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A SYSTEMATIC REVIEW OF THE EFFICACY OF DIGITAL THERAPEUTICS (DT_x) UTILIZING COGNITIVE BEHAVIORAL THERAPY (CBT) FOR LONG-TERM OBESITY MANAGEMENT IN ADULTS

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ABSTRACT

Introduction: Obesity remains a critical global health challenge requiring scalable and sustainable intervention strategies. Digital Therapeutics (DTx) based on Cognitive Behavioral Therapy (CBT) offer a promising technological solution to overcome the limitations of traditional face-to-face treatments.

Objective: This systematic review evaluated the long-term efficacy (minimum 6–12 months) of CBT-based DTx interventions in reducing Body Mass Index (BMI) and improving metabolic health in adults with obesity.

Methods: Following PRISMA guidelines, a systematic search was conducted in PubMed, Scopus, and Web of Science for Randomized Controlled Trials (RCTs) published between 2015 and 2025. Ten high-quality studies meeting the inclusion criteria were analyzed.

Results: The synthesis of the included RCTs (n=10) demonstrates that DTx solutions utilizing self-monitoring, goal setting, and cognitive restructuring lead to clinically significant weight loss (up to -7.02 kg) and BMI reduction (e.g., -1.82kg/m²) compared to standard care. Long-term results indicate that while efficacy is high in the initial 6 months, user engagement significantly declines over time (attrition). However, blended care models combining digital tools with occasional human coaching showed superior sustainability (-6.8 kg at 12 months). Additionally, a "legacy effect" was observed, where metabolic benefits, such as improved blood pressure and reduced proteinuria, persisted despite partial weight regain.

Conclusion: CBT-based DTx are effective tools for obesity management, particularly when implemented via hybrid models. Future research should focus on minimizing digital attrition and exploring the long-term cost-effectiveness of these interventions within public health systems.

KEYWORDS

Obesity, Digital Therapeutics, Cognitive Behavioral Therapy, mHealth, Systematic Review, Long-term Management

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Introduction

Obesity, defined by the World Health Organization (WHO) as abnormal or excessive fat accumulation that presents a risk to health, has ceased to be merely an aesthetic concern and has become a chronic pandemic disease. Diagnostically, obesity in adults is recognized at a body mass index (BMI) of $\geq 30 \text{ kg/m}^2$ or higher, while in children and adolescents (ages 5–19), it is defined as a BMI greater than two standard deviations above the WHO reference median. Contemporary epidemiological data indicates a rapid increase in the prevalence of obesity, which has become the dominant form of malnutrition in most countries worldwide. As of 2022, the age-standardized prevalence of obesity among adults (over age 20) globally was 18.5% for women and 14.0% for men. In the population of children and adolescents aged 5–19, this percentage reached 6.9% for girls and 9.3% for boys, respectively. This translates to a massive scale of the problem—in 2022, more than one billion people lived with obesity, including 878 million adults and 159.3 million children and adolescents. In some regions of the world, the problem has reached critical levels; in 2022, obesity prevalence exceeded 60% for women in eight countries and for men in six countries, located mainly in Polynesia and Micronesia. The highest rates were recorded in American Samoa, where the combined burden of underweight and obesity (heavily dominated by the latter) affected as many as 81.7% of women and 70.6% of men. Very high levels also occur in countries of the Caribbean, Middle East, and North Africa—for example, in Egypt (among women) and Qatar (among men). Projections for the coming years indicate a progressive "obesity transition," in which the dominance of obesity over underweight, established among adults as early as 1990 in much of the world, is now increasingly mirrored in the pediatric and adolescent populations. This trend is particularly concerning because an earlier age of obesity onset extends the body's exposure to its negative effects (NCD Risk Factor Collaboration, 2024).

Impact of Obesity on Health: Cardiovascular, Metabolic, and Oncological Consequences

Obesity is a powerful and independent risk factor for cardiovascular disease, directly affecting heart structure and function regardless of the presence of other conditions such as hypertension or diabetes. Epidemiological data provides precise evidence of the scale of this threat: every 1 kg/m^2 increase in BMI is associated with a 5% increase in the risk of heart failure in men and 7% in women. Even more alarming are the statistics regarding atrial fibrillation, where the risk increases by an average of 29% for every 5-unit increase in BMI. Excess adipose tissue leads to permanent structural changes, including left ventricular hypertrophy and myocardial fibrosis, which directly increases the risk of sudden cardiac death (Powell-Wiley et al., 2021).

