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# Effects of group therapy in treatment of ADHD in adults

**Submission date**
14/02/2016

**Recruitment status**
No longer recruiting

**Registration date**
19/02/2016

**Overall study status**
Completed

**Last Edited**
29/11/2022

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
A growing number of adults are diagnosed with Attention-Deficit Hyperactivity Disorder, or ADHD. People with ADHD can have problems in paying attention, feeling restless or hyperactive and behaving impulsively. Pharmacological (drug) treatments are well established, but a significant number of patients does not respond well or experience adverse effects, which results in them stopping the treatment. Furthermore many patients request for psychological treatment to help them with symptoms that are not resolved by simply taking drugs. There has been interest in looking at the potential effects of structured group therapy ,which has been useful to patients with other conditions. Some studies have shown that structured skills training groups are beneficial for adult sufferers of ADHD in outpatient psychiatric units, reducing ADHD symptoms in people who remained stable regarding their medication status. This study investigates the potential effects of structured skills training groups in a clinically relevant but still controlled setting, and whether they help alleviate symptoms and improve quality of life for adult ADHD sufferers.

Who can participate?
Adults that have been diagnosed with ADHD.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 have weekly active structured skills training group therapy sessions for 14 weeks, followed by their usual treatment for the reminder of the study. Those in group 2 are given their usual treatment, after which they are given 14 weeks of active structured skills training group therapy.

What are the possible benefits and risks of participating?
All patients taking part in this study will be offered an intensive and comprehensive psychological intervention with educational and supportive coaching for training in new mastery in their daily life. This is considered to be associated with significant opportunities for improvements and low risk for adverse effects. Patients will be followed up carefully so that any problems during treatment period could be detected early and dealt with in a clinically appropriate manner. All participants are then assessed in terms of whether their symptoms have improved.

Where is the study run from?
1. Haukeland University Hospital, Psychiatric Department (Norway)
2. Division of Mental Health and Addiction, Vestfold Hospital Trust (Norway)
3. Sørlandet Hospital, Kristiansand (Norway)
4. Stavanger University Hospital (Norway)
5. Østfold Hospital Trust (Norway)

When is the study starting and how long is it expected to run for?
June 2015 to December 2017

Who is funding the study?
1. Oslo University Hospital (Norway)
2. Haukeland University Hospital (Norway)

Who is the main contact?
1. Dr Anne Halmøy (scientific)
2. Dr Mats Fredriksen (scientific)
3. Mrs Bente Ubostad (public)
4. Ms Ellen Kathrine Munkhaugen (public)

# Contact information


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Scientific

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# Additional identifiers

# Study information

### Scientific Title
Effects of structured skills training group in treatment of ADHD in adults: a controlled multicentre study

### Study objectives
The structured skills training group treatment is superior to the control condition 'treatment as usual' in reducing attention deficit hyperactivity disorder (ADHD) symptoms and functional deficits, and increasing quality of life in adults with ADHD.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Regional Committees for Medical Research Ethics - South East Norway, 29/10/2015, ref: 2015/1523 A

### Primary study design

Interventional

## Study design
Multicentre randomised controlled trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Attention deficit hyperactivity disorder

## Interventions
Enrolled patients are randomised into two groups and allocated to either:
1. Group 1 (G1) with start of weekly treatment in active structured skills training group therapy lasting for 14 weeks, following the Norwegian translation of the Swedish version of the ADHD skills training manual/workbook (Hirvikoski 2011; Morgensterns 2015) based on an adaption of Marsha Linehan's dialectical behavior therapy (DBT) for borderline personality disorder. The groups embrace 7 - 10 participants, and two group leaders trained in group therapy, cognitive behavioral treatment or DBT. Each session contains an initial short repetition and feedback on the previous session, followed by review of the homework during the first hour. After a break, a new topic with exercises and homework for the following week is introduced.
2. Group 2 (G2) with treatment as usual/clinical management for the first 15 weeks, followed by delayed admission to the active intervention of structured skills training group therapy (partial cross-over)

## Intervention Type
Behavioural

## Primary outcome(s)
1.Change in executive function impairments (total and separate dimensional scores) assessed by the self/informant-reports of adults aged Behavior Rating Inventory of Executive Function (BRIEF-A) at end of 14-weeks group treatment, and after 6 months post-treatment, compared to baseline and treatment as usual as control treatment strategy
2. Change in emotional regulation (total and separate dimensional scores) assessed by the self /informant-reports Difficulties in Emotion Regulation Scale (DERS) at end of 14-weeks group treatment, and after 6 months post-treatment, compared to baseline and treatment as usual as control treatment strategy

## Key secondary outcome(s)
1. Adult ADHD self-report scale (ASRS), the 18 items version
2. Beck Depression Inventory (BDI)
3. Beck Anxiety Inventory (BAI)
4. Alcohol Use Disorder Identification Test (AUDIT)
5. Drug Use Disorder Identification Test (DUDIT)
6. Weiss Functional Impairment Rating Scale, self-report (WIFRS)
7. Adult ADHD Quality of Life Scale (AAQoL)
8. Global Assessment of functioning (GAF)

## Completion date
15/05/2018

# Eligibility

### Key inclusion criteria
1. Adults (age >= 18 years)
2. Both genders
3. Diagnosis of ADHD according to DSM-IV persisting in adulthood

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Total final enrolment
121

### Key exclusion criteria
1. Any psychotic disorder
2. Recently suicidal behaviour
3. Substance or alcohol abuse or dependence within three months prior to screening for inclusion
4. Pervasive developmental disorder
5. Intellectual disability
6. Seizures or any neurological diseases causing mental handicap

### Date of first enrolment
14/02/2016

### Date of final enrolment
31/12/2016

# Locations

### Countries of recruitment
Norway

### Study participating centre

**Haukeland University Hospital, Psychiatric Department**
Bergen
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**Study participating centre**
**Division of Mental Health and Addiction, Vestfold Hospital Trust**
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**Study participating centre**
**Sørlandet Hospital, Kristiansand**
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**Study participating centre**
**Stavanger University Hospital, Stavanger**
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**Study participating centre**
**Østfold Hospital Trust**
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# Sponsor information

**Organisation**
Haukeland University Hospital

**ROR**
https://ror.org/03np4e098

**Organisation**

Oslo University Hospital

**ROR**
https://ror.org/00j9c2840

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Oslo University Hospital

**Funder Name**
Haukeland University Hospital

# Results and Publications

**Individual participant data (IPD) sharing plan**
Not provided at time of registration

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 28/11/2022 | 29/11/2022 | Yes | No |
| Protocol file | | 29/10/2015 | 01/09/2022 | No | No |