Digital Therapeutics for Cognitive Impairment: A Narrative Review of Innovative Applications and Emerging Challenges

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Submitted to: Journal of Medical Internet Research
on: March 10, 2025

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Abstract

Recent advancements in cognitive neuroscience and digital technology have significantly accelerated the adoption of digital therapeutics for cognitive impairment. This review provides a comprehensive overview of the innovative applications of digital therapeutics in the assessment, intervention, management and monitoring of cognitive disorders, while highlighting key challenges that impede their widespread integration into clinical practice. Drawing on the definition of cognitive digital therapeutics and the multi-stakeholder collaboration required for its development and implementation, this study explores the role of digital technologies in cognitive health and explores challenges from multiple perspectives, including clinical practice, policy framework, user adoption, ethics and privacy, and data interoperability and security. Additionally, the study offers strategic recommendations to promote the sustainable development and scalable implementation of cognitive digital therapeutics, particularly as artificial intelligence (AI) technologies continue to advance, addressing both current applications and emerging challenges.

(JMIR Preprints 10/03/2025:73689)
DOI: https://doi.org/10.2196/preprints.73689

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Abstract: Recent advancements in cognitive neuroscience and digital technology have significantly accelerated the adoption of digital therapeutics for cognitive impairment. This review provides a comprehensive overview of the innovative applications of digital therapeutics in the assessment, intervention, management and monitoring of cognitive disorders, while highlighting key challenges that impede their widespread integration into clinical practice. Drawing on the definition of cognitive digital therapeutics and the multi-stakeholder collaboration required for its development and implementation, this study explores the role of digital technologies in cognitive health and explores challenges from multiple perspectives, including clinical practice, policy framework, user adoption, ethics and privacy, and data interoperability and security. Additionally, the study offers strategic recommendations to promote the sustainable development and scalable implementation of cognitive digital therapeutics, particularly as artificial intelligence (AI) technologies continue to advance, addressing both current applications and emerging challenges.

Keywords: Digital Therapeutics, Cognitive Impairment, Cognitive Health, Innovative Applications, Health Technology, Implementation

1. Introduction

Cognitive impairment is a transitional stage between normal age-associated cognitive deterioration and dementia. Cognitive impairment encompass a range of syndromes characterized by persistent cognitive function deterioration, which lead to a decline in daily living and working abilities, along with behavioral changes, placing a substantial burden on patients, families, and society. Currently, 55 million people worldwide living with Alzheimer's disease and related dementias, with global cost was $2.8 trillion in 2019 and may be expected to exceed $4.7 trillion by 2030 (Nandi et al., 2022). Research indicates that elderly individuals with cognitive impairments utilize significantly more healthcare resources and incur higher medical costs than their cognitively healthy peers, the average annual direct medical cost per person was substantially higher for participants with MCI ($6,499) than for those without ($2,969). Additionally, informal care use was significantly greater among participants with MCI (33% vs. 8.4%), with hospitalizations accounting for nearly half of total medical costs (Zhu et al., 2015). As cognitive impairment progresses, patients lose the ability to care for themselves, requiring full-time assistance (Baldassar & Wilding, 2020). A significant portion of the global economic burden associated with cognitive impairments, such as dementia, is attributed to informal care provided by family members or caregivers (Shaaban, 2024). Informal caregivers often need to reduce their working hours or leave the workforce entirely to provide care, exacerbating economic pressures. They are also more prone to depression, anxiety, and physical health issues compared to the general population (Harris & Sharma, 2018), leading to financial difficulties and significant declines in quality of life for many families. Thus, cognitive impairment not only causes immense suffering for patients but also imposes a substantial burden on families and society. Given the rising prevalence and burden of cognitive impairment, improving care for those affected has become a major public health priority. Delivery of care and services for patients and caregivers, along with advances in diagnosis, biomarker development, and disease monitoring, are among the top research priorities (Shah et al., 2016).

