

BMJ Open Cognitive-behavioural group therapy for adolescents with ADHD: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Persistence of attention deficit hyperactivity disorder (ADHD) into adolescence is a significant burden to patients. Clinical guidelines recommend non-pharmacological therapies, but the evidence to support this recommendation is sparse. This study aims to evaluate the effect of a 12-week group cognitive-behavioural therapy (CBT) programme for adolescents with ADHD aged 14–18 years, who still have impairing symptoms after treatment with medication. We will study the effect of the treatment on ADHD symptoms and examine moderators and mediators of the effect of the treatment on ADHD.

Methods and analysis We conduct a randomised controlled trial of CBT group therapy in adolescents with ADHD recruited from child psychiatric outpatient units in Mid-Norway. 99 adolescents who met inclusion criteria and consented to participation have been randomised to a 12-week group intervention or to a control group receiving treatment as usual. Assessments are made at admission to the clinic, preintervention, postintervention and at a 9-month follow-up, obtaining adolescent, parent and teacher reports. Clinicians blinded to group allocation rate all participants as to their functioning preintervention and at the two postintervention assessment points. The primary outcome is change in symptom scores on the ADHD Rating Scale-IV.

Ethics and dissemination The Regional Committee for Medical and Health Research Ethics in South East Norway approved the study protocol (2015/2115). We will disseminate the findings in peer-reviewed publications and conference presentations, to user organisations and at courses attended by families and professionals. Two PhD students will publish and defend dissertations relating to the study. Planned publications include primary and secondary outcomes and patient satisfaction with the treatment. Furthermore, we plan to publish a manual of CBT group therapy in adolescent ADHD to benefit treatment of patients in Norway and elsewhere.

Trial registration number NCT02937142

INTRODUCTION

Attention deficit hyperactivity disorder (ADHD) is a neurodevelopmental disorder,

Strengths and limitations of this study

- A randomised controlled trial delivered in a real-world setting using practising clinical staff and covering a total catchment area.
- Outcome data collected from multiple informants including parents, adolescents and teachers, and blinded clinician assessment.
- Adequate statistical power to detect a clinically meaningful effect in the primary outcome variable.
- Randomisation does not control for therapy moderators and process variables such as comorbidities, level of engagement, readiness for change and family support.
- Bias may be introduced by patients refusing to enter the study or by patients who are not randomised to their treatment of choice.

which starts in childhood and is characterised by inattention, impulsivity and hyperactivity that impair functioning.¹ ADHD persists across the lifespan in a majority of patients and causes significant impairment across multiple domains of daily functioning. A majority of children with ADHD continue to have symptoms and impairment during adolescence.^{2–3} The core symptoms contribute to impairment in executive functioning, inhibitory control, working memory and motivation. These deficits prevent the acquisition and implementation of compensatory skills such as organising and planning, leading to difficulties in handling everyday challenges. During adolescence, ADHD is associated with low academic achievement, interpersonal difficulties, substance use disorders, mood disorders and anxiety disorders continuing into adult life.^{3–4} A recent study of comorbidity in a large sample of Norwegian adults with ADHD shows that both men and women had a four to nine times higher prevalence of anxiety, depression, bipolar

and personality disorders, schizophrenia and substance use disorder than the remaining adult population,⁵ indicating the potential for introducing preventive measures in young people with ADHD.

Pharmacotherapy with stimulants, atomoxetine or guanfacine is effective in reducing core symptoms of ADHD in most adolescents with moderate to severe ADHD.⁶ Medication may also improve processing speed, work productivity and perseverance.⁷ However, pharmacotherapy alone may not be sufficient to remediate ADHD and its comorbid symptoms and disorders. National and international guidelines for ADHD recommend non-pharmacological therapies as the first-line or add-on treatment for young people with ADHD,^{8,9} even though there is inadequate evidence to support this recommendation. Specifically, there is limited evidence to support psychological treatments in adolescents with ADHD, which have been less studied than psychological treatments in children.¹⁰

