

# STOOL - Stepped Treatment of Older adults On Laxatives

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/08/2009	<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

**Contact name**  
Prof John Bond

**Contact details**  
Centre for Health Services Research  
University of Newcastle upon Tyne  
21 Claremont Place  
Newcastle upon Tyne  
United Kingdom  
NE2 4AA  
+44 (0)191 222 6777  
[john.bond@newcastle.ac.uk](mailto:john.bond@newcastle.ac.uk)

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
HTA 98/32/99

# Study information

## Scientific Title

## Acronym

STOOL

## Study objectives

1. To investigate the clinical and cost effectiveness of bulk forming, stimulant and osmotic laxatives prescribed by primary care to ambulant older people living at home.
2. To investigate the clinical and cost effectiveness of prescribing an additional second type of laxative agent in the treatment of patients whose constipation is not resolved by a single agent.
3. To describe the adherence by patients to treatment protocols.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration.

## Study design

Pragmatic factorial randomised trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

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

Constipation

## Interventions

Different forms of stepped pharmacological treatment of constipation with economic evaluation. An add-on qualitative study of the meaning and experience of constipation to older people and the views of general practitioners.

Added as of 25/08/2009: the trial was closed after recruiting 19 participants due to problem with recruitment.

## Intervention Type

Other

**Phase**

Not Applicable

**Primary outcome measure**

The primary clinical outcome is the reported number of bowel movements per week at the end of each step (6 and 10 weeks after randomisation) and at six months follow-up.

**Secondary outcome measures**

Secondary clinical outcomes include the presence/absence of the other Rome criteria for constipation; adverse effects of treatment (although some of these may also be symptoms of constipation); and relapse rates. In addition to the measurement of these clinical outcomes, patient satisfaction and the impact of the treatment on costs and quality of life will be assessed

**Overall study start date**

01/10/2002

**Completion date**

30/04/2006

**Reason abandoned (if study stopped)**

Participant recruitment issue

## **Eligibility**

**Key inclusion criteria**

People aged 55 or over with chronic constipation living in private households.

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Both

**Target number of participants**

19

**Key exclusion criteria**

Not provided at time of registration.

**Date of first enrolment**

01/10/2002

**Date of final enrolment**

30/04/2006

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**Centre for Health Services Research**

Newcastle upon Tyne

United Kingdom

NE2 4AA

# Sponsor information

## Organisation

Department of Health (UK)

## Sponsor details

Quarry House

Quarry Hill

Leeds

United Kingdom

LS2 7UE

+44 (0)1132 545 843

Sheila.Greener@doh.gsi.gov.uk

## Sponsor type

Government

## Website

<http://www.dh.gov.uk/en/index.htm>

## ROR

<https://ror.org/03sbpja79>

# Funder(s)

## Funder type

Government

## Funder Name

## 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?
<a href="#">Results article</a>	results	01/05/2008		Yes	No