Design and Effectiveness of a serious Game for Children with ADHD

KIM C.M. BUL

PLAN+IT COMMANDER

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DESIGN AND EFFECTIVENESS OF A SERIOUS GAME FOR CHILDREN WITH ADHD

Ontwerp en effectiviteit van een serious game voor kinderen met ADHD

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CONTENTS

ABBREVIATIONS

ADHD	Attention Deficit Hyperactivity Disorder
BRIEF	Behavior Rating Inventory of Executive Function
CBT	Cognitive Behaviour Therapy
CI	Confidence Interval
CD	Conduct Disorder
DBDRS	Disruptive Behavior Disorder Rating Scale
D-KEFS	Delis-Kaplan Executive Function System
DSM-IV-TR	Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision
EFs	Executive Functions
ES	Effect Size
IATQ	It's About Time Questionnaire
IQ	Intelligent Quotient
Kiddie-SADS	Kiddie-Schedule for Affective Disorders and Schizophrenia
LS	Least Squares
MESSY	Matson Evaluation of Social Skills with Youngsters
M.A.	Master of Arts
MTA	Multimodal Treatment of ADHD
NA	Not Applicable
NPC	Non-Playable Character
ODD	Oppositional Defiant Disorder
RCT	Randomised Controlled Trial
SCST	Social Cognitive Skills Test
SDQ	Strengths and Difficulties Questionnaire
SE	Standard Error
SG	Serious Game
SSRS	Social Skills Rating System
TAU	Treatment As Usual
TAUx	Treatment As Usual cross-over
VT	Virtual Twins
WISC	Wechsler Intelligence Scale for Children

Chapter 1

General Introduction

Based on:

Bul, K. C. M., De Ruijter, A. M., Van Wingerden, M., & Maras, A. (2013). Is e-health behandeling binnen de kinder- en jeugdpsychiatrie effectief? Een systematische review van Randomised Controlled Trials. [Is e-health effective within child- and adolescent psychiatry? A systematic review of Randomised Controlled Trials]. *Tijdschrift voor Gezondheidswetenschappen*, *91*, 437-447.

Mental healthcare conditions account for 13% of the global disease burden (Cheek et al., 2015). One of the most common mental disorders in children and adolescents is Attention Deficit Hyperactivity Disorder (ADHD). ADHD is a chronic mental health disorder affecting 3 to 5% of children, adolescents and their families worldwide (Polanczyk, Willcutt, Salum, Kieling, & Rohde, 2014). Core symptoms include difficulty staying focused and paying attention, difficulty controlling behaviour, and hyperactivity. ADHD treatment, including medication, behavioural therapy or a combination of treatments, focuses on reducing these ADHD core symptoms (MTA Cooperative Group, 1999a).

However, one of the main limitations of these interventions is a lack of engagement, alongside a lack of time and difficulties in accessing mental healthcare provisions for children and adolescents (Cheek et al., 2015). There appears to be a major gap between treatment needs of the consumers and the availability of service provision. For example, in high income countries 35% to 50% of the people receive no treatment for severe mental disorders and in low income countries this rate is even higher with 76% to 85% of people not getting the treatment that they need (World Health Organization, 2013). One of the reasons for this is that not all potential patients favour or can access existing modes of treatment delivery. eHealth, the application of information- and communication technology to support or improve healthcare, offers possibilities to close this gap between treatment needs of individuals with mental health conditions and provision of care. eHealth improves accessibility of mental healthcare services and can increase patient motivation and treatment adherence (Frutos-Pascual, Zapirain, & Zorrilla, 2014; Kato, Cole, Bradlyn, & Pollock, 2008; Riper, van Ballengooijen, Kooistra, & de Donker, 2013). Furthermore, it is suggested that eHealth can address one of the biggest challenges that may be faced by the mental healthcare sector, namely the costs of service delivery (Riper et al., 2013), because once developed this care is easy accessible and costs less compared to regular treatment provision. Moreover, it provides patients with greater autonomy as they can access the application anywhere, at any time. This fits into the World Health Organization Mental Health Action Plan 2013-2020, which promotes the development and use of accessible user-driven non-pharmacological intervention options for children and adolescents (Cheek et al., 2015; Coleman, Austin, Brach, & Wagner, 2009; World Health Organization, 2013).

In this dissertation we focus on the potential value of serious gaming within the broader context of eMental health. We explore whether a serious game has potential to improve daily life behaviour skills of children with ADHD. Describing the design process, evaluating its effects and understanding for which subgroups this intervention tool is most effective contributes to more evidence-based knowledge in ADHD research and may have important clinical implications for treatment.

EMENTAL HEALTH WITHIN CHILD AND ADOLESCENT PSYCHIATRY

eHealth within mental healthcare (often referred to as eMental health) creates the possibility to receive information confidentially and anonymously, offers 24-hour availability of information and support, and convenience of access. Further, eMental health treatments can be personalized and interactive by using innovative technologies. One of the main arguments to use eMental health over more traditional methods or interventions is how ubiquitous and familiar technology is for young people, making these applications a comfortable and potentially enjoyable situation (Wong et al., 2007). As such, a growing number of eMental health applications have been developed within child- and adolescent psychiatry (Bul, de Ruijter, van Wingerden, & Maras, 2013). However, as for example mentioned by the review of Riper and colleagues (2013), there is a lack of research into the effectiveness and efficacy of these applications. These effectiveness evaluations may lack behind because of lack of funds or expertise available to conduct such evaluation or purely because of a mainly commercial interest in developing eMental health tools. Research in child- and adolescent psychiatry on the effectiveness of eMental health lacks behind compared to research in adult psychiatry. For example, ample research among adults demonstrates that online psychotherapy [based on Cognitive Behaviour Therapy (CBT) principles] is effective in treating anxiety and mood disorders (Andersson & Cuijpers, 2009; Cuijpers et al., 2009). So far, research in child- and adolescent psychiatry has been mainly focused on the effectiveness of three sub domains of eMental health, namely telepsychiatry, internet therapy and serious gaming that will be shortly addressed below.

Telepsychiatry

Telepsychiatry has been defined as the use of videoconference techniques to deliver mental healthcare services and psychiatric care at a distance. This is especially common in the United States to reach rural areas and urban facilities. Communication is set up through a computer and telecommunication network, in which both the patient as well as the clinician have access to audio- and visual possibilities (Gastmans & Wijnsberghe, 2011; Myers & Cain, 2008). This communication method implies that interaction between clinician and patient is synchronic; there is a minimum amount of reaction time between the patient and clinician. Research on the effectiveness of telepsychiatry for children and adolescents is very limited. Although the use of videoconferencing has been around for over 40 years, most of the clinical literature has been focused on adult patients, related to project descriptions, case reports, satisfaction surveys, or user-experiences (Diamond & Bloch, 2010). There is only a small amount of randomised controlled trials (RCTs) available examining the effectiveness of telepsychiatry to deliver care at a distance for patients suffering from depression, tics or obsessive compulsive disorder

(Bul et al., 2013). This often consists of individual sessions of CBT (Bul et al., 2013). On the basis of these studies it appears that telepsychiatry is feasible and at least as effective as face-to-face treatment. Patients report high levels of satisfaction. Although it seems a reasonable alternative for situations in which it is difficult to deliver face-to-face therapy, more research is needed to establish its clinical benefits.

Internet therapy

The Internet has become an important source of healthcare and medical information. There is a growing number of sites that are delivering (mental) healthcare interventions that patients can use on their own or in combination with face-to-face treatment (Ritterband & Palermo, 2012). A combination of face-to-face treatment and Internet therapy is called blended therapy (Bul et al., 2013). Internet therapy is used to describe the process of interaction between therapist and patient, in which the clinician and patient are situated in different locations and communicate with each other through the Internet (often websites; Manhal-Baugus, 2001). In contrast to telepsychiatry, the interaction between patient and clinicians is not synchronic; this means that there is a longer period of reaction time between the patient and clinician. This fits into the role the therapist has, namely a facilitating and supporting role to increase patient's self-management (Notenboom, Blankers, Goudriaan, & Groot, 2012). These Internet interventions are often based on existing effective behavioural treatments that have been operationalised and transformed for Internet delivery (Ritterband & Palermo, 2012). It is used to offer CBT and self-help programs for example to treat pain, fear and eating disorders thereby improving knowledge, cognitions and training behaviour. There are some randomised controlled studies demonstrating that Internet therapy is as effective as face-to-face treatment or in some cases even superior (Bul et al., 2013). More research is needed to examine its long-term effects. Internet interventions show great promise and may even have some significant advantages over traditional face-to-face therapy. It also has great potential for wide scale dissemination as treatment could be provided to a great number of patients (Ritterband & Palermo, 2012). However, empirical support and validation remains necessary, especially in the field of child- and adolescent psychiatry.

Serious gaming

Video games have been most often used as entertainment. However, there is a growing interest in games as a means to educate and train people (Durkin, 2010). Serious Games are games that are focused on transferring knowledge, learning skills and/or changing behaviour in a playful way within an engaging digital game environment (Annetta, 2010). Offering existing training programs with game elements is defined as gamification (Riper et al., 2013). Learning through play encourages faster, more implicit learning (Prensky, 2005), and digital games in particular have been argued to be especially motivating, encouraging a greater level of engagement than other activities (Gee, 2003; Graesser, Chipman, Leeming, & Biedenbach, 2009; Prensky, 2007). Existing research argues that serious games are able to encourage learning through three sources, namely immersion, flow and by meeting individual's needs for mastery, fantasy, challenge and connectedness (Annetta, 2010; Boyle, Conolly, Hainey, & Boyle, 2012; DeSmet et al., 2014; Kapp, 2012; Lu, Baranowski, Thompson, & Buday, 2012). Immersion allows for the player to be engrossed in the game-play and to develop a sense that the proposed experiences are personally relevant, whereas flow creates a sense of concentration through a balance between the challenges presented and the skills of the player, keeping them engaged and interested (Paras & Bizzochhi, 2005).

Children with ADHD are characterised by having more difficulties at school making schedules, by having difficulties to finish assignments on time, problems with executing complex planning tasks and organizing material needed for assignments, remembering task instructions, setting priorities, and making friends (Abikoff et al., 2009; 2013; Barkley, 2006). These executive functions (EFs) and social problems not only affect daily life for the children and their families, but they also predict a poor prognosis of ADHD even into adulthood (Barkley, 2006). Without intervention, functional impairments in these areas endure and escalate into adolescence and adulthood (Abikoff et al., 2004; 2009; 2013; Barkley, 2006; Langberg, Epstein, Becker, Girio-Herrare, & Vaughn, 2012; Storebø, Skoog, Damm, Thomsen, Simonsen, & Gluud, 2011). Motivation appears to play an important role in explaining the problems children with ADHD encounter in daily life (Haenlein & Caul, 1987; Sagvolden, Johansen, Aase, & Russell, 2005;Sergeant, Oosterlaan, & Van der Meere, 1999; Sonuga-Barke, 2003). Recently, studies have found that gaming can optimise motivation and training effects in children with ADHD (Dovis, Van der Oord, Wiers, & Prins, 2012; Prins, Dovis, Ponsioen, Ten Brink, & Van der Oord, 2011). While these children might be less interested in participating in traditional interventions, serious games are seen as a fun activity, and they therefore start the intervention expecting to enjoy it (Sim, McFarlane, & Read, 2006). Offering treatment with game elements as an adjunct to current treatment repertoire can prove an ideal medium for treatment delivery, especially for patients within child- and adolescent psychiatry such as school-aged children with ADHD (Ramdoss et al., 2012; Van der Oord, 2012; Van der Oord, Ponsioen, Geurts, Ten Brink, & Prins, 2014).

SERIOUS GAMING AND ADHD

One of the groups for which serious games could be specifically appealing and effective is for children and adolescents with ADHD. It is well known that children with ADHD experience motivation deficits and are less stimulated by reinforcement than typically developing children (possibly due to a dopaminergic deficit) and therefore, under normal conditions, are not motivated enough to function on the same level compared to their typically developing peers (Haenlein & Caul, 1987; Sagvolden et al., 2005; Sergeant et al., 1999; Sonuga-Barke, 2003). Because game approaches help to balance motivating and learning elements and to integrate game goals and behavioural/cognitive challenges, they have the potential to keep these children more motivated and positively engaged in therapy processes. Games are very stimulating and give immediate reinforcement on behaviour (Van der Oord, 2012). Also, despite their poor attention span, distractibility, and difficulty staying on task, children with ADHD often show sustained concentration and engagement when playing digital games (Barkley, 2006). This implies that as long as the game presents adequate challenges, children are willing to spend more time on them than they would do by offering traditional learning methods (Bourgonjon, Valcke, Soetaert, & Schellens, 2010; Squire, 2005).

Therapeutic goals that are pursued in the context of an engaging game environment thus may present an opportunity to improve behavioural learning and outcomes in this population. Although research on the effectiveness of gaming approaches to address daily life functioning of children is limited, several controlled trials of serious games have shown promise of impacting "real world" behaviours (e.g., DeSmet et al., 2014 in populations with varying age and gender; Institute of Digital Media and Child Development Working Group on Games for Health et al., 2016). We developed a serious game intervention (called "Plan-It Commander") for children with ADHD with the aim of teaching them behavioural strategies and reinforcing daily life skills. To our knowledge, a serious game designed to enhance behavioural strategies of children with ADHD to improve their daily life functioning has not been empirically evaluated yet.

PROJECT HEALSEEKER

Janssen Pharmaceuticals (a subsidiary company of Johnson & Johnson) initiated the project HealSeeker. This project involved several partner organizations that collaborated in the game development and effectiveness research. The project served as a 'proof-of-concept' to examine how serious games (or game-based interventions) could contribute to patient's daily life functioning. In this project interdisciplinary meetings were organized to exchange and integrate clinical, research, technical and game design knowledge and experiences. The serious game developer company was mainly responsible for designing a game that was educational, attractive and motivating. Furthermore, they took care of the technical implementation and maintenance of the game. In this development process a community board of parents as well as healthcare professionals were involved. Based on their information on deficits of children with ADHD, frequent problems encountered at home and gaps in the literature [i.e., several computerized working memory training formats (Klingberg et al., 2005) were available but none focusing on EFs and social behaviour skills] the learning goals of the game (e.g., improving time management, planning/organizing, and prosocial skills) were proposed. Frequent interactive sessions among the healthcare professionals, researchers, and game designers took place to optimise the link between game design elements and behaviour changes principles. Usability research results from children with ADHD were evaluated and incorporated in this design process. Parallel to testing the first prototype in a small-scale pilot study (see *Chapter 3*), the game was further developed and extended. This resulted in a final version of the game that has been tested for effectiveness in a RCT (see *Chapter 4* and *5*). This project contributes to more knowledge about developing and testing a serious game for ADHD (a specific subgroup within mental healthcare) and makes us aware of the priority of performing effectiveness research, dissemination of the findings and build on them with multidisciplinary partnerships. Furthermore, it fits into the research agenda formulated by the Institute of Digital Media and Child Development Working Group on Games for Health and colleagues (2016) in which the use of adequately powered randomised clinical trials is promoted.

"PLAN-IT COMMANDER"

For a game-based intervention to be successful, it is apparent that only encouraging immersion, flow and mastery is not sufficient and that the game needs to be clear in what behaviours it is targeting and how. The serious game developed during project HealSeeker is called "Plan-It Commander" and is focused on promoting behavioural strategies in domains of daily life functioning such as time management, planning/organizing, and prosocial (i.e., cooperation) skills that have shown to be problematic for school-aged children with ADHD (Abikoff et al., 2004; 2009; 2013; Barkley, 2006; Langberg et al., 2012; Storebø et al., 2011). "Plan-It Commander" is offered as an additional intervention to treatment as usual (TAU) and can be accessed through an online portal at home. This improves accessibility and is expected to provide patients with greater autonomy (Cheek et al., 2015; World Health Organization, 2013). With the aim of achieving behaviour change among end-users, we translated these learning goals into suitable game components. Hereby we based ourselves on relevant psychological theories, namely the Self-Regulation Model (Cameron & Leventhal, 1995), Social Cognitive Theory (Bandura, 1986) and Learning Theory (Barkley, 2006; Kato, 2008). The current intervention is unique in its approach because it differs from existing computerized neurocognitive training formats. Instead of requiring the repetition of executive function tasks normally presented in neurocognitive training format for children with ADHD, "Plan-It Commander" promotes the use of behavioural strategies via a computer game with integrated therapeutic elements (e.g., reinforcement, immediate performance feedback from a mentor, goal setting through missions, modeling, social support, and comparison). The behavioural training aims to improve daily life functioning of children with ADHD (see *Chapter 2* for a more detailed description). Our approach is in line with the analysis of Lewis (2007) about the role of serious games in teaching health related knowledge and skills in changing behaviour. More specifically, these results demonstrate that it is important to consider the theoretical model underlying the design, the rationales for the skills or behaviour taught and finally what the measurable outcomes are and how they map onto the "real world".

THIS DISSERTATION

Computerized training programs currently available for ADHD have been limited in their ability to demonstrate real -life behaviour change. Therefore, we developed a new serious game (called "Plan-It Commander") that was specifically designed to promote behavioural strategies in domains of daily life functioning such as time management, planning/organizing, and prosocial (i.e., cooperation) skills that are known to be problematic for children with ADHD. The translation of learning goals into game-play seems to be specifically challenging here. Next to describing its development (*Chapter 2*) we also tested the usability of a first prototype of "Plan-It Commander" (*Chapter 3*). Performing a pilot study is an important step during the development process as it gives indications for feasibility, data that could be used to improve game design and support further game design decisions. Furthermore, we tested the effectiveness of the final game version in a large clinical ADHD sample on behavioural (*Chapter 4*) and neurocognitive outcomes (*Chapter 5*). Finally, we explored potential subgroups for whom the serious game may be specifically fruitful (*Chapter 6*). Especially, in serious game research there is a lack of studies on moderators. This may help determine the relevance of serious gaming for an individual child with ADHD (Boyer, 2016; Institute of Digital Media and Child Development Working Group on Games for Healthet et al., 2016).

The general research aims of this dissertation were three-fold:

1. To describe the design process and first usability results of the serious game "Plan-It Commander".
2. To explore the effectiveness of "Plan-It Commander" on behavioural and neurocognitive outcomes.

3. To describe moderating variables that identify subgroups for whom "Plan-It Commander" is most effective.

Chapters 2 and *3* describe the development process and user satisfaction of "Plan-It Commander's" first prototype among children with ADHD. *Chapter 4* and *5* present the results of a RCT on the effectiveness of "Plan-It Commander" on behavioural and neurocognitive outcomes in children with ADHD. *Chapter 6* reports results of a moderator analysis to explore which subgroups of children with ADHD benefit the most from the intervention. *Chapter 7* compromises the discussion of all these results.

The RCT was approved by the Erasmus (Dutch; MEC-2012-539) and Leuven (Belgian) Medical Ethical Committees. The study is registered under the International Standard Randomized Controlled Trial Number (ISRCTN): 62056259.

Chapter 2

Development and user satisfaction of ‘‘Plan-It Commander’’, a serious game for children with ADHD

Based on:

Bul, K. C. M., Franken, I. H. A., Van der Oord, S., Kato, P. M., Danckaerts, M., Vreeke, L. J.,…Maras, A. (2015). Development and user satisfaction of "Plan-It Commander", a serious game for children with ADHD. *Games for Health Journal*, *4,* 502-512.

ABSTRACT

The need for engaging treatment approaches within mental healthcare has led to the application of gaming approaches to existing behavioural training programs (i.e., gamification). Because children with Attention Deficit Hyperactivity Disorder (ADHD) tend to have fewer problems with concentration and engagement when playing digital games, applying game technologies and design approaches to complement treatment may be a useful means to engage this population in their treatment. Unfortunately, gamified training programs currently available for ADHD have been limited in their ability to demonstrate in-game behaviour skills that generalise to daily life situations. Therefore, we developed a new serious game (called "Plan-It Commander") that was specifically designed to promote behavioural strategies in domains of daily life functioning such as time management, planning/organizing, and prosocial (i.e., cooperation) skills that are known to be problematic for children with ADHD. An interdisciplinary team contributed to the development of the game. The game's content and approach are based on psychological principles from the Self-Regulation Model, Social Cognitive Theory, and Learning Theory. In this chapter, game development and the scientific background of the behavioural approach are described, as well as results of a survey (n = 42) to gather user feedback on the first prototype of the game. The findings suggest that participants were satisfied with this game and provided the basis for further development and research to the game. Implications for developing serious games and applying user feedback in game development are discussed.

INTRODUCTION

Digital approaches have been increasingly applied to support and improve primary care processes in mental healthcare and are often referred to as eMental health (Riper, Andersson, Christensen, Cuijpers, Lange, & Eysenbach, 2010; Shalini & Carol, 2014). Clinicians and educators are interested in applying game technologies and game design approaches (e.g., serious games) because of their potential to increase patient engagement with existing behavioural training programs (Fernandez-Aranda, Jimenez, & Santamaria, 2012). Game elements that increase patient engagement in therapeutic activities have the potential to increase the effectiveness of neurocognitive training and behavioural learning in different domains of functioning for patients being treated in mental healthcare (Jaeggi, Buschkuehl, Shah, & Jonides, 2014; Parkin, 2000; Van der Oord et al., 2014). Game design and approaches are seen as a natural tool to make existing training and therapeutic programs more appealing to young patients with Attention Deficit Hyperactivity Disorder (ADHD) for several reasons. First, it is well known that children with ADHD experience motivation deficits and react differently to rewards compared with typically developing children (Luman, Oosterlaan, & Sergeant, 2005; Sagvolden, Aase, Zeiner, & Berger, 1988). Because game approaches help to balance motivating and learning elements and to integrate game goals and behavioural/cognitive challenges, they have the potential to keep these children more motivated and positively engaged in therapy processes (Emes, 1997; Tannock, 1997; Van der Oord, 2012). Also, despite their poor attention span, distractibility, and difficulty staying on task, children with ADHD often show sustained concentration and engagement when playing digital games (Barkley, 2006). Therapeutic goals that are pursued in the context of an engaging game environment thus present the opportunity to improve behavioural learning and outcomes in this population.

Large numbers of gamified training programs for ADHD have been designed to improve working memory and executive functioning, thereby addressing specific neurocognitive deficits (Chacko et al., 2014; Melby-Lervåg & Hulme, 2012; Rapport, Orban, Kofler, & Friedman, 2013; Shipstead, Redick, & Engle, 2012). Although these programs show some evidence for short-term effects on targeted working memory outcomes, as measured by neurocognitive tests that are similar to the ones presented in the games, they have not shown compelling evidence that these effects generalise beyond neurocognitive outcomes to important domains of functioning in the everyday lives of children with ADHD (Chacko et al., 2014; Melby-Lervåg & Hulme, 2012; Rapport et al., 2013; Shipstead et al., 2012). The core symptoms of inattention, impulsivity and hyperactivity among children with ADHD are related to their difficulties in executive and social functioning in their daily lives. These problems include difficulties managing time, keeping deadlines, planning/organizing schoolwork, and making friends (Abikoff et al., 2009; Conners, 2003; Sonuga-Barke, Bitsakou, & Thompson, 2010; Storebø et al., 2011). These executive functioning and social problems not only affect daily life for the children and their families, but they also predict a poor prognosis of ADHD even into adulthood (Conners, 2003). Gamified interventions for children with ADHD that address the current difficulties in daily life functioning thus have the potential to tackle difficulties not only in the short term but in the long term as well. Although the research on gaming approaches to addressing daily life functioning of children is limited, several controlled trials of serious games developed for other patient groups have been shown promise of impacting "real world" behaviours (DeSmet et al., 2014).

In addition to the importance of designing a serious game intervention to impact important outcomes that support their functioning in daily life, the intervention itself needs to be designed to be effective and engaging in order to ultimately have an impact. Previous studies provided evidence that gamified interventions based on theoretical concepts tend to be more effective than those without a theoretical framework (Baranowksi, Buday, Thompson, & Baranowksi, 2008). Integrating appropriate behavioural theories into the design of the game is an ongoing challenge for serious game designers but is a key to its ultimate success (Kato, 2012). The focus on integrating behaviour change theories and therapeutic content in serious game design needs to be balanced by technology acceptance through the target audience of children with ADHD and their parents who will likely play a key role in accessing, facilitating, and monitoring the use of the serious games technology. A broad body of evidence has shown that the success of information technologies, such as serious games, depends on user beliefs and attitudes about the technology (e.g., "The game performs reliably, and it is easy to interact with this game"), as well as their behavioural beliefs and attitudes about using the system (e.g., "This game helps me understand how I can plan and organize my time") (Wixom & Todd, 2005). Gathering this information is an important part of the development process to provide an intermediate evaluation of design decisions and a basis for major or minor design decisions to promote the success of the product (Markopoulos & Bekker, 2003).

In this study, we describe the development process of a serious game we developed for children with ADHD that promotes behavioural strategies in important domains of daily life functioning, namely, time management, planning/organizing, and prosocial (i.e., cooperation) skills. We also present results of a user satisfaction survey we conducted on a pilot version of the game.

THEORETICAL BASIS FOR THE SERIOUS GAME INTERVENTION

We developed a serious game called "Plan-It Commander" for a target population of children with ADHD 8–12 years of age. The therapeutic behavioural learning objectives of the serious game were to promote the use of strategies in important domains of daily life functioning, namely, time management, planning/organizing, and prosocial (i.e., cooperation) skills. With the aim of achieving behaviour change among end-users, we translated these learning goals into suitable game components. Hereby we based ourselves on relevant psychological theories, namely the Self-Regulation Model (Cameron & Leventhal, 1995), Social Cognitive Theory (Bandura, 1986) and Learning Theory (Barkley, 2006; Kato et al., 2008).

The Self-Regulation Model of health and illness behaviour focuses on how individuals direct and monitor their activities and emotions in order to attain their goals (Barkley, 2006; Cameron & Leventhal, 1995). Children with ADHD often lack self-regulation, and as a consequence they master skills at a lower level. In addition, they feel incompetent about their performance and think that they cannot cope with situations in which these skills have to be used. The serious game contained components that helped them direct and monitor their activities (e.g., predict how long it would take them to complete a "mission"), regulate their emotions (e.g., slow down to help other characters in the game in order to "win"), and practice as many times as needed in order to reach mastery (e.g., no overt or explicit penalties for "mission failure"). Components such as these were explicitly built into the system to provide a safe environment to practice skills that could be applied in their daily life.

The serious game also included elements from Social Cognitive Theory (Bandura, 1986). According to this theory, children's learning is influenced by interactions among the environment, personal factors, and behaviour. The environment supports mastery of target behaviours by providing models for target behaviours and positive support for behaviour change. This theory was translated into the game by offering children with ADHD structured behavioural goals to reach in the game (e.g., collect minerals with the time that you estimate it will take to complete the task). These goals were presented in an environment that included a virtual mentor figure who was a model of positive behaviour (e.g., polite in social interactions) and also provided emotional encouragement and positive feedback for success and multiple opportunities to practice behaviours to reach mastery. The game environment also included a social community in which peers (other children with ADHD) could interact with each other. Players could also directly or indirectly benefit from positive reinforcements they observed others received or that they received directly as a result of their own successful efforts to reach goals in the game. The concepts of vicarious learning, emotional support, and provision of mastery experiences, which are key components of behaviour change in Social Cognitive Theory (Bandura, 1986), were implemented in the game design.

Lastly, principles of Learning Theory were incorporated in the serious game. Learning Theories are based on the general idea that individuals learn behaviour through behavioural consequences and positive reinforcement (Barkley, 2006; Beale, 2011; Kato et al., 2008). Children with ADHD are less sensitive to negative feedback and learn the most through repetitive positive feedback. In this game we immediately reward positive behaviour, based on this principle. As a result, extensive practice of desired behaviours is stimulated.

COLLABORATIVE GAME DEVELOPMENT

Interdisciplinary collaboration is a key factor in developing a serious (either educative or therapeutic) game, as different expertise from various areas (clinical, research, technical and game design) needs to be integrated (Kato, 2012). Therefore, different parties (i.e., sponsor, game development company, healthcare professionals, researchers, and parents and children with ADHD) were involved in the development of the "Plan-It Commander" game. In collaboration with a community board of parents, the learning goals (e.g., improving time management, planning/organizing, and prosocial skills) were proposed by healthcare professionals based on scientific literature and practical clinical experience. Furthermore, these professionals provided input on the game goals and advised the game designers on how to give feedback to children with ADHD. Frequent interactive sessions among the behaviour experts, researchers, and game designers took place to optimise the link between game elements and the principles of behavioural intervention, allowing game designers to gain additional expertise and knowledge to develop an attractive game that "works" for this target population (Kato, 2012). Results of important deliverables and milestones were presented to the advisory board, consisting of professionals familiar with the content of gaming, research, and clinical practice. Researchers were involved to design and set up research trajectories to test game usability and effectiveness. After each prototype, usability tests were iteratively performed to examine whether children liked the game, as well as understood how to use it and navigate within the game. These user data were evaluated and incorporated in the design process. Parallel to testing the first prototype in a pilot study, the game was further developed and extended resulting in the final version of the game described in this chapter. The stages of game development and evaluation are illustrated in Figure 1.

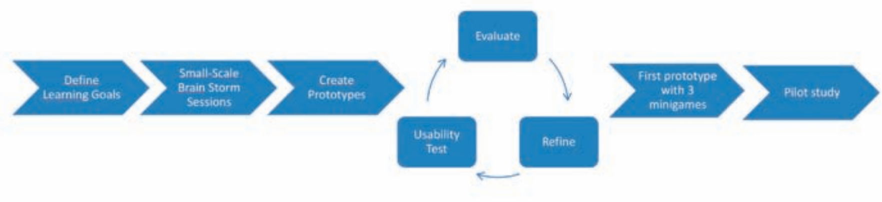


Figure 1. Stages of game development.

GAME DESCRIPTION

"Plan-It Commander" is an online computer game with a futuristic and adventurous character consisting of two parts: (1) the mission game (a game environment with missions and three isolated mini-games with embedded learning goals) and (2) a closed social community for interaction through predefined messages. Each mini-game has levels of increasing complexity and performance challenges. In the game the player is a space captain undertaking missions assigned by his or her mentor who guides the player, gives him or her feedback, and helps wherever he can. The player's goal is to collect and recover rare minerals. Characteristics of "Plan-It Commander" are described in Table 1. To motivate and engage children throughout the game several special features were designed (see Table 2 and Figure 2).

Table 1. Characteristics of a videogame for health: "Plan-It Commander"

Characteristic	**Focus**
Health topic(s)	Mental health
Targeted age group(s)	8–12 years of age
Other targeted group characteristics	ADHD
Short description of game idea	A serious game that promotes behavioural strategies in important domains of daily life functioning.
Target player(s)	Individual
Guiding knowledge or behaviour change theory(ies), models, or conceptual framework(s)	Self-Regulation Model, Social Cognitive Theory, and Learning Theory.
Intended health behaviour changes	Time management, planning/organizing, and prosocial (i.e., cooperation) skills.
Knowledge element(s) to be learned	NA
Behaviour change procedure(s) (taken from Michie inventory) or therapeutic procedure(s) used	Reinforcement, immediate performance feedback from a mentor, goal setting through missions, modeling, social support, and comparison.
Clinical or parental support needed (please specify)	No. This game is offered in the home context and can be played by children independently.
Data shared with parent or clinician	No
Type of game	Adventure, strategy, educational
Story	
Synopsis (including story arc)	The player takes the role of a space captain who works for an interplanetary organization in search of rare minerals throughout the universe. The player is assigned various missions and side missions, each with its own adventurous story line and characters.

Table 1. Characteristics of a videogame for health: "Plan-It Commander" (Continued)

How the story relates to targeted behaviour change	During their missions players are confronted with assignments requiring specific skills to solve problems in the areas of time management, planning/organizing, and prosocial (i.e., cooperation) functioning.
Game components	
Player's game goal/objective(s)	Player's goal is collecting and recovering rare minerals that lie scattered throughout the universe. During their missions, players have various different tasks they have to complete. There are three mini-games with its own specific goals: "Labyrinth", time management; "Explorobot", planning/organizing; and "Space Travel Trainer", prosocial (i.e., cooperation) behaviour.
Rules	Restricted daily play time (45 minutes in main game; 20 minutes in social community); Complete missions/tasks/levels before moving to the next one; Finishing up assignments within a certain time frame; Communicate in the social community through predefined messages; Exchange earned in-game currency for shop items to upgrade your personal space ship.
Game mechanic(s)	Achievements, solving puzzles, fetch quests, dialogs with NPCs, rewards, in-game currency, feedback, making short- and long-term appointments with NPCs, strategy use, goal setting, social community, collaborating with NPCs, levels, customizable space ship, collecting items, inventory.
Procedures to generalise or transfer what's learned in the game to outside the game	This game will enhance skill transference because of the combination of the following elements: theoretical underpinnings, focus on behaviour strategies, use of feedback from a mentor, motivation, and reward system.
Virtual environment	
Setting	A futuristic, science fiction game world with multiple planets in different solar systems, each with its own environment.
Avatar	
Characteristics	Space captain, male/female, nickname (automatically generated)
Abilities	Navigate through the game world, talk to NPCs, collect items in the game world, communicate through predefined messages in social community.
Game platform(s) needed to play the game	Computer
Sensor used	NA
Estimated play time	20 hours

ADHD, Attention Deficit Hyperactivity Disorder; NA, not applicable; NPC, Non-Playable Character.

Table 2. Description of special features in the game.

Special feature	Description
Space ship editor	Once the player is able to access his/her space ship he/she will find the space ship editor. This is an application in the game in which the player is able to customise the ship to his/her liking. Through the game the player will find several items for his space ship, but he can also buy items in shops on the different planets.
Shops	The player will find several shops on different planets in the game. In those shops he/she is able to purchase and sell items. The player knows which items he/she can afford and will receive descriptions of the items so the player knows more about the item.
Inventory	In the game the player finds items which can be categorised into: minerals, Ico (the robot) upgrade, rocket parts and items. These items are stored in his/her inventory. The player can use these items in the shops to sell them or in the space ship editor.
Player profile	The player has a player profile within the game, which includes an avatar picture of the player, together with a list of all the missions the player has completed and the player's current space ship is also visible.

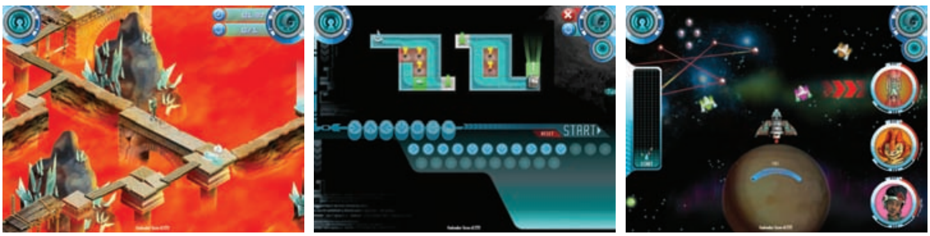
Figure 2. Space ship editor.

Missions and side missions

The game is divided into 10 different missions and several side missions. Missions guide the player's behaviour throughout the game as he or she follows the story line and is confronted with assignments requiring specific skills to solve problems. Completing these assignments ensures skills concerning time management, planning/organizing, and prosocial (i.e., cooperation) behaviour are practiced and trained. Each mission has different tasks, and the player has a mission board to check which missions he or she has completed. Once a mission is completed the next mission becomes available. Side missions are independent missions, separate from the main story line, and are optional. Several side missions focus on triggering the player's prosocial behaviour (e.g., players can ask other players for assistance [e.g., finding special items] and in turn decide whether to provide assistance). In addition, players can make short-term and long-term appointments with other Non-Playable Characters (NPCs; e.g., to retrieve items). Further general learning goals throughout the game include listening to the mentor, dealing with frustration, ignoring distraction, learning to concentrate, being attentive, and inhibiting impulses.

Mini-games

A mini-game is a small, isolated game within the larger game environment that integrates unique game elements offering tools to improve strategic behaviour. Players begin with an explanatory tutorial level and progress through the game by accomplishing levels within the mini-games and missions. Three mini-games with assignments addressing time management, planning/organizing, and prosocial (i.e., cooperation) behaviour are embedded in the game (see Figure 3).



Mini-game 1: Labyrinth   Mini-game 2: Explorobot   Mini-game 3: Space Travel Trainer

Figure 3. Three different mini-games that are offered in successive order.

Mini-game 1: Labyrinth

Within this mini-game the player learns to manage time and to estimate time needed. In addition, players learn that it may be helpful to break down an assignment into pieces or to relax before making decisions. The labyrinth game is divided into two different parts. In the first part the player collects minerals in a maze within a limited time frame. In the second part the player estimates the time needed to collect all the minerals. In both parts of the game several strategies can be used to optimise performance, such as (1) the player planning optimal route on a map before entering cave, (2) clicking on the clock to check time, and (3) using the so-called "safe zones." In these zones time pauses so the player can plan his or her next move or just relax. The player has to collect minerals while facing distractions in the maze, thus learning to keep the main goal in mind. For both parts of this mini-game there are six different levels, increasing in difficulty. A level is completed when the player collects all the minerals within the restricted time frame or when the player finishes on time (i.e., within his or her estimated time frame).

Mini-game 2: Explorobot

Players learn to plan ahead and break down the total assignment into pieces. The player has to collect several minerals that lie scattered in a sewer, using the robot Ico. The player determines the shortest route for Ico and then gives Ico this route description by means of a series of commands. If the player makes a mistake in planning the route, all commands will be deleted, and the player has to plan the route again. As a strategy to optimise performance, players can use checkpoints. If a player makes a mistake after a checkpoint, the robot will jump back to the last checkpoint, and the route can be adjusted from there on. The player can choose to use a limited amount of checkpoints per level. In total, there are 51 levels of difficulty with several tutorial levels. As it may be too hard for some players to find the ideal route, a margin is determined, which is the number of steps needed for the optimal route plus 30 percent (with a maximum of 10 steps). A level is completed when the optimal route (i.e., minimum number of steps) is planned for Ico.

Mini-game 3: Space Travel Trainer

Here players learn to help their team members and to behave in a more prosocial and cooperative manner toward others. The player flies his or her space ship from planet to planet to reach the target planet with three team members. These team members (named Nika, Vesto, and Kortar) are not real players, but are computer generated, and called Non-Playable Characters (NPCs). The team members depend on the player when handling obstacles, such as a star rain, while they follow their predefined route. If the player does not help his or her team members by giving the right commands (e.g., shield, boost, cloak) in time, they inevitably get stuck with low energy levels, which the player has to replenish. Team members ask for help and express their emotions when in dangerous situations. The player can thus use more than one channel to interact with the team members. In total, there are 31 different levels of difficulty. A level is completed when all team members and the player have finished together.

Social community

To stimulate prosocial behaviour, a social community was developed in which players can see each other's profiles and space ships and communicate with each other through pre-defined messages, for example, with a "thumbs up" or "thank you" button (see Figure 4). In addition, players can see each other's rank and current mission status. This aims to stimulate game-play and generates some competition between players. Achievements are related to the learning goals of the intervention and to rewarding players for prosocial behaviour within the social community, such as helping other players or giving compliments.

Figure 4. Social community (called Space Club).

ACCEPTANCE AND USABILITY STUDY

The initial prototype had three mini-games focusing on time management, planning/organizing, and prosocial (i.e., cooperation) behaviour. The player's mission was to collect as many minerals as possible. The above mentioned social community, missions, side missions, and special features had not yet been developed. From October 2011 to March 2012 a pilot study was conducted to test the feasibility of conducting a randomised trial on the full game. As part of the pilot study, participants also filled out questionnaires designed to assess acceptance and usability of several game elements. Acceptance and usability were assessed to inform design decisions for further development of the game to a final version to be evaluated in a RCT for outcome effectiveness.

Participants

Candidates for the pilot study were identified and informed by their therapist. The therapists were all members of the consortium consisting of ADHD specialised mental healthcare services. Once a potential participant was identified, children and parents received information letters from the researcher, allowing them to make an informed consent about voluntary participation in the pilot study. Inclusion criteria were (a) having a clinical DSM-IV-TR ADHD diagnosis (all subtypes were included) set by a certified healthcare professional, (b) between 8 and 12 years of age, (c) being stable on pharmacological and/or psychological ADHD treatment for at least 2 months prior to baseline assessment (determined by healthcare professionals on the basis of medication data and behavioural observation), and (d) availability of a computer workstation at home with Internet and sound facilities. Children were excluded if they had an estimated total IQ of 70 or lower and had a physical and/or cognitive disability (i.e., deafness, blindness) that would predict great difficulties in playing the serious game and would be problematic for standardised measurements.

In total, 66 children were referred by their therapist and informed about the studies' purposes. The final sample consisted of 42 clinically referred children with a primary diagnosis of ADHD. Children's age ranged from 8 to 11 years with a mean age of 9.4 years. Children participating in the study had average intelligence (M=104, SD=12.3). This was tested with the Wechsler Intelligence Scale for Children III short version (Wechsler, 1991). There was an absence of any neurological, sensory (blindness, deafness), or motor disorder as stated by the clinicians and parents. All children except for two were taking ADHD medication at study entry. Comorbidity of dyslexia was present in four children.

Procedure

As part of the pilot study we decided to randomise children to one of the two conditions for playing the "Plan-It Commander" prototype. Twenty children were allowed to play the game for a maximum of three times per two weeks. Twenty-two children were asked trying to play the game about eight times per two weeks. However, as there appeared to be no significant differences ($p>0.05$) among children's and parents' satisfaction scores between the two groups, we decided to present the results for the total group of children. Children played the game at home for eight weeks, divided into four periods of two weeks, with a free choice in playing one of the preferred mini-games during the last two weeks. Every two weeks a different mini-game was unlocked in predefined order.

Children had their own password and ID to log on from their home. Children were asked to play the game for a minimum of 30 minutes and a maximum of 45 minutes each time. Two children were lost to follow-up, and one child dropped out because of acute psychiatric problems.

Ethical approval was obtained from the Committee of Medical Ethics for Mental Health Care in Utrecht, The Netherlands. Written informed consent was obtained from both parents. Questionnaires were developed specifically for this study to assess expectations and satisfaction. Parents filled out questionnaires measuring expectations at baseline (pre-test measurement) and satisfaction at follow-up (post-test measurement). Children filled out a questionnaire at follow-up to assess their satisfaction with the prototype "Plan-It Commander" game.

Pre-test parent expectations

Parents rated their expectations about the game in different domains during pre-test measurement (see Table 3). Ratings were collected on questionnaires specifically designed for this study. Questionnaires were filled out at the study location on a laptop. Questions included, "How much improvement do you expect with regard to the time management skills of your child?" Parents rated their answers on a 10-point Likert scale in which 1 = "none" and 10 = "a lot". Scores from 6 to 10 were combined and interpreted as a positive response. As shown in Table 3, parents had overall high expectations of the game, except where it concerned learning prosocial behaviour and reducing ADHD core symptoms. This might be explained by the fact that parents feel prosocial behaviour is hard to target in a game. Learning prosocial behaviour through a game requires multiplayer options and a different game structure than proposed in this first prototype (Van Rooij, Jansz, & Schoenmakers, 2010). For these reasons, a social community aspect was integrated in the final version of the game. Furthermore, the game was not focused on

Table 3. Proportion of parents providing ratings of positive expectations with regard to the goals of the game.

	Expectation (*n*=42; positive percentage)
General learning effect	42 (100%)
Improvement of time management	30 (71%)
Improvement of planning skills	29 (69%)
Improvement of prosocial skills	22 (52%)
Improvement of frustration tolerance	28 (67%)
Reduction of ADHD symptoms	26 (62%)

Responses were provided as ratings on a Likert scale ranging from 1 = "none" to 10 = "a lot". Participants who provided a rating of 6 or above were categorised as having positive expectations. ADHD, Attention Deficit Hyperactivity Disorder.

diminishing ADHD core symptoms but on improving behavioural skills. Therefore, lower expectation scores regarding this topic reflect a realistic insight into the capabilities of this game intervention.

Post-test parent satisfaction

At post-test measurement, parents answered questions on a 10-point Likert scale (1 = "not at all" and 10 = "totally") concerning parental perceptions about the burden of playing the "Plan-It Commander" game on the child and family. Mean scores ranged from 2.5 to 4.3, indicating that most parents did not feel offering such game intervention was troubling for the family. Furthermore, results demonstrated that parents were overall positive about the game. Their average overall satisfaction with the game was 6.7 (*SD*=1.4) (on a scale from 1 to 10). In addition, a majority of the parents (88 percent) reported they would recommend the game to other parents. All parents (100 percent) indicated (on a yes/no question) they would like access to the game once further developed. These findings assured us that our current approach was acceptable for parents and helped us in deciding on how and to which degree children should be exposed to the game.

Post-test child satisfaction

We also asked the children who played the game to rate their game satisfaction in different areas (see Table 4). Ratings were collected on a paper-and-pencil questionnaire specifically designed for this study. Colours and smiley faces were used to highlight the different answer categories on a 5-point Likert scale (from 1 = "not at all" to 5 = "very"). Table 4 shows the number (percentage) of children who gave a positive opinion (i.e., a combination of the two highest scores) on the satisfaction questionnaire. Although only 44 percent of the children indicated they were motivated to play the game, 67 percent

Table 4. Proportion of children's ratings of satisfaction after playing the game.

	Satisfaction (*n*=39; positive percentage)
Did you like playing the game?	25 (64%)
How motivated were you to play the game?	17 (44%)
Would you like to play more often?	21 (54%)
How do you feel after finishing the game?	17 (44%)
Have you learned anything?	26 (67%)
Should other children with ADHD also be able to play the game?	30 (77%)
Would you like to play this game with friends together?	25 (64%)

Responses were provided as ratings on a Likert scale ranging from 1 = "not at all" to 5 = "very". A combination of the two highest scores were categorised as having a positive opinion. ADHD, Attention Deficit Hyperactivity Disorder.

of the children indicated they had learned from the game, and 77 percent were positive about making the game available for other children with ADHD. A social community, several side missions, and special features were added to the "Plan-It Commander" prototype, making it more attractive and thereby more motivating and challenging for children. This is relevant as motivation is thought to be an important mediator for changing behaviour (Boller, 2012; Jaeggi et al., 2014; Prins et al., 2011; Van Rooij et al., 2010).

Qualitative user experience

At post-test measurement, both parents and children answered an open question concerning changes to the game. They provided useful suggestions and recommendations for improvements, such as requests by children for more characters, travel to different planets, and other characters in the game world. Some parents indicated the game could be made more challenging for their child, especially if they already had broad gaming experience. These important responses and feedback were very supportive in finalising the full game.

SUMMARY AND FUTURE PERSPECTIVES

In this chapter we outlined important aspects of developing a serious game to impact daily life functioning of children with ADHD. We described how developing a serious game is a collaborative project among various experts and users and how that process was carried out in this project. We outlined the theoretical basis for the game as a therapeutic intervention and described how the theory was implemented in various game components. This was followed by a description of the mini-games and structural components of the game in which game components were embodied. The information we provided supports the need in the literature on serious games to provide detailed descriptions on the game themselves, theories that guide them, and the components of the game intended to change behaviours that lead to intended positive outcomes. The information provided is also valuable as a description of a method and approach that represents a significant effort to move beyond serious games aimed at improving neurocognitive functioning, but functioning in important domains of daily life for children with ADHD. The description of our development process was supplemented by a presentation of results for parents and child acceptability and usability ratings of a prototype of the game. We discussed the findings in light of their implications for game development.

Overall, the usability findings indicated positive acceptance of this game intervention by children with ADHD and their parents. These preliminary results, based on a prototype version of the final game, directed further development of the game by including several aspects children proposed themselves (e.g., travel to other planets, more characters, special features). Parents' feedback also helped us in making well-informed decisions about children's play frequency. The advantage of our survey questionnaire approach compared with a more qualitative approach such as a focus group is that the opinions from larger groups of people can be summarised in a standardised way through ratings. A drawback to this approach is that we may have lost the opportunity to gain some important opinions and feedback from participants due to the structured format of the questions and responses. We did, however, also include open-ended questions, which allowed participants to provide their feedback in a less structured approach.

Both parents and children were quite satisfied with the first prototype and indicated they would recommend the game to other parents of children with ADHD. As parents' high expectations might have influenced their ratings, further research should try to control for these expectations by including teacher ratings and more objective measures such as neuropsychological tasks. In the current study, only two children did not use medication as their treatment as usual (TAU). It may well be that medication use is a necessary condition for optimal learning from the current intervention. Future research could examine the effects of this game in a non-medicated sample to further explore the necessity of medication as TAU. With regard to development, it should be considered to extend the game or to create an add-on with different learning goals relevant for different age groups. Games could be made more individualised by creating the option to choose learning modules to suit individual developmental trajectories. This project has created a platform from which future goals could be implemented.

Although these first results regarding expectations and satisfaction are promising, a randomised clinical trial is necessary in order to test the effectiveness of this serious game. As serious games become more popular within mental healthcare, more research is needed on the implementation of such electronic mental health interventions into the primary process of care. This game format presents an alternative to traditional behavioural interventions currently available for children with ADHD that are often presented in school settings by therapists, making them time consuming, costly, and less accessible compared to digital tools (Boyer, Geurts, Prins, & Van der Oord, 2014; Evans, Schultz, DeMars, & Davis, 2011; Kazdin & Blasé, 2011). In sum, the description of the approach and process used in developing "Plan-It Commander," along with the usability findings that led back into the development process, provides an example for developing serious games for similar target groups and outcomes. The findings have implications for defining and describing the complex processes of designing and developing serious games that involve collaborations among diverse stakeholder groups that include structured input from target users and family members.

Chapter 3

Effectiveness of an initial prototype serious game for children with Attention Deficit Hyperactivity Disorder on behavioural outcomes: A pilot Randomised Controlled Trial.

ABSTRACT

Objective: This study evaluated the effectiveness of an initial prototype serious game for children with Attention Deficit Hyperactivity Disorder (ADHD). We examined whether this initial prototype improved children's functional outcomes in different areas of daily life, namely time management, planning/organizing and prosocial (i.e., cooperation) skills, in addition to their treatment as usual (TAU).

Methods: A total of 42 children with ADHD aged 8 to 12 years were randomly assigned to the serious game intervention group (*n*=22) or to a semi-active control group (*n*=20). Children in the intervention condition were asked to play the initial prototype game about eight times per two weeks, whereas children in the semi-active control group were allowed to play a maximum of three times per two weeks. Parental and self-report measures concerning executive function and social behaviour skills were administered before starting the intervention (T0) and after receiving an eight-week intervention (T1).

Results: Both groups showed improvements in time management and planning/organizing skills over time. Children in the intervention condition showed more improvement (borderline significant) in time management than those in the semi-active control group. More frequent game-play was correlated with better learning outcomes concerning time management and prosocial (i.e., cooperation) behaviour.

Discussion: This pilot study demonstrates that this initial prototype serious game might be potentially effective for children with ADHD. The implications of the findings are discussed, including further game development and the need for a randomised controlled trial (RCT) to examine final game format effectiveness.

INTRODUCTION

Several reviews indicate that Internet-based interventions are feasible and efficacious in treating mental disorders among adults (Andersson & Cuijpers, 2009; Baumeister, Reichler, Munzinger, & Lin, 2014). Furthermore, there is an increasing number of studies demonstrating the effectiveness of Internet-based mental healthcare interventions for anxiety and depression in children and adolescents (Ye et al., 2014). Generally, these novel interventions have been proven to be effective in alleviating symptoms but issues with user engagement and attrition do exist, implying a need for more attractive and engaging treatment tools. As such, gamified interventions and serious games for mental healthcare have been developed and are beginning to be explored (Cheek et al., 2015).

Gamified interventions (e.g., using game mechanics or game-like interfaces) appear to be specifically engaging for children with externalizing disorders like Attention Deficit Hyperactivity Disorder (ADHD) as they have difficulties with staying motivated to finish "boring" and repetitive training tasks (Dovis et al., 2012; Frutos-Pascual et al., 2014; Granic, Lobel, & Engels, 2013). Moreover, despite their poor attention span and distractibility, children with ADHD are able to demonstrate sustained concentration and engagement when playing digital games (Emes, 1997; Tannock, 1997; Van der Oord, 2012). This knowledge stimulated the development of several gamified training programs focusing on improving working memory and executive functioning, thereby addressing specific cognitive deficits in ADHD children (Cortese et al., 2015; Sonuga-Barke, Brandeis, Holtmann, & Cortese, 2014). Gamified training formats currently available do promote children's engagement in the task over time and improve short term effects on targeted working memory outcomes (as measured by neurocognitive tests that are similar to the ones presented in the training) but they lack a demonstration of generalisation effects to other important domains of daily life functioning (Chacko et al., 2014; Melby-Lervåg & Hulme, 2012; Rapport et al., 2013; Shipstead et al., 2012). Children with ADHD could profit from an intervention impacting "real world" behaviours given their widespread difficulties in time management, planning/organizing and prosocial (i.e., cooperation) skills. These executive functioning and social problems not only affect the daily life of children and their families, but also predict a poor prognosis of ADHD even into adolescence and adulthood (Abikoff et al., 2009; 2013; Conners, 2003; Nijmeijer, Minderaa, Buitelaar, Mulligan, Hartman & Hoekstra, 2008; Sonuga-Barke et al., 2010).

A serious game could provide an engaging tool for targeting functional outcomes in different areas of daily life. Compared to gamified training tools, serious games offer an overall game environment that allows for exploration and meaningful ongoing "journey narrative" instead of offering a "casual" game-like interface. Examples of such programs that have been evaluated are Camp Cope-A-Lot (Khanna & Kendall, 2010) and SPARX (Merry et al., 2012). For school-aged children with ADHD a gamified executive function training is available (Dovis et al., 2012). However, to our knowledge there are no serious games available for children with ADHD targeting both executive as well as daily social life skills. Building on the evidence of serious games developed for other patient groups we believe that a serious game with therapeutic goals and an engaging game environment can effectively impact "real world" behaviours in this target group as well. As a first step, we developed a first prototype serious game that consists of three isolated mini-games with embedded learning goals concerning time management, planning/organizing and prosocial (i.e., cooperation) skills. At this stage, it does not include an enriched game environment and social community yet. Usability findings indicated positive acceptance of this prototype by children with ADHD and their parents. Learning goals in the game were proposed by healthcare professionals on the basis of scientific literature and clinical experience. A community board of parents of children with ADHD was also involved in deciding upon the learning goals. As previous studies have demonstrated that serious games based on theoretical concepts tend to be more effective than those without a theoretical framework (Baranowski et al., 2008), we decided to integrate elements of the Self-Regulation Model (Cameron & Leventhal, 1995), Social Cognitive Theory (Bandura, 1986) and Learning Theory (Barkley, 2006; Kato et al., 2008) into the prototype (DeSmedt et al., 2014). We have not focused on repeating training tasks but instead promote the use of behavioural strategies via a computer game with integrated therapeutic elements (e.g., reinforcement, immediate performance feedback from a mentor, goal setting through missions, modeling, social support and comparison). The behavioural training aims to improve daily life functioning of children with ADHD (see *Chapter 2* for a more detailed description). As such, we chose to measure children's performances by using parent-reported questionnaires, making it possible to examine whether skills learned in the initial prototype serious game would generalise to important areas of everyday functioning.

To our knowledge, this is the first study examining an initial prototype serious game to enhance behaviour strategies that children with ADHD can apply to improve their functioning in daily life. The present pilot study examined initial effectiveness of the prototype game on executive as well as social domains of functioning in addition to TAU. It was hypothesised that the initial prototype serious game would improve children's time management, planning/organizing and prosocial (i.e., cooperation) skills. Also we explored the relationships between the number of game sessions and outcome measures independently of children's individual characteristics.

METHODS

Participants

Participants were children recruited from ten different mental healthcare clinics and institutions in the Netherlands. A total of 42 children (32 boys, 10 girls) met the inclusion criteria, with an average age of 9.38 years (*SD*=1.12). Inclusion criteria were (a) having a clinical ADHD diagnosis (all subtypes were included) determined by a certified healthcare professional, (b) aged between 8 and 11 years, (c) being stable on pharmacological and/or psychological ADHD treatment for at least two months prior to baseline assessment (determined by healthcare professionals on the basis of medical files and information from parents) and (d) availability of a computer workstation at home with Internet and sound facilities. Children with common comorbid disorders (i.e., dyslexia, oppositional defiant disorder) could participate in the study. Children were excluded when they had an estimated total IQ ≤ 70 and had a physical and/or cognitive disability (i.e., deafness, blindness) that would predict major interference in playing the serious game. Three participants from the control condition dropped out of the study, leaving a final sample composed of 39 children who completed the pre- and post-test measurements.

Game intervention

The initial prototype serious game tested in this study consists of three mini-games focussing on improving domains of daily life functioning with a primary focus on time management (*Labyrinth*; 6 levels), planning/organizing (*Explorobot*; 51 levels) and pro-social (i.e., cooperation) skills (*Space Travel Trainer*; 31 levels). In short, the player is a space captain and his/her mission is to collect as many minerals as they can by playing the three mini-games. Players learn to manage time and to estimate time needed to collect all minerals. Furthermore, they learn to plan ahead and break down the total assignment into pieces. Finally, they learn to help their team members and to behave in a more prosocial and cooperative manner toward others. Players have their own password and ID to log on from their home. They have to successfully complete each level within a mini-game before moving on to the next level. This initial prototype did not yet include an enriched game environment with missions, side missions, special features and social community (see *Chapter 2* for more details).

Design

This study was a randomised open-label parallel-group study in which children were randomised to an intervention or semi-active control group. Participants in the semi-active control condition were allowed to play a maximum of three times per two weeks and participants in the intervention condition were asked to try to play the game about eight times per two weeks. Children in both conditions were asked to play the initial

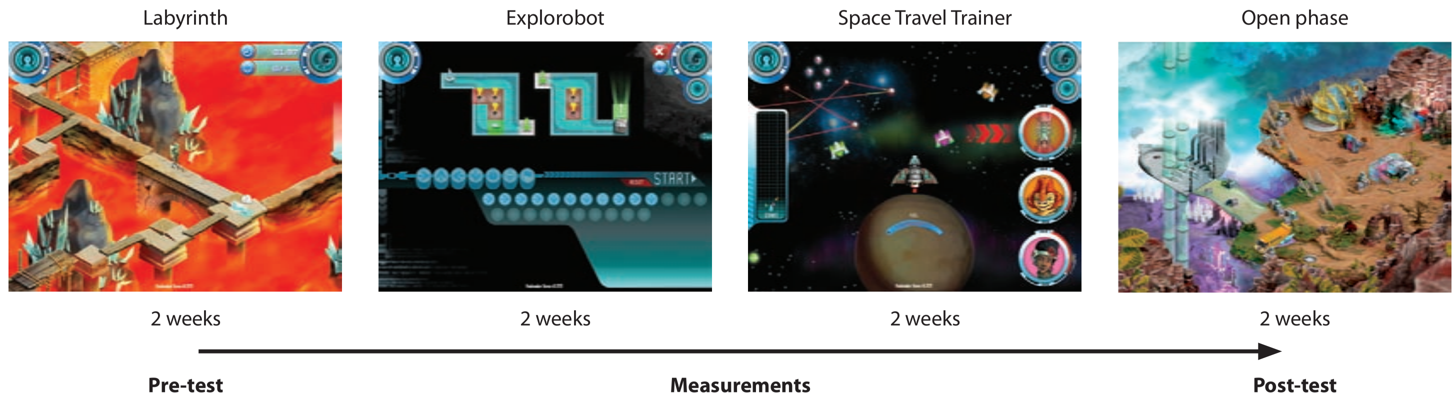


Figure 1. Illustration of three embedded mini-games in initial prototype.

prototype game for a minimum of 30 minutes and a maximum of 45 minutes per game moment. The game was presented for a total period of eight weeks in which every two weeks a new mini-game (with its own learning goal) was offered. In the final two weeks, children in both conditions were allowed to play one of the three mini-games according to their preference (see Figure 1).

Measures

Screening measures

General questionnaire

A general questionnaire was specially developed for this study to assess socio-demographic information, children's treatment history, medication use and parental support.

Wechsler Intelligence Scale for Children III short version

To estimate the total Intelligence Quotient (IQ) the short version of the WISC-III was used (Wechsler, 1991). This version is designed for children between the ages of 6 and 16 years and consists of four subtests: vocabulary, picture concepts, arithmetic and block design. It is a valid screening tool to estimate full-scale intelligence (Sattler, 2001).

Outcome measures: Child

Dutch modification of the matson evaluation of social skills with youngsters

The Dutch modification of the MESSY is a self-report questionnaire to measure prosocial and antisocial skills in children and adolescents from 7 to 18 years old (Matson, Rotatori, & Helsel, 1983). This questionnaire consists of 31 items that reflect propositions about behaviour and cognition. Items are scored on a 5-point Likert scale (never - very often) on two subscales (prosocial and antisocial skills). Scores of each subscale are combined and converted to percentiles. Administration time is approximately 10 minutes. The Dutch modification of the MESSY is an instrument with sufficient reliability and construct validity (Evers, Lucassen, Meijer, & Sijtsma, 2009; Hulstijn et al., 2006).

Outcome measures: Parent

Strengths and difficulties questionnaire

The Strengths and Difficulties Questionnaire (SDQ) is a standardised measure of behavioural and emotional problems in children 4-16 years of age (Goodman, 1997; Widenfelt, Goedhart, Treffers, & Goodman, 2003). The Dutch version of the parent rating form was used in this study. Of the 25 SDQ items, 20 items describe difficulties and 5 items describe prosocial behaviour. The four scales describing difficulties are: Hyperactivity/Inattention, Emotional Problems, Peer Problems and Behavioral Problems. The items are scored on a 3-point Likert scale (not true – somewhat true – entirely true). A total score is calculated by adding the scores on the subscales Hyperactivity/Inattention, Emotional Problems, Peer Problems and Behavioral Problems together. Administration time is approximately 10 minutes. The SDQ is an instrument with sufficient reliability and construct validity (Evers et al., 2009).

Behavior rating inventory of executive function

The Dutch version of the Behavior Rating Inventory of Executive Function (BRIEF) was used to assess executive functioning in the home and school environment in children 5-18 years of age (Gioia, Isquith, Guy, & Kenworthy, 2000). The questionnaire contains 86 items in eight non-overlapping clinical scales and two validity scales. For this study the subscale Plan/Organize was used. The answers are scored on a 3-point Likert scale (never – sometimes - often). This subscale consists of 12 items and takes approximately 10 minutes to fill out. The Dutch version of the BRIEF has a good reliability and construct validity (Elling & Minderaa, 2010).

Time management questionnaire

A time management questionnaire was used to measure children's time management behaviour (see Appendix 1). The questionnaire contains 11 items and provides a more detailed insight into children's behaviour strategies used to improve their time management skills compared to other existing questionnaires (mainly focusing on time perception and/or coordination). Parents were asked to rate children's time management skills on a 10-point Likert scale (ranging from true – not true). Internal consistency within the current sample was good ($\alpha = 0.85$).