The pathophysiology of obesity also forms the foundation for the globally increasing epidemic of complex metabolic conditions, including metabolic syndrome (MS), type 2 diabetes (T2DM), and non-alcoholic fatty liver disease (NAFLD). Between 1990 and 2019, mortality and disability rates related to type 2 diabetes caused by excess body weight increased more than threefold. Taking the US adult population as an example, a clear upward trend in metabolic syndrome was noted, the prevalence of which increased from 28% to 37% between 1999 and 2018, directly driven by rising obesity rates. Simultaneously, a rapid development of the NAFLD epidemic is observed—its global prevalence increased from 25% (1990–2006) to 38% (2016–2019), and projections for 2040 predict that this disease may affect more than half of the world's population (Koliaki et al., 2023).

Systemic consequences of obesity also extend to oncology, where excess body weight accounts for approximately 4–8% of all cancer cases worldwide. Excess adipose tissue is strongly linked to the occurrence of many common malignancies, including postmenopausal breast cancer, colorectal, endometrial, kidney, esophageal, pancreatic, liver, and gallbladder cancers. The presence of obesity is associated with an approximately 17% increase in the risk of cancer-specific death. The pathogenesis of this link is multifactorial and includes chronic inflammation, immune disorders, changes in sex hormone and adipokine secretion, and extracellular matrix remodeling. Furthermore, obesity can negatively affect the course of oncological therapy itself, increasing the risk of adverse effects and determining clinical decisions regarding the choice of treatment methods. All mentioned conditions, resulting from the chronic nature of obesity, drastically reduce patients' life expectancy and constitute a massive burden on global healthcare systems (Pati et al., 2023).

These extensive health effects translate into a huge economic burden, which in 2019 was estimated at an average of 2.19% of global gross domestic product (GDP). These costs show significant variation, ranging from 6 USD per capita in low-income countries to 1110 USD in highly developed countries. Maintaining current trends, it is predicted that by 2060 this burden will rise to 3.29% of global GDP, with low- and middle-income countries projected to see a drastic increase in costs—from 12 to as many as 25 times. The cumulative impact of these conditions drastically reduces life expectancy and strains healthcare systems; implementing effective interventions could bring global savings of 429 billion USD annually (Okunogbe et al., 2022).

Limitations and Effectiveness of Obesity Treatment Methods

Traditional interventions aimed at weight reduction are characterized by low long-term effectiveness, and overall success rates for weight loss programs remain discouraging. It is estimated that approximately half of patients regain their lost weight within just two years of completing a program (Khattab, 2024), and in a five-year perspective, this figure increases to over 80% of the originally lost body mass (Hall & Kahan, 2018). The primary cause of these failures is the body's strong biological resistance; studies indicate that for every kilogram of weight lost, resting energy expenditure drops by about 20–30 kcal per day, while appetite increases by about 100 kcal per day above pre-weight-loss levels. In clinical reality, only about 12% of patients are able to maintain a weight loss of at least 10% over a three-year period. An additional barrier is the extremely low adherence to pharmacotherapy—although medications can support weight loss, the treatment continuation rate after two years drops to just 2%. This nearly universal trajectory of weight regain often leads to obesity treatment being perceived as a futile process, which deepens the stigmatization of patients as individuals lacking willpower, despite the fact that powerful adaptive mechanisms underlie the relapses (Kim, 2020).

The Role of Cognitive Behavioral Therapy (CBT) in Obesity Treatment

A significant barrier to effective obesity treatment is patients' unrealistic expectations regarding the rate and extent of weight reduction, which often deviate significantly from clinical possibilities. Research shows that while patients aim for weight loss in the range of 20–32%, standard lifestyle-based interventions typically allow for a reduction of 5–10%. This discrepancy between subjective desires and biological reality leads to

rapid discouragement and high treatment dropout rates. In this context, the role of Cognitive Behavioral Therapy (CBT) becomes crucial, as it allows for the identification of psychosocial barriers and educates the patient in setting achievable goals (Kim, 2020).

The effectiveness of such an approach is clearly confirmed in the scientific literature. A meta-analysis of nine randomized controlled trials showed that CBT-based interventions have a moderate and statistically significant impact not only on weight reduction itself but also on its long-term maintenance. By including cognitive components, patients—including those with type 2 diabetes—gain support in permanently modifying dietary habits and increasing physical activity, which is essential to avoid the yo-yo effect. The overall positive effect of a model combining behavioral and health indicators clearly emphasizes the role of CBT as an effective tool supporting the treatment of metabolic diseases through permanent and stable behavior change (Kurnik Mesarič et al., 2023).

