The effect of the video game *Mindlight* on anxiety symptoms in children with an Autism Spectrum Disorder.

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The primary objective is investigating the effectiveness of *Mindlight* in treating (sub)clinical symptoms of anxiety in children who are diagnosed with an autism spectrum disorder. The secondary objective is to examine the factors that moderate and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON41055

Source
ToetsingOnline

Brief title
Effect of *Mindlight* on anxiety of children with ASD.

Condition

- Anxiety disorders and symptoms

Synonym
anxiety complaints, anxiety symptoms

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Oost Brabant (Rosmalen)
Source(s) of monetary or material Support: ZonMw subsidie voor academische werkplaats aan de Radboud Universiteit.,GGZ Oost Brabant (Olim foundation).

Intervention

Keyword: Anxiety, Autism, Serious games, Treatment

Outcome measures

Primary outcome

- Anxiety

Secondary outcome

- Anxiety assessed by parents

- Presence of anxiety disorder(s)

- Depression

- Depression assessed by parents

- Social functioning assessed by parents and teachers

- Internalizing and externalizing problem behavior assessed by parents and

teachers

Study description

Background summary

Anxiety disorders are among the most prevalent mental health disorders in children, with prevalence rates 3% to 17%. It is the most frequently diagnosed mental disorder in youth and the earliest to emerge among all forms of psychopathology . Furthermore, there are many more children suffering with high levels of anxiety symptoms, but without significant functional impairment they do not receive a diagnosis .

In the clinical setting, a large proportion of children with an autism spectrum disorder (ASD) experience anxiety problems. It has been shown that between 11% and 84% of children with ASD experience some degree of impairing anxiety. More specifically, research has shown that 21% of the children with ASD suffer from subclinical anxiety and that approximately 40% of the children with ASD meet the criteria of at least one anxiety disorder. Some of the most frequently reported anxiety disorders and symptoms seen in children with ASD are simple

phobias, generalized anxiety disorder, separation anxiety disorder, obsessive-compulsive disorder and social phobia. Moreover, it has been shown that anxiety is an underlying factor of several symptoms of ASD. For example, anxiety has shown to underlie or affect the stereotype or rigid behavior, the oppositional and aggressive behavior, the depressive symptoms and the problems in social functioning that children with ASD often show. Furthermore, it has been reported that anxiety in children with ASD has a negative impact on adaptive functioning, daily living skills and relationships with peers, teachers and family.

The above mentioned information shows that it is important that anxiety in children with ASD is treated and prevented from further escalation. Research has already shown that the traditional form of cognitive behavioral therapy (CBT), which is the most frequently used treatment for children with anxiety problems, is not suitable for children with ASD. This because participating in traditional CBT-interventions requires the ability to talk about and reflect on thoughts and feelings, which children with ASD often lack. Therefore, there is an urgent need for effective modifications of the traditional CBT or alternative interventions focused on treating anxiety in autistic children.

Recently, it has been shown that video games have the potential to enhance mental health and well-being in children and adolescents. From this perspective, the video game Mindlight has recently been developed by a multidisciplinary team of psychologists, clinicians and game designers. This game is aimed at reducing anxiety complaints of children. Because Mindlight is a non-verbal intervention that does not require active introspection, it could possibly be a good alternative anxiety treatment for children with ASD. Therefore, the present study will investigate the effect of Mindlight on (sub)clinical anxiety symptoms in children that are diagnosed with ASD.

Study objective

The primary objective is investigating the effectiveness of *Mindlight* in treating (sub)clinical symptoms of anxiety in children who are diagnosed with an autism spectrum disorder. The secondary objective is to examine the factors that moderate and mediate intervention outcomes.

Study design

The present study is a randomized controlled trial with two conditions (intervention versus control). This design will be used to investigate the effectiveness of the intervention game Mindlight.

Intervention

The intervention that is investigated is called *Mindlight*. This is a video

game aimed at children in the age of 8 - 16 years old and is based on principles of evidence-based interventions for anxiety-disordered children. First of all, it uses exposure techniques, one of the most empirically-validated treatment components of CBT for anxious individuals. During exposure, individuals are gradually exposed to the threatening cues. In this way, they are getting habituated to these cues and eventually they are getting more comfortable and less anxious when being exposed to them. Moreover, Mindlight uses neurofeedback mechanisms of change, which are based on several lines of research that have identified evidence-based strategies for decreasing anxiety. These mechanisms are (a) disattending to threatening cues and shifting attention away from those cues, (b) focusing on positive aspects of the environment in the service of relevant goals, and (c) regulating arousal levels associated with anxiety through relaxation and mindfulness. Altogether, Mindlight is based on solid grounds of past research finding, which increases the potential of Mindlight to serve as an effective new intervention for children with ASD and comorbid (sub)clinical anxiety symptoms.

When children and parents agree with participation after the screening, children will be randomly allocated to the experimental or control condition. Children in the experimental condition will play Mindlight for one hour during 6 consecutive weeks at the recruitment location. The researcher will remain present but children will play the game on their own. When children already receive or start with a treatment at for example a mental health institute, they could continue this parallel with Mindlight. Moreover, children, parents and teachers will fill in questionnaires before, after and at 3-months follow-up to evaluate the game. Children in the control condition will play another game ('Max and the Magic Marker') for one hour during 6 consecutive weeks at the recruitment location, parallel with TAU (if applicable). Moreover, children, parents and teachers in the control group will also fill in questionnaires to evaluate the game on the same time points as the children in the experimental group. Moreover, they will have the opportunity to play the game after the 3-months follow-up. Finally, parents will undergo a semi-structured interview (ADIS-P) to examine the presence of anxiety disorders among the participating children and to evaluate the effect of Mindlight on these diagnoses.

Study burden and risks

The potential value of the study is that we can offer 8-16 year old children with ASD and comorbid (sub)clinical anxiety an intervention that is proven to be effective in treating their anxiety symptoms. In order to achieve this goal we need to evaluate the effectiveness of this intervention in this specific population (8-16 years old, diagnosed with ASD and anxiety symptoms). However, we are of opinion that the risks associated with participation are minimal. Mindlight is based on solid grounds of past research findings on evidence-based treatments of anxiety (e.g. exposure therapy). In this way, the risks associated with participation can be considered negligible. The burden of

the study for both children and parents consists of filling in questionnaires and participating in a clinical interview. To determine whether the intervention contributes to reducing anxiety, we have to determine whether the program has a significant effect on the anxiety complaints of the participating children. The possible risks and burdens for the participants might lead to a new evidence-based anxiety intervention for children with autism.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Age between 8-16 years old.
- Diagnosis of an Autism spectrum disorder (DSM IV; Autism, Asperger, PDD-NOS).
- Score on total scale and/or one or more subscales of SCAS-C and/or SCAS-P > M + 1 SD.

- Sufficient knowledge of the Dutch language.

Exclusion criteria

- Absence of parental permission.
- Presence of prominent suicidal ideation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-05-2015
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	12-01-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-09-2015
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-01-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-05-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20864
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50023.091.14
Other	Wordt aangemeld bij NTR.
OMON	NL-OMON20864