Web-based attention bias modification treatment for childhood anxiety disorders: a randomized, double-blind, controlled trial

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Specific AimsAs reviewed above, childhood anxiety disorders are highly prevalent and debilitating, and there is an urgent need for improvement of current treatment strategies. An innovative, but scarcely examined, treatment option for childhood…

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

Summary

ID

NL-OMON43641

Source
ToetsingOnline

Brief title
Attention bias modification treatment for childhood anxiety

Condition

- Anxiety disorders and symptoms

Synonym
Childhood anxiety disorders, high level of anxiety in children

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: subsidie van de Sophia Stichting voor Wetenschappelijk Onderzoek en een subsidie van de Coolsingel Stichting

Intervention

Keyword: Attention bias modification treatment, Childhood anxiety disorders, Cognitive Behavioral therapy, Internet

Outcome measures

Primary outcome

Diagnostic anxiety disorder status (Diagnostic Interview, T1,2,3,4)

Secondary outcome

Anxiety symptoms (anxiety questionnaire; T1,2,3,4)

Internalising problems (anxiety and depression; T1,2,3,4)

Depression symptoms (T1,2,3, 4)

Quality of Life (T1, 2,3, 4)

Attention bias (T1, 2,3, 4)

Interpretation bias (T1, 2,3, 4)

Parental psychopathology (T1)

Parental anxiety and depression (T1, 2,3, 4)

Parental attention bias (T1, 2,3, 4)

Parenting style (T1, 2,3, 4)

Life events (T1, 2, 3, 4)

Socio-economic Status (T1)

Medical Consumption (T1, 2, 3, 4)

Study description

Background summary

Anxiety disorders are the most prevalent psychiatric disorders, occurring in among 15% to 20% of children. Cognitive behavioral therapy (CBT) is currently the first-choice treatment for anxiety-disordered children. Despite proven efficacy, almost half of them do not respond, causing prolonged suffering. Children with persistent anxiety have an increased risk for other psychiatric disorders, school dropout, social isolation, alcoholism, and suicide attempts. Another concern is that only a small proportion of anxiety-disordered children actually receive treatment. These negative consequences in combination with the limited accessibility of treatment endorse the urgent need to develop more effective and accessible treatments that can enhance effectiveness of current treatment options.
A newly emerging and promising childhood anxiety treatment is Attention Bias Modification Treatment (ABMT). ABMT is build upon evidence that anxious children tend to selectively focus their attention on threatening information in the context of other non-threatening information, and that attention bias is related to development and maintenance of anxiety disorders. Children with an attention bias hypervigilantly scan their environment for potential threat or danger thereby starting a cascade of subsequent processing biases in interpretation and memory, resulting in heightened anxiety.
Hence, as attention bias is an underlying mechanism of anxiety, treatment that diminishes attention bias toward threat in anxiety-disordered individuals should alleviate anxiety. Subsequently, several researchers began to examine the effect of ABMT, which implicitly trains anxiety-disordered individuals to attend away from threat toward neutral information. This is a different approach than CBT, which does not target early and automatic information processes, but addresses later stages of information processing that are under volitional control. Several studies highlighted the potential of ABMT in reducing anxiety levels in adults. A recent meta-analysis revealed that ABMT in adults produces significantly greater reductions in anxiety than placebo control training, with a large effect size in clinical populations. Schmidt and colleagues found that 72% of the adults were free from their primary anxiety disorder after ABMT as compared to 11% after placebo attention training, which is far more than CBT. These training effects were maintained at 4-month follow-up. Importantly, ABMT also modifies neural systems that are involved in the control of attention to emotional stimuli, in particular the lateral prefrontal cortex.
Despite the promising results in adults, ABMT has been scarcely examined in children. Only two studies with small sample sizes have been conducted so far, one in highly anxious children and the other in anxiety-disordered children. Both studies demonstrated a significant anxiolytic effect of ABMT, but not of the placebo control condition. A major limitation of both studies is that sample sizes were quite low and that a limited number of training sessions were

provided. It has been shown that more training sessions enhance the magnitude of treatment effect. This is the first study that examines the effectiveness of a 9-session web-based ABMT in a large sample of anxiety-disordered children as well as examines the additive effect of web-based ABMT on CBT.

