

The effect of abdominal massage on the bowel habit of adults with cerebral palsy

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/10/2019	Condition category Nervous System Diseases	<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
PCC106X

Study information

Scientific Title

The effect of abdominal massage on the bowel habit of adults with cerebral palsy

Study objectives

Adults with complex physical and learning disabilities frequently experience chronic constipation. The standard treatment is a combination of laxative and enema use. This does not always prove a satisfactory form of management and the inappropriate use of these drugs can cause colonic atony and other side effects. It has been suggested that abdominal massage, a safe and non-invasive technique, may provide an effective alternative. This study will measure gastro-intestinal transit time in this population and assess the relative effect on it of both massage and laxatives. Stool consistency, the requirement for enemas and patient well-being will also be assessed in order to evaluate the comparative merits of each treatment. The study population of approximately 36 adults will be drawn from residents of Meanwood Park Hospital who have cerebral palsy/abnormal muscle tone and who have been on regular laxative medication for over 12 months. Although the study group will vary in age, sex, level of mobility and drug management, a randomised cross-over design has been chosen to take account of patient heterogeneity by using intra-subject comparisons. If clinically proven, abdominal massage has the potential to contribute to safer and more effective practice in bowel management. Other benefits could include increased patient well-being, enhanced by the greater staff/carer involvement in their management, and the possible reduction in the requirement for laxatives. The value of this therapy could extend beyond the client group to be studied, and benefit a variety of patients who present with chronic constipation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised cross-over design

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Nervous system diseases: cerebral palsy

Interventions

1. Abdominal massage
2. Regular laxative treatment

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Bowel management and patient well-being

Secondary outcome measures

Not provided at time of registration

Overall study start date

18/09/1995

Completion date

05/10/1996

Eligibility**Key inclusion criteria**

Residential patients with cerebral palsy/abnormal muscle tone and who have been on regular laxative medication for over 12 months.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

36

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

18/09/1995

Date of final enrolment

05/10/1996

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Meanwood Park Hospital

Leeds

United Kingdom

LS6 4QB

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

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Sponsor type

Government

Website

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Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (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