

# D(o)epression Blended

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25040

### Source

Nationaal Trial Register

### Health condition

Depression, CBT, blended intervention, online intervention, adolescents

## Sponsors and support

**Primary sponsor:** Universiteit Utrecht

**Source(s) of monetary or material Support:** ZonMW

## Intervention

## Outcome measures

### Primary outcome

Presence of depressive disorder (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.

### Secondary outcome

Secondary outcomes: Depression severity, suicide risk, comorbidity, and quality of life

Mediators: negative cognitions, cognitive emotion regulation, and attributional style.

Moderators: adolescent characteristics, depression severity, comorbidity, parental depression, and parental psychopathology.

Other outcomes: treatment expectancy, previous treatments, satisfaction with treatment, cooperation with treatment, relationship with the therapist, and treatment integrity program.

## Study description

### Background summary

Depressive disorders in adolescents are amongst the most prevalent disorders with a high burden of disease, and high risk of recurrence or chronicity. Before adulthood, 14 to 25% of the adolescents has experienced a depressive episode. Recent RCT's have shown that CBT is an effective intervention to treat depression. However, 50% of the adolescents is not free of symptoms after being treated and the effect size is moderate. An online version of CBT might improve motivation and treatment expectancies and decrease resistance and drop-out because it can be tailored easily. Online interventions are effective but only studied as preventive interventions. Research shows that face-to-face sessions are necessary to increase the effectiveness and decrease drop-out and suicide risks, especially in curative interventions. D(o)epression Blended is a mixture of online sessions and face-to-face sessions of CBT to treat clinically depressed adolescents. In total, 70 clinically depressed adolescents aged 12 to 21 and their parents will be included 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. Primary aim is to evaluate the (cost-)effectiveness of D(o)epression Blended by comparing D(o)epression blended with D(o)epression face to face and CAU. Secondary aim is to examine for whom specifically D(o)epression Blended is effective by testing moderators and trajectories of change. Additionally, mediating effects will be studied. The presented study uses a quasi-experimental cohort design with one condition. Participants will be matched to participants from a RCT which was already conducted and in which D(o)epression face-to-face was compared to care as usual (NL34064.041.10). This cohort can therefore be seen as a third additional condition.

### Study objective

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**

Six assessments will be executed, namely before the start of the intervention (baseline), during the intervention after 5 weeks, during the intervention after 10 weeks, postintervention, 6-month and 12-month follow-up.

## **Intervention**

D(o)epression Blended (Stikkelbroek & Van Dijk, 2013) is a CBT program based on the 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 and maximum of 15 face-to-face contacts of 45 minutes each, involving the adolescent and the therapist. Additionally, there is unlimited email contact between the adolescent and the therapist and there is a weekly group chat.

## **Contacts**

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## **Eligibility criteria**

## 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

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	16-10-2017
Enrollment:	70

Type: Anticipated

## Ethics review

Positive opinion

Date: 16-10-2017

Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 47445

Bron: ToetsingOnline

Titel:

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

No registrations found.

### In other registers

Register	ID
NTR-new	NL6585
NTR-old	NTR6759
CCMO	NL61804.041.17
OMON	NL-OMON47445

## Study results

### Summary results

N/A