ISRCTN05516741 https://doi.org/10.1186/ISRCTN05516741

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

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/11/2009	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Edmund Sonuga-Barke

Contact details
University of Southampton
Dept of Psychology
Murray Building
Salisbury Road
Southampton
United Kingdom
SO9 4NH
ejb3@soton.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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

Intervention Type
Other

Phase
Not Specified

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/1994

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

Age group
Child

Lower age limit
3 Years

Upper age limit
3 Years

Sex
Both

Target number of participants
Added 18/11/09: 78 children

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
England

United Kingdom

Study participating centre
University of Southampton
Southampton
United Kingdom
SO9 4NH

Sponsor information

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name
NHS Executive South West (UK)

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	01/04/2001		Yes	No