# Impact of attention-deficit hyperactivity disorder (ADHD) on the health and well-being of families

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>Protocol</li></ul>		
08/09/2010				
Registration date	Overall study status	Statistical analysis plan		
23/12/2010	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
12/05/2017	Mental and Behavioural Disorders			

#### Plain English summary of protocol

Background and study aims

Attention deficit-hyperactivity disorder (ADHD) is the most common childhood onset neurobehavioral disorder and is estimated to affect around 4-12% of 6-12 year olds. ADHD is characterised by developmentally inappropriate hyperactivity, impulsivity, and inattention continuing throughout life. Although there is existing research relating to poorer health and social outcomes for ADHD children, little of this work uses generic quality of life measures, or those which can be converted into utility measures, such as Quality Adjusted Life Years (QALYs). This study aimed to address gaps in the existing knowledge base of quality of life of families who have a child with ADHD, through an observational study of children with ADHD and their families. The results will paint a detailed picture of what life is like for families who live with a child with ADHD, and how this impacts upon the health and well-being of all family members.

#### Who can participate?

Children aged 6 to 18 with a current diagnosis of ADHD, and their parents/guardians and siblings. Families where there were no children with ADHD were also recruited as the control group.

#### What does the study involve?

Questionnaires were given to children with ADHD and their families at one time point. There were six questionnaire booklets to be completed by a family, though the number of booklets varied according to the number of family members. There was a booklet for all children to complete, booklets for the main carer to complete about all children, and booklets for both carers to complete. A booklet was also sent to the child with ADHD's teacher and the research nurse completed a booklet from the child with ADHD's clinical notes. In addition, the main carer in 100 of the families recruited also completed a Daily Mood Diary for one week, where a set of 15 questions were asked 10 times a day. Families where there were no children with ADHD were also recruited and completed the questionnaire booklets and the daily diaries; this was the control group.

What are the possible benefits of participating?

There were no direct benefits and there were no risks to the families in taking part in the study as it was an observational study and there was no change to the child with ADHDs treatment due to the study. However, the results of the study may help research into ADHD and the impact this condition has upon families.

Where is the study run from?

Families were recruited from 15 NHS trusts over the UK, and the trial was run from the University of Sheffield (UK).

When is the study starting and how long is it expected to run for? Families were recruited between December 2010 and August 2012, and the control group continued to be recruited up to March 2013.

Who is funding the study? The study was funded by Shire Pharmaceuticals (UK).

Who is the main contact? Prof John Brazier

#### Contact information

#### Type(s)

Scientific

#### Contact name

Prof John Brazier

#### **ORCID ID**

https://orcid.org/0000-0001-8645-4780

#### Contact details

University of Sheffield SCHARR Regent Court 30 Regent Street Sheffield United Kingdom S1 4DA

#### Type(s)

Public

#### Contact name

Ms Katie Briggs

#### Contact details

University of Sheffield SCHARR Regent Court 30 Regent Street Sheffield United Kingdom S1 4DA +44 114 222 6128 c.e.biggs@sheffield.ac.uk

## Additional identifiers

Protocol serial number

8590; Version 1

# Study information

#### Scientific Title

Assessing the impact of children with attention-deficit hyperactivity disorder (ADHD) on the health and well-being of their families: an observational cross-sectional study

#### **Study objectives**

This study will fill in a number of important knowledge gaps regarding attention-deficit hyperactivity disorder (ADHD) and its impact on the child and family members. Questionnaires will be given to children with ADHD (6 - 18 years old) and their families. The data from these questionnaires will be expressed in generic health-related quality of life (HRQoL) or utility measures for families where at least one child has ADHD. The use of HRQoL measures in economic evaluation to aid decision making in the NHS is widespread.

In one geographical area the main carer in the family will complete an electronic mood diary for one week and this will be compared with a control group matched by postcode and family size.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Sheffield Medical Research Ethics Committee (MREC), 26/05/2010, ref: 10/H1308/14

## Study design

Multicentre observational cross-sectional study

#### Primary study design

Observational

#### Study type(s)

Quality of life

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

Attention deficit hyperactivity disorder

#### **Interventions**

Amended as of 12/01/2010:

This is a cross-sectional study administering questionnaires. There are six booklets to be completed by a family, though the number of booklets will vary according to the number of

family members. There is a booklet for all children to complete, booklets for the main carer to complete about all children and booklets for both carers to complete. A booklet will also be sent to the child with ADHD's teacher and the research nurse will complete a booklet from the child with ADHD's medical notes.

The main carer in 100 of the families recruited will also complete a Daily Mood Diary for one week, where a set of 15 questions will be asked 10 times a day.

Follow-up length: 0 months Study entry: registration only

#### Initial information at time of registration:

This is a cross-sectional study administering questionnaires. There are six booklets to be completed by a family, though the number of booklets will vary according to the number of family members. There is a booklet for all children to complete, booklets for the main carer to complete about all children and booklets for both carers to complete. A booklet will also be sent to the child with ADHD's teacher and the research nurse will complete a booklet from the child with ADHD's medical notes.

The main carer will also complete a Daily Mood Diary for one week, where a set of 15 questions will be asked 10 times a day.

Follow-up length: 0 months Study entry: registration only

#### **Intervention Type**

Other

#### **Phase**

Not Applicable

#### Primary outcome(s)

Health related quality of life (parents) is measured using the EQ5D at one time point.

