

Enhancing Emotion Regulation in Adolescents with Externalizing Problem Behavior.

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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-OMON45662

Source

ToetsingOnline

Brief title

Enhancing Emotion Regulation

Condition

- Personality disorders and disturbances in behaviour

Synonym

behavior problems, Disruptive behavior disorder

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: adolescents, emotion regulation, externalizing problem behavior, randomized parallel-group design

Outcome measures

Primary outcome

The main outcome variable is emotion regulation, which will be measured with a multi-process approach.

Secondary outcome

Secondary outcome variables are externalizing problem behavior, internalizing problems and mood variability.

Study description

Background summary

If left untreated, externalizing problem behavior is a serious risk factor for the development of adverse outcomes later in life, such as rejection by peers, school failure, crime involvement and psychopathology. Furthermore, it is demonstrated that costs to society are 10 times higher for youth with elevated levels of externalizing behavior. Over the past years, knowledge regarding the effectiveness of interventions for externalizing problem behavior has increased. Interventions are however generally found to be only moderately effective and treatment responsiveness is variable. Emotion regulation training is incorporated in many effective interventions for aggressive behavior problems, but it is not clear which techniques (e.g. cognitive or behavioral) are most effective. By examining this we hope to enhance the effectiveness of treatment for aggressive behavior problems in youth.

Study objective

The goal of the study is to examine the effectiveness of emotion-regulation training for adolescents with externalizing problem behaviors and an (above) average intelligence (target group A) or mild to borderline intellectual disability (target group B). It will be examined which module (cognitive emotion regulation training vs behavioral emotion regulation training vs both)

most effectively increases emotion regulation capacities.

Study design

We will use a randomized parallel-group design. For target group A, we will use three conditions (two intervention conditions and one control condition). For target group B, we will use two conditions (two intervention conditions). Participants in the intervention conditions (target group A and target group B) will receive both the cognitive and the behavioral module, but in a different sequence. In this way we can examine whether the second module has any effect on top of the effect of the first module. Participants in the control condition receive care-as-usual.

Intervention

Participants in the experimental conditions will receive the Think and Act Cool training, which consists of a behavioral and cognitive module. Both modules consist of 5 sessions of 45 minutes. The behavioral module incorporates techniques such as physical relaxation, time-out, and the use of specific social skills. The cognitive module incorporates techniques such as cognitive relaxation, cognitive restructuring and problem-solving.

Adolescents with mild to borderline intellectual disabilities (target group B) will receive the Think and Act Cool Plus training, which is adapted to their specific needs.

Study burden and risks

The burden placed on the participants is small. Participants fill in the weekly questionnaire for 19 weeks, this will take up only 2 minutes every week. Moreover, additional data collection will take place on four occasions, which will take up 30-45 minutes at each occasion. Participants will fill out the 5-day Daily Diary on three occasions. Participants in the intervention conditions will receive ten 45-minute training sessions. In total, all participants invest 4 hours and participants in the intervention conditions invest an additional 7,5 hours.

Moreover, there is no risk of harm to the participants as a result of participating in the study. The potential value of the study results is however profound. Based on the results, it might be possible to enhance the effectiveness of interventions for aggressive behavior problems in youth. This is specifically important for the target group, because emotion regulation capacities are developing during (early) adolescence and at a later age, interventions are less effective.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Inclusion criteria

Participants are between 12 and 16 years old and experience externalizing problem behavior (TRF subscale externalizing problem behavior t-score >60). For target group A, adolescents have an (above) average IQ (> 85). For target group B, adolescents have mild to borderline intellectual disabilities (IQ 55 - 84).

Exclusion criteria

Profound Autistic Spectrum Disorder symptoms. In addition, adolescents who do not speak Dutch or are deaf/blind 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):	05-11-2017
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO	
Date:	03-05-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	20-09-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL61104.041.17