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Evaluation of the New Forest Parent Training Project with young children in relation to school readiness

Submission date	Recruitment status	[ ] Prospectively registered
29/11/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/12/2010	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
KO1

Study information

Scientific Title

Study objectives
Hypothesis A:
New Forest Parent Training Project (NFPP) will be superior to treatment as usual (TAU) according to parent and teacher ratings of ADHD:
1. At the end of the experimental trial and
2. Over the ensuing 15 weeks
3. In addition, in follow-up (not funded by this grant) NFPP will be associated with delayed initiation of medication treatment and better transition to school

Hypothesis B:
Because NFPP targets oppositional behavior, as well as ADHD, we hypothesize:
1. That NFPP will result in significant reductions in Oppositional Defiant Disorder (ODD) symptoms compared to TAU at the end of the experimental trial
Because of its expected power to reduce ADHD, a known risk for the development of ODD, we hypothesize:
2. That NFPP will be superior to TAU in preventing the onset of ODD symptoms over two years (not funded by this grant)

Hypotheseis C:
NFPP will be associated with significantly more improvement in mothers ratings of their parenting satisfaction and efficacy and in all targeted parenting domains compared to TAU immediately after treatment.

Hypothesis D:
Changes in parenting will have positive mediating effects on childrens improvement in ADHD and ODD symptoms at the end of experimental treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
At a meeting of the Health and Social Services Department's Ethical Committee (16/05/2005) it was agreed to approve the study.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Attention Deficit Hyperactivity Disorder (ADHD)

Interventions
Children will be randomized in equal numbers to NFPP and the control condition.
The New Forest Parenting Package is a manualized treatment program for preschoolers with ADHD, which involves 8 weekly one hour sessions, delivered in the home by trained clinicians.
An Assessment and Referral Treatment as Usual (TAU) group is intended to control for the effects of time and to compare NFPP treatment effects with the potential impact of interventions provided by community-based practitioners on childrens and parents functioning during the course of treatment and follow-up.
Participants randomized to TAU will be assessed at the same time points and on the same measures as those randomized to NFPP. TAU participants will receive no treatment from study staff, nor will they be referred to specific contact. Rather, they will be given contact information for child mental health and related agencies (e.g. AACAP, APA [Psychology and Pediatrics Associations], CHADD etc.).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Significant reductions on parent and teacher ratings of childrens ADHD
2. Reductions on oppositional behaviour
3. Improvement in mothers ratings of their parenting satisfaction and efficacy

Secondary outcome measures
Children's school readiness.

Overall study start date
01/10/2005

Completion date
01/10/2007

Eligibility

Key inclusion criteria
The study will enroll young children who meet diagnostic criteria for ADHD.
At the first stage, children will be selected on the basis of scores of 20 or more on the Werry-Weiss-Peters-Hyperactivity Scale (WWP; Routh, 1978), which is a short pre-school hyperactivity

screening measure. Parents views of the impact of the condition on childrens functioning will then be assessed (stage 2). Finally, children will have to score 18 or more on a pre-school version of the Parental Account of Childhood Symptoms (PACS; Taylor et al., 1991) interview.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
The study will enroll 150 medication naïve children.

Key exclusion criteria
Excluded will be children with pervasive developmental disorder, psychosis, severe receptive language impairment, neurological disorders, or current history of child sexual or physical abuse. Parents will be excluded from the trial only if they are unable to fulfill the requirements for study participation (e.g. allow home visits, fluent in English).

Date of first enrolment
01/10/2005

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Medicine
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Sponsor information

Organisation
HOPE Wessex Medical Trust (UK)

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Sponsor type
Charity

ROR
https://ror.org/0109m8c38

Funder(s)

Funder type
Charity

Funder Name
HOPE Wessex Medical Trust

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	01/10/2009		Yes	No