Modernly, to increase the availability and precision of these interventions, they are increasingly implemented through Digital Therapeutics (DTx). These therapies are defined as evidence-based clinical interventions using software classified as a Medical Device (Software as a Medical Device - SaMD). Although the process of their clinical evaluation—similar to traditional drugs—is mainly based on randomized controlled trials (RCTs), there are significant methodological differences between them. Unlike conventional pharmaceuticals, DTx solutions can be rapidly updated based on collected data, which necessitates a more flexible approach to their validation. Furthermore, the clinical evaluation of DTx increasingly utilizes innovative sources of evidence, such as Real-World Data (RWD) and digital biomarkers. These allow for continuous patient monitoring, which, in the case of obesity treatment and health behavior change, constitutes a key advantage over the traditional, rigid model of medical product development (Huh et al., 2022).

In summary, effective obesity treatment requires bridging the gap between patients' unrealistic expectations and clinical possibilities, which is achieved through the implementation of Cognitive Behavioral Therapy (CBT), which permanently modifies habits and prevents the yo-yo effect. Digital Therapeutics (DTx) are becoming a modern and scalable carrier of this method, offering real-time support as certified medical devices (SaMD). Through the use of Real-World Data (RWD) and digital biomarkers, these solutions allow for continuous patient monitoring and flexible refinement of interventions, which represents a significant advantage over the traditional, rigid model of pharmacotherapy development in combating the chronic nature of obesity.

Objective of the Review

The objective of this systematic review is a critical evaluation of the clinical efficacy and sustainability of the effects of Digital Therapeutics (DTx) interventions based on cognitive-behavioral protocols (CBT) in the treatment of obesity in adults. The work focuses on analyzing to what extent digital therapeutic tools allow for overcoming the barrier of patients' unrealistic expectations and ensure stable weight reduction in the long-term horizon (minimum 6–12 months).

Methods

Protocol and Reporting Standards

This systematic review was conducted in accordance with the PRISMA 2020 (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The choice of this standard ensures methodological rigor and transparency in documenting the literature selection process regarding DTx interventions.

Search Strategy and Eligibility Criteria

To identify relevant studies, the PubMed, Scopus, and Web of Science databases were searched. The search strategy was based on a combination of terms related to obesity, cognitive-behavioral therapy, and digital solutions (SaMD).

Inclusion Criteria:

- Study type: Randomized Controlled Trials (RCTs).
- Population: Adults (BMI ≥ 30 kg/m²).
- Intervention: Digital Therapeutics (DTx) implementing CBT protocols as the primary mechanism of behavior change.
- Duration: A minimum follow-up period of 6–12 months, allowing for a reliable assessment of the durability of clinical effects in long-term conditions.

Data Extraction and Analytical Approach (Narrative Synthesis)

Unlike standard reviews based solely on quantitative summaries, the data extraction process in this study was directed toward an in-depth narrative analysis. From each study, not only hard clinical data (BMI change) were extracted, but primarily:

1. Technological architecture of the intervention: The method of content delivery, the degree of automation, and functionalities supporting engagement (e.g., gamification, real-time support).
2. Specifics of the CBT protocol: Concrete psychological techniques implemented in the software (e.g., cognitive restructuring, digital self-monitoring logs).
3. Behavioral context: Factors influencing the patient's interaction with the digital tool.

This approach enables an individual characterization of each study in the results section (III.A), allowing for the identification of relationships between technological innovation and the therapeutic success achieved.

Quality Assessment and Risk of Bias

The credibility of the included publications was assessed using the Cochrane Risk of Bias 2.0 (RoB 2.0) tool. The risk of bias analysis constituted an integral part of the descriptive synthesis, allowing for a critical interpretation of the results of individual DTx technologies, particularly in the area of the reliability of data self-reported by patients via applications.

Results

1. Characteristics of Included Studies and Technological Architecture

The review identified 10 randomized controlled trials (RCTs) that met the inclusion criteria regarding CBT-based digital interventions for adults with obesity. The technological architecture of the analyzed solutions included dedicated mobile applications (mHealth), web platforms, and health behavior change support systems (HBCSS). Detailed characteristics of these studies are presented in Table 1.

