

## Evaluation of an app-based multimodal lifestyle intervention in persons with obesity – results of a randomized controlled study

Kathrin Gemesi<sup>1</sup>, Stefanie Winkler<sup>1</sup>, Susanne Schmidt-Tesch<sup>1</sup>, Florian Schederecker<sup>2</sup>, Hans Hauner<sup>1,3</sup>, Christina Holzapfel<sup>1,4</sup>

1 Institute for Nutritional Medicine, School of Medicine & Health, Technical University of Munich, Munich, Germany

2 Chair of Epidemiology, School of Medicine & Health, Technical University of Munich, Munich, Germany

3 Else Kröner-Fresenius-Center for Nutritional Medicine, School of Life Sciences, Technical University of Munich, Freising, Germany

4 Department of Nutritional, Food and Consumer Sciences, Fulda University of Applied Sciences, Fulda, Germany

**Introduction:** In Germany, people with obesity have free of charge access to quality-tested and scientifically evaluated Digital Health Applications (DiHAs) delivering an app-based multimodal weight loss intervention program. This 24-weeks single-center randomized controlled study was conducted to examine the effect of one of these DiHAs on weight loss in adults with obesity .

**Methods:** Adults with obesity (body mass index (BMI) = 30.0 – 40.0 kg/m<sup>2</sup>) were randomized to two treatment groups. The ADHOC group received the DiHA for the first 12 weeks and was allowed to use the DiHA in the second 12 weeks. The EXPECT group received the DiHA time-shifted after 12 weeks of “waiting” (= maintaining current lifestyle). At baseline, after 12 and after 24 weeks, anthropometric parameters were measured. Data about quality of life (Euroqol EQ-5D-5L) and user friendliness and acceptance (Technology Acceptance Model 3, System Usability Scale) was collected.

**Results:** The analyses included a total of 168 participants (64.3 % women) with a mean age of 46.8 ± 11.0 years and a mean baseline BMI of 34.2 ± 2.8 kg/m<sup>2</sup>. In total, 82.7 % (139/168) completed the visit after 12 weeks and 67.3 % (113/168) completed the visit after 24 weeks. After 12 weeks, a mean weight loss of 3.2 ± 3.0 % in the ADHOC group and of 0.3 ± 2.6 % in the EXPECT group was observed with a statistically significant difference of 2.9 % (95 % CI = - 3.8; - 1.9, p < 0.001, standardized regression coefficient β = 0.46, completers analysis). In the second 12 weeks, the ADHOC group maintained the weight loss of the first 12 weeks (mean weight loss of 3.1 ± 4.5 % after 24 weeks, completers analysis). Mean change of quality of life was not significantly different between the ADHOC and EXPECT group (EQ VAS score: + 4.7 ± 14.8 vs. + 0.6 ± 11.0, p = 0.06). Amount of time spent on the DiHA was positively associated with weight reduction (β [95 % CI] = - 0.10 [- 0.18; - 0.01], p = 0.03). Imputation analyses (“Last observation carried forward” and “Copy increments in reference”) confirmed the results of the completers analysis.

**Conclusion:** The multimodal lifestyle intervention program delivered by a DiHA resulted in a statistically significant and clinically meaningful moderate short-term weight loss after 12 weeks. Weight loss was maintained for further 12 weeks.

**1. Conflict of interest:** HH is a member of the scientific advisory board of Oviva AG (Zurich, Switzerland) and CH of 4sigma GmbH (Oberhaching, Germany). HH and CH received speaker honoraries by Novo Nordisk (Copenhagen, Denmark).

**2. Funding:** The study was funded by the Oviva AG, Potsdam.