

# Introduction of a community-based intervention for children with chronic constipation

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/04/2016	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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**

N0045126756

## Study information

### Scientific Title

Introduction of a community-based intervention for children with chronic constipation

### Study objectives

To assess the effect of the introduction of a primary care-based intervention for children with constipation compared to conventional hospital based management.

### 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)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Digestive System: Constipation

### Interventions

A randomised controlled trial to compare a new nurse-led service with conventional hospital-based management for children with constipation.

### Intervention Type

Other

### Phase

Not Applicable

### Primary outcome measure

1. Clinical outcomes: remission and relapse of symptoms
2. Quality of life/patient and parental satisfaction
3. Cost benefits: on-going treatment, nurse contacts, out-patient visits and hospital admission

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/04/2003

**Completion date**

31/03/2004

## Eligibility

**Key inclusion criteria**

40 children aged 2-15 years with moderate to severe chronic constipation referred to gastroenterologists and general paediatricians in Birmingham Children's Hospital NHS Trust.

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

2 Years

**Upper age limit**

15 Years

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/04/2003

**Date of final enrolment**

31/03/2004

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Birmingham Children's Hospital**  
Birmingham  
United Kingdom  
B4 6NH

## Sponsor information

**Organisation**  
Department of Health

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.dh.gov.uk/Home/fs/en>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Birmingham Children's Hospital NHS Trust (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