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Nurse-led intervention with medical support for secondary care referrals of children with constipation with or without soiling

Submission date
09/01/2013

Recruitment status
No longer recruiting

Registration date
12/02/2013

Overall study status
Completed

Last Edited
07/07/2016

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Services for children with constipation are often poor. A National Institute for Health and Clinical Excellence (NICE) guideline research recommendation asks: Do specialist nurse-led childrens continence services or traditional secondary care services provide the most effective treatment for children with idiopathic constipation (with or without faecal incontinence) that does not respond fully to primary treatment regimens? This should consider clinical and cost effectiveness, and both short-term (16 weeks) and long-term (12 months) resolution? This study aimed to design and pilot a nurse-led intervention process based on a psychological model of care with medical support, teach this intervention to one nurse, compare the nurse-led intervention with usual consultant paediatrician led care, pilot a cluster trial design based on geographic postcode of residence, examine the utility of a number of outcome measures, and assess the likely efficacy of the nurse-led intervention.

Who can participate?
Children had to be aged 0-13 years and referred by their General Practitioner. They had to be resident in postcode areas covered by NHS Greater Glasgow Health Board boundaries. The main complaint on the GP letter had to be constipation and/or soiling.

What does the study involve?
The study first established an expert group. This group designed the nurse-led intervention and established a number of potential outcome measures. The intervention was piloted by a psychologist and then taught to one nurse. Clinic rooms were made available next to a consultant general paediatric clinic in half the outreach clinic settings in Glasgow. Children were allocated to the clinics based on their postcode of residence. Then outcome for patients seen at the nurse led clinics were compared with patients seen at traditional consultant led general paediatric clinics. Random allocation of clinics to have a nurse led intervention was not used, rather nurse-led clinics were established in those clinics with an extra room available for the nurse (5 clinics) and the rest of the clinics acted as controls (7 clinics).

What are the possible benefits and risks of participating?
Potential benefits were improved outcome due to better training, an evidence based psychological approach, better parent satisfaction. No risks were envisaged from taking part in the study.

Where is the study run from?
The study was run from the Paediatric Epidemiology and Community Health Unit in Glasgow (UK)

When is the study starting and how long is it expected to run for?
The study enrolled patients from March to November 2009. The aim was to follow patients up 4 months after enrolment however attempts to contact were completed by June 2010.

Who is funding the study?
Yorkhill Children's Foundation (UK)
NHS Greater Glasgow & Clyde East Community Health Partnership (UK)
Greater Glasgow & Clyde Director of Public Health's Research and Education Endowment Fund (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
V1

Study information

Scientific Title
Phase I trial of nurse-led intervention for childhood constipation

Study objectives
A nurse-led intervention with medical support is more effective and cost effective than traditional consultant led care for children referred to secondary care by their General Practitioner with constipation with or without faecal incontinence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submission was made to the National Research Ethics Service (NRES) via the query facility and advice indicated that the study was service evaluation and as such did not require to be examined by an ethics committee. Further representation to the chairperson of the local ethics committee was concordant with the NRES decision.

Study design
Phase I cluster non-randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Constipation in childhood

Interventions
Intervention participants received the nurse-led design of care where the first appointment took place in a special hospital constipation clinic in conjunction with a general paediatrician with a special interest in constipation. Follow-up appointments took place in 5 (of 12) general paediatric outreach clinics (Drumchapel, Rowan Park, Hospital, Easterhouse, Castlemilk) with access to another general paediatrician for advice and support (n=75). A new appointment was scheduled for 60 minutes and follow-up 30 minutes. A continence nurse or chartered psychologist provided care supported by a consultant paediatrician with a special interest in elimination disorders. The nurse or psychologist followed up patients in outreach clinics with support from another consultant general paediatrician. The first appointment was in a hospital setting with follow-up in outreach clinics close to the patients homes. A full history was taken by the nurse (or psychologist), the child and parents were educated about how the bowel works and what can go wrong; explanation was given that constipation should be treated as a chronic condition like asthma which can be managed but seldom cured; the problem was reframed in terms of small steps to be taken including sitting on the toilet after an evening meal for 5-10 minutes and using blowing bubbles or blowing up balloons to help stools pass; the patient was examined by a consultant paediatrician, laxatives were prescribed if required; and finally the parent and child were asked about their understanding of their role as trainer and compliant co-worker respectively and the nurses role as remote mentor. The parents and child were informed of the initial 16 week treatment period after which both parties would assess progress. After 16 weeks, agreement was then reached on the utility of further support or whether a 6 month break would focus efforts for a further push towards control of the problem. 1st follow-up was after 2 weeks either by phone or face to face with the continence nurse or psychologist. Subsequent follow-up was organised as required throughout the 16 week follow-up period. Discharge was considered after 16 weeks if treatment had failed to resolve the problem. Parents

who defaulted from follow-up were sent a letter to phone if they would like a further appointment with a copy sent to their GP. If parents did not phone within 4 weeks the family were discharged.

Control participants received normal care provided by consultant general paediatricians either in hospital based clinics or at 7 (of 12) general paediatric outreach clinics in proximity to patients in Glasgow (n=98). A new appointment was scheduled for 30 minutes and follow-up 15 minutes. Consultant paediatricians provided care in a paediatric hospital or outreach clinic setting in a general practice health centre. A history was taken followed by an examination of the child. Diagnosis was made, explanation was given to the child and parents, investigations ordered if required, medication prescribed and other interventions given, and follow-up organised. Follow-up varied between consultants but did not include telephone support. Generally a child was discharged if no further medication was required and the child was symptom free. If two consecutive appointments were missed then patients were discharged.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Resolution of symptoms 16 weeks after first appointment measured as positive if frequency of stools was 3 or greater in the last week for all children and no accidents had occurred outside the toilet pan in the last week for children greater than 4 years.

Key secondary outcome(s))
1. Parent satisfaction with the service. Parent satisfaction was measured as the average over 12 questions on Likert scales of 1-5 where 1 was always the most positive and 5 the most negative.
2. Pain passing stools
3. Withholding of stools in the last week
4. Still on medication (after 16 weeks)
5. Better than before treatment

Completion date
30/11/2009

Eligibility

Key inclusion criteria
1. Children had to be aged 0-13 years and referred by their General Practitioner.
2. They had to be resident in postcode areas covered by NHS Greater Glasgow Health Board boundaries
3. The main complaint on the GP letter had to be constipation and/or soiling

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 years

Upper age limit
13 years

Sex
All

Key exclusion criteria
Referrals from secondary or tertiary care or from other health care workers other than general practitioners

Date of first enrolment
01/03/2009

Date of final enrolment
30/11/2009

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
PEACH unit
Glasgow
United Kingdom
G3 8SJ

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Yorkhill Children's Foundation (UK)

Funder Name
NHS East Community Health Partnership (UK)

Funder Name
Public Health's Research and Education Endowment Fund (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?
Results article	results	20/11/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes