# D(o)epression Blended as innovative e-mental health program for clinically depressed adolescents

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Primary Objective: Primary aim of this study is to evaluate the effectiveness and cost-effectiveness of D(o)epression Blended in clinical practice in reducing depressive symptoms and disorders in clinically depressed adolescents. The modern and...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Mood disorders and disturbances NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON47445

**Source**
ToetsingOnline

**Brief title**
D(o)epression blended

### Condition

- Mood disorders and disturbances NEC

**Synonym**
Depression

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Utrecht
**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** blended, CBT, online depression

## Outcome measures

### Primary outcome

Presence of the diagnosis of depression will be measured by the Kiddie-Schedule for Affective Disorders and Schizophrenia, present and lifetime version (K-SADS-PL) (Kaufman et al., 1997; Reichart, Wals, & Hillegers, 2000). This widely used semi-structured diagnostic interview assesses a wide range of diagnoses (present and life time) including their severity. The view of the adolescent, the parent and the independent clinician are taken into account.

### Secondary outcome

Adolescents

· The degree of depressive symptoms is measured with a self-report measure, the Child Depression Inventory-2 (CDI-2) (Bodden, Stikkelbroek, & Braet, 2016; Kovacs, 2017). The CDI-2 is a revision of the CDI (Kovacs, 1992; Timbremont & Braet, 2002) and was translated in Dutch.

· The severity of the depression is rated by an independent clinician using the K-SADS-PL (Kaufman, Birmaher, Brent, Rao, & Ryan, 1996).

· Suicide risk is assessed with the K-SADS-PL and a newly developed self-report questionnaire Suicide risk taxation (SRT), which focuses on frequency of suicidal thoughts, wishes, plans and actions over the past two weeks.

· Comorbidity and psychopathology is assessed with the K-SADS-PL, and with the Youth Self Report scale (YSR) for adolescents (Achenbach, 1991; Verhulst, Ende, & Van der Koot, 1996).

· For this study, we also constructed the Life Event Scale (LES) (Bodden & Stikkelbroek, 2010a), which is a self-report measure about life events (including drug abuse, bereavement, maltreatment and suicide attempts), their date of occurrence and their impact on the adolescents well-being.

· The degree of conflicts (quarrels, irritations and antagonism in the child* parent relationship) was measured with 6-item Network of relationship inventory (NRI) (Furman & Buhrmester, 1985).

· The Dutch version of the EuroQol Questionaire (EQ-5D adolescent version) (The EuroQol Group, 1990) is used to establish quality of life as expressed in quality adjusted life years (QALYs).

· The Cognitive Negative Cognitive Error Questionnaire (CNCEQ) (Maric, Heyne, Van Widenfelt, & Westenberg, 2011) measures cognitive errors namely the underestimation of the ability to cope, personalizing without mind reading, selective abstraction, over generalizing and mind reading.

· The Cognitive Emotion Regulation Questionnaire (CERQ) (Garnefski, Kraaij, & Spinhoven, 2001) measures a broad set of cognitive emotion regulation strategies which are used in response to the experience of threatening or stressful life events; Self-blame, Other-blame, Rumination, Catastrophizing, Positive refocusing, Planning, Positive reappraisal, Putting into perspective and Acceptance.

· The Children*s Attributional Style Questionnaire (CASQ) (Thompson, Kaslow, Weiss, & Nolen-Hoeksema, 1998) is a self-report measure with three dimensions of attribution; internal- external, stable-unstable and global- specific.

Parents

· The degree of depressive symptoms according to parents is measured with a self-report measure, the Child Depression Inventory-2 parent version (CDI-2 P) (Bodden et al., 2016; Kovacs, 2017). The CDI-2 is a revision of the CDI (Kovacs, 1992; Timbremont & Braet, 2002) and was translated in Dutch.

· The severity of the depression is rated during an interview with the parents by an independent clinician using the K-SADS-PL (Kaufman et al., 1996), and by the therapist on the Clinical Global Impression-severity scale (CGI-S) (Berk et al., 2008).

· Suicide risk is assessed with the K-SADS-PL.

· Comorbidity and psychopathology is assessed with the K-SADS-PL, and with the Child Behavior Check List (CBCL) for parents (Achenbach, 1991; Verhulst et al., 1996).

