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The efficacy of a specialist and a generic parenting programme for the treatment of preschool attention deficit hyperactivity disorder

Submission date
06/02/2012

Recruitment status
No longer recruiting

Registration date
06/02/2012

Overall study status
Completed

Last Edited
04/10/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The main symptoms of attention deficit hyperactivity disorder (ADHD) are inattention, overactivity and impulsiveness. The UK National Institute for Health and Clinical Excellence (NICE) estimated that in 2008 about 210,000 children aged 5-18 years are affected by ADHD in England and Wales. Children and young people with ADHD suffer a wide range of issues that can have a negative impact on their everyday life, family, education and future prospects. There is now an increasing number of children, particulary preschool aged children, attending medical, social and education services for behaviour problems related to this disorder. The personal, social, and financial burden to families and their child with ADHD can be significant and the cost to society of ADHD is high and growing.

Treatment for ADHD generally begins during the school years. Medication is a recommended and effective treatment for older children and adults but parents often have concerns about the use of medication for the control of behaviour in younger children. However, parenting programmes have been recommended for the treatment of behaviour problems. A number of such programmes have been designed particularly to treat behaviour problems in children but have not been developed to tackle the core symptoms of ADHD such as inattention, overactivity and impulsiveness. Children with ADHD may also have other difficulties such as learning or speech and language difficulties and ideally parenting programmes should be adapted to deal with these complications too.

The aim of this study is to decide which of two parenting programmes works best to help children with preschool-type ADHD problems. These programmes are:
1. The Incredible Years (IY), a group-based programme for parents which is carried out in the community, e.g. in a local hall
2. The New Forest Parenting Programme (NFPP) which is carried out with the parent in their own home.

IY has been designed to deal with general behaviour problems in children but has also shown some success in the treatment of children with ADHD behaviours. The NFPP has been designed specifically to tackle the core symptoms of ADHD and other co-occurring difficulties in children. In the current trial both programmes will be 12 weeks long with one session of between 1 and 2 hours every week.

Who can participate?
The parent / main caregiver (18 years of age or over) and their preschool child aged 2 years 9 months to 4 years 6 months who has significant problems with overactive or hyperactive behaviour. We will ask you to complete some questionnaires and assessments to see if you and your family would benefit from participating in a parenting programme.

What does the study involve?
If the child is eligible and agrees to take part in this study, we will ask them either to take part in one of the 12 week parenting programmes which will begin within the following few weeks or we will ask you to continue for 12 weeks as normal receiving the usual type of help and advice in the community. If we ask them to continue as normal then after the 12 weeks they will be asked if they would still like to undertake the parenting programme. So whichever group they are in they will eventually receive a parenting programme, if they wish. They will be free to withdraw from the research at any time, without giving a reason.

Before the start of the programme and after it has finished a researcher will visit the family in their home and ask them to complete a number of questionnaires and assessments measuring ADHD symptoms and other aspects of the childs behaviour and the mothers mental health. This will take about 1 and a half hours of your time. We will also be asking some parents if we can come back 6 months after that second visit in order to complete some further questionnaires. A therapist will also arrange a visit to their home before the start of the programme. During the programme, parents will complete 3 questionnaires each week for 6 weeks. Parenting sessions will be audio- or video-recorded for the purpose of therapist training and supervision.

At some point in this period we will also arrange to collect a saliva sample for DNA. This will help us to see if genetic make-up alters how useful parenting programmes may be for parents and their children.

What are the possible benefits and risks of participating?
It is hoped that the parent or main caregiver will enjoy taking part in a parenting programme and that this will be of benefit to their child with preschool ADHD type problems and to the family in general. We do not feel that any risks are involved in participating in this study which has been approved by the South Central Portsmouth Research Ethics Committee.

Where is the study run from?
The study is being carried out by researchers in four centres across the UK, in Southampton, North Staffordshire, Nottingham and Dundee. We can only enlist parents to the research if they live fairly local to the research centre in each of these areas.

When is the study starting and how long is it expected to run for?
Enlistment of parents/main caregivers to the study will commence in February/March 2012 and the first block of parenting programmes will start in April 2012. We will carry out five block of 12 week parenting programmes over the next 30 months. We hope to enlist more than 300 parent /main caregivers in total across the four centres. Groups of parents will take part in the NFPP and IY programmes which will run alongside each other in these 12 week blocks.

Who is funding the study?
National Institute for Health Research who oversee research in the NHS in the UK.

