

The Effectiveness of Serious Games as Digital Therapeutics for Enhancing the Abilities of Children with ADHD: A Systematic Literature Review

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Table of Contents

Original Manuscript..... 5

Supplementary Files..... 29

 Figures 30

 Figure 1..... 31

 Figure 2..... 32

 Figure 3..... 33

 Multimedia Appendixes 34

 Multimedia Appendix 1..... 35

 Multimedia Appendix 2..... 35

The Effectiveness of Serious Games as Digital Therapeutics for Enhancing the Abilities of Children with ADHD: A Systematic Literature Review

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Abstract

Background: Attention deficit hyperactivity disorder (ADHD) is a neurodevelopmental disorder that often begins in childhood and requires long-term treatment and management. Given the potential adverse effects of medication in children, interest in alternative treatments has grown. Serious games have emerged as promising non-pharmacological interventions for children with ADHD among these alternatives.

Objective: This review examines serious games from the past 14 years using Digital Therapeutics (DTx) criteria, assesses user engagement outcomes such as enjoyment and adherence, and analyzes the impact of these games on competencies including attention, social skills, motor skills, and executive functions in children with ADHD.

Methods: This review was conducted by the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The search encompassed five databases: PubMed, Web of Science, Scopus, IEEE Xplore, and ACM Digital Library, covering January 2010 to January 2024. Studies focused on serious games as Digital Therapeutics to enhance the abilities of children with ADHD were selected. Each publication was evaluated and categorized based on key characteristics such as experiment type, targeted abilities, game software and hardware, publication area, duration, length, and frequency of use. Features from experimental and game designs were systematically tabulated, and the resulting data were analyzed and summarized narratively to assess therapeutic effects.

Results: This review included a total of 29 studies. The review showed that serious gaming interventions might improve attention, social skills, and executive functions. Although findings related to motor skills were inconsistent, somatosensory games that use body movements or gestures as inputs demonstrated higher adherence rates. Additionally, serious games yielded favorable outcomes regarding player enjoyment.

Conclusions: This review indicates that employing serious games as Digital Therapeutics (DTx) can potentially support ADHD treatment in children by enhancing various competencies, enjoyment, and adherence. Future studies are expected to focus on integrating serious games more broadly into treatment protocols and standardizing research methods.

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Original Manuscript

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Keywords: Serious Games; ADHD; Digital Therapeutics; systematic review

Introduction

Background

Attention deficit hyperactivity disorder (ADHD) is a neurodevelopmental disorder [1], often diagnosed in childhood and persisting into adolescence and adulthood [2]. It is associated with a high rate of comorbidity, accidents, and mortality, among others [3,4]. Although ADHD medications exhibit significant therapeutic effects [5], some guardians are reluctant to medicate their children due to potential long-term adverse developmental effects and varying effectiveness across different ADHD subtypes [6,7]. Furthermore, the core symptoms of ADHD, which include inattention and hyperactivity-impulsivity, typically necessitate multiple therapeutic interventions to ensure effective management. [8].

Serious games, which have emerged as a promising alternative therapy, are defined as ‘games that do not have entertainment, enjoyment or fun as their primary purpose’ [9]. Serious games are utilized in medical diagnostics, therapy, prevention, health promotion, and medical or patient education [10]. Serious games have been proposed for neurodevelopmental disorder interventions primarily due to their appeal, engagement, and effectiveness [11,12]. Meanwhile, music therapy [13], exercise therapy [14], and chess therapy [15,16], shown to be effective for managing ADHD symptoms in children, can achieve better therapeutic effects when combined with serious games.

In June 2023, the International Standards Organization (ISO) released Digital Therapies (DTx, ISO/TR 11147), which are evidence-based therapeutic interventions driven by software to prevent, manage, or treat a medical disorder or disease. EndeavorRx, a DTx for ADHD, is the first and only FDA-authorized prescription treatment for inattention in children with ADHD, delivered through a video game experience [17].

To date, only two systematic reviews have specifically examined the effects of games on children with ADHD [18,19], revealing the potential of such interventions to address core ADHD symptoms and underscoring the need for greater collaboration between developers and healthcare professionals. However, Children with ADHD manifests a range of symptoms beyond the core symptoms of inattention and hyperactivity-impulsivity [20], it includes challenges in social interaction, impaired motor skills, and deficits in executive functioning [21,22]. Additionally, further research on non-pharmacological treatments targeting specific abilities in pediatric ADHD patients indicates that interventions designed to enhance social, motor, and executive functioning skills may potentially benefit overall ADHD symptom management [23]. Consequently, an up-to-date literature review is imperative to address existing gaps in research on capability enhancement, and examining of player enjoyment and adherence rates remains critical.

The current evidence is insufficient to demonstrate the specific impact of serious games on children with ADHD, mainly because of several limitations: the limited number of studies included, the insufficient variety of games, and the missing and inconsistent reporting of results. Therefore, this review aimed to include more appropriate studies, expand the coverage of serious games, and diversify the outcome assessments, so that a more comprehensive review could be conducted to further systematically assess the available evidence related to the impact of serious games on the various abilities of children with ADHD.

Objectives

Compared to other systematic reviews, this study offers three unique contributions: First, it provides a comprehensive review of the most recent studies over the past 14 years, employing the basic definition of DTx as part of the inclusion and exclusion criteria, thereby addressing the gap in recent studies that adhere to industry standards. Second, it assesses the effects of serious games as interventions on children's competencies, including attention, social skills, motor skills, and executive functions. Third, it discusses outcomes related to participation, such as enjoyment,

adherence, and adverse effects.

Methods

Overview

Our search began in March 2023, with an update in January 2024 to include new publications. The two searches yielded a total of 4420 records. Using Mendeley Reference Management software, we automatically removed 1022 duplicate records. Subsequently, we manually deleted an additional 7 duplicates and 1 retracted article, resulting in a final set of 3390 records for review. For this systematic review, we adhered to the PRISMA-P (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols; Figure 1) guidelines [24]. Additionally, we followed the recommendations of the Cochrane Consortium for conducting systematic reviews and used the RefHunter website for guidance [25].

