Self-control Beats Anger: Research into a training for children with learning difficulties and challenging behavior

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

Summary

ID

NL-OMON49998

Source
ToetsingOnline

Brief title
Self-control Beats Anger

Condition

- Personality disorders and disturbances in behaviour

Synonym
Aggressive behavior, oppositional defiant behavior

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: behavior problems, externalizing behavior, mild intellectual disability, prevention

Outcome measures

Primary outcome

The primary outcome measure is behaviour problems. This is measured using a multi-informant (i.e., child, parents, and teachers) approach.

Secondary outcome

The secondary outcome measures are also measured using a multi-informant approach (i.e., child, parents, trainers, and teachers). They include the following mediators: social information processing, emotion regulation, and self-control. They include the following moderators: treatment integrity, therapeutic alliance, client comprehension, treatment motivation, client involvement.

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 65 and 85 and deficits in adaptive behavior) display more behavior problems, such as 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 behaviour problems, due to their limited cognitive abilities and other social and psychological risk factors. Therefore, a new school-based targeted prevention program called Self-control Beats Anger, designed specifically for youth with MBID and behavior problems, has been developed, based on an evidence based intervention for children without MBID.

Study objective

The first aim 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 behaviour problems. The second aim is to examine mediating variables (social information processing, emotion regulation, and self-control). The third aim is to investigate moderating variables, including demographic variables, IQ, initial level of problems, and therapy factors (i.e., treatment integrity, therapeutic alliance, client comprehension, treatment motivation, and client involvement).

Study design

The present study is a randomized controlled trial with two conditions and four repeated measures. Participants are randomly assigned to either the intervention condition or the control condition (care-as-usual).

Intervention

Self-control Beats Anger consists of one individual session and ten group sessions (3-5 youth per group) led by a trainer and a co-trainer. The targeted prevention program uses CBT-techniques such as cognitive restructuring, emotion-education, role playing, and modeling. Specific adaptions 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.

Study burden and risks

Participant burden is kept to a minimum. It consists of completing several questionnaires (4 times for teachers, parents and children) and vignette based measures for the children (SIP tasks) over the course of the intervention. Additionally, children, parents en teachers fill out a brief weekly measure during the course of the intervention (11 times). For children, the total measurement battery will take no longer than one school-hour to complete. For parents and teachers, it will take around 20 minutes the first time, and about 15 minutes after that. The number of questionnaires are kept to the minimum needed to draw conclusions about the effectiveness, mediators, and moderators of the intervention. The intervention itself takes about 60 to 85 minutes per session. Further, no risk is expected to be associated with the present study, while the information obtained by youth, their parents, and their teachers is of great clinical and empirical importance. Considering the lack of research

into treatment for youth with MBID, these limited measures should make a large scientific contribution to better understanding and improving the treatment of youth with MBID, as well as the theory behind it.

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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

- Age between 9 and 14 years old
- Subclinical or clinical scores on behavior problems as determined based on a standardized screening questionnaire filled out by the teacher (i.e., the TRF externalizing problems subscale; scores > 84th percentile indicate subclinical or clinical scores)
- An IQ between 65 and 85 (as determined by IQ data provided by the school if

available and if not older than two years; if such data is unavailable, IQ is determined by the administration of seven subtests of the WISC-V-NL)

See protocol section 6 (Methods) for more information on the screening measurements we use to determine whether children do or do not meet the inclusion criteria.

Exclusion criteria

- The presence of an autism spectrum disorder diagnosis, or severe autism spectrum disorder symptoms, as determined by on a standardized screening questionnaire filled out by the teacher (i.e., the ASV symptom score; scores > 95th percentile indicate severe scores)
- The presence of severe deficits in language, auditory, or visual skills (as determined during the formal screening, by means of on a short yes/no questionnaire filled out by the school mental health professional)
- The youth is currently in therapy elsewhere for the same problems they would be treated for in the intervention (i.e., externalizing behavior; as determined during the formal screening, by means on a short yes/no questionnaire filled out by the school mental health professional)

See protocol section 6 (Methods) for more information on the screening measurements we use to determine whether children do or do not meet the exclusion criteria.

Study design

Design

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

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-01-2021
Enrollment:	214
Type:	Anticipated

Ethics review

Approved WMO Date:	22-10-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-12-2020
Application type:	Amendment
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: 27699
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL74665.041.20
OMON	NL-OMON27699