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Does the identification and treatment of comorbid anxiety disorders in children with attention deficit hyperactivity disorder (ADHD) improve outcomes?

Submission date
24/09/2013

Recruitment status
No longer recruiting

Registration date
02/10/2013

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
A large number of children with attention deficit hyperactivity disorder (ADHD) also have an anxiety disorder (25-50%). Children who have both ADHD and anxiety have poorer quality of life, daily functioning, and social functioning, and their parents have increased mental health difficulties and are more likely to miss work. Even when anxiety is identified in these children, symptoms may be managed using medication rather than behavioural interventions, but behavioural interventions may be more acceptable to parents. This study aims to assess the feasibility and acceptability of a cognitive behavioural treatment (CBT) program aiming to treat anxiety problems in children with ADHD and to explore the impact on child and family outcomes.

Who can participate?
Children aged 8-12 years with ADHD and anxiety who have previously participated in ADHD research at the Murdoch Childrens Research Institute and indicated an interest in future research.

What does the study involve?
Participants will be randomly allocated to a either a treatment group or a usual care group Participants in the treatment group will attend 10 sessions with a clinician where they will learn strategies to manage their anxiety. Participants in the usual care group will be able to access usual care for their ADHD from their paediatrician.

What are the possible benefits and risks of participating?
Participants in the treatment group may have improved anxiety which may lead to improvements in the childs behaviour and wellbeing. This may also improve parent wellbeing. Participants in the usual care group will not receive any direct benefit from participation. We do not anticipate any risks, side-effects, or discomforts as a result of participation.

Where is the study run from?
The study has been set up by the Murdoch Childrens Research Institute (MCRI) at the Royal Childrens Hospital (Australia).

When is the study starting and how long is it expected to run for?
The study is expected to start in October 2013. Follow-up information will be collected from participants 5 months after they are enrolled in the study.

Who is funding the study?
Murdoch Childrens Research Institute (MCRI), Australia.

Who is the main contact?
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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
Does the identification and treatment of comorbid anxiety disorders in children with attention deficit hyperactivity disorder (ADHD) improve outcomes: pilot for a large-scale randomised controlled trial

Study objectives
We hypothesise that the intervention will be a feasible and acceptable treatment for anxiety in children with ADHD.

On 08/05/2014 the anticipated end date was changed from 30/04/2014 to 30/07/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Royal Childrens Hospital Human Research Ethics Committee, 30/10/2013

Study design
Single-centre randomised controlled 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 hyperactivity disorder (ADHD) and anxiety

Interventions
Cool Kids Program (intervention group):
The intervention will be administered by a clinical child psychologist and a study-employed research assistant. The research assistant will receive training in the intervention administration by the PI, a clinical child psychologist and will also attend a one day Cool Kids Program training workshop, run by the developers of the program at Macquarie University in Sydney.
Parents and children will be seen for eight weekly hour-long sessions followed by two biweekly hour-long sessions (total of 10 sessions). The Cool Kids Program aims to help families and children to learn about anxiety and worries and to develop the skills to be able to manage child anxiety. Each session will include time with the child alone, time with parents alone and time with the whole family.

Usual care (control group):
Families in the usual care group will be able to access usual care for ADHD from their childs paediatrician and/or other health services.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Acceptability and feasibility will be measured at 4 months post-randomisation through:
1. Participant uptake of the intervention
2. Intervention session attendance
3. Rates of participant drop-out
4. Parent and child completed evaluation of the treatment program

Secondary outcome measures
Secondary child outcomes will be measured at 4 months post randomisation and include:
1. Anxiety diagnoses (Anxiety Disorders Interview Schedule for DSM-IV parent report)
2. Anxiety symptoms (Spence Child Anxiety Scale parent and child report; School Anxiety Scale teacher report)
3. ADHD symptoms (ADHD Rating Scale IV parent and teacher report)
4. Overall behaviour (Strengths and Difficulties Questionnaire parent and teacher report)
5. Quality of life (Pediatric Quality of Life Questionnaire 4.0 parent report)
6. Sleep problem none, mild, moderate, severe (parent report)
7. School attendance over the past 3 months (days late, days missed parent report)

Secondary primary caregiver outcomes will be measured at 4 months post randomisation and include:
1. Mental health symptoms (Depression Anxiety Stress Scale)
2. Work attendance over the past 3 months (days late, days missed)

Overall study start date
14/10/2013

Completion date
30/07/2014

Eligibility

Key inclusion criteria
1. Families of children aged 8-12 years who have previously participated in ADHD research at Murdoch Childrens Research Institute (MCRI) and have indicated an interest in hearing about future research.
2. Participants must live within a 40km radius of the Royal Childrens Hospital and have caregiver report of:
2.1. ADHD symptoms meeting Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria for ADHD (child also needs to have been previously diagnosed with ADHD by a paediatrician)
2.2. Anxiety symptoms meeting DSM-IV criteria for at least one of the following anxiety disorders: generalised anxiety disorder, separation anxiety disorder, or social phobia
3. Participants who are taking medication for anxiety can participate provided they are still experiencing significant anxiety symptoms and have been on stable medication for a minimum of six weeks

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Receiving specialised treatment for their anxiety from a psychologist or psychiatrist
2. Major illness or disability
3. Non-English speaking

Date of first enrolment
14/10/2013

Date of final enrolment
30/07/2014

Locations

Countries of recruitment
Australia

Study participating centre
Royal Children's Hospital
Parkville
Australia
3052

Sponsor information

Organisation
Murdoch Childrens Research Institute (Australia)

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Sponsor type
Research organisation

Website
http://www.mcri.edu.au/

ROR
https://ror.org/048fyec77

Funder(s)

Funder type
Research organisation

Funder Name
Murdoch Childrens Research Institute (MCRI) (Australia) - MCRI Population Health Theme

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	01/03/2018	22/01/2019	Yes	No