A randomized controlled trial testing the effect of the video game ‘Mindlight’ on anxiety symptoms in children with an Autism Spectrum Disorder.

Published: 18-03-2015
Last updated: 13-01-2025

In the present study, it will be investigated whether the game Mindlight is effective in decreasing anxiety symptoms of a Dutch clinical sample of children with an autism spectrum disorder in the age of 8-16 years old. The study is a randomized...

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20864

Source
NTR

Brief title
-

Health condition

- Anxiety symptoms, Autism spectrum disorders - Angstsymptomen, Autisme spectrum stoornissen

Sponsors and support

Primary sponsor: GGZ Oost Brabant.
Source(s) of monetary or material Support: 1. Commissie Onderzoek & Innovatie GGZ Oost Brabant.
2. Behavioral Science Institute of the Radboud University in Nijmegen.

Intervention

Outcome measures

Primary outcome

Anxiety: Spence Children's Anxiety Scale (SCAS)

Secondary outcome

1. Anxiety of the child according to the parents: Spence Child Anxiety Scale for Parents (SCAS-P).
2. The presence of anxiety disorders according to the parents: Anxiety Disorders Interview Schedule for DSM-IV, Parent version (ADIS-P).
3. Depressive symptoms: Child Depression Inventory 2 (CDI 2).
4. Depression according to the parents: Child Depression Inventory 2 for parents (CDI 2:P).
5. Social functioning according to the parents and teacher: Vragenlijst voor Inventarisatie van Sociaal gedrag van Kinderen (VISK).
6. Internalizing and externalizing behaviour problems according to the parents and teacher: Strengths and Difficulties Questionnaire (SDQ).
7. Treatment expectancies according to child and parents will: Parent Expectancies for Therapy Scale (PETS).

Study description

Background summary

In this randomized controlled trial it will be investigated whether the intervention game 'Mindlight' is effective in reducing anxiety symptoms among 8-16 year-old children with an autism spectrum disorder. Participating children will be randomly assigned to the experimental and control condition. Children in the experimental condition will play Mindlight for one hour per week during six weeks. Children in the control condition will play a control game for one hour per week during six weeks. Assessments of primary and secondary outcomes will be conducted at baseline, at post-intervention and at 3-months follow-up.

Study objective

In the present study, it will be investigated whether the game Mindlight is effective in decreasing anxiety symptoms of a Dutch clinical sample of children with an autism spectrum disorder in the age of 8-16 years old. The study is a randomized controlled trial with two conditions (experimental and control group). It is expected that the children who play Mindlight (experimental group) will show lower levels of anxiety symptoms at follow-up, compared to the children in the control group.

Study design

1. Before the first session (baseline)
2. After the last session (post-intervention)
3. Three months after the last session (3-months follow-up)

Intervention

The children with an autism spectrum disorder and with comorbid elevated anxiety symptoms are randomly assigned to the experimental or control condition. The children in the experimental condition will play Mindlight for one hour per week during six weeks. The children in the control condition will play a control game for one hour per week during six weeks. Moreover, both children in the experimental and control condition will fill in questionnaires before the first gaming session, after the last gaming session and at 3-months follow-up. Parents and teachers will also fill in questionnaires on the same time points. Anxiety symptoms will be the primary outcome. Finally, parents will undergo a semi-structured interview (ADIS-P) before the first gaming session and at 3-months follow-up to assess whether Mindlight has an effect on the presence of clinical anxiety disorders in the participating children.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 8-16 years old.
2. Diagnosis of an Autism spectrum disorder (DSM IV; Autism, Asperger, PDD-NOS).
3. Subclinical score on total scale and/or one or more subscales on SCAS-C and/or SCAS-P.
4. Sufficient knowledge of the Dutch language.

Exclusion criteria

1. Absence of parental permission.
2. Presence of prominent suicidal ideation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2015
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion
Date: 18-03-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41055
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4729
NTR-old	NTR5069
CCMO	NL50023.091.14
OMON	NL-OMON41055

Study results

Summary results
N/A