

# Effectiveness study of a CBT-based adolescent coping with depression course

<b>Submission date</b> 27/09/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/10/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/09/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Dropout is a serious problem in upper secondary schools in Norway. Despite studies showing the importance of mental health as a reason for school dropout, interventions have only to a small extent taken this into account. In general, less than 20% of adolescents in need of help for their mental health problems have been in touch with health services for this reason. Based on this we can assume that a relatively large group of students that we meet every day in our schools do not get the proper support to cope with school. One of the most common forms of mental health problems among adolescents are depressive symptoms. We will conduct a study of a group-based adolescent coping with depression course for upper secondary school students. The main aims are to find out whether it can decrease depressive symptoms, and to what extent it prevents dropout and increases academic and social functioning.

### Who can participate?

Students from the 1st or 2nd grade from upper secondary school, who have subclinical depression or mild to moderate depression.

### What does the study involve?

Course leaders are recruited from employees within different primary services like the School Health Service, Public Health Nurses, the Educational and Psychological Counselling Services (PPT). The course leaders recruit first- or second-year students from upper secondary schools to their courses. The course leaders are randomly assigned to administer either the course or what we call 'practice as usual' – that is, the common help given within the system the course-leaders work in (the course leaders that administer 'practice as usual' receive their training as course-instructors after the study).

### What are the possible benefits and risks of participating?

The participants will get help with their depressive symptoms. The treatment they receive is expected to decrease symptoms increase social and academic functioning, and prevent dropout. For some, filling in a questionnaire may activate unpleasant emotions. However, based on clinical practice these conditions seem to be outweighed by the positive things associated with participation.

Where is the study run from?

The study is managed by the researchers at The Norwegian Center for Child Behavioral Development, and between 20 and 30 sites will be involved in recruiting and treating the adolescents in the study.

When is the study starting and how long is it expected to run for?

February 2014 to December 2020

Who is funding the study?

The Norwegian Research Council

Who is the main contact?

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## Contact information

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

238081

## **Study information**

### **Scientific Title**

Effectiveness study of a CBT-based adolescent coping with depression course to prevent dropout in upper secondary school

### **Acronym**

Effectiveness study of ACDC

### **Study objectives**

1. To what extent can depressive symptoms in adolescents be reduced through the ACDC course?
2. To what extent can the ACDC course improve depressed students' ability to function socially and academically in upper secondary school?
3. To what extent can the ACDC course prevent dropout among depressed students' in upper secondary school?
4. If we have enough minority students in the sample we will also explore whether minority status moderates the effect of the intervention
5. To what extent will the establishment of such a course at a school increase the schools' and teachers' awareness of the needs of pupils with depressive symptoms, as well as their ability to meet those needs?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Norwegian Regional Committees for Medical and Health Research Ethics, 30/06/2015, REC South East ref: 2015/1027

### **Study design**

Single-centre cluster-randomized effectiveness trial with active control

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

### **Study setting(s)**

School

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

## **Health condition(s) or problem(s) studied**

Mild/moderate depression among adolescents

## **Interventions**

The Adolescent Coping with Depression Course (ACDC), based on CBT (Cognitive Behavioural Therapy), is a course for adolescents with subclinical or mild to moderate depression. ACDC is based on a new and updated CBT understanding of depression, and contains different approaches and methods taken primarily from Rational Emotive Behaviour Therapy (REBT) and Cognitive Behavioural Therapy (CBT). However, the ACDC is also enlarged through adding more elements from Meta-Cognitive Theory (MCT) and Positive Psychology (PP) in addition to modern neurobiological perspectives. There is a focus on symptom relief within a systemic perspective, meaning family-school-workplace, and separate pamphlets are distributed to those. Practising the techniques learned on the course is emphasized both in and outside the course setting in order to develop the necessary skills. The material includes a manual for the facilitator, a course pamphlet for the participants, a pamphlet addressed to parents and also a pamphlet for the school/workplace as well. Additionally, a short downloadable presentation has been developed for teachers to use in class to present mental health as a theme if required. All the course materials are printed and published by the Norwegian Council for Mental Health (NCMH). The course is delivered in a group format over 8 consecutive weekly sessions, each lasting approximately 120 minutes, with breaks in between.

Approximately 8-12 adolescents of both genders are considered to be a preferred group size. Two follow-up sessions are conducted about 3 and 6 weeks after the last session, lasting approximately 90 minutes.