Who is the main contact?
Dr Donna McCann
dcm1@soton.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Edmund Sonuga-Barke

Contact details
School of Health Sciences
University of Southampton
University Road
Southampton
United Kingdom
SO17 1BJ
-
ejb3@soton.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7669

Study information

Scientific Title
A multicentre randomised controlled trial comparing the efficacy of a specialist and a generic parenting programme for the treatment of preschool ADHD

Acronym
COPPI

Study objectives
Attention Deficit Hyperactivity Disorder (ADHD) is estimated to affect between 3 to 5% of the school aged population. The goal of the programme of which this study is a part is to develop a programme for early detection and intervention for ADHD (PEDIA). In this study a new enhanced version of the New Forest Parenting Package (NFPP) will be used. The trial will assess the

effectiveness and cost effectiveness of e-NFPP relative to a generic group based parent training approach recommended as cost effective by NICE - Incredible Years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central Portsmouth, 20/10/2011, ref: 11/SC/0391

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Attention deficit hyperactivity conduct disorder

Interventions
Description: Four centres will recruit 82/83 families with pre-schoolers

1. a-NFPP and IY, Adapted New Forest Parenting Package(a-NFPP) n=141 parent/child dyads
2. Incredible Years (IY) n=141 parent/child dyads
3. Treatment as usual (TAU) n=47 parent/child dyads

Follow-up length: 6 months

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
ADHD:
SNAP-IV-P ADHD Scale (Parent completed) Questionnaire [61] average score (0-3) on Items 1 -18 measured at T1, T2, T3 for 10 minutes

Secondary outcome measures
1. ADHD:
Childs solo play - observation measure [48] Index of Attention scale assessed from time on task / no. of switches in activity with high scores representing more attention and less switching measured at T1, T2, T3 for 10 minutes
SNAP-IV-T ADHD Scale (Teacher completed) Questionnaire [61] average score (0-3) on Items 1 -18measured at T1, T2, T3 for 5 minutes
2. ODD
Eyberg Child Behaviour Inventory (Parent) [62] - total of 36 items each assessed on Intensity Scale (1-7) and on Problem Scale (Yes/no) indicating problematic for parent. Cut offs representing high risk children are 127 for the Problem Scale and 11 for Intensity Scale measured at T1, T2, T3 for 10 minutes
SNAP-IV-T ODD Scale (Teacher and Parent completed) Questionnaire [61] average score (0-3) on Items 19-26 measured at T1, T2, T3 for 5 minutes
3. Health Economic Costs
Revised - Client Service Receipt Inventory [R-CSRI] - [63] assessment of economic costs based on application of standard unit costs to use by young person of a range of health and social care services within a 6 month window measured at T1, T2, T3 for 15 minutes
4. Quality of Life (Health Related)
EQ(5D) Parent and Child - [64] - Descriptive profile and index value for health status (0-100) measured at T1, T2, T3 for 10 minutes

Overall study start date
01/03/2012

Completion date
30/11/2014

Eligibility

Key inclusion criteria
To be included in the trial children and their families must be:
1. Parents/main caregivers aged 18 years of age or more (with or without moderate health issues)
2. Parents/main caregivers of children aged 2 years 9 months to 4 years 6 months with significant symptoms of preschool ADHD (with or without comorbid conditions such as language and communication difficulties, learning difficulties or conduct problems
3. Children who screen positive for ADHD symptoms based on the parental report Werry Weiss Peters Activity Rating Scale (socre of 20 or more)
4. Children who have a score of 6 or more symptoms on the Inattention Scale together with a rating of impact/impairment or 6 or more symptoms on the Hyperactivity/Impulsivity Scale and a rating of impact/impairement according to the parent reported DISC-IV (ADHD Scale) for Children.
5. Male or female
6. Upper age limit 54 months
7. Lower age limit 33 months

Participant type(s)
Mixed

Age group

Mixed

Sex
Both

Target number of participants
UK Sample Size: 329

Key exclusion criteria
1. Children has a diagnosis of autism
2. Child is in foster care
3. Child has extreme learning difficulties as defined by a score below an age appropriate developmental level for more than 6 out of 12 items taken from 4 scales of the PIP Developmental Scales:
3.1. Physical Development: 3 items
3.2. Development: 4 items
3.3. Eye-Hand Development: 1 item
3.4. Development of Play: 4 items)
4. Child has very poor or no language as defined by a score below an age appropriate developmental level for more than 3 out of 6 items taken from the Language Development Scale of the PIP Developmental Scales
5. Parents/main caregiver does not have a working knowledge of English
6. Parents/main caregivers has a serious mental illness (e.g. psychosis, extreme learning difficulties, manic depressive disorder)
7. Family has a child on the Child Protection Register

Date of first enrolment
01/03/2012

Date of final enrolment
30/11/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Health Sciences
Southampton
United Kingdom
SO17 1BJ

Sponsor information

Organisation
Southampton City Primary Care Trust (UK)

Sponsor details
Occupational Health & Safety Service
Moorgreen Hospital
Botley Road
West End
Southampton
England
United Kingdom
SO30 3JB
+44 (0)23 8029 6904
abc@email.com

Sponsor type
Hospital/treatment centre

Website
http://www.southamptonhealth.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme (UK) ref: RP-PG-0108-10061

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	25/04/2014		Yes	No
Results article	results	01/06/2018		Yes	No