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The Potential and Prospects of Serious Games as Digital Therapeutics

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Abstract

This study explores the potential and prospects of serious games as digital therapeutics. Serious games, designed primarily for education, training, and health improvement, have recently gained attention in the medical field. Research findings indicate that serious games can effectively alleviate symptoms of neurodevelopmental disorders (NDD), dementia, depression, and anxiety. Particularly, they have shown positive effects on improving cognitive functions, social interactions, and motor skills in patients with Attention Deficit Hyperactivity Disorder (ADHD), Autism Spectrum Disorder (ASD), and Down Syndrome. Moreover, these games have demonstrated benefits in enhancing cognitive functions and reducing depression in dementia patients. However, due to research bias and limited clinical evidence, definitive conclusions about the effectiveness of serious games are challenging to draw. Currently, it is recommended to use serious games as a complementary tool to existing treatments. Further research and development of standardized evaluation models are necessary to fully realize the potential of serious games as digital therapeutics.

Keyword: Serious Games, Digital Therapeutics, Neurodevelopmental Disorders, Dementia, Mental Health

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1. Introduction

The image of computer games is predominantly negative. Concerns regarding game addiction and excessive immersion are particularly high, especially in South Korea. Since 2000, there have been 15,470 research papers on this topic, with the majority focusing on the negative impacts of games, particularly in the fields of education and psychology, and predominantly targeting adolescents [1]. The World Health Organization (WHO) began recognizing gaming addiction as an official disorders when it included gaming disorder in the International Statistical Classification of Diseases and Related Health Problems (ICD-11) during the 72nd World Health Assembly in 2019. Following this, there has been active discussion in South Korea regarding the inclusion of gaming disorder in the Korean Standard Classification of Diseases. This societal context has led to a research bias, excessively emphasizing the negative aspects of games and assuming a pathological perspective on gaming.

In contrast, the positive aspects of gaming, specifically the beneficial use of games, are also being studied. Research by Oxford University scholars Przybylski, Rigby, and Ryan [2] indicated that when used appropriately, games can help reduce stress and enhance well-being. Dye, Green, and Bavelier [3] found that playing action video games can improve various cognitive abilities, including attention, visual-cognitive skills, and working memory. Granic, Lobel, and Engels [4] reported that gaming can aid problem-solving skills. In domestic studies, Kim Bi [5] conducted a meta-analysis revealing that computer games correlate with autonomy, competence, and relatedness, with intrinsic motivation showing a significant relationship with beneficial game use. Yoo and Kim [1] also performed a meta-analysis demonstrating that online games positively impact children's communication skills and adolescents' school adaptation, as well as positively influencing self-esteem and stress levels.

Research highlighting the positive aspects of games and providing evidence of their benefits is steadily increasing. Studies and investments in exploring new possibilities of games are also actively underway. A notable example is 'serious games' and their use as 'digital therapeutics.' Serious games are specially designed game content aimed at achieving various educational, training, health, and other purposes through enjoyable and accessible everyday play. The value of serious games lies not only in providing education, training, or assessments through engaging content but also in their accessibility, allowing processes traditionally requiring face-to-face interaction or direct experience to be conducted on a large scale via computers and online access [1].

These serious games offer primary purposes in various fields to a broad audience easily and

enjoyably, reducing the need for basic tasks typically performed in real-world settings. For instance, they can be used to identify early symptoms of dementia in large elderly populations or provide accessible means for treating depression. Additionally, they can enhance social communication with patients.

This study aims to discuss the feasibility and effectiveness of serious games as medical diagnostic tools and digital therapeutics, based on various clinical results and research that have been previously published. While numerous studies in South Korea have discussed digital therapeutics, including their potential, classification criteria, and risks, there is a significant lack of data discussion the feasibility and effectiveness of serious games as digital therapeutics, particularly from the perspectives of neuropsychologists and neuropsychiatrists.

