Op Volle Kracht

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22672

Source
NTR

Health condition

Depression
Anxiety
Internalizing problems
Emotional resilience

Sponsors and support

Primary sponsor: Pluryn
Karakter, child- and adolescent psychiatry
Radboud University Nijmegen
Source(s) of monetary or material Support: ZonMW
Achmea

Intervention

Outcome measures

Primary outcome

The primary outcome will be depressive symptoms as measured by the Dutch version of the Children’s Depression Inventory (CDI) at T2 and T3.

Secondary outcome

Secondary outcomes include anxiety, behavioural problems and responsiveness of group care workers.

Anxiety will be measured using the Dutch translation of the Spence Children's Anxiety Scale (SCAS; Spence, 1997) for both parents and adolescents.

Behavioural problems will be assessed using the Strengths and Difficulties Questionnaire (SDQ; Goodman 1997) for both parents and adolescents.
Responsiveness of group care workers will be assessed using the subscale 'responsiveness' of the Dutch translation of the Prison Group Climate Inventory (Van der Helm, Stams, & Van der Laan, 2011).

Possible mediators include negative cognitive styles and coping styles. Negative cognitive styles will be measured with the Children's Negative Cognitive Errors Questionnaire – Revised (CNCEQ-R; Maric, Heyne, van Widenfelt & Westenberg, 2011).
Response style and coping will be measured with the Children's Response Style Questionnaire (CRSQ).

Study description

Study objective

The aim of this study is threefold: (1) to test the effectiveness of OVK in reducing symptoms of depression compared to treatment as usual (TAU), (2) to identify mechanisms that can explain program effects, and (3) to test the effects of OVK on secondary outcomes. It is hypothesized that OVK will be more effective in reducing symptoms of depression in youth than TAU, immediately after the program and at three months follow-up. Regarding the explanatory mechanisms, it is hypothesized that OVK will decrease negative cognitive biases and increase adequate coping styles. Both of these constructs are expected to mediate the hypothesized effect of OVK on symptoms of anxiety and depression.

Secondary outcomes include anxiety, behavioural problems, and group therapeutic climate.

Study design

T1: Baseline assessment, approximately 1 month before the start of the program. All adolescents will fill out the CDI before they are informed about the condition they are assigne to.

T2: 1 week prior to the start of the intervention. Adolescents will fill out the CDI, SCAS, CNCEQ-R, CRSQ, SDQ and PCGI subscale 'Responsiveness'. Parents will fill out the SCAS, CDI-2 parent version, and SDQ.

T3: 1 week after the last session of the intervention. Adolescents and parents will fill out the full battery as described at T2.

T4: Follow-up, three months after the last session of the intervention. Adolescents and parents will fill out the full battery as described at T2.

Intervention

Op Volle Kracht is an CBT-based group intervention to increase emotional resilience among youth with and without mild intellectual disability (MID) in residential treatment settings.

Adolescents will receive eight 45-minute group-sessions of the OVK-program within a period of 10 weeks. Within the sessions, adolescents are trained in the following cognitive-behavioural skills:

- to recognize and describe their feelings and thoughts

- to detect inaccurate thoughts

- to evaluate the accuracy of inaccurate thoughts

- to challenge inaccurate thoughts by considering alternative interpretations.

The sessions include group talks, individual- and group exercises, and video fragments. After each session, adolescents are assigned a homework task that takes approximately 15 minutes.

Two versions of the program ara available: (1) a program designed for adolesents with average or above-average cognitive capacities (TIQ >90) and age-appropriate social-emotional capacities; and (2) a version for adolescents with mild intellectual disability (TIQ 65-90) and delayed social-emotional development. The content of both versions of the program is the same, however regarding the structure both programs differ on the following points: (1) the MID version contains less verbal and more visual- and practical exercises than the non-MID version; (2) in the MID version adolescents receive more support from social workers (e.g. help in homework, help in detecting inaccurate thoughts and challenging their thoughts) than in the non-MID version; (3) the MID version places a stronger emphasis on behavioural techniques to influence the chain of thought-feeling-behaviour rather than cognitive techniques.

Contacts

Public
Pluryn
RVE Research & Development
Postbus 53, 6500 AB Nijmegen
M. Weeland
Industrieweg 50, 6541 TW Nijmegen
Nijmegen
The Netherlands
088 - 779 50 38
Scientific
Pluryn
RVE Research & Development
Postbus 53, 6500 AB Nijmegen
M. Weeland
Industrieweg 50, 6541 TW Nijmegen
Nijmegen
The Netherlands
088 - 779 50 38

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Admitted to residential treatment within youth mental health care, the youth welfare system or care for youth with MID

• Age between 10;0 -16;11 years

• IQ > 60

Exclusion criteria

Participation in another clinical intervention study simultaneously

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	27-10-2014
Enrollment:	182
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL1802
NTR-old	NTR4836
CCMO	NL-49211.091.14

Study results