Effectiveness and cost effectiveness of a Cognitive Behavioral Therapy (CBT) program in clinically depressed adolescents; individual CBT versus care as usual.

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The aim of this study is to investigate the effectiveness and the cost-effectiveness of the individual CBT program the *D(o)epressie cursus* by means of the following hypotheses;1. Is the individual CBT program the *D(o)epressie cursus* more...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON36268

Source
ToetsingOnline

Brief title
SAD, Study Adolescent Depression

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, Depressive Disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Zonmw Zorg voor Jeugd

Intervention

Keyword: CAU, CBT, cost-effectiveness, Depression, RCT

Outcome measures

Primary outcome

The primary outcome measure is the presence of the depression diagnosis (present or absent) measured by means of a diagnostic interview the K-SADS. Both the adolescent, the parent and the clinician view will be taken into account.

Cost effectiveness

Cost diaries will be assessed to monitor costs and cost-effectiveness. These cost diaries have been used in an earlier study on anxiety (Bodden, Dirksen & Bögels, 2008) and will be complemented by parts of the TiC-P and the PRODISQ. The QALY will be calculated by means of the EuroQol.

Secondary outcome

Secondary outcome measures are:

1. degree of depressive symptoms (CDI, adolescent and parent version)

2. severity of the depression (K-SADS, adolescent, parent and therapist view)

3. suicide risk taxation

4. comorbidity/psychopathology (YSR and CBCL, adolescent and parent version)

5. quality of life (EuroQol, adolescent and parent version)

6. life events (including drug abuse, maltreatment and suicide attempts)

7. depression parents (BDI)

8. psychopathology parents (ASR)

9. parenting (scales from the NOV, APQ, PDI, VTH en PDI)

10. Attachment (PARA)

Moderators

Moderators that will be investigated are demographic characteristics such as gender, age, ethnicity, education level and family income. Besides, comorbidity (YSR and CBCL), severity of the depression (K-SADS), psychopathology of parents (ASR) and depression in parents (BDI) will be taken into account as moderators.

Mediators

The following mediators will be studied in this research; negative automatic thoughts (CATS), cognitive emotion regulation (CERQ) and attribution style (CASQ).

Non-specific treatment variabeles

Non-specific treatment variables that will be investigated are; client expectancy of treatment, treatment adherence, satisfaction with treatment, cooperation with treatment, relationship with therapist, treatment integrity.

Study description

Background summary

Title of the study
Effectiveness and cost effectiveness of a Cognitive Behavioral Therapy (CBT) program in clinically depressed adolescents; individual CBT versus care as usual.

Background of the study
Depressive disorders in adolescents is an important health problem and are (combined with anxiety disorders) one of the most prevalent disorders in adolescence. The year prevalence of depressive episodes among youngsters between 13 and 17 years of age is 2,8% (Verhulst et al., 1997). Before entering adulthood, 14 to 25% of the adolescents has experienced one episode of a depressive disorder (Ryan, 2005). Besides the high prevalence, 40 to 90% of the depressed adolescents has a co morbid disorder such as anxiety (25%), OCD (15%), and ADHD or behavioural disorders (25-40%) (Depressie richtlijn, 2009). Even more, there is a heightened risk of developing social problems, juridical problems, learning problems, substance abuse, negative life events, physical problems, teen pregnancies en suicide (Ryan, 2005; Portzky & van Heeringen, 2009). Depressive disorders in 15 to 24 year olds are in the top-3 of diseases with the highest burden of disease expressed in DALY*s (Hoeymans et al., 2006). Depressive disorders are usually chronic disorders with a high risk of recidivism. Therefore it is important that depression is treated in an early stage with an effective treatment (Ryan, 2005).
In the international literature, there is no consensus on the degree of effectiveness of psychotherapeutic interventions in depressed adolescents. In a meta-analysis, only a modest effect size of 0.34 was found (Weisz et al., 2006). Partially this can be explained by the large diversity of the investigated interventions (prevention to intervention) and the differences in the severity of the depression at pre-treatment (symptom level to diagnosis). Other meta-analyses focussed on psychotherapeutic interventions found effect sizes of respectively 0.72 (Michael & Crowley, 2002) and 1.27 (Lewinsohn & Clarke, 1999). In a meta-analysis solely directed at Cognitive Behavioural Therapy (CBT) an effect size of 0.53 was found (Klein et al., 2007).
Until recently there is no evidence based intervention available for depressive disorders in adolescents in the Netherlands. In the past few years, the focus has been directed at prevention of depressive symptoms with programs like *Grip op je dip* en *Head Up*. Both programs are not (yet) evidence based and not suitable for clinically depressed adolescents. A CBT program that is indeed suitable for this study population is the *D(o)epressiecursus* (translation; D(o)epression course)* (Stikkelbroek, Bouman, & Cuijpers, 2005). This intervention is frequently used in clinical practice. The *D(o)epressiecursus* is a revision of the *Coping with depression course for Adolescents (CWD-A)* (Clarke et al., 1990). The CWD-A is often investigated by means of