Computer games as digital therapeutics or diagnostic tools are increasingly being used in critical treatment and assessment areas, such as neurobehavioral development in children with neurodevelopmental disorders and dementia in the elderly. The trend toward expanding these functions is growing. Therefore, this paper aims to comprehensively discuss the potential of serious games in digital therapeutics and digital diagnostics.

2. Definition and Current Status of Digital Therapeutics

Digital therapeutics (DTx) refers to Software as a Medical Device (SaMD) that provides evidence-based therapeutic interventions to patients for the prevention, management, or treatment of medical disorders or diseases [6].

Digital therapeutics (DTx) can be used in conjunction with traditional treatments such as pharmaceuticals or medical devices, or independently. They can collect real-time patient data, providing meaningful information on the effectiveness of treatments. According to Han [7], the core principles of digital therapeutics are as follows:

The primary treatment or prevention of diseases is conducted mainly through software (SW), supplemented by hardware (HW), wearable devices, services, or pharmacotherapy. This aspect focuses on treating diseases through medical interventions provided via SW.

Compliance with patient data privacy and SW development security certification is essential. Standardization in design and manufacturing is required, and reliable review and approval processes by regulatory agencies support the evaluation of product safety and efficacy.

DTx should enable direct delivery of SW therapeutic interventions to patients, empowering them with the authority over their treatment for disease prevention and management.

Clinical trials and FDA certification are necessary for DTx to be recognized as a valid treatment option that can report or replace conventional therapies.

Digital therapeutics (DTx) can be categorized into four primary application areas. First, DTx can explain medical conditions. Second, they can manage or prevent medical disorders or diseases. Third, DTx can optimize the effectiveness of medical treatments. Fourth, they can treat medical disorders or diseases, categorized for management and supervision purposes [8].

In practice, behavioral correction accounts for 31% of the market, followed by prescription adherence at approximately 30%. Other application areas include chronic disease management and data collection and management, as summarized in [Table 1].

[Table 1] Application Cases of Digital Therapeutics by Field

Chronic Condition Management	Behavior Management	Medication Adherence Support	Data Gathering and Analytics
- Services for correcting or managing chronic diseases - Diabetes, obesity, alcoholism, depression, asthma, diabetes, etc.	- Services for correcting patients' behaviors towards better habits, such as lifestyle modifications - Online behavior correction, communication correction, atient behavior tracking and management, smoking cessation support, consumer behavior decision management, etc.	- Services supporting patients to adhere to prescriptions, uch as prescription management and medication delivery management - Collaboration with Amazon, large pharmacies, etc. - Prescription tracking by pharmacies, medication delivery, medication management, clinical trial management, etc.	- Services that collect patient data in real-time through software such as smartphone applications to monitor patient status and observe the effectiveness of medications - Efficient patient management and data collection

This table illustrates the various application cases of digital therapeutics categorized by four fields: Chronic Condition Management, Behavior Management, Medication Adherence Support, and Data Gathering and Analytics.

In South Korea, the Ministry of Food and Drug Safety defines digital medical devices as ‘Software as a Medical Device (SaMD)’ that provides ‘evidence-based’ ‘therapeutic interventions’ to patients for the prevention, management, or treatment of medical disorders or diseases. While the markets in the United States and Europe are expanding, the domestic market is still considered underprepared and underdeveloped [9].

For digital therapeutics to be recognized as scientifically valid in South Korea, clinical practice guidelines acknowledged by the Korean Medical Association, clinical papers published in peer-reviewed journals, or clinical trial data by researchers must be secured. Therefore, when using digital therapeutics,

one can expect a substantial therapeutic effect on diseases based on medical expertise and technology, compared to non-medical health management services [6].

