

Physiotherapy in Faecal Incontinence Trial

Submission date 27/06/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 27/06/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 31/12/2020	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL952, NTR978

Study information

Scientific Title
Physiotherapy in Faecal Incontinence Trial

Acronym
PhysioFIT

Study objectives

The combined therapy trial arm will have a larger reduction on the primary outcome measure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the Medical Ethical Committee of the University Hospital Maastricht/Maastricht University on the 12th July 2006 (ref: MEC 06-3-048).

Primary study design

Interventional

Study design

Randomised, single blinded, active controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Faecal incontinence

Interventions

Trial arm 1: pelvic floor muscle training and rectal balloon training

Trial arm 2: pelvic floor muscle training

Both groups receive 12 treatments, each 35 minutes in duration, within three months.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Vaizey incontinence score.

The primary and secondary outcome measures will be performed at baseline (prior to physiotherapy intervention), and 3, 6 and 12 months after time of inclusion. The 3 months follow-up after inclusion is done directly after the physiotherapy intervention.

Key secondary outcome(s)

1. Anorectal resting and squeeze pressure
2. Rectal capacity measurements
3. Anorectal sensation
4. Three-week diary results
5. Faecal Incontinence Quality of Life scale
6. PREFAB-score (adapted PRAFAB-score)
7. Global Perceived Effect (GPE-score)

The primary and secondary outcome measures will be performed at baseline (prior to physiotherapy intervention), and 3, 6 and 12 months after time of inclusion. The 3 months follow-up after inclusion is done directly after the physiotherapy intervention.

Completion date

01/03/2010

Eligibility

Key inclusion criteria

1. Adults (aged 18 years and older)
2. Faecal Incontinence (FI) complaints due to different etiologies persisting for at least six months
3. Vaizey incontinence score of at least 12
4. Failure of conservative treatment (including dietary adaptations and pharmacological agents)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Total final enrolment

80

Key exclusion criteria

1. Patients diagnosed with an anorectal tumour within the past two years
2. Absent squeeze pressure of anal sphincter
3. Chronic diarrhoea (always fluid stool three or more times a day)
4. Overflow incontinence
5. Proctitis
6. Colitis ulcerosa
7. Crohn's disease
8. Soiling (defined as leakage of a minimal amount of faeces out of the anal canal)
9. Previous ileo-anal or colo-anal anastomosis and/or rectal prolapse in situ are excluded
10. Participants who received physiotherapy during the previous six months or who are intellectually and/or linguistically incapable to understand therapy are excluded as well

Date of first enrolment

01/09/2006

Date of final enrolment

01/03/2010

Locations

Countries of recruitment

Netherlands

Study participating centre

Maastricht University

Maastricht

Netherlands

6200 MD

Sponsor information

Organisation

University Maastricht (UM) (The Netherlands)

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

Industry

Funder Name

Medeco B.V. (The Netherlands)

Results and Publications

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?
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Results article	results	01/09/2012	31/12/2020	Yes	No
Protocol article	protocol	20/12/2007	31/12/2020	Yes	No