· The Life Event Scale (LES) (Bodden & Stikkelbroek, 2010a), which is a self-report measure about life events (including drug abuse, bereavement, maltreatment and suicide attempts), their date of occurrence and their impact on the adolescents well-being is also filled out by parents.

· The degree of depressive symptoms in parents is assessed with the Dutch version of the Beck Depression Inventory, second edition (BDI-II-NL) (Beck, Steer, Ball, & Ranieri, 1996; Van der Does, 2002).

· Psychopathology of both parents is measured with the Adult Self-Report (ASR) (Achenbach & Rescorla, 2003).

· The degree of conflicts (quarrels, irritations and antagonism in the child* parent relationship) is measured with 6-item Network of relationship inventory

(NRI) (Furman & Buhrmester, 1985) also rated by the parents.

· The economic evaluation is done by registration of costs in a cost diary based on the Trimbos Institute and Institute of Medical Technology Assessment Questionnaire on Costs Associated with Psychiatric Illness (TiC-P) (Hakkaart-Van Roijen, Van Straten, Donker, & Tiemens, 2002) and PRODISQ (Koopmanschap, 2005). The registered costs are directly related to health care or indirect health care (out-of-pocket costs, costs of informal care) and direct costs outside health care (monetary value of production losses caused by absence and reduced productivity).

· The Dutch version of the EuroQol Questionaire (EQ-5D parent version) (The EuroQol Group, 1990) is used to establish quality of life as expressed in quality adjusted life years (QALYs).

Therapists

· Severity of depression was rated by the therapist on the one item Clinical Global Impression-severity scale (CGI-S) (Guy, 1976).

· Improvement of depression was rated by the therapist on the one item Clinical Global Impression-improvement scale (CGI-I) (Guy, 1976)

· Global functioning of the adolescent is rated by the therapist on the Children Global Assessment Scale (CGAS) (Shaffer et al., 1983; Bunte, Schoemaker, & Matthys, 2010).

Other measures

Adolescents

· At baseline we will assess demographic information.

· Treatment expectancy is assessed with the Parent Expectancies for Therapy Scale (PETS) (Kazdin & Holland, 1991) which was revised for adolescents.

· Previous treatments for depression, including complementary and self-help treatments, are administered with the inventory of History of Treatments (VEHI) (Bodden & Stikkelbroek, 2010b).

· Satisfaction with treatment is measured with the Service Satisfaction Scale (SSS) (Bickman et al., 2010).

· The quality of the therapeutic alliance is assessed with the Therapy Alliance Scale for Adolescents (TASC) (Shirk & Saiz, 1992).

Parents

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Therapists

· At baseline we will assess demographic information and information about

education and experience.

· The Cooperation With Treatment scale (CWT) (Tolan, Hanish, McKay, & Dickey, 2002) is used to assess the degree of cooperation with treatment as observed by the therapist.

· The content of treatment is assessed in both conditions with the Therapy Procedure Checklist (TPC) (Weersing, Weisz, & Donenberg, 2002).

· Treatment integrity will be established by recording two randomly chosen sessions that are observed and rated.

# Study description

**Background summary**

Depressive disorders in adolescents are amongst the most prevalent disorders with a high burden of disease and a high risk of recurrence or chronicity (Birmaher, Brent, & AACAP Work Group on Quality Issues, 2007; Ryan, 2005). Before adulthood, 14-25% of the adolescents has experienced an depressive episode (Kessler & Walters, 1998). Additionally, depression shows high comorbidity with other psychiatric diagnoses, and an elevated risk of social problems, juridical problems, learning problems, school drop-out, decreased academic performance, substance abuse, negative life events, physical problems, teen pregnancies and suicide (Birmaher et al., 2007; Portzky & Van Heeringen, 2009; Ryan, 2005). Therefore, it is crucial that depressive disorders are treated effectively in an early stage (Birmaher et al., 2007).
Cognitive Behavioral Therapy (CBT) is described as an effective intervention to treat depression (Weisz, McCarty, & Valeri, 2006). However, a review found that 50% of the adolescents is not free of depressive symptoms after being treated (Watanabe, Hunot, Omori, Churchill, & Furukawa, 2007). In a meta-analysis, the effectsize of CBT was found to be moderate (d = 0.53) (Klein, Jacobs, & Reinecke, 2007). A recent Dutch RCT investigating the effectiveness of the D(o)epression protocol (face-to-face) has shown that CBT was moderately effective compared to CAU (Stikkelbroek, 2016). Despite this, some adolescents were not free of depressive symptoms at posttreatment (24%), the drop-out was high (57%), and it was hard to motivate patients to finish the treatment. Therefore, it seems important to develop an attractive and even more effective treatment for adolescents. A recent meta-analysis showed that alternative interventions (e.g. psychodynamic therapy, social skills training, supportive