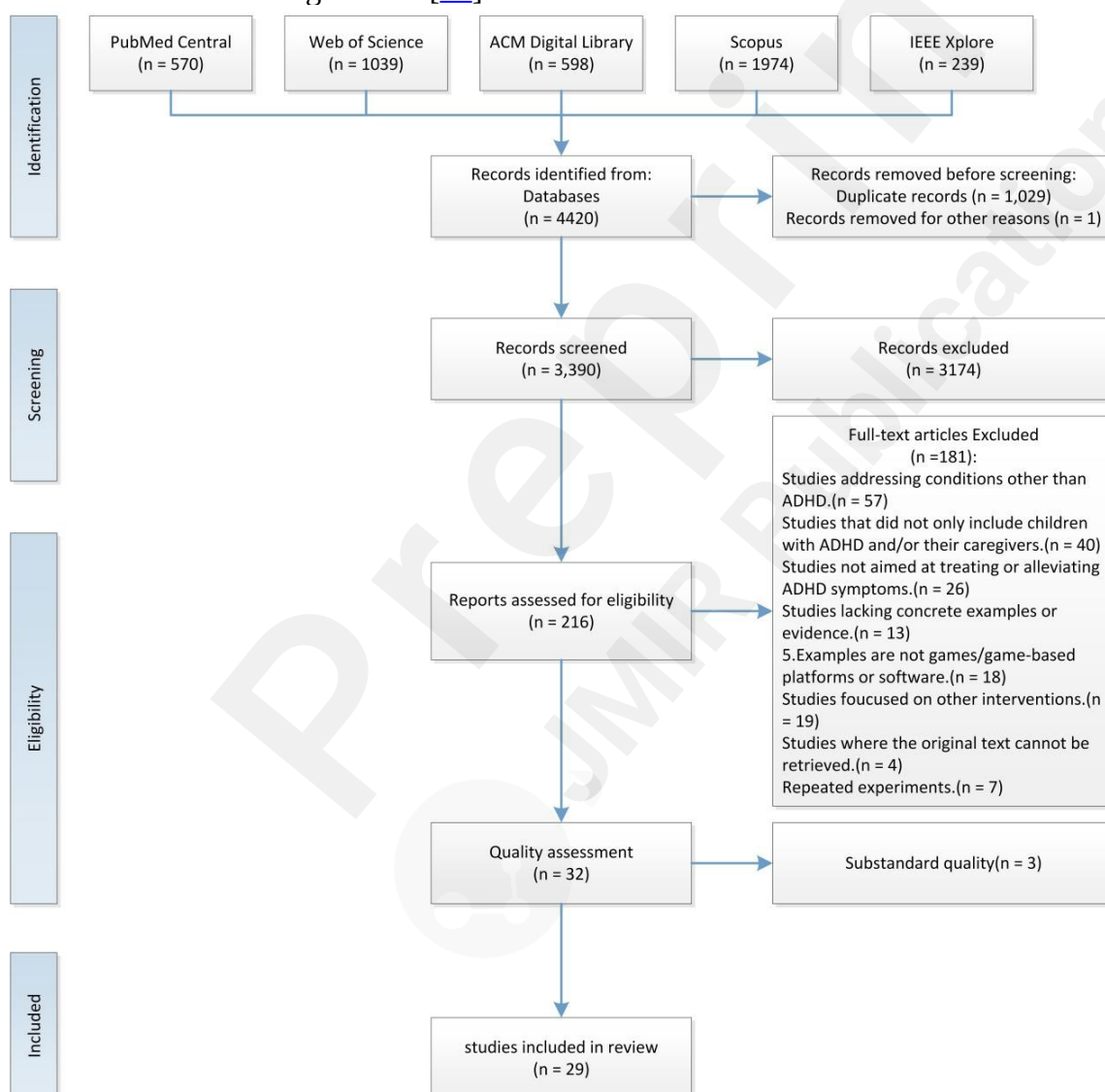


Figure 1. PRISMA-P (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols) flow diagram.

Step 1 Identification: Literature Search

A well-defined research process outlined by Petersen et al. (2008) consists of three steps: specifying the search string, selecting the databases for the search string application, and obtaining the results.

[26]. The first step involves identifying the key terms and their most relevant synonyms. Using the National Library of Medicine's MeSH tags, we searched for ADHD to identify and filter appropriate synonyms, including Attention Deficit Disorder with Hyperactivity, ADHD, Attention Deficit Hyperactivity Disorder, Attention Deficit Disorder, and Hyperkinetic Syndrome.

Close synonyms for 'Serious Games' include 'gamification,' 'gamified,' 'game mechanics,' 'game dynamics,' 'game design,' 'game based,' and 'gaming.' [27]. To minimize limitations, 'DTx' (Digital Therapeutics) and 'DHI' (Digital Health Interventions) were added to the search terms. 'DTx' (Digital Therapeutics) is considered a subset of 'DHI' (Digital Health Interventions), a broader term that encompasses the use of digital technologies to support wellness and healthcare practices, particularly in the management of Neurodevelopmental Disorders. [28-30].

Considering the interdisciplinary nature of this review, the selected databases should include relevant research literature from diverse disciplines, extending beyond psychology, game design, computer science, and medicine. Consequently, databases such as PubMed, Web of Science, Scopus, IEEE Xplore, and ACM Digital Library were chosen to address the needs of interdisciplinary research. After identifying the relevant terms for 'ADHD' and 'Serious Games,' we sought to define the precise search strings. Initially, the search terms were applied in the PubMed database, where various search terms and Boolean operators (Table 1) were tested and refined to optimize the search strings across all selected literature repositories, yielding a total of 4,420 articles.

Table1 Search string.

Databases	Fields of research	Search string
PubMed		
	Life sciences, MEDLIN	(((('Attention Deficit Disorder with Hyperactivity'[Mesh]) OR ADHD) OR Attention Deficit Hyperactivity Disorder) OR Attention Deficit Disorder) OR Hyperkinetic Syndrome AND (((((((serious games) OR games) OR gamified) OR Gamification) OR game design) OR game based) OR gaming) OR Digital health interventions) OR Digital Therapeutics) [Filters applied: from 2010/1/1 - 2024/1/1.]
Web of Science		
	Natural sciences, social sciences, arts, and humanities	(((TS=(Attention Deficit Hyperactivity Disorder)) OR TS=(ADHD)) OR ALL=(Attention Deficit Disorder with Hyperactivity)) OR ALL=(Attention Deficit Disorder)) OR ALL=(Hyperkinetic Syndrome)) AND (((((((TS=(games)) OR ALL=(serious games)) OR ALL=(gamified)) OR ALL=(Gamification)) OR ALL=(game

		design)) OR ALL=(game based)) OR ALL=(gaming)) OR ALL=(Digital health interventions)) OR ALL=(Digital Therapeutics)) [Publicatioin Date:2010-1-1 to 2024-01-01]
Scopus		
	Science, technology, medicine, social sciences, arts and humanities	(‘Attention Deficit Hyperactivity Disorder ‘OR ‘ADHD’OR ‘Attention Deficit Disorder with Hyperactivity’ OR’ Attention Deficit Disorder ‘OR’ Hyperkinetic Syndrome’) AND (games OR ‘serious games’OR gamified OR Gamification OR ‘game design’ OR ‘game based’ OR gaming OR ‘Digital health interventions’ OR’ Digital Therapeutics’) [E-Publication Date: (01/01/2010 TO 01/01/2024)]
IEEE Xplore		
	Electrical engineering, computer science, and electronics.	(ALL (adhd OR ‘Attention Deficit Hyperactivity Disorder’ OR ‘Attention Deficit Disorder with Hyperactivity’ OR ‘Attention Deficit Disorder’ OR ‘Hyperkinetic Syndrome’) AND ALL (games OR ‘serious games’ OR gamified OR gamification OR ‘game design’ OR ‘game based’ OR gaming OR ‘Digital health interventions’ OR ‘Digital Therapeutics’) AND TITLE-ABS-KEY (adhd)) PUBYEAR > 2009 AND PUBYEAR < 2024
ACM Digital Library		
	Computing and information technology	(‘Attention Deficit Hyperactivity Disorder ‘OR ‘ADHD’OR ‘Attention Deficit Disorder with Hyperactivity’ OR’ Attention Deficit Disorder ‘OR’ Hyperkinetic Syndrome) AND (games OR ‘serious games’OR gamified OR Gamification OR ‘game design’ OR ‘game based’ OR gaming OR ‘Digital

