

Biofeedback for faecal incontinence

Submission date 01/03/2001	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 01/03/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 20/10/2010	Condition category Digestive System	☐ 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

Protocol serial number

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Faecal incontinence

Interventions

Conservative management +/- biofeedback

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/06/2003

Eligibility

Key inclusion criteria

Adults with faecal incontinence.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre**Physiology Unit**

Harrow Middlesex

United Kingdom

HA1 3UJ

Sponsor information**Organisation**

Action Medical Research (UK)

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2003		Yes	No