Biofeedback for faecal incontinence

Submission date Recruitment status [X] Prospectively registered 01/03/2001 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 01/03/2001 Completed [X] Results [] Individual participant data Last Edited Condition category 20/10/2010 **Digestive System**

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms Christine Norton

Contact details

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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