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

| Recruitment status | Prospectively registered |
|----------------------|---|
| No longer recruiting | ☐ Protocol |
| Overall study status | Statistical analysis plan |
| Completed | Results |
| Condition category | Individual participant data |
| Digestive System | Record updated in last year |
| | No longer recruiting Overall study status Completed Condition category |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Susan Protheroe

Contact details

Birmingham Children's Hospital Department of Gastroenterology Steelhouse Lane Birmingham United Kingdom B4 6NH +44 (0)121 333 8720 Sue.protheroe@bch.nhs.uk

Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

- 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

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 years

Upper age limit

15 years

Sex

All

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

United Kingdom

England

Study participating centre Birmingham Children's Hospital

Birmingham United Kingdom B4 6NH

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Birmingham Children's Hospital NHS Trust (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? Participant information sheet Participant information sheet 11/11/2025 No Yes