

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

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| Submission date 06/02/2012 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 06/02/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 04/10/2018 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> 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, particularly 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 child's behaviour and the mother's 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 blocks 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?
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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
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 1-18 measured 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 (score 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/impairment 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 |