Cognitive-behavioural therapy (CBT) is a well-known psychological treatment for mental disorders across disorders and age groups. Meta-analyses have documented significant treatment effects on disorders such as obsessive compulsive disorder (OCD), anxiety and depression across age groups and in ADHD in adults.^{11,12} There are currently only three published studies on CBT with adolescents with ADHD, and thus little knowledge exists about short-term and long-term treatment effects of CBT on ADHD in this age group.^{13,14} Vidal and colleagues¹⁵ found significant improvement in adaptive functioning as well as ADHD symptoms in the treatment group in their randomised controlled trial (RCT) of adolescents aged 15–21 years. Patients with emotional disorders were excluded from the study. It is therefore unknown to what extent CBT treatment could help ADHD patients with comorbid emotional disorders, which are frequent in a teenage population with ADHD.¹⁶

Previous studies on CBT in other conditions than ADHD have found that different moderators and mediators have implications for treatment effects. For example, in the treatment of OCD in children and adolescents, comorbidity, age, sex and lower quality of life were found to be important moderators and predictive of treatment effect.¹⁷ Age, symptom severity, comorbidity rate and adaptive functioning seem to moderate the effect of CBT in adolescents with depression.¹⁸ Since research on adolescents with ADHD is scarce, we have very limited knowledge of which moderators make the most impact in this patient group. Of note, Vidal and colleagues¹⁵ did not reveal any moderating effect of demographic variables in their study of CBT group therapy outcome.

As there is little knowledge about the short-term outcome of psychological treatment programmes in adolescents with ADHD, and even less knowledge about long-term outcomes, a study of CBT group therapy would fill a gap in the treatment literature. It would be crucial to know if clinically relevant changes in psychiatric symptoms and functioning were associated with the applied

treatment programme and particularly whether the observed changes last over time. Such a project would have the potential to provide results that could help fill knowledge gaps and promote improved quality and efficacy of services for adolescents with ADHD.

When planning a study of CBT group therapy in adolescents with ADHD, we found no manual in a Scandinavian language suited to the purpose. We therefore developed a research manual in Norwegian based on previous work by one of the authors, SY.¹⁹ The CBT programme developed by SY and her colleague Jessica Bramham for use with adolescents and adults includes group therapy modules addressing core symptoms of ADHD and associated problems. After making the Norwegian translation, we tested the manual and the feasibility and acceptability of the treatment in an 11-week pilot study with eight adolescents aged 15–18 years from a child and adolescent outpatient clinic. We found the weekly manual-based programme was both feasible and well accepted by both adolescents and parents. When planning a large RCT to evaluate the effects of the treatment, we made some further adaptations in language, materials and activities to improve the fit to the adolescent age group. We decided to use telephone coaching in-between sessions to encourage the adolescents to extend new strategies into real-life situations. We expected this to be important in working with adolescents with ADHD who may have planning and organisation difficulties.

Aims

The study Cognitive Behaviour Group Therapy in Adolescents with Attention Deficit Hyperactivity Disorder (Clinical Trials, NCT02937142) aims to improve the quality and effectiveness of treatment and care of adolescents with ADHD. We aim to obtain new knowledge related to group CBT in adolescents with ADHD 14–18 years of age referred to assessment and treatment at the Child & Adolescent Psychiatric (CAP) Clinic, St. Olav University Hospital, Trondheim, Norway. The primary outcome investigated will be treatment effect on ADHD symptoms in a 12-week manual-based group CBT treatment programme. We will study the effect post-treatment and at a 9-month follow-up. The secondary outcomes will be characteristics of functional impairment and psychiatric symptoms and the study of moderators and possible mediators of treatment effects. Furthermore, we wish to study the feasibility of the intervention, patient satisfaction and treatment fidelity, and identify therapist factors associated with positive outcomes. We hypothesise that the CBT group will have fewer ADHD symptoms, less severe ADHD, fewer comorbid problems, higher self-efficacy and better functioning at the end of the treatment and at the 9-month follow-up, than the control group. We expect adolescents who are older, who have a higher intelligence quotient (IQ), come from a higher socioeconomic status (SES) background and have comorbid emotional problems to have a more favourable treatment outcome. We hypothesise that change in anxiety problems during

treatment could be a mediator of the primary outcome, as the intervention has a focus on reducing anxiety and coping with the challenges associated with ADHD. We expect adolescents with more ADHD symptoms at intake, a higher degree of ADHD severity, more executive dysfunction problems, lower adaptive functioning and comorbid behavioural disorder to have a less favourable outcome.

