Using interactive virtual reality to treat aggressive behavior problems in youth

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON46240

Source
ToetsingOnline

Brief title
Virtual reality intervention

Condition

- Personality disorders and disturbances in behaviour

Synonym
Aggressive behavior problems, disruptive behavior disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: NWO

Intervention

Keyword: 8-12 years), Aggressive behavior problems, Children (boys, Intervention, Virtual reality

Outcome measures

Primary outcome

Aggressive behavior problems

Treatment motivation

Secondary outcome

Emotion regulation

Social information processing

Study description

Background summary

A large proportion of children and youth in the mental health care shows externalizing problem behavior, such as aggression (Nederlands Jeugdinsituut, 2015). The prevention and treatment of these problem behaviors is necessary, since this a serious risk factor for the development of adverse outcomes later in live (Sukhodolsky, Kassinove, & Gorman, 2004). Moreover, these children are at enhanced risk for behavior problems later in life, internalizing problem behavior, substance abuse, and school failure (Sukhodolsky, Kassinove, & Gorman, 2004; Weisz & Kazdin, 2001). Furthermore, it is demonstrated that young children with behavior problems will later in life face more problems, receive mental care more often and costs for society are higher (Scott, Knapp, Henderson & Maughan, 2001).

Over the past years, knowledge regarding the effectiveness of interventions for aggressive behavior problems has increased (Weisz & Kazdin, 2017). Moreover, several (group)intervention are found to effectively decrease aggression, even on the long term (Nederlands Jeugdinsituut, 2015).
However, the effects of current evidence-based cognitive behavioral treatments (CBT) on children*s aggressive behavior problems are modest at best and do not work for all children (McCart, Priester, Davies, & Azen, 2006).

Therefore, it is necessary to examine whether the effectiveness of intervention

for children with aggressive behavior problems can be enhanced. Moreover, CBT interventions are expected to be most effective when children*s aggressive cognitions are challenged in emotionally involving social situations, because these are the situations that trigger their aggression in real life (Suveg, Southam-Gerow, Goodman, & Kendall, 2007). Virtual reality allows for such exposure within a controlled treatment context. In addition, virtual reality has been found to enhance treatment motivation, which may foster intervention adherence as well as effectiveness. However, it is yet unknown if virtual reality can enhance treatment effects for children with aggressive behavior problems.

Study objective

The goal of the present research is to test the effectiveness of an interactive virtual reality intervention for children with agression problems. Moreover, it is expected that (1) the VR-intervention will decrease aggressive behavior problems, (2) in addition will possibly be more effective in treating aggressive behavior problems than current treatments (in which cognitions and skills are being practiced in role plays), and (3) that children will have more treatment motivation.

Study design

A randomized controlled trial will be conducted to examine the effectiveness of the interactive virtural reality treatment. Children will be randomized into three groups:
1. The virtual reality intervention. This is an individual cognitive behavior therapy (CBT) intervention consisting of 10 sessions. Children practice the skills in the VR environment.
2. An active control group. This is an individual cognitive behavior therapy (CBT) intervention consisting of 10 sessions. Children practice the skills within role plays with the therapist.
3. An passive control group (care-as-usual). These boys will receive care-as-usual.

Intervention

The current intervention is based on principles of cognitive behavior therapy to enhance emotionregulation and social information processing of boys with aggressive behavior problems. The intervention start with an intake with parents and 10 45-minute sessions with the child will follow. The current intervention will be delivered individually, since earlier research showed larger reductions in cihildren's aggression for individual delivered therapy compared to group delivered therapy. During the intervention children will learn to recognize their anger and train skills to cope with anger. Examples of those skills are taking a time-out, do relaxation exercises and use coping

statements.
Participants receiving the virtual reality intervention will practice the skills during the therapy in a virtural reality environment. Participants in the active control group will practice in role plays with the therapist. Participants in the passive controle group will receive care as usual.

Study burden and risks

The burden placed on the participants is small. The virtual reality condition and active control condition will exist of an intake with parents and 10 intervention sessions with the child (all 45 minutes). This is comparable to current treatments for children (Nederlands Jeugdsinstituut, 2015). Children and their parents will fill in questionnaires at three occasions; this will take 15-30 minutes. In total, all participants and their parents invest a maximum of 1 hour, 30 minutes by filling in questionnaires and children in the intervention conditions invest an additional 7.5 hours in treatment.

Furthermore, the risk of harm to the participants as a result of participating in the study is smal, as also described in our earlier virtual reality study (NL61205.041.17). Since the therapeutic contents of the active and passive control condition are similar to current treatments, no risks are expected.

Since virtual reality allows for practicing skills in realistic, emotionally involving situations, it is expected that VR-scenario's will elicit frustrations or mild aggression that is similar to frustrations and mild aggression in daily life. Previous research has demonstrated that real-time mild provocations and social dilemma's can elicit mild aggressive behavior within ethical boundaries (Matthys et al., 1995; Matthys et al., 1995; Van Nieuwenhuijzen et al., 2005; Kempes, de Vries, Matthys, van Engeland, & van Hooff, 2008).

In addition, virtual reality-environments could elicit cyber sickness. Cyber sickness consists of symptoms of nausea, drowsiness, impaired visual perception and concentration deficits and is caused by a discrepancy between sensory perception and the vestibular system (LaViola Jr., 2000). It is important to note that approximately 30% of participants exhibit some symptoms of cyber sickness (Chen et al., 2011). However, research shows that participants build a tolerance against cyber sickness and that the quality and adjustment of the virtual reality hardware and software can reduce symptoms of cyber sickness (Kennedy, Stanney & Dunlap, 2002; Rebenitsch & Owen, 2016; Kennedy & Fowlkes, 2000). In this study, the discrepancy between sensory perception and the vestibular system is expected to be minimal because participants are able to freely move in the virtual reality-environments and the quality of the hardware and software is high. Therapists will monitor symptoms of cyber sickness and will temporarily pause the session if they perceive symptoms. The session will be proceeded only when participants are feeling well and are willing to

continue.

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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

Boys between 8 and 12 years old with aggressive behavior problems (CBCL subscale aggressive behavior T-score 67 or higher)

Exclusion criteria

Absence of (sub)clinical aggressive behavior problems, an IQ below 80 and/or profound

Autistic Spectrum Disorder symptoms. Children who are deaf/blind/have epilepsy will also be excluded from the study.

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:	Recruitment stopped
Start date (anticipated):	15-07-2019
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	13-12-2018
Application type:	First submission
Review commission:	METC NedMec

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: 26967
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67139.041.18
OMON	NL-OMON26967

Study results

Date completed:	01-07-2021
Actual enrolment:	115