RCT*s in an American population and results repeatedly show that the CWD-A is more effective than care as usual (Clarke et al., 1995; Clarke et al., 2001; Clarke et al., 2002). Because the CWD-A was only investigated by one research Group, it is regarded as probably efficacious (David-Ferdon & Kaslow, 2008).
The effectiveness of the *D(o)epressiecursus* has not been investigated yet. However the databank effective interventions by the Dutch Youth Institute (NJI) has labelled the *D(o)epressiecursus* as theoretically well founded. Besides the guideline depression in youth (Depressie Richtlijn, 2009) recommends the *D(o)epressiecursus* as psychotherapeutic intervention of choice in depressed adolescents. In this study the effectiveness of the individual CBT program the *D(o)epressiecursus* will be investigated by comparing it to care as usual.
The costs of depression in adolescents have not been studied before. A recent cost-of-illness study on children with anxiety disorders shows that both the costs of school absence as productivity loss of the parents are substantial (Bodden et al., 2008). Given the high degree of comorbidity of anxiety and depression and the fact that both disorders are among the internalising disorders, the same high costs are expected in adolescents with depression.
Lynch and colleagues (2005) investigated the cost-effectiveness of a group based prevention course *Coping with Stress* in adolescents with a subclinical depression. It was concluded that group CBT was more cost effective in comparison to care as usual. However, intervention related costs like productivity costs expressed as school absence were not taken into account. These costs will be included in this study.
Within intervention research in depressed adolescents, little is known about possible moderators and mediators of treatment. A lot of authors mention the necessity to investigate these variables (David-Ferdon & Kaslow, 2008; Weisz et al. 2006). Therefore, moderators and mediators will be investigated in this research.

Study objective

The aim of this study is to investigate the effectiveness and the cost-effectiveness of the individual CBT program the *D(o)epressie cursus* by means of the following hypotheses;
1. Is the individual CBT program the *D(o)epressie cursus* more effective than care as usual (without CBT)?
2. Is the individual CBT program the *D(o)epressie cursus* more cost-effective than care as usual (without CBT)?
3. What is the cost-of-illness of clinical depression in adolescents?
4. Which moderators (comorbidity, severity of depression, age, ethnicity, gender, suicidal thoughts and psychopathology in parents) influence the effectiveness of CBT?
5. Which mediators (negative automatic thoughts, cognitive emotion regulation and attribution style) influence the effectiveness of CBT?
6. Do non-specific treatment variables such as therapeutic alliance, client expectancy, client satisfaction and treatment adherence influence effectiveness

of CBT?

