PArents, Teachers and CHildren WORKing together (PATCHWORK)

| Submission date | Recruitment status | Prospectively registered | | |
|-------------------|----------------------------------|--|--|--|
| 18/05/2012 | No longer recruiting | [X] Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 03/07/2012 | Completed | [X] Results | | |
| Last Edited | Condition category | Individual participant data | | |
| 13/06/2016 | Mental and Behavioural Disorders | | | |

Plain English summary of protocol

Background and study aims

Early intervention for childhood behavioural problems may help improve health and educational outcomes in affected children. The National Institute for Health and Clinical Excellence (NICE) guidelines for a common childhood behavioural disorder, Attention Deficit / Hyperactivity Disorder (ADHD), recommend a stepped care approach for the identification and management of behaviour problems in children. Programmes for parents involving educational approaches and behavioural management training may be sufficient for some children and families. Evidence also suggests that the effects of such programmes can be enhanced if information about the behavioural approaches being used is shared with teachers. Through primary schools, we aim to test the implementation of a programme for parents of 4-8 year old children who have high levels of hyperactivity and inattention.

Who can participate?

Parents of 4-8 year old children who score high on a screening measure of hyperactivity and inattention.

What does the study involve?

The first stage involves the parent completing a short questionnaire about their child. Depending on their childs score on the questionnaire, some parents will be invited to take part in the second stage. Participating parents will join one of three approaches involving different amounts of discussion between teachers and parents about approaches to managing childrens behaviour. The choice will depend upon which approach has been assigned at random to the childs school. This will allow us to compare which type of approach works best. Parents will be asked to complete a number of questionnaires before the study starts and again at 3 months and 6 months following this.

What are the possible benefits and risks of participating?

Parent-based programmes looking at how best to manage the behaviour of young children show promise. Most parents find taking part in these programmes enjoyable and helpful. Participating parents will be helping researchers to better understand the acceptability and effectiveness of these approaches. The findings could be very helpful in improving the way in which schools and health services work with parents. Taking part in this research may or may not be of direct

benefit to participating parents and their children. It is hoped that the results will help in the future education of children and in providing better services for children and families. There are no known risks of taking part in this research. However, parents will be asked to give some of their time to complete the initial questionnaire and possibly take part in one of the group discussions with other parents. If this approach is assigned to their childs school, the parent group discussions will take place over three meetings, lasting about one and a half hours each.

Where is the study run from?

From the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Nottinghamshire, Derbyshire and Lincolnshire (NDL) based at the University of Nottingham (UK).

When is the study starting and how long is it expected to run for? From October 2011 for two years.

Who is funding the study? National Institute for Health Research (NIHR) (UK).

Who is the main contact for the study? Dr Kapil Sayal kapil.sayal@nottingham.ac.uk

Study website

http://www.clahrc-ndl.nihr.ac.uk/clahrc-ndl-nihr/research/childrenyoungpeople/patchwork/index.aspx

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Group ADHD Parenting Programme: Early interventions and school-based input for children at risk of ADHD to improve outcomes

Acronym

PATCHWORK

Study objectives

There will be a greater reduction in attention deficit hyperactivity disorder (ADHD) symptoms on a teacher-rated and parent-rated questionnaire in children whose parents and teachers both receive an intervention compared to a parent-only intervention group and a no intervention (control) group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Nottingham Medical School Ethics Committee, 25/08/2010, ref: C/07/2010

Study design

Interventional cluster randomised controlled trial with nested qualitative study

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

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) symptoms, inattention, overactivity, impulsiveness

Interventions

Schools are randomised into 1 of 3 arms:

Following initial screening, all parents who meet the inclusion criteria will be invited into the arm to which the school is randomised.

Arm 1 Parents will be invited to take part in a three session group parent training programme. Teachers will receive an educational training package that covers the strategies being discussed with the parents (combined intervention)

Arm 2 Parents will be invited to take part in a three session group parent training programme (parent-only intervention)

Arm 3 no intervention control arm

Intervention Type

Behavioural

Primary outcome measure

Short version of Conners Teacher and Parent Rating Scales Revised, completed at baseline and follow-up (2 weeks, 3 months, 6 months after intervention)

Secondary outcome measures

- 1. Parental burden (SDQ)
- 2. Parental well-being (Malaise Inventory)
- 3. Child quality of life (EQ5DY)

Measured at baseline and follow up (3 months and 6 months after intervention)

Overall study start date

12/10/2011

Completion date

30/09/2013

Eligibility

Key inclusion criteria

- 1. Parents of 4 to 8 year old children
- 2. Parents of children who score 6 or above on the hyperactivity/inattention subscale of the Strength and Difficulties Questionnaire, parent version (SDQ)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Parents and Teachers of 72-144 children across 6-12 schools.

Key exclusion criteria

Parents of 4 to 8 year old children who score 5 or less on the hyperactivity/inattention subscale of the Strength and Difficulties Questionnaire, parent version (SDQ)

Date of first enrolment

12/10/2011

Date of final enrolment

30/09/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of Nottingham

Nottingham United Kingdom NG7 2UH

Sponsor information

Organisation

University of Nottingham (UK)

Sponsor details

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United Kingdom
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Sponsor type

University/education

Website

http://www.nottingham.ac.uk

ROR

https://ror.org/01ee9ar58

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research [NIHR] (UK) - Collaboration for Leadership in Applied Health Research and Care (CLAHRC)

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 | 03/09/2012 | | Yes | No |
| Results article | results | 17/11/2015 | | Yes | No |
| Results article | results | 01/07/2016 | | Yes | No |