

# Physiotherapy in Faecal Incontinence Trial

<b>Submission date</b> 27/06/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/06/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/12/2020	<b>Condition category</b> Digestive System	<input type="checkbox"/> 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

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

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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?
<a href="#">Protocol article</a>	protocol	20/12/2007	31/12/2020	Yes	No
<a href="#">Results article</a>	results	01/09/2012	31/12/2020	Yes	No