A randomized controlled trial using a video game to reduce anxiety in children.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26083

Source
NTR

Health condition

Anxiety, Prevention, Children, Neurofeedback, Attentional Bias.

Sponsors and support

Primary sponsor: Radboud University Nijmegen
Source(s) of monetary or material Support: NWO Grant, Radboud University Nijmegen Behavioural Science Institute

Intervention

Outcome measures

Primary outcome

- Child scores on the Spence Children's Anxiety Scale (SCAS-C)
- Parent scores on the Spence Children's Anxiety Scale (SCAS-P)

Secondary outcome

- Attentional bias (reaction times on dot-probe and visual search task)
- Coping questionnaire for the child (CQ C)

- Self-efficacy questionnaire for the child (SEQ-C)
- Strengths and difficulties questionnaire for the child (SDQ)
- Strength and difficulties questionnaire according to parent (SDQP)
- Anxiety, depression and stress scale for parents (DASS-21)

Study description

Background summary

In this randomized controlled trial (RCT with 2 conditions, intervention and control group) the effectiveness of an anxiety-reducing training in the form of a video game (Mindlight) will be examined. Children (ages 8-12) with elevated levels of anxiety are randomly assigned to play a video game (either Mindlight or Max and the Magic Marker) 6 times for one hour after school. The aims are to evaluate the effectiveness and gain insight into the underlying mechanisms. Measurements of primary and secondary outcomes will be conducted in the intervention directly before and after the training and at 3 months follow up.

Study objective

This study will use a Randomized Controlled Trial (RCT) to evaluate the effectiveness and underlying mechanisms of the video game Mindlight, a newly developed anxiety-reducing training for children. Mindlight and a control game will be played for several sessions by Dutch primary school children (8–12 years old) with elevated levels of anxiety. It is hypothesized that children playing Mindlight will experience reduced levels of anxiety in comparison with the control group. Attentional bias will be examined as mediator of this effect, and children’s coping abilities and anxiety and stress level of parents will be included as moderators.

Study design

- Screening using SCAS-C
- Pre-test using all primary & secondary instruments (1 week before start intervention)
- Post-test using all primary & secondary instruments except demographics (1 week after training)
- Follow-up using all primary & secondary instruments (3 months after post-test).

Intervention

Children will be randomly assigned in either the experimental or the control condition. Both conditions start with a pre-test where anxiety is measured via questionnaires and attentional bias via the dot-probe task and the visual search task. The parents will also fill out questionnaires this week.
The next weeks, the groups will play a video game for 50 minutes. The experimental condition plays Mindlight, while the control condition plays Max and the Magic Marker. This

will be done for 3 weeks, 2 times a week at the school (after class).
After this training, the children will complete the same questionnaires and attentional bias measuring instruments as used in the pre-test. The parents will also receive questionnaires. 3 months later, a follow up test will use the same measurements again.

Contacts

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Eligibility criteria

Inclusion criteria

Primary school children in grades 5 till 8 (8-12 years old) will be screened using the Spence Children's Anxiety Scale. Passive consent from parents is required for participating in the screening. All children scoring > 1 SD above the mean on at least two subscales (except for the OCD subscale) or on total score of the SCAS will be contacted to join the training. Active consent from the parents is required to participate in the training.

Exclusion criteria

Parents declining participation of their child in either the first (passive) or second (active) consent opportunity or children scoring < 1 SD above the mean on subscales (except for the OCD subscale) or on total score of the SCAS.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-02-2014
Enrollment:	140
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4213
NTR-old	NTR4366
Other	n/a : n/a

Study results

Summary results
N/A