		health interventions' OR' Digital Therapeutics')
		Filters Applied: 2010 - 2023

Step 2 Screening: Title and Abstract Screening

Duplicates were automatically identified using Zotero software (version 6.0.29). Following iterative deduplication, publications underwent manual screening. Initially, two authors independently screened the titles and abstracts of relevant studies. The full texts of eligible studies were then independently assessed by the same authors, based on inclusion criteria (Figure 2), with any arising conflicts resolved through conference discussions.

	Inclusion criteria	Exclusion criteria
Population	Children diagnosed with ADHD	Studies that did not only include children with ADHD and/or their caregivers (guardians, teachers, clinicians). Non-human studies.
Intervention	Research focused on serious games designed specifically for targeting ADHD	Studies focused on other interventions (e.g., Pharmacological interventions, telemedicine, non-healthy sensors, web-based intervention, augmented/virtual reality, robot assistant)
Study Design	<ul style="list-style-type: none"> Any experimental or quasiexperimental evaluative design, including pilot and feasibility studies Non-randomized studies (e.g., pre-post study with no control group) Cohort or longitudinal studies that had pre-post outcome measures Case series or case studies 	<ul style="list-style-type: none"> Theoretical designs or frameworks without empirical data. Studies addressing conditions other than ADHD (e.g., Autism Spectrum Disorder (ASD), anxiety disorders, bipolar disorder, learning disorders). Studies not aimed at treating or alleviating ADHD symptoms.
Outcomes	Focus on outcomes in the following developmental domains: Attention Hyperactivity-inattentiveness Social skills Motor skills/physical activity Executive functions Enjoyment Intervention adherence	<ul style="list-style-type: none"> Studies lacking concrete examples or evidence. Examples are not games/game-based platforms or software. Studies where the original text cannot be retrieved. Repeated experiments.
Publication Type	Peer-reviewed article Full paper proceedings	Conference abstracts, study protocols, books, websites, reviews, theses or dissertations, short conference paper proceedings, posters, and demos.
Publication period	From 1 January 2010 to 1 January 2024	Before 2010, after 1 January 2024
Setting	Any country or region	N/A
Language	English	Any other language

Figure 2. Inclusion Criteria and Exclusion Criteria.

Step 3 Eligibility: Content Screening

Following the preliminary screening based on inclusion criteria, 216 studies were excluded using the exclusion criteria as a benchmark for further content screening (Figure 2). Subsequently, a quality assessment was conducted, where each criterion was rated as 'yes,' 'partially,' or 'no,' and scored respectively with values of 1, 0.5, and 0. The final score, requiring a minimum of four out of seven marks (about 60%), was calculated as an average of the grades. The quality criteria and scoring methodology were based on the research by Coelho et al. [31]. Scores for each selected study are detailed in Multimedia Appendix 1. This step resulted in the exclusion of three articles that failed to meet the minimum threshold of 0.6.

In our literature screening process, it is crucial to ensure that the research selected develops a game specifically designed for treating children with ADHD, possesses a fundamental game structure, and is sufficiently comprehensive to allow for an analysis of its usefulness [32]. However, as most games evaluated are not yet commercially available, the eight DTx guidelines were pragmatically applied to the design of the Exclusion criteria and Quality assessment, drawing upon the concept of Minimum

Viable Product (MVP). Some guidelines were temporarily deprioritized (Figure 3). Despite the limited availability of MVP related content in digital contexts, the MVP concept continues to offer the potential for enhancing product development efficiency, quality, and innovation [33].

	DTx Core Principles	Reasons for deprioritization	Prioritization Recovery
1	Incorporate design, manufacturing, and quality best practices.	N/A	N/A
2	Engage end users in product development and usability processes.	N/A	N/A
3	Incorporate patient privacy and security protections.	N/A	N/A
4	Apply product deployment, management, and maintenance best practices.	During initial development and prototyping, the primary focus might be on validating the therapeutic concept and functionality rather than on the complexities of deployment and ongoing maintenance.	Applying product deployment, management, and maintenance becomes critical as the product approaches a state ready for broader testing or market launch. This ensures scalability, reliability, and user support.
5	Publish trial results inclusive of clinically meaningful outcomes in peer-reviewed journals.	N/A	N/A
6	Be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use.	Early-stage products, particularly those in the research, discovery, or pre-clinical phases, may not have undergone regulatory review.	Regulatory clearance or certification is pursued after proving the product's efficacy and safety, established through clinical trials.
7	Make claims appropriate to clinical evaluation and regulatory status.	In the exploratory stages of development, a DTx product might not yet have undergone extensive clinical evaluation, and thus, cannot make definitive claims about its efficacy, safety, or intended use.	Formal claims become relevant and necessary as the product undergoes clinical trials and seeks regulatory approval.
8	Collect, analyze, and apply real-world evidence and/or product performance data.	N/A	N/A

Figure 3. DTx guidelines temporarily deprioritized.

Step 4 Included: Data Abstraction and Analysis

To screen the final record set for inclusion criteria, after manually removing duplicates (identical game instances with different paper titles), two authors used Zotero to further screen the publications manually. Together, the two authors determined keywords and selected databases in Step 1. In Step 2, the first author screened the titles and abstracts of all records, applying inclusion criteria to identify obvious exclusions. Subsequently, in Step 3, the two authors independently reviewed the remaining papers and resolved any conflicts through discussion, arriving at the final decision.

Significant heterogeneity in study types, comparisons, intervention programs, and outcomes indicated that the data from this review were not suitable for quantitative synthesis. Therefore, descriptive analysis was employed to summarize the impact of serious games on the rehabilitation of children with ADHD. The process of conducting descriptive analysis involved tabulating features of the original studies from two perspectives: experimental design and game design. This included experiment type, targeted abilities, game software and hardware, publication area, duration, length and frequency of use, and sample size and characteristics. Jing Lin and Woo-Rin Chang independently extracted this information using predefined Excel (Microsoft Corp) tables (Multimedia Appendix 2).

