Fantasy, facts and fun: digital health games for impact and implementation

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Abstract:

Digital games have become a recognized and valued option in the health professionals' toolbox when promoting healthy behaviors in a fun and engaging manner. Despite their effectiveness, the implementation of games in real life is limited by cost, lack of varied and relevant expertise, and time. This chapter aims to provide an overview of the state-of-the-art insights of how digital games influence health and health behaviors and address key issues in their development and deployment. We first define 'serious digital games for health' (referred to as G4H) and related concepts, such as serious games and gamification. Next, we discuss some of the broad domains where G4H are applied, including health promotion, disease prevention, treatment, and rehabilitation, including a selection of health topics to illustrate their use. Next, we discuss potential mechanisms and theories used to design G4H and possible mechanisms (mediators) explaining their effects on psychological (e.g., selfefficacy), behavioral (e.g., self-monitoring), physiological (e.g., heart rate) and clinical outcomes (e.g., body mass index). Since G4H derive their strength from being fun and evidence-based, this chapter presents multidisciplinary mechanisms and theories regarding engagement, communication, and behavior change. We then discuss the process of G4H design and research, including interdisciplinary collaboration, participatory development with end-users and stakeholders, cost-effective design approaches, and recommendations for mixed-method, high-quality game research. The chapter concludes with a discussion of challenges often encountered when developing G4H and future directions to advance the field of games and their implementation in practice.

1. Introduction

Most people would like to live a long and healthy life. To get there, they need access to quality healthcare and potentially adopt new healthy behaviors, which can be hard. The adoption of health behaviors can be hindered by lack of time; financial or environmental access constraints; interference with other life goals; and lack of knowledge, awareness, skills, positive attitudes, self-efficacy (confidence in one's ability to perform the behavior), or social support (Kelly et al., 2016). Learning a new behavior often requires repeated exposure to interventions designed to overcome these barriers, and takes practice to learn new skills and create a habit (Gardner et al., 2012). Continued engagement with behavior change interventions is facilitated when the interventions are enjoyable, interesting, or helpful (Yardley et al., 2016). This is exactly the purpose of serious games, which aim to make a learning experience both educational and entertaining. Traditionally, the term 'serious games' refers to games that are not designed to be purely recreational, although more recently, commercial games built for recreation that are used in a 'serious' health context, have also been considered serious games (Ritterfeld et al., 2009). Three qualification criteria for serious digital games for health (G4H) include: 1) elements of play (e.g., setting objectives to meet challenges, safe 'pretend' practice), 2) user experience (e.g., having rules, interaction and feedback, adapting the challenge to balance with available skills) and 3) educational or behavior change elements (e.g., having a learning or behavioral goal, the educational content to acquire the behavior, showing educational progress) (Prensky, 2001; Tan & Zary, 2019). This differentiates serious digital games from other technology-delivered interactions that do not aspire to be fun or entertaining (e.g., interactive multimedia education); are limited in their interaction and feedback (e.g., static, non-interactive websites, instructional videos); are limited in their full integration of entertainment and education, e.g. edutainment that integrates play elements in traditional curricular activities (Ritterfeld et al., 2009), and gamification, which integrates game elements in non-gaming contexts (e.g., rewards and social rankings with smart wearable apps) (Deterding et al., 2011). This chapter focuses on serious games to directly impact a player's health and excludes games for pedagogical purposes (e.g., medical training games). It primarily discusses electronic device-enabled games though we acknowledge that nondigital games for health (e.g., board games) also show promising results for health promotion (Gauthier et al., 2019).

2. Serious digital health games (G4H)

With the rapid development of gaming technology, the market for G4H enjoys strong growth. For example, games for healthcare alone are estimated to garner revenue of around \$47 billion by 2026 (Research Dive Analysis, 2021). A scoping review divided G4H into six general types: 1) educational games (e.g., informing users about a disease or health condition); 2) behavioral games (e.g., improving people's health behavior); 3) cognitive games (e.g., improving aspects of cognitive health); 4) active games (e.g., requiring players to be physically active while playing); 5) rehabilitation games (e.g., facilitating recovery from injury or illness); and 6) hybrid games (i.e., a mix of types) (Kharrazi et al., 2012). A systematic content analysis differentiated G4H by three dimensions: 1) targeted health topic (e.g., asthma), 2) level of claimed influence (e.g., awareness; behavioral change); and 3) play elements (e.g., role-play, fighting) (Lu & Kharrazi, 2018). No universally accepted classification method exists, these may evolve as gaming technologies develop.