Advancements in information technology have paved the way for innovative medical technologies, supporting clinical practice, enhancing disease prevention, and improving prognostic management, offering significant potential in healthcare (Tian et al., 2019). Since the establishment of the Digital Therapeutics Alliance in 2017, digitally-based therapeutic methods — Digital Therapeutics (DTx), have been widely researched and applied, DTx deliver medical interventions directly to patients using evidence-based, clinically evaluated software to treat, manage, and prevent a broad spectrum of diseases and disorders (Bradwell et al., 2019). Currently, there is no universally accepted definition of DTx at the international level, however, DTx solutions commonly share key characteristics, including the use of high-quality software, rigorous evidence-based validation, and targeted therapeutic interventions (Baumel et al., 2019). Digital therapeutics have the potential to reduce healthcare costs, save diagnostic and treatment expenses, improve disease diagnosis and treatment efficiency, increase patient accessibility, optimize disease treatment and management plans, enhance patient adherence, and improve treatment outcomes (Harris & Sharma, 2018). Cognitive digital therapeutics is an innovative application of digital therapeutics in the diagnosis and treatment of cognitive impairment (Braun et al., 2019). Driven by software programs, cognitive digital therapeutics provide evidence-based digital tools for cognitive assessment, monitoring, prevention, treatment, and management, offering innovative solutions and comprehensive approaches to cognitive healthcare.

In the field of cognitive impairment, digital therapeutics have emerged as a promising non-pharmacological intervention, offering valuable support in assessment, treatment and management. Despite their growing adoption, these technologies face a range of significant practical challenges. Although existing literature has explored various aspects of digital therapeutics in cognitive care, it often lacks a comprehensive analysis of the current landscape and critical real-world implementation challenges. This gap highlights the necessity for a thorough review that not only synthesizes recent advancements but also identifies key barriers to adoption, providing actionable insights to inform future implementation strategies.

This review aims to provide a comprehensive summary and analysis of the literature on the application and challenges of cognitive digital therapeutics, offering valuable insights for both practitioners and researchers. Through this exploration, this review seeks to highlight the potential of cognitive digital therapeutics in advancing strategies for healthy aging and optimizing cognitive health management, ultimately supporting improved care outcomes for aging populations.

2. Methods

This study aims to review the relevant literature from two key perspectives: ‘innovative applications’ and ‘existing challenges’. In terms of applications, we will explore three primary areas - assessment, intervention, and management and monitoring based on the definition of cognitive digital therapeutics. The review will analyze the status and effectiveness of digital therapeutics across various clinical and healthcare settings. Regarding challenges, this review will adopt a multi-stakeholder collaboration approach to analyze key obstacles and bottlenecks, including clinical evidence development, policy and regulatory complexities, user acceptance and engagement, ethical and privacy concerns, data security and technical standardization. Additionally, the review will propose strategic solutions to overcome these challenges and facilitate the broader, scalable adoption of cognitive digital therapeutics.

3. Innovative Applications of Digital Therapeutics for Cognitive Impairment

3.1 Digital Cognitive Assessment

Traditional paper-and-pencil cognitive tests, such as the Mini-Mental State Examination (MMSE) and the Montreal Cognitive Assessment (MoCA), are widely utilized in clinical practice. However, these conventional methods exhibit numerous limitations, including the necessity for professional personnel to conduct face-to-face interviews, the potential for human bias in test results, and practice effects resulting from repeated administrations (Sternin et al., 2019; Tierney & Lermer, 2010). To address these challenges, digital cognitive assessments have emerged, leveraging emerging technologies to achieve automated, standardized, convenient, multi-dimensional and in-depth evaluations of cognitive functions. Over the past two decades, digital cognitive assessment has experienced rapid development, with extensive research and adoption in clinical settings (Sternin et al., 2019; Tierney & Lermer, 2010). These digital assessments rely on objective, quantifiable physiological and behavioral data collected by digital devices, enabling continuous ecological assessment and long-term monitoring of cognitive health. Based on functionality, technological characteristics, and application scenarios, digital cognitive assessment could be categorized into three primary types: Computerized Cognitive Assessment, Digital Biomarker-Driven Cognitive Assessment, and Multi-modal Brain Imaging Cognitive Assessment.