3. Serious Games as Digital Therapeutics

Serious games (SG) are a type of game designed with a primary purpose other than mere enjoyment [9]. Specifically, serious games aim to achieve specific goals such as education, training, and health improvement. These games can take various forms, including simulations, role-playing games, and educational games, and can be used in diverse environments such as classrooms, workplaces, and healthcare settings. The goal of serious games is to engage players enjoyably and effectively to achieve intended learning or behavior change outcomes [10]. Here is a comparative table outlining the definitions, key features, and distinctions among digital therapeutics, serious games, and gamification to enhance conceptual clarity, as summarized in [Table 2].

[Table 2] Definitions and Distinctions among Digital Therapeutics, serious games, and gamification

Term	Definition	Key Feautres	Primary Purpose
Digital Therapeutics (DTx)	- Evidence-based software interventions designed to prevent, manage, or treat medical conditions	- Clinically validated - Requires regulatory approval - Often prescribed by clinicians	-Treat or manage diseases
Serious Games	-Games designed with a primary purpose beyond entertainment, often in health, education, or training	- Gameplay-based - Designed for learning or behavior change - May use immersive elements (VR/AR)	-Engage and educate while promoting therapy
Gamification	-Use of game-like elements in non-game contexts to motivate user behavior	- Points, badges, leaderboards - No full game structure - Used to enhance user engagement	-Motivate or influence behavior

Initially, serious games were adopted in the educational field to promote interest and motivation in learning. However, utilizing serious games to improve medical outcomes has recently gained increasing support from scholars, developers, and healthcare professionals. Many now recognize the need to develop clinically-based games specifically designed to address the physical and mental health issues faced by end-users. Game-based therapies are increasingly used in the medical field to enhance motivation, engagement, and the overall sustainability of healthy habits [11].

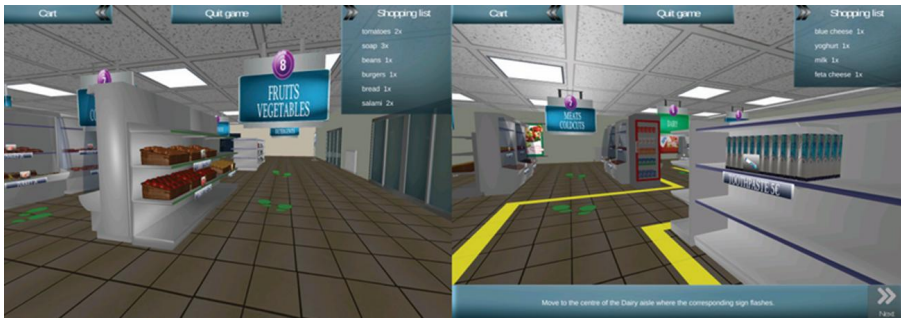
Serious games are particularly useful for large-scale medical diagnosis and screening. One of the

recent major application areas is using medical serious games to test cognitive impairments or dementia in the elderly. Since dementia is difficult to cure once it develops, early detection and response to initial symptoms provide critical advantages in managing the disease and preventing its progression. Identifying early dementia or mild cognitive impairment (MCI) requires repeated testing of many elderly individuals, which poses significant challenges. Serious games can facilitate this large-scale testing, providing an effective means of early detection and intervention.

According to Vacca et al. [12], medical approaches utilizing serious games can be classified as follows:

1. Preventive Games: Serious games that promote physical or mental activities to mitigate the risk of undesirable events.
2. Measurement Games: Serious games used for symptom detection or disability assessment.
3. Therapeutic Games: Serious games aimed at patient treatment and rehabilitation. This last category includes digital therapeutics (DTx), which can complement or optimize existing treatments, providing software-based therapies and interventions [13].

