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Diet and lifestyle vs laxatives in the management of chronic constipation in older people

Submission date 30/06/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/07/2003	**Overall study status** Completed	
Last Edited 02/03/2011	**Condition category** Digestive System	

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

HTA 01/10/04

Study information

Scientific Title

Acronym
LIFELAX

Study objectives
Constipation is a common chronic condition, with considerable costs to the NHS in terms of GP consultations and prescribed laxatives. A systematic literature review has found weak evidence that laxatives can improve stool frequency and consistency and can alleviate related symptoms in older people. Dietary and lifestyle interventions have also been shown to alleviate constipation. More generally, in studies aimed at the modification of individual health-related behaviour, brief interventions have been shown to have limited effect while intensive, patient-tailored interventions have been more effective though costly. The proposed study will compare the effectiveness and cost-effectiveness of brief and intensive lifestyle interventions with medical management in treating chronic constipation in older people.

Main aims:
1. To investigate the clinical and cost-effectiveness of laxatives versus dietary and lifestyle advice.
2. To investigate the clinical and cost-effectiveness of brief, standardised versus personalised dietary and lifestyle advice.

Secondary aims:
1. To describe the adherence by patients to treatment protocols and to estimate its impact on cost-effectiveness.
2. To describe the adherence by health care professionals to intervention protocols.

More information can be found at: http://www.hta.ac.uk/1310
Protocol can be found at: http://www.hta.ac.uk/protocols/200100100004.pdf

Please note that, as of 17 January 2008, the start and anticipated end date of this trial have been updated from 1 October 2002 and 30 April 2006 to 1 June 2003 and 30 September 2008, respectively.

Please note that, as of 24/08/2009, the HTA reference number has been amended from HTA 10 /01/04 to HTA 01/10/04.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Pragmatic cluster randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic functional constipation

Interventions
A prospective, pragmatic cluster randomised (at the level of the general practice) trial, with three arms: 1. Laxatives of GP's choice 2. Brief, standardised dietary and lifestyle advice 3. Intensive, personalised dietary and lifestyle advice. The trial will incorporate an economic evaluation and patients will be followed up for 12 months post-enrolment.
A qualitative component will investigate barriers to and facilitators of adherence to treatment protocols and interventions from the perspective of both patients and practice staff.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of life related to constipation.

Secondary outcome measures
Frequency and severity of symptoms of constipation; subjective perceptions of whether constipated; satisfaction with bowel function; compliance with therapy; treatment side effects and adverse events; relapse and re-consultation rates.

Overall study start date
01/06/2003

Completion date
30/09/2008

Eligibility

Key inclusion criteria
Older adults (aged 55 and over) with prevalent chronic constipation

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Added May 2008: 27 GP practices

Key exclusion criteria
Added May 2008:
1. Patients resident in long-term care
2. Patients with inflammatory bowel disease, intestinal obstruction/bowel strictures, known colonic carcinoma and conditions contra-indicative to the prescription of laxative preparations
3. Inability to read and understand written treatment plans and educational material
4. Inability to complete outcome assessments, even with assistance (eg major cognitive impairment, lack of understanding of English)

Date of first enrolment
01/06/2003

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Health Services Research,
Newcastle upon Tyne
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Sponsor information

Organisation
Department of Health (UK)

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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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?
Protocol article	protocol on the development and piloting of the patient information leaflets	04/01/2007		Yes	No
Results	results	01/11			

article	/2010	Yes	No