E-TRAIN: Internet-based emotion regulation training in adolescents with depressive and anxiety disorders.

No registrations found.

Ethical review   Positive opinion
Status   Recruiting
Health condition type -
Study type   Interventional

Summary

ID

NL-OMON26632

Source
NTR

Brief title
E-TRAIN

Health condition

Depression
Anxiety
Emotion regulation
Psychiatric disorders

Sponsors and support

Primary sponsor: Arkin Amsterdam
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Acceptability and feasibility of add-on ERT training and trial design
Quantitative data:
- Patient satisfaction with ERT training (modified version of the Client Satisfaction Questionnaire; CSQ-8) (T2, 6 months after baseline)
- Intervention uptake of both CBT and ERT, based on electronic patient record registrations and online intervention data. We will register the compliance (i.e., amount of completed sessions) for both CBT and ERT, as well as the amount of no shows (for CBT), and the reasons for termination of treatment (for CBT and ERT).
- Recruitment and refusal rates, retention rates, follow-up rates of all outcome measures of both patients and their parents.
- Therapist satisfaction with internet module (System Usability Scale)
Qualitative data:
- Qualitative evaluation of ERT training by respondents in focus groups
- Adolescent patients preferences regarding add-on e-health interventions
- Evaluation of feasibility for therapists to guide participants through the add-on ERT training in focus groups

Secondary outcome

Patients

Depressive symptoms
- Dutch version of the Children's Depression Inventory, second edition. The primary endpoint for patients with a primary depressive disorder is the level of depressive symptoms (continuous variable) at T2 (6 months after baseline).

Anxiety symptoms
- Screen for Child Anxiety Related Emotional Disorders. The primary endpoint for patients with a primary anxiety disorder is the level of anxiety symptoms (continuous variable) at T2.

- Emotion Regulation (Feel KJ) (T0, T1, T2)

- Behavioural competency and problems (Youth Self-report Scale, Child version)* (T0, T2)
*To reduce workload for participants, only the subscale "Internalizing problems" will be used.

Parent/caregivers
- Behavioural competency and problems (Child Behaviour Checklist List, Parent version) (T0, T2)
- Depressive symptoms of patient (CDI-2 parent version) (T0, T1, T2)
- Anxiety symptoms of patient (SCARED parent version) (T0, T1, T2)

Therapists
- Clinician's view of the patient's global functioning and improvement (Clinical Global Impressions scale; CGI) (T0, T1, T2)

Study description

Background summary

Depressive and anxiety disorders are highly prevalent among adolescents. Research suggests emotion dysregulation to play an important role in this critical developmental phase. Given the important role of emotion regulation in the development and duration of depressive and anxiety disorders, we hypothesize that enhancing regular treatment for these disorders with an internet-based emotion regulation training may reduce depressive and anxiety symptoms.
The primary aim of the proposed study is to examine the acceptability and feasibility of an add-on internet-based emotion regulation training investigated in a randomized controlled trial (RCT) in adolescents with depressive and anxiety disorders and their therapists. Second, this study aims to provide a first estimate of the effectiveness of CBT + ERT in reducing depressive and anxiety symptoms against CBT alone in adolescent patients (aged 13-18) with depressive or anxiety disorders, in preparation of a future, larger RCT.

Study objective

Anxiety and depressive disorders are common in children and adolescents. Given the high prevalence and detrimental effects of anxiety and depressive disorders in adolescents, it is of utmost importance to gain insight into potential mechanisms underlying these disorders in this vulnerable group. Research suggests emotion dysregulation to play an important role in this critical developmental phase. Given the important role of emotion regulation in the development and duration of depressive and anxiety disorders, we hypothesize that enhancing regular treatment for these disorders with an internet-based emotion regulation training may reduce depressive and anxiety symptoms.
The primary aim of the proposed study is to examine the acceptability and feasibility of an add-on internet-based emotion regulation training investigated in a randomized controlled trial (RCT) in adolescents with depressive and anxiety disorders and their therapists. Second, this study aims to provide a first estimate of the potential effectiveness of CBT + ERT in reducing emotion regulation difficulties, depressive symptoms, and anxiety symptoms against CBT alone in adolescent patients (aged 13-18) with depressive or anxiety disorders, in preparation of a future, definitive RCT.

Study design

T0: Baseline (0 months)
T1: 3 months after baseline
T2: 6 months after baseline

Intervention

Intervention: An internet-based Emotion Regulation Training that consists of 6 sessions, with guidance by a trained ER therapist will be added to treatment as usual (cognitive behavioural

therapy).

Control intervention: regular Cognitive Behavioral Therapy.

Contacts

Public
Arkin
Marike Wisman

06-29388853
Scientific
Arkin
Marike Wisman

06-29388853

Eligibility criteria

Inclusion criteria

(1) Primary diagnosis of depressive disorder or anxiety disorder;

(2) Enrolling for cognitive behavioural therapy at Arkin Jeugd & Gezin in Amsterdam;

(3) Age 13-18 years;

(4) At least moderately proficient in Dutch;

(5) Regular access to a computer, tablet or mobile phone with internet connection;

(6) Informed consent regarding study participation provided by the participant, and in case the patient is <16 years, both parents.

Exclusion criteria

(1) Current psychotic disorder;

(2) Acute suicidal behavior;

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-09-2019
Enrollment:	64
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	14-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48366
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8304
CCMO	NL69405.100.19
OMON	NL-OMON48366

Study results

Summary results
N/A