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

Submission date	Recruitment status	[X] Prospectively registered
30/01/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/02/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/04/2017	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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

Secondary outcome measures
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.

Overall study start date
01/03/2010

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

Age group
Child

Lower age limit
18 Years

Sex
Both

Target number of participants
70 (35 intervention group, 35 control group)

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
England

United Kingdom

Study participating centre
Department of Child and Adolescent Psychiatry
London
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Sponsor information

Organisation
Kings College London (UK)

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De Crespigny Park
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Sponsor type
University/education

Website
http://www.kcl.ac.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/03/2020		Yes	No