Table 1
Characteristics of Included Randomized Controlled Trials (RCTs) Investigating CBT-based DTx for Obesity

Author (Year)	Duration	Primary Technology (DTx)	Key CBT Techniques
Bertoli et al. (2025)	6 months	App (DEMETRA)	Self-monitoring, Goal setting
Lautenbach et al. (2025)	6 months	App (zanadio)	Cognitive restructuring
Vaz et al. (2021)	6 months	Interactive App	Behavioral education
Hurkmans et al. (2018)	12 months	Blended model	Coaching support
Kohl et al. (2023)	12 months	Web-based platform	Automated feedback
Christensen et al. (2017)	24 months	Telehealth / Coaching	Problem solving
Svetkey et al. (2015)	24 months	App (CITY)	Activity monitoring
Jakicic et al. (2016)	24 months	Wearables + Web (IDEA)	Behavioral motivation
Mesarič et al. (2025)	18 months	Online CBT	Stimulus control
Turkkila et al. (2025)	60 months	HBCSS System	Habit change

2. Effectiveness of weight and BMI reduction

Analysis of the included studies demonstrated that CBT-based digital therapeutics (DTx) are highly effective in initiating weight loss, reaching clinical significance thresholds of over 5% of initial body mass in most short-term observations. The most spectacular differences between groups were observed in studies with a follow-up of 4 to 6 months. In the DEMETRA study, the group using dedicated digital therapy achieved an average weight reduction of -7.02 kg, a result nearly twice as high as the control group, which reduced weight by -3.50 kg (Bertoli et al., 2025). Similar results were obtained in a study of a standardized health application, where participants reduced their body mass by an average of 5.29% after 6 months compared to only 0.73% in the group receiving standard care (Lautenbach et al., 2025). In specific patient populations, such as individuals with chronic kidney disease, a 16-week CBT protocol allowed for a weight loss of -5.42 kg, corresponding to a BMI reduction of -1.82 kg/m², while the control group reduced by only -1.53 kg (Kurnik Mesarič et al., 2025). Innovative approaches based on interactive mobile applications also demonstrated superiority over traditional educational materials in BMI reduction among adults (Vaz et al., 2021).

As the follow-up period extended to 12–24 months, studies began to point to challenges associated with weight maintenance and differences in the effectiveness of various therapy delivery models. A hybrid model, combining an application with specialist support, proved more effective than a mobile-only intervention, leading to a reduction of -6.8 kg after 12 months (Hurkmans et al., 2018). Web-based platform interventions also showed sustained weight loss and improvement in cardiometabolic parameters over a one-year horizon (Kohl et al., 2023). In a 24-month horizon, telehealth programs integrated with primary healthcare demonstrated the ability to sustain significant weight reduction in patients with obesity and type 2 diabetes (Christensen et al., 2022). Nevertheless, some studies suggest limitations of the technology itself, as demonstrated by the IDEA study, in which the group using wearable devices achieved a poorer result (-3.5 kg) after 24 months than the group receiving a standard behavioral intervention without additional gadgets (-5.9 kg) (Jakicic et al., 2016). Similarly, in the CITY study aimed at young adults, no statistically significant differences in body weight were noted after 24 months between the group using a mobile application and the control group (Svetkey et al., 2015).

The longest available observation, covering a period of 5 years, indicates a phenomenon of slow return to baseline weight in all groups. Although CBT-based health behavior change support systems are effective in the first two years, after 5 years, the differences between system users and the control group fade, although early digital intervention is associated with a more lasting change in health habits (Turkkila et al., 2025).

3. Secondary outcomes

3.1. Adherence and digital engagement (attrition)

Analysis of user engagement in digital interventions revealed a common tendency for activity to decrease over time, a phenomenon described as digital attrition. The CITY study recorded a drastic reduction in the number of interactions with the mobile application, which fell from an average of 4.6 contacts per day in the first six months to just 0.7 per day after 24 months of observation (Svetkey et al., 2015). A similar trend was observed in the case of web-browser-based systems, where the frequency of logging in decreased proportionally to the duration of the program (Kohl et al., 2023). The importance of this parameter was confirmed by the DEMETRA study, which showed a direct correlation between high adherence and clinical efficacy, indicating that patients regularly using digital tools achieved nearly twice the weight reduction results of the control group (Bertoli et al., 2025). A key element of engagement also proved to be the regularity of body weight self-monitoring; in the CITY intervention group, participants weighed themselves an average of 4 times per week at the start of the intervention, but after two years, this frequency fell to 2.1 times, which negatively affected the durability of the effects (Svetkey et al., 2015).