3. Mechanisms and theories for G4H design

3.1. How do G4H games work?

In many health domains, behavior change is needed to positively impact clinical outcomes (e.g., self-monitoring of symptoms, changing diet to prevent obesity, practicing skills in rehabilitation). Theories organize the many and complexly related factors that could influence behavior. Health behavior change theories have therefore been applied in G4H to ensure behavioral determinants and mechanisms of change guide game design. Further, game design also needs to be guided by theories on play, and on user experience. For an optimal game design, all three elements need to be addressed. Frequently used theories will be briefly described here.

3.1.1. Building blocks

Theories often cover similar concepts, sometimes with different terms (e.g., self-efficacy and self-perceived competence) or slightly deviating content (e.g., individual tailoring and personalization). To avoid confusion in terms, taxonomies or classification systems give a uniform description of a concept. Taxonomies of behavior change techniques (BCTs) exist to define methods for change (Michie et al., 2013), and describe which behavioral determinants they fit with and their conditions for effectiveness (Kok et al., 2016). Examples of BCTs include modeling, self-monitoring, feedback, reinforcement, and social comparison. Several papers have described how to integrate BCTs in G4H (DeSmet, Van Cleemput, et al., 2016; Thompson et al., 2010). Taxonomies also exist for gaming elements. Some serious game taxonomies are relatively broad and distinguish application area, interface, device, platform, genre, usage context, target audience, and gaming features of narrative, feedback, players, monitoring, adaptation, interaction, dedication (similar to behavioral engagement), and gameplay (similar to affective engagement) (De Lope & Medina-Medina, 2017; Rego et al., 2018). These BCTs and gaming elements are fundamental in several theories on G4H design.

3.1.2. Theoretical models

Behavior change theories

Social Cognitive Theory (SCT) has been commonly used to guide the content development of behavioral interventions (Michie et al., 2014), including G4H (Krath et al., 2021). SCT contends that behavior is a function of reciprocal interactions with the environment and personal characteristics, such as self-efficacy (Bandura, 2019). Self-efficacy is enhanced through personal mastery (e.g., experiencing success), observational learning (e.g., watching valued others accomplish a task), performance feedback (e.g., appraisal of actions in relation to goal attainment), persuasive language (e.g., encouragement), and psychological states such as emotional arousal (e.g., positive feelings associated with success) (Bandura, 1986). These features can be readily incorporated into G4H (Thompson, 2017). Other behavior change theories used in G4H design include Theory of Planned Behavior (e.g., 'Negotiation Battle' for awareness of lifestyle-related diseases (Egashira et al., 2022)), Reasoned Action Approach (e.g., 'Friendly ATTAC' against cyberbullying (DeSmet, Van Cleemput, et al., 2016)), Self-regulation theory (e.g., 'SPARX' for mental health (Merry

et al., 2012)), and the Transtheoretical Model (e.g., 'COVID Pacman' for COVID-19 awareness and prevention (Mulchandani et al., 2022)).

Recent reviews mentioned self-determination theory (SDT) as most often used in serious game design (Hammady & Arnab, 2022; Krath et al., 2021). SDT emphasizes motivational aspects of behavior, especially intrinsic or autonomous motivation, reflected in doing an activity because it is personally interesting, satisfying in itself, or helps to achieve a personally relevant goal (as opposed to extrinsic or controlled motivation, which occurs when doing an activity to please an external influencer or achieve an external reward). SDT proposes that behavior change can be enhanced by fulfilling three basic psychological needs, including competence (the belief one has the ability to successfully perform a behavior, similar to the concept of self-efficacy), autonomy (the belief one can choose their own behaviors) and relatedness (social connectedness or reflecting a person's goals in life) (Ryan & Deci, 2000). The more the basic psychological needs are satisfied, the greater the likelihood the behavior will be integrated into one's self-concept, thereby increasing the likelihood they will continue to engage in the behavior over time (Ryan & Deci, 2000). A game that promotes choice, feelings of mastery, and a sense of relatedness may facilitate the development of autonomous motivation to engage, or continue to engage, in a behavior.

