# Efficacy of Supervised Pelvic Floor Muscle Training and Biofeedback Vs Attention-Control Treatment in Adults With Fecal Incontinence

Ussing, Anja; Dahn, Inge; Due, Ulla; Sørensen, Michael; Petersen, Janne; Bandholm, Thomas

*Published in:*
Clinical Gastroenterology and Hepatology

*DOI:*
10.1016/j.cgh.2018.12.015

*Publication date:*
2019

*Document version*
Publisher's PDF, also known as Version of record

# Efficacy of Supervised Pelvic Floor Muscle Training and Biofeedback vs Attention-Control Treatment in Adults With Fecal Incontinence

Anja Ussing,[*,‡] Inge Dahn,[§] Ulla Due,[‖,¶] Michael Sørensen,[§] Janne Petersen,[‡,#] and Thomas Bandholm[*,‡,**]

*[*]Department of Physiotherapy and Occupational Therapy, [‡]Optimed, Clinical Research Centre, [§]Department of Surgical and Medical Gastroenterology, [#]Section of Biostatistics, Department of Public Health, [**]Physical Medicine and Rehabilitation Research–Copenhagen, Copenhagen University Hospital, Hvidovre, Denmark; [‖]Department of Obstetrics and Gynaecology, [¶]Department of Occupational and Physical Therapy, Herlev Hospital, Herlev, Denmark*

**BACKGROUND & AIMS:** **Pelvic floor muscle training (PFMT) in combination with conservative treatment is recommended as first-line treatment for patients with fecal incontinence, although its efficacy is unclear. We investigated whether supervised PFMT in combination with conservative treatment is superior to attention-control massage treatment and conservative treatment in adults with fecal incontinence.**

**METHODS:** **We performed a randomized, controlled, superiority trial of patients with fecal incontinence at a tertiary care center at a public hospital in Denmark. Ninety-eight adults with fecal incontinence were randomly assigned to groups that received supervised PFMT and biofeedback plus conservative treatment or attention-control treatment plus conservative treatment. The primary outcome was rating of symptom changes, after 16 weeks, based on scores from the Patient Global Impression of Improvement scale. Secondary outcomes were changes in the Vaizey incontinence score (Vaizey Score), Fecal Incontinence Severity Index, and Fecal Incontinence Quality of Life Scale.**

**RESULTS:** **In the intention-to-treat analysis, participants in the PFMT group were significantly more likely to report improvement in incontinence symptoms based on Patient Global Impression of Improvement scale scores (unadjusted odds ratio, 5.16; 95% CI, 2.18–12.19; $P = .0002$). The PFMT group had a larger reduction in the mean Vaizey Score (reduction, -1.83 points; 95% CI, –3.57 to –0.08; $P = .04$). There were no significant differences in condition-specific quality of life. In the per-protocol analyses, the superiority of PFMT was increased. No adverse events were reported.**

**CONCLUSIONS:** **This randomized controlled trial of adults with fecal incontinence provides support for a superior effect of supervised PFMT in combination with conservative treatment compared with attention-control massage treatment and conservative treatment. We found that participants who received supervised PFMT had 5-fold higher odds of reporting improvements in fecal incontinence symptoms and had a larger mean reduction of incontinence severity based on the Vaizey Score compared with attention control massage treatment. Clinicaltrials.gov no: NCT01705535.**

*Keywords:* Fecal Incontinence; Pelvic Floor Muscle Training; Biofeedback; Attention-Control Treatment; Physiotherapy; Physical Therapy Modalities.

***Abbreviations used in this paper:*** **EMG, electromyography; FIQL, Fecal Incontinence Quality of Life Scale; FISI, Fecal Incontinence Severity Index; MCID, minimum clinically important difference; PFMT, pelvic floor muscle training; PGI-I, Patient Global Impression of Improvement Scale; Vaizey Score, Vaizey Incontinence Score.**



1542-3565
https://doi.org/10.1016/j.cgh.2018.12.015

Most current article

**Watch this article's video abstract and others at http://bit.ly/1C2wSLn.**

Scan the quick response (QR) code to the left with your mobile device to watch this article's video abstract and others. Don't have a QR code reader? Get one by searching 'QR Scanner' in your mobile device's app store.

Approximately 8% to 9% of the adult population is suffering from fecal incontinence.[1] The condition is surrounded by taboo[2,3]; it can have a devastating impact on quality of life[2–4] and lead to major limitations in daily life.[3,4]

Fecal incontinence often has multifactorial causes, and the recommended first-line treatment consists of a multimodal approach including information, fiber supplements, antidiarrheal medication, laxatives, pelvic floor muscle training (PFMT), and biofeedback training.[5,6] PFMT is defined as systematic training of the pelvic floor muscles and the external anal sphincter with the aim of increasing muscle strength, endurance and/or coordination.[5,7] In most trials, PFMT is supplemented with biofeedback training, in which the patient receives feedback on a voluntary pelvic floor muscle contraction and/or rectal filling.[5–7]

Evidence from randomized controlled trials regarding the effect of PFMT for fecal incontinence is lacking.[5] A recent Cochrane systematic review[5] included 20 randomized controlled trials to investigate the efficacy of PFMT and/or biofeedback training for the treatment of fecal incontinence in adults. Most of the interventions were complex and included multiple active elements. With the exception of 2 trials, which evaluated vs surgery or evaluated PFMT and biofeedback training after surgery vs surgery alone, the included trials compared different training modalities and thus lacked a nontraining comparator.[5] Two recent trials published after the Cochrane review[8,9] compared the effect of PFMT and biofeedback training with a group not receiving PFMT. However, neither of these trials controlled for the nonspecific trial effect associated with the attention given by the health care professional delivering the training interventions.[8,9] This nonspecific trial effect is known to exist and may result in better outcomes for trial participants.[10] To evaluate the effect of PFMT, there is a need for a trial that uses a comparator to control for this nonspecific trial effect associated with the attention given by the health care professional. The aim of the current trial was to investigate if supervised PFMT in combination with conservative treatment (mainly information) is superior to attention-control massage treatment and conservative treatment in adults with fecal incontinence. This possible superiority effect was based on the primary outcome of changes in fecal incontinence symptoms after 16 weeks of treatment using the Patient Global Impression of Improvement Scale (PGI-I).

## What You Need to Know

### Background

Pelvic floor muscle training in combination with conservative treatment is recommended as first-line treatment for fecal incontinence. We performed a randomized controlled trial to determine the effects of supervised pelvic floor muscle training.

### Findings

Participants receiving supervised pelvic floor muscle training had a 5-fold higher odds of reporting improvements of fecal incontinence and had a larger mean reduction in incontinence severity than an attention-control group.

### Implication for patient care

Pelvic floor muscle training should be offered, in combination with conservative treatment, as first-line treatment for adults with fecal incontinence.