3.2 Metabolic parameters and cardiometabolic risk DTx interventions brought measurable benefits in objective indicators of physical health, extending beyond the change in BMI alone.

Users of web platforms achieved a significant reduction in waist circumference and systolic blood pressure (Kohl et al., 2023). Particularly valuable data was provided by the five-year observation, which suggests the existence of a so-called legacy effect; despite weight regain in some patients, early and intensive digital intervention prevented the rise in blood pressure that naturally progresses with age in the control group (Turkkila et al., 2025). In populations of patients with comorbidities, such as chronic kidney disease, implementation of a CBT protocol led to a significant reduction in proteinuria, which is a key parameter slowing the progression of renal failure (Kurnik Mesarič et al., 2025). Additionally, telehealth programs integrated with medical care proved effective in improving glycemic profiles in people with type 2 diabetes (Christensen et al., 2022).

3.3. Behavioral outcomes and quality of life (HRQoL)

The impact of digital cognitive-behavioral therapy also encompassed the sphere of psychological well-being and modification of health habits. The use of a 16-week CBT protocol in individuals with obesity resulted in a significant reduction in anxiety and depression levels, as well as an improvement in patients' psychological flexibility (Kurnik Mesarič et al., 2025). In a study on a standardized health application, a statistically significant improvement in quality of life was recorded in all domains of the WHOQOL-BREF questionnaire, as well as a significant increase in nutritional competence (Lautenbach et al., 2025). Interactivity of digital tools favored a better understanding of emotional eating triggers and facilitated the process of cognitive restructuring of dysfunctional beliefs (Vaz et al., 2021). The strongest synergy in terms of lasting lifestyle modification was demonstrated in hybrid models, where technological support was reinforced by occasional contact with a specialist (Hurkmans et al., 2018).

Discussion

Synthesis and interpretation of main results

The analysis of 10 randomized controlled trials confirms that digital therapeutics (DTx) based on cognitive-behavioral therapy (CBT) protocols are an effective tool for initiating clinically significant weight loss in adults. The results indicate that in the short term (4-6 months), these interventions systematically achieve a reduction threshold of over 5% of initial body mass, which is considered the standard for clinical significance in obesity treatment. Particularly spectacular effects were noted in studies using dedicated mobile applications, such as the DEMETRA project, where the intervention group achieved a reduction of -7.02 kg, which was almost twice as good as the control group. A similar trend, indicating a clear advantage of DTx over standard medical care, was confirmed by the results of Lautenbach (2025), where weight reduction was more than seven times higher in the app-using group (5.29%) compared to the control group (0.73%). This effectiveness is not limited only to the general population but also includes patients with comorbidities, such as chronic kidney disease, in whom a 16-week CBT protocol allowed for a significant BMI reduction of 1.82kg/m².

However, the interpretation of long-term results (over 12 months) reveals a more complex picture of the effectiveness of digital technologies. While hybrid models and interventions based on web platforms show an ability to maintain weight loss (e.g., -6.8 kg after a year in a blended model), studies with the longest time horizon indicate a regression phenomenon. The analysis by Turkkila (2025) suggests that after 5 years, differences in body weight between users of health behavior change support systems (HBCSS) and the control group fade. It can therefore be concluded that CBT-based DTx are highly effective in the active weight reduction phase, but their role in the very long term shifts from weight control itself toward permanent modification of health habits and the prevention of metabolic complications. An important interpretive point is also the fact that the mere presence of technology does not guarantee success, as shown by the IDEA study – the group equipped with wearable devices obtained poorer results than the group using a standard behavioral intervention. This suggests that the key success factor is not the "gadget" itself, but a precisely implemented CBT psychological mechanism within the software architecture.

Mechanisms of digital CBT and barriers to engagement (The Attrition Problem)

The phenomenon of "digital attrition" identified in this review represents the most serious barrier to the long-term effectiveness of DTx interventions. Analysis of behavioral results indicates a common tendency for user activity to decline over time, which was most clearly illustrated in the CITY study, where the average number of mobile app interactions fell from 4.6 contacts per day in the first half-year to just 0.7 after 24 months of observation (Svetkey et al., 2015). This decline is critical, as data from the DEMETRA study confirm a direct correlation between high adherence and clinical efficacy – patients regularly using digital tools achieved almost twice the weight loss results compared to the control group (Bertoli et al., 2025).

Theoretical explanation of these mechanisms is provided by the "force-resource model," which explains attrition as a dynamic interaction between a "system of driving forces" (such as motivation and attitudes) and a "system of supporting resources" (e.g., app utility, social support) (Wang et al., 2024). According to this concept, participants are initially driven to participate in the intervention by a desire to improve health; however, the lack of dynamic alignment of digital resources (e.g., personalization of messages) with declining internal motivation over time leads to the cessation of the behavioral change process (Wang et al., 2024).

Another important aspect is the difference between treatment initiation and maintenance. Studies indicate that internet-based CBT interventions are more readily and quickly undertaken by patients than

traditional face-to-face sessions, which is associated with lower logistical barriers and the possibility of immediately starting the program after randomization. Nevertheless, after starting therapy, both formats of treatment show comparable dropout and attrition rates, suggesting that the delivery format alone does not solve the problem of sustained engagement. Building a digital therapeutic alliance (DTA), where software mechanisms mimic human support and empathy, may play a key role in maintaining motivation (Linardon et al., 2025).

Attention should also be paid to the so-called "sedentary technology paradox". Digital tools aimed at fighting obesity paradoxically require users to spend significant time in front of a screen (logging meals, viewing reports), which may inadvertently deepen sedentary behaviors and displace time intended for physical activity. Furthermore, the effort required for precise diet monitoring is often perceived as tedious and discouraging after the novelty effect fades, which encourages abandoning the tool (Singh et al., 2025). This is confirmed by the results of the CITY study, in which the regularity of body weight self-monitoring fell from 4 to 2.1 times per week over two years, which directly translated into the weakening of the durability of obtained clinical effects (Svetkey et al., 2015).

Hybrid model (Blended Care) as the golden mean

Analysis of gathered evidence indicates that the hybrid model (blended care), combining digital therapy automation with occasional specialist support, currently constitutes the most effective strategy in long-term obesity management. Results of the conducted review confirm this thesis – the mixed model, integrating an app with coaching support, proved to be more effective than mobile-only interventions, allowing for the maintenance of a weight reduction of -6.8 kg after 12 months of observation (Hurkmans et al., 2018). Similar effectiveness was demonstrated in telehealth programs integrated with primary healthcare, which effectively sustained clinical effects in patients with obesity and type 2 diabetes over a 24-month horizon (Christensen et al., 2022).

The advantage of the hybrid approach finds strong support in the latest review studies, which show that hybrid coaching leads to a higher level of patient engagement and better health outcomes compared to solutions based solely on artificial intelligence (AI). Although AI algorithms provide scalability, these interventions are often perceived by users as "shallow and transactional," encouraging rapid abandonment. Including the human factor allows for building a meaningful therapeutic relationship that bridges the gap between impersonal technology and individual patient needs, which is crucial for establishing permanent health habits (Loughnane et al., 2025).

Practical implementation of such models in healthcare systems is becoming increasingly realistic, as confirmed by pilot studies conducted within primary healthcare. Systems combining modern IT tools with behavioral services delivered via telemedicine show high feasibility and effectiveness in reducing cardiovascular risk factors in patients with obesity. Such synergy allows for the automation of the tedious process of monitoring clinical data, leaving key motivational interventions and emotional support in the hands of specialists (Ackermann et al., 2025).

The necessity of maintaining the "human element" in digital therapy is clearly highlighted by the failures of interventions based solely on hardware (wearables) without specialist supervision. An example is the IDEA study, in which the group using wearable devices without intensive behavioral support obtained significantly poorer results after 24 months (-3.5 kg) than the group using a standard intervention (-5.9 kg). This suggests that technology alone, devoid of being rooted in a relationship and professional coaching, may distract the patient's attention from significant cognitive changes, leading to poorer therapeutic effects (Jakicic et al., 2016). In this light, the hybrid model emerges as the "golden mean," offering the scalability of digital solutions while maintaining clinical effectiveness resulting from direct human interaction (Loughnane et al., 2025).

Metabolic benefits and the "legacy effect" (Legacy Effect)

Analysis of the results of included studies suggests that CBT-based DTx interventions bring cardiometabolic benefits extending beyond weight reduction alone. This phenomenon, described in literature as the "legacy effect," refers to long-term health benefits that may persist for many years after the end of an intensive intervention period, even despite the cessation of active treatment. This mechanism is closely linked to the concept of "metabolic memory," according to which obtaining good early control of risk factors, such as hyperglycemia, allows for the reduction of oxidative stress and the formation of advanced glycation end products (AGEs), which permanently protects the vascular system against complications (Viñas Esmel et al., 2020).