counseling) are less effective than CBT, and that only IPT and Problem-solving therapy are comparable to CBT (Barth et al., 2013). So using other treatments does not seem to be the answer. Improving CBT does.
One improvement in CBT could be online sessions. Online intrevntions increase motivation and treatment expectancies and decrease resistance and drop-out because they can be tailored easily to the needs of adolescents and adjusted to their daily lives (Gulliver, Griffiths, & Christensen, 2010). Another benefit of online interventions is the high accessibility. Only 25% of the adolescents who suffer from depression receives treatment, and improving access to treatment is crucial (Makarushka, 2011). Online interventions increase independence and self-confidence, strengthen own competences (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010), and peer contact through online chat improves social support (Van der Zanden, Kramer, Gerrits, & Cuijpers, 2012). Furthermore, adolescents seem to prefer self-help, such as online interventions (Gulliver et al., 2010).
A major benefit of online interventions for therapists is that they can easily give feedback to their patients between face-to-face sessions. Also, less face-to-face sessions are needed which in turn can decrease the therapist workload of therapist and the duration of the waiting list (Andrews et al., 2010), reducing societal cost (McCrone et al., 2004). A recent meta-analysis and two reviews have shown that online CBT interventions are effective in reducing depressive symptoms in adolescents (Ebert et al., 2015; Calear & Christensen, 2010; Richardson, Stallard, & Velleman, 2010). In the Netherlands, two online depression prevention programs for young adults (18-25) have shown to be effective compared to a waiting list condition (Kramer, Conijn, Oijevaar, & Riper, 2014; Van der Zanden et al., 2012). This shows that online depression prevention programs are effective, but it is still unknown whether online treatment programs for clinically depressed adolescents are effective. The importance of guidance by a therapist in online interventions is shown by a meta-analysis on computer-based psychological treatments for depression (Richards & Richardson, 2012). In this meta-analysis, it was found that interventions with guidance by a therapist are more effective than without guidance. Moreover, therapeutic guidance in treatment of depression is necessary because the suicide risk has to be monitored.
It can be concluded that blended treatment (online sessions and face-to-face sessions) is preferred, but this type of treatment has hardly been studied in clinically depressed adolescents (Riper, Van Ballegooijen, Kooistra, De Wit, & Donker, 2013). Blended treatment is expected to be more effective, especially in psychiatric care, because the benefits of face-to-face interventions are combined with the benefits of online interventions. With this in mind, the treatment protocol D(o)epression Blended is developed for treatment of depressive disorders in adolescents (www.Doepressie-online.nl). D(o)epression Blended might increase motivation, decrease resistance and reduce drop-out, and therefore, it could be more effective than Doepression face-to-face and CAU. D(o)epression Blended is attractive for adolescents because it can be tailored easily to their treatment preferences and daily lives.
D(o)epression Blended is already frequently being used in treatment of

adolescents with depressive disorders, but the effectiveness has never been studied before. Therefore, this study will examine the effectiveness and cost-effectiveness of D(o)epression Blended and contribute to evidence-based treatment of adolescents in psychiatric care. Besides examining the effectiveness, several moderators (comorbidity, depression severity, age, ethnicity, gender, family income, parental psychopathology) and mediators (negative automatic thoughts, cognitive emotion regulation, attributional style) will be examined to study for whom the intervention is effective and how the intervention works.

## Study objective

Primary Objective:
Primary aim of this study is to evaluate the effectiveness and cost-effectiveness of D(o)epression Blended in clinical practice in reducing depressive symptoms and disorders in clinically depressed adolescents. The modern and innovative D(o)epression Blended will be compared to D(o)epression face-to-face and care as usual (CAU), of which the latter two conditions have already been studied in an earlier RCT (NL34064.041.10).

Secondary Objective(s):
Secondary aim of this study is to examine for whom specifically D(o)epression Blended is effective by testing moderators and individual trajectories of change. Additionally, mediating effects will be studied. Further, drop-out will be compared between D(o)epression Blended and D(o)epression face-to-face and treatment us usual. Lastly, the feasibility and the expectancies adolescents and therapists of Doepression blended will be studied.

