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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

#### Contact name

Dr Maite Ferrin

#### Contact details

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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 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

# 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 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(s)

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

### Key secondary outcome(s))

- 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.

#### 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** 

# 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

01/09/2009

#### Date of final enrolment

01/09/2010

# Locations

# Countries of recruitment

Spain

#### Study participating centre

Fundacion para la Investigacion Biosanitaria de Andalucia Oriental (FIBAO)

Granada

Spain

18014

# Sponsor information

## Organisation

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

# 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**

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? Participant information sheet 11/11/2025 11/11/2025 No

Participant information sheet Yes