Procedure

Participants were recruited by their pediatricians or other healthcare professionals from different mental healthcare institutions. Parents were informed about the purpose and procedure of the study and telephonically screened to check whether their child met the inclusion criteria. They were invited for an intake session in which written informed consent was obtained from the parents and an IQ test was performed (if not already available). Pre-test measurements (T0) were performed after inclusion and prior to randomisation. After the eight-week intervention period post-test measurements (T1) were taken. During the intervention period, children's motivation and the accessibility of the initial prototype game were monitored by means of weekly telephone contact by trained research assistants. All children received small gifts (i.e., collectible cards from game characters) every week and their parent(s) received a refund of their travel expenses. The Committee of Medical Ethics for Mental Health Care (METIGG) in Utrecht approved the protocol and written informed consent procedure of the study.

Data analyses

Differences in baseline characteristics were tested with an independent sample *t*-test (for continuous variables) or chi-square test (for categorical variables). Repeated measure analyses of variance (ANOVAs) were conducted to examine both the main effect of time (pre-test, post-test) as well as the interaction effect for differential treatment effects between the two conditions. The Pearson correlation test was used to explore relations between the number of game sessions and the outcome measures. The linear trend at point was used as an imputation method for drop-outs. Effect sizes (Cohen's *d*) were reported for all analyses (Cohen, 1988). All statistical analyses were performed using SPSS 19.0 statistical software and were two-sided, with a level of significance of 0.05 (IBM Corp, 2010).

RESULTS

Demographics

In Table 1, demographics and baseline characteristics are presented. There were no significant differences between intervention and semi-active control conditions on any

Table 1. Demographics and baseline characteristics of children in intervention and semi-active control conditions (N=42).

	Total (N=42)		Intervention (*n*=22)		Semi-active control (*n*=20)		*p* value
Mean age (years)	9.38	(1.13)	9.09	(1.11)	9.70	(1.08)	.08[b]
No. male (%)	32	(76%)	18	(82%)	14	(70%)	.37
Total IQ	103.93	(12.31)	104.09	(11.60)	103.75	(13.35)	.93
SDQ subscale hyp. + inatt.	7.79	(1.82)	7.77	(1.88)	7.80	(1.80)	.96
ADHD combined subtype (%)	26	(62%)	15	(68%)	11	(55%)	.45
Ethnic – Dutch (%)	35	(83%)	18	(82%)	17	(85%)	.78
Co morbidity (%)	15	(36%)	8	(36%)	7	(35%)	.32
Use of medication (%)	40	(95%)	21	(96%)	19	(95%)	.95
Special education (%)	6	(14%)	1	(5%)	5	(25%)	.06[b]
Repeated a class (%)	11	(26%)	5	(23%)	6	(30%)	.59

ADHD, Attention Deficit Hyperactivity Disorder, IQ, Intelligent Quotient, SDQ, Strengths and Difficulties Questionnaire subscale Hyperactivity and Inattention.
[b] = borderline significant

demographics or baseline variables. Three children from the semi-active control condition discontinued the study. Two children were lost to follow-up and one child dropped out because of acute psychiatric problems.

Play frequency and progression

Children's play frequency is illustrated in Table 2. Children from the intervention condition played the initial prototype game on average 5.11 times per two weeks (*SD*=2.16). Children's average play frequency in the semi-active control condition was 2.20 times per two weeks (*SD*=0.83). Overall, children played the initial prototype game for about 39 minutes (with a *SD* of 7 minutes, *Min.*=35 minutes, *Max.*=44 minutes) per day.

Children had to finish different levels of each mini-game. In the first mini-game (*Labyrinth*), the first five levels, in which children had to collect minerals within a limited time frame, were successfully completed by more than 50% of the children in both groups. Four (22%) children from the semi-active control condition and 9 (41%) children in the intervention condition completed at least one level in which children had to estimate the time needed to collect all minerals. During the second mini-game (*Explorobot*), children in the intervention condition progressed on average to level 36 (*SD*=16.42; *Min.*=2; *Max.*=50). In the semi-active control condition, children reached on average level 27 (*SD*=8.20; *Min.*=10; *Max.*=41). During the third mini-game (*Space Travel Trainer*), children from the intervention condition progressed on average to level 23 (*SD*=10.96; *Min.*=1; *Max.*=30) versus level 16 (*SD*=8.32; *Min.*=4; *Max.* =30) reached by children from the semi-active control condition.

Table 2. Children's number of days played in intervention and semi-active control conditions.

	Intervention		Semi-active control	
	n=22		*n*=18	
Week 1 & 2	1-3 days*	6 (27%)	1 day	1(5%)
	4-7 days	11 (50%)	2 days	5 (28%)
	8-10 days	5 (23%)	3 days	12 (67%)
	n=21		*n*=17	
Week 3 & 4	1-3 days	3 (14%)	1 day	0
	4-7 days	10 (48%)	2 days	6 (35%)
	8-10 days	8 (38%)	3 days	11 (65%)
	n=20		*n*=17	
Week 5 & 6	1-3 days	7 (35%)	1 day	4 (24%)
	4-7 days	10 (50%)	2 days	4 (24%)
	8-10 days	3 (15%)	3 days	9 (53%)

*Game-play frequency in days

Table 3. Scores at pre-test and post-test for children in the intervention and semi-active control condition (N=42).

	Intervention			Semi-active control			Time effect		Interaction effect	
	Pre-test	Post-test	*d*	Pre-test	Post-test	*d*	*F* value	*p*	*F*	*p*
BRIEF	26.4 (4.4)	24.6 (3.6)	-0.45	26.3 (3.8)	24.3 (4.1)	-0.51	15.08	<.001*	0.03	.85
Time management	39.7 (14.7)	49.5 (18.2)	0.40	46.6 (19.5)	46.7 (15.5)	0.01	3.47	.07[b]	3.26	.08[b]
SDQ (prosocial)	7.3 (2.1)	7.4 (2.2)	0.05	7.2 (1.9)	7.1 (1.6)	-0.06	0.03	.88	0.09	.76
MESSY (prosocial)	47.2 (11.3)	47.3 (11.1)	0.01	50.3 (9.7)	49.6 (6.5)	-0.08	0.06	.81	0.12	.74
MESSY (antisocial)	30.8 (8.2)	30.7 (8.6)	-0.01	29.4 (8.3)	29.0 (8.3)	-0.05	0.06	.81	0.01	.93

[b] = borderline significant, *$p < 0.01$.

Note. BRIEF = Behavior Rating Inventory of Executive Function. SDQ = Strengths and Difficulties Questionnaire. MESSY = Matson Evaluation of Social Skills with Youngsters. Analyses excluding drop-outs (*n*=3) and children playing less than twenty percent of the recommended play frequency demonstrate similar results with regard to its significance, except for time management ($p < 0.05$).

Child and parent outcomes

Repeated measures ANOVAs indicated a general improvement over time, for the subscale Plan/Organize of the BRIEF (*F* [1,40]=15.08, $p<.001$, η_p^2=0.27). A trend over time was found on the time management questionnaire (*F* [1,40]=3.47, *p*=.07, η_p^2=0.08; see Table 3). The other outcome measures demonstrated no significant improvement over time, SDQ (subscale prosocial; *F* [1,40]=0.03, *p*=.88), MESSY (prosocial; *F* [1,40]=0.06, *p*=.81) and MESSY (subscale antisocial; *F* [1,40]=0.06, *p*=.81). Furthermore, repeated measure ANOVAs showed that there was an interaction effect on the time management questionnaire that approached significance, *F* [1,40]=4.26, *p*=.08, η_p^2=0.08. Parents of children in the intervention group reported an improvement in their children's time management skills, whereas parents from children in the control condition reported no change of their children's time management skills. The other outcome measures demonstrated no significant interaction effect, BRIEF (*F* [1,40]=0.03, *p*=.85), SDQ (subscale prosocial; *F* [1,40]=0.09, *p*=.76), MESSY (prosocial; *F* [1,40]=0.12, *p*=.74), MESSY (subscale antisocial; *F* [1,40]=0.01, *p*=.93).

Relationships between play frequency and outcome measures

Relations between play frequency and gain scores on the time management questionnaire, BRIEF (subscale Plan/Organize), SDQ (subscale prosocial) and MESSY (subscale prosocial) are presented in Table 4. There was a moderate positive correlation between play frequency (week 1-2; *Labyrinth*) and improvement in time management skills, *r*=0.31, *p*=.045. In addition, there was a moderate positive correlation between play frequency (week 3-4; *Explorobot*) and improvement in prosocial skills as measured by the SDQ, *r*=0.33, *p*=.034. A trend was demonstrated towards a correlation between play frequency (week 5-6; *Space Travel Trainer*) and improvement in prosocial skills as measured by the SDQ, *r* =0.27, *p*=.088. There were no other significant correlations.

Table 4. Pearson correlation coefficients between game -play frequency and gain scores on outcome measures (N=42).

	Play frequency week 1-2	Play frequency week 3-4	Play frequency week 5-6
Time management	.31*	.30	.24
Plan/Organize	-.11	-.10	-.22
SDQ (prosocial)	.22	.33*	.27[b]
MESSY (prosocial)	.19	.22	.22

[b] = borderline significant, *$p<0.05$

DISCUSSION

The results of the current study fit into upcoming initiatives of Internet-based and game interventions for child and youth mental healthcare (Institute of Digital Media and Child Development Working Group on Games for Health et al., 2016; Ye et al., 2014). We have reported the results of a pilot study in which we examined the effects of an initial prototype serious game, consisting of three mini-games, for children with ADHD. Both groups of children with ADHD, low and medium frequent players, showed marginal improvements over time in their planning/organizing and time management skills. However, there was only a borderline significant effect detectable between groups demonstrating more improvement of time management skills in the intervention group over time. These results could indicate that even limited use of the game has a positive impact on behavioural learning or could be explained by effects of multiple testing, the passage of time or non-specific treatment effects (e.g., effects of expectancies, attention; Mawjee, Woltering, & Tannock, 2015). This should be examined more thoroughly in a study that includes a larger sample.

Furthermore, findings indicate that there are positive correlations between the number of game sessions and outcome measures of time management and prosocial behaviour. As another study examining the relationship between game-play frequency and behavioural effects found no clear evidence of an association between those characteristics more research is needed (Clark, Tanner-Smith, & Killingsworth, 2014). Because differences in play frequency between the intervention and semi-active control conditions were moderate to small, this might explain why improvements in behavioural outcomes between both groups did not reach statistical significance in this pilot study with a relatively small number of subjects. Improving executive functioning in daily life is of specific interest for the treatment of children with ADHD because this contributes to more self-control and self-efficacy, which in turn are important predictors of academic and social functioning (Langberg, Epstein, & Graham, 2008; Luszczynska, Gutiérrez-Dona, & Schwarzer, 2005). Therefore, the first study results regarding this initial prototype serious game are quite promising and challenge both researchers and game developers to optimise and finalise the current prototype in order to gain maximal effects of behavioural learning and to move to a larger RCT.

Results did not demonstrate improvement in prosocial behaviour among the two groups and this could be explained by the fact that the current initial prototype serious game did not sufficiently target this type of behaviour. Games developed to improve social behaviour often consist of community games or multiplayer games (Van Rooij et al., 2010). Integrating such elements could make the game more interactive. Another explanation might be that this behaviour was self-reported by children with ADHD. It is considered that children are unaware of their own symptoms and behaviour, indicating that the reliability and validity of self-report measures of children with ADHD is not well established yet (Bell, Kellison, Garvan, & Bussing, 2010). Additionally, scores for prosocial behaviour were relatively high, leaving less room for improvement. This study provides us with further tools to expand this initial prototype with elements that are more focused on social behaviour. Future research must use a multi-informants approach (children, parents and teachers) to measure targeted outcome measures. Given the fact that children become more socially active with peers during their school-going period, teacher data seems valuable.

The findings of this study must be considered in the light of several limitations. First, in the absence of a placebo control condition, it cannot be ascertained that the observed improvements are not related to non-specific treatment factors or a consequence of repeated measurements. Second, due to the small sample size, the power to detect smaller differences between groups was too low. The fact that we nevertheless found a borderline significant effect on time management skills underlines the potential clinical impact of this game. Again, a randomised controlled study with a larger sample should provide further answers. Finally, as study results mainly rely on behavioural checklists, neuropsychological/cognitive tests are recommended to measure effects on core cognitive deficits concerning time management, planning/organizing and prosocial behaviour (Institute of Digital Media and Child Development Working Group on Games for Health et al., 2016)

As the current initial prototype, consisting of three mini-games, has not yet been fully developed, we could not draw firm conclusions about its effectiveness but it provides us with some preliminary indications for game design and behaviour change on targeted executive and social behaviours in this target population. Results provide input for further game development and design choices, with the expectation to augment its effects on the outcome measures. Furthermore, the pilot design represents a fundamental phase of the research process to examine feasibility and preliminary effectiveness of this approach that is intended to be used in a larger scale study (Leon, Davis, & Kraemer, 2011). Serious gaming might be a cost-effective intervention method as it is easily accessible and can be offered ambulatory by mental healthcare professional and pediatricians. These professionals can easily be trained and supervised in monitoring this innovative additional treatment in children with ADHD. With regard to treatment engagement, there were only three drop-outs during the study. This indicates that the serious game proved feasible in a home-based context. Although the current initial prototype serious game needs further development, results seem promising and stimulate game development as positive results were demonstrated concerning time management skills for the intervention group. These pilot study results underline the importance of evaluating this additional treatment in a RCT to examine whether skills learned in the game generalise to “real world” settings. Overall, this study may have wider implications on the future development of new, innovative interventions for children with psychiatric disorders.

Chapter 4

Behavioural outcome effects of serious gaming as an adjunct to treatment for children with Attention Deficit Hyperactivity Disorder: A Randomised Controlled Trial.

Based on: Bul, K. C. M., Kato, P. M., Van der Oord, S., Danckaerts, M., Vreeke, L. J., Willems, A.,…Maras, A. (2016). Behavioral outcome effects of serious gaming as an adjunct to treatment for children with Attention Deficit Hyperactivity Disorder: A Randomized controlled trial. *Journal of Medical Internet Research*, *18*, 1-18.

ABSTRACT

Objective: The need for accessible and motivating treatment approaches within mental health has led to the development of an Internet-based serious game intervention (called "Plan-It Commander") as an adjunct to treatment as usual for children with Attention Deficit Hyperactivity Disorder (ADHD). The aim was to determine the effects of "Plan-It Commander" on daily life skills of children with ADHD in a multisite randomised controlled crossover open-label trial.

Methods: Participants (N=170) in this 20-week trial had a diagnosis of ADHD and ranged in age from 8 to 12 years (male: 80.6%, 137/170; female: 19.4%, 33/170). They were randomised to a serious game intervention group (SG; *n*=88) or a treatment as usual crossover group (TAUx; *n*=82). Participants randomised to SG group received a serious game intervention in addition to treatment as usual for the first 10 weeks and then received treatment as usual for the next 10 weeks. Participants randomised to TAUx group received treatment as usual for the first 10 weeks and crossed over to the serious game intervention in addition to treatment as usual for the subsequent 10 weeks. Primary (parent-report) and secondary (parent, teacher, and child self-report) outcome measures were administered at baseline, 10 weeks, and 10-week follow-up.

Results: After 10 weeks, participants in SG group compared to TAUx group achieved significantly greater improvements on the primary outcome of time management skills (parent-reported; *p*=.004) and on secondary outcomes of the social skill of responsibility (parent-reported; *p*=.04), and working memory (parent-reported; *p*=.02). Parents and teachers reported that total social skills improved over time within groups, whereas effects on total social skills and teacher-reported planning/organizing skills were nonsignificant between groups. Within SG group, positive effects were maintained or further improved in the last 10 weeks of the study. Participants in TAUx group, who played the serious game during the second period of the study (weeks 10 to 20), improved on comparable domains of daily life functioning over time.

Discussion: "Plan-It Commander" offers an effective therapeutic approach as an adjunct intervention to traditional therapeutic ADHD approaches that improve functional outcomes in daily life.

INTRODUCTION

Attention Deficit Hyperactivity Disorder (ADHD) is the most common childhood neurodevelopmental disorder with young patients experiencing functional impairments in different areas of daily life (American Psychiatric Association, 2013; Conners, 2003; Polanczyk et al., 2014; Sonuga-Barke et al., 2010; Subcommittee on Attention-Deficit/Hyperactivity Disorder and Steering Committee on Quality Improvement and Management, 2011). Compared to children without the disorder, children with ADHD have more difficulties at school making schedules to finish assignments on time, executing complex planning tasks, organizing material needed for assignments, remembering task instructions, and setting priorities (Abikoff et al., 2009; 2013). Thus, it is not surprising that children with ADHD are more likely to show academic underachievement, poor academic performance, and educational problems compared to their counterparts without the diagnosis (Loe & Feldman, 2007). Children with ADHD also show impairments in social functioning. They are rejected more often by their peers and have more conflicts with other children and adults compared to their counterparts who do not have ADHD (Nijmeijer et al., 2008). Although understudied, impaired social functioning in children with ADHD has serious long-term consequences for the development of conduct disorder and even some substance use disorders (Greene, Biederman, Faraone, Sienna, & Garcia-Jetton, 1997). Without proper interventions, functional impairments in the areas of time management, planning/organizing, and prosocial (i.e., cooperation) behaviour skills often endure and escalate into adolescence and adulthood (Abikoff et al., 2004; 2009; 2013; Barkley, 2006; Langberg et al., 2012; Storebø et al., 2011).

Although stimulant medication has been shown to reduce ADHD core symptoms among children with ADHD, effects are limited with regard to children's behavioural, social, and cognitive functioning in daily life (Graziano, Geffken, & Lall, 2011). Behavioural interventions developed to improve these children's functional outcomes, although effective (Abikoff et al., 2004; 2013; Langberg, Epstein, & Graham, 2008), are often time-consuming, costly, and not easily accessible to all children who might benefit from them (Boyer et al., 2014; Evans, Schultz, Demars, & Davis, 2011; Kazdin & Blasé, 2011). Moreover, it appears that 50% of patients with ADHD discontinue treatment regardless of its effectiveness or symptom severity (Pappadopulos et al., 2009). Because of their difficulties with sustaining attention and motivation, patients with ADHD experience low engagement during therapy (Bussing et al., 2012). Consequently, there is a need to explore more rich interactive experiences with visual effects in computer-based therapy approaches in addition to traditional pharmacological, school-based, and mental health approaches that positively impact the daily life functioning of children with ADHD. The use of Internet-based therapeutic approaches to support and improve healthcare is growing because of their potential to offer attractive, easily accessible, and efficient interventions outside the clinical setting (Cheek et al., 2015; Kazdin & Blasé, 2011; World Health Organization, 2013). This fits into the World Health Organization Mental Health Action Plan 2013-2020, which promotes accessible user-driven options emphasizing early intervention and autonomy of individuals, thereby promoting non-pharmacological therapies for young patients (Cheek et al., 2015).

A growing number of computerized training programs for ADHD have been designed to improve working memory and executive functioning, thereby addressing specific neurocognitive deficits and ADHD core symptoms (Cortese et al., 2015; Sonuga-Barke et al., 2014). Commercial versions of the tasks used in these studies have become readily available (e.g., Cogmed, Cognifit, and Memory Booster; Melby-Lervåg & Hulme, 2013). Although these programs show some evidence for short-term effects on targeted working memory outcomes as measured by neurocognitive tests similar to the ones practiced in the games, they have not shown compelling evidence that these effects generalise beyond neurocognitive outcomes to important domains of functioning in the daily lives of children with ADHD (so-called "far-transfer effects"; Chacko et al., 2014; Rapport et al., 2013; Shipstead et al., 2012). These findings are consistent with studies examining the effectiveness of "brain training" games within a "normal" population (Owen et al., 2010). Moreover, few have game mechanics features with a narrative journey structure. It is worth exploring whether or not an Internet-based therapeutic approach with richer interactive experiences with visual effects could improve functional outcomes in children with ADHD. Serious gaming (i.e., [digital] games used for purposes other than purely entertainment) is a novel and promising approach to support the treatment of clinical symptoms and improvement of adaptive functioning among diverse patient groups (Fiellin, Hieftje, & Duncan, 2014; Griffiths, 2002; Kato et al., 2008; Kato, 2010; Merry et al., 2012). Such games offer an environment in which attractive learning tasks are presented in a way that addresses the difficulties that children with ADHD often have in engaging with "boring" and repetitive training tasks (Dovis et al., 2012; Frutos-Pascual et al., 2014; Granic et al., 2014). These games are characterised by a high-intensity immediate reinforcement and this appears to improve task performance, especially within ADHD populations (Jaeggi et al., 2014; Van der Oord et al., 2014). Serious games differ from existing computerized neurocognitive training programs in several ways. Firstly, they offer an overall game environment that allows for exploration and a meaningful ongoing "journey narrative" instead of offering a "casual" game-like interface (Deterding, Dixon, Khaled, & Nacke, 2011). Secondly, these games not only focus on repeating training tasks, but also promote the use of behavioural strategies via a computer game with integrated therapeutic elements (e.g., reinforcement, immediate performance feedback from a mentor, goal setting through missions, modeling, social support, and comparison). The behavioural training aims to improve daily life functioning of children with ADHD (see *Chapter 2* for a more detailed description). Serious games offer an attractive and accessible online learning environment in which children with ADHD stay motivated to train their skills and learn strategies to deal with impairments that affect functional outcomes in daily life. Although the scientific evaluation of serious games precludes making conclusive statements about their impact on "real world" behaviours, several controlled trials of serious games have shown to affect these behaviours in diverse patient groups (DeSmet et al., 2014).

To our knowledge, a serious game designed to enhance behaviour strategies for children with ADHD to improve their daily life functioning has not been scientifically evaluated in the literature. We developed a serious game intervention for children with ADHD to teach behaviour strategies to improve daily life skills, such as time management, planning/organizing, and prosocial (i.e., cooperation) skills (see *Chapter 2*). Previous exploratory research in a pilot study of a prototype of the game demonstrated improvement of time management (see *Chapter 3*). This study examines the effects of this serious game (called "Plan-It Commander") as an additional Internet-based adjunct to the treatment of ADHD in children. We hypothesised that participants playing the serious game would improve on primary outcome measures of time management, planning/organizing, and prosocial (i.e., cooperation) skills compared to participants in the crossover control group. We hypothesised that participants would also improve on secondary outcome measures of working memory, social skills (i.e., responsibility, assertiveness, and self-control) and self-efficacy because these skills were also trained within the overall game environment. We further hypothesised that treatment effects would be maintained at 10-week follow-up for the group that played the serious game for the first 10 weeks of the study.

METHODS

A total of 182 participants were recruited from January to March 2013 across 4 outpatient mental healthcare clinics and institutions in the Netherlands and Belgium. Eligible parents and children were informed by their clinician about this study. In other cases, the patient organization provided information about the study to their members; these parents directly applied for the study. Once the clinician identified eligible parents and children, they received detailed written and verbal information about the study from the researcher. After signing informed consent, they were invited for a screening visit (performed by trained research assistants with M.A. in psychology) to verify inclusion and exclusion criteria. This resulted in a sample of 170 participants. Inclusion criteria were (1) a *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (*DSM-IV-TR*) diagnosis of ADHD (confirmed by the Kiddie Schedule for Affective Disorders and Schizophrenia-Lifetime version [K-SADS; Puig-Antich & Chamber, 1978; Reichart, Wals,

& Hillegers, 2000]), (2) aged between 8 and 12 years, (3) stable on pharmacological and/or psychological treatment for ADHD eight weeks before baseline (determined by healthcare professionals on the basis of medication data and behavioural observation), (4) no initiation or change of pharmacological and/or psychological treatment for ADHD during the study period, (5) availability of a computer workstation at home with Internet and sound facilities, and (6) sufficient understanding of the Dutch language by the child and by at least one of the parents. ADHD severity was measured by the parent version of the Disruptive Behavior Disorder Rating Scale (DBDRS; Oosterlaan, Scheres, Antrop, Roeyers, & Sergeant, 2000; Pelham, Gnagy, Greenslade, & Milich, 1992) and children with common comorbid disorders of ADHD (e.g., oppositional defiant disorder as measured by the DBDRS) could participate in the study.

Exclusion criteria were (1) an estimated total Intelligent Quotient (IQ) lower than 80 (determined by vocabulary and block design subtests of the Wechsler Intelligence Scale for Children III [WISC-III] (Sattler, 2001; Wechsler, 1991), (2) substance abuse problems (e.g., drugs, alcohol), (3) conduct disorder, (4) autism spectrum disorder (both previously diagnosed by healthcare professionals), (5) comorbid acute psychiatric disorder (e.g., depression, mania; confirmed by the K-SADS; Puig-Antich & Chamber, 1978; Reichart et al., 2000), and (6) participation in a previous pilot study with a prototype of "Plan-It Commander". Children with a severe physical disability (e.g., blindness, deafness) or learning disability (e.g., dyslexia) were also excluded on the basis of the child's medical file and a standardised interview administered by phone to parents. Written informed consent was obtained from parents and children aged 12 years. All study procedures were approved in advance by the Erasmus (Dutch; MEC-2012-539) and Leuven (Belgian) Medical Ethical Committees.

Design

This study used a 20-week multisite randomised controlled crossover open-label trial design (see Figure 1). The intervention was an online serious game called "Plan-It Commander". Participants were randomised to a serious game intervention group (SG group) or a treatment as usual crossover group (TAUx group). Participants randomised to SG group received a serious game intervention in addition to TAU for the first 10 weeks and then received TAU only for the next 10 weeks. Participants randomised to TAUx group received TAU for the first 10 weeks and crossed over to the serious game intervention in addition to TAU for the subsequent 10 weeks. All participants in the study received TAU and most participants (91.8%, 156/170) were on medication. Participants were instructed to play the serious game for a maximum of 65 minutes approximately three times per week. The game was programmed so that participants could not play more than 65 minutes in one 24-hour period to prevent excessive use of the game.

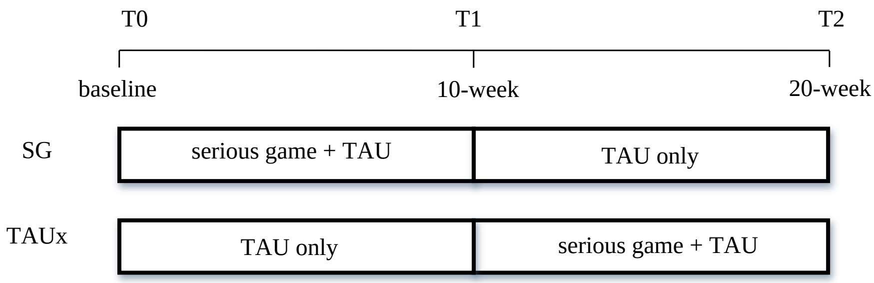


Figure 1. Study design with SG intervention and TAUx groups.

Randomisation and blinding

Randomisation was carried out on a 1:1 ratio and based on a pre-specified computer-generated randomisation list. Allocation was stratified by study site and gender and arranged in permutated blocks. Group assignment was performed online using the next available number on the randomisation list corresponding to the site and gender of the participant. It was not possible to blind participants to their treatment allocation. After screening and baseline assessment, parents received an email with the notification to which group (SG group vs. TAUx group) their child was allocated. Although all efforts were made to keep the investigator blind during baseline assessments, full blinding of researchers and teachers at the other assessment points could not be guaranteed because participants could spontaneously talk about the game during the study.

Intervention

The serious game is an online adventure game (called "Plan-It Commander") developed by healthcare professionals, researchers, and game experts in collaboration with parents and children with ADHD. In collaboration with a focus group of parents, the multidisciplinary game development team agreed on the game's learning goals and play frequency/time. After each prototype build, usability tests were iteratively performed to examine whether children liked the game and understood how to use it and navigate within the game. User data were evaluated and incorporated in the design process for the final game format, which was examined in this study. "Plan-It Commander" was designed to improve domains of daily life functioning with a primary focus on time management, planning/organizing, and prosocial (i.e., cooperation) skills in children with ADHD. Unifying their knowledge and expertise resulted in a unique online learning environment in which principles of behaviour therapy and game-based learning were combined (see *Chapter 2*). Players had their own password and ID to log on to the Internet-based serious game from their home where they could access two game components: (1) a mission-guided game environment with mini-games related to the learning goals of improving time management, planning/organizing, and prosocial (i.e., cooperation) skills and (2) a closed social community. The game was linked to a database in which data about play frequency and duration were registered from each participant.

"Plan-It Commander" is a mission-guided game divided into 10 different missions and several side missions (see Figure 2). Missions guide the player's behaviour throughout the game as he or she follows the story line and is asked to solve problems requiring specific skills. Central parts are the three mini-games addressing time management, planning/organizing, and prosocial (i.e., cooperation) behaviour that are embedded in the structure of the game. The first mini-game is focused on teaching the player time estimation and time management skills. The second mini-game is focused on enhancing planning skills; the player is taught to plan ahead and break down the total assignment into pieces. The third mini-game focuses on enhancing prosocial behaviour, teaching the player to help their team members and to cooperate with each other. In addition to the mission-guided game, players could access a closed social community (called "Space Club") to stimulate prosocial behaviour (e.g., helping other players, giving compliments) (see Figure 3). Players can ask for help or help other players through predefined messages and reward them with a thank you message. The player's profile is presented within the community and shows an overview of his or her progression throughout the game. When a player completes certain "challenges" in the mission-guided game, an achievement is unlocked in the community. Every player has an overview of awarded

Figure 2. Screenshot of "Plan-It Commander" game world.

Figure 3. Screenshot of game social community (called "Space Club")

achievements in the form of badges or medals in their profile within the community. By making progress in the game and reaching certain milestones, the player unlocks rewards in the community. Rewards can vary in form, such as papercraft models, desktop wallpapers, and music from the game. Players can see each other's profiles and this generates competition between players. Details of the development and content of "Plan-It Commander" are described in *Chapter 2*.

Measures

Multi-informant (parent, teacher, and self-report) measures were administered at baseline (T0), at 10 weeks (T1), and at 10-week follow-up (T2). Parent and teacher reports were administered through online questionnaires. Questionnaires were administered to the children during face-to-face appointments at each assessment time point. At baseline, demographic information and children's game experience were collected through parent reports. The parent reported on the game experience of their child as starter, amateur, experienced, or expert. For the primary outcomes, parents filled in the following questionnaires during the three assessment time points: (1) a time management questionnaire (see Appendix 1), (2) the subscale Plan/Organize of the Behavior Rating Inventory of Executive Function (BRIEF; parent version; Gioia et al., 2000; Smidts & Huizinga, 2009) and (3) the subscale Cooperation of the Social Skills Rating System (SSRS; parent version; Gresham & Elliott, 2008; Van der Oord et al., 2005). The time management questionnaire gave a more detailed insight into children's behaviour strategies used to improve their time management skills compared to other existing questionnaires (primarily focusing on time perception and/or coordination) and demonstrated good reliability (α=.85) in a pilot study (see *Chapter 3*). Secondary outcomes consisted of parent, teacher, and self-reports. Parents filled in the subscale Working Memory of the BRIEF (parent version); the subscales Responsibility, Assertiveness, Self-Control, and Total of the SSRS (parent version); and the It's About Time Questionnaire (IATQ; parent version; Barkley, 1990). In addition, teachers were asked to fill in the time management questionnaire, the subscales Plan/Organize and Working Memory of the BRIEF (teacher version), and the SSRS (teacher version) to provide an indication of how the participant functioned at school. Further, we asked participants to fill in a self-efficacy questionnaire (Bandura, 2006; see Appendix 2). After receiving the serious game, both parents and participants filled in a satisfaction questionnaire indicating general satisfaction with the serious game on a 10-point Likert scale. Table 1 includes a description of each measure.

Table 1. Description of primary and secondary outcome measures.