Subsequently, the authors thoroughly reviewed and validated the collected data to ensure accuracy and reliability. In cases of disagreement, consensus was reached through discussion. Finally, the data were organized and categorized for each specific outcome to enable a comprehensive assessment of the findings.

Results

Overview

The review retrieved 4,420 relevant papers from five repositories using a string search, excluding 1,029 duplicates and one retracted article. After screening titles and abstracts, 216 articles met the inclusion criteria, and upon complete reading of each article, 184 articles met the exclusion criteria. Finally, after a quality assessment excluded 3 articles, 29 publications were screened to fulfill the basic DTx criteria.

The 29 papers in our review were published in journals or conference proceedings across a variety of fields (based on the journal descriptions), as described in the journals. Of these, 13 were from interdisciplinary publications, 7 from computer science, 5 from psychology and medicine, 3 from

education, and 3 from design.

The selected papers encompassed 978 participants, with sample sizes ranging from 1 to 184. Gender was recorded for 20 of the 29 trials, totaling 604 children—429 boys and 148 girls. This data reaffirms that boys are more likely to develop ADHD than girls [34].

Table 2. Overview of included papers.

	Software	Description	Duration
	Length and frequency	Sample Size and Characteristics	
Giannaraki, Marina, et al [35]			
	ADDventurous Rhythmical Planet	Players use the tin drum to produce rhythms and collaborate in multi-user mode to achieve common goals.	N/A
	4 children (including 2 with ADHD) and 4 expert educators	3 boys and 1 girls	
Rodrigo-Yanguas, Maria, et al [36]			
	The Secret Trail of Moon	Including five VR mini-games, each aimed at enhancing specific cognitive skills.	Single sessions for 10-40 min
	37 children and adolescents	25 boys and 12 girls	
Aghdam, Khadijeh Salehi, and Masoud Hasani Alavi [37]			
	MIND PRO Working Memory Game	In the auditory section of the game, players identify and select boxes that produce distinct sounds from multiple options. The visual section requires players to select boxes that contain matching images.	30 min per session, 12 sessions total
	6 children with ADHD, ages 6 to 11	2 girls and 4 boys	
Batista, Bruno G., et al [38]			

	Taboo!	The game utilizes an endless runner format where the player avoids obstacles and solves math problems.	N/A
	184 children with ADHD, ages 7-14	Predominantly boys	
Wiguna, Tjhin, et al [39]			
	Indonesian computer-based game prototype	A role-playing game features children acting as fruit car drivers, tasked with delivering color-specific fruits to corresponding houses.	30 min per session, 20 sessions total over 4 weeks
	10 children with drug-naïve ADHD, aged 7–12 years	9 boys and 1 girl	
Ou, Yang-Kun, et al [40]			
	Fishing Master/Fruit Train/Ocean Manager	The games enhance hand-eye coordination and balance through activities like catching fish, picking fruit on a moving train, and feeding fish while dodging obstacles.	40 min per session, 3 times a week for 3 months
	3 children aged 8–12 years old diagnosed with ADHD	1 boys and 2 girls	
Capelo, David Chilcañán, et al [41]			
	Multisensory Virtual Game	In a multisensory game, children use the Leap Motion controller to match virtual objects to containers based on their color and shape.	N/A
	20 children aged 7 to 12, including both children with and without ADHD	Mixed (10 children with ADHD and including 4 girls and 6 boys; 10 children without ADHD and including 4 girls and 6 boys)	
García-Baos, Alba, et al [42]			
	RECOGNeye	In the word recognition task,	30 min per

	s	participants need to identify correct words displayed among scrambled words at the screen's center.	session, 3 times per week for 3 weeks
	28 children aged 8–15 years diagnosed with ADHD	18 boys and 10 girls	
Avila-Pesantez, Diego, et al [43]			
	ATHYNOS	AR game, activities in the ATHYNOS prototype include 'Drag and Drop' and 'Shapes', focusing on improving hand-eye coordination.	20 min per session, 2 times per week during a month
	11 children diagnosed with ADHD, aged 7-10	9 boys and 2 girls	
Kanellos, Tassos, et al [44]			
	REEFOCUS	A management simulation game set in an underwater environment where players engage in tasks.	45 min per session for 8 weeks
	75 children diagnosed with ADHD aged 8-14	N/A	
Machado, Fabiana SV, et al [45]			
	N/A	A dry EEG wireless headset captures the player's brain activity, gameplay involves tasks like collecting stars or managing fuel levels.	20-60 min per session
	3 children aged 7-12 diagnosed with ADHD	3 boys	
De la Guía, Elena, María D. Lozano, and Víctor MR Penichet [46]			

	StiCap	The games utilize tangible user interfaces with RFID technology for engaging learning activities.	N/A
	12 children with ADHD, ages 5-16	4 girls and 8 boys	
Avila-Pesantez, Diego, et al [47]			
	CIUDAD PUZZLE	A puzzle game that incorporates NFC tags to interact with physical game pieces.	15 min per session, 2 times per week for 3 months
	20 children diagnosed with ADHD	14 boys and 6 girls	
Schena, Annamaria, et al [48]			
	IAmHero	The application features three VR mini games to enhancement of various abilities.	30 min weekly for 6 months
	60 children with ADHD, age 5-12	33 boys and 27 girls	
Blandón, Diego Zamora, et al [49]			
	Harvest Challenge		
Vita, Salvatore, and Andrea Mennitto [50]			
	NEUROBOT	Gameplay is controlled by monitoring attention levels via a Brain-Computer Interface (BCI).	30 min per session, 2 sessions total
	9 children diagnosed with ADHD, ages 5 to 12	N/A	
Chen C L, Tang Y W, Zhang N Q, et al [51]			
	N/A	The game features tasks that require players to respond in	Twice a week, 30-60

		real-time to changes in their brainwave status.	min per session for 14 sessions
	10 children diagnosed with ADHD	N/A	
Soysal, Ömer M., Fettah Kiran, and Jianhua Chen [52]			
	Tetris	The study explored how different types of background music affect the attention levels of children while playing Tetris.	N/A
	6 children, including 2 diagnosed with ADHD	N/A	
Weerdmeester, Joanneke, et al [53]			
	Adventurous Dreaming Highflying Dragon	Players control avatars through full-body movements to solve cognitively challenging tasks in the game.	15 min per session, 2 times per week for 3 weeks
	73 school-aged children with elevated ADHD symptoms	58 boys and 15 girls	
Ivett Daniela Jácome V., et al [54]			
	DIVIDI2	Set on Mars, the gameplay transforms each child into an astronaut on various adventures.	2 weekly sessions for a month
	5 children diagnosed with ADHD	3 boys and 2 girls	
Kim, Seongki, et al [55]			
	Eye-contact game	An eye-contact game encourages children to recognize faces and improve attention and social interaction skills.	30 min per session, 15 sessions total over 6 weeks