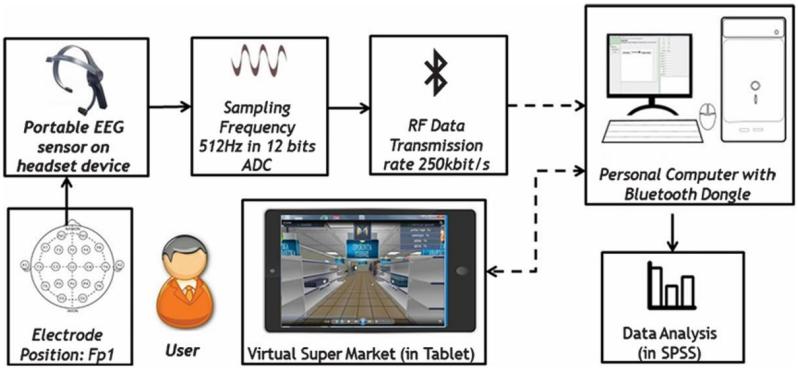
Various approaches are currently adopted to implement serious games as digital therapeutics (DTx). These approaches may vary depending on the patient category, intended purpose, the need to monitor patient progress or the requirement for data collection to provide feedback on game adaptation. Additionally, the availability of low-cost devices such as smartphones and tablets has increased the accessibility of serious games. The advent of immersive augmented reality (AR) and virtual reality (VR) systems has enabled the creation of more engaging and immersive environments, as summarized in [Fig. 1].



[Fig. 1] The Virtual Supermarket Test (VST) digital environment (tablet view)

Furthermore, the introduction of collection devices such as electroencephalogram (EEG) helmets, wristbands, and motion sensors, which track user movements and physiological parameters, has led to the rapid emergence of applications that monitor game activities and collect physiological information for

biofeedback [14]. Smart wearable devices can directly interact with AR/VR systems, detecting and evaluating speed, movement angles, and applied force, allowing therapists to optimize training plans, as summarized in [Fig. 2].



[Fig. 2] The overall architecture of the EEG data collection and game synchronization system

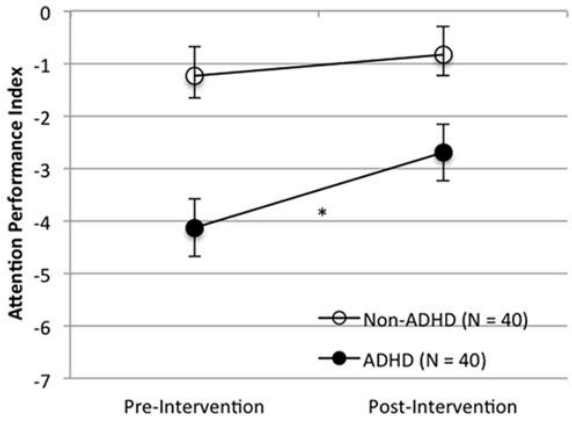
3.1 NDD-Related Disorders and Serious Games

In recent years, technological advancements have enhanced the development of video game-based assessment and therapeutic tools, complementing traditional approaches [15]. SG-based therapeutic interventions have been well-received by children with cognitive disorders such as Autism Spectrum Disorder (ASD), Attention-Deficit/Hyperactivity Disorder (ADHD), Down Syndrome (DS), and Fragile X Syndrome (FXS). These interventions have generally been effective in improving cognitive domains, social interactions, and motor skill functions, as summarized in [Fig. 3].

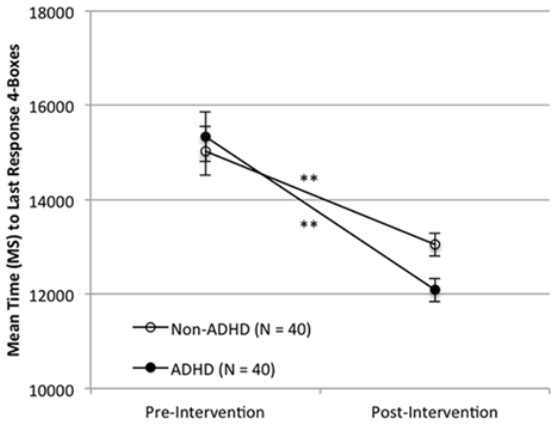
[Fig. 3] Example of a Project: Evo task

Davis et al. [16] observed significant improvements in computer-based attention tasks in a severe ADHD group, while no changes were noted in the non-ADHD group. Spatial working memory also improved in the ADHD group.