Confirmation of the clinical effectiveness of DTx in improving metabolic profiles is provided, among others, by studies on the Vitadio system, which demonstrated that digital therapy leads to favorable changes in body composition and lipid metabolism, including a reduction in triglyceride levels and a significant increase in the HDL cholesterol fraction. Furthermore, app users experienced a significant reduction in glycated hemoglobin (HbA1c) by an average of 0.38%, indicating the potential of digital solutions in preventing the progression of type 2 diabetes and improving glycemic control in patients with obesity. The reduction of abdominal obesity, represented by a significant decrease in waist circumference, further supports the improvement of metabolic parameters and slows down the development of metabolic syndrome (Moravcová et al., 2024).

According to meta-analysis results, behavioral weight management programs (BWMP) allow for the reduction of cardiometabolic risk factors, such as systolic blood pressure or blood glucose levels, with effects persisting for at least 5 years after program completion. Although these benefits may gradually weaken as body weight is regained, the "protective window" created by intensive behavioral intervention ensures a permanent reduction in exposure to cardiovascular risk factors (Hartmann-Boyce et al., 2023). This indicates the high clinical value of DTx, which through early habit modification "program" the body to better handle metabolic burdens in the future (Viñas Esmel et al., 2020, Hartmann-Boyce et al., 2023).

These conclusions are directly reflected in the results of this review, where, among other things, a significant reduction in proteinuria was noted in patients with obesity, which is a key parameter slowing the progression of renal failure. Additionally, digital support models integrated with medical care proved effective in improving glycemic profiles in people with type 2 diabetes, confirming the role of technology in comprehensive and long-term metabolic health management. This means that the effectiveness of digital interventions should not be evaluated solely through the prism of absolute weight loss, but primarily through the durability of the obtained improvement in biochemical parameters and organ protection (Hartmann-Boyce et al., 2023).

Strengths and Limitations

The assessment of the credibility of the collected evidence using the Cochrane RoB 2.0 tool revealed systematic methodological challenges characteristic of research in the field of digital health (mHealth). The primary source of risk of bias in the analyzed studies is the widespread reliance on self-reported data by patients, particularly regarding body mass and caloric intake logged in apps. These types of measurements are prone to reporting bias, which in the domain of outcome measurement in the RoB 2.0 tool can lead to underestimating the actual BMI and overestimating adherence to dietary recommendations. Additionally, the specifics of technological interventions prevent full blinding of participants and staff, increasing the risk of performance bias, although this is a limitation inherent in the nature of research on lifestyle modification (Pujja et al., 2025).

A significant limitation of this review is the relatively small number of studies with an observation period exceeding 24 months, which makes it difficult to formulate unambiguous conclusions regarding the durability of digital CBT effects in a multi-year horizon. Most available evidence focuses on the active weight reduction phase (6-12 months), and the few studies with the longest time horizon, such as the 5-year observation by Turkkila et al., suggest a weight regression phenomenon after the end of intensive digital support (Turkkila et al., 2025). The lack of standardized endpoints in long-term studies makes evaluating the "durability" of the intervention a methodological challenge requiring further, standardized research.

Another factor limiting direct comparisons of results is the significant technological diversity of included interventions. Analyzed systems cover a wide spectrum of solutions – from simple mobile apps used for self-monitoring to interactive internet platforms and advanced behavior change support systems (HBCSS) integrated with wearable devices. Such high heterogeneity in software architecture and varying degrees of implementation of CBT techniques make it difficult to precisely identify the "active ingredient" of the therapy, which most determines clinical success. Despite these limitations, the strength of the review is its reliance on rigorous PRISMA guidelines and the inclusion of the latest RCT studies published up to 2025, providing an up-to-date picture of the dynamically developing digital therapeutics market.

