

A randomized controlled trial of physiotherapy in patients with fecal incontinence

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This study is carried out to assess the effectiveness of rectal balloon training (RBT) combined with pelvic floor muscle training (PFMT) compared to pelvic floor muscle training alone in a population of patients with FI.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON31614

Source

ToetsingOnline

Brief title

PhysioFIT

Condition

- Gastrointestinal motility and defaecation conditions

Synonym

bowel incontinence, fecal incontinence

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Conservative treatment, Fecal incontinence, Physiotherapy, Randomized controlled trial

Outcome measures

Primary outcome

Primary study outcome is the Vaizey incontinence score. Deze score reflects the severity of FI and ranges from 0 (complete continence) to 24 (complete incontinence).

Secondary outcome

Secondary outcome measures are medication use, anorectal manometry, rectal capacity measurement, anorectal sensation, symptom diary, Fecal Incontinence Quality of Life scale (FIQL), PREFAB-score (severity score) and the Global Perceived Effect score (GPE-score).

Study description

Background summary

Fecal incontinence (FI) is a major health care problem, which is highly embarrassing and affects about 2 to 24% of the adult population. FI can be defined as the recurrent involuntary excretion of feces in inappropriate places or at inappropriate times. FI is dependent on sensory, motoric and reservoir functions. Often, a multifactorial cause is present. Initially, treatment consists of dietary adaptations and pharmaceutical interventions. In case of failure, physiotherapeutic treatment of FI is often considered a first-line approach due to its safe and non-invasive nature. However, the effectiveness of physiotherapy in FI is unclear.

Study objective

This study is carried out to assess the effectiveness of rectal balloon training (RBT) combined with pelvic floor muscle training (PFMT) compared to

pelvic floor muscle training alone in a population of patients with FI.

Study design

One hundred patients are randomized to receive either PFMT combined with RBT or PFMT alone. Baseline measurements consist of the standard work-up, the Vaizey incontinence score, Fecal Incontinence Quality of Life scale (FIQL) and the PREFAB-score. Follow-up measurements are at three, six and 12 months. Physiotherapeutic treatment is performed in the office by skilled motivated pelvic physiotherapists, who are registered at the Dutch Society for Physical Therapy in Pelvic Floor Disorders and Pre- and Postnatal Healthcare (NVFB). Twelve physiotherapeutic treatments are administered during three months according to a standardized protocol. Success of physiotherapy is defined as a reduction in Vaizey score of \geq four points compared to baseline measurement.

Intervention

Physiotherapeutic treatment is administered according to a standardized protocol, which has been developed by clinicians and physiotherapists specialized in the field of pelvic floor disorders. Physiotherapeutic treatment consists of pelvic floor muscle training and rectal balloon training (only trial arm 1). Patients receive 12 physiotherapeutic treatments within three months.

Study burden and risks

In total, the patient visits the hospital 5 times during approximately 14 months. The first three visits are part of the normal routine assessments at the clinic. Visit 4 and 5 are planned to follow the progress of the patient in time. Visit 1, 3, 4 and 5 are 30 minutes in duration, whereas visit 2 is four hours in duration. The diary is filled in at home (5 minutes a day during three weeks) and the questionnaires in between the diagnostic tests (15 minutes per visit).

The content of the physiotherapy program differs between both groups, although overall treatment time is equal. It is possible that the results in both groups are comparable concerning the functional recovery. In this case, a lower burden is present in the group that only receives PFMT.

It is hypothesized that the combined use of RBT and PFMT is more effective than PFMT alone. This means that patients in this group might have a quicker functional recovery after physiotherapeutic treatment.

Both RBT as well as PFMT have less reported side effects and therefore are often tried before surgery. In rare cases, snapping of the rectal balloon might occur, which is harmless but can give the patient a fright. Treatment is administered by specialized registered pelvic physiotherapists, who act according to the guidelines of the Dutch Society for Physical Therapy in Pelvic

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Adults (aged 18 and over)

Fecal incontinence complaints due to different etiologies persisting for at least 6 months

Vaizey incontinence score of at least 12

Failure of conservative treatment (dietary adaptations and pharmacological agents)

Exclusion criteria

Physiotherapy during previous six months
Intellectually or linguistically incapable to finish therapy
Anorectal tumor within past two years
Chronic diarrhea
Overflow incontinence
Proctitis
Colitis ulcerosa
Croh's disease
Soiling
Ileo-anal or colo-anal anastomosis
Rectal prolapse in situ

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2006
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO	
Date:	20-07-2006
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	19-05-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL12569.068.06