Cognitive-behavioral therapy for depression in youths

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One of the recommendations of NICE for future research is comparing the effects of various psychological treatments for depression in youths. In particular, there is a need for studies in which parents are involved in the treatment (Birmaher et al...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Psychiatric disorders
Study type	Interventional

Summary

ID

NL-OMON31391

Source
ToetsingOnline

Brief title
CBT for depression in youths

Condition

- Psychiatric disorders

Synonym
Depressive disorder, dysthimic disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cognitive-behavioral therapy, Depression, Emotion coaching, Youths

Outcome measures

Primary outcome

All participants will complete a basline meeting, a measurement after treatment has completed, and two follow-up measurements (three months and six months after treatment completion). The following questionnaires will be completed:
The Anxiety Disorder Interview Schedule (ADIS; Siebelink & Treffers, 2001) is a semi-structured interview assessing anxiety and depression, which is administered by the research assistant during the baseline measurement (only if it has not already been administered during the intake procedure). During the measurement after treatment has completed, only the diagnoses that at baseline will be re-assessed. The ADIS is not administered during the follow-up measurements. The following outcome measures are to be completed during all measurements:
Th Children's Depression Inventory (CDI; KOvacs, 1981) is used to measure depressive symptomatology and consists of 27 items which contains three statements (e.g., Sometimes I am sad; I am very often sad; I am always sad) of which one has to be picked. The trait version of the State Trait Anxiety Inventory for Children (STAI-C; Spielberger, 1973) is used to investigate whether additional symptoms of anxiety will also be reduced as a result of the depression treatment. The STAI-C consists of 20 items (e.g., I am afraid that I might do things wrong) that are rated on a three-point scale (almost never, sometimes, often).

In addition to these primary outcome variables, a number of process variables are included. The Self-Perception Profile for Children (Competentiebelevingsschaal in Dutch, Muris et al., 2003) is used to assess (changes in) self-esteem in different domains of life. This questionnaire contains 36 items. Respondents have to choose between two statements (e.g., Some children are very good at their schoolwork vs. Other children sometimes worry about whether they do their schoolwork well). For each item, respondents indicate whether the statement is entirely true or a little true. To measure changes in social skills, the Social Skills Rating System (SSRS; van der Oord et al., 2005) is used. The SSRS consists of 34 items (I easily make friends) that are rated on a three-point scale (never, sometimes, often). To assess changes in negative thoughts about the self, the world, and the future, the Cognitive Triad Qestionnaire will be used (CTRK; Timbremont & Breat, 2006). Teh CTRK consists of 36 items (I have lots of talents and skills) that are rated on a seven-point scale (fully agree to fully disagree).

Both parents and the child complete a measure of rearing styles for which the Egna Minnen Betraffende Uppfostran (EMBU; Castro et al., 1993) will be used. The EMBU consists of 40 items that tap rearing styles that are directly related to the concept of emotion coaching. With respect to the expected load, the ADIS interview will take about 45 mintues and the remaining questionnaires will take another 45 mintues. For parents, completion of the EMBU will take about 10 minutes.

Secondary outcome

not applicable.

Study description

Background summary

Depression is one of the most common psychological disorders in children and adolescents. Prevalence rates vary between 2% and 8% (AACAP, 1998; Birmaher e.a., 1998; De Wit & Kroesbergen, 1992). Cumulative prevalence rates are about 35% for females and 19% for males at the age of eightteen (Lewinsohn & Clarke, 1999). These numbers plea for the development of effective treatments of depression in youths. In 2005, the National Institute for Clinical Excellence (NICE) has produced guidelines with respect to psychological treatments of depression in children and adolescents (see for a summary Murray & Cartwright-Hatton, 2006). According to these guidelines, cognitive-behavioral therapy (CBT), interpersonal psychotherapy, and short-term family therapy are among the evidence-based treatents, which have proven its effectiviness in randomized controlled trials for moderate to severe depression in children and adolescents.