To become instructor requires a minimum of three years of relevant education from university or similar, in the area of child and adolescent mental health. This may include medical doctors, psychologists, teachers, social workers, nurses etc. To be certified as a course instructor, individuals have to attend a five-day intensive training programme of 36 hours. The training programme is run by a psychologist specialized in cognitive therapy, with experience of running such group courses.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Center for Epidemiological Studies Depression Scale, CES-D for adolescents, at Pre-test, T1, T2, T3, T4
2. Dysfunctional Attitudes Scale (DAS) (short version) at Pre-test, T2, T3, T4
3. Automatic Thoughts Questionnaire (ATQ) (short version) at Pre-test, T2, T3, T4
4. Ruminative Response Scale (RRS) (short version) at Pre-test, T2, T3, T4
5. Emotion regulation at Pre-test, T2, T3, T4
6. Dropout (from school and official registries) at T1, T2, T3, T4
7. Grades at T1, T2, T3, T4

Pre-test: November/December 2015, T1: January 2016 (at intervention start), T2: June 2016, T3: December 2016, T4: June 2017

### **Secondary outcome measures**

1. Intentions to quit school at Pre-test, T2, T3, T4
2. Social and Cognitive Competence at Pre-test, T2, T3, T4
3. Life events at Pre-test, T2, T3, T4

Pre-test: November/December 2015, T1: January 2016 (at intervention start), T2: June 2016, T3: December 2016, T4: June 2017

### **Overall study start date**

12/02/2014

### **Completion date**

31/12/2020

## **Eligibility**

### **Key inclusion criteria**

This is a cluster-randomized design where the course-leaders are recruited from the School Health Service, Public Health Nurses, the Educational and Psychological Counselling Services (PPT). They are then taught how to recruit a group of 1st or second year students from Upper Secondary School (Videregående skole).

A complete assessment of possible participants (adolescents) has to be made by the course instructors before acceptance into the study.

Inclusion criteria for adolescents:

1. The target population for this course is 14/15-20 years old adolescents
2. Who have subclinical depression or mild to moderate major depressive disorder (MDD), according to the criteria of the DSM
3. Inclusion criteria require normal intellectual functioning
4. With normal reading abilities, and that was evaluated through the interview.

### **Participant type(s)**

Mixed

### **Age group**

Child

### **Lower age limit**

14 Years

### **Upper age limit**

20 Years

### **Sex**

Both

### **Target number of participants**

35 clusters with 8-12 adolescents within each cluster

**Total final enrolment**

228

**Key exclusion criteria**

Exclusion criteria for adolescents:

1. Bipolar disorder
2. Psychosis
3. Substance-use
4. ADHD or ADD
5. Brain damage
6. Danger of suicide
7. Adolescents who are easily agitated
8. Adolescents who lack the ability to function in a group

**Date of first enrolment**

01/11/2015

**Date of final enrolment**

31/01/2017

## **Locations**

**Countries of recruitment**

Norway

**Study participating centre**

**Norwegian Center for Child Behavioural Development**

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## **Sponsor information**

**Organisation**

The Norwegian Center for Child Behavioral Development

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**Sponsor type**

Research organisation

**Website**

<http://www.atferdssenteret.no/english/category28.html>

## **Funder(s)**

**Funder type**

Research council

**Funder Name**

Norges Forskningsråd

**Alternative Name(s)**

Forskningsrådet, Norwegian Research Council, Research Council of Norway

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Norway

## **Results and Publications**

**Publication and dissemination plan**

Articles will be written intended for international researchers and educationalists. A preliminary plan for the publications is four international articles in 2016 and 2017, based on some possible topics:

1. Effect of ACDC (the intervention) on depression
2. Effect of ACDC on dropout
3. Effect of ACDC on achievement
4. Effect of ACDC on social functioning
5. Immigrant status as possible moderator of the effects of ACDC
6. Fidelity and attitudes of course leaders as predictor of effectiveness
7. Teachers' experiences

We will also reach Norwegian educationalists and policy makers. Additional articles will therefore be published in national journals, professional journals, newspapers as well as on the internet. Participants are members of educational and psychological organizations, and conference papers will be presented in 2016 and 2017. Several of the participants teach at master and PhD levels in psychology and education, as well as giving national courses through their positions as employed at national competence centers. All in all we have very good opportunities to disseminate our results to a broad audience

## Intention to publish date

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	18/07/2016		Yes	No
<a href="#">Results article</a>	results	22/05/2019	24/05/2019	Yes	No
<a href="#">Results article</a>	6- and 12-month follow-up results	05/09/2020	07/09/2020	Yes	No