

# Trial of self-management for young children with asthma

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/11/2009	<b>Condition category</b> Respiratory	<input type="checkbox"/> 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

**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

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**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  
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**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?
<a href="#">Results article</a>	results	01/01/2002		Yes	No