#### Key secondary outcome(s))

Secondary outcome measures as of 12/05/2017:

#### Children:

- 1. Health related quality of life is measured using the Child Health Utility (CHU-9) questionnaire at at one time point
- 2. Health related quality of life is measured using the EQ-5D-Y (Youth version) at at one time point
- 3. Life satisfaction is measured using questions taken from the survey "Understanding Society" at one time point
- 4. Sibling bullying is measured using questions taken from the survey "Understanding Society" at one time point

#### Parents:

- 1. Life satisfaction is measured using questions taken from the survey "Understanding Society" at one time point
- 2. Marital satisfaction is measured using questions taken from the survey "Understanding Society" at one time point

- 3. Positive mental health is measured using questions taken from the survey "Understanding Society" at one time point
- 4. Positive moods is measured using questions taken from the survey "Understanding Society" at one time point
- 5. Productivity is measured using questions taken from the survey "Understanding Society" at one time point
- 6. Sleep disruptions are measured using questions taken from the survey "Understanding Society" at one time point
- 7. ADHD symptoms of the child with ADHD are measured using ADHD rating scale (ADHD RS-IV) at one time point
- 8. The impact of behavioural symptoms on daily functioning of the child with ADHD are measured using the Strength and Difficulties Question (SDQ) at one time point
- 9. The impact of behavioural symptoms on daily functioning of the child with ADHD are measured using the WEISS Functional Impairment Scale at one time point
- 10. ADHD symptoms of the parent are measured using the Adult self-report scale (ASRS v1.1) at one time point

#### Original secondary outcome measures:

- 1. For children:
- 1.1. Child Health Utility (CHU-9)
- 1.2. EQ-5D-Y (Youth version)
- 1.3. Life satisfaction
- 1.4. Sibling bullying
- 2. For parents:
- 2.1. Life satisfaction
- 2.2. Marital satisfaction
- 2.3. Positive mental health
- 2.4. Positive moods
- 2.5. Productivity
- 2.6. Sleep disruptions

#### Completion date

31/12/2012

## **Eligibility**

#### Key inclusion criteria

- 1. A child with a current diagnosis of ADHD aged 6 to 18 years, either sex
- 2. Siblings must be between 6 and 18 and living at home with the ADHD child
- 3. Parents/guardians must be living at home with the ADHD child

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Child

#### Lower age limit

6 years

#### Upper age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. A child with a comorbid diagnosis of conduct disorder
- 2. The ADHD child is attending the clinic for the first time following their diagnosis

#### Date of first enrolment

01/12/2010

#### Date of final enrolment

30/09/2012

## Locations

#### Countries of recruitment

**United Kingdom** 

England

Scotland

#### Study participating centre Medway Maritime Hospital

Residence 13 Gillingham United Kingdom ME7 5NY

#### Study participating centre Ashurst Child and Family Centre

Lyndhurst Road Ashurst Southampton United Kingdom SO40 7AR

#### Study participating centre

#### Centre for Child Health

19 Dudhope Terrace Dundee United Kingdom DD3 6HH

# Study participating centre CAMHS

Benton House Sandyford Road Newcastle upon Tyne United Kingdom NE2 1QE

#### Study participating centre Queen's Medical Centre

Child and Adolescent Psychiatry Department E Floor South Block Nottingham United Kingdom NG7 2UH

# Study participating centre CAMHS

Derbyshire Mental Health Services NHS Trust The Townhouse 1235 Green Lane Derby United Kingdom DE1 1RZ

#### Study participating centre John Coupland Hospital

Lincolnshire Partnership NHS Foundation Trust CAMHS Morton Centre Ropery Road Gainsborough United Kingdom DN21 2TJ

# Study participating centre Wolfson Research Institute

Tees Esk & Wear Valleys NHS Foundation Trust Centre for Integrated Healthcare Research University Boulevard Thornaby Stockton-on-Tees United Kingdom TS17 6BH

# Study participating centre CAMHS

Rotherham Doncaster and South Humber Mental Health NHS Foundation Trust Rotherham United Kingdom S65 1DJ

#### Study participating centre Great North Children's Hospital

Newcastle Upon Tyne Hospitals NHS Foundation Trust CAHMS Queen Victoria Road Newcastle upon Tyne United Kingdom NE1 4LP

#### Study participating centre Ryegate Children's Centre

Sheffield Children's NHS Foundation Trust CAMHS Tapton Crescent Road Sheffield United Kingdom S10 5DD

# Study participating centre Harlow CAMHS

North Essex Partnership NHS Foundation Trust Wych Elm Harlow United Kingdom CM20 1QR

# Study participating centre Valentine Centre

Leicestershire Partnership NHS Trust CAMHS Leicester United Kingdom LE7 7GX

# Study participating centre Sustain (CAMHS)

Coventry and Warwickshire NHS Trust Gulson Clinic Gulson Road Coventry United Kingdom CV1 2SU

# Sponsor information

#### Organisation

University of Sheffield (UK)

#### **ROR**

https://ror.org/05krs5044

# Funder(s)

#### Funder type

Industry

#### **Funder Name**

Shire (Jersey) (UK)

#### Alternative Name(s)

Shire Pharmaceuticals

## **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

For-profit companies (industry)

#### Location

Ireland

## **Results and Publications**

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as consent was not sought from participants for this. There may be some scope for the sharing of anonymised data, please contact the study lead John Brazier.

#### IPD sharing plan summary

Not expected to be made available

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2016		Yes	No
Participant information sheet	version V7	15/11/2011	12/05/2017	No	Yes
Participant information sheet	version V6	27/03/2011	12/05/2017	No	Yes
Participant information sheet	version V4	27/03/2011	12/05/2017	No	Yes
Participant information sheet	version V5	27/03/2011	12/05/2017	No	Yes
Participant information sheet	version V2	16/04/2010	12/05/2017	No	Yes
Participant information sheet	version V4	27/03/2011	12/05/2017	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes