ISRCTN97589104 https://doi.org/10.1186/ISRCTN97589104

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

Submission date
23/08/2007

Recruitment status
No longer recruiting

Registration date
23/08/2007

Overall study status
Completed

Last Edited
31/12/2020

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

Contact information

Type(s)
Scientific

Contact name
Dr H.M. Schuppert

Contact details
University Medical Centre Groningen (UMCG)
Department of Psychiatry
P.O. Box 30001
Groningen
Netherlands
9700 AR
-
m.schuppert@accare.nl

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 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.

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
Division University Centre for Child and Adolescent Psychiatry
P.O. Box 660
Groningen
Netherlands
9700 AR
+31 (0)50 361 0973
info@accare.nl

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