METHODS AND ANALYSIS

The main study design

The design is a randomised, controlled, rater-blinded study to evaluate the effectiveness of CBT group therapy for adolescents aged 14 to 18 years with ADHD. We recruited adolescent patients, who received medical treatment but still had impairing symptoms into the study. The patients were randomly assigned to the intervention group or a control group who received treatment as usual. Eligible participants who provided written consent were randomly assigned to the intervention and control groups in a 1:1 ratio. The randomisation was performed using a computer program supplied by the Unit for Applied Clinical Research, a centre of expertise in the Central Norway Health Region. The two groups are followed prospectively to assess the effectiveness of the CBT group programme. We completed the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT)²⁰ checklist of recommended items to address in a clinical trial process. A flow chart for the timeline for recruitment, follow-up assessments and undertaking analyses is shown in figure 1.

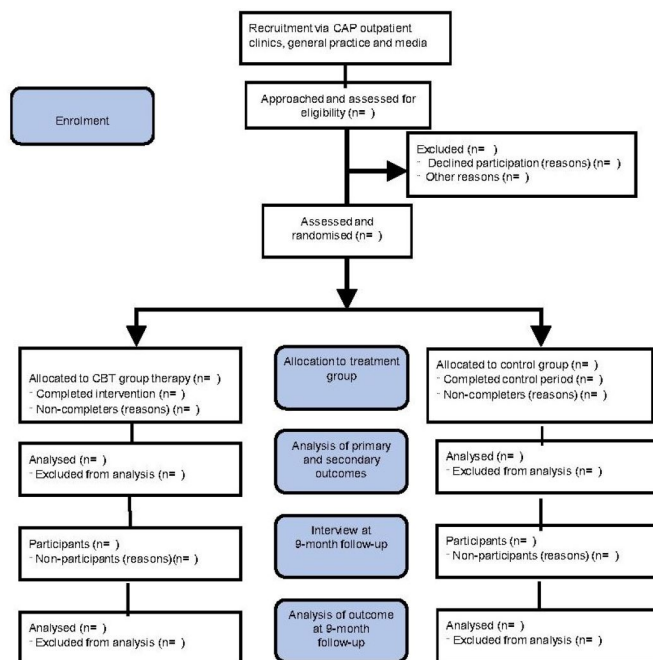


Figure 1 Flow chart diagram of participants in CBT group for adolescents with ADHD: a randomised controlled study. ADHD, attention deficit hyperactivity disorder; CAP, Child & Adolescent Psychiatric; CBT, cognitive-behavioural therapy.

Study recruitment

Patients aged 14 to 18 years with a diagnosis of ADHD according to the International Statistical Classification of Diseases and Related Health Problems, 10th revision²¹ were recruited to the study from two CAP outpatient units at the St. Olav University Hospital with a catchment area of around 230 000 inhabitants (city of Trondheim and a few surrounding municipalities). The recruitment period lasted 2 years and 9 months starting in Winter 2017 and ending in September 2019. Very few private practitioners do assessments and treatment of suspected ADHD adolescents in the area. The number of adolescents with ADHD as the main diagnosis or comorbid diagnosis in the age group 14–18 years in the outpatient clinics was 330 as per February 2019. Most adolescent patients with ADHD are prescribed medication. We assessed and recruited a few additional participants in the study from general practitioners responsible for patients discharged from the clinic on stable medication, through user organisations and through advertisements in media and the local newspaper.

Participants and procedure

The diagnostic process at the admission to the clinic (T1) includes information from multiple informants (patients, parents and teachers), including developmental history, somatic status and school functioning. The routine assessment includes interviews with the adolescent and parents, and the administration of various questionnaires. These include an assessment of emotional and behavioural problems with the Achenbach system of empirically based assessment (ASEBA) checklists²² and ADHD symptoms by the ADHD Rating Scale-IV (ADHD-RS-IV).²³ IQ scores are obtained using Wechsler Intelligence Scales for Children, Fourth Edition.²⁴ Adaptive functioning is scored using the Children's Global Assessment Scale (CGAS).²⁵ Routine clinical treatment include adolescent and parent education about ADHD. Patients with moderate to severe ADHD symptoms are offered medical treatment. A brief intervention for emotional problems may be given before starting medical treatment if indicated. We evaluated the patients in relation to the inclusion criteria after at least 1 month of stable medical treatment with the same medication and dosage.

