

# Keeping Control of Anger

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27699

### Source

Nationaal Trial Register

### Brief title

TBA

### Health condition

Externalizing behavior problems

## Sponsors and support

**Primary sponsor:** Utrecht University

**Source(s) of monetary or material Support:** The study described in this study protocol is funded by the Faculty Of Social and Behavioral Science (FSBS) at Utrecht University. The funding body had no role in the study design, writing the manuscript, or the decision to submit the paper for publication.

## Intervention

## Outcome measures

### Primary outcome

- Child behavior problems: CBCL (parent report), TRF (teacher report), Brief Problem Monitor (child report) externalizing behavior subscale, and 3 items of a weekly questionnaire

### Secondary outcome

- Emotion regulation: Emotion Regulation Checklist (parent and teacher report), FEEL-KJ (child report), and 3 items of a weekly questionnaire
- Social Information Processing: The Social Information Processing Task ([Sociale Informatieverwerkingstest], and 3 items of a weekly questionnaire

## Study description

### Background summary

Youth with mild intellectual disabilities and borderline intellectual functioning (hereby referred to as Mild to Borderline Intellectual Disabilities, or MBID; youth with an IQ between 50 and 85 and deficits in adaptive behavior) display more behavior problems (e.g., oppositional defiant and aggressive behavior) than children without MBID, and these behavior problems are more likely to persist later in life. However, research into interventions specifically for youth with MBID is limited. Such specific interventions are needed, because standard intervention protocols may be less suitable for youth with MBID and behavior problems, due to their limited cognitive abilities and other social and psychological risk factors. Therefore, a new school-based targeted prevention program called Keeping Control of Anger, designed specifically for youth (between 9 and 14 years old) with MBID and behavior problems, has been developed, based on an evidence based intervention for children without MBID.

The study is a randomized controlled trial with two conditions and four repeated measures. Schools are randomly assigned to either the intervention condition or the control condition (care-as-usual). Participants are youth with limited cognitive functioning, congruent with MBID and elevated behavior problems between 9 and 14 years old.

### Study objective

The first aim of this study is to test the effectiveness of the school-based targeted prevention program for youth with mild intellectual disabilities and behavior problems (e.g., aggressive and oppositional defiant behavior) at reducing behavior problems. It is expected that the intervention is effective in reducing behavior problems, compared to a care-as-usual control group.

The second aim is to examine mediating variables. It is expected that social information processing and emotion regulation mediate the intervention effectiveness.

The third aim is to investigate moderating variables. It is expected that variables such as demographic variables, IQ, initial level of problems, and therapy factors (i.e., treatment integrity, therapeutic alliance, client comprehension, client motivation, and client involvement) moderate the intervention effectiveness.

### Study design

Four: pre-intervention, during the intervention, post-intervention, 4 to 6 month follow-up

## **Intervention**

Keeping Control of Anger consists of one individual session and ten group sessions (3-5 youth per group) led by a trainer (mental health professional either employed by or working at the special education school) and a co-trainer ([remedial] teacher at the school). The targeted prevention program uses CBT-techniques such as cognitive restructuring, emotion-education, role playing, and modeling. Specific adaptations have been made to tailor the program to the needs of youth with MBID (e.g., set session structure, pictorial aids, limited and easy text, repetition of learned skills, and use of videos to make hypothetical situations more life-like and to limit the amount of reading). Homework exercises are given after most sessions and these are discussed in the following session. A month after the tenth session, a booster session is given.

## **Contacts**

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## **Eligibility criteria**

### **Inclusion criteria**

- Age between 9 and 14 years old
- Subclinical or clinical scores on behavior problems
- An IQ between 65 and 85

### **Exclusion criteria**

- The presence of an autism spectrum disorder diagnosis, or severe autism spectrum disorder symptoms

- The presence of severe deficits in language, auditory, or visual skills
- The youth is currently in therapy elsewhere for the same problems they would be treated for in the intervention (i.e., externalizing behavior)

## 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):	01-01-2021
Enrollment:	214
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Positive opinion	
Date:	23-11-2020
Application type:	First submission

## Study registrations

## Followed up by the following (possibly more current) registration

ID: 49998

Bron: ToetsingOnline

Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL9068
CCMO	NL74665.041.20
OMON	NL-OMON49998

## Study results