# Effectiviteit en kosteneffectiviteit van de D(o)epressie cursus voor adolescenten met een depressie; individuele CGT versus reguliere zorg.

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| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20844

**Bron**
NTR

**Verkorte titel**
Study Adolescent Depression SAD

**Aandoening**

Depression, CBT, adolescents

### Ondersteuning

**Primaire sponsor:** University of Utrecht
**Overige ondersteuning:** ZON-MW, The Netherlands Organization for Health Research and Development

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Depression in adolescents is a huge societal problem because of the prevalence, the burden of the illness, the chronicity, the comorbidity and the high number of suicides. Therefore, an effective intervention for clinical depression seems necessary. International studies have shown that CBT is effective in reducing depressive symptoms. However, in the Netherlands, no effective intervention for clinical depression in adolescents is available. The D(o)epressie course is a individual Cognitive Behavioural Therapy program which is developed specifically for adolescents with a clinical depression.
In this multi-centre trial, a randomised controlled trial will be executed in which individual CBT (D(o)epressie) will be compared to care as usual. In total, 140 adolescents will be included and 4 assessments will be conducted. The pre-test assessment will take place immediately prior to the beginning of treatment, post-test assessment will take place immediately after treatment, and follow up assessments will be conducted 6 months and 1 year after the end of treatment. Besides the effectiveness, the cost-effectiveness of individual CBT will be investigated. Furthermore, a cost-of-illness study will be conducted in adolescents with a clinical depression and moderators (comorbidity, severity, age, ethnicity, gender, income and psychopathology of the parents) and mediators (negative automatic thoughts, cognitive emotion regulation and attribution style) will be investigated.

### Doel van het onderzoek

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?

2. Is the individual CBT program the “D(o)epressie cursus” more cost-effective than care as usual?

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?

**Onderzoeksopzet**

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).

**Onderzoeksproduct en/of interventie**

Adolescents are randomly assigned to the CBT program the “D(o)epressie cursus” or care as usual.

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.

# Contactpersonen

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 12 until 21 years;

2. A primary diagnoses of depression (regardless the severity: mild, moderate or severe);

3. Referred to a participating mental health institution.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Acute suicide 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;

6. Not fluent in Dutch, Turkish, Arabic or Berber language.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Dubbelblind |
| Controle: | Geneesmiddel |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-02-2011 |
| Aantal proefpersonen: | 140 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 03-01-2011 |

Soort: Eerste indiening

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL2558 |
| NTR-old | NTR2676 |
| Ander register | ZonMw : 157004005 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A