Measures[a]	Respondent	Description	Cronbach α[b]
Primary outcomes			
Time management questionnaire	Parent and teacher report	This 11-item scale is a measure of children's time management behaviour. Parents were asked to rate this behaviour on a 10-point Likert scale (ranging from true to not true). The total score ranges from 11 to 110. Higher scores indicate better time management skills.	.83/.90
BRIEF (subscale Plan/Organize)	Parent and teacher report[c]	A measure of executive functioning in home situations in children aged 5-18 years. For this study, the subscale Plan/Organize, consisting of 12 items, was used to measure children's planning and organizing skills. The answers are scored on a 3-point Likert scale (never—sometimes—often). The total score ranges from 12 to 36. Higher scores indicate better planning skills.	.81/.80
SSRS (subscale Cooperation)	Parent and teacher report[d]	A measure of social functioning in children aged 8- 12 years. This questionnaire consists of four subscales (i.e., Cooperation, Responsibility, Assertiveness, Self-Control) of 10 items each. The answers are scored on a 3-point Likert scale (never—sometimes—often). Two items load on two subscales; therefore, the total scale consists of 38 items and has a possible range from 0 to 80. Higher scores indicate better social skills.	.70/.84

Table 1. Description of primary and secondary outcome measures. (continued)

Measures[a]	Respondent	Description	Cronbach α[b]
Secondary outcomes			
IATQ	Parent-report	A measure of children's skills in time perception and orientation. It consists of 25 items scored on a 3-point Likert scale ranging from 0 "rarely" to 3 "almost always." The total score ranges from 0 to 75. Higher scores indicate better time-oriented behaviour.	.74
Self-efficacy	Self-report	A measure of one's confidence in his/her ability to carry out specific behaviours related to time management, planning, and social functioning. This measure was constructed in accordance with the standard method for designing self-efficacy scales (Bandura, 2006). As such, it was designed specifically for this study to assess self-efficacy beliefs targeted in the game. Children were asked to rate 14 items on a scale from 0 to 10 how certain they are that they can master certain skills. The total score ranges from 0 to 140. Higher scores indicate more perceived self-efficacy.	.88
Satisfaction	Parent and self-report	Satisfaction was indicated on a 10-point Likert scale in which both children and parents were asked: "What grade would you give to this game?"	N/A

[a] BRIEF: Behavior Rating Inventory of Executive Functioning; SSRS: Social Skills Rating System; IATQ: It's About Time Questionnaire.

[b] Cronbach alpha is an indication of construct validity. Coefficients were calculated from baseline data in this sample.

[c] The subscale Working Memory (10 items) from the BRIEF was used as a secondary measure for parents (Cronbach alpha=.83) and teachers (Cronbach alpha=.85).

[d] The subscales Assertiveness, Responsibility, and Self-Control and the Total Score were used as secondary outcome measures for parents and teachers (except for the subscale Responsibility).

Statistical power and analyses

The sample size was determined in advance by power calculations on the basis of previous pilot study descriptive results (*M*, *SD*) on primary outcome measures, which indicated that 78 participants per group would give 87% power to detect differences of a medium effect size (at least 0.5) between groups (α=.05; two-sided). In the current study, differences in baseline characteristics were tested with an independent samples *t* test or a chi-square test. For primary and secondary outcome measures, changes from baseline to 10 weeks (reflected by its difference scores) were compared between SG group and TAUx group with ANCOVAs, with baseline score as a covariate and gender and site as factors. To assess improvement during treatment within both groups, paired samples *t* tests were performed on primary and secondary outcome measures before and after playing the serious game. To assess whether effects were maintained after playing the game for 10 weeks within SG group, within-group comparisons of changes at 10 weeks versus 10-week follow-up were performed. Intention-to-treat analyses were used and included all randomised participants. Linear trend at point was used as an imputation method. All statistical analyses were performed using SPSS version 19.0 statistical software (IBM Corp, 2010) and were two-sided with a level of significance of $\alpha=.05$. The significance level for primary outcome measures was adjusted on the basis of the Hochberg procedure (Hochberg & Benjamini, 1990). Effect sizes were reported for all analyses using Cohen's *d* (Cohen, 1988).

RESULTS

Patient flow

A total of 170 participants met the inclusion criteria and participated in the study. Mean scores for primary and secondary outcome measures and characteristics of SG and TAUx groups did not differ significantly at baseline (see Table 2). Most participants (91.8%, 156/170) received medication as their TAU. Medication use did not differ between 4 outpatient mental healthcare clinics and institutions ($\chi^2_3=3.7$, $p=.29$).

At 10 weeks (T1), 152 of 170 participants (89.4%) completed the study and 139 of 170 (81.8%) completed at the 10-week follow-up (T2). At 10 weeks (T1), the drop-out rate was higher in SG group compared to TAUx group ($\chi^2_1=8.0$, $p=.01$). The drop-out rate did not differ between the two study groups at 10-week follow-up ($\chi^2_1=2.5$, $p=.12$). Participants who dropped out during the study period did not differ according to age ($t_{168}=-1.34$, $p=.18$), gender ($\chi^2_1=2.2$, $p=.13$), ADHD subtype ($\chi^2_2=2.5$, $p=.29$), or intelligence ($t_{168}=-1.66$, $p=.10$) compared to participants who did not drop out (for flow diagram see Figure 4). However, children who dropped out during the study ($M=45.06$, $SD=15.79$) had higher ADHD severity scores compared to children who completed the study ($M=39.07$, $SD=14.16$; $t_{168}=2.09$, $p=.04$).

Participants played for a mean 19.04 ($SD=9.61$) days in the mission-guided game and a mean 11.20 ($SD=8.55$) days in the closed social community. Additionally, participants played the mission-guided game for a total duration of a mean 12.56 ($SD=6.57$) hours and engaged with the closed social community for a median of 35.31 minutes. A difference was seen between SG group ($M=13.53$, $SD=6.25$) and TAUx group ($M=11.53$, $SD=7.25$) with regard to the amount of time playing the mission-guided game ($t_{155}=1.81$, $p=.07$) but it did not meet statistical significance. There was a significant difference between SG group ($M=12.61$, $SD=8.60$) and TAUx group ($M=9.70$, $SD=8.28$) with regard to the number of days they engaged with the closed social community ($t_{157}=2.17$, $p=.03$). With regard to the amount of time playing in the closed social community, there was a difference

Table 2. Demographic information of the sample at baseline.

Baseline characteristics	Total (N=170)	SG group (*n*=88)	TAUx group (*n*=82)	Group comparison		
				t (168)	χ^2 (df)	*p*
Sex, n (%)					0.1 (1)	.72
Male	137 (80.6)	70 (79.5)	67 (81.7)			
Female	33 (19.4)	18 (20.5)	15 (18.3)			
Age (years), mean (*SD*)	9.85 (1.26)	9.89 (1.28)	9.82 (1.24)	–0.36		.79
Total IQ,[a] mean (*SD*)	106.18 (14.79)	105.40 (14.46)	107.02 (15.18)	0.72		.55
ADHD subtypes, *n* (%)					3.2 (2)	.21
Combined	126 (74.1)	66 (75.0)	60 (73.2)			
Inattentive	38 (22.4)	17 (19.3)	21 (25.6)			
Hyperactive-Impulsive	6 (3.5)	5 (5.7)	1 (1.2)			
Attention deficit,[b] *n* (%)					1.6 (1)	.21
Normal	62 (36.5)	36 (40.9)	26 (31.7)			
(Sub)clinical	108 (63.5)	52 (59.1)	56 (68.3)			
Hyperactivity,[b] *n* (%)					1.9 (1)	.17
Normal	84 (49.4)	39 (44.3)	45 (54.9)			
(Sub)clinical	86 (50.6)	49 (55.7)	37 (45.1)			
Oppositional defiant disorder,[b] *n* (%)					2.1 (1)	.14
Normal	149 (87.6)	74 (84.1)	75 (91.5)			
(Sub)clinical	21 (12.4)	14 (15.9)	7 (8.5)			
Game experience, *n* (%)					4.3 (3)	.23
Starter	29 (17.1)	13 (14.7)	16 (19.5)			
Amateur	55 (32.4)	29 (33.0)	26 (31.7)			
Experienced	82 (48.2)	42 (47.7)	40 (48.8)			
Expert	4 (2.4)	4 (4.5)	0 (0)			
Special education? (yes), *n* (%)	25 (14.7)	14 (15.9)	11 (13.4)		0.2 (1)	.65
Medication use? (yes), *n* (%)	156 (91.8)	80 (90.9)	76 (92.7)		0.2 (1)	.67
Psycho education for parents? (yes), *n* (%)	9 (5.3)	5 (5.7)	4 (4.9)		0.1 (1)	.82

[a] IQ: Intelligence Quotient.
[b] ADHD and ODD severity are based on clinical and subclinical scores on the parent version of the DBDRS.

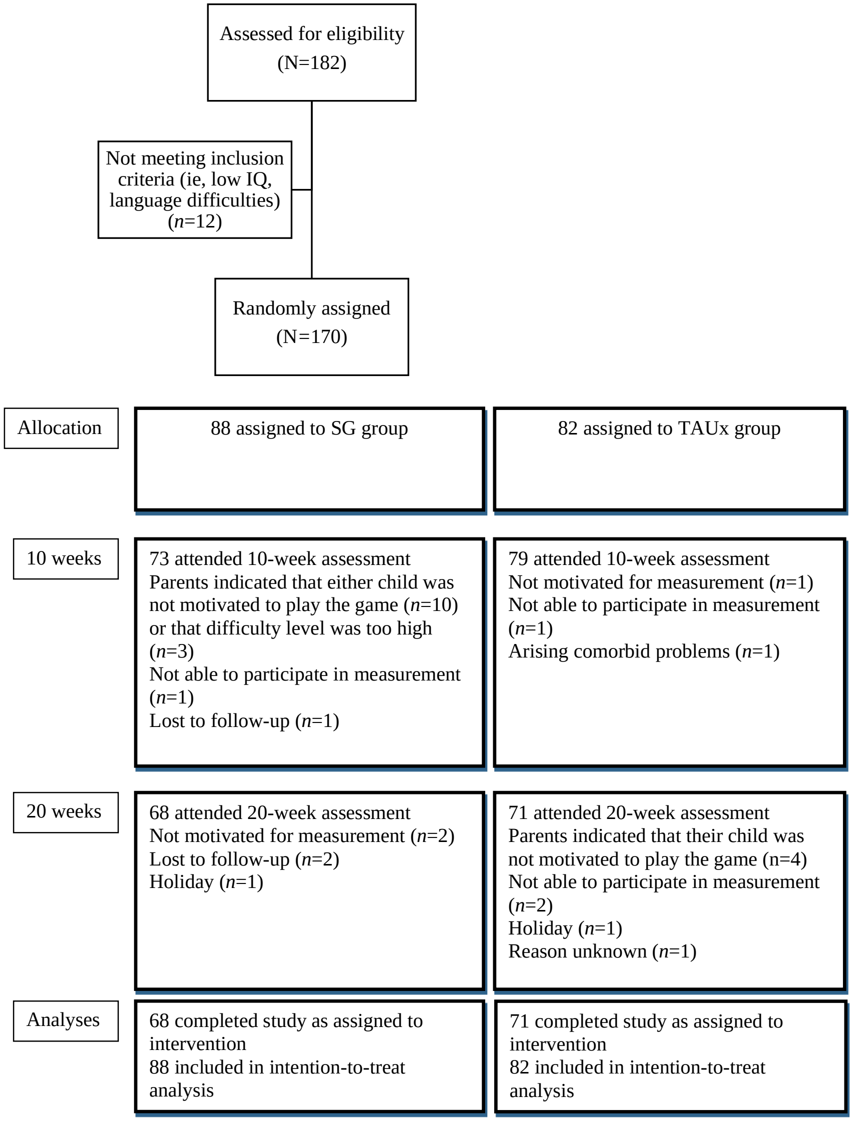


Figure 4. Study flow diagram.

between SG group (M=1.04, SD=1.16) and TAUx group (M=0.44, SD=1.02; t_{156}=1.82, p=.07), although this was not statistically significant. There were no differences between the two groups with regard to the number of days playing the mission-guided game. Both parents (M=6.96, SD=1.40) and participants (M=7.33, SD=1.87) reported moderate to high satisfaction with receiving the serious game intervention.

Between-group difference (SG group versus TAUx group)

To test the hypothesis that participants playing the serious game would improve on primary and secondary outcome measures, differences between SG group and TAUx group from baseline to 10 weeks (T1; post-test) were evaluated with ANCOVAs (see Table 3). On the primary outcome measures, SG group showed significantly greater improvements in parent-rated time management skills compared to participants in TAUx group. SG

Table 3. Univariate analyses of covariance comparing SG group and TAUx group on primary and secondary outcome measures during first 10 weeks.

Measures[a]	SG group (*n*=88)		TAUx group (*n*=82)		ANCOVA		
	LS Mean (*SE*)	95% CI	LS Mean (*SE*)	95% CI	$F_{1,163}$ [b]	*p*	*d*
Parent reported							
Primary outcomes							
Time management	10.66 (1.64)	7.42, 13.89	4.68 (1.72)	1.29, 8.07	8.56	.004[c]	0.39
BRIEF (subscale Plan/Organize)	1.47 (0.36)	0.75, 2.18	0.64 (0.38)	−0.11, 1.39	3.32	.07[c]	0.35
SSRS (subscale Cooperation)	1.10 (0.34)	0.43, 1.78	0.46 (0.36)	−0.25, 1.16	2.32	.13[c]	0.16
Secondary outcomes							
It's about time	2.74 (0.73)	1.30, 4.17	1.18 (0.76)	−0.32, 2.68	2.98	.09	0.20
BRIEF (subscale Working Memory)	0.75 (0.32)	0.11, 1.38	−0.17 (0.33)	−0.83, 0.49	5.16	.02	0.51
SSRS (Total)	2.24 (0.81)	0.64, 3.83	0.58 (0.85)	−1.09, 2.26	2.68	.10	0.05
SSRS (subscale Assertiveness)	0.32 (0.27)	−0.22, 0.85	−0.06 (0.28)	−0.62, 0.49	1.28	.26	0.04
SSRS (subscale Responsibility)	0.75 (0.25)	0.27, 1.23	0.11 (0.26)	−0.39, 0.62	4.28	.04	0.04
SSRS (subscale Self-Control)	0.24 (0.29)	−0.34, 0.81	0.22 (0.31)	−0.38, 0.83	0	.97	0.07
Teacher reported							
Time management	5.30 (1.32)	2.70, 7.90	−0.16 (1.38)	−2.88, 2.56	11.05	.001	0.41
BRIEF (subscale Plan/Organize)	0.78 (0.34)	0.11, 1.44	0.14 (0.35)	−0.55, 0.84	2.30	.13	0.18
BRIEF (subscale Working Memory)	1.32 (0.34)	0.65, 2.00	0.50 (0.36)	−0.20, 1.20	3.79	.05	0.22
SSRS (Total)	2.95 (0.67)	1.64, 4.27	2.36 (0.70)	0.98, 3.74	0.51	.48	0
Self-reported							
Self-efficacy	3.06 (2.42)	−0.73, 7.84	−2.13 (2.55)	−7.16, 2.90	2.95	.09	0.26

[a] BRIEF: Behavior Rating Inventory of Executive Function; SSRS: Social Skills Rating Scale.
[b] Pillai's Trace.
[c] Adjusted *p* values are .01, .14, and .13 for parent-reported time management, BRIEF (subscale Plan/Organize), and SSRS (subscale Cooperation), respectively.

group also showed more improvement in parent-reported planning/organizing skills compared to TAUx group, although this did not meet statistical significance (p=.07). There were no differences concerning participants' cooperation skills.

Regarding the secondary outcome measures, SG group also improved significantly more than the TAUx group on measures of parent-reported working memory and responsibility skills. Participants in SG group showed greater improvements in participants' time perception compared to TAUx group, although this did not meet statistical significance (p=.09). Teachers reported greater improvements in SG group than TAUx group on the measure of time management and working memory, although this latter effect did not meet statistical significance (p=.05). Finally, the same accounted for participants' self-efficacy in which participants in SG group showed greater improvements as compared to TAUx group (p=.09), but it did not meet statistical significance. No differences were found on parent-rated total social skills (with subscales assertiveness and self-control) and teacher-rated total social skills and planning/organizing skills.

TAUx within-group effects

Within-group differences for TAUx group were evaluated (see Table 4). While receiving TAU for the first 10 weeks, participants improved significantly on parent-reported time management and teacher-reported social skills. After crossing over to the serious game intervention in addition to TAU for the subsequent 10 weeks, significant improvements in outcomes of parent-reported time management, time perception, planning/organizing, working memory, and social skills (primarily cooperation and assertiveness) were found. Furthermore, significant improvements were demonstrated for all teacher-reported outcomes. Self-reported self-efficacy also significantly improved after receiving the intervention (see Table 4).

SG group within-group effects and 10-week (T2) follow-up effects

Within-group differences for SG group were then evaluated (see Table 5). While playing the serious game intervention in addition to TAU for the first 10 weeks, significant improvements in outcomes of parent-reported time management, time perception, planning/organizing, and social (primarily cooperation and responsibility) skills were found. Furthermore, significant improvements were demonstrated for participants' time management, working memory, and social skills as reported by their teachers. Within-group effects showed significant improvement from 10 weeks to 10-week follow-up for parent-reported time management, working memory, time perception, and social skills (primarily cooperation, responsibility, and self-control). Furthermore, significant improvements were demonstrated for teacher-reported time management and working memory skills (see Table 5). This implies that most effects maintained or even further improved at 10-week follow-up.

Table 4. TAUx group results of paired samples *t* tests of primary and secondary outcome measures at baseline, 10-week, and 20-week assessments.

Outcomes[a]	Assessment, mean (*SD*)			T0 vs T1			T1 vs T2		
	Baseline (T0)	10 weeks (T1)	20 weeks (T2)	*t* (81)	*p*	*d*	*t* (81)	*p*	*d*
Parent reported (*n*=82)									
Primary outcomes									
Time management	48.88 (15.25)	52.95 (18.17)	60.00 (14.71)	2.80	.006	0.24	4.36	<.001	0.43
BRIEF (subscale Plan/Organize)	20.41 (4.61)	20.76 (4.54)	22.01 (4.27)	1.07	.29	0.08	3.29	.001	0.28
SSRS (subscale Cooperation)	8.73 (3.68)	8.90 (3.46)	9.86 (3.16)	0.55	.58	0.05	2.85	.006	0.29
Secondary outcomes									
It's about time	30.88 (7.82)	31.61 (7.58)	33.89 (7.15)	1.05	.30	0.09	3.05	.003	0.31
BRIEF (subscale Working Memory)	14.23 (3.29)	14.42 (3.13)	16.39 (3.36)	0.63	.53	0.06	5.36	<.001	0.61
SSRS (subscale Assertiveness)	14.52 (3.81)	14.35 (3.73)	15.18 (2.65)	–0.67	.50	0.05	2.91	.005	0.26
SSRS (subscale Responsibility)	13.63 (3.16)	13.41 (2.92)	13.97 (2.61)	–0.95	.35	0.07	1.97	.05	0.20
SSRS (subscale Self-Control)	10.06 (3.78)	10.19 (3.95)	10.74 (3.15)	0.50	.62	0.03	1.50	.14	0.20
SSRS (Total)	44.24 (10.50)	44.08 (10.67)	46.83 (8.84)	–0.23	.82	0.02	2.96	.004	0.28
Teacher reported (*n*=82)									
Time management	65.04 (16.37)	64.68 (14.78)	70.20 (10.46)	–0.27	.79	0.02	4.09	<.001	0.43
BRIEF (subscale Plan/Organize)	20.17 (3.96)	20.16 (3.77)	20.92 (3.18)	–0.05	.96	0	2.40	.02	0.22
BRIEF (subscale Working Memory)	18.57 (3.73)	18.97 (3.87)	20.42 (3.18)	1.19	.24	0.11	4.11	<.001	0.41
SSRS (Total)	34.87 (7.62)	36.76 (7.21)	38.37 (6.33)	2.74	.01	0.25	2.52	.01	0.24
Self-reported (*n*=82)									
Self-efficacy	87.35 (23.63)	86.12 (25.55)	90.87 (22.32)	–0.48	.64	0.05	2.08	.04	0.20

[a] BRIEF: Behavior Rating Inventory of Executive Function; SSRS: Social Skills Rating Scale.

Table 5. SG group results of paired samples *t* tests of primary and secondary outcome measures during baseline, 10-week, and 20-week assessments.

Outcomes[a]	Assessment, mean (*SD*)			T0 vs T1			T1 vs T2		
	Baseline (T0)	10 weeks (T1)	20 weeks (T2)	*t* (87)	*p*	*d*	*t* (87)	*p*	*d*
Parent reported (*n*=88)									
Primary outcomes									
Time management	49.73 (16.41)	59.45 (15.28)	64.70 (11.32)	5.82	<.001	0.61	4.66	<.001	0.39
BRIEF (subscale Plan/Organize)	21.32 (4.21)	22.19 (3.70)	22.58 (3.63)	2.18	.03	0.22	1.25	.22	0.11
SSRS (subscale Cooperation)	8.53 (2.71)	9.45 (3.24)	10.29 (2.27)	2.62	.01	0.31	3.12	<.01	0.30
Secondary outcomes									
It's about time	30.62 (7.21)	33.04 (6.55)	35.08 (6.36)	3.02	.003	0.35	3.48	.001	0.32
BRIEF (subscale Working Memory)	15.50 (3.52)	16.06 (3.32)	16.78 (3.48)	1.61	.11	0.16	2.29	.03	0.21
SSRS (subscale Assertiveness)	14.14 (3.33)	14.48 (2.69)	14.63 (3.04)	1.24	.22	0.11	0.62	.54	0.05
SSRS (subscale Responsibility)	12.83 (2.88)	13.53 (2.69)	14.06 (2.54)	2.83	.006	0.25	2.55	.01	0.20
SSRS (subscale Self-Control)	9.66 (3.51)	9.93 (3.03)	10.82 (3.05)	0.94	.35	0.08	3.58	.001	0.29
SSRS (Total)	42.57 (8.81)	44.58 (8.50)	46.85 (8.69)	2.46	.02	0.23	3.93	<.001	0.26
Teacher reported (*n*=88)									
Time management	65.31 (16.12)	70.31 (12.43)	73.92 (10.07)	3.45	.001	0.35	2.95	.004	0.32
BRIEF (subscale Plan/Organize)	20.30 (3.81)	20.87 (2.97)	21.38 (2.39)	1.54	.13	0.17	1.79	.08	0.19
BRIEF (subscale Working Memory)	18.49 (3.65)	19.75 (3.33)	20.62 (2.47)	3.87	<.001	0.36	2.55	.01	0.30
SSRS (Total)	33.73 (9.42)	36.75 (6.92)	36.38 (7.04)	4.03	<.001	0.37	–0.52	.60	–0.05
Self-reported (*n*=88)									
Self-efficacy	89.39 (25.03)	92.33 (22.01)	94.09 (20.66)	1.29	.20	0.12	1.62	.29	0.08

[a] BRIEF: Behavior Rating Inventory of Executive Function; SSRS: Social Skills Rating Scale.

Adverse events

While playing the serious game, adverse events were registered by the researcher and checked by a healthcare professional. Overall, there were 10 adverse events that could be related to the intervention that were reported by parents, teachers, or participants themselves. All adverse events were of mild (n=5) or moderate (n=5) severity, but this was no reason to discontinue study participation. Examples of adverse events were pain in the fingers, irritability, and headache. An adverse event was a reason to discontinue the study for only one known participant. This participant did not want to play the game anymore because he could not concentrate during his school activities. Sounds reminded him of the game and this consequently distracted and frustrated him. No serious adverse events were reported.

DISCUSSION

The findings of this 20-week multisite randomised controlled crossover open-label trial demonstrate the effectiveness of an Internet-based serious game specifically developed for children with ADHD. Participants who played the serious game during the first 10 weeks significantly improved in their daily life functioning across domains of time management, social skills (e.g., responsibility) and working memory compared to participants in the TAUx group. These effects were small to medium and were maintained or even further improved at the 10-week follow-up for SG group. Children from TAUx group, who played the serious game during the second period of the study (weeks 10 to 20), improved on comparable domains of daily life functioning over time. In contrast to previous studies that typically demonstrate that computerized neurocognitive interventions for ADHD improve working memory skills but do not have a strong impact on daily life functioning ("far-transfer effects") (Chacko et al., 2014; Melby-Lervåg & Hulme, 2012; Owen et al., 2010; Rapport et al., 2013; Shipstead et al., 2012), the findings of the current study provide clear evidence that a serious game for children with ADHD can improve the performance of these children in important daily life skills. Of particular interest is the clear effect seen on time management skills because dysfunctional time management is one of the core problems in ADHD, affecting social and executive domains of daily life functioning (Frutos-Pascual et al., 2014; Sonuga-Barke et al., 2010). It should be noted that the improvements in time management and working memory were reported by parents at home and teachers at school supporting the claim that positive behavioural adaptations resulting from use of the serious game generalised across different settings. Although improvements in planning/organizing skills have been shown by other computerized neurocognitive training programs as well (Beck et al., 2010; Van der Oord et al., 2014), this serious game is unique because it elicits its effects by promoting behavioural strategies instead of training executive functions by offering repeated cognitive exercises. As such, this approach provides sustainable therapeutic effects by improving behavioural strategies that can be applied in daily life.

"Plan-It Commander" demonstrated improvement of total social skills over time, but had nonsignificant between-group effects as reported by parents and teachers. Multiplayer and cooperative game-play could be more explicitly integrated to improve social benefits of the current game format. Improvements in social responsibility among players was observed. This was expected given that game elements, such as a mentor figure or NPCs and peers with ADHD with whom they could interact (e.g., asking for help, being polite, and dealing with compliments in a good way), enabled players to practice socially responsible behaviours in the game that could be practiced in the "real world" as well. This finding is important given that well-developed social responsibility skills in children contribute to academic success and an optimal learning environment (Gresham & Elliott, 2008; Van der Oord et al., 2005).

Another goal of "Plan-It Commander" was to improve children's self-efficacy. Children were more confident in self-control with regard to their time management and planning skills and engagement in positive social interactions. However, the between-group effect on self-efficacy did not meet statistical significance. It may be important that further development of serious gaming addresses aspects of the concept of self-efficacy (e.g., modeling behaviour) more thoroughly because increased self-efficacy has been shown to correlate significantly with self-esteem and adaptive behaviours such as persistence in reaching goals in daily life (Bandura, 2006; Edbom, Lichtenstein, Granlund, & Larsson, 2006; Lieberman, 1997). Overall, this study introduces serious gaming as an effective and attractive behavioural intervention for children with ADHD, especially for time management with evidence for effects on certain social skills and self-efficacy as well.

Clinical implications

ADHD is a chronic health problem and previous studies have emphasized the need for efforts to treat impairments outside the therapy context and provide patients with greater autonomy (Cheek et al., 2015; Coleman et al., 2009; World Health Organization, 2013). The Internet-based serious game intervention in this study fulfills this need by addressing impairments associated with ADHD among school-aged children in the home and school context. Results demonstrated that parents as well as children were satisfied with their treatment. The current intervention was positioned as an adjunct to TAU. No therapist or parent explicitly intervened during the game intervention. Furthermore, no additional rewards were given and no prompts to play the game regularly were explicitly provided outside the game. Given that young patients with ADHD have engagement and motivation issues in general, easy accessible interventions such as serious games can stimulate them to co-manage their healthcare processes as part of the Chronic Care

Model of Child Health and the World Health Organization Mental Health Action Plan 2013-2020 (Cheek et al., 2015; Van Cleave & Leslie, 2008; World Health Organization, 2013).

The current intervention is unique in its contribution to the adjunctive ADHD treatment repertoire because it differs from existing computerized neurocognitive training formats. Instead of requiring the repetition of executive function tasks normally presented in neurocognitive training format for children with ADHD, "Plan-It Commander" promotes the use of behavioural strategies via a computer game with integrated therapeutic elements (e.g., reinforcement, immediate performance feedback from a mentor, goal setting through missions, modeling, social support, and comparison) that increase functional outcomes within a relatively short period of time. Even more important is the fact that participants labeled as "clinically stable" by their clinicians still showed significant improvements in daily functioning. It is encouraging that significant results were obtained over and above medication effects. Future research could examine the effects of this serious game in a nonmedicated sample to disentangle its effects. Notably, participants with higher severity scores on ADHD symptoms were more likely to drop out from the study, which implies that we can only generalise our results to children with less severe ADHD symptoms, but this remains speculative because symptoms were within the normal range. Furthermore, future research should consider family factors (e.g., social support network, socioeconomic status, parental ADHD) as well in contributing to study drop-out.

Limitations

The results of this study must be considered in the light of several limitations. TAUx group followed TAU and did not use a non-therapeutic "placebo game." Therefore, this study could be controlled for changes in time and effects of repeated measurements, but not for placebo effects. Further, parents were not rater-blinded and rater-blindness of teachers could not fully be guaranteed because children were free to report game experiences. Questionnaires to assess time management and self-efficacy were designed on theoretical basis and guidelines by Bandura (Bandura, 2006). Both instruments show good reliability. The time management questionnaire was developed because of a lack of instruments for this age group. This questionnaire was used previously in a randomised controlled pilot study (see *Chapter 3*). Future research should evaluate the psychometric characteristics of these questionnaires in more detail.

CONCLUSIONS

The current randomised controlled study demonstrated that "Plan-It Commander" is an effective adjunctive Internet-based behavioural intervention for children with ADHD. It is a unique contribution to the literature on serious games because it showed that a serious game for ADHD, as an adjunct to TAU, improves functional outcomes of time management as well as working memory and social responsibility. It fits into the current interest in nonmedical treatment options for ADHD and stimulates young children to manage their impairments by offering an easy, accessible home treatment intervention. The findings contribute to scientific knowledge about the impact of serious game interventions on behavioural outcomes, Internet-based interventions for mental health that are consistent with the Chronic Care Model of Health, and innovative approaches to treating people coping with chronic mental health conditions.

Chapter 5

Neurocognitive effects of serious gaming as an adjunct to treatment for children with Attention Deficit Hyperactivity Disorder: A Randomised Controlled Trial.

ABSTRACT

Objective: In a multisite randomised controlled crossover open-label trial, behavioural effects of an Internet-based serious game intervention (called "Plan-It Commander") for children with ADHD were found. This chapter aims to examine effects of "Plan-It Commander" on secondary outcomes; i.e., neurocognitive performance tests.

Methods: Participants (N=170) in this 20-week trial had a diagnosis of ADHD and ranged in age from 8 to 12 years (81% males; 19% females). Participants were randomised to a serious game intervention group (SG; *n*=88) or a treatment as usual crossover group (TAUx; *n*=82). The serious game primarily focused on improving time management, planning/organizing and prosocial (i.e., cooperation) skills. Participants randomised to the SG group received a serious game intervention in addition to treatment as usual for the first 10 weeks and then received treatment as usual for the next 10 weeks. Participants randomised to the TAUx group received treatment as usual for the first 10 weeks and crossed over to the serious game intervention in addition to treatment as usual for the subsequent 10 weeks. In both groups, neurocognitive performance tests of planning, working memory and social cognitive domains were administered at baseline, 10 weeks and 10-week follow-up as secondary outcome measures.

Results: There were no significant differences between the SG and TAUx groups on any neurocognitive performance tests. Significant within-group improvements were found on planning and social cognitive test performances for both groups. Moreover, neurocognitive functioning at baseline did not appear to be a significant predictor of behavioural improvement, except for social behaviour skills.

Discussion: Although behavioural effects were found for "Plan-It Commander" as compared to TAU, there were no between-group improvements on neurocognitive functioning as measured by neurocognitive performance tests. This suggests that serious game interventions for children with ADHD should focus more directly on impacting "real world" behaviours rather than the neurocognitive functions underlying them.