3.1.1 Computerized Cognitive Assessment

Computerized cognitive assessments include both scale-based assessments and task-based assessments, developed based on tradition pencil and paper tests, which have been viewed as the gold standard for diagnosis. For example, digitalized versions of the Montreal Cognitive Assessment (MoCA), Mini-Mental State Examination (MMSE), and Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-cog) have been validated and show good consistency with traditional paper-and-pencil methods (Yang et al., 2021), offering advantages such as automated scoring and real-time data analysis. Meanwhile, task-based assessments like the Cambridge Neuropsychological Test Automated Battery (CANTAB) (Holecki et al., 2020; Yang et al., 2021), Brain-Check (Campos-Magdaleno et al., 2021), Neuro-track cognitive Battery (Groppell et al., 2019), and BABRI Brain Health System evaluate cognitive abilities such as memory, attention, and executive function through interactive tasks and simulated environments (Chan et al., 2020). Moreover, virtual reality (VR) environments and computerized cognitive games constitute significant components in this category. These digital technologies either simulate traditional cognitive assessments or create novel interactive tasks to evaluate a broad range of cognitive functions. For example, the Virtual Supermarket (VSM) uses immersive environments to simulate shopping tasks, providing an effective method for assessing executive functions and memory capabilities (Yan et al., 2021). Additionally, computerized cognitive games, such as Episode Gamification, engage user engagement through gamified design while simultaneously evaluating various cognitive domains, including memory, attention, and executive functions (Nacimiento-García et al., 2024).

3.1.2 Digital Biomarker-Driven Cognitive Assessment

Digital biomarkers are objective, quantifiable physiological and behavioral data collected and measured through digital devices, such as embedded environmental sensors, portable devices, and wearable. These data can be gathered in the context of daily activities with minimal intrusion, enabling ecological monitoring. Digital biomarkers are increasingly used for the early detection and follow-up of cognitive impairment. For instance, older adults with cognitive impairments show significantly reduced daily activity ranges compared to cognitively normal older adults, with more restricted and stable activity patterns (Seelye et al., 2017; Tung et al., 2014). Therefore, monitoring their daily behavior trajectories can provide early warnings. Furthermore, by integrating machine learning and deep learning algorithms and incorporating speech and natural language processing from both healthy and patient populations, classifiers can be constructed to identify cognitive impairments. It has been found that speech fluency, complexity, and coherence can also serve as markers for early screening (Sevcik & Rusko, 2022). Additionally, significant oculomotor impairments have been observed in cognitive impairment patients (Hannonen et al., 2022), which monitors eye movements and visual attention through tasks such as reading comprehension and visual search, providing insights into abnormal attention and visual behaviors (Vecchio et al., 2022).

3.1.3 Multi-modal Brain Imaging Cognitive Assessment

Multi-modal imaging techniques offer diverse perspectives for observing and analyzing the brain, providing critical imaging evidence for the early diagnosis of Alzheimer's disease (AD) by assessing structural, functional, and metabolic changes. Currently, commonly used multi-modal imaging techniques for AD include positron emission tomography (PET), high-resolution structural magnetic resonance imaging (sMRI), diffusion tensor imaging (DTI), blood oxygen level-dependent functional magnetic resonance imaging (BOLD-fMRI), and magnetic resonance spectroscopy (MRS), among others (Aramadaka et al., 2023; F. Li et al., 2020), and no one imaging modality can serve all purposes as each have unique strengths and weaknesses (Johnson et al., 2012). In recent years, machine learning techniques have become increasingly integrated with multi-modal imaging data, improving diagnostic efficiency and accuracy by Classification and prediction. A widely used machine learning and deep learning approach in this context is Ensemble Learning (EL), which integrates multiple machine learning models to optimize fusion strategies. For instance, Shukla et al. (2023)applied EL to PET and T1-weighted MRI data from the ADNI data-set for both binary and multi-class classification of AD, cognitive impairment, and cognitively normal individuals. Their approach achieved up to 99% accuracy for binary classification and 96% for multi-class classification, demonstrating its potential in early AD diagnosis (Shukla et al., 2023). Convolutional Neural Networks (CNNs) have also shown strong performance in AD classification. Farooq et al. (2017) utilized deep CNNs with a four-way classifier to categorize AD progression stages, achieving 98.8% accuracy on the ADNI data-set. Furthermore, neuromorphic computing, inspired by human brain mechanisms such as neural connectivity and synaptic plasticity, enhances both machine learning and deep learning models, excelling in cognitive function analysis and medical imaging tasks. In AD research, Turkson et al.(2021) demonstrated that Spiking Neural Networks (SNNs) outperform traditional machine learning methods in predicting AD classification. And a hybridization of machine learning and deep learning is also used to classification of Alzheimer's disease, which achieves 91.84% accuracy on test data (Raza et al., 2024).

