Internet-based emotion-regulation training in adolescents with depressive and anxiety disorders: a pilot randomized controlled trial of its feasibility and acceptability.

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Primary Objective: - To examine the acceptability and feasibility of an add-on internet-based ERT training and the trial design in adolescent patients (aged 13-18) with depressive or anxiety disorders, their parents, and their therapists as...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48366

Source
ToetsingOnline

Brief title
Depression and anxiety in adolescents: online emotion-regulation training

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
anxiety, Depression, mood disorder

Health condition

angststoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Arkin (Amsterdam)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: adolescents, depressive and anxiety disorders, e-mental health, emotion regulation

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)

- 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

We will conduct a focus group with a random sample of 12 participants of the experimental condition to examine the acceptability of the internet-based ER training. Qualitative research methods aimed at analyzing focus groups will be used; audio tapes will be separately analyzed by two researchers. To motivate participants for these focusgroups every participant will receive a reward of ¤25,- (bol.com voucher). A similar focusgroup will be organized will all therapists that used the ERT-intervention.

Secondary outcome

Patients

- Depressive symptoms

Depressive symptoms will be measured with the Dutch version of the Children*s Depression Inventory, second edition (Bodden, Braet, & Stikkelbroek, 2016). A CDI-2 cut-off score of 16 is indicative of *significant* depressive symptoms according to the Dutch Mental Health Care guideline (Buitelaar et al., 2009: Multidisciplinaire Richtlijn GGZ, Addendum Depressie bij Jeugd, 2009). Patients will fill in this questionnaire at T0, T1, and T2. The primary endpoint for patients with a primary depressive disorder is the level of depressive symptoms (continuous variable) at T2. The continuous primary outcome measures are depressive symptoms (as measured with the CDI-2) and anxiety symptoms (as

measured with the SCARED) at T2.

- Anxiety symptoms

Anxiety symptoms will be measured with the Screen for Child Anxiety Related Emotional Disorders (SCARED; Muris, Bodden, Hale, Birmaher, & Mayer, 2007). With the SCARED it is possible to assess different anxiety disorders, according to the DSM-IV (Hale et al., 2009). The questionnaire distinguishes between panic disorder, separation anxiety, specific phobia (animal type, medical type, and situational type), social phobia, obsessive-compulsive disorder, posttraumatic stress disorder, and general anxiety. The total score of the SCARED ranges between 0 and 207. Both the child and parent version have been demonstrated to have good psychometric properties and clinical relevance (Runyon et al., 2018). Patients will fill in this questionnaire at T0, T1, and T2. 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)

Other study parameters

- Demographic characteristics (T0)

- Treatment expectation (T0)

Study description

Background summary

Anxiety and depressive disorders are common in children and adolescents (Merikangas, Nakamura, & Kessler, 2009; Patel, Flisher, Hetrick, & McGorry, 2007). Among youths aged younger than 18 years, global prevalence rates are estimated at 6.5% for anxiety disorders and 2.6% for depressive disorders (Polanczyk, Salum, Sugaya, Caye, & Rohde, 2015). Prevalence of mental disorders further increases during the transition from childhood to adolescence (see Costello, Copeland, & Angold, 2011, for a review), with prevalence rates estimated at 10.7% for anxiety disorders and 6.1% for depressive disorders in adolescents aged between 12 and 19 years (Costello et al., 2011). During adolescence, many mental disorders manifest for the first time (Lee et al. 2014; Patel et al., 2007). Sub threshold symptoms of anxiety and depression are prevalent in adolescents as well: in a large European sample of adolescents aged 14-16 years from 11 countries, 32% were sub threshold-anxious and 29.2% were sub threshold depressed - with a higher prevalence for each additional year (Balász et al., 2013). Both full-blown and subthreshold depressive and anxiety disorders are more prevalent in girls than in boys (Hyde, Mezulis, & Abrahamson, 2008; Balasz et al., 2013; Costello et al., 2003). The increased prevalence in girls appears to develop after the age of 14 (Wade, Cairney, & Prevalin, 2002).