	40 children diagnosed with ADHD by DSM-5 criteria	N/A	
Martínez, Fernando, et al [56]			
	KAPEAN	Children can interact with digital games using either a traditional mouse or hand gestures detected by a Leap Motion device.	10 min for 4 months
	15 children with ADHD	N/A	
Crepaldi, Maura, et al [57]			
	Antonyms	Players role-play as superheroes in a realm where usual rules are inverted, needing to restrain impulsive actions to advance.	45 min per session
	16 boys aged 8–11, including 8 with ADHD and 8 controls	16 boys	
Bul, Kim CM, et al [58]			
	Plan-It Commander	The game engages players in a 10-mission online adventure, requiring specific skills to overcome challenges guided by a narrative.	65 min per session, 3 times per week, over 20 weeks
	170 children with ADHD diagnosis, aged 8-12 years, and their parents and teachers	137 boys and 33 girls	
Castro, Rodrigo, and Deyby Huamanchahu a [59]			
	Casa de Spots	The math learning game covers basic mathematics, including even and odd numbers,	N/A

		fractions, and geometric shapes.	
	35 children (19 with ADHD, 16 without ADHD)	N/A	
Celis, Gianella, et al [60]			
	Dilud	Interactive and dynamic games designed to reinforce rote learning in children with ADHD employ the Tajima Cognitive Test method.	10 min daily
	15 children with ADHD and their parents	N/A	
Retalis, Symeon, et al [61]			
	Kinems	Touchless motion-based games utilize the player's body movements and gestures for interaction.	30 min per session, 2-3 times per week for a month
	11 children diagnosed with ADHD	10 boys and 1 girl	
Dovis, Sebastiaan, et al [62]			
	Braingame Brian (BGB)		
Gizatdinova, Yulia, et al [63]			
	PigScape	The game alternates between active and still phases to enhance impulse control, challenging children to mimic and hold postures.	N/A
	10 Children with ADHD	N/A	

Enjoyment

72% (21/29) of the studies investigated participants' enjoyment of these serious games. Children as the primary target group not only expressed their enjoyment through interviews and questionnaires, some also directly expressed a desire to continue playing the game [36,54]. Although the games initially appeared very appealing, interest varied over time and could wane once children mastered

them, leading to reduced enthusiasm [40,43]. In 45% (13/29) of the studies, player enjoyment was maintained by customizing the difficulty. However, children demonstrated consistently high satisfaction with the game intervention in most experiments. Most measures of enjoyment were obtained through pre- and post-intervention observations and assessments, satisfaction surveys, and EEG signal analyses. In particular, the game 'StiCap' measures player enjoyment by testing the user experience Smileyometer tests [46].

Attention

Attention, identified as the competency most in need of improvement in children with ADHD, received focus in 76% (22/29) of the studies[35-56], with 1 study emphasizing visual attention[42]. Among these games, 45% (10/22) of the studies focused on using carefully crafted game rules to promote attention [35-44]. And 36% (8/22) of the studies concentrated on attentional training utilizing various technologies[45-52]. Specifically, six studies employed EEG headsets to capture brainwave data for observing attention levels [44,49-52,56], and 2 of these used attention levels, as measured by the Brain-Computer Interface (BCI), to control gameplay [50,52]. 18% (4/22) of the studies focused on utilizing in-game interaction design to motivate player focus, with 75% (3/4) using a Kinect sensor to recognize players' movements or gestures and input this data into the virtual world to generate interactions [43,53,56], and 25%(1/4) study utilized concepts from the EMOINAD guide for creating mobile interfaces [54].

Changes in attention before and after the experiments were assessed using various methods, the most common being standardized tests such as the Conners-3 scales, the Italian Battery for ADHD (BIA), the Attention Test for Elementary School Children (ATESC), and SNAP-IV ratings, along with behavioral observations and EEG signal analyses. Specifically, the game CIUDAD PUZZLE employs the Perception of Differences Test (Faces-R) to measure improvements in attention performance [47].

Social skills

In total, 14% (4/29) of the studies focused on research related to social skills. In 2 of these studies, the single-player game 'Plan-It Commander' provides an interactive environment and includes a social community [58]. The 'Eye-contact Game' requires participants to match and maintain eye contact with a virtual character [55]. The multiplayer game 'PigScape' supports co-located gameplay, meaning that children play in pairs. This setup aims to create a learning environment in which children can support each other and enhance their social interactions and communication skills [63]. In particular, 'ADDventurous Rhythmical Planet' offers the option to play alone or in collaboration with others, employing a multi-user mode that fosters teamwork and communication. In addition to observational assessments, social skills can be scientifically assessed using the Social Skills Rating System (SSRS) [35].

Motor skills

In total, 4 studies (4/29; 14%) focused on motor skills. 75% (3/4)of these studies were designed to engage children in physical activities, utilizing their body movements to interact with the game via a Kinect camera [53,61,Error: Reference source not found]. However, instead of directly targeting motor skills for enhancement, these studies aimed to encourage physical movement, thereby aiding in impulse control and self-regulation. The remaining study employed VR technology to train body coordination, specifically focusing on hand-eye and hand-foot coordination [Error: Reference source not found]. Assessing motor abilities in individuals with ADHD involves observations and neuropsychological tasks that examine both fine and gross motor skills. [53].

Executive Functions

In total, 41% (12/29) of the studies focused on enhancing executive functioning, comprising three core functions: Working Memory, Cognitive Flexibility, and Inhibitory Control. 42% (5/12) studies targeted Working Memory, primarily through repetitive practice in the games, with 2 studies focused on enhancing math skills [38,59]. And 3 studies focused on auditory and visual memory, rote learning ability, and 'Non-verbal intelligence' [37,60,61]. 17% (2/12) of the studies aimed at enhancing children's emotion regulation [39,56], viewed as integrating cognitive flexibility and inhibitory control. Another 17% (2/12) of the studies focused on improving Hyperactivity-Impulsivity symptoms with counter-intuitive game rules designed to stimulate impulsive responses, requiring players to inhibit these responses to succeed, and the game's difficulty can be adjusted based on the child's progress [57,63]. The remaining 3 studies reported synthesizing improvements in executive function through multiple mini-games [41,48,58].

Improvements in executive functioning are evaluated primarily through observational assessments by parents and teachers, and through scientific tests such as the Wechsler Memory Scale, Tower of London task (TOL), Behavioral Rating Inventory of Executive Function (BRIEF), and Wisconsin Card Sorting Test (WCST). Additionally, it is assessed by the scores achieved by the children during the game [60,62], and through EEG technology to monitor the children's emotional and cognitive states during gameplay [56].

Discussion

To our knowledge, this is not the inaugural systematic review in this field. However, it incorporates DTx guidelines to provide current and industry-standard insights, critically examining many original studies, serious games of various types, and outcomes. Additionally, it addresses the multi-symptom nature of ADHD, focusing on enhancements in social interactions, motor skills, and executive functions, extending beyond the core symptoms of inattention and hyperactivity-impulsivity, to include children's enjoyment of games. The review suggests that serious games hold great promise in the field of treatment for children with ADHD. However, findings were interpreted cautiously using descriptive analyses due to the wide variation in study design, sample size, targeting ability and duration, outcomes, and associated risks.