3.2 Digital Cognitive Intervention

There is currently no definitive cure or intervention for cognitive impairment, with existing management strategies primarily aimed at symptom control and slowing disease progression (Eshkoor et al., 2015), in addition, Alzheimer disease (AD) drug development has an exceptionally high failure rate of 99.6% (Cummings, 2018). Given the lack of a intervention for cognitive impairment and dementia, research has increasingly focused on delaying disease progression and developing interventions to enhance and preserve cognitive function (Klimova & Maresova, 2017). Digital therapeutics (DTx) are increasingly being developed for older adults with cognitive impairment, these interventions can be broadly categorized into three types: the first involves strengthening existing cognitive pathways through behavioral exercises to enhance specific cognitive functions; the second targets the direct modulation of brain activity to improve overall brain function or the function of specific brain regions; and the third aims to identify and manage risk factors associated with cognitive decline, such as lifestyle choices, chronic diseases, and mental health issues, thereby the root causes of cognitive impairment and reducing its onset.

3.2.1 Behavioral Training for Cognitive Enhancement

Many traditional cognitive interventions have been adapted for use on current technological devices, such as smartphones, tablets, and computers, and corresponding digital interventions have been developed based on identified evaluation metrics. These approaches are not only cost-effective alternatives but also innovative solutions for cognitive enhancement (Meiland et al., 2017). For instance, CogniFit™ implements personalized and gamified cognitive tasks that participants can perform at home. This intervention effectively enhances cognitive function while promoting engagement and adherence through psycho-education and behavior modification techniques. It has been shown to significantly improve cognitive impairments in older adults (Embon-Magal et al., 2022). Furthermore, video games combining cognitive gameplay with physical exercise, referred to as "Exergames" have been developed. These games have been shown to improve physical function, reduce depression, and enhance cognition and quality of life in older adults (Chao et al., 2015). Virtual Reality (VR) also represents a promising intervention, with its immersive and interactive features making it well-suited for simulating complex environments and tasks to improve cognitive training outcomes. Although studies validating the effectiveness of VR remain relatively limited, existing research suggests its potential to improve memory function and social interaction (Robert et al., 2015). Further research is needed to optimize the design and broaden the application of these technology-based interventions (Bauer & Andringa, 2020).

3.2.2 Direct Modulation of Brain Activity for Cognitive Improvement

This approach primarily uses neuro-modulation technologies to target specific brain regions or neural circuits, enhancing or restoring brain function. Repetitive transcranial magnetic stimulation (rTMS) is a widely used technique that has been shown to improve cognitive function in patients with both mild cognitive impairment and Alzheimer's disease, and various combinations of rTMS parameters have been found effective in enhancing different cognitive domains (Chou et al., 2020). Connectome-based approaches suggest that cognitive impairments are linked to distributed brain networks rather than isolated regions. The corticohippocampal circuit, crucial for long-term memory, can be targeted through Paired Associative Stimulation (PAS) to enhance memory connections. Studies have shown that PAS improves delayed recall in cognitive impairment by synchronizing neuronal activity within this network (Hampstead et al., 2023). Additionally, PAS mimics sleep-related neural oscillations, facilitating memory consolidation and optimizing memory training outcomes (Staresina, 2024).

3.2.3 Identification and Intervention of Risk Factors for Cognitive Decline

Another approach to improving cognitive abilities involves addressing risk factors that impair cognitive development, such as diabetes, depression, and hypertension (Li et al., 2016). For example, BlueStar provides users with blood glucose level feedback, generates daily reports and treatment recommendations, and can also send these reports to the patient's healthcare team (McCall et al., 2021). Deprexis, a digital tool based on psychotherapy, helps improve mood and increase positive emotions and behaviors (Giehl et al., 2024). The HERB System alleviates hypertension by offering interactive education and lifestyle guidance, including reducing salt intake, controlling weight, exercising, improving sleep quality, and managing stress (Kario et al., 2021). Additionally, other digital intervention tools targeting diet, smoking, and alcohol consumption can also be effectively utilized to address these risk factors.

3.3 Digital Cognitive Management and Monitoring

Cognitive management and monitoring involve continuous tracking of cognitive functions over time. It provides a comprehensive, longitudinal perspective on an individual's cognitive health, capturing fluctuations in cognitive abilities and detecting early signs of decline.

3.3.1 Cognitive Assistance Technology

Cognitive assistance technologies leverage information and communication devices and decision-support systems to help individuals with cognitive impairment and their caregivers in managing daily activities. These technologies enhance quality of life, improve efficiency of caregiving, and support independent living. Personal digital assistant programs, such as smartphone applications, assist with daily life management by helping patients remember important events, plan activities, and manage time. These programs significantly enhance executive functions in patients with acquired brain injuries (Brandt et al., 2020). Additionally, they can integrate health monitoring functions, such as medication reminders and health data tracking, providing valuable support to medical teams. Wearable devices, such as smartwatches and fitness trackers, further enable cognitive assistance by monitoring physical activity, sleep patterns, and cognitive performance, adjusting interventions as necessary (Zhang et al., 2025). Video, audio, and internet-based assistive tools offer rich resources for caregivers, including online training, remote video calls for timely support, and AI-based decision support systems that generate personalized care plans based on patients' health data (Davies et al., 2019).