Similarly, Dovis et al. [17] reported effects on short-term memory (STM) and working memory (WM), with a reduction in ADHD symptoms. Serret et al. [18] conducted a study with children with autism using a serious game called SEMA-TIC. The literacy skills of the trained group significantly improved compared to the non-trained group after training, as measured by specific experimental tasks (alphabet knowledge, word reading, word and non-word differentiation, sentence reading, word segmentation) (all $p \leq 0.001$). Importantly, three out of twelve children in the training group were able to decode words effectively post-intervention, while none in the non-training group could. This study provides preliminary evidence that French school-aged children with autism can learn literacy skills through the non-verbal cognitive abilities-based serious game SEMA-TIC. Another study by Jouen et al. [19] showed limited but positive effects of a six-month intervention using serious games with children with autism. Garcia-Redondo et al. [20] found that participants with ADHD and specific learning disorders (SLD) showed significant improvement in attention performance (visual attention) after training with ten games based on multiple intelligences, compared to a control group of neurotypical individuals, as summarized in [Fig. 4]. As summarized in [Fig. 4-6], these findings indicate that improving multiple intelligences, talents, or unique abilities through educational video games can play a key role in addressing attention-related deficits in students with learning disabilities.



[Fig. 4] Performance on the TOVA API pre- and post-intervention for the ADHD group and the non-ADHD group.
Note: Error bars represent standard error of the mean ($p<0.005$)



[Fig. 5] Performance on the spatial working memory task pre- and post-intervention for the ADHD group and the non-ADHD group. Note. Scores represent mean time to last response with 4 boxes. Error bars represent standard error of the mean ($p < 0.005$)

Most Frequently Played Games (% of Total Time Played)	BOT-2 Subtest or Biodex BioSway Measure
Wii sport: Bowling (56%)	• Upper-limb coordination[a] (*) • Bilateral coordination[a] (−)
Wii sport: Baseball (22%)	• Upper-limb coordination[a] (*) • Balance[a] (+) • Bilateral coordination[a] (−) • Manual dexterity[a] (+) • Postural stability[b] (see Table 5) • Limits of stability[b] (see Table 6)
Wii Fit (aerobic): Rhythm boxing (14%)	• Upper-limb coordination[a] (*) • Bilateral coordination[a] (−) • Manual dexterity[a] (+) • Balance[a] (+) • Postural stability[b] (see Table 5) • Limits of stability[b] (see Table 6) • Untested: stamina
Wii Fit (balance): Snowboard (8%)	• Balance[a] (+) • Postural stability[b] (see Table 5) • Limits of stability[b] (see Table 6) • Running speed and agility[a] (+) • Upper-limb coordination[a] (*) • Bilateral coordination[a] (−)

[a]BOT-2 subtest.
[b]Biodex BioSway Measure.
"+" indicates improved performance score; "*" indicates improved performance score not exceeding the minimum important difference (MID) according to Wuang and Su[28]; "−" indicates decrease in performance score. The MID establishes when the difference between 2 scores constitutes a clinically significant difference.

[Fig. 6] Analysis BOT-2 or Biodex BioSway Measure Score Changes

In a study by Berg et al. [21], children diagnosed with Down syndrome (DS) played Nintendo Wii games at home for 20 minutes, four times a week, over eight weeks. Results indicated improvements in postural stability, running speed, and agility. Derks and colleagues recently provided a meta-analysis of several trials assessing the efficacy of SG in enhancing adaptive and cognitive abilities in pediatric populations with NDD [22]. The findings, supported by an updated literature review and meta-analysis data, underscore the effectiveness of SG for these specific child groups and highlight the importance of early interventions for children with intellectual disabilities and ASD, presenting a new perspective in developmental psychology [23].