## Methods

### *Trial Design*

This was a randomized, controlled, superiority trial comparing supervised PFMT with attention-control massage treatment. Both treatments were given in combination with conservative treatment. The trial is reported in accordance with Consolidated Standards of Reporting Trials.[11,12] Reporting details can be found in the Supplementary Materials and Methods section, if indicated. The trial was preregistered with ClinicalTrials.gov (NCT01705535), and a detailed trial protocol, including the statistical analysis plan, was published before the data were analyzed and the trial was unblinded.[13]

### *Participants and Setting*

The trial was conducted at Copenhagen University Hospital (Hvidovre, Denmark). From October 15, 2012, to December 15, 2015, consecutive patients referred for treatment of fecal incontinence at the Department of Surgical and Medical Gastroenterology were screened for eligibility.

Inclusion criteria were fecal incontinence for at least 6 months and a minimum age of 18 years. Exclusion criteria were as follows: pregnancy, chronic diarrhea, severe neurologic disorders (multiple sclerosis, Parkinson's disease, spinal cord injury, major stroke, or neuromuscular junction diseases), rectal prolapse, previous cancer surgery or radiotherapy in the lower abdomen, inadequate Danish, cognitive impairment, and having received more than 2 sessions of individually supervised PFMT in the previous 12 months. The trial was approved by the Regional Health Research Ethics Committee (ID: H-2-2012-067) and the Danish Data

Protection Agency (ID: HVH-2012-031). Written informed consent was obtained from all participants.

### Randomization and Blinding

Participants were allocated to 2 parallel groups (supervised PFMT or attention-control massage treatment) by simple randomization using a 1:1 ratio. Randomization and allocation were managed by staff not otherwise involved in the trial. A computer-generated sequence of random group assignments was produced and managed using sealed, opaque, numbered envelopes. The primary investigator (A.U.), who was blinded to the allocation sequence, enrolled the participants. It was not possible to blind the participants or the physiotherapists delivering the PFMT. Instead, we tried to blind the participants to the trial hypothesis.[14] This was attempted by presenting the 2 treatments as equal both in the verbal and written information given at enrolment and at follow-up evaluation. All health care providers and outcome assessors were instructed not to reveal the trial hypothesis. The nurses delivering the conservative treatment and all outcome assessors were blinded.

### Interventions

**Conservative treatment program.** Both trial groups received the same conservative treatment program consisting of standard information about optimizing bowel emptying and the use of fiber supplements and if appropriate, information about antidiarrheal medication (loperamide) and/or laxatives with local effect in the rectum (glycerol). More details are provided in the Supplementary Materials and Methods section.

**Supervised pelvic floor muscle training and biofeedback.** The PFMT intervention has been described previously in detail.[13] The protocol for the PFMT intervention, including the complete training materials, is freely available for download (https://doi.org/10.1016/j.conctc.2017.07.006). In brief, the participants in the PFMT group received 6 individual treatments distributed over 16 weeks. Each treatment lasted 45 minutes and consisted of individually supervised PFMT. The participants were taught correct pelvic floor contractions verbally and by digital vaginal and rectal examination. At every session, they received an examination of their pelvic floor muscle function by digital vaginal and rectal examination and by intra-anal electromyography (EMG) biofeedback. They were instructed to perform an individually tailored home training program daily. The program progressed individually and consisted of 3 sets of 10 pelvic floor muscle contractions sustained for up to 10 seconds and 2 sets of 3 contractions sustained for up to 30 seconds. A training diary was used to quantify training adherence. More details are provided in the Supplementary Materials and Methods section.

**Attention-control massage treatment.** To match the attention associated with the supervised PFMT, the attention-control group received 6 individual treatments performed over 16 weeks. Each treatment lasted 30 minutes and consisted of massage of the neck and back. The participants were given no instructions in PFMT.

### Outcome Measures

The primary outcome was improvement according to the PGI-I after the 16 weeks of treatment.[15] By using the PGI-I, the participants rated changes in incontinence symptoms after treatment using a 7-point scale (very much better, much better, a little better, unchanged, a little worse, much worse, or very much worse).[15] Supporting secondary outcomes were the Vaizey Incontinence Score (Vaizey Score),[16] the Fecal Incontinence Severity Index (FISI),[17] and the Fecal Incontinence Quality of Life Scale (FIQL).[18] All questionnaires were self-administered. Other secondary outcomes were anorectal manometry (resting pressure and maximum squeeze increment pressure), rectal capacity measurements (sensory threshold, urge sensation, and maximum tolerable volume), and fecal incontinence episodes recorded via 14-day bowel diary. For more details about the anorectal manometry and rectal capacity measurements and for the covariates collected at baseline, see the Supplementary Materials and Methods section. Outcome measures were assessed at baseline before randomization and within 14 days after completion of the intervention (primary end point). Data collection for the 36-month follow-up evaluation still is ongoing and results from this long-term follow-up evaluation will be reported separately. Deviations from the trial protocol and registration, together with explanations, have been described elsewhere.[13]

### Sample Size

Based on previous findings in the literature, we hypothesized that 30% in the attention-control group[19,20] and 60% in the PFMT group[5,21] would achieve improvement of their fecal incontinence symptoms. We consider this difference to represent the minimum clinically important difference (MCID). Improvement was defined as a score of very much better, much better, or a little better at the PGI-I (primary outcome). Based on a binomial distribution, we needed a sample size of 84 to show this difference in treatment effects between groups using a statistical power of 80% and a significance level of 5% (2-tailed). To account for a drop-out rate of up to 16%, we included 102 participants.

### Statistical Analyses

The statistical analysis plan has been described previously in full.[13] The primary outcome, the PGI-I ratings after 16 weeks of treatment, were analyzed by logistic regression using the intention-to-treat principle. For the primary analysis, the PGI-I outcome was dichotomized into symptom improvement (3 upper values on the PGI-

I) or unchanged or worsening symptoms (4 lower values at PGI-I). Missing data for the PGI-I were imputed with a score of unchanged in both groups.

As a sensitivity test, we conducted a multiple logistic regression of the primary outcome. The model was adjusted for use of fiber supplements, use of antidiarrheal medication, stool consistency, incontinence type, presence of urinary incontinence, and confirmed sphincter injuries as described in the statistical analysis plan. In the review process the sex and age variables were added to the adjusted analyses. The covariates were added one at a time and subsequently all at once. As a goodness-of-fit, the same variables were examined as modifiers one by one, by adding them in interaction terms with the group variable to the fully adjusted model.

Finally, per-protocol logistic regression analyses were conducted following the principles outlined earlier. These analyses included participants who had attended at least 4 of 6 PFMT consultations, and had documented home training on at least 70% of the possible training days.

The FIQL, FISI, Vaizey Score, anorectal manometry data, rectal capacity measurements, and number of fecal incontinence episodes were analyzed using general linear regression. The primary analyses were unadjusted. As sensitivity analyses, we conducted adjusted analyses adding all the covariates at once. The analyses were conducted using the per-protocol principle as described earlier. For the FIQL, FISI, and Vaizey Score, the analyses also were conducted using the intention-to-treat principle. Missing values for total scores were imputed by multiple imputation using the monotone method, except for the bowel diary, for which we used the Markov Chain Monte Carlo method. A total of 10 imputed data sets were used. The imputation models included baseline values for the missing end point value and group. All general linear regression models were controlled for goodness-of-fit by visual evaluation of residual plots to check the assumptions of linearity, variance homogeneity, and normal distribution of the residuals.

All analyses were conducted in SAS version 9.4 (SAS institute Inc, Cary, NC). All estimates are reported along with 95% CIs and actual *P* values (2-sided). The level of significance was set at .05. All authors had access to the trial data and reviewed and approved the final manuscript.

## Results

### *Participants, Baseline Characteristics, and Attrition*

Between October 15, 2012, and December 15, 2015, we screened 458 patients for eligibility. In total, 98 participants were randomized, 49 to supervised PFMT and 49 to attention-control massage treatment. The overall patient flow including attrition can be seen in Supplementary Figure 1. The baseline characteristics are shown in Table 1. The Participants in the PFMT group were slightly older than the participants in the attention-control group, with median ages of 65 and 58 years, respectively. There were 6 men in the attention-control group and 3 in the PFMT group.

### *Outcomes*

**Primary outcome.** In the PFMT group, 35 participants (74.5%) reported improvement of their incontinence symptoms vs 16 participants (35.5%) in the attention-control group. The exact distribution of the participant PGI-I ratings is shown in Table 2.

The unadjusted and adjusted results for the primary outcome and the per-protocol analyses are shown in Table 3. The intention-to-treat analyses showed an unadjusted odds ratio of 5.16 (95% CI, 2.18–12.19) for reporting improvement in the PFMT group compared with the attention-control group ($P = .0002$). When only a score of very much better or much better was defined as improvement the result still was significant, with an unadjusted odds ratio of 2.98 (95% CI, 1.15–7.73; $P = .025$).

There were no signs of interaction between the groups and any of the examined covariates.

Secondary and explorative analyses of the primary outcome including a subgroup analysis according to incontinence severity at baseline are shown in Supplementary Table 1.

**Secondary outcomes.** The intention-to-treat analysis of the Vaizey Score showed that the PFMT group had a statistically significantly larger mean reduction in incontinence severity than the attention-control group, the unadjusted mean difference in change being -1.83 points (95% CI, -3.57 to -0.08; $P = .04$) (Table 4). There were no statistically significant differences between groups in condition-specific quality of life or in incontinence severity measured with FISI (Table 4). The per-protocol analysis showed statistically significant differences in favor of PFMT both for the Vaizey Score and the 2 FIQL subscales of Lifestyle and Coping/behavior (Table 4).

There were no significant differences in change between groups in the anorectal manometry measurements, the rectal capacity measurements, or in the number of fecal incontinence episodes as recorded in the 14-day bowel diary (Supplementary Table 2).

The median number of consultations was 5 (range, 0–6) in both groups. The PFMT group documented a median of 95 home training days (range, 0–112 d) in the training diaries, corresponding to 84.8% of the possible training days. In the PFMT group, 43 (87.8%) attended at least 4 of the 6 consultations, and 33 (67.4%) documented home training on at least 70% of the possible training days. These 33 participants were included in the per-protocol analyses. No adverse events were reported.

**Table 1.** Baseline Characteristics

| Variable | PFMT (n = 49) | Attention-control (n = 49) |
|---|---|---|
| Demographics | | |
| Age, *y*, median (range) | 65.13 (34.30–77.29) | 58.43 (26.80–89.23) |
| Women | 46 (93.9%) | 43 (87.8%) |
| Ethnicity, North Europe | 46 (93.9%) | 47 (95.9%) |
| Body mass index, $kg/m^2$, median (range) | 24.5 (17.3–36.1) | 23.2 (18.3–47.6) |
| Incontinence history | | |
| Duration of fecal incontinence, *y*, median (range) | 3.25 (0.67–50) | 4.0 (0.75–24) |
| Stool consistency | | |
| Loose/mushy | 19 (38.8%) | 14 (28.6%) |
| Soft, but formed | 11 (22.5%) | 13 (26.5%) |
| Hard, firm | 3 (6.1%) | 1 (2.0%) |
| Varying | 16 (32.7%) | 21 (42.9%) |
| Incontinence type | | |
| Passive | 10 (20.8%) | 16 (33.3%) |
| Urgency | 18 (37.5%) | 14 (29.2%) |
| Mixed, both | 20 (41.7%) | 18 (37.5%) |
| Use of medication/fiber | | |
| Fiber supplements | 24 (49%) | 22 (44.9%) |
| Antidiarrheal medication | 4 (8.2%) | 5 (10.2%) |
| Laxatives | 5 (10.2%) | 7 (14.3%) |
| Medical history | | |
| Previous urogynecological surgery | 30 (61.2%) | 21 (43.8%) |
| Previous anal surgery | 16 (33.3%) | 21 (43.8%) |
| Presence of urinary incontinence | 27 (55.1%) | 24 (49%) |
| Diabetes mellitus | 2 (4.1%) | 4 (8.2%) |
| Inflammatory bowel diseases | 2 (4.1%) | 4 (8.2%) |
| Other diseases | 21 (43.8%) | 27 (55.1%) |
| Obstetric history | | |
| Number of women who delivered | 44 (95.7%) | 36 (83.7%) |
| Parity among women, median (range) | 2 (0–4) | 2 (0–4) |
| Self-reported questionnaires | | |
| Vaizey Score, median (range) | 14 (6–22) | 14 (2–20) |
| FISI, median (range) | 27 (8–57) | 28 (8–50) |
| FIQL Lifestyle, median (range) | 3.40 (1.20–4.00) | 3.20 (1.46–4.00) |
| FIQL Coping/behavior, median (range) | 2.00 (1.11–4.00) | 2.00 (1.00–4.00) |
| FIQL Depression/self-perception, median (range) | 3.19 (1.43–3.81) | 2.91 (1.48–3.81) |
| FIQL Embarrassment, median (range) | 2.33 (1.00–3.67) | 2.33 (1.00–3.67) |
| 14-day bowel dairy | | |
| Number of fecal incontinence episodes, median (range) | 2.0 (0–23) | 1.5 (0–32) |
| Anorectal manometry | | |
| Resting pressure, *mm Hg*, median (range) | 67.6 (38.6–124.0) | 72.2 (34.4–163.5) |
| Maximum squeeze increment pressure, *mm Hg*, median (range) | 109.6 (49.2–216.3) | 124.4 (55.6–256.30) |
| Rectal capacity measurements | | |
| First sensation, *mL*, median (range) | 30 (10–60) | 20 (10–90) |
| Urge sensation, *mL*, median (range) | 60 (20–180) | 50 (20–170) |
| Maximum tolerable volume, *mL*, median (range) | 110 (40–350) | 100 (30–400) |
| Endoanal ultrasound, assessed at 16 weeks | | |
| Anal sphincter injuries | 19 (38.8%) | 14 (30.4%) |
| Defect $<120^\circ$ | 8 (42.1%) | 2 (14.3%) |
| Defect $\geq 120^\circ$ | 11 (57.9%) | 12 (85.7%) |

NOTE. Values are numbers (percentages) unless stated otherwise.
FIQL, Fecal Incontinence Quality of Life Scale (range, 1–4); FISI, Fecal Incontinence Severity Index (range, 0–61); PFMT, pelvic floor muscle training; Vaizey Score, Vaizey Incontinence Score (range, 0–24).

## Discussion

After 16 weeks of treatment, the participants in the PFMT group had 5.16 times higher odds of reporting improvement of incontinence symptoms compared with the attention-control group.

Two other trials have reported results comparable with our results.[9,19] Damon et al[9] reported an odds ratio of 2.34 for successful improvement after PFMT and biofeedback in combination with conservative treatment. However, in contrast to our findings, this was not reflected in reduced severity. This may be explained by different severity measures. Heymen et al[19] showed symptom relief for 76% after supervised PFMT and sensitivity biofeedback vs 41% in a non-supervised PFMT group. This was accompanied by a

**Table 2.** Number and Percentages of the PGI-I Ratings in the 2 Groups

| PGI-I ratings | PFMT (n = 47), frequency (%) | Attention-control (n = 45), frequency (%) |
|---|---|---|
| Very much better | 5 (10.6) | 2 (4.4) |
| Much better | 13 (27.7) | 6 (13.3) |
| A little better | 17 (36.2) | 8 (17.8) |
| **Improvement**[a] | **35 (74.5)** | **16 (35.6)** |
| Unchanged | 12 (25.5) | 26 (57.8) |
| A little worse | 0 (0) | 1 (2.2) |
| Much worse | 0 (0) | 2 (4.4) |
| Very much worse | 0 (0) | 0 (0) |
| **Unchanged or deterioration**[a] | **12 (25.5)** | **29 (64.4)** |
| **Total** | n = 47 (100) | n = 45 (100) |

PFMT, pelvic floor muscle training; PGI-I, Patient Global Impression of Improvement Scale.
[a]Boldface shows PGI-I scores were dichotomized as follows: improvement: a score of very much better, much better, or a little better; unchanged/deterioration: a score of unchanged, a little worse, much worse, or very much worse. Across all 6 cut-off points on the PGI-I scale, the PFMT group had significantly higher odds for reporting their symptom change in a higher/better category than the attention-control group ($P = .0003$).

significant reduction in the FISI. In contrast, we were not able to show significant changes in severity on the FISI, but all mean between-group differences in the FISI score, however, were in favor of PFMT and greater than the MCID of -3.56.[22]

Contrary to our findings, Norton et al[20] did not show additional benefit from offering PFMT and/or biofeedback to conservative treatment. This may be explained by the fact that the conservative treatment contained an urge-resistance program with instructions of resistance to fecal urgency by holding sustained sphincter contractions for progressively longer time durations (up to 10 minutes). Whether these contractions for urge-resistance differ from voluntary pelvic floor muscle contractions and whether the control group reflected a true control group could be questioned. The conclusions of Norton et al[20] of no additional benefit from PFMT could be subject for discussion.

Sjödahl et al[8] did not show an effect of supervised PFMT in combination with strength biofeedback compared with conservative treatment. This result could be owing to small sample size, minimal supervision, and/or the chosen outcome measures (bowel diary and anorectal manometry). When PFMT and conservative treatment were given in combination, the trial showed a significant reduction in incontinence episodes from baseline.

In the current trial, the mean between-group differences in changes on the Vaizey Score were between -1.83 and -2.24 points, this is comparable with results reported by other investigators[20,23–25] and may represent the MCID.[23,24,26]

Similar to other investigators,[9,19] we were not able to show the effect of PFMT on the FIQL in the intention-to-treat analysis. We found a significant effect on the Lifestyle and Coping/behavior subscales only in the per-protocol analyses. Our sample size was calculated in relation to the primary outcome and it is possible that we did not have enough power to show significant differences on the FIQL.

In the current trial, more than one third of patients had sphincter injuries confirmed at endoanal ultrasound, this reflects the tertiary setting of our trial. However, our results may be highly relevant in a primary setting because there is an unmet need for treatment of fecal incontinence in primary health care,[27] and the interventions do not necessarily need to be conducted at specialized centers.[27] The number of sphincter injuries may have contributed to the fact that we were not able to show any significant differences at the anorectal manometry. Another reason could be that the median baseline resting and maximum squeeze pressure in the current trial were comparable with the median for healthy controls measured with comparable equipment.[28] Similar to the current trial, 2 other trials found no significant increase in squeeze pressure after PFMT and conservative treatment,[8,24] whereas most other trials have found that PFMT improved maximum squeeze pressure.[19–21,29,30] However, improvement in squeeze pressure is not always correlated with improvement in

**Table 3.** Primary Outcome: Odds Ratios for Reporting Improvement on the PGI-I in the PFMT Group After 16 Weeks of Treatment

| | ITT analysis, unadjusted (n = 98)[a] | ITT analysis, adjusted[b] (n = 92)[c] | Per-protocol analysis, unadjusted (n = 82)[d] | Per-protocol analysis, adjusted[b] (n = 78)[c] |
|---|---|---|---|---|
| OR (95% CI) | 5.16 (2.18–12.19) | 7.26 (2.55–20.69) | 7.66 (2.75–21.38) | 7.97 (2.39–26.55) |
| *P* value | .0002 | .0002 | .0001 | .0007 |

NOTE. PGI-I scores were dichotomized as participants reporting either improvement of their incontinence symptoms (a score of very much better, much better, or a little better) or unchanged/deterioration (a score of unchanged, a little worse, much worse, or very much worse).
ITT, intention-to-treat; OR, odds ratio; PFMT, pelvic floor muscle training; PGI-I, Patient Global Impression of Improvement Scale.
[a]Imputed 6 values for missing PGI-I values.
[b]Adjusted for age, sex, antidiarrheal medication at baseline, fiber supplements at baseline, incontinence type, presence of urinary incontinence, stool consistency, and anal sphincter injuries (at 16-week follow-up evaluation).
[c]No imputations were made because of simultaneous missing values for both outcome and covariates.
[d]Imputed 4 values for missing PGI-I values.

**Table 4.** Supportive Outcomes

| | Change from baseline to follow-up evaluation, mean change (SD) | | 16-week follow-up evaluation<br>Mean between-group difference in change from baseline to follow-up evaluation, mean difference (95% CI), *P* value | | | |
|---|---|---|---|---|---|---|
| | | | ITT analyses | | Per-protocol analyses | |
| Outcomes | PFMT (n = 47)[a] | Attention-control (n = 45)[a] | Unadjusted (n = 98)[b] | Adjusted[c] (n = 92)[d] | Unadjusted (n = 82)[e] | Adjusted[c] (n = 78)[d] |
| Vaizey Score range, 0–24 | −2.57 (4.51) | −0.67 (4.05) | −1.83 (−3.57 to −0.082), .040 | −1.87 (−3.88 to 0.13), .067 | −2.08 (−4.09 to −0.07), .042 | −2.24 (−4.57 to 0.097), .060 |
| FISI range, 0–61 | −4.23 (10.86) | −0.40 (13.05) | −3.80 (−8.65 to 1.061), .13 | −4.64 (−10.029 to 0.76), .092 | −5.12 (−10.61 to 0.37), .067 | −5.88 (−12.16 to 0.40), .067 |
| FIQL | | | | | | |
| Lifestyle | 0.16 (0.48) | −0.031 (0.50) | 0.19 (−0.0068 to 0.38), .059 | 0.18 (−0.033 to 0.40), .010 | 0.22 (0.011–0.44), .040 | 0.24 (−0.0017 to 0.49), .052 |
| Coping/behavior | 0.20 (0.59) | 0.073 (0.43) | 0.12 (−0.084 to 0.33), .24 | 0.08 (−0.15 to 0.31), .48 | 0.23 (0.01–0.45), .037 | 0.18 (−0.059 to 0.43), .14 |
| Depression/self-perception | −0.017 (0.46) | 0.014 (0.48) | −0.031 (−0.22 to 0.16), .75 | −0.086 (−0.30 to 0.13), .43 | 0.022 (−0.18 to 0.22), .83 | −0.016 (−0.25 to 0.22), .90 |
| Embarrassment | 0.19 (0.80) | 0.19 (0.66) | −0.0056 (−0.30 to 0.29), .97 | 0.042 (−0.29 to 0.37), .80 | 0.14 (−0.17 to 0.45), .38 | 0.095 (−0.27 to 0.46), .61 |

FIQL, Fecal Incontinence Quality of Life Scale (a condition-specific quality-of-life scale consisting of 4 subscales: Lifestyle, Coping/behavior, Depression/self-perception, and Embarrassment; subscales range from 1–4, with 1 = worst quality of life, 4 = best quality of life); FISI, Fecal Incontinence Severity Index (with 0 = complete continence, 61 = complete incontinence); ITT, intention-to-treat; PFMT, pelvic floor muscle training; Vaizey Score, Vaizey Incontinence Score (with 0 = complete continence, 24 = complete incontinence).

[a]No imputations.

[b]Imputed 6 values for missing end point values for each of the secondary outcomes.

[c]Adjusted for age, sex, antidiarrheal medication at baseline, fiber supplements at baseline, incontinence type, presence of urinary incontinence, stool consistency, and anal sphincter injuries (at 16-week follow-up evaluation).

[d]No imputations were made because of simultaneous missing values for both outcome and covariates.

[e]Imputed 4 values for missing end point values for each of the secondary outcomes.

clinical outcomes.[21,30] It is not surprising that we did not find any changes in the rectal capacity measurement because EMG biofeedback is not expected to change sensory thresholds, as one would expect from, for example, sensitivity biofeedback.

We were not able to show any differences between groups in the number of fecal incontinence episodes. We had much missing data in the bowel diaries and we can only guess what the result would have been if the data had been more complete. Electronic assessment of incontinence episodes could be a way to reduce the amount of missing data in future trials.

In our trial all outcome assessors and researchers were blinded, and we did try to blind the participants to the trial hypothesis. It was not possible to blind the participants or the physiotherapists to the treatment allocation. The lack of blinding may have resulted in a higher placebo response in the PFMT group[14] owing to higher expectations of treatment effect. We did not measure to what extent the participants believed that they were receiving effective treatment, so we cannot tell if differences in expectations between groups influenced the subjective outcomes. However, all primary and secondary results were in favor of supervised PFMT, which makes it less possible that our findings should be owing solely to higher expectations in the PFMT group.

The attention-control massage treatment was chosen as a physiologically inactive control treatment to control for the nonspecific trial effect[10] related to the attention given by the health care professional. We could have chosen a sham training intervention instead, but given the fact that many patients are unable to conduct a correct pelvic floor muscle contraction, we found it unethical to teach the participants sham contractions with the risk of rehearsing a wrong contraction that may be difficult to correct later.

## Conclusions

This trial provides support for a superior effect of supervised PFMT in combination with conservative treatment compared with attention-control massage treatment and conservative treatment in adults with fecal incontinence. Participants in the PFMT group had a 5-fold higher odds of reporting improvements in fecal incontinence symptoms and had a larger mean reduction of incontinence severity at the Vaizey Score. Based on the results, PFMT in combination with conservative treatment should be offered as first-line treatment for adults with fecal incontinence.

## Supplementary Material

Note: To access the supplementary material accompanying this article, visit the online version of *Clinical Gastroenterology and Hepatology* at www.cghjournal.org, and at https://doi.org/10.1016/j.cgh.2018.12.015.

## References


1. Ng K-S, Sivakumaran Y, Nassar N, et al. Fecal incontinence: community prevalence and associated factors–a systematic review. Dis Colon Rectum 2015;58:1194–1209.
2. Brown HW, Wexner SD, Segall MM, et al. Quality of life impact in women with accidental bowel leakage. Int J Clin Pract 2012; 66:1109–1116.
3. Bharucha AE, Zinsmeister AR, Locke GR, et al. Prevalence and burden of fecal incontinence: a population-based study in women. Gastroenterology 2005;129:42–49.
4. Olsson F, Berterö C. Living with faecal incontinence: trying to control the daily life that is out of control. J Clin Nurs 2015; 24:141–150.
5. Norton C. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. Cochrane Database Syst Rev 2012;7:CD002111.
6. Whitehead WE, Rao SSC, Lowry A, et al. Treatment of fecal incontinence: State of the Science Summary for the National Institute of Diabetes and Digestive and Kidney Diseases Workshop. Am J Gastroenterol 2015;110:138–146.
7. Bo K, Frawley HC, Haylen BT, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction. Int Urogynecology J 2017;28:191–213.
8. Sjödahl J, Walter SA, Johansson E, et al. Combination therapy with biofeedback, loperamide, and stool-bulking agents is effective for the treatment of fecal incontinence in women - a randomized controlled trial. Scand J Gastroenterol 2015; 50:965–974.
9. Damon H, Siproudhis L, Faucheron J-L, et al. Perineal retraining improves conservative treatment for faecal incontinence: a multicentre randomized study. Dig Liver Dis 2014;46:237–242.
10. Braunholtz DA, Edwards SJ, Lilford RJ. Are randomized clinical trials good for us (in the short term)? Evidence for a "trial effect." J Clin Epidemiol 2001;54:217–224
11. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c869.
12. Boutron I, Altman DG, Moher D, et al. CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts. Ann Intern Med 2017;167:40.
13. Ussing A, Dahn I, Due U, et al. Supervised pelvic floor muscle training versus attention-control massage treatment in patients with faecal incontinence: statistical analysis plan for a randomised controlled trial. Contemp Clin Trials Commun 2017;8:192–202.
14. Hróbjartsson A, Boutron I. Blinding in randomized clinical trials: imposed impartiality. Clin Pharmacol Ther 2011;90:732–736.
15. Yalcin I, Bump RC. Validation of two global impression questionnaires for incontinence. Am J Obstet Gynecol 2003;189:98–101.
16. Vaizey CJ, Carapeti E, Cahill JA, et al. Prospective comparison of faecal incontinence grading systems. Gut 1999;44:77–80.
17. Rockwood TH, Church JM, Fleshman JW, et al. Patient and surgeon ranking of the severity of symptoms associated with fecal incontinence. Dis Colon Rectum 1999;42:1525–1531.
18. Rockwood TH, Church JM, Fleshman JW, et al. Fecal incontinence quality of life scale. Dis Colon Rectum 2000;43:9–16.
19. Heymen S, Scarlett Y, Jones K, et al. Randomized controlled trial shows biofeedback to be superior to pelvic floor exercises for fecal incontinence. Dis Colon Rectum 2009;52:1730–1737.