Play theories

While behavior change theories aim to understand what needs to be learned or changed for the new behavior to occur, play theories focus on how the game can provide these learning and change opportunities. Play theories generally distinguish between game mechanics, dynamics, and aesthetics or emotions. The Mechanics-Dynamics-Aesthetics (MDA) framework is an often-cited model to design and analyze games (Hunicke et al., 2004) and decomposes games into: 1) Mechanics, i.e. the actions and control mechanisms that players have within a game context and are linked to the game rules (e.g., run, jump); 2) Dynamics, i.e. the system aspects (e.g., feedback rewards); and 3) Aesthetics, i.e. the emotional experience during play (e.g., identification with characters). MDA proposes to start the design process from the desired aesthetics (e.g., connectedness, co-operation), to then decide on the dynamics (e.g., beating the opponent in a quiz as a team) and the mechanics needed to achieve these dynamics (e.g., answering quiz questions). Despite being highly cited in game design literature, the MDA model is infrequently used in serious game design, as are other play theories (Krath et al., 2021).

Most frequently used theories in serious games focus on the learning content and creating an enjoyable user experience, whereas play theories that describe how to exactly turn the learning experience into an enjoyable user experience, and connect learning and engagement, are less often used. A potential reason for the infrequent use of play theories is that game developers may feel that using theoretical frameworks in game design cramps their creative style (Junior & Silva, 2021). There is, however, growing consensus that in serious games, theories that connect learning objectives and game design components are needed (Junior & Silva, 2021). Some recent models that aim to do so include: 1) the Learning Mechanic - Game Mechanic (LM-GM) descriptive model which is derived from a pedagogical game context and aims to match learning methods (e.g., incentives) with corresponding serious games (ATMSG). ATMSG builds upon the Activity Theory which states that all human learning is based on an activity that : 1) is driven by a motive; 2) divided into a set of actions that together aim to reach a certain goal; and 3) can vary by context, skills and motivations

(Carvalho et al., 2015). ATMSG was built to specifically apply to serious games by using existing taxonomies of game, learning and instruction components, and reorganizing these according to the levels of gaming, learning or instructional actions, tools, and goals. Feasibility analyses by user testing were conducted and it was applied to several existing serious games (Carvalho et al., 2015). Usability testing indicated LM-GM is easier to use, but ATMSG is more complete (Carvalho et al., 2015). ATMSG stands out by its systematic approach to design and usability testing in serious games but to our knowledge has not yet been applied to G4H.

User experience theories

A critical characteristic of G4H is that they need to be engaging. User engagement comprises 'behavioral engagement' (e.g., duration and frequency of exposure, continued use) and 'engagement as subjective experience' (e.g., flow, enjoyment) (Perski et al., 2017). Validated scales exist to measure game engagement (Brockmyer et al., 2009; Poels et al., 2007; Ryan et al., 2006), that cover dimensions of flow, immersion, positive and negative affect, presence, psychological absorption and dissociation, tension, challenge, competence, relatedness, autonomy, and intuitive controls. To our knowledge, no widely used validated scale exists to measure engagement specifically for G4H. It is, however, possible that other dimensions not covered by general game engagement scales, such as interest (Short et al., 2018), perceived relevance (Crutzen et al., 2016), and perceived progress to achieving a goal outside of the game world, also termed macro engagement (Yardley et al., 2016), would be relevant for G4H that aim to achieve more than entertainment. The concept of macro engagement also relates to how actions that are taken by players within a game translate to actions in real life. Transfer of learning effects from games is assumed to occur more often when the learning content and context more closely resembles the real-life situation (Barnett, 2014). This need for similar settings may contradict some of the benefits of serious games, that often use safe environments without real-life consequences or that use fantasy worlds, often preferred by players than more realistic game settings. However, a certain degree of realism can also be achieved without losing the fantasy element of games, for example by using metaphorical representations of real life in the game (Kuipers et al., 2017); or by increasing perceived realism, such as authentic settings that could happen in terms of situations, characters and interactions, rather than recreating real-life settings that have happened (Ribbens & Malliet, 2010). Game analytics (e.g., game play duration, following the player's path in the game and whether this fits with what was intended) can moreover assess user engagement in a way that represents low respondent burden.