3.2 Dementia and Serious Games

The application of serious games has been primarily in the area of neurodevelopmental disorders in children, as demonstrated in the previous examples. Another significant area of research and application is dementia. Dementia is a severe disease threatening aging societies, causing substantial physical and mental harm to patients and imposing a significant burden on their families. While medications have been used for dementia treatment, they have not achieved significant success. However, serious games, as a new form of dementia treatment, stand out among various therapeutic methods and are paving the way for effective dementia care. In the field of serious games for dementia care (SGDC) in aging societies, there is active research related to this topic.

Saragih, Everard, and Lee [24] conducted a meta-analysis of 12 studies on the therapeutic effects of serious games on dementia. The results indicated that serious games can improve cognitive, social, and behavioral abilities by increasing playtime and game difficulty. These games were found to enhance cognitive function and reduce depression in dementia patients. Similarly, Ning et al. [25] reviewed the development process of SGDC, the various symptoms at different stages of dementia, and existing research on SGDC from these perspectives. They suggested that a comprehensive and specialized evaluation model is urgently needed for the use of SGDC as digital therapeutics.

More recent research between 2023 and early 2024 has extended these findings by integrating AI-powered cognitive training systems and mobile-based therapeutic game interventions. For example, Vacca et al. [26] introduced a deep learning-enabled serious game designed to detect early cognitive impairment using real-time behavioral data, demonstrating significant predictive accuracy for mild dementia. Additionally, Lee et al. [27] proposed a mobile-based intervention using an adaptive gameplay system that responds to emotional and cognitive inputs, showing improved patient adherence and measurable cognitive benefits in early-stage dementia patients. These advancements reflect the rapid

evolution of SGDC technologies and underline the importance of incorporating AI and mobile platforms in therapeutic strategies.

3.3 Depression, Anxiety, and Serious Games

Depression is a common mental disorder characterized by disturbances in mood, thoughts, or behavior. Serious games have been utilized as non-pharmacological therapeutic interventions for depression, and numerous studies have collected evidence on the effects of these games in alleviating depressive symptoms. Many studies and meta-analyses of existing research have been conducted. In the most recent study, Abd-Alrazaq et al. [28] performed a meta-analysis of 16 rigorously selected studies out of 966 depression-related papers. The results indicated that computer-based cognitive-behavioral therapy (CBT) games had a statistically and clinically significant impact on the severity of depressive symptoms compared to control groups (P = .003). However, the authors concluded that due to the high risk of bias in the individual studies reviewed and the low quality of the meta-analyzed evidence, definitive conclusions about the effectiveness of serious games could not be drawn.

Anxiety is a mental disorder characterized by feelings of worry, tension, and related behavioral disturbances. There have been many attempts to use serious games as interventions for anxiety. In the study by Abd-Alrazaq et al. [28], a meta-analysis was conducted on 22 RCT studies that met strict criteria. Findings from 9 RCTs and 5 RCTs indicated that exergames (games involving physical exercise) did not have a statistically significant impact on anxiety levels. However, studies using computer-based cognitive-behavioral therapy (CBT) games in 6 RCTs showed statistically and clinically significant effects on reducing anxiety levels (P = .01). Lastly, 3 RCTs compared traditional games with biofeedback games, demonstrating that biofeedback games, as a type of serious game, had statistically and clinically significant effects on anxiety levels (P = .03).

4. Limitations of Serious Games as Digital Therapeutics

In addition to regulatory and methodological constraints, the clinical deployment of serious games must contend with several technical and ethical challenges. These include concerns about data privacy in game-based health tracking, the reliability of biometric and behavioral data collected during gameplay, and the potential for reward mechanics to unintentionally promote compulsive or addictive behavior. Addressing these issues is crucial to establishing both the credibility and safety of serious games as legitimate therapeutic tools.

