

Op Volle Kracht: An intervention to increase emotional resilience among youth in residential treatment centers

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Main: 1. To investigate whether a short term CBT-based group program is more effective in reducing symptoms of depression and anxiety than treatment as usual (TAU), among adolescents aged 10-16 within residential treatment settings in the youth...

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|------------------------------|-------------------------------------|
| Ethical review | Approved WMO |
| Status | Pending |
| Health condition type | Mood disorders and disturbances NEC |
| Study type | Interventional |

Summary

ID

NL-OMON41104

Source

ToetsingOnline

Brief title

At Full Strength

Condition

- Mood disorders and disturbances NEC

Synonym

depression, depressive disorder

Research involving

Human

Sponsors and support

Primary sponsor: Pluryn

Source(s) of monetary or material Support: ZONMW (subsidie Academische werkplaats Jeugd)

Intervention

Keyword: depression, mild intellectual disability (MID), residential care, resilience

Outcome measures

Primary outcome

-Depression, assessed through a clinical interview, and self- and parent report.

Secondary outcome

-Anxiety, assessed through parent- and self-report questionnaires.

-Cognitive styles, assessed through self-report

-Response styles, assessed through self-report

-Group climate on the treatment group, assessed through adolescents' reports

Study description

Background summary

Adolescents admitted to residential treatment in youth care and youth mental health care often show complex combinations of internalizing (anxiety, depression, somatization) and externalizing problems (aggression, oppositional behaviour, substance abuse etc), and there is some evidence that internalizing problems play a causal role in the development of externalizing problems. A systematic approach to internalizing problems in residential youth welfare system and youth mental health care is expected to improve treatment outcomes and adolescents' developmental perspective (Granic, 2012). Currently, such a systematic approach is lacking and internalizing problems are often underrecognized and undertreated.

The aim of this study is to test the effectiveness of a CBT-based group program aimed to increase adolescents' emotional resilience by training them in using positive cognitive styles and attributions, and to prevent development of clinical levels of anxiety and depression on a long-term perspective. The program will be delivered by trained social workers and nurses and treatment will be integrated within the therapeutic climate on the treatment group.

Study objective

Main:

1. To investigate whether a short term CBT-based group program is more effective in reducing symptoms of depression and anxiety than treatment as usual (TAU), among adolescents aged 10-16 within residential treatment settings in the youth welfare system and youth mental health care.

Secondary:

2. To investigate whether a short term CBT-based group prevention program is more effective in changing adolescents cognitive- and response styles than treatment as usual (TAU), among adolescents aged 12-16 within residential treatment settings in the youth welfare system and youth mental health care.

3. To investigate the effects of the intervention on the treatments group therapeutic climate

4. To investigate the role of possible mediators (e.g. cognitive styles, coping styles) and moderators (e.g. setting, intelligence, gender) .

Study design

Open matched-pair cluster randomised study with blinded raters

Explanation:

Within the residential treatment settings in the Netherlands, adolescents usually reside in treatment groups of 8-10 clients each. Randomization is based on these natural treatment groups: each of the 20 groups is matched to another group with a similar population (MID/ non-MID, age, sex), within the same setting (youth mental health care, the youth welfare system, care for youth with MID). Within each pair one group will be randomly assigned to the intervention condition, and one group will be assigned to the TAU-condition.

Intervention

84 subjects receive 8 sessions of the program *Op Volle Kracht* (*At Full strength*; an adapted version of the Penn Resiliency Program), 84 subjects receive treatment as usual (TAU).

Description intervention program (Op Volle Kracht):

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.

Within the residential treatment settings in the Netherlands, adolescents usually reside in treatment groups of 8-10 clients each, and treatment is delivered by a permanent team of nurses and social workers. Adolescents will receive the OVK-program within these natural treatment groups and the program will be delivered by trained nurses and social workers from the team.

Study burden and risks

The burden for the subjects consists of three assessments (pre- and post-treatment, follow up) and the intervention itself consisting of 8 sessions for 45 minutes, and weekly homework tasks that take approximately 15 minutes. Adolescents and their parents are asked to report depressive symptoms and suicidal ideation; they run the risk to be faced with unexpected adverse results based on these assessments (e.g. evidence for clinical depression or anxiety, the presence of suicidal ideation). Risks and side effects of the intervention itself are not expected.

The benefit involves of the a priori chance of positive effect of the OVK intervention on symptoms of anxiety and depression, to increase adolescents emotional resilience and to prevent clinical levels of anxiety and depression. Because research shows that strategies to alter cognitive styles and to prevent depression are most effective in young adolescents, adolescent aged 12-16 years will form the target population of this study. Adolescents with mild intellectual disability are included because they are at higher risk to develop clinical levels of internalizing problems as compared to their non-disabled peers.

Contacts

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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

- Admitted to residential treatment within youth mental health care, the youth welfare system or care for youth with Mild Intellectual Dysfunction (MID)
- Age between 10;0 -16;11 years
- IQ > 65

Exclusion criteria

- Participation in another clinical intervention study simultaneously
- There are no other exclusion criteria because this study aims to examine the effectiveness of the program for all youth in residential treatment settings, under conditions as they apply to clinical practice. Two versions of the program protocol are available: a standard version for youth with average intellectual capacities, and a version adapted to the level of cognitive and social-emotional development of youth with MID.

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: | Pending |
| Start date (anticipated): | 01-09-2014 |
| Enrollment: | 168 |
| Type: | Anticipated |

Ethics review

| | |
|--------------------|--------------------------------------|
| Approved WMO | |
| Date: | 04-11-2014 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

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 | NL49211.091.14 |