Serious Gaming for children with Attention deficit/Hyperactivity disorder (ADHD): A pilot study

Published: 02-10-2011
Last updated: 30-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Developmental disorders NEC
Study type	Interventional

Summary

ID

NL-OMON35573

Source
ToetsingOnline

Brief title
Serious Gaming & ADHD

Condition

- Developmental disorders NEC

Synonym
Attention hyperactivity deficit disorder (ADHD)

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Yulius
Source(s) of monetary or material Support: Janssen-Cilag

Intervention

Keyword: Attention Deficit Hyperactivity Disorder (ADHD), Children, Pilotstudy, Serious Game

Outcome measures

Primary outcome

The main outcome variables in this research are: background characteristics of

the child, behavioral characteristics and planning skills, time management,

frustration tolerance, social and risk behavior.

Secondary outcome

Secondary outcome variables are parental expectations of the prototype Serious

Game, (signs of) resistence and the satisfaction of parents and child after the

intervention.

Study description

Background summary

Psycho stimulants are recognized as most effective treatment to reduce the core symptoms of ADHD. Reducing the core symptoms of ADHD offers the possibility to stimulate and teach new behavior. Additional interventions appear to be particularly valuable for this purpose. It is therefore important that a multimodal treatment also aims to reduce associated and co morbid problems, next to reducing the core symptoms of ADHD. It appears that these problems strongly predict the prognosis of ADHD and largely impact the daily functioning of the ADHD child and his/her family. Next it is important to improve the self management of children with ADHD. This means that children understand that making certain choices influences a certain situation and they learn to trust their own capacities to achieve goals and, as a consequence, develop a positive identity (empowerment). Serious Gaming can possibly contribute to this process and increase self management and treatment compliance of children with ADHD.

Study objective

The purpose of this study is to evaluate the preliminary effects of the prototype Serious Game on children with ADHD, in preparation of a randomized controlled trial (RCT). The goal of the intervention is to improve skills as: planning, time management, frustration tolerance, social functioning and decrease risk behavior. Furthermore the effect of the intervention on children*s self efficiency and behaviour is examined. A secondary goal of this study is to examine the usabilty and whether the research design is applicable on a larger research population.

Study design

The design of this pilot study is a randomized pre-post test design. Children play the prototype of Serious Game during two months. Children are randomly allocated to one of the two conditions: (1) children playing the prototype Serious Game for a minimum of eight times per two weeks; (2) children playing the prototype Serious Game for a maximum of three times per two weeks. This last group of children functions as a control group in this study. A first measurement is conducted before starting the intervention, a second measurement takes place after two months.

Intervention

The intervention in this research is a prototype Serious game, which is developed for children with ADHD. The theme of this innovative and interactive game environment is *Sience Fiction*. The prototype is web-based and therefore can be played at the child*s home for two months. The prototype includes three mini games. Each minigame has to be played for two weeks and are offered seperately. After six weeks there is an open phase (two weeks) where the children can play their favorite mini game. The mini games are accessible for a maximum of 45 minutes per play session.

Study burden and risks

The extent of the burden and risks associated with participation in this pilot study is limited. Children and parents have to invest time in filling out the questionnaires. It takes children approximately 55 minutes to fill out the questionnaires. For parent this takes approximately 45 minutes. The prototype Serious Game is played for two months at the child*s home. A child who plays the prototype Serious Game for a minimum of eight times per two weeks, spends at least 1440 minutes (= 24 hours) on the game. A child who plays the prototype Serious Game for a maximum of three times per two weeks, spends a maximum of 540 minutes (=9 hours) on the game. This intervention can be played at the child*s home and therefore parents do not have to travel, which limits the extent of burden. Children diagnosed with ADHD are usually very motivated to play a computer game. The parents are not expected to be involved in this activity. There are no (medical) risks related to the intervention and side

effects are not expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1. Aged 8-11 years
2. Total IQ above 70
3. Signed informed consent by the parents and the child
4. Sufficient understanding of the Dutch language by parents and child
5. The child has a current ADHD diagnosis that is diagnosed by a child psychiatrist, GZ-psychologist, clinical psychologist or a pediatrician (specialized in social pediatrics). Children with ADHD and co morbid disorders (as Dyslexia or Oppositional Defiant Disorder) are also allowed to participate in this pilot study.
6. Children must be at a stable dose of medication and/or receive other forms of psychological treatment (e.g. behavior therapy) for their ADHD for at least two months. They

are supposed to continue their treatment during the 2 months of the pilot study. All kinds of medication for ADHD are allowed in this research.
7. Acces to a PC with a sound system and internet acces.

Exclusion criteria

As severe physical or cognitive impairments (as blindness, deafness, motor or mental handicap) may interfere with filling out standardized measures and playing the prototype Serious Game, children with these impairments are not able to participate in this research.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-10-2011
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-10-2011
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL37983.097.11