UROGYNECOLOGY

Can pelvic floor muscle training reverse pelvic organ prolapse and reduce prolapse symptoms? An assessor-blinded, randomized, controlled trial

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OBJECTIVE: The aim of this study was to investigate the effectiveness of pelvic floor muscle training in reversing pelvic organ prolapse and alleviating symptoms.

STUDY DESIGN: This assessor-blinded, parallel group, randomized, controlled trial conducted at a university hospital and a physical therapy clinic randomly assigned 109 women with prolapse stages I, II, and III to pelvic floor muscle training (n = 59) or control (n = 50). Both groups received lifestyle advices and learned "the Knack." In addition, pelvic floor muscle training comprised individual physical therapy sessions and home exercise. Student *t* test, Mann-Whitney *U* test, odds ratio, and effect size were used to compare groups.

RESULTS: Eleven (19%) women in the pelvic floor muscle training group improved 1 Pelvic Organ Prolapse Quantification System stage vs 4 (8%) controls ($P = .035$). Compared with controls, the pelvic floor muscle training group elevated the bladder (difference: 3.0 mm; 95% confidence interval, 1.5–4.4; $P < .001$) and rectum (5.5 mm; 95% confidence interval, 1.4–7.3; $P = .022$) and reduced frequency and bother of symptoms compared with controls.

CONCLUSION: Pelvic floor muscle training is without adverse effects and can be used as treatment for prolapse.

Key words: conservative treatment, pelvic floor muscle training, pelvic organ prolapse, prolapse symptoms, stage of prolapse

Cite this article as: Brækken IH, Majida M, Ellström Engh M, et al. Can pelvic floor muscle training reverse pelvic organ prolapse and reduce prolapse symptoms? An assessor-blinded, randomized, controlled trial. Am J Obstet Gynecol 2010;203:170.e1-7.

It has been estimated that approximately 50% of women lose some of the supportive mechanisms of the pelvic floor caused by childbirth, leading to different degrees of pelvic organ prolapse (POP).[1] The prevalence of symptomatic POP is reported to be 3–28%,[2-4] with prolapse symptoms such as vaginal bulging and heaviness being the most specific symptoms.[2,5] These symptoms can greatly impair a woman's quality of life and are the main indication for surgery.[6] POP accounts for 20% of women on waiting lists for major gynecologic surgery.[1] However, prolapse recurs in up to 58% of women after surgery, and about one-third of women who are operated on undergo at least 1 more surgery for prolapse.[7,8] This highlights the need for prevention measures that could reduce the impact of POP.

Activity in the pelvic floor muscles (PFM) plays a critical role in supporting the pelvic organs.[9] Women with POP have reduced PFM strength,[10,11] and the severity of POP seems to increase with increasing PFM dysfunction.[12,13] Pelvic floor muscle training (PFMT) is without adverse effects, and anatomic understanding of PFM function provides a theoretical basis for strength training of the PFM to be effective in prevention and treatment of POP.[14]

A survey revealed that 92% of women's health physical therapists (PTs) assessed or treated women with POP, despite a poor evidence base and lack of clinical referral guidelines.[15] To date, only 3 randomized controlled trials (RCTs) have investigated the effect of PFMT on POP. One trial[16] scored low on methodologic quality,[17] 1 is a small pilot study,[18] and 1 small trial, published in French, assessed symptoms only.[19] A recent Cochrane review concluded that available evidence is insufficient to understand the role PFMT may play in reducing POP and recommends RCTs with high methodologic quality.[17] The aim of the current study was to evaluate whether PFMT can (1) reverse and prevent further development of POP and (2) reduce symptoms related to POP.

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Presented at the 39th Annual Meeting of the International Continence Society, San Francisco, CA, Sept. 29-Oct. 3, 2009.

Received Oct. 9, 2009; revised Dec. 8, 2009; accepted Feb. 15, 2010.

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This study was supported by the Norwegian Foundation for Health and Rehabilitation and the Norwegian Women's Public Health Association.

0002-9378/$36.00 • © 2010 Mosby, Inc. All rights reserved. • doi: 10.1016/j.ajog.2010.02.037

Materials and Methods

Design

This explanatory study is an assessor-blinded, randomized, controlled, parallel

group trial with stratification on severity of POP. Participants were women with POP stages I, II, and III as determined by the Pelvic Organ Prolapse Quantification System (POP-Q).[20] Women with POP, regardless of symptoms, were enrolled by community gynecologists and advertisements in newspapers. The study was approved by the Regional Medical Ethics Committee (S-05146), Norwegian Social Science Data Services (200501371 SMRH), and registered at ClinicalTrials.gov (NCT00271297). All subjects gave written informed consent.

Participants were at least 1 year postpartum. Exclusion criteria included POP stage 0 or IV, inability to contract the PFM, breastfeeding, previous POP surgery, radiating back pain, pelvic cancer, neurologic disorders, psychiatric disorders, untreated urinary tract infection, planning to become pregnant during the next 6 months, or to be away for more than 4 weeks of the intervention period.

As preliminary data on effect size of PFMT to treat POP were not available at the start of the study, we used an effect size of 0.6 to calculate the sample size. This was found in a multicenter RCT evaluating the effect of PFMT for stress urinary incontinence (SUI).[21] With a 2-sided alpha of .05 and a power of 80%, a sample size of 45 per group was required.[22] Because of the possible dropouts, we chose to include at least 50 women in each group.