Anxiety and depressive disorders negatively impact adolescents* social functioning and educational achievements (Essau, Conradt, & Petermann, 2000; Fletcher, 2010), employment rates (Jaycox et al., 2009; Keenan-Miller, Hammen, & Brennan, 2007), nicotine dependence (McKenzie, Olsson, Jorm, Romaniuk, & Patton, 2010) and general health (Keenan-Miller et al., 2007). In addition, childhood anxiety and depressive disorders predict a range of mental health problems in adulthood, including anxiety, depression, bipolar disorders, and substance-use (Copeland, Shanaham, Costello, & Angold, 2009; Fergusson & Woodward, 2002; Ferdinand, Blüm, & Verhulst, 2001; Merikangas et al., 2010; Wolitzky-Taylor et al., 2014). Moreover, these disorders are associated with an increased risk of suicide (Hawton, Saunders, & O'Connor, 2012): the second most prevalent cause of death in adolescents (Patton et al., 2009). 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. Therefore, this proposed study aims to examine the acceptability and feasibility of an add-on emotion regulation training. Second, this study aims to provide a first estimate of the potential effectiveness of adding an internet-based emotion regulation training to regular treatment in a randomized controlled trial.

Adolescence is a critical phase for the development of mental disorders (Lee et al., 2014); in general, the important developmental period of adolescence is characterized by large endocrinological and socio-emotional changes that coincide with more frequent experiences of negative emotions (Spear, 2000; Zeman, Cassano, Perry-Parrish, & Stegall, 2006). Compared to early childhood, adolescence comes with increasingly intense and instable emotions and stress (Dahl, 2001; Ahmed, Bittencourt-Hewitt, & Sebastian, 2015). Therefore, adolescence is an essential phase in the development of adaptive emotion regulation skills - increasingly without the aid of parents - and adolescents are at risk for dysfunctional emotion regulation (Zeman et al., 2006; Ahmed et al., 2015; Steinberg & Avenevoli, 2000). Emotion regulation refers to *the processes responsible for monitoring, evaluating, and modifying emotional reactions, especially their intensive and temporal features, to accomplish one*s goals* (Thompson, 1994, pp. 27-28). Emotion regulation difficulties particularly appear to develop at the age of 12-15, and are an important precursor of subsequent development of mental health problems (Cracco, Goossens, & Braet, 2017). Research suggests that the characteristics and impact of emotion regulation differs between adolescent boys and girls (Nolen Hoeksema, 2012; Stikkelbroek, Bodden, Kleinjan, Reijnders, & van Baar, 2016).

Study objective

Primary Objective:
- To examine the acceptability and feasibility of an add-on internet-based ERT training and the trial design in adolescent patients (aged 13-18) with depressive or anxiety disorders, their parents, and their therapists as preparation of a future, definitive trial. Therefore, we will:

1. Assess the acceptability and feasibility of the add-on ERT-intervention, in terms of both quantitative and qualitative evaluation by patients and their therapists (using questionnaires and focus groups).
2. Assess the preferences of adolescent patients with depressive and anxiety disorders regarding add-on e-health interventions (using questionnaires and focus groups).
3. Determine study recruitment, refusal and retention rates (i.e., how many eligible respondents consent to participate in the study, how many parents consent with the participation of their child and themselves, what are follow-up rates of patients and parents at the 3 month and 6 month follow-up assessments, and what are reasons not to participate with the study or not to complete one or more assessments?).
4. Determine treatment adherence and drop-out rates (i.e., how many treatment sessions will participants allocated to ERT complete, and how many participants will drop-out of treatment?).
5. Examine whether the eligibility criterium regarding age (13-18 years) is too broad or too narrow in terms of both recruitment rates and acceptability of the intervention
6. Assess the acceptability and feasibility of the outcome measures as methods to measure efficacy of the interventions within a future, definitive trial in both participants and their parents.
7. Assess the feasibility for therapists to guide participants through the add-on ERT intervention, and to determine which problems they may experience in the procedures for delivering the intervention (i.e., time-management, giving feedback on pre-agreed moments, motivate participants)

Secondary Objective:
- To provide a first estimate of the potential effectiveness of CBT + ERT in reducing emotion regulation difficulties, depressive symptoms, anxiety symptoms, and internalizing symptoms against CBT alone in adolescent patients (aged 13-18) with depressive or anxiety disorders, including completion rates, missing data, estimates, variances and 95% confidence intervals for both between-group and within-group (i.e., pre-post) differences.

