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The effectiveness of a serious game for children with attention deficit hyperactivity disorder

Submission date
05/12/2013

Recruitment status
No longer recruiting

Registration date
23/12/2013

Overall study status
Completed

Last Edited
18/02/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
An educational computer game (so called serious game) can possibly contribute to optimizing daily functioning of children with attention deficit hyperactivity disorder (ADHD). The main objective of this study is to examine the effectiveness of an online serious game for improving time management, planning and organisation and social behaviour skills of children with ADHD.

Who can participate?
Children with ADHD (all subtypes) randomly selected among registered mental health care institutions, private psychology practices and paediatric practices across The Netherlands and Belgium.

What does the study involve?
Children are randomized to one of two groups:
1. An immediate treatment group (the game is available from week 0 to week 10)
2. A delayed treatment group (the game is available from week 10 to week 20)
This study involves an online serious game that is offered as an additional intervention to treatment as usual. Children are encouraged to play the game three times a week for one hour. Assessments were carried out at baseline and at 10 and 20 weeks.

What are the possible benefits and risks of participating?
This study provides children with ADHD the opportunity to join a non-medical intervention to improve time management, planning and organising and social behaviour skills. The game is available in the home context as it is offered online. Risks of participation in this study are limited as children play the game within a restricted time frame. Possible side effects are the side effects that can be expected from using a computer (like Repetitive Strain Injury; RSI). Side effects of the game itself are not expected.

Where is the study run from?
This study has been set up by Stichting Yulius, Erasmus University Rotterdam and Catholic University of Leuven and conducted in collaboration with Mondriaan Care Group, Netherlands.

When is the study starting and how long is it expected to run for?
January 2013 to August 2013

Who is funding the study?
Janssen-Cilag (Netherlands) and Flanders' Care (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CONCERTAATT4110

Study information

Scientific Title
The effectiveness of a serious game for children with attention deficit hyperactivity disorder: an open, randomized, controlled, multicenter trial

Study objectives
Does the serious game improve skills in the area of time management, planning and organisation and social behaviour skills of children with attention deficit hyperactivity disorder (ADHD) from 8 to 12 years of age? The expectation is that playing the serious game will lead to significant improvements in skills in the areas of time management, planning and organisation and social behaviour skills compared to a control group condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Medisch Ethische Toetsings Commissie Erasmus MC, 31/01/2013, ethics board reference number: MEC-2012-539, general reference number: NL40860.078.12
2. Commissie Medische Ethiek Universitaire Ziekenhuizen KU Leuven, 17/01/2013, ethics board reference number: S54837 - ML8901

Study design
20-week immediate versus delayed intervention open-label randomised controlled multicenter trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Attention deficit hyperactivity disorder (ADHD)

Interventions
The intervention in this study is a serious game called HealSeeker. HealSeeker is an online computer game with a futuristic and adventurous character. This game is offered as an additional intervention to treatment as usual.

Children are randomized to one of the following two groups:
1. An immediate treatment group (in which the game is available from week 0 to week 10)
2. A delayed treatment group (in which the game is available from week 10 to week 20)

In the first 10 weeks, children from the immediate treatment group will be asked to play the game, continuing their treatment as usual. The results from this group will be compared to the other group following treatment as usual. After 10 weeks, the game will be available for the delayed treatment group. Several missions and three minigames are embedded in the game. These minigames are related to three learning goals: time management, planning and organisation and social behaviour. A closed social community is included in which children can communicate with each other and ask each other for help through predefined messages. The game is web-based and the children can play this game at home during the study period.

Children will be encouraged to play three times a week and each playing session will last a maximum of 45 minutes. Children can access the social community for a maximum of 20 minutes per session.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Time management, measured using a self-constructed questionnaire
2. Planning and organisation, measured using the subscale Plan/Organize from the Behaviour Rating Inventory of Executive Function (BRIEF)
3. Social behaviour skills, measured using the subscale Cooperation from the Social Skills Rating System (SSRS)

During the study period of 20 weeks, these outcomes will be measured at baseline and after 10 and 20 weeks.

Secondary outcome measures
1. Working memory
2. Self-efficacy

These outcome measures will be evaluated at baseline and after 10 and 20 weeks by different questionnaires filled out by parents, teachers and by tasks and a short questionnaire for the child. Socio-demographic information will be available through a parent-reported questionnaire at baseline.

Overall study start date
28/01/2013

Completion date
15/08/2013

Eligibility

Key inclusion criteria
1. All children included in the study will be from 8 to 12 years of age.
2. All children must have an official Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV ADHD diagnosis (all subtypes). The diagnosis must have been previously set by a child and adolescent psychiatrist, healthcare psychologist, clinical psychologist or paediatrician specialised in social paediatrics. Children with common diagnosed comorbid disorders (i.e., dyslexia, oppositional defiant disorder) can participate in the study.
3. All participants need to be stable on ADHD treatment, both pharmacological and psychological, for at least two months prior to start of the intervention. All types of treatments, both pharmacological and psychological, are accepted. Stable treatment can also include no pharmacological and psychological treatment. Whether subject receives stable ADHD treatment will be collected through self-constructed questionnaire filled out by patents/legal guardians.
4. Minimum total intelligence quotient (TIQ) score must greater than or equal to 80. If the total intelligence score is not known, has been established by a non-COTAN approved test or has been

performed more than two years previous to the start of the intervention, total intelligence score will be established using two subtests of the Wechsler Intelligence Scale for Children third version (WISC-III-NL; Wechsler, 2005).
5. Children can only be included after a written informed consent has been signed by both parents or legal guardians, indicating that they understand the purpose of and procedures required for the study and are willing to participate in the study. Twelve year olds must give their own written informed assent in addition to their parents/legal guardians.
6. The child and at least one of the parents/legal guardians must have a reasonable understanding of the Dutch language in order to understand the messages in the game, and have clear communication with the investigators.

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
170

Key exclusion criteria
1. Children with a severe physical (i.e., developmental coordination disorder), auditory (i.e., deafness), visual (i.e., blindness), neurological (i.e., epilepsy), speech and language (i.e., expressive receptive language disorder) or cognitive (i.e., mental handicap) disability will encounter great difficulties in playing the game, as will children with severe dyslexia (if they are not able to read texts), and are problematic for standardised measurements.
2. Furthermore, children who are addicted to drugs, alcohol and/or gaming, have conduct disorder (CD) or have severe acute psychiatric disorders, psychotic disorder, major depressive disorder and mania will be excluded.
3. Children with an autism spectrum disorder and pervasive developmental disorder not otherwise specified.
4. Children that have previous played the serious game.

Date of first enrolment
28/01/2013

Date of final enrolment
15/08/2013

Locations

Countries of recruitment
Belgium

Netherlands

Study participating centre
Mathenesserlaan 202
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3014 HH

Sponsor information

Organisation
Janssen-Cilag (Netherlands)

Sponsor details
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5026 RH

Sponsor type
Industry

Website
http://www.janssen.com/

ROR
https://ror.org/04cxegr21

Funder(s)

Funder type
Industry

Funder Name
Janssen-Cilag (Netherlands), ref: CONCERTAATT4110

Funder Name

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/02/2016		Yes	No