Think and Act Cool: A Cognitive Versus Behavioral Approach to Emotion Regulation Training for Externalizing Behavior Problems in Adolescence

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23274

Source
Nationaal Trial Register

Brief title
Think and Act Cool

Health condition

externalizing behavior problems; emotion regulation; adolescence

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 Netherlands Organisation for Health Research and Development (ZonMW grant number 729300014.). 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

Emotion regulation difficulties. The Dutch version of the brief Difficulties in Emotion Regulation Scale (DERS) will be used to measure emotion regulation problems. The DERS is a 15-item self-report measure that assesses difficulties in emotion regulation. The items (e.g., “When I am upset, I become out of control”) are rated on a 5-point scale from 1 (almost never) to 5 (almost always).

Emotion regulation strategies. Emotion regulation strategies in response to feelings of anger will be assessed with the Dutch version of the Fragensbogen zur Erhebung der Emotionsregulation bei Kinder und Jugendlichen (FEEL-KJ). The subscale anger is assessed in this study and consists of 30 items (e.g., “If I feel angry… I do something fun”) that are rated on a 5-point scale from 1 (never) to 5 (almost always). The questionnaire distinguishes adaptive and maladaptive emotion regulation strategies.

In addition, cognitive and behavioral emotion regulation strategies will be measured with a newly developed vignette measure. The measure is based on earlier vignette measures. The adolescent reads a vignette that is meant to elicit feelings of anger, and rates how likely it is that he/she will use a specific emotion regulation strategy, on a 7-point scale from 0 (definitely not) to 6 (definitely). Per vignette, there are six behavioral strategies (adaptive strategies: relaxation, behavioral distraction, social support; maladaptive strategies: direct expression, indirect expression, avoidance), and six cognitive strategies (adaptive strategies: cognitive reappraisal, cognitive distraction, putting into perspective; maladaptive strategies: self-blame, rumination, suppression).
Externalizing behavior. Externalizing behavior will be measured from a multi-informant perspective, with subscales of the ASEBA-questionnaires that are administered to adolescents, their teachers, and parents. Adolescents (YSR), Teachers (TRF), and Parents (CBCL) will complete respectively the 32, 32, and 35 items of the externalizing scale of the Dutch ASEBA versions [53]. Items (e.g., “Fights a lot / I fight a lot”) are rated on a 3-point scale from 0 (not true) to 2 (very true or often true).

Weekly measure. Emotion regulation and aggression will also be assessed with a 6-item self-reported weekly measure. The questionnaire contains three items for emotion regulation (e.g., “how often this week did you become so angry, that you could not control yourself?”) and 3 items for aggression (e.g., “How often did you hit someone this week?”) that are rated on a 5-point scale from 0 (never) to 4 (more often, … times). The measure is based on items of the DERS and YSR.

Secondary outcome

Secondary outcome measures.

Mood variability. Mood variability will be measured with the Daily Mood Device, an adapted version of the Electronic Mood Device. In the current study, the mood variability measure is

integrated in the weekly measure smartphone application. At each measurement moment, adolescents are asked to rate the intensity of their daily mood for happiness, sadness, anger, and anxiety (“Today I feel …”) on five consecutive days. Each mood state will be measured with three items (12 items in total), that are rated on 9-point scale from 1 (not happy / angry / …) to 9 (happy / angry / …). The words that are used for happiness are “glad”, “happy”, and “cheerful”, for sadness: “sad”, “down”, and “dreary”, for anger: “angry”, “cross”, and “short-tempered”, and for anxiety: “afraid”, “anxious”, and “worried”.

Internalizing problems. Internalizing problems will be reported by the adolescents with the internalizing scale of the Youth Self Report age 11-18. This subscale consists of 34 items (e.g., “I cry a lot”) that are rated on a 3-point scale from 0 (not true) to 2 (very true or often true).

Potential mediators.

Emotion regulation skills (see for measures the primary outcome section) and social information processes are viewed as protentional mediators for models in which the effects of the Think Cool Act Cool training on externalizing behavior problems are tested.

Social information processing. Social information processing skills biases and deficits will be assessed with the Sociale Informatie Verwerkings Test (SIVT). The SIVT consists of six videos that show hostile, ambiguous or accidental interpersonal problems, involving a peer or adult perpetrator. In all videos, the outcome of the situation is negative for the victim. Different steps of social information processing (encoding, interpretation, goal setting, response generation, response evaluation and selection) are measured with a semi-structured interview and multiple-choice questions. In the current study, only ambiguous and accidental situations will be used because earlier research shows that with hostile situations, aggressive and non-aggressive are not very well distinguishable [57]. At each time point, the adolescent will view two videos; an ambiguous and an accidental situation with both a peer and adult perpetrator, but the order will be counterbalanced.

Potential moderators.

Affective reactivity. Reactivity will be assessed with the Affective Reactivity Index (ARI-S) [58]. The ARI-S is a 6-item self-report measure that assesses irritability (e.g., “I often lose my temper”) on a 3-point scale from 0 (not true) to 2 (certainly true).

Parental acceptance-rejection. Parental acceptance-rejection will be measured with 18-items of the short version Parental Acceptance-Rejection Questionnaire (PARQ). Parents will report on three subscale of the PARQ; warmth, neglect and undifferentiated rejection (e.g., “I say nice things about my child”). Items are rated on a 4-point scale from 1 (almost never true) to

4 (almost always true).