3.3.2 Cognitive Real-time Monitoring Technology

Real-time cognitive monitoring technologies collect objective and quantifiable physiological and behavioral data from patients, enabling continuous assessment of cognitive function and daily living abilities. By utilizing devices such as actigraphy, GPS, cameras, and EEG, these technologies facilitate real-time tracking, analysis, and evaluation of cognitive status and treatment efficacy. Smartphone apps and mobile health solutions are becoming increasingly popular for real-time monitoring, with apps that provide immediate feedback based on cognitive tasks, aiding in tracking cognitive performance over time (Wisniewski et al., 2019). Additionally, advanced EEG techniques, such as quantitative EEG, are being integrated into real-time monitoring devices, allowing for the detection of abnormal brain wave patterns and early identification of cognitive issues, and Machine learning algorithms applied to real-time data can predict future cognitive decline based on identified patterns, enabling early diagnosis and proactive intervention (Smailovic et al., 2018).

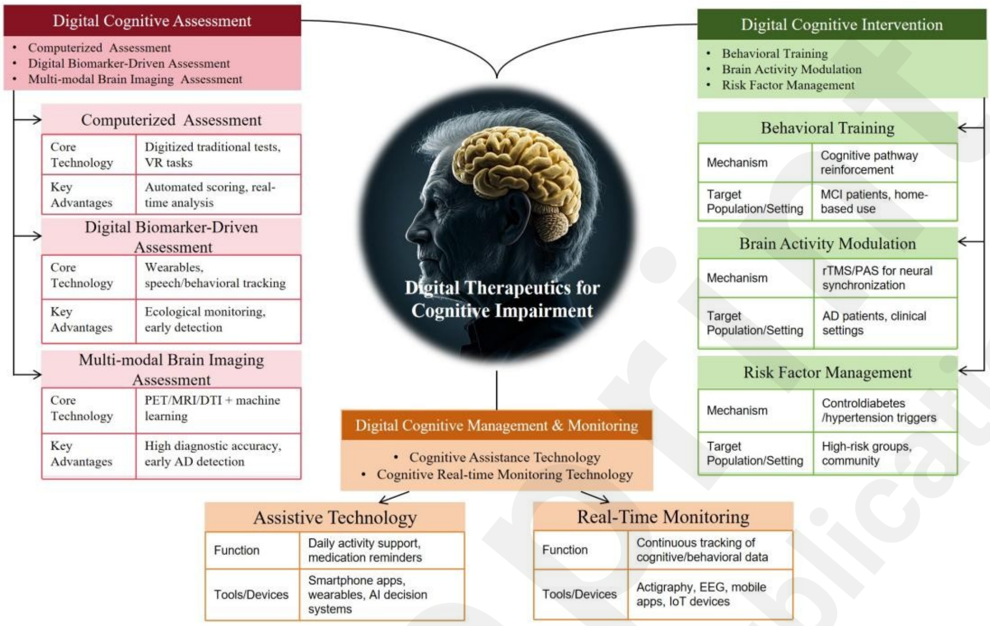

Figure 1. Cognitive Digital Therapeutics

4. Challenges and Prospects of Digital Therapeutics for Cognitive Impairment

4.1 Clinical Effectiveness & Efficacy

The effectiveness and efficacy of cognitive digital therapeutics in the treatment of cognitive impairment require rigorous clinical validation to ensure widespread adoption and integration into healthcare systems. One of the primary challenges is the heterogeneity of the cognitive impairment populations complicates the creation of standardized protocols and metrics for evaluating outcomes (Haas et al., 2024), making it difficult to draw consistent and generalizable conclusions from clinical trials. Another obstacle is the dynamic nature of DTx technologies, which often evolve faster than clinical guidelines and regulatory frameworks can keep pace. This rapid innovation can result in discrepancies in trial designs, endpoint selection, and outcome measures, affecting the comparability and generalizability of results across studies (Yao et al., 2024). Additionally, cultural and geographical variations in healthcare systems and practices create further challenges when attempting to develop evidence frameworks that can be universally applied (Adu-Brimpong et al., 2023).