INTRODUCTION

Next to its core symptoms, children with ADHD demonstrate impairments in executive functions. Executive functions (EFs) are described as neurocognitive processes (such as planning and working memory) that enable self-control (Lezak, 1995) and allow individuals to regulate their behaviour, thoughts and emotions (Abikoff et al., 2013; Holmes, Gathercole, & Dunning, 2009; Klingberg et al., 2005). Planning is generally defined as the process of formulating a sequence of operations intended to achieve a goal in an organized, strategic, and efficient manner (e.g., Hayes-Roth & Hayes-Roth, 1979). The term working memory refers to temporary storage and manipulation of information necessary for complex cognitive tasks such as language comprehension, learning, and reasoning (Baddeley, 1997). Children with ADHD have difficulties in both of these areas of neurocognitive functioning (Baddeley, 2002; Holmes et al., 2009) as compared to typically developing children.

Studies also reveal deficits in processes by which these children understand themselves and other people (i.e., social cognition; Beer & Ochsner, 2006), making it more difficult for them to successfully interact with other people (Nijmeijer et al., 2008). Because of their deficits in executive functions and social cognition, children with ADHD are at high risk of experiencing negative long-term outcomes such as academic underachievement and difficulties sustaining social relationships (Barkley, Murphy, & Fisher, 2008; Greene et al., 1997). It may be helpful to focus interventions not only on symptom reduction, but also on daily life functioning in order to improve outcome, prevent problems escalating into adolescence and minimize the impact of ADHD in terms of costs and its burden on patients, their families and society.

Computerized neurocognitive training programs have recently been described in the literature as interventions for children with ADHD (Redick et al., 2013; Tajik-Parvinchi, Wright, & Schachar, 2014). Neurocognitive training such as Cogmed (Klingberg et al., 2005) and Braingame Brian (Van der Oord et al., 2014) typically entails the repeated exercise of cognitive processes that are involved in goal-directed behaviour (so called executive function skills). In these programs, performance gains on trained tasks are expected, and more importantly, it is assumed that these performance gains will generalise to untrained tasks and eventually to behavioural measures (Holmes et al., 2009; Tajik-Parvinchi, Wright, & Schachar, 2014). Recent studies demonstrate that improvements are present for the more proximal skills (i.e., working memory) and skills that were measured with tasks that closely resembled the training tasks in the program (Chacko et al., 2014; Melby-Lervag & Hulme, 2013; Shipstead et al., 2012). Improved performance on these tasks are termed *near transfer* (Shipstead et al., 2012). Although *near transfer* effects are generally found and reported, most research on computerized neurocognitive training programs fails to assess information about the functioning of the child in a "real world" setting assessed, for example by parent and teacher rated questionnaires of academic or family functioning, so called *far transfer* effects (Chacko et al., 2014). Studies that are available and demonstrate *far transfer* effects on parent-rated executive functioning and ADHD behaviour often include a non-active control group or assessors who were not blind to treatment allocation (Cortese et al., 2015). Because when well-designed and properly blinded trials are used there appears to be no generalisation effect of training to untrained tasks and behavioural outcomes (Cortese et al., 2015; Sonuga-Barke et al., 2013). So far, it is also not clear whether *near transfer* is the mechanism through which *far transfer* results may be explained (Cortese et al., 2015; Shipstead et al., 2012).

In general, computerized neurocognitive training programs are characterised by a repetition of neurocognitive tasks and a quite intense training period (Klingberg et al., 2005; Van der Oord, 2012). A criticism of these training programs is that a typical requirement of repeating the same task, is tedious for users, especially for children with ADHD who often demonstrate motivational deficits for treatment engagement (Prins et al., 2011; Luman et al., 2005) and are at higher risk of treatment drop-out (Johnson, Mellor, & Brann, 2008). As such, there is a need for attractive and engaging training formats that focus on improving behavioural strategies among children with ADHD (see *Chapter 4*). Gamified training programs (e.g., using game mechanics or a game-like interface) may be beneficial, especially for these children. Recently, studies have found that gaming optimizes motivation and training effects in children with ADHD (Dovis et al., 2012; Prins et al., 2011). Moreover, several serious games demonstrate cognitive benefits for visual attention, executive functioning and learning preparation (Bavelier et al., 2012; Flynn et al., 2014; Green & Bavelier, 2006). Serious games differ from existing computerized neurocognitive training programs and gamified interventions in several ways. First, they offer an overall game environment instead of offering a "casual" game mechanics or game-like interface (Deterding, Dixon, Khaled, & Nacke, 2011). Second, these games not only focus on repeating neurocognitive performance tests such as Cogmed (Klingberg et al., 2005) and Braingame Brian (Van der Oord et al., 2014) but promotes the use of behavioural strategies via a computer game with integrated therapeutic elements (e.g., reinforcement, immediate performance feedback from a mentor, goal setting through missions, modeling, social support, and comparison). The behavioural training aims to improve daily life functioning of children with ADHD (see *Chapter 2* for a more detailed description). However, to date current study designs (e.g., non-randomised, no use of objective measures, lack of power) limit definite conclusions about their effectiveness. The Institute of Digital Media and Child Development Working Group on Games for Health and colleagues (2016) recently formulated a research agenda to promote the use of adequately powered randomised clinical trials with objective measures (i.e., neurocognitive tests) when examining the effectiveness of serious games in (mental) healthcare.

This study examines the effects of an Internet-based serious game intervention (called "Plan-It Commander") for school-aged children with ADHD on neurocognitive performance tests of planning, working memory and social cognitive skills. The serious game intervention was offered as an adjunct to their treatment as usual (TAU). As reported previously, this multisite randomised controlled crossover open-label trial demonstrated behavioural effects on unblinded parent-reported outcomes (see *Chapter 4*). More specifically, participants who played the serious game intervention (SG) improved significantly more on the parent-rated primary outcome measure of time management and secondary parent-rated outcome measures of responsibility and of working memory as compared to the treatment as usual crossover (TAUx) group (see *Chapter 4*). The primary intervention goal was to improve daily life functioning in children with ADHD through serious gaming. Accordingly, the game was designed for this purpose. However, in this current chapter we examined whether improvement in neurocognitive functioning (as secondary outcome measures) could be observed next to the behavioural effects already addressed. Therefore, we included neurocognitive performance tests as secondary outcome measures to assess potential improvement of planning, working memory and social cognitive skills after children played the serious game. Additionally, we explored if improvement on parent-reported planning/organizing, working memory and social behaviour skills was predicted by neurocognitive functioning at baseline. We hypothesized that participants playing the serious game would improve on planning, working memory and social cognitive skills (as measured by different neurocognitive performance tests) compared to participants in the TAUx group. We further hypothesized that effects would be maintained at 10-week follow-up for the SG group.

METHODS

Participants

Participants were recruited between January and March 2013 across 4 outpatient mental healthcare clinics and institutions in the Netherlands and Belgium. The final sample consisted of 170 participants (aged between 8 and 12 years) who had a DSM-IV-TR ADHD diagnosis (confirmed by the Kiddie Schedule for Affective Disorders and Schizophrenia-Lifetime version [K-SADS; Puig-Antich & Chamber, 1978; Reichart, Wals, & Hillegers, 2000]) and met further inclusion and exclusion criteria. See *Chapter 4* for a more detailed description of the inclusion/exclusion criteria and screening measures that have been used.

Design

This study used data from a 20-week multisite randomised controlled crossover open-label trial consisting of a serious game intervention (SG) and a treatment as usual cross-over group (TAUx) that is described in more detail in *Chapter 4*. Participants randomised to the SG group received a serious game intervention in addition to TAU for the first 10 weeks and then received TAU for the next 10 weeks. Participants randomised to the TAUx group received TAU for the first 10 weeks and crossed over to the serious game intervention in addition to TAU for the subsequent 10 weeks. Participants were instructed to play the serious game for a maximum of 65 minutes approximately three times per week.

Randomisation was carried out on a 1:1 ratio and based on a prespecified computer generated randomisation list. Allocation was stratified by study site and gender and arranged in permuted blocks. In both groups neurocognitive performance tests were administered during face-to-face appointments (preferably in the morning) at baseline, 10 weeks and 10-week follow-up. All study procedures were approved in advance (31.01.2013) by the Erasmus (Dutch; MEC-2012-539) and Leuven (Belgian) Medical Ethical Committees. Extensive information concerning the procedures for randomisation is reported in *Chapter 4*.

Intervention

The intervention is an online adventure game (called "Plan-It Commander") designed to improve functional outcomes in daily life with a primary focus on time management, planning/organizing, and prosocial (i.e., cooperation) skills. Players had their own password and ID to log on to the Internet-based serious game from their home where they could access two game components: (1) a mission-guided game environment with mini-games related to the learning goals of improving time management, planning/organizing, and prosocial (i.e., cooperation) skills and (2) a closed social community. Missions guide the player's behaviour throughout the game as he or she follows the story line and is asked to solve problems requiring specific skills.

Central parts are the three mini-games that are embedded in the structure of the game. The first mini-game (*Labyrinth*) is focused on teaching the player time estimation and time management skills. The second mini-game (*Explorobot*) is focused on enhancing planning skills; the player is taught to plan ahead and break down the total assignment into pieces. The third mini-game (*Space Travel Trainer*) focuses on enhancing prosocial behaviour, teaching the player to help their team members and to cooperate with each other. The game was linked to a database in which game data from each participant were registered. Details of the development and content of "Plan-It Commander" are described elsewhere (see *Chapter 2*). Ninety two percent of the participants received medication as their TAU.

Measures

Tower Test

The Tower Test is a neuropsychological subtest in the Delis-Kaplan Executive Function System (D-KEFS) battery and measures several executive functions such as spatial planning, rule learning, inhibition of impulsive responding and establishing and maintaining instructional set in children and adults from 8 to 89 years (Delis, Kaplan, & Kramer, 2001). The material consists of 5 disks that vary in size from small to large and a board with three vertical pegs. The objective is to move all the disks to the rod on the right, observing the following rules: only one disk may be moved at a time, a larger disk may not be placed on top of a smaller disk and disks must always be placed on one of the rods. It is important that children perform this task in a minimal number of steps as quickly as possible. It takes around 30 minutes to administer the test. Research into the Tower of London Test (a comparable test) indicates that this is a reliable (Cronbach alpha = .80) and valid method to measure planning skills in children (Culbertson & Zillmer, 2001; Unterrainer et al., 2004). In this study the total achievement score was the main outcome measure.

Chessboard-Task

The Chessboard-Task is a recently developed computer-based working memory performance task based on the Letter – Number sequencing task from the Wechsler Adult Intelligence Scale (WAIS; Wechsler, 1958) and the Corsi Block Tapping Task (Corsi, 1972; Dovis et al., 2012). The task assesses ability to manipulate/reorganize and maintain visual-spatial information relevant to the task at hand (Dovis et al., 2013). On the computer screen, a sequence of stimuli (squares that light up) is presented one by one on a four by four grid with green and blue squares in a chessboard formation. Each stimulus lights up for 900ms, after which a 500ms inter-stimulus interval is presented. Participants respond by clicking on the lit squares, ordering the presented stimuli by clicking on the green squares first, and then the blue squares. After two consecutive correct reproductions, the sequence is increased by one stimulus and after two consecutive incorrect reproductions; the sequence is shortened by one stimulus. For this study 30 trials were presented. The main measure of interest was the average length of correctly reproduced sequences from trial 12 onwards. This choice was made as children typically need these first trials to reach their optimal difficulty level (a sequence length higher than 5 or 6 stimuli; Dovis et al., 2013).

Social-Cognitive Skills Test

The Social-Cognitive Skills Test is an instrument that measures eight social cognitive skills of children between 4 and 12 years of age (SCST; Van Manen, Prins, & Emmelkamp, 2001). One of the aims of the SCST is to determine the specific deficits in the social cognitive functioning of a child. The stories of the SCST are all about a social situation. The child in the story encounters a troublesome situation with another child or adult. The test consists of 7 short stories with corresponding pictures and each story contains 8 questions that represent the eight social cognitive skills. The sequence of eight hierarchically organized social cognitive skills is: Identifying, Discriminating, Differentiating, Comparing, Perspective-taking, Relating, Coordinating and Taking into account. The corresponding social cognitive levels are: Egocentric, Subjective, Self-reflective and Mutual. For this study it was decided to use the short version of the SCVT (version A), consisting of three stories. A maximum score of 16 on one story means that the child masters the eight social cognitive skills. The reliability, construct and discriminant validity of the SCST are sufficient (Van Manen, Prins, & Emmelkamp, 2001; 2009).

Details of parent-reported outcome measures concerning planning/organizing (subscale BRIEF; Smidts & Huizinga, 2009), working memory (subscale BRIEF; Smidts & Huizinga, 2009) and social behaviour skills (total scale SSRS; Van der Oord et al., 2005) are described in *Chapter 4*.

Data analyses

Changes from baseline to 10 weeks (reflected by its difference scores) were compared between SG and TAUx groups with ANCOVAs, with baseline score as a covariate and gender and site as factors. To assess improvement during treatment within both groups, paired samples *t*-tests were performed on the neurocognitive performance tests before and after playing the serious game. To assess whether effects were maintained after playing the game for 10 weeks within the SG group, within-group comparisons of changes at 10 weeks versus 10-week follow-up were performed. Linear regression analyses were performed to predict improvement on parent-reported planning/organizing, working memory and social behaviour skills (reflected by difference scores from baseline to 10 weeks) by neurocognitive functioning at baseline. Intent to treat analysis was used and included all randomised participants. Linear trend at point was used as an imputation method. Data analyses were conducted using the SPSS version 19.0 statistical software (IBM Corp, 2010) and were two-sided with a level of significance of 0.05. Effect sizes were reported for all analyses using Cohen's *d* (Cohen, 1988).

RESULTS

Demographics

A total of 170 participants met the inclusion criteria and participated in the study. Eighty-eight children were randomised to the SG group and 82 children to the TAUx group. Demographic characteristics did not differ significantly at baseline between these groups. Nighty two percent of the participants (81% males; 19% females) received medication as their TAU and most of them had a combined ADHD diagnosis (74%). Twelve percent of the children demonstrate (sub)clinical symptoms of oppositional defiant disorder. Among the total sample the average age was 9.85 years (*SD*=1.26) at baseline with an average total intelligence score (*M*=106.18, *SD*=14.79). A smaller proportion (15%) of the children was receiving special education services.

Mean scores for neurocognitive outcomes at baseline indicated no significant between-group differences. At 10 weeks (T1), 152 of 170 participants (89%) completed assessment and at 10-week follow-up (T2) 139 of 170 participants (82%) completed the assessment. Participants who dropped out during the study did not differ with regard to their baseline characteristics compared to children who completed the study, apart from their ADHD severity scores with higher ADHD severity scores among children who dropped out during the study compared to children who completed the study ($t_{(168)}$ =2.09, *p*=.04; *M*=45.06, *SD*=15.79 versus *M*=39.07, *SD*=14.16). Baseline characteristics and attrition analyses are described in more detail in *Chapter 4*.

Game data

Participants played for a mean of 19.04 (*SD*=9.61) days in the mission-guided game and a mean 11.20 (*SD*=8.55) days in the closed social community. Participants played the mission-guided game for a mean total duration of 12.56 (*SD*=6.57) hours and engaged with the closed social community for a median of 35.31 minutes. There were no differences between the two groups (those that played the serious game in addition to treatment as usual for the first 10 weeks and those that played the serious game after receiving treatment as usual for the first 10 weeks) with regard to the number of days playing the mission-guided game and the amount of time playing the mission-guided game and social community. However, there was a significant difference between the SG group (*M*=12.61, *SD*=8.60) and TAUx group (*M*=9.70, *SD*=8.28) with regard to the number of days they engaged with the closed social community (t_{157}=2.17, *p*=.03). Moderate to high satisfaction scores regarding "Plan-It Commander" were reported by both parents (*M*=6.96, *SD*=1.40) and participants (*M*=7.33, *SD*=1.87) on a 10-point Likert scale.

Between-group differences (SGg roup versus TAUx group)

To test the hypothesis that participants playing the serious game would improve on neurocognitive test performances, differences between SG group and TAUx group from baseline to 10 weeks (T1; post-test) were evaluated with ANCOVAs (see Table 1). Baseline score was included as a covariate and gender and site as factors. No significant group differences were found on neurocognitive planning, working memory and social cognitive test performances.

TAUx group within-group effects

Within-group differences for TAUx group were then evaluated to test the hypothesis if participants playing the serious game would improve on neurocognitive test performances; differences between 10-week and 20-week scores were evaluated with paired samples *t*-tests (see Table 2). While receiving TAU for the first 10 weeks, participants improved significantly on planning, working memory and social cognitive test performances. After crossing over to the serious game intervention in addition to TAU for the subsequent 10 weeks, again significant improvements in outcomes of planning and self-reflective skills were found (see Table 2).

SG group within-group effects and 10-week (T2) follow-up effects

Within-group differences for SG group were then evaluated to test the hypothesis if participants playing the serious game would improve on neurocognitive test performances (see Table 3). While playing the serious game intervention in addition to TAU for the first 10 weeks, significant improvements in planning and social cognitive skills were found. The improvement of participants' working memory was borderline significant. To test the hypothesis that effects would be maintained at 10-week follow-up for participants who played the serious game during the first 10 weeks; differences between 10-week (T1; post-test) and 10-week follow-up scores were evaluated with paired samples *t*-tests (see Table 3). Within-group effects showed significant improvement from 10 weeks to 10-week follow-up for planning and self-reflective skills (see Table 3). This implies that most significant effects maintained or even improved further at 10-week follow-up.

Table 1. Univariate analyses of covariance comparing SG intervention and TAUx groups on neurocognitive testperformances during first 10 weeks.

Measures	SG (*n*=88)			TAUx (*n*=82)			ANCOVA		
	LSMean	SE	95% CI	LS Mean	SE	95% CI	$F^1(1, 163)$	*p*	*d*
Tower Test	1.36	0.33	[0.71, 2.01]	0.94	0.34	[0.26, 1.62]	1.04	.31	0.18
Chessboard-Task	0.23	0.10	[0.03, 0.44]	0.23	0.11	[0.01, 0.44]	0	.96	0.15
Social-Cognitive Skills Test	6.21	0.69	[4.85, 7.57]	6.38	0.72	[4.96, 7.80]	0.04	.84	0.03
Egocentric	0.86	0.18	[0.51, 1.21]	0.97	0.18	[0.61, 1.34]	0.28	.60	0.03
Subjective	0.97	0.24	[0.49, 1.44]	1.00	0.25	[0.51, 1.50]	0.02	.90	0.03
Self-reflective	2.06	0.28	[1.51, 2.61]	2.03	0.29	[1.45, 2.60]	0.01	.92	0
Mutual	2.37	0.34	[1.69, 3.04]	2.36	0.36	[1.66, 3.06]	0	.99	0.07

[1]Pillai's Trace

Table 2. TAUx group results of paired samples *t*-test of neurocognitive test performances during baseline, 10-week and 20-week assessment (*n* =82).

	Baseline (T0)	10-week (T1)	20-week (T2)	*t*-test T0 vs. T1			*t*-test T1 vs. T2		
	M (SD)	*M (SD)*	*M (SD)*	*t*	*p*	*d*	*t*	*p*	*d*
Tower Test	16.02 (3.03)	17.42 (3.00)	18.60 (2.33)	2.99	.004	0.46	3.40	.001	0.44
Chessboard-Task	4.99 (0.92)	5.26 (1.15)	5.32 (1.03)	2.74	.008	0.26	0.61	.55	0.06
Social-Cognitive Skills Test	54.92 (10.59)	62.50 (7.78)	62.18 (8.01)	7.26	<.001	0.82	-0.33	.74	-0.04
Egocentric	15.57 (2.50)	16.83 (1.60)	16.62 (1.77)	4.78	<.001	0.60	-0.99	.33	-0.12
Subjective	15.13 (2.82)	16.40 (2.19)	16.74 (1.65)	3.60	.001	0.50	1.22	.23	0.18
Self-reflective	13.96 (3.50)	15.84 (2.74)	16.52 (2.16)	4.67	<.001	0.60	2.35	.02	0.28
Mutual	10.24 (4.54)	13.43 (3.61)	13.56 (3.14)	7.26	<.001	0.78	0.32	.75	0.04

Table 3. SG group results of paired samples *t*-test of neurocognitive test performances during baseline, 10-week and 20-week assessment (*n*=88).

	Baseline (T0)	10-week (T1)	20-week (T2)	*t*-test T0 vs. T1			*t*-test T1 vs. T2		
	M (*SD*)	*M* (*SD*)	*M* (*SD*)	*t*	*p*	*d*	*t*	*p*	*d*
Tower Test	16.71 (2.73)	17.90 (2.30)	18.92 (2.48)	3.40	.001	0.47	3.46	.001	0.43
Chessboard-Task	5.22 (0.94)	5.41 (0.86)	5.54 (0.88)	1.83	.071	0.21	1.54	.13	0.15
Social-Cognitive Skills Test	56.57 (10.33)	62.73 (5.49)	62.35 (7.94)	6.09	<.001	0.74	-0.50	.62	-0.06
Egocentric	15.98 (2.18)	16.79 (1.48)	15.60 (1.60)	3.56	.001	0.43	-1.01	.31	-0.77
Subjective	15.64 (2.55)	16.46 (1.86)	16.65 (1.82)	3.09	.003	0.37	0.89	.38	0.10
Self-reflective	13.82 (3.54)	15.83 (2.15)	16.35 (1.92)	5.06	<.001	0.69	2.30	.02	0.26
Mutual	11.14 (4.95)	13.65 (3.00)	14.03 (3.03)	4.91	<.001	0.61	1.15	.26	0.13

Effects of neurocognitive functioning on behavioural improvement

First, a linear regression was performed to predict improvement on parent-reported planning/organizing behaviour (subscale BRIEF; difference score from baseline to 10 weeks) based on Tower Test performance at baseline for the SG group. A nonsignificant regression equation was found (F (1, 86) = 0.10, p=.76), with an R^2 of 0.001. Second, a linear regression was performed to predict improvement on parent-reported working memory behaviour (subscale BRIEF; difference score from baseline to 10 weeks) based on Chessboard-Task performance at baseline for the SG group. A nonsignificant regression equation was found (F (1, 86) = 1.07, p=.30), with an R^2 of 0.012. Finally, a linear regression was performed to predict improvement on parent-reported social behaviour (total scale SSRS; difference score from baseline to 10 weeks) based on Social-Cognitive Skills Test performance at baseline for the SG group. A significant regression equation was found (F (1, 86) = 5.28, p=.02), but only explaining 6% of the variance. Given that the beta coefficient (β=-0.24) is negative, an increase in Social-Cognitive Skills Test performance at baseline will lead to lower scores on parent-reported social behaviour (total SSRS; difference score from baseline to 10 weeks).

DISCUSSION

The aim of the study was to examine if planning, working memory and social cognitive skills, as measured by neurocognitive performance tests, among children with ADHD improved after playing an Internet-based serious game intervention compared to TAU. The results show that both groups improved on their planning, working memory and social cognitive test performances during the first 10 weeks, with no between-group differences. Therefore, the findings of the current study provide evidence that "Plan-It Commander" does not improve planning, working memory and social cognitive skills as measured by neurocognitive performance tests. However, previous results (see *Chapter 4*) did demonstrate improvement on executive functioning as assessed by behavioural questionnaires. This suggests that improvement on daily life skills is independent from neurocognitive performance skills. This is supported by results demonstrating that neurocognitive functioning at baseline is not a significant predictor of behavioural improvement.

The main aim of "Plan-It Commander" was to improve daily life skills by promoting the use of behavioural strategies via a computer game with integrated therapeutic elements (e.g., reinforcement, immediate performance feedback from a mentor, goal setting through missions, modeling, social support, and comparison) and not repetitive training of neurocognitive functions. As such, we tried to integrate more ecologically valid training elements that directly aimed at improving daily life skills of children with

ADHD (see *Chapter 2* for a more detailed description). Results of this study are in line with the primary goal of "Plan-It Commander" to improve daily life skills instead of improving performances on neurocognitive performance tests. Recent computerized neurocognitive training formats often demonstrate improvements on working memory measured with tasks that closely resemble the training tasks in the program (Chacko et al., 2014; Melby-Lervag & Hulme, 2013; Shipstead et al., 2012), but not to untrained tasks or behavioural measures (Cortese et al., 2015; Mawjee et al., 2015).

Our current serious game intervention did not integrate neurocognitive performance tests that resembled the tests we used for outcome measurement concerning planning (Tower Test; Delis, Kaplan, & Kramer, 2001), working memory (Chessboard Task; Dovis et al., 2012) and social cognitive skills (Social Cognitive Skills Test; Van Manen et al., 2001). The fact that behavioural improvements were found but could not be explained by improved neurocognitive functioning is in line with more recent ADHD research (Coghill, Hayward, Rhodes, Grimmer, & Matthews, 2014). Instead, this game included several mini-games in which players learned to estimate and manage time, plan ahead and break down the total assignments into pieces, help team members and to behave in a more prosocial and cooperative manner towards others. Several strategies (e.g., use of a clock, plan route on a map) could be used to optimise performance, thus daily life functioning as reported by parents were our primary outcome. One could also wonder whether a treatment that focuses on daily life skills at the behavioural level is able to alter neurocognitive skills (Boyer, 2016). Neurocognitive improvements over time are probably the result of practice or learning effects. Various reasons have been discussed to explain these effects, such as reduced anxiety in or growing familiarity with the testing environment, recall effects, improvement of underlying functions, procedural learning, test sophistication, or regression to the mean (Anastasi, 1988; Benedict & Zgaljardic, 1998; Hausknecht, Halpert, Di Paolo, & Gerrard, 2007; McCaffrey, Duff, & Westervelt, 2000).

From the literature, it appears that there is no definitive relationship between performance on neurocognitive tests and the ability to cope in everyday life (Baddeley et al., 2002). Studies show low and nonsignificant correlations between questionnaires and neuropsychological tasks measuring planning skills in individuals with ADHD (Boyer et al., 2014; Toplak, West & Stanovich, 2013). Moreover, in the current study neurocognitive functioning at baseline did not predict behavioural improvement, except for social behaviour skills, but here the explained variance of baseline neurocognitive functioning was rather small. From a broader perspective, it is interesting to discuss the ecological validity of neurocognitive performance tests used in the current study. Performance-based tests measure how well a child performs in a structured testing session, in which little distraction and few external influences are operating. These measures often do not tap the flexibility and the scope of attentional functions needed to adequately assess the wider range or executive function impairments in real-life. To increase chances of finding improved daily life functioning resulting from serious gaming, training tasks should be made more ecologically valid (e.g., by using training tasks that resemble the complexity of problematic situations in daily life) and should be intertwined with relevant real-life activities as is also suggested by Boyer (2016).

The results of this study should be considered in the light of several limitations. First, the power analyses performed for this study to estimate optimal sample size were based on previous pilot study results with regard to the primary outcome measure of the parent-reported time management questionnaire. As such, the current study was not specifically powered to demonstrate effects on these neurocognitive outcome measures. However, compared to other game intervention studies, the current study included a relatively large sample size supporting the reliability of our findings (Flynn et al., 2014). Second, it is also possible that a follow-up period of 10 weeks is not sufficient to detect later-emerging or 'sleeper' effects, as has been previously reported (Hovik, Plessen, Skogli, Andersen, & Øie, 2013).

CONCLUSIONS

Previous results suggest that an innovative and engaging gaming intervention approach has been developed and can be offered as an additional treatment tool to TAU for children with ADHD to support them in their daily life behaviour (see *Chapter 4*). The current study showed that these improvements in the gaming condition on behavioural measures were not corroborated by improvements on planning, working memory and social cognitive skills as measured by neurocognitive performance tests. Overall, to improve executive functioning behaviour in children with ADHD, serious game interventions do not necessarily be based on the gamification of neurocognitive tasks.

Chapter 6

A serious game for children with Attention Deficit Hyperactivity Disorder: Who benefits the most?

ABSTRACT

Objectives: The aim of the current study was to identify for whom the serious game intervention was most effective among children with ADHD.

Methods: Moderator analyses were conducted using the Virtual Twins method with 10 pre-treatment characteristics to explore subgroups for whom the SG intervention was most effective. Primary outcome measures were difference scores (i.e., change from baseline to post-test) in parent-reported time management, planning/organizing and prosocial (i.e., cooperation) behaviour skills.

Results: The serious game intervention was more effective in improving the planning/organizing skills of girls (n=26). Furthermore, boys with a lower score on hyperactivity and a higher score on conduct disorder symptoms at baseline showed more improvements in their planning/organizing skills (n=47) when they received the serious game intervention.

Discussion: Some subgroups are likely to benefit more from the serious game intervention than other subgroups. More importantly, these results may be useful for personalised intervention allocation.

INTRODUCTION

Attention Deficit Hyperactivity Disorder (ADHD) is one of the most common neurodevelopmental disorders with a worldwide prevalence rate of 5.29% among children up to 18 years old (Polanczyk et al., 2014). In addition to its core symptoms of hyperactivity, impulsivity and inattention, these children show functional impairments in different areas of daily life such as planning their homework, estimating the time needed to complete an assignment, staying on task and building and maintaining meaningful relationships with their peers (Abikoff et al., 2013; Greene et al., 2001; Stobero et al., 2011). As a consequence, these problems have been shown to adversely impact the daily life functioning of children with ADHD (Conners, 2003). Recently, healthcare professionals have been exploring new ways to optimise daily life functioning in children with ADHD, and heighten their engagement with treatment, such as the use of games to support behavioural treatment goals (Baranowski et al., 2008). The integration of game elements in current treatment procedures has the potential to enhance motivation and treatment effectiveness (Duivenvoorden, 1982; Geen, 1995; Perwien, Hall, Swensen, & Swindle, 2004; Kato, 2010; Van der Oord et al., 2014).

As an adjunct to treatment as usual (TAU) for children with ADHD, we developed an engaging and accessible serious game (called "Plan-It Commander") aimed at improving functional outcomes in different areas of daily life such as time management, planning/organizing and prosocial (i.e., cooperation) skills. We recently examined the effectiveness of "Plan-It Commander" in a multisite randomised controlled open-label trial (N=170) and results demonstrated that the group of children with ADHD who played the serious game intervention (SG) improved significantly more on the parent-rated primary outcome measure of time management and secondary outcomes measures of responsibility and working memory as compared to treatment as usual crossover (TAUx) group (see *Chapter 4*). Although children in the SG intervention condition improved (on average) across several behavioural outcomes, it is of clinical interest to identify potential subgroups of children that differ in relative treatment effectiveness as this gives healthcare professionals some guidelines on how to match patients to the most effective treatment (Owens et al., 2003). This can support clinicians in deciding for which patients it would be most beneficial to offer "Plan-It Commander". In the current study, the role of 10 pre-treatment characteristics [i.e., gender, age, intellectual level of functioning (IQ), medication use, computer experience, ADHD subtype, severity of inattention problems, severity of hyperactivity/impulsivity problems, comorbid oppositional defiant disorder (ODD) and conduct disorder (CD) symptoms] as possible moderators were explored.

Due to the more recent development of eHealth applications within child mental healthcare, studies on moderating factors of eHealth interventions are lacking. Most of the available literature on potential treatment moderators in the treatment of children with ADHD comes from the Multimodal Treatment of Attention Deficit Hyperactivity Disorder study (i.e., MTA Cooperative Group, 1999ab), the largest treatment study to date in young patients with ADHD. Additionally, a more recent smaller scale study explored moderators of response to a behavioural parent training (Van den Hoofdakker et al., 2010, 2014). On the basis of the literature available, severity of ADHD and comorbidity appear to be significant moderators of treatment outcomes in ADHD. More severe ADHD symptoms are generally associated with worse treatment outcomes (Hinshaw, 2007; MTA Cooperative Group, 1999ab; Owens et al., 2003). Furthermore, children who have double comorbidity show worse treatment outcomes than children who do not have comorbidity or have a single-type comorbidity (Hinshaw, 2007; Jensen et al., 2001; March et al., 2000; MTA Cooperative Group, 1999ab; Murray et al., 2008; Ollendick et al., 2008; Van den Hoofdakker et al., 2010, 2014). Other possible moderating variables such as age, IQ and medication use have been reported to be nonsignificant (Hinshaw, 2007; MTA Cooperative Group, 1999ab; Owens et al., 2003; Van den Hoofdakker et al., 2010).