Several theories focus on concepts that influence user engagement. For example, SDT can refer to motivation for the health behavior but can also apply to game-play motivation. If the game has a high level of user control (autonomy), feeling connected to others in the game world or via collaborative play (relatedness) and enables the player to accomplish a mission and go to the next level (competence), the autonomous motivation to play the game will likely be higher. Whether the game is delivering the desired emotional experience (i.e., the aesthetics component of the MDA-framework) may also influence user engagement.

Two theories have a pivotal role in game engagement literature. The first is Flow Theory (Nakamura & Csikszentmihalyi, 2009). Flow is a state of high concentration in which the player experiences a balance between skills and challenge. Experiencing flow, the player is in a state that is so enjoyable that they want to continue this activity. Ideally, the challenge can adapt to the level of the player via dynamic difficulty adjustment (DDA) to create this balance. DDA measures varying levels of skills in real-time and accordingly varies the game activity to keep the player in a state of flow. DDA can be based on the player's performance (e.g., via biofeedback of the target behavior during game-play (Schwarz et al., 2021)), or on a real-time measurement of engagement or affect (Liu et al., 2009). A second noteworthy theory is Transportation theory (Green et al., 2004). User engagement can derive from immersion or transportation, a state in which the player becomes absorbed in the play without disbelief. When immersed in a narrative or story, the player may change their attitudes and behavior in line with the narrative. Whatever we experience in the narrative becomes transported to real-life. Narrative transportation in G4H may help reduce counterarguments against the recommended behavior change (Crutzen et al., 2016).

Games are not by definition engaging; they need to be designed such that they appeal to the target audience. A problem with G4H has been that players may complete a few brief sessions, lose interest, and stop playing soon after, thereby limiting game impact by limiting intervention dose (Baranowski & Lyons, 2020; Schwarz et al., 2021). Low initial engagement appears to be influenced by aesthetics (e.g., unattractive graphics), lack of encouragement and technical problems, whereas continued engagement may be more driven by flow, presence, challenge, ease of use, novelty, sense of achievement and perceived usefulness (Schwarz et al., 2021). User-centered design, an iterative game design approach based on understanding the whole user experience and involvement of end users in the design, may help prevent such engagement issues (Chen, 2019).

3.2. What works for whom?

The effectiveness of G4H has been evaluated in meta-analyses in diverse health domains and populations. A non-exhaustive overview of findings is provided here in the domains of health promotion, improvement of cognitive functioning, mental health treatment, illness self-management, and rehabilitation (Table 1).

3.2.1. Overview of meta-analytic findings

The overview demonstrates that G4H overall have had positive effects in various health domains and age groups, across different gender/sex groups and for both clinical and non-clinical populations (Table 1). Most meta-analyses also showed considerable remaining, unexplained heterogeneity in results, suggesting that some other characteristics of the game, user or play setting than those included in the meta-analyses may explain differential effects. Effects may be greater on cognitive outcomes than on emotional outcomes. In certain health domains, too few experimental studies were available in the meta-analyses to conduct detailed moderator analyses, making it difficult to conclude what works for whom.

Table 1. Overview of meta-analytic findings

Authors	Health topic	Populations	Game type	Study types included	Number of papers included / combined sample size	Main findings
Health promo	tion					
(DeSmet et al., 2014)	Healthy lifestyle promotion	All ages and populations	G4H (excluding commercial games)	Experimental studies	n=54 / ranging between n=9367 and n=314790 depending on the meta- analysis	 small positive effects on behavior, determinants, and clinical outcomes no difference in effects by participants' age and gender/sex, or by health domain maintained effects on correlates of behavior but not on the behavior itself larger when games were tailored to user characteristics and based on a play/user experience theory (regardless of whether it was combined with a behavior change theory) largest effects for knowledge and attitudes, and smallest for social norms, perceived barriers, and self-efficacy
(Bossen et al., 2020)	Increase PA	Youth with a chronic disease (aged 6-18y)	G4H (incl. commercial games for PA)	RCT	n=8 / n=837	 no effect on PA, but small positive effects on BMI (n=2 in this sub-meta- analysis)

