessed at 6 months including weight change (primary endpoint), quality of life (WHOQOL-BREF), and food literacy (SFLQ). Intention-to-treat-data were analyzed using a linear regression model and estimated marginal means.

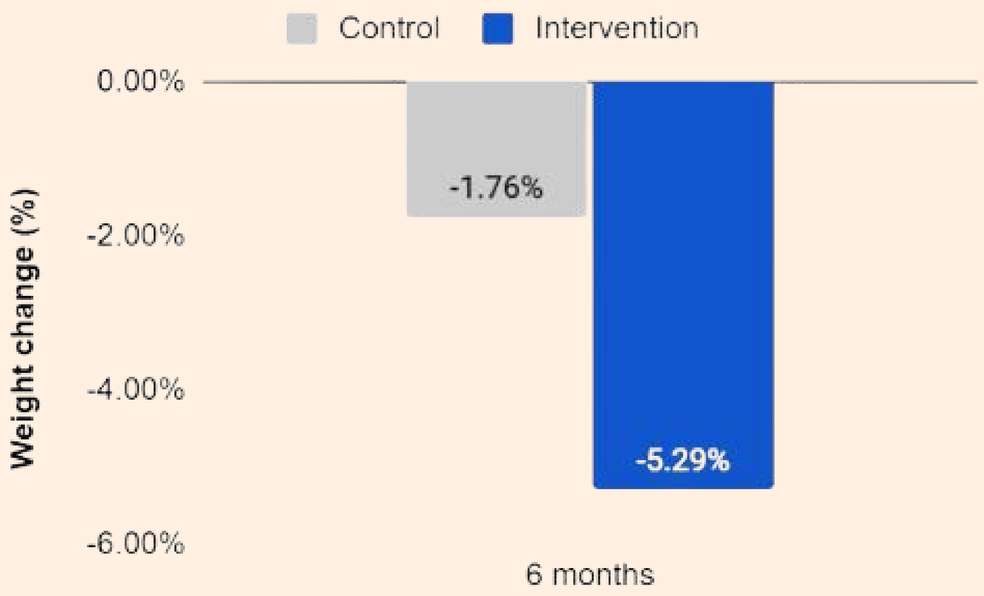

Figure 1. Weight change (%) from baseline to 6 months (i.e. 24 weeks) (primary endpoint)

References:

1. Gemesi K., Winkler S., Schmidt-Tesch S., Schederecker F., Hauner H., and Holzapfel C. Efficacy of an app-based multimodal lifestyle intervention on bodyweight in persons with obesity: results from a randomized controlled trial. Int J Obes. 2023 Nov:1–9.

Results

At 6 months, the intervention group achieved a mean weight loss of 5.29% (SE: 0.73) compared to 1.76% (SE: 0.68) in the control group (difference: -3.53%; $p < 0.001$) with a large effect size (Cohen's $d = 0.80$) (Fig. 1). The intervention group consistently showed greater weight reduction than the control group at all time points, with marginal differences (the difference between the intervention and the control group) increasing over time (Fig. 2). 49% of participants in the intervention group achieved ≥ 5% weight loss, compared to 4.8% in the control group. Quality of life improved significantly in the intervention group ($p = 0.010$, Cohen's $d = 0.40$), particularly in psychological and social domains. Participants in the intervention group also showed significantly greater improvements in food literacy at 12 and 24 weeks compared to controls ($p < 0.001$).

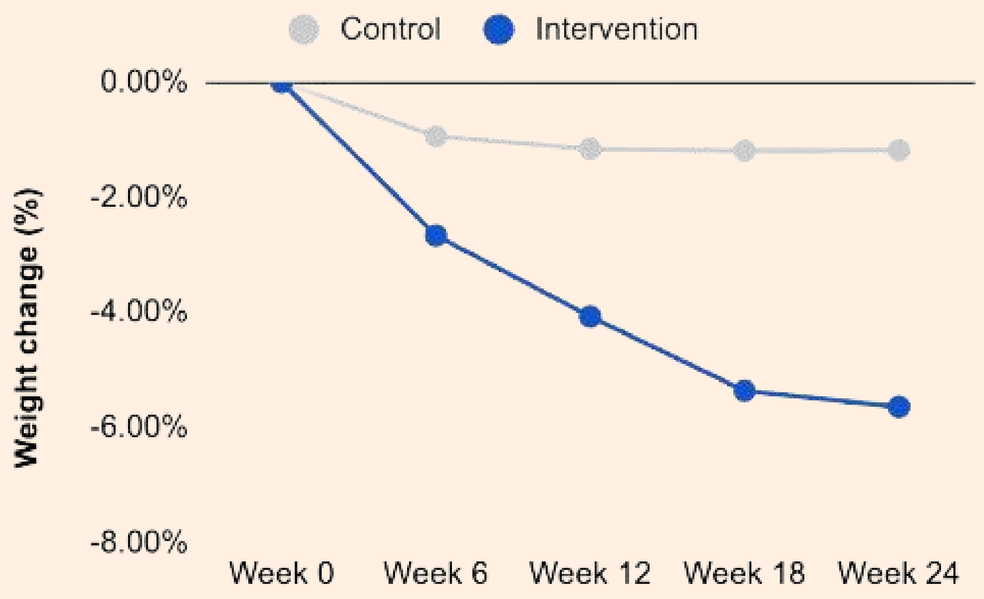

Figure 2. Weight change (%) over time. Estimated marginal means (EMMs) for percent change in body weight over time in the intention-to-treat (ITT) population (exploratory endpoint)

Conclusion

The AMODA trial demonstrates the clinical efficacy of Oviva Direkt for Obesity, facilitating meaningful weight loss, enhancing quality of life, and improving food literacy at 6 months for adults with BMI 30-45 kg/m². These results highlight the potential of digital lifestyle interventions as a valuable, patient-centered tool for obesity management. Follow-up data is being collected to the explore long-term efficacy of Oviva Direkt for Obesity.