Inclusion criteria. A diagnosis of ADHD and a Clinical Global Impression Severity (CGI-S)²⁶ score ≥ 3 (mildly ill, some impairment in one setting). Participants should receive medical treatment for ADHD, but patients could be included in the study if they had tried medication with little effect or experienced intolerable side effects. Participants with comorbid diagnoses (typically mild to moderate depressive disorders, anxiety disorders, bipolar disorders, behavioural disorders, tic disorders and mild degree of autism spectrum disorders) were included in the study. **Exclusion criteria** were psychosis, mental retardation (IQ < 70), ongoing substance use

disorder, severe conduct disorder, suicidal behaviour and severe depression.

The adolescent (and parents) were asked to participate in the study through an open invitation brochure providing information about the aim of the project, the randomisation process and the intervention. We invited adolescents who consented to participate into the study.

Assessment procedures

Two clinicians, a clinical neuropsychologist and a child and adolescent psychiatrist interviewed the adolescents using a semistructured psychiatric interview, the Kiddie-SADS-PL.²⁷ We also assessed executive functions, general adaptive functioning, anxiety and depression, sleep patterns, self-esteem and self-efficacy. After the preintervention assessments (T2), follow-up evaluations were performed postintervention (T3) and at a 9-month follow-up (T4). All participants filled in questionnaires at T2 and T3. Participants in the intervention group filled in an additional questionnaire about patient satisfaction with the therapy, at T3. Clinicians blinded to patient assignment complete pre-evaluation and postevaluation. All participants medicated for ADHD were asked during a weekly telephone call if they used their medication as prescribed and further if they had started psychotherapy or other treatment. During the interview at T4, the participants report on ADHD symptoms, emotional and behavioural problems, school functioning and self-efficacy. The interviewers score general and adaptive functioning. In addition, the interviewers ask about current and past treatment during the past 9 months and the adolescents' impression of the CBT group therapy in a longer perspective. See [table 1](#) for a SPIRIT²⁰ table for the evaluation of the study.

INTERVENTIONS

CBT group. The intervention consists of 12 weekly CBT sessions addressing core difficulties and concerns of the adolescent population with ADHD, each session lasting 90 min. The last two sessions consists of a review of the contents and planning for the future ([table 2](#)). Parents are not involved in the treatment sessions. The manual is structured and includes methods and key points, which are used in each session. The key points are visualised in a power point presentation. We included six participants in each group. Two clinicians conducted the sessions (usually a psychologist working together with either another psychologist, a psychiatrically trained special education teacher or a physician). The group leaders received manual training and supervision by an experienced adolescent psychiatrist and CBT supervisor. Between sessions, the participants got a weekly phone call by a coach to motivate them and follow-up on home assignments. Participants could not receive any other treatment than CBT group therapy and medication in the 12-week period. One routine medical follow-up was performed during the intervention period, with registration of blood

pressure, weight and side effects of medication according to standard clinical follow-up in the CAP clinic.

Control group. Participants in the control group continued with medical treatment and received one routine medical follow-up according to standard clinical follow-up in the same way as the intervention group. This is in accordance with treatment-as-usual, as only medical treatment is offered routinely in the clinic at this stage. As in the CBT group, participants who did not use medication received one session with a clinician to monitor their clinical status. After the post-treatment assessments (at T3), there was no offering to enter a CBT group, but patients could start other treatments according to their clinical needs.

TREATMENT FIDELITY

Treatment fidelity in this project has the overall goal of increasing confidence that changes in the dependent variable are attributable to the independent variables. Analysis of treatment fidelity may help to explain study findings, revise interventions for future testing and increase statistical power and effect size by reducing random and unintended variability.²⁸ All sessions (except session 1 and 12) were videotaped and adherence to the manual and to CBT core principles relevant for this study will be assessed through observations by independent raters from a random selection of around 20% of the sessions. The Competence and Adherence Scale for Cognitive Behavioural Therapy²⁹ covers basic CBT components as well as specific session goals. The user can specify the goals for the particular treatment. The scale was originally developed for the treatment of anxiety disorders. It has shown good to excellent reliability. Additional items on group dynamics are included. In addition, each group leader filled in a self-rating scale after each session to evaluate goal achievement in the session and to provide an overall rating of their own work.

Adherence and dropouts

We assess treatment adherence by recording the number of completed CBT sessions. In the case of dropouts, the participants were asked to let the questionnaires filled in before the intervention at T2 remain in the study to be included in the data analysis.