(Gao et al., 2015)	Increase PA	Youth ≤18y	Exergames	Within-subject or between subject comparison studies	n=35 / n=3339	-	large positive effects on PA when compared to sedentary activities small effects on energy expenditure when compared to other exercises intervention duration or game type did not significantly moderate effects
(David et al., 2020)	Physical and mental health promotion	Youth ≤18y, clinical and non-clinical populations	G4H (educational and therapeutic games)	RCT	n=34 / NR	-	small positive effects in a healthy (and asthmatic) population, but not in other clinical populations no significant effect on maintained behavior significant effects for behavioral and cognitive outcomes, but not for emotional or psychophysiological outcomes larger effects for younger populations and for shorter intervention durations
Cognitive hea				[1	
(Derks et al., 2022)	Adaptive and cognitive skills	Children with an intellectual disability and/or autism disorder (4- 12y)	G4H or gamified interventions	RCT	n=11 /n=654	-	small positive effects on adaptive and cognitive skills
(Zhang & Kaufman, 2016)	Cognitive functioning	Older adults (≥55y, incl. healthy and	G4H (incl. commercial games used	Experimental and quasi- experimental studies	n=36 / NR	-	small to moderate positive effects on cognitive functioning

		impaired	for health			
		populations)	purposes)			
Mental health	treatment	populations	purposes			
(Lau et al., 2017)	Various mental health outcomes	All ages (7- 80y)	G4H	RCT	n=9 / n=674	 moderate positive effects on reducing mental-disorder-related symptoms compared to a passive control condition no differences by age, nor between clinical and non-clinical populations
(Abd- Alrazaq, Alajlani, et al., 2022)	Anxiety reduction	All ages (≥5y), both healthy and clinical populations	G4H (incl. commercial games used for health purposes)	RCT	n=22 / ranging between n=281 and n=1602 depending on the meta- analysis	levels between exergame and regular exercise interventions
(Abd- Alrazaq, Al- Jafar, et al., 2022)	Depressive symptom reduction	All ages and populations	G4H (incl. commercial games used for health purposes)	RCT	n=16 / ranging between n=333 and n=1229 depending on the meta- analysis	exergames and conventional exercises
Illness-self ma	anagement					
(Charlier et al., 2016)	Illness knowledge or self- management	Children and adolescents with chronic disease (no	G4H (incl. commercial games used	RCT	n=7 / n=823	 small, positive effects on knowledge and self-management behaviors

		age range reported)	for health purposes)			
Rehabilitation	<u>1</u>					
(Doumas et al., 2021)	Upper limb (UL) rehabilitation	Adults (≥18y) after a stroke	G4H designed for neuro- rehabilitation purposes	RCT	n=42 / n=1760	 small positive effects on function and moderate positive effects on participation in comparison to conventional therapies for UL function, the positive effect for G4H was retained at follow-up but was not superior to conventional therapies for UL activity and participation larger effects for games that integrated more neurorehabilitation principles
(Tăut et al., 2017)	Motor rehabilitation	Adults (≥18y) with brain damage	G4H (incl. commercial games used for health purposes)	RCT, controlled studies, case series designs	n=61/n=1627	 moderate positive effects larger effects in studies including more women; combining individual and group activities; using fantasy scenarios no difference in effects by age and game characteristics such as type, agent, amount of feedback; competition; social context: tailoring; characters; audiovisual background

Legend: RCT Randomized controlled trial; CBT Cognitive Behavioral Therapy; PA Physical Activity; BMI: Body Mass index; NR not reported