Study objective

Specific Aims
As reviewed above, childhood anxiety disorders are highly prevalent and debilitating, and there is an urgent need for improvement of current treatment strategies. An innovative, but scarcely examined, treatment option for childhood anxiety disorders is ABMT.
The primary aim is to compare internet-ABMT-augmented CBT with CBT as monotherapy on recovery rates for anxiety disorders and changes in anxiety. The secondary aim is to compare internet-ABMT with internet placebo attention training on anxiety disorder recovery rates and changes in anxiety.

Study design

A randomized, placebo-controlled, double-blind trial of web-based Attention Bias Modification Treatment for childhood anxiety disorders will be conducted. One hundred twenty-eight children will be randomly allocated to a 9 session internet-delivered ABMT or placebo attention training.
Children and parents will be assessed before (placebo-)ABMT (T1), after (placebo-)ABMT (T2), one week after the tenth CBT sessions (T3), and at 6-months follow-up (T4).

Intervention

Internet-ABMT: A trial begins with a fixation cross (+) presented in the centre of the screen for 500 ms, immediately followed by a stimuli pair consisting of a neutral and threatening stimulus that is centred horizontally. Stimuli pairs consist of two faces, pictures or words. After presentation of the stimuli pair, a probe (: or ..) always appears on the location of the neutral stimulus. The probe remains on the screen until the participant presses the corresponding key (: or ..), after which the next trial begins (see figure 1). During each sessions, participants see 160 trials that comprises various combinations of probe type (: or ..), probe and stimulus position (left or right), and stimulus type (faces, pictures or words). Of the 160 trials, 128 trials include one neutral and one threatening stimulus. The remaining 32 trials include a neutral-neutral stimuli pair.

Internet-Placebo attention training: The probe appears with equal frequency on the location of the neutral and threatening stimulus.

All children, regardless of anxiety status after treatment, will receive a

cognitive behavioral treatment (CBT).

CBT: The FRIENDS program is an evidence-based, World Health Organisation acknowledged, CBT protocol, comprising psycho-education, relaxation, breathing exercises, exposure, problem-solving skills training, social support training, and cognitive restructuring training.

Study burden and risks

NUMBER OF ASSESSMENTS AND MEASURES

ADIS-C (anxiety interview; child and parents, 1 hour; T1,2,3, 4)
SCARED-R (anxiety questionnaire, child and parents, 15 minutes; T1,2,3, 4)
CBCL/YSR/RF (internalising problems questionnaires, child and parents and teacher, 20 minutes, T1,2,3, 4)
CDI (depression questionnaire, child, 10 minutes, T1,2,3, 4)
TACQOL-PF/TACQOL-CF/TAAQOL (quality of life questionnaire, child and parents, 15 minutes, T1,2,3, 4)
Attention bias (computertask, child, 20 minutes, T1,2,3, 4)
Interpretation bias (computertask, child, 15 minutes, T1,2,3, 4)
EMBU-C, EMBU-P (questionnaire parenting style, 15 minutes, child and parents, T1,2,3,4)

Life events questionnaire (10 minutes, child, T1,2, 3, 4)
SES (social-economic status questionnaire, parents, 10 minutes, T1)
Medical consumption questionnaire (5 minutes, parents, T1, 2, 3, 4)

EXTRA MEASURES WHEN PARENT AS SUBJECT
CIDI (interview psychopathology parents, parents, 1 hour, T1)
ASR (anxiety and depression questionnaire, 15 minutes, parents, T1,2,3, 4)
Attention bias (computertask, parents, 20 minutes, T1,2,3, 4)

RISK ASSOCIATED WITH PARTICIPATION
Negligible for the intervention study. No risk for active paritication of parents.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

One of the following anxiety disorders as primary diagnosis: specific phobia, separation anxiety disorder, social phobia and generalized anxiety disorder, based on the Anxiety Disorders Interview Schedule for Children (ADIS-C).

Exclusion criteria

IQ below 85, poor command of the Dutch language, serious physical disease, psychosis, substance abuse, pervasive developmental disorder, obsessive-compulsive disorder, posttraumatic stress disorder, acute stress disorder, panic disorder, major depression, serious school refusal, current psychotherapy/anxiety medication, two or more completed cognitive behavioural therapies for anxiety, anxiety treatment in the past six months

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2013
Enrollment:	128
Type:	Actual

Ethics review

Approved WMO Date:	29-10-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL43150.078.13