OUTCOME MEASURES

Well-established and validated instruments are used to assess psychiatric morbidity and cognitive and overall functioning at four time points. When adequate, adolescent, parent and teacher reports are acquired. The following instruments are used to collect data from various informants on adolescent psychiatric morbidity including diagnoses, diagnostic classification, symptom load assessment and psychosocial functioning at one or more time points from T1 to T4 ([table 3](#)).

Table 1 SPIRIT table for the evaluation of the CBT group therapy for adolescents with ADHD: a randomised controlled trial

	Study period						Close-out
	Enrolment*	Allocation†	Postallocation				
			Pre-T2	Mid-T2	Post-T3	9-month follow-up T4	
Coh1: Q1 2017	Coh1: Q1 2017	Q1 2017	Coh1: Q1 2017	Coh1: Q1 2017	Coh1: Q2 2017	Coh1: Q1 2018	
Coh2: Q3 2017	Coh2: Q3 2017	Q3 2017	Coh2: Q3 2017	Coh2: Q3 2017	Coh2: Q4 2017	Coh2: Q3 2018	
Coh3: Q1 2018	Coh3: Q1 2018	Q1 2018	Coh3: Q1 2018	Coh3: Q1 2018	Coh3: Q2 2018	Coh3: Q1 2019	
Coh4: Q3 2018	Coh4: Q3 2018	Q3 2018	Coh4: Q3 2018	Coh4: Q3 2018	Coh4: Q4 2018	Coh4: Q3 2019	
Coh5: Q1 2019	Coh5: Q1 2019	Q1 2019	Coh5: Q1 2019	Coh5: Q1 2019	Coh5: Q2 2019	Coh5: Q1 2020	
Coh6: Q3 2019	Coh6: Q3 2019	Q3 2019	Coh6: Q3 2019	Coh6: Q3 2019	Coh6: Q1 2020	Coh6: Q4 2020	Coh6: Q4 2020
Enrolment:							
Eligibility screen‡			X				
Informed consent	X						
Allocation		X					
Interventions:							
<i>Int.: CBT+medication</i>				↔			
<i>Ctr.: Medication</i>				↔			
Assessment:							
Psychiatric diagnosis§			X				
Illness severity¶			X		X	X	
Psychosocial function**			X		X	X	
Primary Outcome							
ADHD symptoms††			X‡		X	X	
Secondary Outcomes							
Behavioural problems‡‡						X	
Emotional problems‡‡						X	
Functional impairment§§			X		X		
Anxiety¶¶¶			X		X		
Depression***			X		X		
Sleep†††			X		X		
Self-esteem‡‡‡			X		X		
Self-efficacy§§§			X		X	X	
Executive functioning¶¶¶¶			X		X		
Treatment satisfaction					X	X	
Treatment fidelity							X

Continued

Table 1 Continued

	Study period			
	Enrolment*	Allocation†	Postallocation	Close-out
*Enrolment occurs in the semester of the delivery of the intervention. Each cohort represents a group of adolescents recruited during the semester.				
†Allocation (randomisation) is conducted at the individual level.				
‡Study eligibility for individual adolescents is based on ADHD diagnosis and being stable on medication (primary outcome measure).				
§Kiddie-SADS-PL.				
¶Clinical Global Impression Severity.				
**Children's Global Assessment Scale.				
††ADHD-Rating Scale-IV.				
‡‡ASEBA Brief Problem Monitor.				
§§Weiss Functional Impairment Rating Scale.				
¶¶¶Screen for Anxiety Related Emotional Disorders				
***Mood & Feelings Questionnaire.				
†††Adolescents' Sleep-Wake Scale.				
‡‡‡Rosenberg Self-Esteem Scale.				
§§§General Perceived Self-Efficacy Scale.				
¶¶¶¶Behaviour Rating Inventory of Executive Function.				
ADHD, attention deficit hyperactivity disorder; CBT, cognitive-behavioural therapy; Kiddie-SADS-PL, Schedule for Affective Disorders and Schizophrenia for School-Age Children—Present and Lifetime version; SCARED, Screen for Child Anxiety Related Emotional Disorders; SPIRIT, Standard Protocol Items: Recommendations for Intervention Trials.				