20. Norton C, Chelvanayagam S, Wilson-Barnett J, et al. Randomized controlled trial of biofeedback for fecal incontinence. Gastroenterology 2003;125:1320–1329.
21. Solomon MJ, Pager CK, Rex J, et al. Randomized, controlled trial of biofeedback with anal manometry, transanal ultrasound, or pelvic floor retraining with digital guidance alone in the treatment of mild to moderate fecal incontinence. Dis Colon Rectum 2003;46:703–710.
22. Jelovsek JE, Chen Z, Markland AD, et al. Minimum important differences for scales assessing symptom severity and quality of life in patients with fecal incontinence. Female Pelvic Med Reconstr Surg 2014;20:342–348.
23. Bols EMJ, Hendriks HJM, Berghmans LCM, et al. Responsiveness and interpretability of incontinence severity scores and FIQL in patients with fecal incontinence: a secondary analysis from a randomized controlled trial. Int Urogynecology J 2013; 24:469–478.
24. Johannessen HH, Wibe A, Stordahl A, et al. Do pelvic floor muscle exercises reduce postpartum anal incontinence? A randomised controlled trial. BJOG 2017;124:686–694.
25. Young CJ, Zahid A, Koh CE, et al. A randomised control trial of four different regimes of biofeedback program in the treatment of faecal incontinence. Colorectal Dis 2018;20:312–320.
26. Bols EMJ, Hendriks EJM, Deutekom M, et al. Inconclusive psychometric properties of the Vaizey score in fecally incontinent patients: a prospective cohort study. Neurourol Urodyn 2010;29:370–377.
27. Whitehead WE, Palsson OS, Simren M. Treating fecal incontinence: an unmet need in primary care medicine. N C Med J 2016;77:211–215.
28. Gundling F, Seidl H, Scalercio N, et al. Influence of gender and age on anorectal function: normal values from anorectal manometry in a large Caucasian population. Digestion 2010;81:207–213.
29. Ilnyckyj A, Fachnie E, Tougas G. A randomized-controlled trial comparing an educational intervention alone vs education and biofeedback in the management of faecal incontinence in women. Neurogastroenterol Motil 2005;17:58–63.
30. Dobben AC, Terra MP, Berghmans B, et al. Functional changes after physiotherapy in fecal incontinence. Int J Colorectal Dis 2006;21:515–521.

**Reprint requests**
Address requests for reprints to: Anja Ussing, MSc, Department of Physiotherapy and Occupational Therapy, Optimed, Clinical Research Centre, Copenhagen University Hospital, Kettegaards Allé 30, DK-2650, Hvidovre, Denmark. e-mail: anja.ussing@regionh.dk.

**Acknowledgments**
The authors thank all of the participants who contributed to the trial. The authors thank the staff at the Department of Physiotherapy and Occupational Therapy and the Department of Surgical and Medical Gastroenterology. The authors especially thank the physiotherapists Cathrine Blegvad Stenz and Susanne Høgsberg Knudsen for conducting the supervised pelvic floor muscle training, and Sarah Le Basson and Louise Hein Sommer for providing the attention-control massage treatment. The authors thank the nurses involved in the screening of eligible participants and the conduct of the conservative treatment. Finally, the authors thank the staff at the Clinical Research Centre for their highly valued support and academic discussions and contributions.

**Conflicts of interest**
These authors disclose the following: Anja Ussing has received grants to fund the current trial from the Danish Foundation for Research in Physiotherapy, the Research Foundation at Copenhagen University Hospital, The Lundbeck Foundation (UCSF), and the Foundation of Aase and Ejnar Danielsen, and has been paid as a consultant for the Danish Physiotherapy Foundation; Michael Sørensen is proctor for Medtronic and has received a speaker's fee and teaching fee from Medtronic, and funding of projects from Medtronic and Helsefonden (a national public foundation funding social and health-related topics); Ulla Due is chairwoman of The Danish Society of Urological, Gynacological and Obstetrical Physiotherapy, a board member of the Danish Continence Society (a nonprofit patient organization), and has received fees for developing free website information (gynzone.dk) and apps for women about pelvic floor disorders for Gynzone; and Thomas Bandholm is a physiotherapist and exercise physiologist. The remaining authors disclose no conflicts.

**Funding**
This trial was supported by the Danish Foundation for Research in Physiotherapy, the Research Foundation at Copenhagen University Hospital, The Lundbeck Foundation (UCSF) (Grant number FP13/2013, 2013), and the Foundation of Aase and Ejnar Danielsen (Grant number 10-000918, 2013). The funders were not involved in the design of the trial; in the collection, analysis, or interpretation of data; or in the writing or the decision about submitting the manuscript for publication.

## Supplementary Material and Methods

### *Detailed Description of the Conservative Treatment Program*

Both trial groups received a conservative treatment program consisting of standard information about optimizing bowel emptying and the use of fiber supplements and, if appropriate, information about the use of antidiarrheal medication (loperamide) and/or laxatives with a local effect in the rectum (glycerol).

Participants were informed about regulation of stool consistency, and following a healthy and varying the diet with regular meals and high-fiber content was recommended. In addition, they were recommended fiber supplements such as psyllium. Psyllium was recommended as a powder or capsules. Participants were recommended to have 2 teaspoons of powder (3 g) or 6 capsules (3 g), both to be consumed twice a day. As an alternative to or supplement to psyllium, participants were informed that they could have a breakfast cereal with high-fiber content. They were recommended to drink 2.5 L liquid every day. Participants were informed that if they were bothered by thin stool, they could use antidiarrheal medicine (loperamide). They were recommended to start with half a tablet (equaling 1 mg) and then increase the dose until their stool was formed and they avoided accidents, but did not become constipated. Participants were informed that they may achieve more complete bowel emptying by using a laxative with a local effect in the rectum such as glycerol. They were informed that suppositories can be used to achieve more complete emptying after a spontaneous bowel movement or to initiate a bowel movement.

The information in the conservative treatment program was delivered by 1 of 3 nurses who was specialized in fecal incontinence and was initiated on the first visit to the outpatient clinic at the Department of Surgical and Medical Gastroenterology before inclusion in the trial. The information was followed up by a telephone call from the nurse after approximately 1 month, thus the conservative treatment in both groups was continued parallel to the allocated intervention after the randomization.

