EASO European Association for the Study of Obesity

ECO 2025 32nd European Congress on Obesity

32nd EUROPEAN CONGRESS ON OBESITY

11-14 MAY, 2025 | MALAGA, SPAIN

Enhancing obesity treatment and care with Digital Therapeutics - a 12-week randomized control trial

Authors: M.A Larsen[1], M.I Aukan[2]

1 Gastroenterology and Nutrition Research Group, Department of Clinical Medicine, UiT The Arctic University of Norway

2 Obesity Research Group, Department of Clinical and Molecular Medicine, Faculty of Medicine, Norwegian University of Science and Technology

INTRODUCTION

Obesity is a chronic, relapsing, multifactorial disease and a major public health concern. Despite its visibility, it remains one of the world's most neglected diseases, causing an estimated 4 million deaths globally in 2015. Traditional behavioral interventions are costly, requiring significant healthcare resources. Digital therapeutics (DTx) offer a scalable, cost-effective alternative.

AIM

The aim of this interim analysis was to assess the short-term effect of Wellapy DTx alongside care as usual (CAU) versus CAU with obesity education over a 12 week period.

The primary outcome was body weight. Secondary outcomes included quality of life, well-being, patient autonomy and internalized weight stigma assessed with validated questionnaires, as well as body mass index and central adiposity.

RESULTS

Group allocation significantly influenced weight loss outcomes (p = 0.035). The intervention group (IG) showed a significant weight loss from baseline to week 12 (IG: -3.15%, p = 0.003, versus controls: -1.89%, p = 0.052), with a significantly larger relative reduction in body weight by 1.26 percentage points (95% CI: 0.10 - 2.42, d = 0.46, p = 0.034). A multivariate approach revealed an odds ratio of 4.87 ([95% CI: 1.36 - 23.1], p= 0.024) in favor of the intervention group of reducing body mass index category. *See Figure 1.*

Additionally, a greater proportion in the IG had meaningful improvement in the WHOQOL-BREF psychological component score (IG:16.7% vs. CG: 2.1%; OR: 9.01 [1.08–422.52], p = 0.024). No other secondary outcomes reached significance at 12 weeks, though some trends neared significance.

The study was registered in the German Clinicial Trials Register (Ref: DRKS00033906)

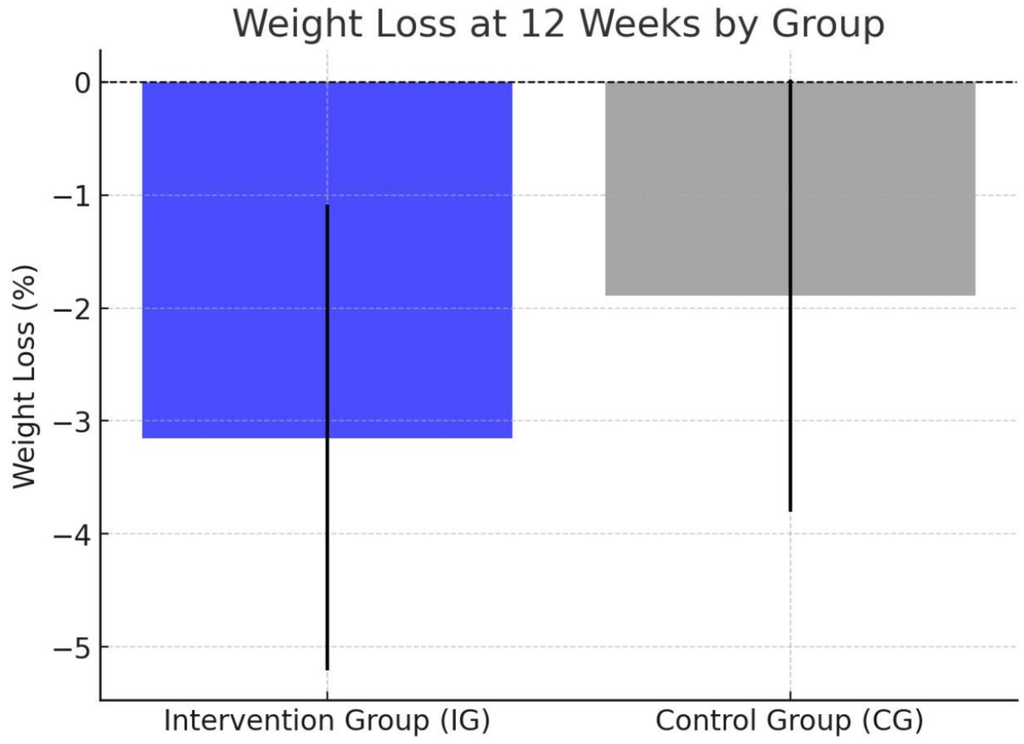

***Figure 1**: Weight loss by group after 12 weeks.*

METHOD

This two-arm, single-blinded randomized controlled trial enrolled 224 adults with obesity class I-II (BMI 30–40 kg/m²) for a 48-week intervention. Participants were block-randomized (stratified by BMI and sex) into (1) control group (CG) or (2) intervention group (IG). 100 patients were included in the interim results at 12 weeks. Outcome assessments were performed at "Klinische Forschung Berlin Mitte" GmbH at baseline (T0) and after 12 weeks (T3). Study personnel were divided into blinded (screening) and unblinded (study-related) teams.

CONCLUSIONS

These interim results suggest that the **Wellapy DTx effectively supports healthy weight loss along with improvements in health-related quality of life in individuals with obesity,** as compared to CAU alone.

Longitudinal data are needed to confirm the long-term effects.

ACKNOWLEDGEMENT

Aknowledgements: The authors thank all the participants for their time and commitment, and the study center Klinische Forschung Berlin Mitte" GmbH for carrying out the trial and statistical analyses.

Conflict of interest: M.A.L and M.I.A hold medical and scientific positions in Lifeness AS. M.A.L is a shareholder in Arlen AS.

Funding: This study was funded by Lifeness AS.

REFERENCES

Lyzwinski LN. A Systematic Review and Meta-Analysis of Mobile Devices and Weight Loss with an Intervention Content Analysis. Journal of Personalized Medicine. 2014;4(3):311-85.

Sorgente A, Pietrabissa G, Manzoni GM, Re F, Simpson S, Perona S, et al. Web-Based Interventions for Weight Loss or Weight Loss Maintenance in Overweight and Obese People: A Systematic Review of Systematic Reviews. J Med Internet Res. 2017;19(6):e229.

Washington TB, Johnson VR, Kendrick K, Ibrahim AA, Tu L, Sun K, et al. Disparities in Access and Quality of Obesity Care. Gastroenterol Clin North Am. 2023;52(2):429-41.

Crane N, Hagerman C, Horgan O, Butryn M. Patterns and Predictors of Engagement With Digital Self-Monitoring During the Maintenance Phase of a Behavioral Weight Loss Program: Quantitative Study. JMIR Mhealth Uhealth. 2023;11:e45057.

CONTACT INFORMATION

Maria Arlén Larsen, Department of Clinical Medicine, UiT The Arctic University of Norway.
E-mail: maria.a.larsen@uit.no