

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

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

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

Protocol serial number

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 than 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

15 years

Upper age limit

18 years

Sex

All

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 ungdomspsykiatiska kliniken, Centrallasarettet i Växjö

Sweden

351 85 Växjö

Study participating centre

BUP mottagningen i Falun

Falun

Sweden

791 82

Study participating centre

Barn och ungdomspsykiatrin, Västmanlands sjukhus

Västerås

Sweden

721 89

Study participating centre

Barn och ungdomspsykiatrin, Västra Götaland

Gothenburg

Sweden

416 74

Sponsor information

Organisation

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

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Uppsala University Hospital Research Fund (Sweden)

Results and Publications

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?
Results article	results	01/03/2021	16/03/2021	Yes	No
Results article	follow-up data	06/12/2022	08/12/2022	Yes	No

<u>Protocol article</u>	protocol	10/06/2019	12/06/2019	Yes	No
<u>Participant information sheet</u>	Participant information sheet	11/11/2025	11/11/2025	No	Yes