To address these challenges, innovative strategies have been proposed. One promising approach is the implementation of home-based and remotely supervised interventions, including combined cognitive and physical training programs. These solutions reduce the burden on participants and caregivers while enabling more extensive and scalable data collection (Hong et al., 2024). Another effective approach is to integration real-world data collected from electronic health records and wearable devices, complementing clinical trial data and providing a more comprehensive understanding of DTx outcomes (Zhu et al., 2024). Collaboration among stakeholders, including researchers, clinicians, and patient advocacy groups, is essential to establish standardized protocols and consensus on outcome measures (Mezei et al., 2023). International efforts to align clinical trial methodologies and share best practices can further facilitate evidence accumulation and ensure the reliability and validity of findings.

4.2 Regulatory Policy

Cognitive digital therapeutics face significant regulatory challenges due to the absence of dedicated pathways for their development, validation, market access, and post-market monitoring. Existing medical device regulations lack flexibility, leading to uncertainties in approval, compliance, and clinical adoption (Dang et al., 2020; Mantovani et al., 2023). The absence of harmonized standards results in inconsistent prescribing criteria, which complicate clinical integration (Patel & Butte, 2020). Additionally, debates over prescription models versus direct-to-consumer approaches further hinder regulatory alignment, influenced by differing marketing strategies and jurisdictional differences (Zovi et al., 2025). Moreover, existing policies struggle to incorporate dynamic mechanisms that keep pace with the rapid advancements in technology (Wang et al., 2023). Varying evidence requirements across regions create redundant approval processes, increasing costs and slowing down adoption (Coder et al., 2024).Furthermore, current regulatory assessments fail to fully capture DTx’s broader impact on patient education, behavior change, and system efficiency (Rajendran et al., 2024). And weak post-market surveillance further complicates real-world monitoring, limiting insights into long-term safety and efficacy (Coder, PharmD, Mba, 2023).

In response to these challenges, recent policy developments, including the guidelines issued by the National Health Commission (NHC), the National Administration of Traditional Chinese Medicine (NATCM), and the Chinese Center for Disease Control and Prevention (CDC) on AI+ applications, have provided a strategic framework and instruction for the application of AI in healthcare (National Health Commission Office, National Administration of Traditional Chinese Medicine, & Chinese Center for Disease Control and Prevention, 2024).These guidelines promote the innovation and integration of AI technologies, including digital therapeutics, into the healthcare sector, supporting the advancement of digital solutions in cognitive health and ensuring alignment with regulatory standards.

To overcome the challenges faced by cognitive DTx, tailored regulatory frameworks are needed to establish standardized safety, efficacy, and usability criteria while enabling adaptive policies that can accommodate ongoing technology innovations (Sverdlov et al., 2018; Fassbender et al., 2024). One possible strategy to bridge the gap between rapid technology innovation and regulatory policies is to integrate "regulatory sandboxes", which provide controlled environments where companies can test digital health technologies while meeting specific safety standards. This approach would allow regulatory bodies to monitor emerging technologies more closely, thereby accelerating the approval processes while ensuring safety (Sovacool et al., 2024).

Additionally, greater collaboration among regulators, clinicians, and industry stakeholders will be essential to standardizing prescribing guidelines(Wang et al., 2023). Harmonizing clinical evidence requirements across jurisdictions would reduce approval redundancies, improving scalability and accelerating market access (Coder et al., 2024). Finally, strengthening post-market surveillance through real-time data analytics, patient registries, and adverse event tracking will improve regulatory responsiveness, ensuring that digital therapeutics remain safe and effective over time(Coder, PharmD, Mba, 2023).

4.3 Patient Acceptance and Engagement

The adoption of digital therapeutics depends significantly on user acceptance and engagement, which is influenced by various factors such as perceived usefulness, ease of use, trust, and accessibility. One challenge that persists is the potential for dropouts and non-adherence to treatment plans, often linked to difficulties in sustaining interest and motivation over time (Shaw et al., 2017). For instance, cognitive impairments or limited digital literacy among certain patient populations may hinder the effective use of digital platforms. This mismatch often leads to frustration or disengagement, which in turn affects the success of DTx products. Perceived usefulness is another critical factor, users must see tangible benefits in terms of improved health outcomes and efficiency compared to traditional treatment methods (Serres et al., 2024). If users do not perceive digital interventions as effective in improving their cognitive abilities or enhancing their quality of life, they are less likely to engage with them consistently. Meanwhile, complicated interfaces or lack of technical support can act as barriers to acceptance (Carvalho et al., 2024). A study examining the use of a cognitive training Digital Therapeutics platform by older adults involved 15 participants who underwent a play test and semi-structured interviews. The study revealed that while some users faced challenges in understanding instructions and tasks, their overall engagement was high. Participants found the platform challenging yet enjoyable, demonstrated a strong awareness of the importance of cognitive training, and expressed a willingness to use the platform, particularly if it was recommended by medical professionals (Hackett et al., 2022).