Based on the available limited findings on moderators in ADHD treatment of children we explored several clinically relevant pre-treatment characteristics (i.e., age, IQ, medication use, ADHD subtype, severity of inattention problems, severity of hyperactivity/impulsivity problems, comorbid ODD and CD symptoms) as possible moderators for whom the SG intervention is especially effective on the three primary outcome measures time management, planning/organizing and prosocial (i.e., cooperation) behaviour skills. Additionally, we included some moderators that may be specific for this type of game intervention (Baranowski, Baranowski, Thompson, & Buday, 2011; De Boo & Prins, 2007; Van den Hoofdakker et al., 2010). For example, Chou and Tsai (2007) demonstrated that boys not only spent more time playing computer games than girls, but they also enjoyed it more. This may suggest that gender can influence children's involvement in serious game interventions, and in turn might moderate relative treatment effectiveness. Furthermore, previous research has shown that children with high levels of game experience were more familiar with the concept of serious gaming (Cheek et al., 2015). This implies a potential moderator role of children's computer game experience. Therefore, we explored gender and computer experience as possible moderator variables that may have a more specific impact on the effectiveness of game-based interventions.

We would like to note that in general, moderator analyses in clinical trials are more likely to be hypothesis generating rather than hypothesis testing (Kraemer et al., 2008). Moreover, the field of eHealth and serious gaming is relatively new and therefore still focuses on outcome results instead of identification of moderating variables. Due to the lack of earlier studies focusing on moderator effect of serious gaming in children with ADHD, we had to rely our hypothesis regarding the strength of specific moderators or the direction of effects on other studies describing moderator effects of medication and behavioural treatment in ADHD (Hinshaw, 2007; Jensen et al., 2001; March et al., 2000;

MTA Cooperative Group, 1999ab; Murray et al., 2008; Ollendick et al., 2008; Owens et al., 2003; Van den Hoofdakker et al., 2010, 2014).

METHODS

Participants

Across four sites in the Netherlands and Belgium, 170 participants were recruited and selected. Participants' mean age was 9.85 years (*SD*=1.25) at intake and they were all diagnosed with ADHD. The sample was 81% male and had an average intelligence level (*M*=106; *SD*=14.76). Participants were stable on pharmacological and/or psychological treatment for ADHD eight weeks prior to baseline. Comorbidities common to ADHD like ODD were allowed. Participants with a clinical diagnosis of CD, autism spectrum disorder or acute psychiatric problems (i.e., substance abuse problems, depression, mania) requiring immediate or other medical treatment were excluded. Written informed consent was obtained from parents and 12-year-old children. All study procedures were approved by the Erasmus (Dutch) and Leuven (Belgian) Medical Ethical Committees. More details about the subject recruitment and retention can be obtained from *Chapter 4*.

Design

This study used data from a 20-week multisite randomised controlled open-label trial consisting of a serious game intervention (SG) and a treatment as usual crossover group (TAUx). Participants randomly assigned to SG group received a serious game intervention in addition to TAU for the first 10 weeks and then received TAU for the next 10 weeks. Participants randomly assigned to the TAUx group received TAU (medication in 92% of the cases) for the first 10 weeks and crossed over to the SG intervention in addition to TAU for the subsequent 10 weeks. In this study, we compared outcomes between the SG intervention and TAUx conditions during the first 10 weeks. Participants were instructed to play the serious game for one hour three times a week. Multi-informant (parent, teacher and self-report) measures were administered at baseline (T0), at 10 weeks (T1) and at 10-week follow-up (T2).

Randomisation and blinding

Randomisation was carried out in a 1:1 ratio and based on a pre-specified computer in permuted blocks. Group assignment was performed online using the next available number on the randomisation list corresponding to the site and gender of the participant. It was not possible to blind participants to their treatment allocation. After screening and baseline assessment, parents received an email with the notification to which group (SG vs. TAUx group) they were allocated. Although all efforts were made to keep the investigator blind during baseline assessments, full blinding of researchers at 10-weeks could not be guaranteed because participants spontaneously talked about the game during the study period. Further details about the design and allocation procedures are reported elsewhere (see *Chapter 4*).

Intervention

The serious game is an online futuristic and adventurous computer game (called "Plan-It Commander"), developed by healthcare professionals, game experts, researchers, parents and children with ADHD. It is designed to improve functional outcomes in daily life with a primary focus on time management, planning/organizing and prosocial (i.e., cooperation) skills in children with ADHD. Participants have their own password and ID to log on from their homes, in which they can access two game components: (a) a mission-guided game environment with mini-games related to the learning goals of improving time management, planning/organizing and prosocial (i.e., cooperation) skills and, (b) a closed social community. More details of the game content are described in *Chapter 2*.

Outcome measures

The primary outcome measures (in line with our previous analyses; see *Chapter 4*) were difference scores (i.e., change from baseline to post-test) of parent-reported time management, planning/organizing, and prosocial (i.e., cooperation) behaviour skills. These skills were primarily trained in the mini-games of the SG intervention and therefore decided to be the most important outcomes for the current study.

Behaviour Rating Inventory of Executive Function

The parent-rated version of the BRIEF assesses executive functioning in home situations in children aged from 5-18 years (Gioia et al., 2000; Dutch translation: Smidts & Huizinga, 2009). The questionnaire contains 86 items in eight non-overlapping clinical scales and two validity scales. The answers are scored on a 3-point Likert scale (never – sometimes - often). An item example is: "Forgets to hand in homework, even when it is completed". For this study the subscale Plan/Organize, consisting of 12 items, was used in order to measure children's planning/organizing skills. The BRIEF has good reliability and construct validity (Mahone et al., 2002).

Social Skills Rating System

The SSRS parent version was used to measure social functioning in children from 8 to 12 years old (Gresham & Elliot, 1990; Dutch translation: Van der Oord et al., 2005). This questionnaire consists of four subscales (e.g., Cooperation, Responsibility, Assertiveness, Self-Control) of 10 items each. The answers are scored on a 3-point Likert scale (never – sometimes - often). The total scale consists of 38 items and has a possible range from 0 to 80. An item example is: "Helps you with household tasks without being asked". For this study only the subscale Cooperation, consisting of 10 items, was used in order to measure children's cooperation skills. The total scale score is reliable (α = .88; Van der Oord et al., 2005).

Time management questionnaire

A time management questionnaire was used to measure children's time management behaviour (see Appendix 1). We used this time management questionnaire because at the time of our study no other standardised measures were available to measure this construct in young children. The questionnaire contains 11 items and addresses specific time management behaviours. Parents were asked to rate the time management skills of their child on a 10-point Likert scale (ranging from true – not true). An example item is: "My child frequently uses his/her watch to check upon the time". From a previous pilot study, it appeared that this questionnaire is reliable (α=.85; N=42) (see *Chapter 3*) and results from our RCT indicated comparable reliability in a larger sample of children (α=.83; N=170) (see *Chapter 4*).

Potential moderators

Socio-demographics

A questionnaire was constructed for this study to assess background characteristics such as age (in years), gender, medication use (yes/no) and computer game experience; parents could indicate how experienced their child was in computer gaming on the basis of four categories (starter-amateur-experienced-expert).

Intelligence Quotient

Children's intellectual level of functioning (IQ) was assessed by two subtests (i.e., vocabulary and block design) of the Wechsler Intelligence Scale for Children III (WISC-III; Wechsler, 1991; Sattler, 2001). This IQ estimation has satisfactory reliability (r=0.91) and correlates highly with the full-scale IQ score (Dovis et al., 2011; Sattler, 2001).

ADHD diagnosis

The Kiddie-Schedule for Affective Disorders and Schizophrenia-Lifetime version (K-SADS; Puig-Antich & Chamber, 1978; Reichart, Wals & Hillegers, 2000) is a semi-structured interview designed to assess current and past episodes of psychopathology in children and adolescents according to the DSM-III-R and DSM-IV criteria. For this study the K-SADS was used to determine ADHD subtype. Parents were interviewed by trained research assistants with M.A. in psychology and had to answer questions about the period in which ADHD symptoms were most severe.

Severity of ADHD symptoms

The Disruptive Behavior Disorders Rating Scale (DBDRS; Pelham et al., 1992; Dutch translation: Oosterlaan et al., 2000) assesses DSM-IV disruptive behaviour symptoms in children between 6 and 12 years. It consists of 42 items and four subscales (that were used in this study): inattention (nine items), hyperactivity/ impulsivity (nine items), oppositional defiant (eight items), and conduct disorder symptoms (16 items). For this study severity raw scores of these subscales were used. Items are scored on a 4-point Likert scale, ranging from "not at all" to "very much". The Dutch translation has adequate reliability (α range = .88–.94) and construct validity.

Data analytic plan

As we have no clear a priori hypotheses on the potential treatment moderators that describe the subgroups of children for which the SG intervention strongly outperforms TAU, we could not use standard moderator analyses such as a factorial analysis of variance (ANOVA) with a first factor pertaining to treatment methods and a second one to subgroups (Shaffer, 1991), and regression analyses with suitable interaction terms being included in the regression model (see, e.g., Dixon & Simon, 1991; Hayward et al., 2006) to address our research question. For such a situation in which no clear a priori hypotheses exist on the subgroups for which an intervention is especially effective, Virtual Twins (VT; Foster, Taylor, & Ruberg, 2011) is a suitable method to use. This method explicitly aims at identifying subgroups that are likely to get a high benefit from the treatment under study in comparison to TAU (for an extensive comparison of methods, see Doove et al., 2014). In the present study, we will use VT to find subgroups in which the effect of the SG intervention is considerably better than the effect of TAUx. For an example of a recent successful application of VT in the field of psychotherapy and pharmacogenetic research, see Doove and colleagues (2014), and Hou and colleagues (2015), respectively.

The VT methodology is based on the concept of counterfactual or potential outcomes (Rubin, 1974). In the setting of VT, for every person two potential outcomes can be defined; one for the SG intervention and one for TAUx. These potential outcomes represent the outcomes that would be observed if the person in question were subject to the SG intervention or TAUx, respectively. As a first step, VT estimates for each person the two potential outcome values (also referred as virtual twins); the difference between these estimates represents for each person an estimate of that person's individual differential treatment effect. In a second step of VT, this estimated individual differential treatment effect is entered as the criterion variable in a regression tree analysis (Hastie, Tibshirani, & Friedman, 2009), together with the available pre-treatment characteristics as predictors. Such a regression tree analysis implies that the total group of participants is repeatedly subdivided on the basis of binary splits of the pre-treatment characteristics into subgroups (i.e., leaves) that are increasingly homogeneous with respect to the criterion variable. The resulting series of splits can be represented by a tree structure like

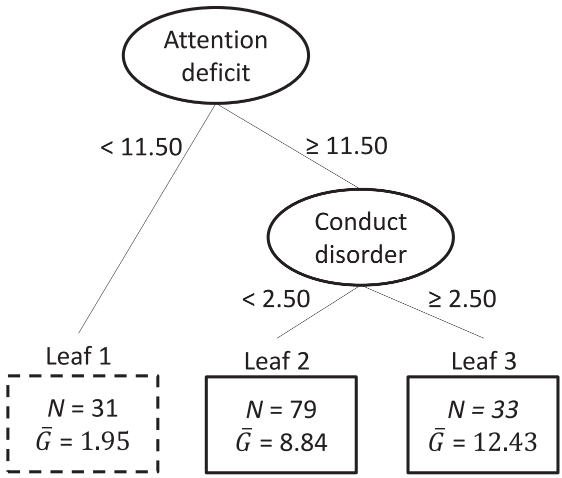


Figure 1. Results of the application of Virtual Twins with as outcome time management. The ellipses in the figure represent the internal nodes containing the split variables, with below each ellipsis the corresponding split point. The upper ellipsis represents the root node corresponding to the complete group of children. The rectangles represent the leaves of the tree, that is, the final subgroups of children; each rectangle contains the sample size of the corresponding subgroup (N), and the mean estimated individual differential treatment effect ($\bar{G}$). The leaves in which the estimated individual differential treatment effect exceeds the threshold c are represented by solid rectangles. It should be noted that after post-processing of the results, it appears that there is insufficient evidence that the subgroups in these leaves have a significantly better outcome on time management skills compared to the total group of children.

Figure 1 (which will further be discussed in the Result section). The union of the leaves of such a tree for which the average individual differential treatment effect exceeds some pre-specified threshold *c*, then constitutes the subgroup that is outputted by the VT algorithm. Subsequently, an estimate of the enhanced treatment effect in the subgroup compared with the average treatment effect is determined. For this we will rely on the so-called re-substitution method as proposed by Foster and colleagues (2011), where the difference between the estimated treatment effect in the subgroup and in the total group of persons is being calculated (based on observed rather than estimated potential outcome values). In this study, we analysed data on the three primary outcome measures with VT. As threshold for determining which leaves of a fitted tree is part of the subgroup with enhanced treatment effect, we put *c* equal to the overall mean of estimated individual differential treatment effect. When VT outputs a subgroup with enhanced treatment effect for one or more of the outcome measures, we will accompany the estimate of the enhanced treatment effect in the subgroup by confidence intervals as measure of reliability of the estimate (so-called percentile bootstrap confidence intervals, see, e.g., Efron & Tibshirani, 1993). These confidence intervals will give insight into whether there is sufficient evidence from the data that the subgroup found by VT has a significantly better outcome than the total group of participants.

RESULTS

Descriptives

Presented in Table 1 are the pre-treatment characteristics and baseline scores of the three primary outcome measures for the participants enrolled in the current study. Mean scores and pre-treatment characteristics of the intervention and TAU only control groups did not differ significantly at baseline, with one exception: Participants in the control condition scored significantly higher on parent-reported cooperation skills (demonstrating better skills) at baseline than participants from the intervention condition (see Table 1). On the primary outcome measures, the SG group showed significantly greater improvements in parent-rated time management skills than participants in the TAUx group (p=.004). The SG group also showed more improvement in parent-reported planning/organizing skills than the TAUx group (marginally significant; p=.07). After correcting for multiplicity with the Hochberg procedure, this effect was no longer significant. There were no differences between groups in cooperation skills. For further details see *Chapter 4*.

Table 1. Socio-demographic information of the sample.

	Total (N=170)	SG (*n*=88)	TAUx (*n*=82)	Group Comparison
Pre-treatment characteristics				
Gender				
Boys	137 (81%)	70 (80%)	67 (82%)	$\chi^2 = 0.13$, $p = .72$
Girls	33 (19%)	18 (20%)	15 (18%)	
Age in years	9.85 (1.26)	9.89 (1.28)	9.82 (1.24)	$t = -0.36$, $p = .79$
Total IQ	106.18 (14.79)	105.40 (14.46)	107.02 (15.18)	$t = 0.72$, $p = .55$
ADHD subtypes (K-SADS)				
Combined	126 (74%)	66 (75%)	60 (73%)	
Inattentive	38 (22%)	17 (19%)	21 (26%)	$\chi^2 = 3.17$, $p = .21$
Hyperactive-Impulsive	6 (4%)	5 (6%)	1 (1%)	
ADHD symptoms				
Inattention	16.22 (5.10)	15.82 (5.19)	16.66 (4.99)	$t = 1.07$, $p = .28$
Hyperactivity/Impulsivity	13.91 (5.73)	14.44 (5.29)	13.34 (6.16)	$t = -1.25$, $p = .19$
Comorbidity				
Oppositional deficient disorder	8.13 (4.77)	8.61 (4.97)	7.61 (4.52)	$t = -1.37$, $p = .37$
symptoms	1.90 (2.48)	2.14 (2.55)	1.65 (2.38)	$t = -1.29$, $p = .10$
Conduct disorder symptoms				
Game experience				
Starter	29 (17%)	13 (15%)	16 (19%)	
Amateur	55 (32%)	29 (33%)	26 (32%)	$\chi^2 = 4.32$, $p = .23$
Experienced	82 (48%)	42 (48%)	40 (49%)	
Expert	4 (3%)	4 (4%)	-	
Medication use?				
Yes	156 (92%)	80 (91%)	76 (93%)	$\chi^2 = 0.18$, $p = .67$
Primary outcome measures at baseline				
Time management	49.32 (15.82)	49.73 (16.41)	48.88 (15.25)	$t = -0.35$, $p = .58$
BRIEF (planning/organizing)	20.88 (4.42)	21.32 (4.21)	20.41 (4.61)	$t = -1.34$, $p = .68$
SSRS (cooperation)	8.63 (3.21)	8.53 (2.71)	8.73 (3.68)	$t = 0.40$, $p = .02$*

Note. IQ = Intelligence Quotient; DBDRS = Disruptive Behaviour Disorders Rating Scale.
* p < .05.

Time management skills

Figure 1 displays the regression tree resulting from VT with time management as an outcome. As the overall mean of estimated individual differential treatment effect equalled 8.18, the threshold *c* was set to be equal to 8.18. This implied that the subgroup (*n*=112) with enhanced treatment effect coincided with Leaves 2 and 3. The estimated treatment effect in this subgroup was 8.07 (*d*=0.56), while the estimated marginal treatment effect in the total group of participants was equal to 6.99 (*d*=0.48). Thus, the re-substitution estimate of the enhanced treatment effect in the subgroup compared with the average treatment effect (see Methods Section) equalled 1.08 (95% CI: -2.12, 3.80). As the 95% confidence interval around this estimate included 0, there was insufficient evidence that the subgroup identified using the VT method had a significantly better outcome on time management skills than the total group of participants. That is, none of the potential moderator variables in the VT analysis identified subgroups for whom the intervention increased time management skills.

Planning/organizing skills (BRIEF)

Figure 2 displays the regression tree resulting from VT with planning/organizing skills as an outcome. The overall mean of the estimated individual differential treatment effect estimate equalled 0.67, which implied *c*=0.67. This further implied that the subgroup (*n*=73) with enhanced treatment effect coincided with Leaves 1 and 3. The estimated treatment effect in the induced subgroup was 2.17 (*d*=0.65), while the estimated marginal treatment effect in the total group of participants was equal to 0.65 (*d*=0.20). Thus,

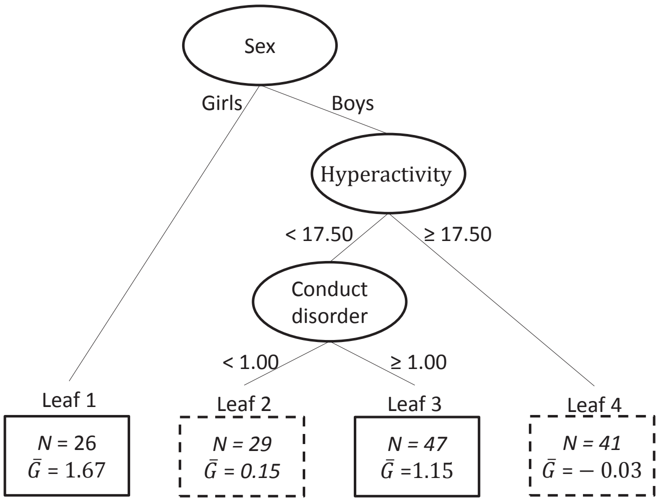


Figure 2. Results of the application of Virtual Twins with as outcome Behaviour Rating Inventory of Executive Function (BRIEF). The ellipses in the figure represent the internal nodes containing the split variables, with below each ellipsis the corresponding split point. The upper ellipsis represents the root node corresponding to the complete group of children. The rectangles represent the leaves of the tree, that is, the final subgroups of children; each rectangle contains the sample size of the corresponding subgroup (N), and the mean estimated individual differential treatment effect ($\bar{G}$). The leaves in which the estimated individual differential treatment effect exceeds the threshold c are represented by solid rectangles. Post-processing of the results suggest that there is an indication that the subgroups in these leaves have a significantly better outcome on BRIEF compared to the total group of children.

the re-substitution estimate of the enhanced treatment effect in the subgroup compared with the average treatment effect equalled 1.52 (95% CI: 0.43, 2.75). This suggested that the subgroup identified by the VT method had significantly better planning/organizing skills than the total group of participants. That is, two types of participants seemed to benefit from increased planning/organizing skills as a result of the intervention: 1) Girls (*n*=26), and 2) Boys with a lower score on hyperactivity (< 17.50) and a score on CD symptoms higher or equal to 1.00 (*n*=47).

Cooperation skills (SSRS)

Figure 3 displays the regression tree resulting from VT on cooperation skills. The overall mean of the estimated individual differential treatment effect estimate equalled 0.43, which implied that *c*=0.43. This further implied that the subgroup (*n*=87) with enhanced treatment effect coincided with Leaves 1 and 2. The estimated treatment effect in the induced subgroup was 1.39 (*d*=0.44), while the estimated marginal treatment effect in the total group of participants was equal to 0.69 (*d*=0.23). The re-substitution estimate of the enhanced treatment effect in the subgroup compared with the average treat-

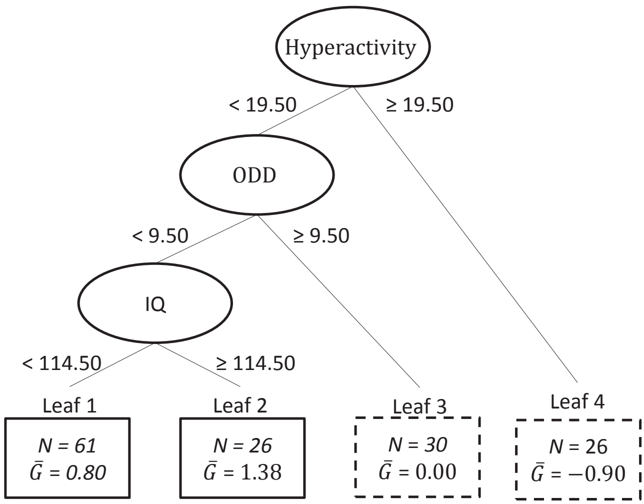


Figure 3. Results of the application of Virtual Twins with as outcome Social Skills Rating System (SSRS). The ellipses in the figure represent the internal nodes containing the split variables, with below each ellipsis the corresponding split point. The upper ellipsis represents the root node corresponding to the complete group of children. The rectangles represent the leaves of the tree, that is, the final subgroups of children; each rectangle contains the sample size of the corresponding subgroup (N), and the mean estimated individual differential treatment effect ($\bar{G}$). The leaves in which the estimated individual differential treatment effect exceeds the threshold c are represented by solid rectangles. It should be noted that after post-processing of the results, it appears that there is insufficient evidence that the subgroups in these leaves have a significantly better outcome on SSRS compared to the total group of children.

ment effect thus equalled 0.70 (95% CI: -0.12, 1.58). The confidence interval around this estimate implied that there was insufficient evidence that the subgroup identified by the VT method had a significantly better outcome on cooperation skills compared with the total group of participants.

DISCUSSION

Although there is emerging research examining the effectiveness of interventions using game-based approaches and designs, there is still scant literature examining moderating variables. Results of a multisite randomised controlled open-label study indicated the superiority of a SG intervention for instance on the parent-rated primary outcome measure of time management and secondary outcomes measures of responsibility and working memory (see *Chapter 4*). We used the VT method to explore the role of several clinically relevant pre-treatment characteristics as possible moderators of enhanced treatment effects on time management, planning/organizing and prosocial (i.e., co-operation) skills (included as primary outcome measures). Although, children appear to improve mainly on their time management skills (group-level), our findings about moderator effects were on the outcome variable of planning/organizing skills. On this variable, we found that two groups benefitted more from the SG intervention, compared with the total group: girls, and boys with a lower score on hyperactivity/impulsivity symptoms and a higher score on CD symptoms. Furthermore, we found no moderating effects of age, IQ, medication use, game experience and ADHD diagnosis on the three primary outcome measures. On the basis of these subgroups we are able to tailor the SG intervention to the needs of specific patients.

In the MTA study, gender was tested as a moderator, but was not associated with outcomes in any of the treatment conditions (MTA Cooperative Group, 1999ab; Owens, Hinshaw, Kraemer, Wilson, Fairburn, & Agras, 2003). However, our results indicated that gender influences treatment success: in our study, girls benefitted more strongly from the intervention. This may be because girls experience lower levels of ADHD symptoms, both in the current sample, and in previous research in this area (Gaub & Carlson, 1997). Hence, our study, one of the first to examine gender as a moderator, contributes to the ADHD literature by demonstrating that game-based interventions are not equally effective for boys and girls.

In addition, we also found enhanced treatment effects for boys with lower initial levels of hyperactivity/impulsivity and a higher CD symptom score. The finding with hyperactivity/impulsivity is in line with previous findings from the MTA study, which found that those with subclinical ADHD symptoms were more likely to be normalised by additional treatment on top of their TAU (Owens et al., 2003; Murray et al., 2008). In our study, boys with scores falling in the normal to subclinical range of hyperactivity/impulsivity symptoms, who are therefore likely to be more stabilised on their TAU, benefitted the most from the intervention. In contrast, our finding with CD symptoms is more counter-intuitive. CD symptoms are associated with aggressive/externalizing behaviour, which suggests that they may interfere with treatment effectiveness, as has been demonstrated in the MTA study (Hinshaw, 2007; MTA Cooperative Group, 1999ab). Hence, the CD symptoms score for our participants fell within the normal range, suggesting that there were no serious clinical symptoms that could interfere with the intervention. This subgroup of participants with additional comorbid CD symptoms might have benefitted more from the intervention because they were more engaged with the adventurous character of the game format (Dovis et al., 2011; Favelle, 1995; Zentall & Zentall, 1983). Future research should test this assumption more thoroughly as the CD symptom score fell within the normal range, suggesting low clinical relevance in the current treatment context.

In *Chapter 4*, we only found a marginal treatment effect of the SG intervention on participant's planning/organizing skills (group-level). However, we did find a moderating effect on this outcome measure in the current study. This was surprising, and illustrates the value of examining moderator variables even if overall treatment effects are not present (see *Chapter 4*). It is necessary to characterise those participants gaining highest response effects by this kind of intervention as our results suggest that SG intervention may still be of value in improving the planning and organizing skills of subgroups of children with ADHD.

Clinical implications

Thus far, there has been a lack of studies examining moderating variables in the field of serious gaming within mental healthcare (Institute of Digital Media and Child Development Working Group on Games for Health et al., 2016). It is important to examine moderator variables because individuals and their characteristics differ from each other. The current study, one of the first to investigate the role of moderating variables, gives some indications for whom the intervention works best. These results could be used to direct decisions regarding intervention delivery. The results indicate that gender, levels of hyperactivity/impulsivity, and presence of CD symptoms should be taken into account when deciding upon treatment in clinical practice (Rucklidge, 2008). Our results demonstrate that girls, and boys with lower hyperactivity/impulsivity and a higher CD symptom score, benefitted the most from the intervention. In short, the SG intervention improves time management skills in children with ADHD (who already receive TAU) and enhanced treatment effects are present for specific subgroups on planning/organizing skills. Other kind of treatment might be indicated for participants who need improvement in functional outcomes (especially cooperation skills) of daily life, but do not fit this profile.

Our results are also important from a clinical perspective, as they may help stimulate personalised and targeted interventions. These results could contribute to a personalised clinical approach, indicating for whom an additional serious game treatment is most effective. In this regard, the DBDRS questionnaire (Pelham et al., 1992; Dutch translation: Oosterlaan et al., 2000), which was used in the current study to screen for ADHD and comorbid ODD and CD symptoms, could be used as a screener to support treatment indication. This questionnaire is a widely used and accepted instrument within the clinical field.

Limitations

There are also some limitations of this study that should be addressed in future work. First, although non-parametric approaches like VT have clear advantages over linear models (Kraemer, 2008), in this study, the power to detect subgroups was relatively low. Despite this issue, we did find several significant moderators, to prevent ourselves from overfitting these data, we used a bootstrap-based procedure for estimating a measure of uncertainty. As compared to other RCTs, our sample size of children with ADHD was relatively large, but for the current method, even larger samples are needed to replicate these findings (Lee, Lei, & Brody, 2015). Second, although it is clinically important to determine long-term effects, we were not able to examine moderator effects at follow-up, as these data were not available for the TAUx group. Third, although we included a broad range of moderators, we acknowledge that we did not investigate the potential role of other pre-treatment characteristics as possible moderators of treatment outcome. For example, we did not test the role of parental support, parental ADHD diagnosis, or motivation, all factors that have been demonstrated to be relevant by other studies (Baranowski et al., 2011; Jaeggi et al., 2014; Owens et al., 2003; Sonuga-Barke et al., 2002; Van den Hoofdakker et al., 2010). Finally, although our results are intriguing and relevant for clinical practice, we can only speculate why our subgroups show enhanced treatment effects. We hope that future research examining mediating factors will address this question as well.

CONCLUSION

In conclusion, this study found two groups that benefitted most from SG intervention among a clinical sample of children with ADHD: girls, and boys with a lower score on hyperactivity and a higher score on CD symptoms. These profiles should be considered when referring these patients to treatment. This work, together with future research on the mechanisms of the serious game, can begin to specify with greater precision the subgroups for whom treatment works best.

Chapter 7

General Discussion

SUMMARY AND GENERAL DISCUSSION

The aims of project "HealSeeker" fit into the current need to improve accessibility of mental healthcare and motivate and engage patients for treatment by integrating user-driven technology (World Health Organization Action Plan, 2013). Previous study results indicate that the integration of game elements into current treatment practices may be specifically appealing and motivating for children with ADHD (Dovis et al., 2012; Prins et al., 2011). The goal of this dissertation was to describe the design process of the serious game "Plan-It Commander" and to explore its effectiveness on behavioural and neurocognitive outcomes in school-aged children with ADHD. In addition, we tried to identify subgroups of children for whom "Plan-It Commander" was most effective. First, a summary of the main findings from the design process, pilot study and will be provided, followed by an overall discussion of the results. Next, the clinical implications of our findings and limitations of our studies will be discussed. The discussion is completed by suggestions for future research with regard to the development and application of serious gaming in child- and adolescent psychiatry.

Summary of main findings

Chapter 2 describes the design process of "Plan-It Commander" and presents some first usability results from children with ADHD as well as their parents. Developing a serious game is a dynamic process and requires collaboration between various stakeholders, each of them contributing with their own expertise. The learning goals (e.g., improving time management, planning/organizing, and prosocial skills) were proposed by mental healthcare professionals and a community board of parents, reflecting input from scientific literature as well as clinical experience. With the aim of achieving behaviour change among end-users, we translated these learning goals into suitable game components. Hereby we based ourselves on relevant psychological theories, namely the Self-Regulation Model (Cameron & Leventhal, 1995), Social Cognitive Theory (Bandura, 1986) and Learning Theory (Barkley, 2006; Kato, et al., 2008). Furthermore, the game structure, mini-games, social community and special features of "Plan-It Commander" are described in more detail in *Chapter 2*. Finally, usability results with regard to the first prototype were assessed among children and their parents. These results indicated positive acceptance among users and suggestions for further game design.

Chapter 3 describes the results of a randomised controlled pilot trial in which the preliminary effectiveness of "Plan-It Commander's" first prototype was tested. The sample consisted of 42 children with ADHD (aged 8 to 12 years) who were randomly allocated to the serious game intervention group (n=22) or semi-active control group (n=20). In both groups the serious game was offered in addition to their TAU. Participants in the intervention condition were asked to play the serious game about eight times per two weeks, whereas participants in the semi-active control group were allowed to play a maximum of three times per two weeks. The game was presented for a total period of eight weeks in which every two weeks a new mini-game (with its own learning goal) was presented. Participants in the intervention condition played on average five times per two weeks whereas participant's average play frequency in the semi-active control condition was on average two times per two weeks. Results demonstrated within-group improvements for both groups with regards to parent-reported planning/organizing skills. A borderline significant between-group effect was shown; participants in the intervention condition showed more improvement in their time management skills compared to the semi-active control group. Furthermore, correlation analyses were performed to test the hypothesis that children who played the game more frequently, would improve more with regard to their behavioural outcomes. This analysis showed a significant correlation between play frequency and improvement in time management skills, which provides some first indications for this 'dose-response relationship'. While no firm conclusions with regards to effectiveness could be drawn on the basis of this pilot study, we agreed that the first prototype of "Plan-It Commander" had enough potential to continue game design and pursue further research as described in subsequent chapters.

