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

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|-------------------------------|--|--|--|--|
| 23/08/2007 | | ☐ Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 23/08/2007 | Completed | [X] Results | | |
| Last Edited 31/12/2020 | Condition category Mental and Behavioural Disorders | Individual participant data | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

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

Acronym

ERT - evaluation

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multicentre, randomised, single-blind, active controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Borderline personality disorder in adolescents

Interventions

ERT consists of 17 weekly group sessions (6 to 9 participants, 1.75 hours), one psychoeducational 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.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Primary outcome measures at baseline, directly after the training and at six months follow-up: 1. Severity of Borderline Personality symptoms (Borderline Personality Disorder Severity Index for adolescents, fourth version [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 measures

Secondary outcome measures at baseline, directly after the training and at six months follow-up: 1. DSM diagnosis axis II (Personality Diagnostic Questionnaire [PDQ-4], parts of kiddie-Schedule for Affective Disorders and Schizophrenia [k-SADS] and Structured Clinical Interview for DSM-IV [SCID-II])

- 2. Mental health disorders (Child Depression Inventory [CDI], Rutgers Alcohol Problems Index [RAPI], Symptom Check List [SCL-90], Strengths and Difficulties Questionnaire [SDQ])
- 3. Locus of Control (Multidimensional Anxiety Locus of Control scale [MALC-ERT])
- 4. Quality of Life (Youth 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)

Overall study start date

01/08/2007

Completion date

01/10/2010

Eligibility

Key inclusion criteria

- 1. Aged 14 to 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 Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV) criteria of Borderline Personality Disorder (BPD)
- 4. Minimum score of 15 on the Borderline Personality Disorder Severity Index adolescent version

Participant type(s)

Patient

Age group

Child

Lower age limit

14 Years

Upper age limit

18 Years

Sex

Not Specified

Target number of participants

128

Total final enrolment

109

Key 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 (Intelligence Quotient [IQ] less than 80)

Date of first enrolment

01/08/2007

Date of final enrolment

01/10/2010

Locations

Countries of recruitment

Netherlands

Study participating centre University Medical Centre Groningen (UMCG)

Groningen Netherlands 9700 AR

Sponsor information

Organisation

Accare (The Netherlands)

Sponsor details

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Sponsor type

Research organisation

Website

http://www.accare.nl/

ROR

https://ror.org/02h4pw461

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/12/2012 | 31/12/2020 | Yes | No |