To overcome such challenges, strategies should focus on integrating user feedback early in the design process through iterative co-design approaches. Co-design methodologies emphasize the importance of involving end-users throughout development to ensure that digital therapies meet their specific needs (Nuseibeh et al., 2024), participatory design frameworks, such as those used for the iReadMore app, have been shown to enhance user engagement and accessibility (Langford et al., 2022). Another way is tailoring digital therapies to the cognitive and physical capabilities of the target demographics. Additionally, User-centered design and co-creation approaches improve adoption and adherence by aligning solutions with user preferences and capabilities (Mimoso et al., 2024) Meanwhile, leveraging trusted sources such as healthcare professionals to recommend and endorse these platforms can significantly increase user trust and adoption. Wong et al. (2022) emphasize that user-centered design not only improves usability but also ensures integration with clinical workflows, enhancing the credibility of digital tools when endorsed by medical professionals. Furthermore, Strauss et al., (2022) argue that cross-functional frameworks, including input from patients and healthcare providers, result in solutions that are both effective and engaging. By addressing these barriers and emphasizing user-centered design, digital therapies can achieve greater acceptance and adherence among diverse patient populations. As Vial et al.(2023) discuss, human-centered and empathic design processes ensure that digital mental health interventions are both accessible and aligned with user needs, fostering trust and long-term usage.

4.4 Ethics and Privacy

The rapid development of digital therapeutics presents significant ethical and privacy challenges that must be addressed to ensure patient trust, safety, and equitable access. One of the foremost challenges is data privacy and security, as DTx platforms rely on the collection and processing of sensitive health data, creating vulnerabilities to breaches and unauthorized access. These concerns are further complicated by regional differences in data protection laws, leading to inconsistencies in privacy safeguards (Asif et al., 2025). Another critical issue is the need for informed consent. Many patients struggle to fully understand the implications of data sharing, particularly when consent forms and data practices are opaque or overly complex, undermining genuine informed consent (Saurabh Pahune & Noopur Rewatkar, 2024). Additionally, equity and accessibility pose ethical concerns, as DTx platforms often require internet access, digital literacy, and compatible devices, which can exclude underserved populations, exacerbating health disparities (Asif et al., 2025). Furthermore, the lack of robust post-market surveillance frameworks presents a dilemma, as real-world monitoring of DTx performance and safety is often insufficient. Without continuous oversight, the potential for adverse effects or diminished efficacy remains unaddressed (Sharma et al., 2024).

To mitigate these challenges, several strategies can be implemented. Strengthening data protection frameworks is crucial, including mandatory encryption, anonymization, and adherence to international standards like GDPR to safeguard patient data (Pesqueira et al., 2025). Transparent communication and simplified consent processes can empower patients by clearly explaining how their data will be used, ensuring informed decision-making (Manole et al., 2024). Addressing algorithmic biases through regular audits, inclusive design processes, and accountability mechanisms is also essential to uphold fairness and reliability (Stanney et al., 2025). Establishing comprehensive post-market surveillance systems, including real-time monitoring, patient registries, and adverse event reporting frameworks, can enhance the safety and effectiveness of DTx over time (Sharma et al., 2024). Multistakeholder collaboration among regulatory bodies, clinicians, industry representatives, and patient advocates is equally important to develop ethical guidelines and address emerging challenges. This collaboration ensures diverse perspectives are considered, leading to policies and practices that uphold trust and ethical standards (Gupta & Mathur, 2025).

