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

Submission date
08/09/2010

Recruitment status
No longer recruiting

Registration date
23/12/2010

Overall study status
Completed

Last Edited
12/05/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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

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

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cross-section survey

Study setting(s)

Other

Study type(s)
Quality of life

Participant information sheet
See additional files

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

Secondary outcome measures

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

Overall study start date
01/04/2009

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

Age group
Child

Lower age limit
6 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
1000 families, approx 4000 individuals

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
England

Scotland

United Kingdom

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)

Sponsor details

Samuel Fox House
Sheffield
England
United Kingdom
S1 4DT

Sponsor type
University/education

Website
http://www.sheffield.ac.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

Publication and dissemination plan
Other publications regarding the results in relation to parent outcomes and on Part B of the study (daily diaries) are planned.

Intention to publish date
31/12/2017

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