Hypotheses:
1. D(o)epression Blended is more effective and costeffective than CAU.
2. D(o)epression Blended is equally effective as D(o)epression face-to-face.
3. D(o)epression Blended is more costeffective than D(o)epression face-to-face.
4. D(o)epression Blended will lead to a faster decrease in depressive symptoms than D(o)epression face-to-face.
5. D(o)epression Blended will lead to less drop-out and lower costs because of the reduction in face-to-face contacts.
6. Adolescents are more satisfied being treated with D(o)epression-blended than with D(o)epression face-to-face.*

## Study design

The presented study uses a quasi-experimental cohort design with one condition. Additionally, data from a previous study will be used, in which an RCT was conducted and D(o)epression face-to-face was compared to care as usual (NL34064.041.10). Therefore, this cohort can be seen as a third additional condition. Assessments and instruments will be identical to the previous study

comparing CBT with CAU. Participants in this study can, when necessary, be compared to participants from the earlier executed RCT based on matching and propensity scores (Bartak et al., 2008). Results of thisThe study will be reported conducted according to the CONSORT Statement (Schulz, Altman, Moher, & Consort Group, 2010).
Adolescents between 12 and 21 years old with a depressive disorder referred for treatment and their parents will be asked to participate in this study. Researchers will obtain informed consent before enrolling participants in this study. All adolescents meeting the eligibility criteria and willing to participate, will be assigned to the D(o)epression Blended intervention. Before the start of the intervention, the baseline assessment will be executed. Following assessments are during the intervention, after 5 weeks and after 10 weeks, post-intervention, 6-month and 12-month follow-up.

**Intervention**

D(o)epression Blended (Stikkelbroek & Van Dijk, 2013) is a cognitive behavioral treatment program based on the evidence-based treatment program Coping with Depression course (Clarke, Lewinsohn, & Hops, 1990). D(o)epression Blended consists of 4 online modules and a minimum of 5 face-to-face contacts of each 45 minutes between the adolescent and the therapist. Additionally, there is unlimited email contact between the adolescent and therapist and there is a weekly group chat.
During the face-to-face contacts, the new modules are introduced, the therapeutic relationship is improved, exercises are practiced, the treatment is tailored to the adolescent*s needs, and suicide risk is examined. Further, there are two face-to-face contacts with parents; one after three weeks and one after the start of the fourth module. Parents receive psycho-education, information about cognitive behavioral therapy, and suggestions on how parents can contribute to the treatment.
The content of D(o)epression Blended is equal to the face-to-face intervention and consists of the following components: psycho-education, setting realistic goals, self-monitoring, activation, improvement of social and communication skills, relaxation skills, cognitive restructuring, role play, problem solving skills and relapse prevention (Stikkelbroek, Bouman, & Cuijpers, 2005). These components are divided into four online modules which are offered sequentially and are called start, do, think and future. New modules can only be started when the previous module is finished. The exercises and registration of activities is completely online. The exercises are introduced during the face-to-face contacts and are practiced online and at home, this increases the generalizability to real life situations. The online environment offers tremendous convenience and flexibility to which adolescents can tailor their treatment preferences, such as pace, frequency, and location. This means that blended treatment is vastly different from regular treatment and allows to tailor the treatment to the preferences of each individual.

**Study burden and risks**

Adolescents, parents and therapists are burdened with filling out questionnaires. In addition, a semi-structured interview (KSADS) will be conducted with adolescents and parents The diagnostic interview and some of the questionnaires are part of the standard procedure (diagnostic proces) of the participating institutions. There are no risks involved in particpation in this study.

# 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

(1) a primary diagnoses of Depressive Disorder (regardless the severity: mild, moderate or severe) or Dysthymic disorder
(2) age 12 to 21 years
(3) referred to one of the participating mental health institutions.

### Exclusion criteria

(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

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 16-11-2017 |
| Enrollment: | 70 |
| Type: | Actual |

# Ethics review

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|---|---|
| Approved WMO Date: | 13-10-2017 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 17-04-2018 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 12-12-2018 |
| Application type: | Amendment |
| 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

ID: 25040
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL61804.041.17 |
| OMON | NL-OMON25040 |