In addition to the conservative treatment program, the participants in both groups received their allocated interventions within 14 days of their randomization. The interventions in both groups were delivered as individual face-to-face visits at the Department of Physiotherapy and Occupational Therapy and were distributed over 16 weeks, with treatment offered in treatment weeks 0, 2, 5, 8, 12, and 16 ($\pm$1 week).

### *Detailed Description of the Supervised Pelvic Floor Muscle Training Intervention*

Participants in the PFMT group received 6 individual treatments of 45 minutes consisting of individually supervised PFMT. The treatments were given by 1 of 2 physiotherapists who was specialized in treatment of fecal incontinence. The participants were taught correct pelvic floor contractions verbally and by digital vaginal and rectal examination. The verbal instruction was "squeeze around the anus as if you were about to hold back air or stool passing from the bowel." At every session, the participant received an examination of their pelvic floor muscle function by digital vaginal and rectal examination and by intra-anal EMG biofeedback. The EMG biofeedback was used to give the participants visual and auditory feedback on a voluntary contraction to enhance awareness, strength, and endurance of a voluntary contraction and to support the performance of correct pelvic floor muscle contractions in different body positions and during movements. The participants were instructed to perform an individually tailored daily home training program. The program consisted of 3 sets of 10 pelvic floor muscle contractions sustained for up to 10 seconds, and 2 sets of 3 contractions sustained for up to 30 seconds. The participants also were taught to contract the pelvic floor muscle in response to fecal urgency and in situations with increased abdominal pressure. A training diary was used as a motivational tool and to quantify training adherence. Progressive overload was achieved by increasing the duration of the contractions and by performing the exercises against gravity in different body positions and during movements. The PFMT intervention was standardized in a protocol, and protocol adherence was recorded by the physiotherapists filling in case report forms.

### *Detailed Description of the Anorectal Manometry, Rectal Capacity Measurements, and Endoanal Ultrasonography*

**Anorectal manometry.** The investigation was conducted with the water-perfused catheter technique. Resting pressure and maximum squeeze increment pressure were determined. Both measures were recorded in the high-pressure zone using the pull-through technique. Maximum squeeze increment pressure was measured as the average of 3 squeezes using the pull-through technique (1 mm/s).

**Rectal capacity measurements.** A catheter was inserted into the rectum and then slowly inflated with air. The sensory threshold was determined as the minimum volume of filling at which a rectal sensation was perceived. Urge sensation was determined as the volume associated with the initial urge to defecate, and the maximum tolerated volume was determined as the volume at which the participants felt a strong desire to defecate and felt pain or discomfort.

Anorectal manometry and rectal capacity measurements were measured by a trained nurse with more than 10 years of experience in conducting these investigations.

### *Descriptive Variables and Covariates Collected at Baseline*

In addition to the outcome measures, the baseline data consisted of demographic background information, a medical history with an emphasis on the history of fecal incontinence, and known risk factors for fecal incontinence, and for women an obstetric history as well. An endoanal ultrasonography also was conducted (at 16 weeks) to detect internal and/or external anal sphincter defects. Defects were defined as a gap in the muscle ring or a loss of muscle substance in a range of more than 60°. The extension of sphincter defect was measured in degrees.

## Results

### *Secondary Analyses of the Primary Outcome*

An intention-to-treat proportional odds model was fitted with the PGI-I scores as outcome using all 7 categories.

The model showed that the participants in the PFMT group had 4.45 times higher odds (95% CI, 2.02–9.78) for rating their symptom changes in a higher (better) PGI-I category across all 6 cut-off points of the PGI-I scale ($P = .0002$.)

During the review process, it was suggested to conduct a subgroup analysis of the effect at the PGI-I according to incontinence severity. We did this by dividing the participants into 3 subgroups according to the Vaizey Score at baseline (Vaizey Score subgroups: 1–8, 9–16, and 17–24). The subgroup effect was examined in an intention-to-treat logistic regression model in which the severity variable was added as an interaction term with the group variable. The model was unadjusted because the trial was not powered to conduct an adjusted subgroup analyses. The analysis showed significant interaction between baseline severity and group ($P = .0076$). There was no significant effect for the group with the lowest severity at baseline (subgroup 1), whereas both subgroups 2 and 3 had a significant effect of supervised PFMT. The effect was most pronounced for the group with the highest severity (subgroup 3) (Supplementary Table 1).

**Supplementary Table 1.** Odds Ratios for Reporting Improvement on the PGI-I in the PFMT Group After 16 Weeks of Treatment by Severity Subgroups

| | Incontinence severity at baseline measured with the Vaizey Score | | |
|---|---|---|---|
| ITT analysis, unadjusted | Subgroup 1, Vaizey Score between 1 and 8 | Subgroup 2, Vaizey Score between 9 and 16 | Subgroup 3, Vaizey Score between 17 and 24 |
| OR (95% CI) | 1.2 (0.12–11.87) | 6.9 (2.16–22.098) | 14.4 (1.38–150.81) |
| *P* value n | .88 n = 15[a] | .0011 n = 60[b] | .026 n = 23[a] |

NOTE. PGI-I scores were dichotomized as participants reporting either improvement of their incontinence symptoms (a score of very much better, much better, or a little better) or unchanged/deterioration (a score of unchanged, a little worse, much worse, or very much worse).
ITT, intention-to-treat; OR, odds ratio; PFMT, pelvic floor muscle training; PGI-I, Patient Global Impression of improvement; Vaizey Score, Vaizey Incontinence Score.
[a]Imputed 1 value for a missing PGI-I value.
[b]Imputed 4 values for missing PGI-I values.

**Supplementary Table 2.** Explorative Outcomes

| | Change from baseline to follow-up evaluation | | 16-week follow-up evaluation Mean between group difference in change from baseline to follow-up evaluation | | | |
|---|---|---|---|---|---|---|
| | Per protocol[a] | | | | | |
| | PFMT (n = 33) | Attention-control (n = 46) | Per-protocol analyses, unadjusted (n = 82)[b] | | Per-protocol analyses, adjusted[c] (n = 78)[d] | |
| | Mean change (SD) | Mean change (SD) | Mean difference in change (95% CI) | *P* value | Mean difference in change (95% CI) | *P* value |
| Anorectal manometry | | | | | | |
| Resting pressure, *mm Hg* | −4.49 (14.38) | 3.21 (18.55) | −7.07 (−14.75 to 0.60) | .07 | −7.06 (−15.69 to 1.58) | .11 |
| Maximum squeeze increment pressure, *mm Hg* | −0.72 (23.00) | 1.90 (24.53) | −1.77 (−12.55 to 9.004) | .75 | 3.16 (−8.07 to 14.39) | .58 |
| Rectal capacity measurements | | | | | | |
| Sensory threshold, *mL* | −1.82 (17.22) | −1.96 (14.39) | −0.10 (−7.10 to 6.89) | .98 | 1.14 (−6.75 to 9.025) | .77 |
| Urge sensation, *mL* | −3.33 (22.59) | −4.13 (25.70) | 0.32 (−10.55 to 11.19) | .95 | −0.67 (−12.97 to 11.63) | .91 |
| Maximum tolerated volume, *mL* | −9.70 (46.53) | −9.78 (37.86) | 0.19 (−18.19 to 18.56) | .98 | −5.77 (−26.13 to 14.59) | .57 |
| 14-day bowel diary | | | | | | |
| Fecal incontinence episodes | −0.65 (3.87) n = 17 | 0.15 (4.91) n = 27 | | | | |
| Multiple imputation | | | 0.70 (−2.99 to 4.40) (n = 82) | .71 | 1.12 (−2.97 to 5.21) (n = 78) | .59 |
| Imputation with zero | | | −0.15 (−2.53 to 2.22) (n = 79)[e] | .90 | −0.71 (−3.66 to 2.25) (n = 75)[f] | .63 |
| Complete case | | | −0.80 (−3.63 to 2.044) (n = 44) | .57 | −1.73 (−5.08 to 1.63) (n = 43) | .30 |

