

# Structured skill training for adolescents with attention deficit hyperactivity disorder - a randomized controlled study

<b>Submission date</b> 11/05/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/06/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/12/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Attention deficit hyperactivity disorder (ADHD) is a group of behavioural symptoms that include inattentiveness, hyperactivity and impulsiveness. Dialectical Behavior Therapy is a kind of behavioral therapy and has been adjusted to be used for adults with ADHD. The treatment focuses on mindfulness, acceptance/change and applied behaviour analysis. DBT in groups has shown promising results in adult populations in both Germany and Sweden with a reduction in ADHD symptoms and aggressive behaviour, as well as higher quality of life. Since no study has been done on children, the aim of this study is to investigate if the same results can be achieved with adolescents.

### Who can participate?

Patients aged 15-18 with ADHD

### What does the study involve?

Participants are randomly allocated to receive either the DBT treatment or a psycho-educational treatment (focusing on psycho-education about ADHD and strategies to cope with the symptoms). The treatment effects are assessed using questionnaires before, during and after treatment.

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

Benefits include increased awareness of ADHD symptoms and increased capacity to cope with them, as well as the experience of social support from the group. The risks are that increased awareness leads to negative emotions and perceived stigma.

### Where is the study run from?

Uppsala County Council, Child and Adolescent Psychiatry (Sweden)

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

December 2015 to February 2019.

Who is funding the study?  
Uppsala University Hospital Research Fund (Sweden)

Who is the main contact?  
Dr Johan Isaksson

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Johan Isaksson

**Contact details**  
Akademiska sjukhuset, ing 10  
Uppsala  
Sweden  
751 85

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
2015/257

## Study information

**Scientific Title**  
Structured skill training in groups for adolescents with attention deficit hyperactivity disorder - a randomized controlled study comparing effect of dialectical behavioral therapy and psycho-educational intervention on symptoms of ADHD and level of functioning

**Acronym**  
ADHD/DBT/SKILLS

**Study objectives**  
Dialectical behavioral therapy will be more effective then psycho-educational intervention at reducing symptoms of ADHD and increasing level of functioning.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Regional Ethical Review Board in Uppsala, 26/08/2015, Dnr 2015/257

**Study design**

Randomized controlled study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Attention deficit hyperactivity disorder (ADHD)

**Interventions**

One hundred adolescents diagnosed with ADHD will be recruited from child psychiatric outpatient units situated in the Swedish counties Falun, Gävle, Karlstad, Mölndal, Uppsala and Växjö. The adolescents (15-18 years old) who agree to take part in the study will be randomized into either the Dialectical Behavioral Therapy (DBT) treatment or the psycho-educational intervention (focusing on psychoeducation about ADHD and strategies to cope with the symptoms). The treatment effects will be assessed using standardized questionnaires, before, during and after treatment.

**Intervention Type**

Behavioural

**Primary outcome measure**

1. Adult ADHD Self-Report Scale Adolescent version (ASRS-A)
2. Sheehan Disability Scale (SDS)
3. Visual Analogue Scale measuring impact of ADHD symptoms on daily life
4. Global Quality of Life scale (GQL)
5. Five Facets Mindfulness Questionnaire-Swedish version (FFMQ-SWE)

All measurements: One to two weeks before treatment starts, and one to two weeks after treatment ends and six months after treatment ends

After every session: GQL, VAS

At half time of the DBT treatment, participants will fill in GQL, VAS and ASRS, SDS and PAS

**Secondary outcome measures**

1. Strength and Difficulties Questionnaire (SDQ)
2. Hospital Anxiety and Depression Scale (HAD)
3. Pressure Activation Stress scale (PAS)
4. Karolinska Sleep Questionnaire (KSQ)

All measurements: One to two weeks before treatment starts, and one to two weeks after treatment ends and six months after treatment ends

After every session: GQL, VAS

At half time of the DBT treatment, participants will fill in GQL, VAS and ASRS, SDS and PAS

**Overall study start date**

01/12/2015

**Completion date**

28/02/2019

## Eligibility

**Key inclusion criteria**

1. 15-18 years old
2. Patient at the child psychiatric clinic
3. Fullfilling criteria for ADHD, ADD, HDD or ADHD NOS
4. No change in medication during the previous month before start of treatment
5. No other ongoing psychological treatment

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

15 Years

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

100

**Total final enrolment**

184

**Key exclusion criteria**

1. Ongoing substance use disorders
2. Suicide risk
3. Mental retardation

4. Neurological disorder
5. Autism spectrum disorder
6. Manic episode
7. Severe depressive episode

**Date of first enrolment**

01/12/2015

**Date of final enrolment**

01/02/2018

## **Locations**

**Countries of recruitment**

Sweden

**Study participating centre**

**Barn och ungdomspsykiatri, Akademiska sjukhuset**

Sweden

75185 Uppsala

**Study participating centre**

**Barn och ungdomspsykiatri, Centralsjukhuset i Karlstad**

Sweden

65185 Karlstad

**Study participating centre**

**Barn och ungdomspsykiatri, Region Gävleborg**

Sweden

801 30 Gävle

**Study participating centre**

**BUP mottagningen, Mölndal**

Sweden

431 02 Mölndal

**Study participating centre**

**Barn och ungdomspsykiatriska kliniken, Centrallasarettet i Växjö**

Sweden

351 85 Växjö

**Study participating centre**  
**BUP mottagningen i Falun**  
Falun  
Sweden  
791 82

**Study participating centre**  
**Barn och ungdomspsykiatri, Västmanlands sjukhus**  
Västerås  
Sweden  
721 89

**Study participating centre**  
**Barn och ungdomspsykiatri, Västra Götaland**  
Gothenburg  
Sweden  
416 74

## **Sponsor information**

### **Organisation**

Uppsala County Council, Child and Adolescent Psychiatry (Landstinget i Uppsala län, Barn och ungdomspsykiatri) (Sweden)

### **Sponsor details**

Akademiska sjukhuset  
Uppsala  
Sweden  
751 85

### **Sponsor type**

Hospital/treatment centre

### **ROR**

<https://ror.org/01dv86r63>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### Funder Name

Uppsala University Hospital Research Fund (Sweden)

## Results and Publications

### Publication and dissemination plan

Publication is planned in 2019

### Intention to publish date

10/12/2020

### Individual participant data (IPD) sharing plan

Consent was obtained from all participants, data is made anonymous and all participants have a study number. Participants reported on web-based questionnaires, and they are retrieved and stored on a encrypted server. Diagnostic and data collected with paper-pencil is stored in a locked repository situated at the hospital. Anonymous databases are stored on a server protected with personal passwords, available only for the research group. Any request for access to data should be sent to Dr Johan Isaksson, and evaluated in accordance with the ethical approval.

### IPD sharing plan summary

Stored in repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	10/06/2019	12/06/2019	Yes	No
<a href="#">Results article</a>	results	01/03/2021	16/03/2021	Yes	No
<a href="#">Results article</a>	follow-up data	06/12/2022	08/12/2022	Yes	No