Many meta-analyses discussed earlier report a high overall risk of bias in data collection. This is primarily attributed to the concentration of data in high-income countries such as the United States and Europe. Additionally, the quality of the meta-analyzed evidence was somewhat low, and there were relatively few studies that recruited actual patients, which could pose challenges in drawing definitive conclusions about the effectiveness of serious games.

In particular, for depression and anxiety, there were very few studies that recruited actual patients, necessitating cautious interpretation of the results. In most cases, until stronger evidence is secured, it can only be recommended that healthcare providers consider offering serious games as a complementary means to existing treatments.

Serious games are now widely used in many medical treatments. Therefore, the efficacy of serious game therapy must be recognized and trusted. An effective and reliable evaluation method for SG as digital therapeutics is necessary. At a time when transparency in current clinical trials is somewhat problematic, the development of standardized evaluation models will be crucial. Furthermore, as the use of SG in mental health management increases, it is necessary to investigate the neurobiological mechanisms in the brain. Studying how the psychosocial and positive experiences derived from SG manifest in specific neurobiological pathways or circuits will be one way to definitively validate therapeutic mechanisms.

Another limitation of serious games as digital therapeutics is that the expected enjoyment and satisfaction from the patient's perspective are often not high. While serious games typically have clear objectives regarding their purpose and effectiveness, they frequently lack engaging elements found in conventional games, such as fun and immersion. Many existing serious games resemble cognitive psychology tests rather than well-designed games. From a psychological perspective, incorporating the characteristics of conventional games into the design could lead to higher efficacy, as patients may be more likely to engage voluntarily for longer periods.

To further address the practical implementation of serious games as digital therapeutics, it is essential to consider user experience (UX) design elements that directly affect patient engagement and adherence. Features such as adaptive difficulty levels can tailor challenges to individual cognitive or emotional states, while real-time feedback systems provide immediate reinforcement and guidance. Personalization, through avatar customization or scenario-based content, allows patients to see themselves reflected in the game world, which may improve emotional investment. Additionally, gamified goal tracking and visual progress representations (e.g., progress bars or character evolution) can serve as motivational anchors that encourage long-term participation. These strategies not only enhance the perceived enjoyment of serious

games but also help mitigate dropout rates in clinical contexts.

Moreover, research should not only focus on the gaming aspect but also integrate other therapeutic methods, such as music therapy and reminiscence therapy, to enhance the effectiveness of game therapy. This integration could provide more innovative ideas for game design and improve the overall therapeutic outcomes.

5. Conclusion

To complement the paper's focus on technical and regulatory aspects, it is also necessary to consider ethical dimensions. These include potential psychological risks associated with behavioral nudging, as well as the over-reliance on extrinsic reward systems that may undermine intrinsic motivation or even foster compulsive engagement patterns in vulnerable users.

Numerous empirical studies have demonstrated that games are effective in reducing symptoms of neurodevelopmental disorders (NDD), dementia, depression, and anxiety. However, despite the positive data, clinical research in the field of digital therapeutic interventions is still in its early stages.

The prevailing opinion is that the use of serious games as digital therapeutics could achieve optimal results when used in conjunction with traditional treatments such as pharmacotherapy and behavioral therapy. Although there are still many limitations to their standalone use, serious games can adequately serve as adjuncts or complement to existing treatments. Experts emphasize that digital therapeutics play a unique role in motivating patients voluntarily and encouraging sustainable physical activity through engaging game content.

According to the WHO guidelines [29], the social approach to individuals with mental disorders should shift from mere social separation to overcoming social barriers and disabilities, empowering and enhancing their capabilities. This transition involves a lengthy and challenging process of social inclusion and integration, engaging families, institutions, trainers, and clinicians. In this context, the development of digital therapeutic strategies, including SG, presents an opportunity to strengthen the cognitive, emotional, and relational skills of these young patients, thereby facilitating social integration.

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