*ASEBA-YSR Brief Problem Monitor (YSR-BPM)*²² is a short version of the Youth Self-Report school-age form. It includes questions about behavioural and emotional problems and is used for monitoring and follow-up in research and clinical assessment.

*Adolescent Sleep-Wake Scale*³⁰ is a 28-item scale and widely used measure of sleep quality in adolescents.

*ADHD-RS-IV*²³ is a questionnaire completed by parents (home version) or teachers (school version) to detect ADHD symptoms in children and adolescents. The questionnaire contains 18 questions regarding a child's or an adolescent's behaviour during a specified timeframe rated on a 4-point Likert scale.

*Kiddie-SADS-PL Schedule for Affective Disorders and Schizophrenia for School-Age Children—Present and Lifetime version*²⁷ is a semistructured diagnostic interview designed to assess current and past episodes of psychopathology in children and adolescents. Diagnoses of interest to the present study

include ADHD, anxiety disorders, mood disorders, tic disorders, conduct disorders and sleep disorders.

*CGAS*²⁵ is a numeric scale (1 through 100) used to rate the general psychosocial functioning of children under the age of 18 years. A score >70 denotes good functioning.

*CGI-S*²⁶ is used to rate the severity of a patient's illness at the time of assessment. It is a 7-point scale ranging from 1='Normal, not at all ill' to 7='Among the most extremely ill patients', with 0='Not assessed'.

Weiss Functional Impairment Rating Scale for parents and adolescents (*WFIRS-P*, *WFIRS-S*)³¹ are questionnaires appropriate for parent report and adolescent and adult self-report of functional impairment typically affected in ADHD. The questions assess to what degree an individual's behavioural or emotional problems have affected various clinically relevant domains of functioning.

*Screen for Child Anxiety Related Emotional Disorders (SCARED)*³² is a 41-item self-report screening questionnaire for anxiety symptoms in youth.

*Mood and Feelings Questionnaire (MFQ)*³³ is a 33-item inventory self-report tool that measures depressive symptoms in children and adolescents. The last question in the 34-item Norwegian version, "I wasn't as happy as usual even when praised and rewarded," is from the MFQ parent version.³⁴

*General Perceived Self-Efficacy Scale*³⁵ is a 10-item scale designed to assess optimistic self-beliefs to cope with a variety of difficult demands in life.

*Rosenberg Self-Esteem Scale*³⁶ is a 10-item scale widely used as self-report instrument for evaluating individual self-esteem in adolescents and adults.

*Behaviour Rating Inventory of Executive Function (BRIEF)*³⁷ parent form (*BRIEF-P*) is an 86-item assessment of executive function behaviours at home and at school for children and adolescents aged 5–18 years. The *BRIEF*

Table 2 Core treatment modules in the research manual

Core symptom modules	What is ADHD?	1
	Attention	2
	Memory	3
	Organisation and time management	4
	Impulsivity	5
Comorbid disorders and difficulties	Problem solving	6
	Anxiety	7
	Sadness and depression	8
	Sleep	8
	Communication	9
	Frustration and anger	10
The future	Preparing for the future	11 to 12

ADHD, attention deficit hyperactivity disorder.

Table 3 Instruments used with various informants at admission to the CAP clinic and during time points in the study

Instruments used in study (informant)	T1: admission to CAP	T2: pre-	T3: post-	T4*: 9-month follow-up
Kiddie-SADS psychiatric interview (S)		x		
ADHD-RS (ADHD symptoms) (P,T,S)	X(P,T)	X (P,T,S)	X (P,T,S)	X(S)
Children's Global Assessment Scale (CGAS) (C)	x	x	x	x
ASEBA YSR Brief Problem Monitor (S)				x
Clinical Global Impression (CGI) (C)		x	x	x
SCARED (Anxiety) (S)		x	x	
Mood & Feelings Questionnaire (MFQ) (S)		x	x	
BRIEF (Executive Functioning) P,T,S	X (P,T)	X (P,T,S)	X (P,T,S)	
Weiss Functional Impairment Rating Scale (P,S)		x	x	
Adolescent Sleep Wake Scale (S)		x	x	
Rosenberg Self-Esteem Scale (S)		x	x	
General Perceived Self-Efficacy Scale (S)		x	x	x
User satisfaction, usefulness of coaching (S)			x	x

*Telephonic interview.