Study design

This research includes a multi-center and randomized clinical trial. Within the participating institutions, adolescents with a clinical depression will be assigned at random into either treatment group (D(o)epressie cursus) or control group (care as usual without CBT). Clients will be recruited via First and second order Mental health care institutions. An intake procedure and a diagnostic procedure are executed for each client. If the adolescent meets the inclusion and exclusion criteria and thus is diagnosed with a primary depression diagnosis, he or she will receive oral and written information about the research project. Also the parents are the legal authorised persons will receive information. If the adolescent is 18 years or older, parents will only be approached to participate in this research if the adolescent gives his or her permission (also in informed consent). If both the adolescent and the parents are willing to participate, they are asked to confirm their participation by signing an informed consent form; both the adolescent and the parents sign this form. If the adolescent is 18 years or older, he or she can also particpate withouth his or her parents. Random assignment per client will be executed using computer generated block randomisation so an equal number of adolescents is assigned to the treatment group and the control group. The content or the kind of treatment the adolescent receives in the control group will be decided within the institution. Four assessments will be executed namely prior to the beginning of treatment (pre-test assessment), immediately after treatment (post-test assessment or after 15 sessions), 6 months after the end of treatment (6 month follow-up) and 1 year after treatment (1 year follow-up).
Measurements will consist of a diagnostic interview with the parent and the adolescent, questionnaires (adolescent and parent) and reviews by the therapist. The diagnostic interviews will be assessed by independent researchers that are blinded to condition. Also temporary assessments will take place to investigate possible mediators. This mediator assessment consists of a small questionnaire each 5 sessions. To calculate the cost-effectiveness, quality of life and cost diaries will be assessed. For each completed assessment, the family will receive a gift cheque of 10 euro*s. To obtain a high treatment integrity in both conditions, a few treatment sessions will be chosen ad random that are videotaped or audio taped.

Intervention

Adolescents are randomly assigned to the CBT program the *D(o)epressie cursus* or care as usual (without CBT).

Adolescents assigned to the experimental condition, the D(o)epressie cursus, will receive a individual CBT program. This program is a protocolised

individual version of CBT and consists of 15 weekly sessions that last 45 minutes and two parent sessions after 3 and 9 weeks. The D(o)epressie cursus is based on the social learning theory about the aetiology of depressions by Lewinsohn (Lewinsohn, Antonuccio, Steinmetz, & Teri, 1984). According to this theory, there is a connection between the number of positive interactions between a person and his environment on one hand, and depression on the other. A triggering event such as a radical life event, causes a person to have less positive interactions with his environment. Because of this a negative spiral of negative thoughts, even less positive interactions with the environment and a deteriorating depressed mood emerges. The D(o)epressiecursus is a CBT program that aims to reduce depressive complaints in adolescents with a depressive disorder. Because depressive episodes are multi-factorial determined and because of the interaction between biological, social, cognitive and environmental factors, the focus of the intervention is broad. The intervention contains the following components; psycho-education (information about depression and the rationale for the aetiology of the complaints and the treatment of them), setting attainable goals (translate large goals into realistic short term goals), self monitoring (registration of the mood, activities and thoughts), activation (planning frequent, joyful activities), improving social skills and communication skills (improvement and stimulation of social behaviour), relaxation techniques, cognitive restructuring (identifying and changing unrealistic negative thoughts about the self, others and events), role play and problem solution skills (teaching the creation of solutions for problems via brainstorm, choosing, trying and evaluating) and relapse prevention. The exercises will be executed within the sessions and will be generalised into real life by means of homework assignments. In the parent sessions, parents will receive psycho education and information on CBT.

The control treatment consists of care as usual for clinical depression like it is now offered within the participating institutions. Care as usual will consist of elements of Interpersonal Therapy (IPT), family therapy, parent counselling, medication, mindfulness, acceptance commitment therapy (ACT), psychodynamic therapy (short duration), (non-directive) conversation therapy, creative therapy and running therapy, except for CBT. As far as possible, the control condition will be a reflection of care as usual as it is currently offered. Within the control condition no CBT will be offered.
Until now, the content of care as usual for depressed adolescents in the Netherlands is unknown. One of the sub aims of this study is to direct the question of; Which treatments are executed in clinical practice and to which degree are these treatments executed in accordance to the basic treatment principles? We conducted a survey by Phone among the participating institutions. This inventory showed that the current care as usual in clinical practice consists of a large scale of protocolised and non-protocolised treatments such as Interpersonal Therapy (IPT), family therapy, parent counselling, medication, mindfulness, ACT, psychodynamic therapy (short duration), (non-directive) conversation therapy, creative therapy and running therapy. It appears that in clinical practice, the recent guidelines of the

guide depression in youth (Depressie Richtlijn, 2009) are not applied yet. The guideline recommend CBT, IPT and medication as treatment of choice. Besides, an eclectic method of working is utilised in clinical practice, in which elements of different treatments are combined based on the clinician*s view as was also shown in a American study (Weersing & Weisz, 2002). Therefore, it is important to register the content of care as usual per session. This will be obtained by using the Therapy Procedures Checklist (TPC; Weersing, Weisz & Donenberg, 2002). The therapist will fill in the TPC to monitor the treatment techniques he or she uses in each session. In such a way, care as usual in adolescents with a clinical depression can be surveyed.

