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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20864

Bron
Nationaal Trial Register

Verkorte titel
-

Aandoening

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

Ondersteuning

Primaire sponsor: GGZ Oost Brabant.
Overige ondersteuning: 1. Commissie Onderzoek & Innovatie GGZ Oost Brabant.
2. Behavioral Science Institute of the Radboud University in Nijmegen.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Anxiety: Spence Children’s Anxiety Scale (SCAS)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Before the first session (baseline)

2. After the last session (post-intervention)

3. Three months after the last session (3-months follow-up)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Absence of parental permission.

2. Presence of prominent suicidal ideation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-03-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41055
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A