In *Chapter 4* we present the results of a 20-week multisite randomised controlled crossover open-label trial that was aimed at testing the effectiveness of the final version of "Plan-It Commander" on behavioural outcomes. A sample of 170 children with ADHD were recruited from several outpatient mental healthcare clinics and institutions in the Netherlands and Belgium. Participants were randomised to a serious game intervention group (n=88) or a treatment as usual crossover group (n=82). Participants randomised to the serious game intervention group were offered to play "Plan-It Commander" in addition to TAU for the first 10 weeks and then received TAU for the next 10 weeks. Parent, teacher and child questionnaires were administered at baseline, 10 weeks and 10-week follow-up. Participants randomised to the treatment as usual crossover group received TAU for the first 10 weeks and crossed over to the serious game intervention in addition to TAU for the subsequent 10 weeks. Participants played on average 19 days in the mission-guided game and 11 days in the closed social community. Participants who played the serious game during the first 10 weeks demonstrated within-group effects with regard to parent-reported (i.e., time management, time perception, planning/organizing and social skills) as well as teacher-reported (i.e., time management, working memory and social skills) outcome measures. Participants from the treatment as usual crossover group demonstrated comparable within-group effects after playing the game. Participants who played the serious game during the first 10 weeks improved more in their time management, responsibility and working memory skills compared to participants who received TAU during the first 10 weeks, indicating significant between-group effects. Improvements on these outcomes among participants who played the serious game during the first 10 weeks were maintained or further improved in the last 10 weeks of the study. The current study provides indications that next to treatment as usual "Plan-It Commander" is an effective approach to improve daily life outcomes in children with ADHD.

Chapter 5 examined the effects of "Plan-It Commander" on neurocognitive performance tests assessing planning, working memory and social cognitive skills. Although the serious game intervention mainly focused on improving daily life behaviour, neurocognitive test performances were included as secondary outcome measures. Neurocognitive data of 170 children with ADHD were collected. In both the serious game intervention group (n=88) and the treatment as usual crossover group (n=82) neurocognitive performance tests were administered at baseline, 10 weeks and 10-week follow-up. Both groups improved with regard to their planning and social cognitive test performances during the first 10 weeks, demonstrating within-group effects. There were no significant differences between the serious game intervention and TAU groups on participant's planning, working memory and social cognitive test performances during the first 10 weeks. So, in contrast to the behavioural results presented in *Chapter 4*, no between-group results were present among the neurocognitive test performances. A more elaborate discussion about possible explanations of this discrepancy in findings can be found in the general discussion section of this chapter.

In *Chapter 6* we used an innovative statistical approach (Virtual Twins; Doove et al., 2014) to explore the role of 10 pre-treatment characteristics (i.e., gender, age, intellectual level of functioning (IQ), medication use, computer experience, ADHD subtype, severity of inattention problems, severity of hyperactivity/impulsivity problems, comorbid oppositional defiant disorder (ODD) and conduct disorder (CD) symptoms) as possible moderators of enhanced treatment effects on time management, planning/organizing and prosocial (i.e., cooperation) skills. As a first step, VT estimates for each participant the two potential outcome values, namely one for the serious game condition and one for the TAU condition (also referred to as Virtual Twins). The difference between these estimates represents for each participant an estimate of that participant's individual differential treatment effect. As a second step, VT uses this estimate as the criterion variable in a regression tree analysis together with the available pre-treatment characteristics. The total group of participants is repeatedly subdivided on the basis of binary splits of the pre-treatment characteristics into subgroups that are increasingly homogeneous with respect to the criterion variable. The difference between the estimated treatment effect in the subgroup and the total group of participants is calculated and subsequently results in an estimate of the enhanced treatment effect for a certain subgroup compared with the average treatment effect. See the Method section of *Chapter 6* for a more detailed description of VT. Results demonstrated that the serious game intervention was specifically effective in improving planning/organizing skills among girls (n=26) compared to the total group of participants. In addition, boys with a lower score on hyperactivity symptoms and a higher score on conduct disorder symptoms at baseline (*n*=47) showed more improvements in their planning/organizing skills when they received the serious game intervention compared to the total group of participants. Further implications of identifying subgroups with enhanced treatment effect for personalised intervention allocation are discussed below.

General discussion

Game development

This dissertation describes an innovative serious game intervention for children with ADHD aimed at improving daily life skills. Introducing a new intervention within mental healthcare is a challenging task. It takes many years, from development to effectiveness testing and evaluation of implementation, for new interventions to be fully developed and subsequently integrated into practice (Gitlin, 2013). In this context, describing the target population, clinical problem, and theoretical background is seen as an important first step in developing serious games within (mental) healthcare. With our contribution in *Chapter 2,* this dissertation responded to the need of researchers, serious game developers and clinicians to provide a more detailed description of serious game development. More specifically, we elaborated on the background of our design choices regarding the current game format. We also described behavioural theories used in the game aiming to positively change behaviour. A more elaborate description of the theoretical framework used in serious games has also been recommended for example by the *Games for Health Journal*. Using their proposed standardised format of game description (see Table 1; *Chapter 2*) within our current study enables better comparison between "Plan-It Commander" and other serious games within (mental) healthcare. It also shows the game design we used and how expertise between researchers, serious game developers and clinicians in the field was shared.

Additionally, we present acceptability and usability results from parents and children with regard to the first prototype of "Plan-It Commander" in *Chapter 2*. Several results of this study were useful for the further game design of "Plan-It Commander". First, one of the most obvious remarks from parents was that they did not expect that their children would socially profit from the serious game in the prototype version. To enhance the games' potential to improve social behaviour we then decided to include a social community aspect in the final version of the game (Van Rooij et al., 2012). However, because of ethical and safety issues, this interactive platform had to be developed with the use of preset dialogue options and actions between players. This compromise in design may relate to the lack of effects on social outcomes presented in *Chapter 4,* as direct communication between children might be necessary to improve their social skills. Second, on the satisfaction questionnaire a substantial part of the children indicated that they had learned from the game. Parents and children also indicated on this questionnaire that they would certainly recommend the game to others and that they wanted to have access once it was further developed. However, based on children's suggestions and self-reported level of motivation to play the game it became clear that the game environment could be made more immersive. Balancing learning content and core game mechanics is one of the major challenges when designing serious games (Prensky, 2001). Therefore, we decided to make the final prototype of the game more enjoyable by including different characters and special features.

Pilot study phase

This dissertation demonstrates an important initial step in exploring a novel intervention approach by performing a small scale pilot study (N=42; *Chapter 3*). This study mainly provided justification for further game development and performance of a larger RCT. The pilot study demonstrated significant within-groups effects on planning/organizing and a marginal significant difference between groups in the expected direction; participants in the intervention condition showed more improvement in their time management skills compared to the semi-active control group. This is in line with one study demonstrating the potential of digitalised tools to support time management skills among patients with ADHD (Frutos-Pascual et al., 2014).

In our study, children in the intervention condition played the game less frequent than was advised to them, causing a less pronounced difference between the intervention and semi-active control conditions with regard to play frequency. This might explain the absence of intervention effects on other outcomes as participants who had played the game in the semi-active control condition may have already some benefits from playing the game (Clark et al., 2014; Donkin et al., 2013; Kato et al., 2008;). The role of play frequency in improving learning outcomes has not been clarified in the literature yet, some have found associations between play frequency and outcomes others not (Clark, Tanner-Smith, & Killingsworth, 2014; Donkin et al., 2013; Kato et al., 2008;). In our study we found a positive association between play frequency and time management skills, which points towards dose-response effects and potential less difference as expected between our intervention conditions. As such, effects might have been stronger if a non-active control group was included.

However, in this initial testing phase in which we did not include a game-free or placebo game control condition, we cannot ascertain that the observed improvements in both conditions can be attributed to the specific treatment procedures instead of non-specific treatment factors (e.g., effects of expectancies, attention, maturation; Mawjee et al., 2015). Given the short intervention period of 10 weeks and the persistent nature of ADHD, this latter explanation of maturation seems less straightforward. It is possible that parental attention played a role in the significant within-group effects, for example by making sure that their children had access to a computer and played the game on time. Moreover, as demonstrated by usability and feasibility results (*Chapter 2*) parents had overall a high expectation with regard to the game's learning potential, which may have influenced their ratings. Further, as the game was still a prototype and not fully developed yet, optimal intervention effects might not have been achieved. These results did inform us about the need of further modifications for the final game development and design of the RCT.

Effects on behavioural outcomes

Previous studies indicate the need to improve daily life functioning in school-aged children with ADHD (Connors, 2003; Nijmeijer et al., 2008; Sonuga-Barke et al., 2010). Studies have also demonstrated that available computerized neurocognitive interventions for ADHD improve basic trained neurocognitive functions but do not have a strong impact on daily life functioning (Chacko et al., 2013; Cortese et al., 2015; Melby-Lervåg & Hulme, 2013; Morrison & Chein, 2011; Owen et al., 2010; Rapport et al., 2013; Shipstead et al., 2012). Our findings in *Chapter 4* demonstrated that children improved more on multiple daily life skills (as reported by parents and teachers) after playing the serious game compared to children who received TAU. This is in line with results of gamified approaches for ADHD, in which game design principles are applied to existing neurocognitive tasks or training programs (Dovis et al., 2012; Van der Oord et al., 2014). However, it should be noted that these effects are obtained in a different way than in other formats: "Plan-It Commander" promotes the use of behavioural strategies via a computer game with integrated therapeutic elements (e.g., reinforcement, immediate performance feedback from a mentor, goal setting through missions, modeling, social support, and comparison). The behavioural training aims to improve daily life functioning of children with ADHD instead of repeating executive function tasks normally presented in neurocognitive training formats (see *Chapter 2* for a more detailed description). Additionally, in contrast to other neurocognitive training formats, "Plan-It Commander" uses a mission guided story line that is linked to different levels of the in-game embedded mini-games. The use of this story line is assumed to be beneficial for engaging players with specific learning goals.

Although the results are promising, for the current serious game to be considered as an evidence-based treatment, it needs to be proven to be at least equally effective as already proven effective non-pharmacological ADHD treatments (Chambless & Ollendick, 2001; Evans, Owens, & Bunford, 2014). Unfortunately, we cannot draw this conclusion based on the current study as we had no group with the already established non-pharmacological ADHD treatments. Further, we did not use completely blinded outcome measures. As parents and children were involved in giving or doing the treatment they may be biased in their ratings, which possibly results in overestimated treatment effects. Considerable differences in outcomes have been demonstrated when using blinded measures in computerized neurocognitive training formats (Cortese et al., 2015; Sonuga-Barke et al., 2013) as compared to unblinded outcome measures, suggesting such effects may be present in our study as well. However, our study did include teacher ratings which may be less biased as children played the game at home and they were not actively involved in the treatment. However, we could not guarantee this to be a fully blinded outcome because children might spontaneously tell their teacher at any time during the study that they are playing the game. In the future, to rule out possible expectancy effects, placebo game controlled studies should be applied.

For pragmatic reasons (e.g., time and money) we did not include a placebo control group and it is therefore not possible to conclude that the significant between-group effects on time management, working memory and responsibility skills can be attributed to specific treatment effects instead of non-specific effects (such as attention). In designing our study we considered using an off the shelf game as a control group but this was deemed not a suitable placebo condition as some players would probably know the control game. Additional methodological constraints, such as not being able to capture game metrics (play frequency, duration) contributed to the decision. Another option considered was offering “Plan-It Commander” without the active learning elements, but this would potentially risk a higher drop-out rate making it impossible to compare intervention and control groups. Moreover, research into the active learning ingredients of serious games is complex so it would be hard to decide upon which elements this placebo game should exclude (The Institute of Digital Media and Child Development Working Group on Games for Health et al., 2016). Therefore, in this evaluation we chose to compare children who receive TAU with children who play the game on top of their TAU. Results indicate that there is still room for improvement of their daily life skills, even when children with ADHD are already treated for their core symptoms of impulsivity, hyperactivity and attention deficit.

Effects on neurocognitive outcomes

In contrast to effects found on behavioural outcomes, we did not find comparable improvements on neurocognitive outcome measures of planning (Tower Test; Delis et al., 2001), working memory (Chessboard Task; Dovis et al., 2012) and social skills (Social Cognitive Skills Test; Van Manen et al., 2001) as presented in *Chapter 5*. Moreover, neurocognitive functioning at baseline did not appear to be a significant predictor of behavioural improvement, expect for social behaviour skills. This may not be surprising given that the intervention focused on improvement more at the behavioural level (e.g., use a clock, break down assignments into pieces) than on improving neurocognitive functions by repetitive basic training of these functions. “Plan-It Commander” focuses on usage of compensatory strategies for these deficits and may not ameliorate the deficits themselves. Performance-based tests measure how well a child performs in a structured testing session, in which little distraction and few external influences are operating. These measures often do not tap the flexibility and the scope of attentional functions needed to adequately assess the wider range or executive function impairments in real-life. To increase chances of finding improved daily life functioning resulting from serious gaming, training tasks should be made more ecologically valid (e.g., by using training tasks that resemble the complexity of problematic situations in daily life) and should be intertwined with relevant real -life activities as is also suggested by Boyer (2016). Overall, on hindsight, as neurocognitive measures are not highly correlated with behavioural outcomes (Boyer et al., 2014; Boyer, 2016) it may be best to limit the use of neurocognitive measures as treatment outcomes to treatments explicitly aimed at altering underlying deficient neurocognitive constructs like cognitive training or neurofeedback (Bink, van Nieuwenhuizen, Popma, Bongers, & van Boxtel, 2014; Boyer, 2016).

What works for whom

The Institute of Digital Media and Child Development Working Group on Games for Health and colleagues (2016) state that the role of moderators, indicating subgroups with enhanced treatment effects, needs further study in serious game interventions. To our knowledge, this dissertation contains the first study on moderation of serious game treatment effects in school-aged children with ADHD. A novel statistical analysis technique, Virtual Twins (Doove et al., 2014), was used and examined the presence of subgroups with enhanced treatment effects regarding three primary parent-reported outcome measures (i.e., time management, planning/organizing and cooperation). Given the heterogeneous nature of ADHD, these analyses are of great importance because they give direction to personalised treatment assignment. The moderation analyses of this dissertation demonstrated that the serious game intervention was more effective in improving planning/organizing skills among two subgroups, namely (1) in girls and (2) in boys with a lower score on hyperactivity and a higher score on conduct disorder symptoms at baseline. This shows that serious game interventions are not equally effective for boys and girls with regard to their planning/organizing skills. Further results indicated that levels of hyperactivity/impulsivity and presence of conduct disorder symptoms in boys should be taken into account when deciding upon serious game treatment in clinical practice. Of particular relevance is that the cut off point for conduct disorder symptoms (< 1.0) fell within the normal range and is therefore less valid and difficult to use in clinical practice. Overall, identifying subgroups with differential treatment effectiveness is important so that these characteristics can be considered when allocating serious game treatment.

CLINICAL IMPLICATIONS

This dissertation brings forth some clinical implications. ADHD is a chronic health problem and previous studies have emphasized the need for efforts to treat impairments outside the therapy context and provide patients with greater autonomy (Cheek et al., 2015; World Health Organization, 2013). The Internet-based serious game intervention in this study fulfills this need by addressing impairments associated with ADHD among school-aged children in the home and school context. The description of the design process and usability findings provides a methodological example for game developers, clinicians and researchers on how to develop serious game interventions for mental healthcare. Thereby, it offers more insight into the stakeholders that are involved and the way that iterative testing can contribute to considered decision making in further game design. This could stimulate new initiatives to develop serious games within child- and adolescent psychiatry.

The findings of this dissertation suggest that an innovative and engaging intervention approach has been developed that can be offered as an additional treatment tool for patients with ADHD, which may support them in the daily life problems they encounter. Children who played the serious game improved more in their time management, responsibility and working memory skills than children who only received their TAU. Ten week follow-up assessments indicated maintenance or further improvement of these effects over time among children who played the serious game during the first 10 weeks. As there was no control group available for these follow-up results, we were not able to draw firm conclusions about its long-term effects but results provided us at least with some indications that effects are not limited to immediately after the intervention.

Children and their parents from the pilot study (*Chapter 3*) as well as the larger study trial (*Chapter 4*) indicated that they were satisfied with their treatment. Intervention effects and satisfaction rates might have been improved when children received more therapist-guided feedback on their performances which was not the case in the current study design. As this serious game has been introduced independently of therapist guidance, more research is necessary on how these tools should be implemented in clinical practice. It is expected that therapists could play a role in emphasizing behavioural strategies that children used in the game, thereby potentially supporting generalisation of these strategies to "real world" contexts. Generating discussion about this with the patient could be specifically fruitful to improve motivation for playing the game more frequently and thereby possibly increase intervention effects. To increase the use of behavioural strategies in real -life additional tips and counselling can be offered to children and their parents (Pivec, 2007; Thompson, Baranowski, Buday, Baranowski, Thompson, Jago, & Griffith, 2010). An idea is to design and add a dashboard so that therapists can monitor children's progression. Further research could examine if therapists' feedback and monitoring could provide additional value for this current game format and booster its learning effects for children with ADHD.

When evaluating treatment outcomes in a RCT, no effects were found on children's neurocognitive test performances. This might be explained by the focus of the intervention on teaching children behavioural strategies, therefore compensating for underlying neurocognitive deficits and not ameliorating the deficits themselves. The serious game environment did not include neurocognitive performance tests itself because improvement on these tasks after the game was not a goal itself (so called near-transfer effects). In the current context, treatment potential should be evaluated at the behavioural level through parent- and teacher reported questionnaires instead of neurocognitive outcome measures (*Chapter 4* and *5*). Nowadays, routine outcome monitoring has been performed within mental healthcare and follows the same line of thinking in which questionnaires are most often used to demonstrate treatment impact on daily life behaviour (Boswell, Kraus, Miller, Michael, & Lambert, 2013). For clinical practice it is important that clinicians make considered decisions about which measures to use for evaluating treatment effectiveness and that fits treatment focus.

Results of moderator analyses indicated that two subgroups are likely to benefit more from the serious game intervention than the total sample. Therefore, clinicians should be aware that the current treatment could be specifically fruitful for some subgroups as was indicated in *Chapter 6*. More research into moderating variables of serious gaming could help clinicians to select the best ADHD treatment approach or may determine the relevance of serious gaming for an individual child with ADHD.

Next to moderators, mediators may be important. Although we did not examine mediator variables in the current dissertation, it seems important to be aware of working mechanisms that predict potential effectiveness in serious game interventions. Examples of such mediators include immersion, attention, functional knowledge, self-regulatory skill development (e.g., goal setting, self-monitoring, decision making), self-efficacy, internal motivation, and feelings of competence, autonomy, and relatedness (Thompson et al., 2010). As therapists attempt and are experienced in changing thoughts and behaviour of children with psychopathology in clinical settings, it is important that these clinical experts collaborate and share knowledge with game developers to decide upon which clinical relevant elements should be included in game design. However, as most serious game environments already include a lot of mediators it is often hard to disentangle their effects. Therefore it is questionable whether this is a realistic aim for further research as the synergetic interplay of factors that may be at work is inherently related to the multifaceted nature of a game.

Although medication use was not a significant moderator variable, it could be the case that this was a precondition for reaching optimal intervention effects. Medication lowers hyperactivity and improves attention, implying that children are in an optimal state for learning (MTA Cooperative Group, 1999a). Further research should therefore test this hypothesis in a sample of unmedicated children to see if comparable effects are established. This will enable clinicians to make considered treatment decisions when appointing serious game interventions to children with ADHD.

Although no serious adverse events were detected in the RCT and play duration was restricted (*Chapter 4*), it seems important that clinicians encourage parents to monitor their children's play frequency and inform them about the risks and benefits of video game use in general (Mijland & Kisjes, 2011). Gaming on a young age and impulsivity predict initial pathological gaming symptoms and increases in pathological gaming, which in turn predict increased levels of depression, anxiety, and social phobia and poorer grades (Gentile, Choo, Liau, Sim, Li, Fung, & Khoo, 2011). Given the fact that children with ADHD are more sensitive to addiction, parents and clinicians should be cautious about these possible negative long term-outcomes of gaming (Elkins et al., 2007; Lee et al., 2011). So far, no serious adverse events have been reported in emperical studies of serious games as these games include therapeutic goals in which positive behaviour is consistently rewarded. Nontheless, more research is necessary to make sure negative effects can be excluded (Institute of Digital Media and Child Development Working Group on Games for Health et al., 2016).

In this dissertation the effectiveness of "Plan-It Commander" has been examined. While the absence of an placebo game control group asks for a cautious interpretation of the study results, the current study provides a good first step to prove that children can improve on multiple domains of daily life functioning (as rated by parents and teachers) and potentially proves that specific subgroups could profit even more from this intervention approach.

LIMITATIONS

Although results were promising, several limitations of this dissertation should be considered when interpreting the results. As already discussed, an important limitation in the pilot study as well as in the larger clinical trial is that we did not use a "placebo game" as a control condition. Therefore, it is not possible to conclude that all effects can be attributed to specific treatment effects instead of non-specific effects such as attention or maturation. Furthermore, we are not able to rule out expectancy effects as parents were not rater-blinded and rater-blindness of teachers could not fully be guaranteed.

Secondly, although no between-group effects were found on neurocognitive outcomes it is important to mention that studies with negative or inconclusive results of the effects of serious games should be published to prevent bias in publishing studies with positive results, also known as the file drawer problem (Rosenthal, 1979).

Thirdly, we used a survey questionnaire approach with several open-ended questions during our usability research. A drawback to this approach is that we may have lost the opportunity to gain some important opinions and feedback from participants due to the structured format of the questions and responses. On the other hand, our approach made it possible to summarise the results in a standardised way. A focus group approach should be considered in future usability research (Reichlin, Mani, McArthur, Harris, Rajan, & Dacso, 2011). Research must address the optimal role of usability findings in designing serious games, the sample size that is needed and whether post-intervention interviews to assess whether an intervention met user needs and suggestions for enhancement are needed (Institute of Digital Media and Child Development Working Group on Games for Health et al., 2016).

Fourthly, questionnaires to assess time management and self-efficacy were self-constructed. During the pilot study we developed the time management questionnaire because this is one of the primary learning goals of "Plan-It Commander". At the time of planning and designing our study there were, to our knowledge, no questionnaires available to assess time management in school-aged children. The time management questionnaire gives a more detailed insight into children's behaviour strategies used to improve their time management skills than another existing questionnaire (the "It's about time" questionnaire) that mainly focuses on time perception and orientation which is different from time management (Barkley, 1990). The self-efficacy questionnaire was constructed in accordance with the standard method for designing self-efficacy scales (Bandura, 2006). The questions needed to be specifically focused on self-efficacy beliefs concerning the learning goals (e.g., improving time management, planning/organizing and prosocial behaviour skills) of the game, thus developing a new questionnaire was necessary. These questionnaires demonstrated good reliability but we do acknowledge the absence of a more elaborate psychometric investigation of these primary and secondary outcomes as a limitation. Future research should evaluate the psychometric characteristics of these questionnaires in more detail.

Fifthly, although it is clinically important to determine long-term effects, we were not able to compare effects at follow-up, as these data were not available for the treatment as usual crossover group (TAUx). Whether serious games maintain the positive effects, thus far described in effectiveness studies, has yet to be determined as most of the peer-reviewed literature describes open or randomised controlled studies where a short window of engagement exists with participants. Finally, as compared to other RCTs, our sample size of 170 children with ADHD is relatively large, but for the VT method, even larger samples with adequate power are needed to examine other moderator variables (Lee, Lei, & Brody, 2015).

Taking a more general overview, an important limitation in the field of serious gaming is that a lot a serious games have been developed but often lack funding sources to perform a RCT to evaluate their effectiveness (Kato, 2010; 2012). As a result, often a lot of money, time and effort have been put in to start-ups and innovative projects, which eventually do not reach their end-users because empirical evidence is missing. Developing a business model in which its costs and benefits are described and a strategy is explained on how the serious game can be distributed to the end-users when proven effective should be considered at the start of a project because this will lead to a more successful implementation. From a research perspective, other evaluation approaches than large scale RCTs (e.g., quasi experiments) or joint efforts of several research groups in testing effectiveness should be considered because technology develops so fast that once its effects have been proven, technology has often become outdated, lowering interest and engagement of its end-users (Mayer et al., 2014). This dissertation tries to inform researchers, developers, clinicians and governmental decision-makers about the 'lessons learned' aiming to move the field of serious gaming forward.

FUTURE DIRECTIONS

Based on this dissertation, several directions for future research are proposed. Future research should focus on how the current serious game format could contribute to daily life functioning of a broader audience within child- and adolescent psychiatry. Psychological theories used to design "Plan-It Commander" as well as the principles of game-based learning are more generalisable across serious games. However, it cannot be presumed that this serious game will be efficacious for other age groups or populations, such as children with autism who also encounter problems in executive and social functioning (Geurts, Verte, Oosterlaan, Roeyers, & Sergeant, 2004) or children with below average intelligence. Future research could examine which learning goals and game design elements have to be integrated to make the current game suitable and more personalised for other target groups within child- and adolescent psychiatry.

Although this was outside the scope of this dissertation, it would be interesting to examine game metrics more thoroughly. Game metrics are numerical data obtained from the user interaction with the game software. These data offer quantitative time-stamped information about every event occurred while playing the game. Overall, there is a lack of frameworks to interpret these extensive data (Tychsen & Canossa, 2008). From a psychology point of view, research should ideally focus on the relationship between game metrics and outcome measures assessing daily life functioning. For example, in the current project it would have been interesting to test if strategies used in the game are related to improvement in daily life functioning. From a game design perspective it is interesting how these metrics could feed into game design decisions such as the narrative and game mechanics. Because these metrics offer insights into how people are actually playing the game, whether or not a game provides the diversity of possible play-styles and interaction options needed to keep people engaged could be tested and evaluated (Tychsen & Canossa, 2008). The main advantage of game metrics is that they are objective, can be collected in large numbers and can map precisely to a point in a game map or level. Unlike qualitative data and survey-based information, metrics are precise and therefore are helpful for game development team.

One of the challenges in offering Internet therapy is to keep patients engaged. It is expected that serious games are more engaging through their interactive components and therefore improve treatment adherence (Riper, Van Ballengooijen, Kooistra, De Wit & Donker, 2013). As motivation is an important predictor of intervention success, this is particularly relevant to serious games. How the element of entertainment mediates user motivation is unknown in this context at this time. Given that treatment adherence in the current randomised controlled clinical trial was moderate, future research should examine the role of motivation, engagement and flow in serious game interventions. Also the contribution of family factors (e.g., social support network, socioeconomic status, parental ADHD) should be considered when examining treatment adherence. Tools to measure motivation have been used in online learning (Cheek et al., 2015), also physiological measures (e.g., facial electromyography, cardiovascular measures, galvanic skin response and electroencephalography) can provide an indication of player engagement and flow (Bellotti, Kapralos, Lee, Moreno-Ger, & Berta, 2013). Providing a meaningful interpretation of these results remains challenging but it seems promising within the field of serious gaming as it could assist in validating the critical design elements and further inform design choices (Bellotti et al., 2013). As discussed before, future research could also examine which features facilitate game transfer to real-life behaviour, for example therapists' role in giving feedback and monitoring performances (Institute of Digital Media and Child Development Working Group on Games for Health et al., 2016).

Based on the current dissertation results, we can only speculate why some subgroups show enhanced treatment effects. The role of other moderator and mediator variables in serious gaming should be examined more extensively. So far, the role of play frequency or duration remains unclear. In general, it is assumed that longer play durations are associated with better learning outcomes which, implies a (linear) dose-response relationship. However, several studies contradict this and demonstrate that duration of game-play itself is unrelated to effectiveness (Clark et al., 2014; De Smedt et al., 2014; Donkin et al., 2013; Kato et al., 2008 It is likely that other game characteristics impact effectiveness more considerably (e.g., use of a narrative, in-game challenge, scaffolding levels; Kapp, 2012; Lu et al., 2012). This work, together with future research on the mechanisms of the serious game, can begin to specify with greater precision the subgroups for whom treatment works best.

As already mentioned, this is the first study that scientifically evaluated the effectiveness of a serious game focusing on improving daily life functioning in school-aged children with ADHD. Once more studies evaluate the effects of serious gaming within mental healthcare, a meta-analysis could be performed to assess its overall effect. Currently, synthesizing the literature and making overall conclusions on the effects of serious games is challenging because most studies are very diverse in terms of target demographics, interventions, game formats and measures (Baranowski et al., 2008; Institute of Digital Media and Child Development Working Group on Games for Health et al., 2016). Moreover, serious game initiatives designed for ADHD do exist (e.g., RESET) but do not appear in the empirical literature potentially because of the file drawer problems, lack of funds for empirical testing or expertise available to conduct an evaluation, or purely a commercial interest in developing a game for ADHD (Kato, 2010; 2012). Hopefully, the current project stimulates well-designed effectiveness research and dissemination of the findings, not only in the scientific but also in the public area. As such, serious games will be more broadly acknowledged as potential evidence-based treatments or as effective next to evidence-based treatments. These serious games may be an easy accessible option for broad groups of vulnerable patients within mental healthcare.

Chapter 8

Dutch summary

(Nederlandse samenvatting)

ACHTERGROND

Aandachtstekortstoornis met hyperactiviteit (ADHD) is één van de meest voorkomende psychiatrische stoornissen en treft wereldwijd drie tot vijf procent van alle kinderen en adolescenten. De kernsymptomen van ADHD bestaan uit hyperactiviteit, impulsiviteit en aandachtstekort. Naast deze symptomen ondervinden kinderen diverse problemen in hun dagelijks functioneren. Zo heeft een groot deel van de kinderen met ADHD moeite met het inschatten van de tijd, afmaken van opdrachten, complexe planning taken uitvoeren, het herinneren van taak-instructies en prioriteiten stellen. Dit worden ook wel executieve functies genoemd. Tevens vertonen kinderen met ADHD beperkingen op het vlak van sociaal functioneren, zoals het initiëren en onderhouden van vriendschappen. Deze problemen in het dagelijks functioneren kunnen tot negatieve langetermijn uitkomsten leiden zoals academisch onderpresteren en moeite met het onderhouden van sociale relaties.

Medicatie en gedragstherapie zijn 'bewezen effectief' in de behandeling van ADHD. Echter, medicatie richt zich met name richt op het verminderen van de kernsymptomen en gedragsinterventies zijn ondanks hun effectiviteit vaak tijdrovend, kostbaar en niet toegankelijk genoeg. Bovendien blijkt dat de helft van de patiënten met ADHD hun behandeling stopzet, ongeacht de ernst van de symptomen en effectiviteit van behandeling. Behandeling dient zich niet alleen te richten op het verminderen van de kernsymptomen van ADHD maar ook op het verbeteren van het dagelijks functioneren. Hiermee kan een escalatie aan problemen tijdens de adolescentie worden voorkomen en kan de impact van ADHD, in termen van kosten en belasting voor patiënten, hun familie en de maatschappij, worden vermindert. Vanwege de beperkingen in het huidige behandelaanbod en lage therapietrouw van patiënten met ADHD zijn er recentelijk meerdere studies verschenen naar de mogelijkheid om eHealth als behandeling in te zetten binnen de kinder- en jeugdpsychiatrie.

eHealth, het gebruik van informatie- en communicatietechnologie ter ondersteuning of verbetering van de gezondheid en gezondheidszorg, heeft een enorme impuls gegeven aan de toegankelijkheid van de gezondheidszorg en het verhogen van de eigen regie van patiënten. Men spreekt over eMental health wanneer men verwijst naar eHealth binnen de geestelijke gezondheidszorg. Binnen deze context wordt serious gaming als een kansrijke en motiverende behandelvorm gezien om executief en sociaal functioneren in kinderen met ADHD te verbeteren. Serious games stellen gebruikers in staat om spelenderwijs kennis en/of vaardigheden aan te leren binnen een aantrekkelijke digitale spelomgeving. Zo laten diverse studies zien dat serious gaming een positieve invloed heeft op gedrag in het dagelijks leven, zoals een gezonde leefstijl en zelfmanagement.

