

Evaluation of a grouptraining for adolescents (Emotion Regulation Training) with emotion regulation problems - a randomised controlled clinical trial.

No registrations found.

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

Summary

ID

NL-OMON22089

Source

Nationaal Trial Register

Brief title

ERT - evaluation

Health condition

64 Adolescents who followed the Emotion Regulation Training will be compared to 64 adolescents who had treatment as usual only.

Keywords:

Borderline Personality Disorder

Adolescents

Therapy

RCT

Netherlands:

Borderline persoonlijkheidsstoornis

Adolescenten

therapie

RCT

Sponsors and support

Primary sponsor: Accare University Centre for Child- and Adolescent Psychiatry Groningen, the Netherlands

Source(s) of monetary or material Support: ZonMW (project: OOG; opleiding tot onderzoeker in de geestelijke gezondheidszorg) and initiator.

Intervention

Outcome measures

Primary outcome

Primary outcome measures at baseline, directly after the training and at 6 months follow-up:

1. Severity of Borderline Personality symptoms (BPDSI-IV-adolescents, semi-structured interview) measuring the current severity and frequency of the DSM-IV BPD manifestations;
2. Life Problems Inventory (LPI, questionnaire), measuring the main symptoms of BPD.

Secondary outcome

Secondary outcome measures at baseline, directly after the training and at 6 months follow-up:

1. DSM diagnosis axis II (PDQ-4, parts of k-SADS and SCID-II);
2. mental health disorders (CDI, RAPI, SCL-90, SDQ);
3. Locus of Control (MALC-ERT);
4. Quality of Life (YQOL);
5. Raising style, parental stress and parental functioning (EMBU, PSI and GHQ);
6. Consumption of public health services;
7. global functioning (CGAS or GAF score).

Study description

Background summary

Emotional dysregulation is the main symptom of borderline personality disorder (BPD). BPD is an invalidating disorder with much impact on the patient's functioning. Self-injury and suicide attempts frequently occur. These patients pose an enormous demand on public health care, with frequent interventions and many crises. BPD is rarely diagnosed before the age of 18. Nevertheless, symptoms of BPD are often seen at a younger age and lead to significant distress in the adolescent and his or her family. Treatment at an early stage may prevent the development of a full-blown personality disorder in adulthood as well as the negative consequences related to BPD. Although there are different ways of treating adults with BPD, no effective treatment program for adolescents is available in the Netherlands.

At the outpatient clinic of Accare we developed a course for adolescents that was based on a course for adults (STEPPS, developed by Bartels, Crottie and Blum). Adolescents learn to

handle emotional dysregulation. A pilot study has currently been conducted. Thus, the practical feasibility of the course is already tested and the measures are explored. Getting control over your emotions and thoughts and taking responsibility for your own behaviour are the main goals of the Emotion Regulation Training. In the pilot study, the ERT gave a significant improvement in patient's feelings of having control over their emotions, shown by an increase on a scale measuring the locus of control.

The goal of the study is to evaluate the effectiveness of the course, to obtain information on follow-up, and to give an impuls for implementation of the course in the participating centres for mental health care.

The design is a randomised controlled clinical trial. 128 Adolescents in at least five settings for mental health care will be included and randomised into two conditions, namely 1. 17-week course + standardised (embedded) treatment as usual or 2. treatment as usual only. Assessments take place before and after the course and at one-year follow-up.

Adolescents aged 14-18 years, who were referred to mental health care centres in the North of the Netherlands, suffering from emotional dysregulation, and their parents or caretakers, will be asked to participate in the study.

ERT consists of 17 weekly group sessions (6-9 participants, 1,75 hours), one psycho-educational session with parents/caretakers and/or partners and two booster sessions, at three and six months after the weekly course. The first aim is to learn how to deal with daily stress and psychological vulnerability. Reducing self-harm or harm to others is an important issue.

After the training there will be a session with the adolescent, his or her parents or caretakers, the therapists of the training and the individual therapist, to offer good continuation in the regular treatment.

Study objective

Has the Emotion Regulation Training for adolescents a surplus value compared to treatment as usual?

Intervention

ERT consists of 17 weekly group sessions (6-9 participants, 1,75 hours), one psycho-educational session with parents/caretakers and/or partners and two booster sessions, at three and six months after the weekly course. The first aim is to learn how to deal with daily stress and psychological vulnerability. Reducing self-harm or harm to others is an important issue.

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Contacts

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Eligibility criteria

Inclusion criteria

1. Age 14-18 years;
2. Affective instability due to a marked reactivity of mood (e.g., intense episodic dysphoria, irritability, or anxiety usually lasting a few hours and only rarely more than a few days;
3. At least two other DSM-IV criteria of BPD; 4. Minimum score of 15 on the Borderline Personality Disorder Severity Index - adolescent version.

Exclusion criteria

1. Psychotic disorders (except short, reactive psychotic episodes);
2. Conduct disorder;
3. Addiction of such severity that clinical detoxification is indicated;
4. Mental retardation (IQ less than 80).

Study design

Design

| | |
|---------------------|-------------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Masking: | Single blinded (masking used) |

Control: Active

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-08-2007
Enrollment: 128
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 | NL958 |
| NTR-old | NTR984 |
| Other | : |
| ISRCTN | ISRCTN97589104 |

Study results

Summary results

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