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Trial of self-management for young children with asthma

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
19/11/2009	Respiratory	

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
MCH 16-15

Study information

Scientific Title

Study objectives
This study was designed to test the hypothesis that the introduction of an educational package and self-management guide to the parents of pre-school children who have recently attended hospital for troublesome asthma or wheeze will reduce morbidity. While the primary objective was to assess the effect of the intervention on the number of hospital readmissions and GP consultations, also investigated were the effects on the child's and family's quality of life and their knowledge of asthma. A cost-evaluation of introducing the intervention was performed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Leicestershire Research Ethics Committee (Added 19/11/09)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory tract diseases: Asthma

Interventions
The intervention consisted of three elements:
1. A general education booklet about asthma in pre-school children
2. A written, guided self-management plan
3. Two 20 minute, structured, educational sessions between a specialist respiratory nurse and the parent(s) and child.
Children randomised to the intervention group and recruited as in-patients received the first education session on the ward on the day of discharge and returned to a special clinic one month later for the second session. Children recruited from A&E or the Children's (Emergency) Assessment Unit (LRI) received their initial education session in the clinic within two weeks of attendance at A&E/CAU and returned one month later for their follow-up visit. The first

educational session focused in sequence on the topics covered in the booklet and included personalization of the self-management plan while the second session aimed to be parent-led, discussing issues raised by the parents with a review of parents' techniques in administering medicines to their child. Children randomised to the control group received usual care (a range of medical and nursing approaches presently used with parents, according to the skills of the health professionals).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
All subjects were assessed at three, six and 12 months following recruitment. The primary outcomes were GP consultation rates, hospital re-admissions and attendances at A&E/CAU. These were collected from the child's GP records and from hospital notes and records. Several secondary outcomes were measured. The child's asthma symptoms and consequent level of disability as perceived by the parents was assessed using Usherwood's (1990) Index of Perceived Symptoms in Asthmatic Children (IPSAC). The parent's or caregiver's quality of life was assessed using Juniper's Paediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ). Symptom diaries were used to measure morbidity over a period of four weeks prior to each follow-up visit. Three further measures were developed for use in this study to assess the parent's or caregiver's knowledge of asthma, their perceived confidence in caring for their child and the social and economic impact on the family of caring for a child with wheeze.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/1997

Completion date
30/09/2000

Eligibility

Key inclusion criteria
Children eligible for inclusion in the study were aged 18 months to five years inclusive at the time of admission to a children's ward as an in-patient or attendance at either an Accident and Emergency Department or the Children's (Emergency) Assessment Unit (CAU at LRI) with a primary diagnosis of acute severe asthma or wheezing. The study was not confined to children admitted for the first time for wheeze/asthma. Children could only be recruited to the study once during the trial period. The study was conducted in two centres; the Children's Hospital, Leicester Royal Infirmary (LRI) and Booth Hall Children's Hospital, Manchester (BH) (secondary care centres). 200 children were recruited to the study of which 101 were assigned to the control group and 99 to the intervention group.

Participant type(s)
Patient

Age group
Child

Lower age limit
18 Months

Upper age limit
5 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/05/1997

Date of final enrolment
30/09/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester Childrens Asthma Centre
Leicester
United Kingdom
LE2 7LX

Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health
Richmond House
79 Whitehall
London
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SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
NHS Mother and Child Health National Research and Development Programme (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	01/01/2002		Yes	No