3.2.2. Potential negative side-effects and how to overcome these

Recreational game research reveals that games can also negatively affect health outcomes, but G4H may be used to counter these aversive influences. Extended sedentary digital game play has been linked to the onset of child obesity (Robinson et al., 2017) and Attention Deficit Hyperactivity Disorder-ADHD (Beyens et al., 2018), but may have positive effects on cognitive health (Bediou et al., 2018). Alternatively, using more active G4H can improve physical activity and may reduce negative effects of sedentary game play (Lu et al., 2013). Games with violent content have a small effect on increased aggression, especially among those already aggressive, with effects peaking among 13-14-year-olds (Burkhardt & Lenhard, 2022). Alternatively, games with prosocial content (e.g., role-playing games on helping behavior) can increase prosocial actions (Greitemeyer & Osswald, 2010). Even firstperson shooter games may increase prosocial action, presumably as these involve collaborative gameplay that can increase helping behavior (De Simone, 2013). Moreover, playing digital games may reduce sleep quality. Gameplay shortly before bedtime (e.g., 1 hour) in an intensive manner can cause arousal and cognitive alertness, and reduce sleep quantity and quality (Peracchia & Curcio, 2018). When designing G4H, play shortly before bedtime should be discouraged. Excessive play duration may have adverse effects. Sufficient exposure and repetition are often needed to achieve learning effects, but longer time spent gaming may increase the risk of problematic gaming (Mihara & Higuchi, 2017). However, exact cut-off points of the time spent gaming to be at risk are not available. One study indicated more than 5 hours per day may be problematic (Hellström et al., 2012). In sum, it is important to consider which game to use for what health purpose, how to design a game to avoid unwanted effects, and to understand its mechanisms of change.

3.3. How to design and evaluate G4H?

3.3.1. Design process models

Apart from theoretical models that aim to understand successful gameplay or behavior change (see 3.2), models exist that guide G4H design in a stepwise approach. Most models share as a founding principle that game design should be iterative, with active enduser and stakeholder involvement. Two well-known design models are the Intervention Mapping protocol (IMP), derived from health intervention literature, and the Scrum approach, derived from software development literature.

IMP states that development should be evidence- and theory-based, iterative, and involve end-users and stakeholders at every step of the process. It distinguishes six phases in the intervention design: 1) needs assessment; 2) creating change matrices that define the desired outcomes; 3) selecting intervention methods; 4) designing program material; 5) preparing adoption and implementation; and 6) the evaluation plan (Eldredge et al., 2016). This design process model is elaborately described, both in terms of theoretical foundation, project management and practical guidelines. Several G4H were developed with IMP (e.g., to change patients' attitudes towards antirheumatic drugs (Pouls et al., 2022); 'Friendly ATTAC' game against cyberbullying (DeSmet, Van Cleemput, et al., 2016); 'Balance It' for overweight prevention (Spook et al., 2015) and 'PR:Epare' for relationship and sexual education (Arnab et al., 2013)). IMP is aimed at health interventions in general, the intervention methods therefore do not consider the need for balancing education and engagement. A G4H-specific interpretation of IMP would be of added value. Some design process models, such as the

MECHA (G4H Mechanics, Experiences, and Change) process model (Robertson et al., 2021), largely follow IMP steps but consider the specificity of games in the method selection. MECHA is based on the Behaviour Change Wheel, but adds to the selection of BCTs, the identification of target players' experience and game mechanics (Robertson et al., 2021).

The SCRUM method was originally developed for commercial software design and consists of frequent iterative product testing, often with tests (called sprints) of a preliminary feature every 2 to 4 weeks (Schwaber & Sutherland, 2020). It deviates from the traditional approach in health sciences of a long, single development phase, followed by an RCT of the finished product. As the direction for the desired final product often becomes clearer once a prototype is available, this method aims to reduce the time until this first prototype is ready. Frequent testing allows for incremental improvements to the intervention, in a strong multidisciplinary collaboration and close connection to end users and stakeholders. Examples of G4H developed with SCRUM include games for COVID-19 prevention (Gaspar et al., 2020) and motor rehabilitation therapy (Amengual Alcover et al., 2018).

3.3.2. Participatory design

Involving end-users and stakeholders is crucial to ensure the game fits the target group's preferences and needs. When the intervention fits the target group's needs and preferences, it is more likely to be engaging, adopted by end users and disseminated by stakeholders (Eldredge et al., 2016). Participatory design encompasses not only listening to the target group when designing the game but actively involving them as a full team member. Several terms are used interchangeably for user involvement, such as co-creation, community-based participatory design, user-centered design, and collaborative design, but these often vary in intensity of user involvement, and a uniform definition appears to be lacking. The target group can be involved in game design as users, testers, informants, or co-designers. As users or testers, they are observed during play of a game version developed without their input and are asked to rate its acceptability and/or usability. This is not considered participatory design as users had no direct input in design choices. When the target group takes on the role of informant, they are asked for input and feedback, whereas as co-designer, they are equal partners in the design. There are varying degrees of associations of participatory design with effectiveness: for co-design to be effective, users should be involved in deciding the challenge or dynamics, and not merely the looks and story of the game. Informant design may be more effective than full-blown co-design (DeSmet, Thompson, et al., 2016).