Study burden and risks

In this research a structured clinical interview and questionnaires will be assessed which are frequently used in clinical practice and research worldwide. The structured interview with the adolescent and the parent (K-SADS) and a couple of questionnaires (CBCL and YSR) are part of the routine diagnostic cycle within mental health care (duration 2 hours for the adolescent and 2 hours for the parent). These interviews and questionnaires will also be assessed if someone doesn*t participate in research. In clinical practice, the K-SADS and a couple of questionnaires are also assessed at post treatment to monitor if the depression diagnosis is still present (2 hours adolescent and 2 hours parent), so this also is a part of the routine in clinical practice. At the 2 follow-up measurements, the K-SADS and questionnaires will be assessed as well (2x 2 hours adolescent and 2x2 hours parent), this is not routine. The time investment for filling in the extra questionnaires (not the routine questionnaires) is therefore limited, namely at pre-treatment 1,5 hour for the adolescent and 1,5 hour for the parent. At post treatment, follow-up1 and follow-up2, the time investment will be somewhat lower namely 1 hour and 20 minutes for the adolescent and 1 hour for the parent. Even more, adolescents and parent have to fill in a questionnaire twice to monitor the mediator variables. This short questionnaire takes two times 15 minutes. In total, the time investment will be 14 hours for the adolescent (inclusive the 4 hours routine measurements) and 13 hours for the parent (inclusive 4 hours routine measurements). Besides, no burden and no risks are associated with the assessment of the measurements. In contrary, filling in some of these questionnaires can give more awareness of the risks that are present in adolescents with a depression (and thus reduces risk). For example, a suicide taxation list is assessed through which suicide thoughts and attempts ill be identified faster and therefore can be handled faster. The adolescent is in treatment so if parents or the adolescent have a supplementary question or treatment goal based on filling in the questionnaire, they have direct access to their therapist. Some of these measurements were also assessed in previous studies of Clarke.
The intervention in the experimental condition is based on CBT. According to the guideline depression (Depressierichtlijn, 2009), CBT is recommendend as tretament of chouice for adolescent with a clinical depression. Therefore, no

harmful effects are expected of the d(o)epressie cursus. Besides, therapists are trained and supervised. The control condition consists of care as usual that the institution offers to adolescents with a depression. In this condition, the adolescent isn*t denied care that is offered in regular treatment except CBT.
To investigate the treatment integrity, two treatment sessions will be selected that will be sound- or videotaped. Videotaping or sound taping sessions is very common and almost routine within the mental health care setting and is used for intervision and training purposes. Adolescents aged 12 to 18 years and their parents have to give their formal permission before the session is taped. They are given information on the purpose (treatment integrity) and that two sessions with the adolescent will be taped. Both the adolescent and the parent have to sign an Informed consent and are free to refuse the taping. If they refuse to cooperate with taping two sessions, this will have no consequences for the treatment. If the adolescent is 18 years or older, than only the permission of the adolescent is sufficient to tape two treatment sessions. The adolescent has to sign an Informed consent.
The investment of the therapists is also limited in time. The therapist fills in characteristics of the depression and the treatment by means of questionnaires. A part of this, such as filling in the treatment record is part of the routine method of working. The assessment of additional questionnaires and the interview will be done by a research assistant. The contribution of the therapists is not a burden and does not pose any risks.
The above mentioned burden and risks are very small and do not outweigh the advantage that, based on this research, information about the effectiveness of treatment for adolescents with a depression will be available.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The inclusion criteria are: (1) age 12 until 21 years, (2) a primary diagnoses of depression (regardless the severity: mild, moderate or severe), and (3) referred to a participating mental health institution.

Exclusion criteria

The criteria for exclusion are: (1) acute suïcide risk, (2) drug abuse (as primary diagnosis), (3) pervasive developmental disorder (as primary diagnosis), (4) bipolar disorder (as primary diagnosis), (5) day care or admission to the clinical setting and (6) not fluent in Dutch, Turkish, Arabic or Berber language.

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:	Recruitment stopped
Start date (anticipated):	20-12-2011
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Date:	15-06-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL34064.041.10
Other	NTC 2676