Er zijn recentelijk diverse initiatieven ontwikkeld om executief functioneren bij kinderen met ADHD te verbeteren middels gecomputeriseerde training. Hoewel positieve effecten op het executief functioneren en het door ouder gerapporteerde ADHD gedrag worden aangetoond, wordt door leerkrachten vaak geen verbetering gerapporteerd. Tevens blijkt uit de klinische praktijk dat het lastig is om kinderen met ADHD te motiveren deze training dagelijks uit te voeren omdat dezelfde oefeningen vaak herhaald worden. Dat gaming vooral motiverend lijkt te zijn voor kinderen met ADHD, kan vanuit de motivationele theorieën van ADHD verklaard worden. Kinderen met ADHD vertonen een beperkte motivatie en zijn minder gevoelig voor beloning in vergelijking met kinderen zonder ADHD. Dit betekent dat zij onder dezelfde omstandigheden minder gemotiveerd zijn om op hetzelfde niveau te presteren in vergelijking met hun leeftijdsgenoten. Games zijn zeer stimulerend en geven per definitie onmiddelijke bekrachtiging van gedrag en er is altijd uitzicht op een toekomstige beloning. Uit diverse studies blijkt dan ook dat gaming de motivatie en taakprestatie van kinderen met ADHD verbetert.

Serious gaming biedt kansen om als aanvullende behandeling het executief en sociaal functioneren van kinderen met ADHD te verbeteren. Serious games verschillen op een aantal punten van bestaande gecomputeriseerde trainingen zoals Cogmed en Braingame Brian. Ten eerste wordt er bij serious gaming een innovatieve spelomgeving aangeboden in plaats van een toevoeging van spelelementen aan bestaande taken en/of behandeling. Verder richten serious games zich niet op het herhalen van bestaande neurocognitieve taken maar richten zij zich vooral op het verbeteren van gedragsstrategiëen middels het inzetten van diverse therapeutische elementen (zoals bekrachtiging, onmiddelijke feedback van een mentor, doelen stellen door missies, aanbieden van een rolmodel, en sociale competitie) om het dagelijkse functioneren te verbeteren. Op deze manier wordt geprobeerd om de transfer van de geleerde vaardigheden binnen het spel naar de toepassing in het dagelijks leven te bevorderen.

De centrale doelstelling van dit proefschrift is om de ontwikkeling van de serious game "Plan-It Commander" te beschrijven en te onderzoeken of gedrag in het dagelijks leven (zoals gerapporteerd door ouders en leerkrachten) en executief functioneren (zoals gemeten door neurocognitieve taken) verbeterd met behulp van serious gaming voor kinderen met ADHD in de basisschoolleeftijd. Daarnaast wordt onderzocht of "Plan-It Commander" meer effectief is voor bepaalde subgroepen kinderen. Deze resultaten worden in vijf hoofdstukken beschreven. Hieronder wordt een samenvatting van de belangrijkste bevindingen gepresenteerd, gevolgd door de klinische implicaties.

SAMENVATTING VAN DE BEVINDINGEN

Game ontwikkeling

De ontwikkeling van een serious game als "Plan-It Commander" is een creatief en dynamisch maar complex proces omdat er samenwerking vereist wordt tussen diverse professionals met elk hun eigen expertise en eigen taal. De eerste doelstelling van dit proefschrift is om het ontwerpproces van "Plan-It Commander" te beschrijven. In *Hoofdstuk 2* wordt dit proces beschreven en worden de eerste gebruikerservaringen van kinderen met ADHD en hun ouders gepresenteerd. Leerdoelen op het gebied van tijdmanagement, planning en organisatie en prosociaal gedrag werden vastgesteld door experts binnen de geestelijke gezondheidszorg en door een klankbordgroep van ouders. Dit proces weerspiegelt zowel input vanuit de wetenschappelijke literatuur alsook (klinische) ervaring. Om daadwerkelijk gedragsverandering te kunnen bewerkstelligen, werden de leerdoelen vertaald in game elementen, gebaseerd op relevante psychologische theorieën zoals het Zelfregulatie Model (Cameron & Leventhal, 1995), de Sociaal Cognitieve Theorie (Bandura, 1986) en de Leertheorie (Barkley, 2006; Kato, Cole, Bradlyn, & Pollock, 2008). Verder worden in dit hoofdstuk de game structuur, de drie mini-games, de social community en verdere kenmerken van "Plan-It Commander" in meer detail beschreven. Op basis van de positieve feedback van kinderen en ouders werden suggesties voor het verdere ontwerp van de serious game gedaan. Dit proces wordt eveneens beschreven in *Hoofdstuk 2*.

Pilot studie

In *Hoofdstuk 3* wordt een gecontroleerde en gerandomiseerde pilot studie beschreven waarmee de preliminaire effectiviteit van het eerste prototype op bovengenoemde leerdoelen werd getoetst. De steekproef bestond uit 42 kinderen met ADHD in de leeftijd van acht tot en met twaalf jaar die willekeurig werden toegewezen aan een serious game interventie conditie (n=22) of een semi-actieve controle conditie (n=20). In beide condities werd de serious game als aanvulling op de huidige behandeling aangeboden. De serious game werd voor een periode van acht weken aangeboden, waarbij elke twee weken een nieuwe mini-game (met bijbehorend leerdoel) werd aangeboden en gespeeld. Aan deelnemers uit de serious game interventie conditie werd gevraagd om de serious game elke twee weken acht keer te spelen. Aan deelnemers uit de semi-actieve controle conditie werd gevraagd om de serious game elke twee weken maximaal drie keer te spelen. Uit de resultaten blijkt dat kinderen uit de serious game interventie conditie ongeveer vijf keer per twee weken speelden terwijl kinderen uit de semi-actieve controle conditie het spel gemiddeld twee keer per twee weken speelden.

Een belangrijke bevinding is dat kinderen uit beide condities verbeterden wat betreft ouder gerapporteerde planning en organisatie vaardigheden. Hoewel dit resultaat net niet significant was, lieten kinderen uit de serious game interventie conditie meer verbetering zien wat betreft ouder gerapporteerde tijdmanagement vaardigheden in vergelijking met kinderen uit de semi-actieve controle conditie. Verder werden er correlatie-analyses uitgevoerd waarmee de hypothese wordt getoetst of kinderen die het spel vaker speelden ook meer vooruit zouden gaan wat betreft hun tijdmanagement, planning en organsiatie en prosociale vaardigheden. Er was een significante correlatie tussen speelfrequentie en verbetering in tijdmanagement vaardigheden, hetgeen duidt op de mogelijke aanwezigheid van een 'dosis-respons relatie'. Het feit dat kinderen in beide condities vooruit gingen, laat zien dat zelfs een beperkt aanvullend gebruik van de serious game een positieve impact kan hebben op het aanleren van vaardigheden. Echter, men moet er rekening mee houden dat deze resultaten ook verklaard kunnen worden door herhaaldelijk testen, tijdeffecten of dat niet-specifieke behandeleffecten zoals verwachtingen en aandacht, een rol spelen. Hoewel er geen conclusies over effectiviteit getrokken kunnen worden op basis van de resultaten uit deze pilot studie, gaven deze resultaten voldoende houvast om verder te gaan met de ontwikkeling van de game en het uitvoeren van onderzoek naar de effecten ervan.

Effecten op gedragsuitkomsten

Het tweede doel van dit proefschrift is om de effectiviteit van "Plan-It Commander" op zowel gedrag in het dagelijks leven (zoals gerapporteerd door ouders en leerkrachten) als executief functioneren (zoals gemeten door neurocognitieve taken) aan te tonen. In *Hoofdstuk 4* worden de resultaten van een gerandomiseerd en gecontroleerd onderzoek gepresenteerd. De steekproef bestond uit 170 kinderen met ADHD die werden gerekruteerd vanuit diverse geestelijke gezondheidszorg klinieken en instellingen in Nederland en België. Deelnemers werden willekeurig toegewezen aan een serious game interventie conditie (*n*=88) of een reguliere behandelconditie (*n*=82). Aan deelnemers die werden toegewezen aan de serious game interventie conditie werd gevraagd de serious game de eerste 10 weken naast hun reguliere behandeling te spelen, waarna zij uitsluitend hun reguliere behandeling vervolgden gedurende de laatste 10 weken van het onderzoek. Deelnemers die toegewezen werden aan de reguliere behandelconditie ontvingen hun reguliere behandeling voor ADHD tijdens de eerste 10 weken van het onderzoek en speelden de serious game in de daarop volgende 10 weken in combinatie met hun reguliere behandeling. Vragenlijsten werden ingevuld door ouders, leerkrachten en de kinderen tijdens de voormeting, na 10 weken en na 20 weken.

Uit de resultaten blijkt dat kinderen de missiegestuurde game gemiddeld 19 dagen speelden en dat zij gemiddeld 11 dagen gebruik maakten van de social community. Kinderen die de serious game gedurende de eerste 10 weken speelden, verbeterden in vaardigheden die door ouders (waaronder tijdmanagement, tijdperceptie, planning/organisatie en sociale vaardigheden) alsook door leerkrachten (waaronder tijdmanagement, werkgeheugen en sociale vaardigheden) werden gerapporteerd. Kinderen uit de reguliere behandelconditie lieten op dezelfde uitkomsten vooruitgang zien nadat zij de serious game hadden gespeeld. Echter, kinderen die gedurende de eerste 10 weken de serious game hadden gespeeld lieten meer vooruitgang zien wat betreft hun tijdmanagement, mate van verantwoordelijkheidsgevoel en werkgeheugen in vergelijking met kinderen die op dat moment hun reguliere behandeling voor ADHD ontvingen. Deze positieve effecten hielden stand of verbeterden zelfs gedurende de laatste 10 weken van de studie. De huidige studie biedt eerste aanwijzingen dat "Plan-It Commander" een effectieve aanvullende therapeutische behandeling is om dagelijks functioneren van kinderen met ADHD te verbeteren.

Effecten op neurocognitieve uitkomsten

Op basis van dezelfde steekproef en studieopzet worden in *Hoofdstuk 5* de effecten van "Plan-It Commander" op executief functioneren (zoals gemeten door neurocognitieve taken) onderzocht. Hoewel de serious game interventie zich vooral richt op het verbeteren van gedrag in het dagelijks leven werden een drietal neurocognitieve prestatietaken als secundaire uitkomstmaten van planning, werkgeheugen en sociaal-cognitieve vaardigheden meegenomen. Deze taken werden afgenomen tijdens de voormeting, na 10 weken en na 20 weken. Gedurende de eerste 10 weken lieten kinderen uit de serious game interventie conditie en de reguliere behandelconditie beiden een verbetering zien op de prestatietaken gericht op planning en sociaal-cognitieve vaardigheden. Echter, er waren geen verschillen tussen beide condities tijdens de eerste 10 weken. Dat wil zeggen dat kinderen die de serious game gedurende de eerste 10 weken speelden niet meer verbeterden op de drietal neurocognitieve prestatietaken in vergelijking met kinderen die hun reguliere behandeling voor ADHD ontvingen. Deze resultaten staan in contrast met de effecten die gevonden werden op gedragsvaardigheden. Een meer uitgebreide discussie met betrekking tot mogelijke verklaringen van deze resultaten wordt gepresenteerd in de algemene discussie sectie van *Hoofdstuk 7*.

Wat werkt voor wie?

Tenslotte wordt in *Hoofdstuk 6* met behulp van de innovatieve analysetechniek Virtual Twins eigenschappen van kinderen op de voormeting (namelijk geslacht, leeftijd, IQ, medicatie gebruik, computerervaring, ADHD subtype, ernst van aandachtstekort problemen, ernst van hyperactiviteit/impulsiviteit problemen, comorbide oppositioneel-opstandige gedragsstoornis en comorbide antisociale gedragsstoornis) onderzocht als mogelijke moderatoren van het gevonden behandeleffect op gedragsvaardigheden. De uitkomstmaten betreffen verschilscores in ouder gerapporteerde tijdmanagement, planning/organisatie en prosociale gedragsvaardigheden (de primaire uitkomstmaten van het onderzoek beschreven in *Hoofdstuk 4*). De resultaten van de Virtual Twins analyse laten zien dat de serious game interventie meer effectief was voor planning- en organisatie vaardigheden bij meisjes (n=26) in vergelijking met de totale groep kinderen. Aanvullend bleek dat jongens met een lage score op hyperactiviteit en een hoge score op een comorbide antisociale gedragsstoornis (n=47) meer verbeterden wat betreft hun planning- en organisatie vaardigheden na het spelen van de serious game interventie in vergelijking met de totale groep van kinderen. De implicaties van deze bevindingen worden hieronder gepresenteerd.

KLINISCHE IMPLICATIES

ADHD is een chronische stoornis. Eerder onderzoek toont aan dat het noodzakelijk is om de beperkingen die kinderen ten gevolge van deze stoornis ervaren ook buiten de therapiecontext te behandelen en kinderen gedurende de behandeling van meer autonomie te voorzien. De serious game interventie die in dit proefschrift centraal staat, sluit aan op deze aanbevelingen en richt zich op het verbeteren van het dagelijks functioneren van kinderen met ADHD binnen de school- en thuiscontext. De beschrijving van het ontwerpproces en de gerapporteerde gebruikservaringen van ouders en kinderen bieden een methodologisch voorbeeld van hoe serious game interventies binnen de geestelijke gezondheidszorg ontwikkeld dienen te worden. De in dit proefschrift beschreven werkwijze biedt meer inzicht in de samenwerking tussen betrokken professionals en hoe tussentijds testen kan bijdragen aan weloverwogen design beslissingen. Hiermee kan dit proefschrift nieuwe initiatieven om serious games binnen de kinder- en jeugdpsychiatrie te ontwikkelen stimuleren.

De bevindingen van het huidige proefschrift impliceren dat “Plan-It Commander” een innovatieve en motiverende aanvullende behandeling is om kinderen met ADHD te ondersteunen in hun dagelijks functioneren. Kinderen die de serious game speelden, verbeterden meer wat betreft hun tijdmanagement, verantwoordelijkheid en werkgeheugen vaardigheden in vergelijking met kinderen die hun reguliere behandeling voor ADHD ontvingen. Follow-up metingen, 10 weken nadat kinderen de serious game gespeeld hadden, toonden stabiliteit of zelfs verdere verbetering aan. Omdat er geen controlegroep beschikbaar was voor deze follow-up metingen is het niet mogelijk om conclusies te trekken over langetermijn effecten. Echter, vooralsnog lijken effecten zich niet te beperken tot korte-termijn effecten direct na de interventie.

Uit de pilotstudie (*Hoofdstuk 3*) en de grotere klinische studie (*Hoofdstuk 4 en 5*) blijkt dat kinderen en ouders tevreden zijn met hun behandeling. De interventie effecten en tevredenheid zouden wellicht verbeterd kunnen worden wanneer er meer gerichte feedback op game prestaties door de therapeut plaatsvindt. Hoewel de huidige serious game onafhankelijk van therapeuten geïntroduceerd is, is meer onderzoek nodig naar hoe deze interventievorm in de klinische praktijk geïmplementeerd zou moeten worden teneinde grotere effecten te kunnen bewerkstelligen. De verwachting is namelijk dat therapeuten een rol kunnen spelen in het versterken van de gedragsstrategieën die kinderen in de game leren toepassen. Dit kan vervolgens de generalisatie van de geleerde vaardigheden binnen de game naar het dagelijks leven ondersteunen. Daarom zal er een dashboard ontwikkeld moeten worden zodat het voor therapeuten mogelijk is om de progressie van kinderen te monitoren. Verder onderzoek kan dan uitwijzen of monitoring en feedback door de therapeut van meerwaarde is binnen het huidige game format en de aangetoonde leereffecten kan versterken bij kinderen met ADHD.

In de gerandomiseerde en gecontroleerde studie worden geen effecten gevonden op de neurocognitieve taakprestaties. Dit kan wellicht verklaard worden door de focus van de interventie op het aanleren van gedragsstrategieën, waarbij men compenseert voor onderliggende neurocognitieve beperkingen maar deze niet direct behandeld. De serious game omgeving omvat geen bestaande neurocognitieve taken omdat verbetering op deze taken geen doel op zich was. Binnen de geestelijke gezondheidszorg wordt tegenwoordig gebruik gemaakt van routine outcome monitoring. Hierbij worden vragenlijsten gebruikt om de behandelimpact op het dagelijks functioneren van patiënten aan te tonen. Wanneer "Plan-It Commander" in de klinische praktijk wordt aangeboden dan lijkt impact ook het beste gëevalueerd te worden door middel van ouder- en leerkracht gerapporteerde vragenlijsten in plaats van neurocognitieve uitkomstmaten (*Hoofdstuk 4 en 5*). Voor de klinische praktijk is het belangrijk dat clinici weloverwogen beslissingen maken over hoe zij het beste hun behandeleffecten kunnen evalueren.

Op basis van de resultaten uit *Hoofdstuk 6* blijkt dat bepaalde subgroepen kinderen meer profiteren van de serious game interventie. Het is belangrijk dat clinici zich ervan bewust zijn dat "Plan-It Commander" voor bepaalde subgroepen kinderen effectiever is. Meer onderzoek naar modererende variabelen voor het behandeleffect van "Plan-It Commander" is noodzakelijk en kan clinici ondersteunen in het selecteren van de meest geschikte behandeling voor een individu met ADHD. Hoewel medicatie gebruik geen modererende factor is, kan het zijn dat dit een voorwaarde was voor het behalen van optimale interventie effecten. Medicatie vermindert hyperactiviteit en verbetert aandacht, dat voor een optimale leersituatie zorgt. Verder onderzoek dient deze hypothese te onderzoeken in een steekproef van kinderen die geen medicatie gebruiken. Op deze manier kan bepaald worden of "Plan-It Commander" bij deze subgroep vergelijkbare effecten heeft. Dit zal clinici ook beter in staat stellen om weloverwogen beslissingen te maken bij het toewijzen van serious gaming als interventie voor kinderen met ADHD.

Hoewel we geen mediatoren in dit proefschrift hebben onderzocht, is het belangrijk om bewust te zijn van de werkzame mechanismen die de potentiële effectiviteit van serious game interventies beïnvloeden. Voorbeelden van dergelijke mediatoren zijn aandacht, kennis, zelfregulatie (onder andere doelen stellen, zelf-monitoring, maken van beslissingen), zelfefficiëntie, intrinsieke motivatie, en gevoel van competentie, autonomie en verwantschap. Omdat therapeuten zich richten op gedragsverandering is het belangrijk dat klinische experts met game ontwikkelaars kennis delen en samenwerken om te bepalen op welke klinisch relevante elementen men zich binnen de interventie gaat richten om gedrag te veranderen. Echter, doordat serious games vaak een groot aantal aan mediatoren omvatten die ook nog eens onderdeling gerelateerd zijn, is het moeilijk om de specifieke invloed van separate variabelen op effecten te onderscheiden.

Hoewel er geen serious adverse events binnen deze studie voorkwamen en speeltijd beperkt gehouden werd (*Hoofdstuk 4*), lijkt het belangrijk dat clinici ouders aanmoedigen om de speelfrequentie van hun kind te monitoren en hen te informeren over de risico's en voordelen van gaming in het algemeen. Gamen op jonge leeftijd en impulsiviteit kunnen pathologisch gamen voorspellen en kan vervolgens leiden tot depressie, (sociale) angst en slechtere schoolprestaties. Wetende dat kinderen met ADHD gevoeliger zijn voor verslaving is het belangrijk dat ouders en clinici zich bewust zijn van deze negatieve langetermijn uitkomsten. Tot op heden zijn er nog geen serious adverse events gerapporteerd in serious games omdat zij pedagogische en/of therapeutische principes integreren en positief gedrag consistent belonen. Meer onderzoek is nodig zodat mogelijke serious adverse events kunnen worden uitgesloten.

In dit proefschrift werd de effectiviteit van "Plan-It Commander" onderzocht. Ondanks dat het ontbreken van een placebo gecontroleerde controlegroep ervoor zorgt dat er geen harde conclusies getrokken kunnen worden met betrekking tot effectiviteit, voorziet deze studie in een gedegen eerste stap om aan te tonen dat kinderen op diverse domeinen verbeteren (zoals door ouders en leerkrachten gerapporteerd) en specifieke subgroepen van kinderen een verhoogd behandeleffect laten zien. Clinici moeten zich ervan bewust zijn dat verder onderzoek nodig is om de effectiviteit van deze aanvullende behandeling aan te tonen. Patiënten en ouders dienen hierover geïnformeerd te worden zodra "Plan-It Commander" geïmplementeerd en beschikbaar is.

Voor een meer inhoudelijke discussie, beperkingen van het huidige onderzoek en suggesties voor verder onderzoek verwijs ik u naar *Hoofdstuk 7* van dit proefschrift.

Appendixes

- Time management questionnaire
- Self-efficacy questionnaire

APPENDIX 1. TIME MANAGEMENT QUESTIONNAIRE.

Instructions

Please read the statements below and respond to each one by circling the number (from 1 to 10) which best describes your child during the past two weeks.

		False 1	2	3	4	5	6	7	8	9	True 10
1	My child is able to finish a task within a pre-defined time frame.	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
2	My child can figure out how much time is needed to finish a task before the dead-line.	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
3	My child is able to perform the morning routine by himself/herself within a certain time frame.	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
4	My child is able to independently perform daily activities within a reasonable time frame.	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
5	My child is able to adjust his/her homework planning on the basis of other activities (for example: starting earlier to anticipate going to sport or music class that evening)	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
6	My child is able to start his/her long-term projects on time thereby minimizing the chance of time pressure.	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
7	My child often finishes his/her homework before going to bed.	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
8	My child makes good decisions about setting priorities when time is restricted (for example: going home immediately after school to finish a long-term assignment instead of playing with friends).	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
9	My child is able to work on a long-term project over several days.	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
10	My child bungles his/her task at the last moment.	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
11	My child regularly checks his/her watch to keep track of the time.	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍

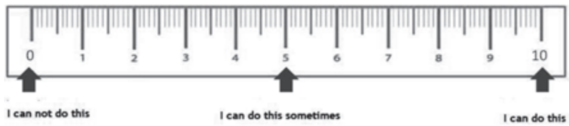
APPENDIX 2. SELF-EFFICACY QUESTIONNAIRE.

Instructions

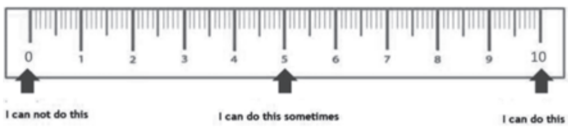
Fill in the example first, so as to know how to answer the real questions below.

Example

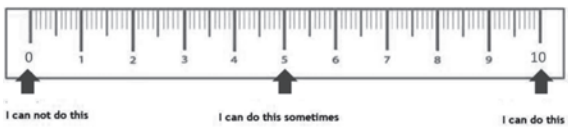
If you were asked to lift up several materials with a certain weight, how certain are you that you can lift up the following items? Indicate how certain you are by choosing a number from 0 to 10 on the scale below.



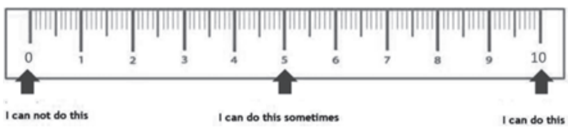
I can lift up a sugar pack



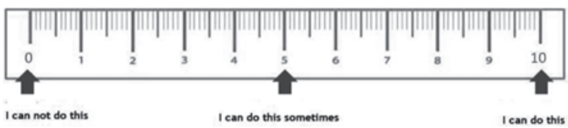
I can lift up a packed suitcase



I can lift up a table



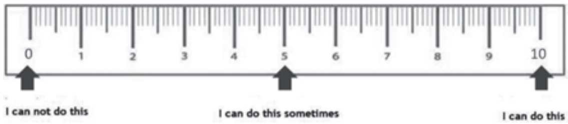
I can lift up a car



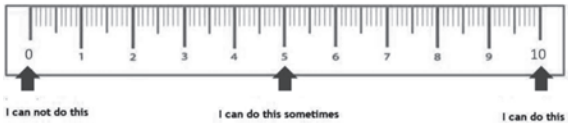
Instructions

We designed this questionnaire to gain a better understanding about the things children have difficulties with. Indicate below how certain you are that you can do these things by choosing a number from 0 to 10.

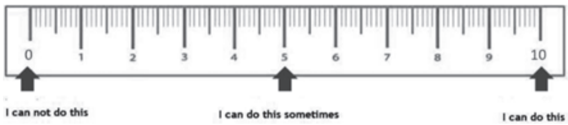
1. I am confident that I can listen to instructions while I am in a hurry.



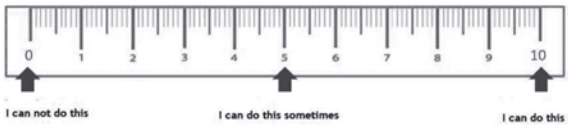
2. I am confident that I can plan my tasks within a certain time frame.



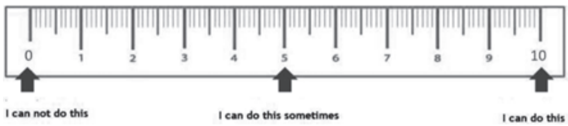
3. I am confident that I can help a friend or classmate, even when I have things to do.



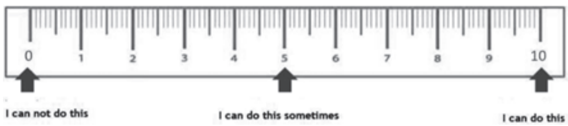
4. I am confident that I can keep track of time by looking at a clock or watch, so that I get things done on time.



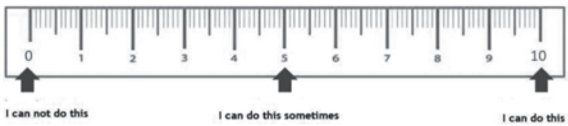
5. I am confident that I can listen to instructions people give me without interrupting them.



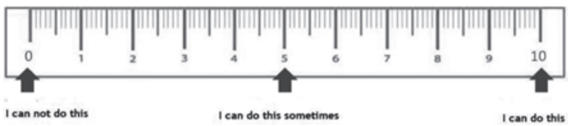
6. I am confident that I can get things done in the amount of time I planned to get them done.



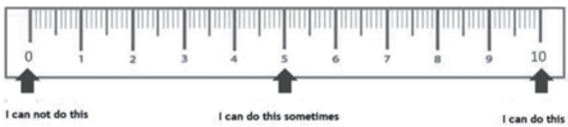
7. I am confident that I can stay focused so that I get things done in the amount of time I planned.



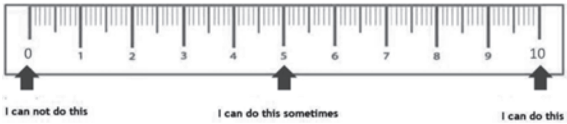
8. I am confident that I can do my tasks within the time I planned.



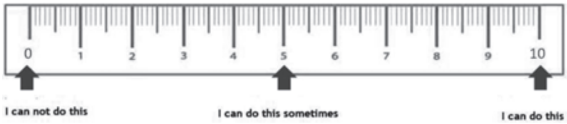
9. I am confident that I can keep trying to make a plan that works even if I fail the first time.



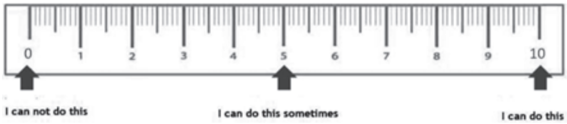
10. I am confident that I can practice to get better at finishing my tasks on time.



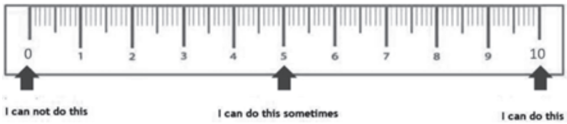
11. I am confident that I can stay calm and keep trying to succeed even when my plan doesn't work.



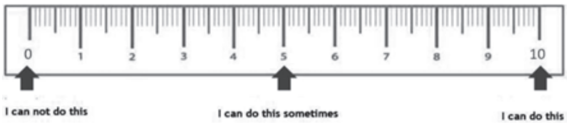
12. I am confident that I can get things I need to get done without getting distracted or bored.



13. I am confident that I can learn new ways to finish my tasks on time.



14. I am confident that I can keep trying to make good plans even if my plans don't work out.



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Curriculum vitae

CURRICULUM VITAE

Kim Bul was born on 11th of June 1986 in Oosterhout, the Netherlands. After finishing her clinical and international research master at Utrecht University, she started to work as a researcher at the Yulius Academy in Rotterdam. She joined her colleagues at the neuropsychiatric research program, with a specific focus on ADHD research. Since 2011, her research focused on the development and testing of a serious game for children with ADHD. Parallel to this research focus, she worked as a researcher for the Dutch Knowledge Centre for Child- and Adolescent Psychiatry where she was responsible for making an overview of the available and scientifically grounded eHealth tools within child- and adolescent psychiatry. She worked as a project coordinator at the Research Centre Innovations in Care at the University of Applied Sciences in Rotterdam in which she was managing a project focusing on developing and testing a serious game for children with autism to support them in their transition from primary to secondary school. In this context, she also tried to integrate research results into the curricula of students. She is involved as a reviewer for the *Games for Health Journal* and *Journal of Medical Internet Research*. She joined Professor Pamela Kato's team at Coventry University to contribute to evidence-based knowledge for serious gaming within (mental) healthcare.

List of publications

LIST OF PUBLICATIONS

Journal articles

Bul, K. C. M., Kato, P. M., Van der Oord, S., Danckaerts, M., Vreeke, L. J., Willems, A.,…Maras, A. (2016). Behavioral outcome effects of serious gaming as an adjunct to treatment for children with Attention Deficit Hyperactivity Disorder: A Randomized Controlled Trial. *Journal of Medical Internet Research*, *18*, 1-18.

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Presentations

Presentation "It's all in the game: Training of executive functioning through serious gaming" at National Special Educational Needs conference, Ede, September 2015.

Presentation "Healseeker project: Development & testing of a new serious game for children with ADHD" at ESCAP conference, Dublin, July 2013.

Presentation "Healseeker: A prototype serious game for children with ADHD" at ADHD symposium, Antwerp, November 2012.

Presentation "New trends in ADHD treatment: Healseeker ADHD game – What's in it for the pediatrician?" at NVK conference, Veldhoven, November 2012.

Poster presentations

Poster presentation "HealSeeker project: The effectiveness of a newly developed serious game for children with ADHD in an open randomized controlled multicenter trial" at 23rd Eunethydis network meeting, Prague, October 2013.

Poster presentation "HealSeeker: An innovative and playful learning environment focused on promoting self-management and empowerment of children with ADHD" at Eunethydis conference, Barcelona, May 2012.

Poster presentation "ADHD as a risk factor for obesity: Search for possible mechanisms" at Eunethydis conference, Barcelona, May 2012.

Poster presentation "Research into the prototype of HealSeeker, a Serious Game for children with ADHD" at NVvP spring conference, Maastricht, April 2012.

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Cheers, Kim