Implications for clinical practice and health policy

The results of this review have significant importance for shaping modern strategies for fighting the obesity epidemic, pointing to digital therapeutics (DTx) as an essential element of healthcare systems. The scalability of software-based solutions is a direct response to the mounting economic burden; total economic costs associated with overweight and obesity are projected to reach 3.29% of global GDP by 2060 (Okunogbe et al., 2022). Introducing certified DTx interventions allows for optimizing the effectiveness and method of healthcare delivery, offering support where traditional system resources are insufficient (Rajendran et al., 2024). Thanks to high scalability, digitally delivered CBT protocols allow for the mass implementation of behavioral interventions while simultaneously lowering logistical barriers and unit costs of treatment (Linardon et al., 2025).

In terms of clinical practice, the future of obesity treatment lies in deep personalization of interventions. The use of software as a medical device (SaMD) enables precise alignment of therapy to individual needs and the metabolic profile of the patient, which constitutes a revolution in the management of chronic diseases (Rajendran et al., 2024). Modern strategies, such as adaptive just-in-time interventions (JITAs), allow for delivering behavioral support exactly at critical moments for the patient, which significantly increases the effectiveness of habit modification (Wang et al., 2024). Furthermore, to prevent the phenomenon of attrition and "technology fatigue," it is essential to implement mechanisms that increase engagement, such as gamification, interactive feedback systems, and real-time support (Singh et al., 2025).

From a health policy standpoint, regulatory frameworks must evolve toward treating DTx as full-fledged medicinal products. Implementing quality standards for digital therapeutic applications is necessary to ensure the safety and clinical effectiveness of solutions offered to patients (Rajendran et al., 2024). Integrating DTx with traditional treatment pathways in a "beyond the pill" model creates possibilities for synergy between pharmacotherapy and behavioral support, allowing for more lasting metabolic effects (Rajendran et al., 2024). Investment in digital therapeutic infrastructure, promoting early metabolic intervention and utilizing the "legacy effect," can bring systemic savings in the perspective of decades by reducing the number of cardiovascular and renal complications in the adult population with obesity (Hartmann-Boyce et al., 2023, Viñas Esmel et al., 2020).

Conclusion and Future Research

This systematic review confirms that digital therapeutics (DTx) based on cognitive-behavioral protocols (CBT) represent an effective and highly scalable tool for the long-term management of obesity in adults. It has been demonstrated that these interventions allow for achieving clinically significant weight reduction (>5%), which in the active intervention phase (6-12 months) surpasses the effectiveness of standard medical care. A key conclusion drawn from the analysis is that the potential of DTx extends beyond weight control alone; thanks to the "legacy effect" mechanism, digital CBT induces permanent improvement in the cardiometabolic profile, protecting patients from complications of hypertension and type 2 diabetes even in the face of subsequent weight regression.

In conclusion, the hybrid model (blended care) is recognized as the most effective implementation strategy for digital therapies. Combining the high availability and precision of SaMD (Software as a Medical Device) algorithms with personalized support from a human specialist allows for minimizing the attrition phenomenon and building deeper patient engagement. CBT-based DTx should therefore not be perceived as a replacement for traditional therapy, but as a technological enhancement of the care system that enables the mass implementation of the "gold standard" in behavior modification while simultaneously limiting the global economic costs of obesity.

Despite promising results, significant research gaps have been identified that should guide future analyses:

1. Lack of ultra-long-term observations: Most available RCT studies conclude at 12-24 months. It is essential to conduct studies with observations lasting from 3 to 5 years (or longer) to fully understand the dynamics of weight maintenance in a digital environment.
2. Cost-effectiveness analyses: Although the theoretical scalability of DTx suggests savings for public systems, there is a lack of rigorous economic analyses confirming the return on investment (ROI) within national reimbursement systems.
3. Technological heterogeneity: The high diversity of application architectures makes it difficult to isolate the most effective CBT components (e.g., self-monitoring vs. cognitive restructuring). Future research should aim to deconstruct digital interventions to identify the so-called "active ingredients" of the software.

4. Synergy with pharmacotherapy: In light of the growing popularity of new-generation drugs (e.g., GLP-1 analogs), an important research direction will be assessing how DTx can support patients in maintaining results after discontinuing pharmacotherapy and preventing the yo-yo effect.

In summary, the integration of digital technologies with established behavioral psychology protocols opens a new chapter in the fight against the global obesity epidemic. This review proves that digital therapeutics (DTx), especially those implemented in a hybrid model, offer a unique opportunity to scale effective medical care, providing patients not only with weight reduction but, above all, with lasting protection of metabolic health. In an era of rising economic and health costs of obesity, the implementation of DTx into the standard of clinical practice appears to be an indispensable step toward modern, sustainable, and personalized 21st-century medicine.

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