3.3.3. Resources

The development of G4H usually requires a multidisciplinary team, including health behavior scientists, animation and graphic design specialists, programmers, game designers, story writers, user experience experts, end users and stakeholders. This can make G4H development costly in terms of time and resources. An expert roundtable in digital health interventions proposed that building and maintaining relationships; creating shared plans and agreements; supporting culture shifts; and investment in people who can bridge disciplines are potential solutions to facilitate multidisciplinary collaborations (Perski et al., 2022). Creative ways of developing less resource-intensive games include re-using existing games or their components (e.g., open-source software, see 'Diabetic Mario' for an adaptation of an open-source game into a G4H (Baghaei et al., 2016)) or developing 'indie games' (by small independent developers as opposed to big budget commercial companies).

3.3.4. G4H impact evaluation

For an intervention to have public health impact, it needs to not only demonstrate effectiveness, but also needs to reach and be adopted by users, implemented by stakeholders, and maintained for as long as exposure is needed to achieve effects. These elements have been integrated in the RE-AIM model (reach, effectiveness, adoption, implementation, and maintenance). To the best of our knowledge, no overview of the RE-AIM qualities of G4H exists. A quick search of the literature, however, shows the focus of G4H evaluations is mainly on efficacy (i.e., change in outcomes under identified/controlled circumstances) and less on RE-AIM elements.

To create G4H that can maximize reach, effectiveness, adoption, implementation and maintenance, interventions are ideally tested in several phases. During development, formative research or participatory development is recommended to assess whether the intervention fits the target groups' needs and preferences. To design with the end use in mind, Contextual Inquiry (Beyer & Holtzblatt, 1999) can be used in formative research to anticipate the context in which users would play the game and how they will interact with the game in daily life. An early version is usually tested in an 'Alpha' testing phase that tests the basic principles, sometimes with team members rather than end-users; and a revised version in a 'Beta' testing phase with end-users to identify issues in game performance. Mixedmethod research, that integrates quantitative (e.g., user engagement scales, game analytics) and qualitative research (e.g. interviews, open-ended questions), can be useful in early testing rounds, to indicate how users evaluate the game, why users evaluate it as such and how it can be improved (e.g., (Schwarz et al., 2019). An experimental study of the finalized tool is needed to demonstrate that the game changes the targeted outcomes (efficacy trial in lab conditions, or effectiveness trial under real-life circumstances). In a final stage, research investigates the success of the large roll-out of the program (dissemination trial), by assessing how many people know and use the game, for how long, and whether they use it as intended.

4. Dissemination and implementation: getting G4H into routine practice

So far, little research has examined dissemination (i.e., the targeted distribution of G4H to its main audience) and implementation (i.e., the methods to promote the uptake of G4H by its target group and into routine practice) of G4H. An overview of what facilitates or hinders dissemination and implementation (D&I) in G4H is to our knowledge not yet available. The KiVA game against bullying at school can be considered a success story in D&I as it is used countrywide in Finland and is also used in parts of 14 other countries (Sainio et al., 2020). It highlights success factors for sustained implementation such as perceived effectiveness, adaptability to the context, fit with the target group's needs, ongoing support from the program designer, socioeconomic and political support, and leadership at the implementer side. The game is, however, integrated in a larger whole-school program, and the implementation success may be due to other components than the game. Indeed, having played the game did not have a significant effect on the sustained implementation of the overall intervention (Sainio et al., 2020).

