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The evaluation of the cognitive behavioural treatment of pre-school children referred with hyperactivity

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
18/11/2009

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
C/40/93/Sonuga; National Research Register ID: N0467011916

Study information

Scientific Title

Study objectives
To establish the efficacy of a health visitor administered treatment package for pre-school hyperactive children - assess the generalisability of treatment effects across therapists, situations and over time - examine its effects on parents moods and perceptions of their relationships with their children - test the relationship between parental perceptions, mood and child behaviour.
The study will provide a systematic examination of the therapeutic value of a relatively inexpensive primary care intervention strategy which has the potential to reduce the long term social and economic costs associated with the generally poor prognosis of the hyperactive pre-school child. It will make available the sort of information that allows consultants and managers to make judgements about the potential of this sort of approach in their own areas of responsibility. It will provide the basis for the establishment of a centre of clinical excellence for the treatment of pre-school hyperactivity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Interventions
1. Parent training
2. Parent counselling and support
3. Waiting list (no treatment group)

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Measures of child symptoms and mothers' well-being were taken before and after intervention and at 15 weeks follow-up.

Key secondary outcome(s)
Not provided at time of registration

Completion date
28/09/1997

Eligibility

Key inclusion criteria
Three-year-old children displaying a preschool equivalent of attention-deficit/hyperactivity disorder (ADHD)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Years

Upper age limit
3 Years

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/1994

Date of final enrolment
28/09/1997

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

University of Southampton
Southampton
United Kingdom
SO9 4NH

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive South West (UK)

Results and Publications

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	01/04/2001		Yes	No