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Abstract

Weight Loss Effect of an App-Based Multimodal Lifestyle Intervention in Adults with Obesity—A Randomized Controlled Trial †

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Abstract: Quality-proven Digital Health Applications (DiGAs) or "apps on prescription" in Germany extend obesity treatment options. This 24-week single-center randomized controlled trial aimed to examine the weight-lowering effect of an evidence-based multimodal weight loss intervention program delivered by a DiGA. Methods: Adults with a body mass index (BMI) between 30.0 and 40.0 kg/m^2 were randomized. In the first 12 weeks, participants either received the app (ADHOC group) or were asked to maintain their current lifestyle (EXPECT group). In the second 12 weeks, the ADHOC group were invited to continue app use and the EXPECT group started with the app intervention. At three visits (baseline, after 12, and 24 weeks), anthropometric variables were measured and quality of life, app usage, and user acceptance were collected by questionnaires (Euroquol, Technology Acceptance Model 3, System Usability Scale). A total of 168 participants (age: 46.8 ± 11.0 years, BMI: 34.2 ± 2.8 kg/m^2, 64.3% women) were included. The total adherence rates were 82.7% after 12 weeks and 67.3% after 24 weeks. After 12 weeks, the ADHOC group showed a mean weight loss of 3.2 ± 3.0% and the EXPECT group a mean weight loss of 0.3 ± 2.6% with a statistically significant difference between the groups ($p < 0.001$, completers analysis). At the 12-week follow-up, the ADHOC group maintained body weight (weight loss after 24 weeks: 3.1 ± 4.5%, completers analysis), whereas the EXPECT group—starting with the app intervention—lost weight. The investigated multimodal intervention program delivered by a DiGA resulted in a significant and clinically meaningful short-term weight loss with weight maintenance for a further three months.

Keywords: digital; e-Health; weight management

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethical Committee of the School of Medicine and Health at the Technical University of Munich (number: 45/22 S-NP, date: 3 March 32022). The study protocol has been submitted to BfArM (Federal Institute for Drugs and Medical Devices) for reviewing before

starting the trial. The study is registered in the German Register of Clinical Studies (Registration number: DRKS00025291).

Informed Consent Statement: Informed consent was obtained from all participants involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

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