Treatment integrity. Treatment integrity is conceptualized in this study as the extent to which the intervention is implemented as intended. To measure treatment integrity, clinicians will fill in a questionnaire after each session. The questionnaire is based on other measures of treatment integrity and consists of several domains; treatment exposure, treatment adherence, and treatment differentiation (e.g., “It was difficult to focus on behavior rather than cognitions in this session”). The questionnaire also measures participant comprehension and responsiveness (e.g., “The adolescent participated actively in this session”). In total, the measure consists of approximately 25 items, depending on the content of the session. Items are answered on 4-point scale from 1 (not at all) to 4 (totally). Moreover, all training sessions will be audiotaped. A random selection of 10% of the sessions will be scored on different aspects of treatment integrity (e.g., adherence, differentiation) by independent coders.

Other information.

Demographic information (gender, ethnicity and socioeconomic status) will be assessed at baseline. In addition, the received care-as-usual and additional help will be measured at T3.

Study description

Background summary

Interventions for adolescents with externalizing behavior problems are generally found to be only moderately effective, and treatment responsiveness is variable. Therefore, this study aims to increase intervention effectiveness by examining effective approaches to train emotion regulation, which is considered to be a crucial mechanism involved in the development of externalizing behavior problems. Specifically, we aim to disentangle a cognitive and behavioral approach to emotion regulation training.

Study objective

We hypothesize that the Think Cool Act Cool emotion regulation training is effective in improving emotion regulation skills and decreasing externalizing behavior problems, compared to care-as-usual. We also hypothesize that the training has a small effect on mood variability and comorbid internalizing problems. In addition, we compare the contrasting hypotheses that the cognitive (Think Cool) module is more effective than the behavioral (Act Cool) module or vice versa and hypothesize that completing both modules is more effective than completing only one module. In addition, we compare the contrasting hypotheses that it is more effective to first receive the cognitive module and secondly the behavioral module

(sequence Think Cool + Act Cool) or vice versa (sequence Act Cool + Think Cool). We expect that overall, emotion regulation mediates the effect of the Think Cool Act Cool training on externalizing behavior problems. In particular, we expect that behavioral emotion regulation mediates the effect of the Act Cool module on externalizing behavior problems and that both cognitive emotion regulation and social information processing mediate the effects of the Think Cool module. Regarding moderation effects, we expect that overall, the Think Cool Act Cool training is more effective for adolescents who report higher levels of affective reactivity, and for adolescents whose parents show more acceptance and less rejection. In addition, we expect that the Think Cool module is more effective for adolescents with higher intelligence, whereas the Act Cool module is more effective for adolescents with lower intelligence. Finally, we expect that higher treatment integrity is related to increased effectiveness.

Study design

If participants meet the inclusion criteria, they are randomly assigned to either the intervention or the control condition. Randomization takes place at the individual level, by means of computer-generated random numbers. Adolescents, their parents and teachers will obviously notice the condition in which they are participating, so allocation will not be blind. Nevertheless, participants will not be aware of the fact that we examine the difference between two training sequences. Subsequently, adolescent download a questionnaire application on their smartphone and start with the weekly and daily questionnaires. First, a 3-week baseline of the weekly measure (see measures section) will be established. Moreover, adolescents fill in the first Daily Diary measure on five consecutive days. In addition, adolescents, their parents and teachers complete the baseline measures at T1, the first of three assessments. The adolescent questionnaires and tasks are administered individually at school by a trained research assistant at each assessment point. Adolescents fill out the questionnaires on a computer. Teachers fill out the questionnaires on paper. Parents are sent links to the questionnaires via email.

Participants in the intervention condition start with either the cognitive module (Think Cool) or the behavioral module (Act Cool). After five weeks, in which participants in the intervention condition follow five individual therapy sessions, all participants, parents and teachers complete the T2 measures. Next, there is a 3-week training break, which allows us to measure possible delayed effects. During the training break, all participants continue to fill in the weekly questionnaire and fill in the second Daily Diary measure. Subsequently, participants in the intervention condition follow the second module (Think Cool or Act Cool, depending on the first module), which also consists of five individual sessions. Eventually, the post-test measures are completed by all participants at T3. There also is a 3-week post-measure of the weekly measure, in which participants also complete the third Daily Diary measure.

Intervention

Participants in the intervention condition will receive 11 individual 45-minute sessions of the Think Cool Act Cool emotion regulation training. This is a manualized experimental training, that is designed based on components of evidence-based treatments for adolescents with

externalizing behavior problems, such as Coping Power and Aggression Replacement Training. The training is provided at the school of the participant, by a trained clinician with a background in child psychology.

Before the actual modules, participants start with an introduction session, in which they get to know the trainer, the content of the training, and set personal goals. Next, participants first receive either the Think Cool module or the Act Cool module, followed by the other module. Both modules consist of five individual sessions. In both modules, adolescents are instructed to make daily at-home assignments, the “anger thermometer logbook”, in which they briefly describe in which situations they became angry and what strategies they used to regulate their anger and solve the issues. The situations they describe in the logbook are used in the training sessions as practice material. If adolescents do not complete the at-home assignment, clinicians use other situations from adolescents’ lives.

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Eligibility criteria

Inclusion criteria

The following inclusion criteria will be used: a subclinical or clinical level of externalizing behavior problems as reported by teachers (TRF externalizing subscale > 84th percentile) and average or above average intelligence (estimated IQ score > 80).

Exclusion criteria

Participants are excluded if they experience severe Autism Spectrum symptoms as reported by their teacher (ASV symptom score > 98th percentile) and/or if their language, auditory or visual skills are severely hindered (as evidenced by an indication of the school psychologist that the adolescent possesses insufficient Dutch language skills to understand questionnaires and training, or has an auditory or visual disability).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-11-2017
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-07-2018
Application type:	First submission

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
NTR-new	NL7136
NTR-old	NTR7334
Other	: CCMO \NL61104.041.17

Study results

Summary results
None