CBT in children and adolescents can be divided into an operant part and a cognitive part. The operant part of the treatment is inspired by the work of Lewinsohn et al. (1984) as well as of Martell et al. (2001), and consists of gradual increase of pleasurable and satisfying events, excercising social skills, and teaching problem-solving techniques. The content of the cognitive part is less strictly defined in the literature. In many protocols, negative automatic thoughts are traced and challenged by the therapist according to the methods described by Beck et al. (1979). Additionally, elements form rational emotive therapy (Ellis, 1962) and increasing coping skills are subsumed under the heading 'cognitive'.

Research aimed at examining the effectiviness of CBT for depression in children and adolescents has started in the eighties by means of case studies (see for example Frame et al., 1982; Petti et al., 1980). These case studies were the first step towards randomised controled studies examining the effectiveness of CBT in children and adolescents (see for example Reynolds & Coats, 1986; Stark et al., 1987; Lewinsohn et al., 1990; Lerner & Clum, 1990; Kahn et al., 1990; Vostanis et al., 1996; Wood et al., 1996). A meta-analsis in which the aforementioned studies are included showed a medium effect size (d=0.68) in reducing symptoms of depression in chilren and adolescents and that long-term effects are favorable (Reneicke et al., 1998). The effectiviness of CBT can be increased by involving the parents in the treatment.

Study objective

One of the recommendations of NICE for future research is comparing the effects of various psychological treatments for depression in youths. In particular,

there is a need for studies in which parents are involved in the treatment (Birmaher et al., 1996; Kaslow & Racusin, 1994). This research proposal is a pilot study (in preparation to a multi-centre trial), in which individual cognitive therapy for the child is compared to individual cognitive therapy for the child added by emotion coaching of the parents (Gottman, 1997). The most important primary goals of this study are to finetune both treatment protocols on the basis of experiences from therapists and to compute an effect size of both treatments in order to be able to conduct a power calculation for the multi-center trial. In addition, the secundary goal of this study is to evaluate the reduction in depressive symptoms as well as to evaluate the role of some important process variables. These evaluations will be done in a descriptive way (will not be statistically tested) due to the limited numbers of participants.

Study design

This study is an intervention study in which youths aged between 10 and 17 diagnosed with depressive disorder are randomly allocated to indidivual CBT or individual CBT with emotion coaching of the parents. Random allocation to each of the two treatment arms is done after participants have received information and signed the consent form. As this study examines the added effect of emotion coaching, and the effectiveness might depend on the age of the child, we choose to stratify on age. Youths are divided in two groups: 10 to 12 and 13 to 17 years old. Within these strata, randomisation to either of the two treatment arms occurs. In all participants, a baseline measurement, measurement after treatment is completed as well as two follow-up measurements will take place.

Intervention

The construction of individual CBT is derived from the treatment protocol used in adults (Boelens, 2004). The CBT is adapted to the perception of the environment of children and adolescents. The CBT consists of 12 sessions with the child in which the first six sessions are devoted to operant techniques (increase pleasurable activities, exercising social skills), whereas the remaining six sessions are devoted to cognitive techniques according to the method of Beck (Beck et al., 1979), in which negative automatic thoughts are being traced and challenged in a way that suits children and adolescents. In the protocol, there is also room for tracing and challenging anxious cognitions. The end of the treatment is focused on the prevention of relapse. Parents are seen three times during the treament: sessions one, six and twelve (last session).

For emotion coaching, parents are seen four times apart form their child (in addition to the three times in the CBT protocol). These four sessions are devoted to emotion coaching. In the first session, a meta-emotion interview takes place with the purpose of letting parents become aware of their own

emotions. In the remaining sessions, parents learn how to respond to the emotions of their child (anxiety, depressed mood, and anger). Whit the approval of the child and the parents, all sessions are taped so that treatment adherence can be examined. Every session has homework. Both CBT and emotion coaching have been carefully checked by a group of well experienced therapist.

Study burden and risks

The burden is minimal and risks are neglectable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

* Primary diagnosis of major depressive disorder or dysthymic disorder
* Age between 10 - 17
* IQ > 80
* Being able to speak, read and understand the Dutch language
For parents, inclusion will take place when permission is given for their child and the parents themselves to participate in this study and in the case that they will be able to sufficiently speak, read and understand the Dutch language.

Exclusion criteria

* Depression with psychotic features or psychotic decompensation
* Mentally retarded

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	19-07-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL17507.068.07