

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

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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