The results indicate that serious games may be beneficial for improving inattention, potentially serving as an effective alternative or supplement to traditional rehabilitation methods for key ADHD symptoms. Changes in EEG patterns, especially in the alpha and beta bands, support the effectiveness of serious games for enhancing attention [49]. Serious games provide a more engaging and digital format, enhancing enjoyment and promoting adherence among children [36,62]. This factor has been recognized as crucial for improving adherence to interventions [54]. The findings reveal that serious games utilize feedback mechanisms and an engaging digital experience through game rules, technology, and interaction design to maximize participant motivation and minimize boredom [64,65]. Serious games can also be tailored to individual patient needs, resulting in more personalized and effective treatment. However, further research is necessary to examine the long-term effects of serious games on attention.

The results of the study suggest that serious games may enhance the social skills of children with ADHD. Multiplayer gaming is not a requirement, games are primarily set in virtual environments that facilitate interaction or collaboration among peers, thereby aiding children with ADHD in developing their social skills. Most studies report consistent results, showing improvement in children's social skills after using serious games, compared to the pre-experimental period. Children found the games engaging and expressed a desire to share their experiences with friends. However, when playing games with peers, children may experience frustration from not keeping up with friends for various reasons, leading to a loss of interest in continuing the game [35].

The current study does not find evidence to suggest a positive effect of serious games on the motor

abilities of children with ADHD. However, the use of a Kinect sensor for full-body interaction during serious games is reported to be more engaging than traditional forms of exercise, enhancing both fine and gross motor skills [53]. Additionally, limitations in motor skills enhancement results may stem from variations in measurement methods and study quality. Most studies concentrate on improving attention and inhibitory control in children with ADHD through exercise or physical activity, rather than sports instruction. Further research examining motor practice in serious games could shed more light on potential benefits for individuals with ADHD. This review also indicates that somatosensory digital systems, which utilize body movements and gestures as inputs, may achieve higher adherence rates than traditional games [63]. This underscores the importance of incorporating digital systems in serious gaming interventions, which could significantly affect their effectiveness. However, adherence rates may vary by population and specific intervention [66], necessitating further research to fully assess the impact of digital systems on adherence in serious gaming interventions.

Findings suggest that serious games may be beneficial and may improve executive functioning in children with ADHD. The studies in this review focused on working memory for executive functions, such as math skills, reading memory, visual memory, and inhibitory control-related impulsivity symptoms and emotion regulation. In addition, the review also addresses hyperactivity-impulsivity symptoms, emotion regulation, and the combined improvement of executive functions through multiple mini-games. It should be emphasized that improvements in executive functioning may be influenced by a variety of factors and therefore may result in a lack of observed improvements [67]. Improvements in working memory can be more intuitively reflected in scores on games, and inhibitory control-related abilities are improved to some extent primarily by completing impulse-suppressing game challenges. Beyond this, it is not clear whether long-term interventions lead to significant improvements, which is consistent with the results of previous reviews [68].

The results of the current research on the likability of serious games are generally positive. As the aim of these serious games is to improve various symptoms of ADHD, this often results in a relatively repetitive gameplay process. While games are initially appealing, participant interest varies over time, making compliance with the program one of the most significant challenges. [40,43,59]. Therefore, controlling the game's difficulty is crucial, a game that is too difficult can frustrate children, leading them to give up [35,50,53]. However, games that are too easy may become uninteresting to children once mastered, leading to reduced enthusiasm unless new games are introduced. Of the 29 studies reviewed, 16 discussed customizing the game: three were customized for appearance only, while the remaining 13 involved adjusting levels and tasks according to the player's performance. This suggests that game designers, to prevent boredom during gameplay, employ progressively increasing levels of difficulty to stimulate children's desire for a challenge [69]. At the same time, the game utilizes gamification elements such as points, rewards, rankings, and levels as feedback mechanisms to minimize tedium [59,60]. Higher interactivity enhances player acceptance, and appropriate difficulty control can gain more favor among players. For example, in the game 'The Secret Trail of the Moon', among the five mini-games, Teka Teki is highly interactive but also the most difficult, with a strict difficulty curve that impedes progress and may lead to a decline in initial motivation. In contrast, Kuburi, another reasonably difficult and interactive mini game, received the highest usability score [36]. While serious games aim to address these issues through Interesting experiences, they may still struggle to fully engage children who have severe attention deficits and impulsivity, traits that are common in ADHD [49,50,56]. It appears that a suitable solution for this issue has not yet been identified and requires further in-depth examination by future research.

Although the probability of having more than one co-morbid condition in people with ADHD is high [3], no in-depth or categorical studies of co-morbid conditions were found in the included studies. Instead, researchers chose to prioritize a more representative sample of children with ADHD over a 'pure' ADHD sample, which would be less generalizable. Meanwhile, only one study categorized and discussed the subtypes of study participants to target treatment more effectively [36]. This

oversight of co-morbidities and subtypes may increase the difficulty of integrating the game into daily patient use.

Most studies in this review did not report safety outcomes associated with serious games. Of the 4 studies using VR technology, only one reported adverse effect, such as dizziness and virtual reality motion sickness [36]. Some children found the EEG headsets uncomfortable and encountered challenges in setting up and using this equipment effectively during gameplay [40]. Some children exhibited decreased performance in certain cognitive tasks after participating in game-based interventions, indicating that these games may not enhance all cognitive functions equally [44]. This indicates that potential adverse effects have not been fully identified, necessitating future studies to assess the safety outcomes of serious games and identify any possible adverse effects.

Limitations

This review covers only original research in English from PubMed, Web of Science, Scopus, IEEE Xplore, and ACM Digital Library databases, published from January 2010 to January 2024. However, given the highly interdisciplinary nature of the subject, limiting the review to these five databases might exclude relevant research published elsewhere. To the best of our ability, this limitation has been minimized by combining search strings and including more broadly defined terms in the keywords. Although the review incorporated DTx guidelines into the inclusion and exclusion criteria to comply with industry standards, the temporary deprioritization of certain fundamental DTx principles that do not currently apply to the research has also contributed to the limitations of the study.

Despite the mostly positive results for targeting enhancement abilities, bias was observed in some studies due to insufficient sample sizes and a frequent lack of rigorous methodology, randomization, and blinding procedures. Despite limiting the study population to children with ADHD, the included studies were highly heterogeneous in terms of experiment type, game type, duration, sample size, targeting ability, assessment methods, and findings. This heterogeneity necessitated descriptive rather than meta-analyses in this review. However, these studies initially demonstrate the potential for using serious games in ADHD treatment, providing data and insights for future research. They are expected to serve as a basis for obtaining clinical trial data and conducting more in-depth studies.

