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Physiotherapy in Faecal Incontinence Trial

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

Study design
Randomised, single blinded, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/09/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
100

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)

Sponsor details
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Sponsor type

University/education

Website
http://www.unimaas.nl/default.asp?taal=en

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
Industry

Funder Name
Medeco B.V. (The Netherlands)

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