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Evaluation of a group training for adolescents (emotion regulation training) with emotion regulation problems

Submission date
19/12/2005

Recruitment status
No longer recruiting

Registration date
19/12/2005

Overall study status
Completed

Last Edited
13/06/2014

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.accare.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1558; NTR356

Study information

Scientific Title

Study objectives
Adolescents with emotion regulation problems who followed the emotion regulation training will show improvement on the following items:
1. Symptoms of emotional dysregulation
2. Positive and negative coping behaviour
3. Stress symptoms in the adolescent
4. Stress symptoms in the parents (or care-takers)
5. Consumption of public health services
Compared to a waitlist control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

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)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Psychiatric, mental disorders/illness, borderline personality disorder

Interventions
The emotion regulation training (ERT) is a skills training (17 weekly sessions of 1.75 hours as well as one session for significant others) based on psycho-education, cognitive behavioural principles, and exercises for relaxation.

Care as usual generally includes individual sessions with the adolescent and medication checks, sometimes combined with family sessions, crisis intervention or parent training.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Borderline Personality Disorder Severity Index (BPDSI and BPDSI - parent version): a semi-structured interview based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) classification of psychopathology. Trained psychologists will conduct this semi-structured interview.
2. VERS-scale: to measure negative as well as positive behaviour in a certain period. This questionnaire is to be completed by the adolescent as well as the parents.

Secondary outcome measures
Questionnaires completed by the adolescents as well as the parents:
1. Frequency list of Emotion Regulation Problems (F-ERP)
2. Global Assessment of Functioning (GAF): present level of functioning (axis V of DSM-IV)
3. MALC-ERT: list of 18 items to draw up an inventory of cognitions on emotional dysregulation (locus of control)
4. Child Behaviour Checklist (CBCL): consists of 118 items describing a wide domain of behaviour problems of children

Questionnaire only to be completed by parents:
Nijmeegse Ouderlijke Stress Index (NOSI; Parental Stress Index): to measure stress in parents (124 items)

Questionnaire only to be completed by the adolescent:
Healthcare consumption: a short list to be completed weekly during the training, about different types of healthcare being used in the last week (e.g. primary healthcare, emergency rooms, crisis contact psychiatry department).

Overall study start date
01/06/2005

Completion date
01/09/2006

Eligibility

Key inclusion criteria
1. Age 14 - 18 years
2. Emotion regulation problems
3. Some self-awareness
4. Sufficient internal motivation
5. Willing to share his or her experiences in a group
6. Environment is rather stable

7. Capable to join a group-session without aggressive behaviour
8. No substance abuse and self-mutilating behaviour during the session

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
If the adolescent does not meet the inclusion criteria.

Date of first enrolment
01/06/2005

Date of final enrolment
01/09/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
Groningen
Netherlands
9700 AR

Sponsor information

Organisation
University Medical Centre Groningen (UMCG) (Netherlands)

Sponsor details

Hanzeplein 1
Groningen
Netherlands
9713 GZ

Sponsor type
Hospital/treatment centre

Website
http://www.umcg.nl/azg/nl/english/azg/

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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	01/11/2009		Yes	No