Although these limitations could not be addressed, the review still provides important implications for further research to enhance the evidence supporting serious games as digital therapeutics for enhancing ADHD treatment effectiveness in children.

Conclusion

This review comprehensively summarizes findings indicating that serious games can effectively engage children with ADHD in therapeutic interventions and potentially improve various patient abilities. The reviewed research demonstrates that using serious games as Digital Therapeutics, shows promise in improving attention, social skills, and executive functions among children with ADHD. However, more rigorous, long-term studies are necessary to further characterize the effectiveness and safety of serious games as digital therapy. Due to the highly heterogeneous nature of the included studies, the review opted for descriptive analysis over meta-analysis, yet it still offers significant reference value for future research. As an interdisciplinary field, researchers should enhance their collaboration, which will facilitate the effective integration of serious games into a broader spectrum of ADHD treatment programs amid growing interest in this area.

Abbreviations

ADHD: Attention deficit hyperactivity disorder

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition

ISO: Global standards for trusted goods and services

DTx: Digital Therapeutics

PRISMA-P: Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols

DHI: Digital health interventions

Conflicts of Interest

None declared.

Multimedia Appendix 1 Quality assessment.

Game reference	1. Does the study's research design adhere to low risk of bias and random principles?	2. Is the primary subject population of this study children with ADHD?	3. Does the study discuss randomisation?	4. Are there any blinding issues? (blinding in the number of data used in this study?)	5. Does the study's outcome measurement focus on the measurement of core symptoms associated with ADHD or does it evaluate aspects such as functional skills, executive functions, and social skills?	6. Does the study provide a detailed description of the game used?	7. Do the interventions described in the study meet the fundamental definitions of Digital Therapeutics (DTx)?	Total score
A 3D Rhythmic Serious Game for Calibrating Improvement of Children with ADHD	1	1	1	0.5	1	1	1	0.93
A Feasibility Study on the Effectiveness of a Full Body Movement Intervention for Decreasing Attention Deficit Hyperactivity Disorder Symptoms	1	1	1	0.5	1	1	1	0.93
A Virtual Reality Game (The Secret Trail of Nemo) for Treating Attention Deficit/Hyperactivity Disorder	1	1	1	0	1	1	1	0.96
Development and Usability Study of a Serious Game for Improving Inhibitory Control of Impulsivity in Children with ADHD	1	1	1	0.5	1	1	1	0.93
Effectiveness of a Computerized Learning Strategy to Support Learning Strategies with ADHD	0.5	0.5	1	0	0.5	1	0.5	0.57
Behavioral Outcome Effects of Serious Gaming as an Adjunct to Treatment for Children With Attention Deficit/Hyperactivity Disorder: A Randomized Controlled Trial	1	1	1	1	1	1	1	1.00
Designing HHO (HO: Working Memory Game) and evaluating its effects on working memory in ADHD children	1	1	1	0.5	1	1	1	0.93
Developing an interactive game model for children with ADHD based on social skills, working memory, and IQA model	1	1	1	0.5	1	1	0.5	0.96
Developing and testing a hybrid of the inductive and deductive game prototype for children with ADHD on deficit/hyperactivity disorder	1	1	1	0.5	1	1	0.5	0.96
Development and validation of a Gamified Adaptive for Math Learning in Children with Attention Deficit/Hyperactivity Disorder (GADeM)	1	1	1	0.5	0.5	1	0.5	0.79
Development of Serious Game for Personalized Education of Children with ADHD through Reinforcement	1	1	1	0	1	1	0.5	0.79
Development of a virtual reality educational game for children with attention deficit hyperactivity disorder (ADHD): A Novel Application to Reinforce Basic Learning in Elementary School Children with Attention Deficit Hyperactivity Disorder	1	1	1	0.5	1	1	1	0.93
Effectiveness of a Gamified Attention Training for Children with ADHD Through a Mobile Application	1	1	1	0	1	1	1	0.96
Educational game based on distributed and tangible user interface to enhance cognitive abilities in children with ADHD	1	1	1	0.5	1	1	1	0.93
Improving children with ADHD learning disability through the Kinect-based learning game	1	1	1	0.5	1	1	1	0.93
Improving the Effectiveness of Feedback Game with Children with ADHD	0.5	1	1	0	0	1	0	0.50
Improving Learning in Non-Formal Educational Based Serious Game in Children with ADHD	1	1	1	0.5	1	1	0.5	0.96
Open-Source Game Using Virtual Reality for the Treatment of Children With ADHD	1	1	1	1	1	1	1	1.00
Robotic: Preliminary Findings of an Experimental Study to Reduce the Social Skills Deficiencies of children with ADHD Conducted through the Use of Serious Games in Virtual Reality	1	1	1	0.5	1	1	1	0.93
Improving Executive Functions in Children with ADHD: Training Multiple Executive Functions within the Context of a Computer Game: A Randomized Double-Blind Placebo-Controlled Trial	1	1	1	0	1	1	0.5	0.93
Impact of a 3D-based feedback videogame in children with ADHD	1	1	1	0	1	1	0.5	0.79
Improving Understanding of Relative Status of Children with ADHD	1	1	1	0	0	1	0	0.57
Keep Attention: A Personalized Serious Game for Attention Training	1	0.5	1	0	0	1	0	0.50
Multi-sensory Virtual Game with Use of the Data Log Platform to Improve the Lack of Attention in Children of 7-12 Years with ADHD	1	1	1	0.5	1	1	0.5	0.96
NEURONET: A video-adaptation tool to perform neural feedback training in children with ADHD	1	1	1	0	1	1	1	0.96
Real-time Feedback-Based Attention Training for Children with ADHD	1	1	1	0	1	1	1	0.96
Real-time Feedback-Based Training Game for Training Attention in Children With Attention Deficit/Hyperactivity Disorder	1	1	1	0.5	1	1	1	0.93
Proposed: An extended video game for cognitive performance training of executive and behavioral control in children with ADHD	1	1	1	0	1	1	1	0.96
Quantifying Brain Activity by State-Dependent of Background Music in a Serious Game on Attention of Children	1	0.5	1	0	1	1	1	0.79
Toward the improvement of ADHD children through augmented reality serious game: Brain-based social learning	1	1	1	0	1	1	1	0.96
User Experience Evaluation of the PROGRESS ADHD Management Gaming System	1	1	1	0.5	1	1	1	0.93

Multimedia Appendix 2 Descriptive analysis.