Based on anecdotal evidence from other games, engaging the implementer early on and using up-to-date programming languages may facilitate D&I. For example, the Friendly ATTAC game against cyberbullying investigated the collaboration with a publisher to expand, update, and distribute the game to schools after it was proven effective (DeSmet, Van Cleemput, et

al., 2016). But after a thorough exploration, the publisher considered the remaining costs as prohibitive (A. DeSmet, personal communication, 17th July, 2022). The Plan-It Commander to self-manage ADHD was developed in collaboration with a pharmaceutical company (Bul et al., 2015), and its D&I was taken over by a social enterprise. However, the software in which it was programmed had become outdated and funds were lacking to transfer it to a new platform (K. Bul, personal communication, 17th July, 2022). An additional challenge lies in the recognition of G4H as medical devices. Currently, digital tools for health promotion or illness self-management without treatment suggestions are not considered medical devices by the US Food & Drug Administration, but tools to support disease prevention and treatment may be, if they could pose a risk to patients' safety when dysfunctional (US Food and Drug Administration, 2019). An example of a G4H recently approved as medical device is EndeavorRx for ADHD therapy, based on the Neuroracer game for cognitive training in the elderly (Anguera et al., 2013). Existing guidelines for the use of health apps in prevention and treatment (Henson et al., 2019) may help to prepare the recognition of G4H as medical devices.

5. Conclusions and future directions for research and practice

G4H, despite being relatively recent, have shown some effectiveness in a wide variety of populations and health domains. Given their high heterogeneity in effectiveness, more rigorous experimental research with sufficiently large sample sizes is needed to allow testing moderators and mediators of effects, in specific subpopulations, indicating what works for whom. Essential in G4H effectiveness is a good balance between educational and engaging elements. G4H are generally based on health behavior change and engagement theories, but research is needed to understand and apply play theories that translate how game elements can deliver an engaging experience. The use of play theories is currently limited in G4H. Ontologies can further support insights in the relations between the game's elements and its engaging and learning experience. Ontologies define components and interrelations and go beyond the current focus in G4H on taxonomies, that only describe features (e.g., rewards, narratives) or game types (e.g., role-playing games), but not how these relate to game engagement or effectiveness. To our knowledge, no G4H ontology exists that describes such relations. An existing ontology for serious game design defines technical game components, but does not describe the relation with learning or engagement components (Tang & Hanneghan, 2011). Involving experts from several disciplines in G4H when developing an ontology is recommended to crystalize all connections, e.g., via consensus exercises, online feedback or workshops (Norris et al., 2021), and may support the further refinement and use of play theories.

Process design models that are theory- and evidence-based can guide game development but require some adaptation to specifically apply to G4H. Highly frequent prototype testing and user involvement may be a better approach to the design of effective G4H than the classical approach of a long development phase followed by a single efficacy trial. As the design and implementation of G4H typically bridges multiple fields, an approach is needed that has the implementation in mind at the start of the development, led by a skilled project manager who can promote a common vision among all those involved.

Unfortunately, to our knowledge, few G4H have been widely disseminated; only limited research is available to guide this important aspect of G4H. Hybrid effectiveness-implementation designs provide a framework for including key stakeholders of potential D&I

channels throughout design, development, and evaluation (Curran et al., 2012). An advantage of these designs is that they can used at any stage of evaluation. By considering D&I throughout design, development, and evaluation, the time to dissemination in real-world settings can be shortened, thus getting effective G4H in the hands of people who can benefit from them (Landes et al., 2020).

While to the best of our knowledge not many G4Hs have yet received clearance as medical devices, a few, covering different aspects of health, have been approved. Aside from EndeavorRx, which received approval fast partly due to the pandemic-prompted urgency for access to psychiatric treatment, other FDA-cleared G4H include RelieVRx by AppliedVR, a home-based immersive virtual reality treatment for adult chronic lower back pain; Luminopia's One virtual reality neuro-visual therapy game for children with amblyopia; and MindMotion G0 by MindMaze, a mobile game-based neurorehabilitation therapy. This trend towards developing G4Hs as medical devices is increasingly internationalized (e.g., the Switzerland-based MindMotion Go has been trialed across the United Kingdom, Italy, and Germany (Wiskerke et al., 2022)). This internationalization is likely to help establish more rigorous clinical trial evidence for acceptance of G4H as medical devices. To conclude, G4H are a valuable tool for health professionals, with important challenges ahead in the field of evidence-based tailoring (what works for whom), theories (understanding what leads to higher engagement and learning effects), and real-life implementation (sustained use and use in the medical field).

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