ADHD, attention deficit hyperactivity disorder; ADHD-RS, ADHD Rating Scale; BRIEF, Behaviour Rating Inventory of Executive Function; C, clinician evaluation; CAP, Child & Adolescent Psychiatric; P, parent report; S, self-report; SADS, Schedule for Affective Disorders and Schizophrenia for School-Age Children; SCARED, Screen for Child Anxiety Related Emotional Disorders; T, teacher report; YSR, Youth Self-Report.

self-report (BRIEF-SR) provides an adolescent's or an adult's own view of his or her executive functioning behaviours.

Adolescent Interview at 1-year follow-up (T4). The telephone interview includes questions about present school situation or other daytime activity, ADHD medication, and furthermore health assessment and treatment in CAP or adult psychiatry, private psychologists or psychiatrists, or primary care during the past 9 months. The interviewer administers the ADHD-RS-IV, YSR-BPM and the General Perceived Self-Efficacy Scale during the interview. The interviewer scores the CGAS and CGI blinded to information about group participation.

Medical history and sociodemographic information

In addition to data collection via validated instruments at T1, T2, T3 and T4, we extract data from medical records, including information about parent SES. Treatment history from T3 to T4 is registered at T4 by type (cognitive, neurobiological, psychodynamic, psychoeducational, social-relational, medication), participant (individual, group, parent, family), number of sessions, length of treatment, inpatient or outpatient, indirect patient work and counselling from community services. SES will be defined as follows: the highest level of parental education will determine parent SES, divided into four categories (≤ 2 years of high school, completed high school +1 year, ≤ 4 years academy/university, ≥ 5 years academy/university).

STATISTICS

Outcome measures at T3 contain ADHD symptom scores; clinician-rated functioning; self- and parent-reported functioning; self-, parent- and teacher-reported executive

functioning; and self-reported anxiety, depression, sleep, self-esteem and self-efficacy. Outcome measures at T4 contain self-reported ADHD symptom scores, clinician-rated functioning, self-reported functioning, anxiety and depression, and self-efficacy. Data will be analysed using mixed-effect models for longitudinal data. Variables included in the assessment of possible interactions with treatment effect will be age, gender, SES, IQ, type of ADHD and comorbidity. Clinical and demographic variables will be included in the mixed-effect model to explore these effects. Potential mediators will be defined before carrying out mediation analyses. We will carry out the mediation analyses following recommendations by Hayes and Rockwood.³⁸ Unless the participants withdraw the consent to participate, we will use all available data from participants with relevant outcome data in an intention-to-treat analysis.

SAMPLE SIZE

Sample size was calculated for a two-sample Student's t-test, for a six-point difference assuming a SD of 9 on the ADHD-RS-IV.²³ The rationale for the use of a six-point difference is supported by the work of Coghill and Seth³⁹ who provide a guide for clinical interpretation of scores from the ADHD-RS-IV. They interpret total scores of 19–26 after a medication trial as partial response, and 26% reduction in scores as a good response. The two previous RCTs of CBT in adolescent ADHD used a six-point difference in ADHD-RS scores¹⁵ or a 30% reduction in ADHD-RS scores,¹⁴ respectively. With significance level 5%, we needed 37 participants in each group to obtain

80% power. To allow for dropouts, we aimed at including at least 48 participants in each group, in total 96.

Ethics and dissemination

All participating parents and adolescents 16 years or older were required to provide informed consent. The recruitment process explained that participation is voluntary and that participants can withdraw from the study at any time without consequences regarding their treatment in the clinic. All participants received documents explaining the purpose and procedures in the study. We record the data obtained by questionnaires and clinical assessment in electronic files that are password protected. Participants received anonymous study IDs that are stored with the collected data. Identifying information is not stored alongside the parent-, self- or teacher-report data. Only the main investigator and researchers directly involved in data analysis will have access to de-identified data.

We will disseminate the results in peer-reviewed international scientific journals. Furthermore, the study group will present the results of the study at regional, national and international scientific conferences, in reports to funders, reports to patient advocacy organisations and press releases to news media. Two PhD students will publish and publicly defend dissertations relating to the study. Planned publications include primary and secondary outcomes, feasibility and patient satisfaction with the treatment and fidelity to the intervention. A main goal of the study group is to publish a Norwegian evidence-based manual for the benefit of patients locally and elsewhere. The CAP clinic and Regional Centre for Child and Youth Mental Health and Child Welfare (RKBU) cooperate extensively with user and patient advocacy organisations, and the research results will be presented to the public during educational seminars arranged by the St. Olav Hospital Learning Centre.