Study design

A 2-arm randomized controlled trial with a parallel group design, comparing effects of CBT + ERT vs. CBT in adolescents with depressive and anxiety disorders. Follow-up assessments will take place at 3 and 6 months after the baseline assessment.

Randomization will be carried out after completion of the baseline assessment. Randomization of participants will be performed by an independent datamanager of the Arkin Research Department, who is not involved in the research project, nor involved in providing any kind of mental health care. Randomization will take place at an individual level, stratified by primary disorder (anxiety disorder or depression) using a computer-generated block randomization

schedule. To ensure that an equal number of patients will be allocated to CBT and CBT + ERT, the allocation ratio will be 1:1. To prevent selection bias, researchers will be blind to block size and order, and will not have access to the randomization schedule. Due to the nature of treatments, blinding of participants, parents, and therapists to treatment condition is not applicable. Since all other measures concern web-based questionnaires that are filled out by the participants themselves, double data entry procedures are not applicable.

Intervention

ERT consists of 6 online sessions of 25 minutes. These will be combined with 2 face-to-face sessions, resulting in a so-called blended treatment. The study will make use of the online Therapieland platform: a e-mental health platform for youths that meets all technical demands and guidelines with regard to privacy and data security, such as EN 7510. The ERT program includes various (interactive) methods such as videos with psycho-education, exercises, chat functions, and a library with relevant YouTube videos. Patients will be guided by a trained clinical or health youth psychologist. After each online session, these psychologists will provide feedback and guidance using secured email within the online platform. One face-to-face session will be scheduled at the start of ERT, in order to make patients acquainted with their psychologist, and vice versa, and to determine treatment goals. A second face-to-face session will be scheduled halfway to monitor the patient's progress. Based on the patient's preference, the 6 sessions of ERT can be completed on a weekly or biweekly schedule; hence, ERT will be completed in 6 to 12 weeks. The content of the program is based on existing face-to-face ER interventions for children and adolescents (Southam-Gerow, 2014). The intervention comprises three core elements of ER: 1) emotional awareness, 2) emotional comprehension, and 3) emotion regulation. With emotional awareness, adolescents will learn to identify emotions in themselves and others, and how emotions can be expressed in adaptive and maladaptive ways (including facial expressions, body language, and communication techniques). Additionally, they will learn to focus on their emotions, and to evaluate their characteristics and intensity. Emotional comprehension intends to increase the adolescents' knowledge about their own emotions and the situations that cause them. Also, patients will learn which helpful and unhelpful behavioral tendencies are triggered by their emotions, and how they can cope with these tendencies. Emotion regulation focusses on gaining control of difficult emotions, expressing emotions in helpful ways, and learning behavioral strategies that help coping with emotions. Patients will learn various skills to manage and regulate emotions (e.g., by discussing/ writing about them, taking time-outs, relaxation, and movement).

Study burden and risks

Burden:

Subjects will have to invest time when participating in this study. Subjects in the experimental condition will need too invest more time than subjects in the control condition. On the other hand, they will participate in an extra intervention of which we assume that it improves emotion regulation skills and reduces anxiety and depression symptoms.
Participants in both conditions will complete questionnaires at baseline, 3 months, and 6 months after randomization.

Risks:
There are no anticipated risks involved in participating in this research. Patients in both the control and experimental condition receive treatment-as-usual.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

1) Primary diagnosis of depressive disorder or anxiety disorder according to DSM-5 criteria
2) Indication for CBT at Arkin Jeugd&Gezin
3) Age 13-18 years
4) Regular access to a computer, tablet or mobile phone with internet connection
5) Informed consent regarding study participation provided by the participant, and in case patient is <16 years, both (authoritative) parents.

Exclusion criteria

1) Psychotic disorder according to DSM-5 criteria
2) Acute suicidal behavior
3) Insufficient understanding of the spoken and written Dutch language
4) Substance dependency that requires treatment

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-09-2019
Enrollment:	64
Type:	Actual

Ethics review

Approved WMO Date:	16-08-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-11-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26632
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL69405.100.19
OMON	NL-OMON26632