NOTE. As described in the statistical analysis plan,[13] we conducted a sensitivity analysis for the bowel diary because the missing data exceeded 10% (only 44 of the 82 participants in the per-protocol analysis had complete outcomes for fecal incontinence episodes). In this analysis, missing values for incontinence episodes were imputed with a value of zero because missing values predominantly were judged not to be missing at random but seemed to be negative answers. As an extra analysis, we conducted a per-protocol analysis without imputations, only including the 44 participants with complete outcomes. This complete case analysis was not prespecified but included because of the large amount of missing data. For the same reason, we did not analyze the number of stools recorded in the bowel diary, as had been prespecified.

[a]No imputations.

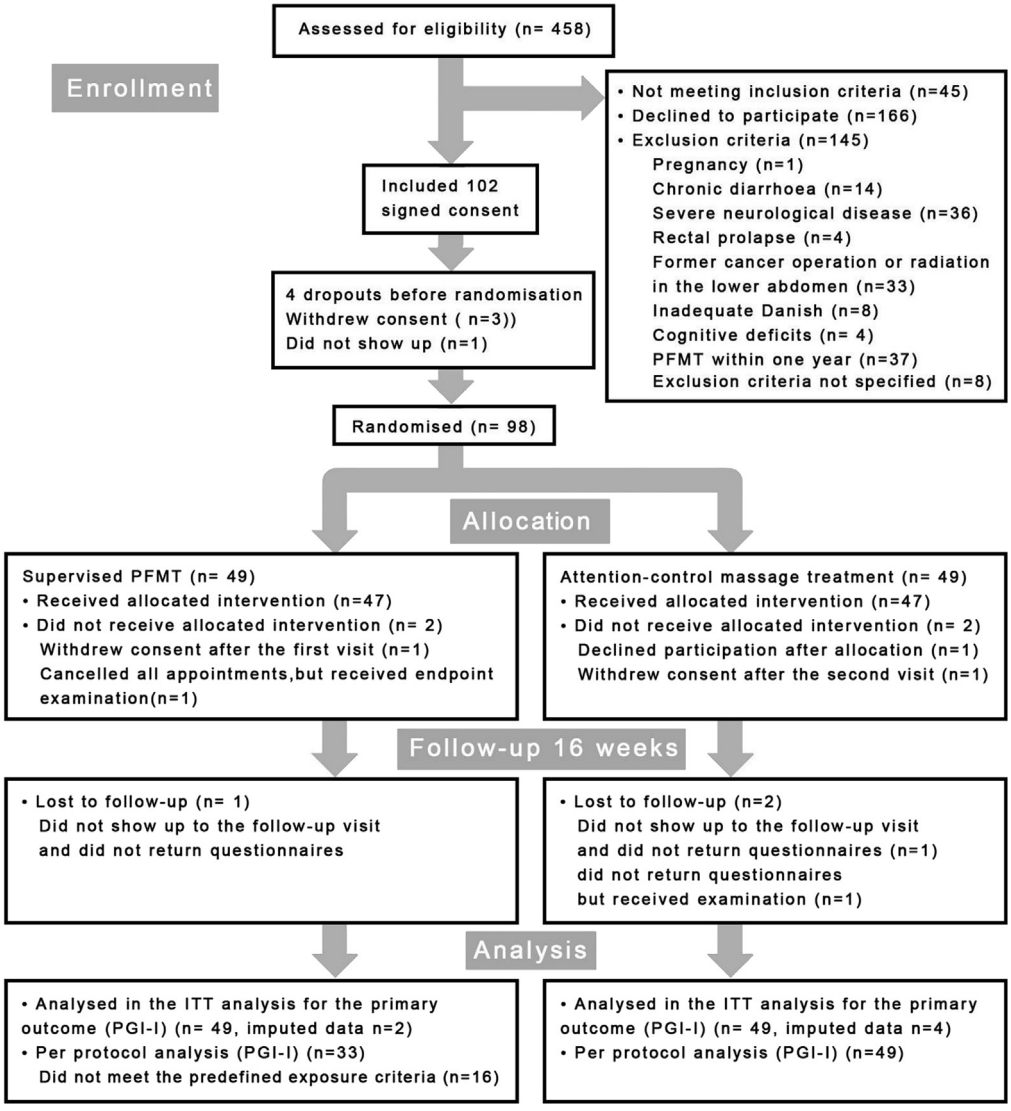
[b]Imputed 3 values.

[c]Adjusted for age, sex, antidiarrheal medication at baseline, fiber supplements at baseline, incontinence type, presence of urinary incontinence, stool consistency, and anal sphincter injuries (at 16-week follow-up evaluation).

[d]No imputations were made because of simultaneous missing values for both outcome and covariates.

[e]Imputed 35 values, missing values were imputed with zero.

[f]Imputed 32 values, missing values were imputed with zero. The results from the 14-day bowel diary should be interpreted with great caution because of the large amount of missing data.




**Supplementary Figure 1.** Flow diagram describing patient flow through each stage of the trial. We screened 458 patients for eligibility, of whom 45 did not meet the inclusion criteria. Among those who met the inclusion criteria, 145 were excluded because of the presence of exclusion criteria and 166 declined participation. The main reasons for declining were long distance to the hospital or unwillingness to attend the required 9 appointments. A total of 102 participants signed the informed consent form, but 4 dropped out before randomization. Thus, 98 participants were randomized, 49 to supervised PFMT and 49 to attention-control massage treatment. Of the 98 randomized participants, 93 were seen at the 16-week follow-up evaluation and the primary end point was assessed in 92 participants (93.9%), except for the anorectal manometry and rectal capacity measurements, which were measured in 93 participants. Thus, end point data for the PGI-I, the Vaizey Score, the FISI, and the FIQL were missing for 6 participants (6.1%). ITT, intention-to-treat; PFMT, pelvic floor muscle training; PGI-I, Patient Global Impression of Improvement Scale.