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Psychoeducation in families of children with attention deficit hyperactivity disorder (ADHD) in Spain

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

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 Spain: evaluation of the efficacy in a randomised controlled trial

Study objectives
1. Psychoeducation intervention 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 intervention 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 intervention 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)
Local medical ethics committee (Complejo Hospitalario de Jaen, Spain) approved in September 2007

Study design
Single centre randomised controlled double-blind parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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 12 weekly sessions, 90 minutes length, groups of 8 - 10 families.

Sessions organisation:
1. 10 - 20 minutes: "warm-up" period, informal conversation, doubts from the previous session
2. 30 - 35 minutes: lecture on the topic
3. 10 minutes: brief pause
4. 30 - 40 minutes: topic discussion
Participants encouraged to ask and make comments.

Psychoeducation program for ADHD:
Session 1: Presentations and group functioning rules. What is ADHD?
Session 2: Core symptoms. Diagnostic procedures
Session 3: Etiological, maintaining and perpetuating factors
Session 4: Comorbidities in ADHD
Session 5: Prognosis and outcome: ADHD in the adolescent and the adult
Session 6: Executive function
Session 7: Pharmacological treatments: stimulants and non-stimulants
Session 8: Diets and other treatments
Session 9: Cognitive behavioural treatment and other management approaches
Session 10: Dealing with everyday-life problems at home I
Session 11: Dealing with everyday-life problems at home II
Session 12: Dealing with everyday-life problems at school
Session 13: Summarising, final questions and doubts. Closing down session.

Support group (active control group):
Families of ADHD children/adolescents. Parents attending 12 weekly sessions, 90 minutes length, groups of 8 - 10 families, non-structured support groups provided by the same Child and Adolescent Psychiatrist. Control group only differs on the educational content provided.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
ADHD-symptoms by Conners Scale, measured at baseline, 12 weeks, 6 months, 9 months, and 15 months

Secondary outcome measures
1. Attitudes Towards Treatment Questionnaire (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), 3th Edition

Assessments on all measures pre-treatment and post-treatment. Follow-up assessment on all measures after 3 months, 6 months and 12 months.

Overall study start date
01/09/2009

Completion date
01/09/2010

Eligibility

Key inclusion criteria
1. Diagnosis of attention deficit disorder (ADD)/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 3 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
01/09/2009

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
Spain

Study participating centre
Fundacion para la Investigacion Biosanitaria de Andalucia Oriental (FIBAO)
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Sponsor information

Organisation
Fundacion para la Investigacion Biosanitaria de Andalucia Oriental (FIBAO) (Spain)

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Sponsor type
Research organisation

Website
http://www.fibao.es/

Funder(s)

Funder type
Charity

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