PATIENT AND PUBLIC INVOLVEMENT

We consulted the user committee in the Clinic of Psychiatry at St. Olav University Hospital during the planning state of the study to receive feedback to the principal investigator. The ADHD Association, Mid-Norway, was informed about the project at its planning stage and recommended it to funding authorities and to members. The CAP clinic has an active cooperative network with user organisations and arranges 'learning and mastery' course days where patients with ADHD and family members share their experiences. During the course, clinicians give lectures to patients, families and healthcare providers. Information about the project has been conveyed on such occasions. We will set up a reference group of adolescents from the Norwegian ADHD association as recently suggested by user organisations. The reference group will aid the project with respect to discussion and dissemination of the results.

DISCUSSION

To date there are few RCT studies of CBT in adolescent ADHD. We have designed an RCT that aims to test the

effectiveness of CBT group therapy, with a programme uniquely tailored to the needs of the adolescents. In addition, we will test for patient satisfaction and treatment feasibility. We test the effectiveness of CBT group therapy in a younger age group than a previous RCT of CBT group therapy in adolescents and young adults with ADHD.¹⁵

The present study offers an advantage in its delivery of group CBT in a real-world setting using practising clinical staff and covering a total catchment area. The study employs a different type of control condition than previous studies¹⁵ with a defined limited clinical follow-up. This is less likely to result in exaggerated short-term effects of the intervention compared with the use of waiting list controls.⁴⁰ Another advantage is the use of multiple informants in the assessment of the outcome. Teachers may be as accurate as parents are when evaluating ADHD symptoms⁴¹ and provide an important additional perspective to parents and adolescents.

At the 9-month follow-up, some findings may be limited by the fact that the adolescents are the only informants. Self-ratings may be less valid than parent ratings in the prediction of ADHD persistence.⁴² The sample recruitment may be biased in ways that are difficult to measure. For example, participants may be those who are more engaged and ready for change or have better family support. Further, randomisation does not control for therapy moderators such as psychiatric comorbidities and personality factors associated with these comorbidities. In addition, bias may be introduced by adolescents who refuse to enter the study or by adolescents who do not get their treatment of choice after randomisation.

If the group CBT is shown to be significantly more effective compared with treatment-as-usual, this may encourage the wider dissemination and utilisation of the treatment in the care of adolescents with ADHD. Such initiatives have the potential to increase the number of adolescents who receive effective care to benefit patients in Norway and elsewhere. When designing the study, we decided to examine the effect of group CBT as an add-on to medication, as this seems a reasonable first step before studying the effect of the treatment in adolescents who do not receive medication. Steps might be taken to study the feasibility and treatment effects in adolescents who do not use medication in the future.

COLLABORATION

The study is an active collaboration between the Child and Adolescent Psychiatric Clinic, St. Olav University Hospital and the Regional Competence Centre for Youth—Mental Health and Child Welfare, Norwegian University of Science and Technology, Trondheim, Norway. The core research team make up an international, interdisciplinary research group.

Trial status

The study has recruited 99 patients by the end of the recruitment period in September 2019. The treatments were finalised in January 2020. Data from the 9-month follow-up are being collected until October 2020. Two PhD students have been appointed in the project by August 2019.

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Contributors TSN conceived of the study and wrote the applications for funding. The main research team/steering group undertook the research design: TSN, AMS, PHT, SY and SL. A-LJH, the first PhD student in the study, contributed to the CBT treatment manual in collaboration with TSN and SY and participates in the gathering of data. AMS supervises the therapists in the study, while TSN, AMS, PHT and SL supervise the PhD students. All authors read and provided substantial contribution to the final version of the study protocol and approved the final version of the manuscript.

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Competing interests TSN has received a speaker's fee from Medice in the last year. PHT has received speaker's fees from MEDICE and Shire in the last 3 years. SY has received honoraria for consultation and/or educational talks in the last 5 years from Janssen, HB Pharma and/or Shire. She is author of the 'ADHD Child Evaluation (ACE) and ACE+ (for adults)' and lead author of 'R&R2 for ADHD Youths and Adults'. AMS has received travel support and congress fee from MEDICE in the last year.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods and analysis section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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