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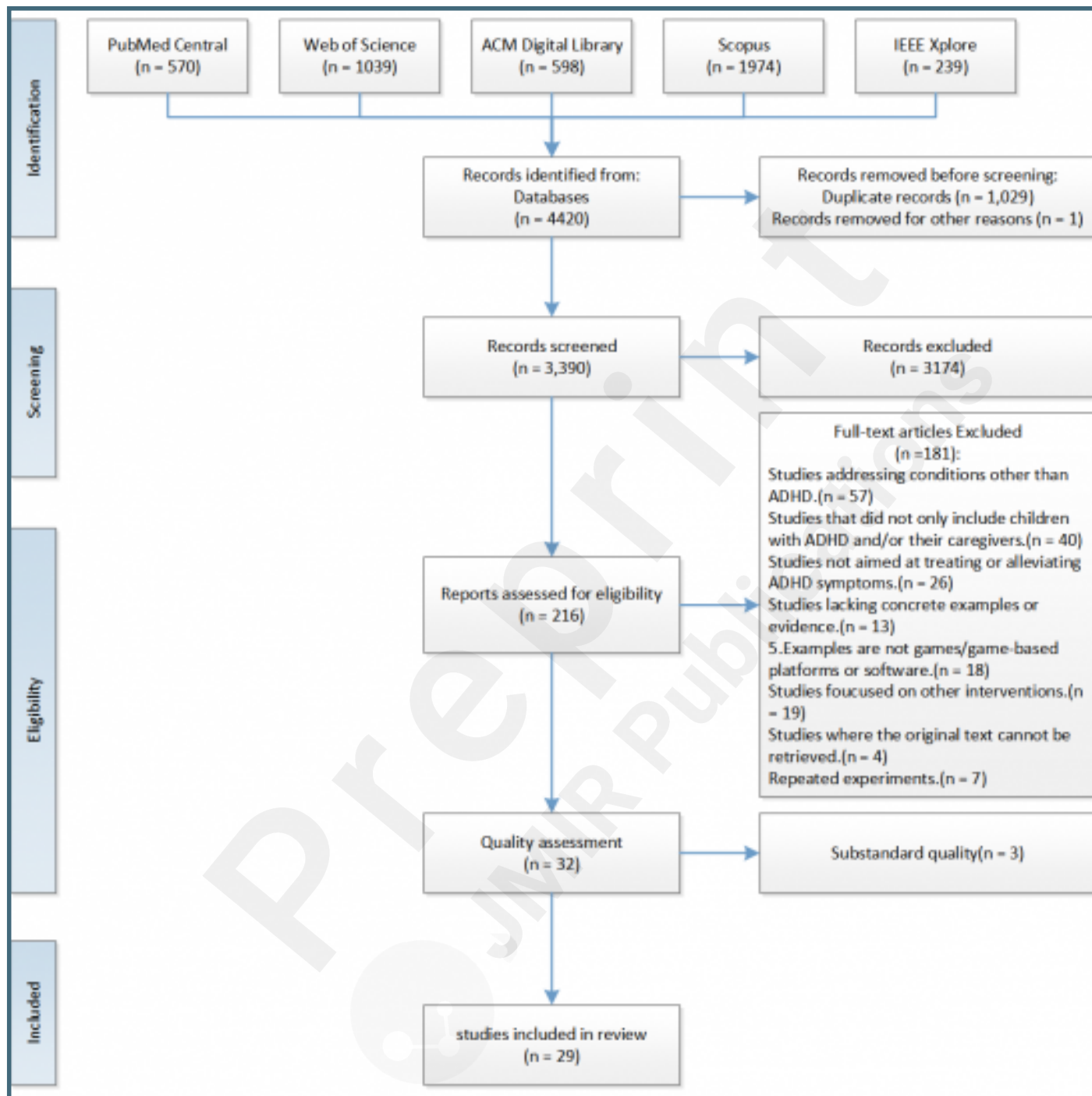
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Supplementary Files

Figures

PRISMA-P (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols) flow diagram.



Inclusion Criteria and Exclusion Criteria.

	Inclusion criteria	Exclusion criteria
Population	Children diagnosed with ADHD.	Studies that did not only include children with ADHD and/or their caregivers (guardians, teachers, clinicians). Non-human studies.
Intervention	Research focused on serious games designed specifically for targeting ADHD.	Studies focused on other interventions (e.g., Pharmacological interventions, telemedicine, m-health/sensors, web-based intervention, augmented/virtual reality, robot assistant)
Study Design	<ul style="list-style-type: none"> Any experimental or quasiexperimental evaluative design, including pilot and feasibility studies Non-randomized studies (e.g., pre-post study with no control group) Cohort or longitudinal studies that had pre-post outcome measures Case series or case studies 	<ul style="list-style-type: none"> Theoretical designs or frameworks without example data. Studies addressing conditions other than ADHD (e.g., Autism Spectrum Disorder (ASD), anxiety disorders, bipolar disorder, learning disorders). Studies not aimed at treating or alleviating ADHD symptoms.
Outcomes	Focus on outcomes in the following developmental domains: Attention Hyperactivity-impulsivity Social skills Motor skills/physical activity Executive functions Enjoyment Intervention adherence	<ul style="list-style-type: none"> Studies lacking concrete examples or evidence. Examples are not games/game-based platforms or software. Studies where the original text cannot be retrieved. Repeated experiments.
Publication Type	Peer reviewed article. Fullpaper proceedings.	Conference abstracts, study protocols, books, websites, reviews, theses or dissertations, short conference paper proceedings, posters, and demos.
Publication period	From 1 January 2010 to 1 January 2024	Before 2010, after 1 January 2024
Setting	Any country or region	N/A
Language	English	Any other language

DTx guidelines temporarily deprioritized.

	DTx Core Principles	Reasons for deprioritization	Prioritization Recovery
1	Incorporate design, manufacturing, and quality best practices.	N/A	N/A
2	Engage end users in product development and usability processes.	N/A	N/A
3	Incorporate patient privacy and security protections.	N/A	N/A
4	Apply product deployment, management, and maintenance best practices.	During initial development and prototyping, the primary focus might be on validating the therapeutic concept and functionality rather than on the complexities of deployment and ongoing maintenance.	Applying product deployment, management, and maintenance becomes critical as the product approaches a state ready for broader testing or market launch. This ensures scalability, reliability, and user support.
5	Publish trial results inclusive of clinically meaningful outcomes in peer-reviewed journals.	N/A	N/A
6	Be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use.	Early-stage products, particularly those in the research, discovery, or pre-clinical phases, may not have undergone regulatory review.	Regulatory clearance or certification is pursued after proving the product's efficacy and safety, established through clinical trials.
7	Make claims appropriate to clinical evaluation and regulatory status.	In the exploratory stages of development, a DTx product might not yet have undergone extensive clinical evaluation, and thus, cannot make definitive claims about its efficacy, safety, or intended use.	Formal claims become relevant and necessary as the product undergoes clinical trials and seeks regulatory approval.
8	Collect, analyze, and apply real-world evidence and/or product performance data.	N/A	N/A

Multimedia Appendixes

Quality assessment.

URL: <http://asset.jmir.pub/assets/4ec77818d3da967363f17c71d90f9395.xlsx>

Descriptive analysis.

URL: <http://asset.jmir.pub/assets/85478aa80da477b8b6fc02da6944a92f.xlsx>

