

Biofeedback for faecal incontinence

Submission date 01/03/2001	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/03/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/10/2010	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Christine Norton

Contact details
Physiology Unit
St Mark's Hospital
Watford Road
Harrow Middlesex
United Kingdom
HA1 3UJ
+44 (0)20 8235 4167
csnorton@aol.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AP0679

Study information

Scientific Title

Biofeedback for faecal incontinence: a randomised controlled trial

Study objectives

Added 09/01/2009:

Behavioural treatment (biofeedback) improves faecal incontinence when compared to standard care.

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Faecal incontinence

Interventions

Conservative management +/- biofeedback

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Added 09/01/2009:

1. Diary
2. Symptom questionnaire
3. Continence score
4. Patient's rating of change
5. Quality of life (36-item Short-Form Health Survey [SF36] and disease specific)

6. Psychologic status (Hospital Anxiety and Depression Scale)

7. Anal manometry

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2003

Completion date

01/06/2003

Eligibility

Key inclusion criteria

Adults with faecal incontinence.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

171

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2003

Date of final enrolment

01/06/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Physiology Unit

Harrow Middlesex

United Kingdom
HA1 3UJ

Sponsor information

Organisation

Action Medical Research (UK)

Sponsor details

Vincent House
Horsham West Sussex
United Kingdom
RH12 2DP

Sponsor type

Charity

Website

<http://www.action.org.uk/>

ROR

<https://ror.org/01wcqa315>

Funder(s)

Funder type

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

actionmedres, action medical research for children, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

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?
Results article	results	01/11/2003		Yes	No