4.5 Data Interoperability and Security

The integration of cognitive digital therapeutics products with existing healthcare infrastructures, such as electronic health records (EHRs), primarily around data interoperability and security. Data interoperability and security issues hinder seamless data exchange, impeding the effectiveness and scalability of digital health solutions (Kilintzis et al., 2019), inconsistent technical standards across platforms and fragmented digital health ecosystems are key barriers to creating a unified infrastructure (Masuda et al., 2021). Additionally, healthcare systems often lack the infrastructure to integrate DTx products effectively (Masuda et al., 2021b). For example, although frameworks like HL7 FHIR are gaining traction, their implementation remains inconsistent across different regions and healthcare organizations. Furthermore, devices connected to the Internet of Things (IoT), such as wearables, often face compatibility issues with cloud-based EHR systems, which complicates data aggregation, access, and use in clinical settings (Tsiouris et al., 2020).

Establishing an open ecosystem and adopting globally recognized interoperability standards will significantly enhance the usability and scalability of healthcare technology (Bathelt et al., 2025), adopting universal standards is crucial to address healthcare data interoperability challenges. In recent years, HL7 FHIR (Fast Healthcare Interoperability Resources) has emerged as a key framework for facilitating data sharing and system integration in the healthcare industry. Its modular architecture and open API design enable seamless data exchange between different healthcare systems (Fischer, 2025). Moreover, DTx combined with EHR can provide patient-specific clinical decision support, reducing diagnostic errors (Thompson et al., 2025). Additionally, FHIR integrated with blockchain enhances trust in data sharing and reduces data breach risks (Bathelt et al., 2025), ensuring that healthcare data can be exchanged across systems while maintaining strict privacy and security standards.

Table 1 Challenges vs. Mitigation Strategies Matrix

Challenge	Key Issues	Mitigation Strategies
Clinical Validation	Population heterogeneity, inconsistent trial designs, regional evidence disparities	Home-based interventions, real-world data integration, international protocol standardization
Regulatory Gaps	Lack of approval pathways, regional evidence misalignment, prescription model debates	Regulatory sandboxes, cross-stakeholder collaboration, regional evidence harmonization
Patient Engagement	Digital literacy, perceived usefulness, complex interfaces, low adherence	Co-design frameworks, clinician endorsement, simplified user interfaces
Ethics & Privacy	Data breaches, inadequate informed consent, algorithmic bias	GDPR-compliant encryption, transparent consent processes, regular bias audits
Data Interoperability	Fragmented standards, IoT compatibility issues	HL7 FHIR adoption, blockchain-EHR integration, open ecosystem development

5. Conclusion

Cognitive impairment presents a significant global health challenge, affecting millions of individuals and placing a substantial burden on patients, caregivers, and healthcare systems. Digital therapeutics (DTx) have emerged as a promising innovation in the assessment, intervention, and management of cognitive disorders. However, several critical challenges remain, including the need for rigorous clinical validation, the establishment of comprehensive regulatory frameworks, and the enhancement of patient acceptance and engagement to support widespread adoption. Furthermore, ethical and privacy concerns, data interoperability and security issues, and cost considerations must be addressed to ensure the seamless integration of DTx into clinical practice.

Despite these challenges, the potential of cognitive digital therapeutics to transform the care and management of cognitive impairment is undeniable. Innovations in digital cognitive assessment, intervention, and management and monitoring technologies offer unprecedented opportunities for early detection and more efficient, patient-centered care in healthcare delivery. The rapid advancement of AI technologies, exemplified by innovations such as ChatGPT and DeepSeek, highlights the expanding role of digital therapeutics in cognitive health. As the field progresses, sustained collaboration among researchers, clinicians, policymakers, and technology developers will be crucial in addressing existing challenges and facilitating the responsible, widespread adoption of digital therapeutics.

Ultimately, the successful integration of digital therapeutics into clinical practice has the potential to transform cognitive healthcare, improving patient outcomes while alleviating the burden on caregivers and healthcare systems globally. As artificial intelligence (AI) continues to drive innovation, accelerating both the development and scalable implementation of these solutions, cognitive digital therapeutics are poised to play a pivotal role in shaping the future of cognitive impairment care.

Author contributions

G.Z. conducted the literature search, writing, reviewing, and editing of the manuscript. Y.H. assisted with the literature search and manuscript writing. Y.T, L.S, A.S., K.R. and J.W. reviewed, edited, and approved the final manuscript.

Acknowledgements

This work was funded by the National Key R&D Program of China (Project Title: Research on the Current Situation and Development Trends of Elderly Disease in China, No. 2022YFC3603000).

Data Availability

No data was used for the research described in the article.

Conflict of Interest

The authors have no conflict of interest to disclose.

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Supplementary Files

Figures

Cognitive Digital Therapeutics.