

# Psychoeducation in families of children with attention deficit hyperactivity disorder (ADHD) in the United Kingdom

<b>Submission date</b> 30/01/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 24/02/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/04/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

## **Scientific Title**

Psychoeducation in families of children with attention deficit hyperactivity disorder (ADHD) in the United Kingdom: evaluation of the efficacy in a randomised controlled trial and a qualitative examination of the program

## **Study objectives**

1. Psychoeducation program in families of attention deficit hyperactivity disorder (ADHD) children/adolescents will lead to a significant reduction of ADHD symptoms in these children in comparison with a control group
2. Psychoeducation program in families of ADHD children/adolescents will lead to improvement of treatment adherence rates in these children in comparison with a control group
3. Psychoeducation program in families of ADHD children/adolescents will lead to improvement of quality of life in these families in comparison with a control group

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. NHS Research Ethics Committee (NREC), 07/07/2009, ref: 09/H0723/20
2. Research and Development (R&D) Ethics Committee, 30/09/2009, ref: 2009/053

## **Study design**

Single-centre randomised controlled single-blind parallel group trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Attention deficit disorder (ADD)/attention deficit hyperactivity disorder (ADHD)

## **Interventions**

Psychoeducation intervention (experimental group):

Families of ADHD children/adolescents attending psychoeducation sessions. Psychoeducation provided by Child and Adolescent Psychiatrist and consisting of 6 weekly sessions, 120 minutes length, groups of 8 - 10 families.

Sessions organisation:

1. 10 minutes: 'warm-up' period, informal conversation, doubts from the previous session
2. 45 minutes: lecture on the topic
3. 10 minutes: brief pause
4. 40 minutes: topic discussion

Participants encouraged to ask and make comments.

Psychoeducation program for ADHD (adapted from Psychoeducation in Bipolar Disorder):

Session 1: Presentations and group functioning rules, what is ADHD?, core symptoms, diagnostic procedures

Session 2: Aetiological, maintaining and perpetuating factors, comorbidities in ADHD

Session 3: Prognosis and outcome - ADHD in the adolescent and the adult, executive function

Session 4: Pharmacological treatments - stimulants and non-stimulants, diets and other treatments

Session 5: Cognitive behavioural treatment and other management approaches, dealing with everyday-life problems at home I

Session 6: Dealing with everyday-life problems at school, summarising, final questions and doubts, closing down session

Posterior qualitative approach using Focus Group techniques to explore perceived efficacy of the psychoeducation program.

Control group:

Routine medical care including medication treatment and check-ups, crisis interventions, and parent counselling and support.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

ADHD symptoms by Conners Scale, measured at baseline, 12 weeks, 6 months and 9 months

### **Key secondary outcome(s)**

1. Attitudes Towards Treatment by QATT
2. Adherence levels measured by direct questioning to families and pill counting (integrated into a composite)
3. Psychiatric conditions: Strengths and Difficulties Questionnaire (SDQ)
4. Children's Global Assessment Scale (C-GAS)
5. Clinical Global Impression (CGI)
6. Quality of life by PedsQL™ Core Version 4 and Cognitive Scale
7. Satisfaction with psychoeducation program by the Consumer Satisfaction Questionnaire
8. Parents Stress Index (PSI) 3rd Edition

Assessments on all measures pre-treatment and post-treatment. Follow-up assessment on all measures after 3 months and 6 months.

### **Completion date**

01/09/2011

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosis of attention deficit disorder (ADD)/attention deficit hyperactivity disorder (ADHD) in child (Diagnostic and Statistical Manual of Mental Disorders, 4th Edition [DSM-IV]), with most of their co-morbidity represented (except for the exclusion criteria), and any treatment prescribed
2. Age of child between 4 and 19 years, either sex
3. Informed consent of the parents and the children available
4. Parents' age greater than or equal to 18 years
5. Responsibility and legal capacity in parents

6. Participant on clinical ADHD symptoms stabilisation for at least 1 month before entering the study (with or without medical treatment)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Severe Autistic Spectrum Disorders (\*)
2. Severe learning disabilities (\*)
3. Earlier or current participation in other intervention trials that might interfere with the current study

(\*) due to added problems to ADHD, thus requiring a different sort of intervention

**Date of first enrolment**

01/03/2010

**Date of final enrolment**

01/09/2011

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

Department of Child and Adolescent Psychiatry

London

United Kingdom

SE5 8AZ

**Sponsor information**

## Organisation

Kings College London (UK)

## ROR

<https://ror.org/0220mzb33>

## Funder(s)

### Funder type

Charity

### Funder Name

South London and Maudsley NHS Charitable Funds (UK)

### Funder Name

The Alicia Koplowitz Foundation (Fundacion Alicia Koplowitz) (Spain)

### Funder Name

Carlos III Institute of Health (Instituto de Salud Carlos III) (Spain) (ref: ETS 07/90902)

## Results and Publications

### 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="#">Results article</a>	results	01/03/2020		Yes	No