Intervention

Women in both the PFMT and the control group were advised to avoid straining and taught how to contract their PFM before and during increases in abdominal pressure ("the Knack").[23] The controls were asked not to change frequency of, or to start, PFMT during the intervention period. Women in the PFMT group were advised to do 3 sets of 8–12 close to maximum PFM contractions per day and to record home training adherence in an exercise diary.[21,24] Each woman was individually supervised by a PT once a week during the first 3 months and every second week during the last 3 months. All women in the PFMT group also received a booklet and a DVD showing the exercise program. This program has been successfully used in several RCTs on women with SUI.[21,24]

Primary outcome measures

Stage of POP

The internationally recommended classification system POP-Q was used to test severity of POP.[20,25]

Position of bladder and rectum

The participants emptied their bladder, and a bladder volume of <50 mL was confirmed by ultrasound. The women stood with legs slightly apart during the ultrasound examination. A GE Voluson 730 expert and an E8 ultrasound system (GE Healthcare, Oslo, Norway) were used, with a 4–8 MHz curved array 3-dimensional/4-dimensional (3D/4D) ultrasound transducer (RAB 4–8 l/obstetric) placed on the perineum in the sagittal plane. The women were told to relax their PFM, while recording 3D volumes. Position of the bladder and rectum was quantified by locating the urethrovesical junction (bladder neck)[26] and rectal ampulla,[27] respectively. The height of the organs was defined as the vertical distance perpendicular from the central axis of the symphysis pubis on a rectangular coordinate system in the midsagittal plane, as described by Schaer et al[26] and found to be reliable.[27,28]

Frequency and bother of prolapse symptoms

Participants completed a validated questionnaire[29] to describe frequency (daily, weekly, monthly, or less than once per month) and bother (4-point scale) of prolapse symptoms (feeling of vaginal bulging and/or heaviness). Women were considered symptomatic if they had monthly symptoms or more often. Improvement was present if the women reported less frequent symptoms or less bother on the 4-point scale at 6 months posttest compared with baseline answers.

Secondary outcome measures

Frequency and bother of bladder and bowel symptoms

The same validated questionnaire[29] was used to describe frequency and bother of bladder symptoms (SUI, urge urinary incontinence) and bowel symptoms (flatus, loose, and solid fecal incontinence, problems with emptying bowel). In addition, the International Consultation on Incontinence Urinary Incontinence Short Form questionnaire (ICIQ-UI SF)[30] was used to assess urinary incontinence and its impact on quality of life.

Independent variable

PFM function was evaluated by a vaginal balloon catheter (ballon size 6.7 × 1.7 cm) connected to a high-precision pressure transducer (Camtech AS, Sandvika, Norway).[31] Muscle strength was calculated as the mean of 3 maximal voluntary contractions. This method has been found to be reliable and valid if used with simultaneous observation of inward movement of the catheter and perineum during PFM contraction.[31,32] Vaginal resting pressure was measured as the difference between atmospheric pressure and the vaginal high-pressure zone at rest, without any voluntary PFM activity. PFM endurance was defined as a sustained maximal contraction and was quantified during the first 10 seconds as the area under the curve (cmH_2O sec).

Procedure, randomization, and blinding

The participants answered the postal questionnaires before baseline assessment. A PT (I.H.B.) examined the ability to contract the PFM and measured PFM function. Assessment was performed in a physical therapy clinic. All POP-Q and ultrasound examinations were performed by a gynecologist (M.M.) at a university hospital. Thereafter, women were stratified into 2 groups by severity of prolapse: (1) maximal vaginal descent at or above the hymen, and (2) maximal vaginal descent below the hymen. Within each strata, a computer-generated random number system with concealed envelopes, generated by a statistician, randomly assigned the women to either PFMT or control. The participants opened an opaque, sealed envelope with their group assignment. The gynecologist (M.M.) performing all the POP-Q and ultrasound examinations was blinded to group allocation, clinical, and background data. Before the 6-month posttest, all participants of both groups completed the postal questionnaire and

were retested with the same outcome measures as baseline. The PT (I.H.B.) was blinded for all outcome measures but not the independent variable (PFM function). The ultrasound images were stored by deidentified code numbers and analyzed offline (4D View v 5.0 and 6.3; GE Healthcare) by 1 investigator (I.H.B.) blinded to group allocation, clinical, and background data.

Statistical analysis

Statistical analyses were carried out in SPSS version 15 (SPSS, Inc, Chicago, IL). The results are given as frequencies and percentages for categorical data and means, with 95% confidence intervals (CIs) for continuous data. Continuous data were checked for normality by Kolmogorov-Smirnov and Shapiro-Wilk tests. Between and within groups comparisons were tested with Student *t* test (normally distributed data), Wilcoxon signed rank test, and Mann-Whitney *U* test (not normally distributed data). Differences between groups in baseline categorical data were analyzed by χ^2. To determine treatment effect, differences between groups with 95% CI and odds ratios (ORs) with 95% CI were calculated for categorical data, whereas effect sizes were calculated for continuous data using the formula: (mean of PFMT group – mean of control group)/SD. The 1 variable that significantly differed between groups at baseline (prolapse symptoms) was additionally analyzed with ordinal logistic regression analyses, using the final values as the dependent and baseline as the independent variable, together with the group as the exposure variable. The relationship between increase in PFM strength and changes in position of bladder and rectum, improvement in POP-Q, and subjective improvements were analyzed with Pearson product-moment correlation (*r*) for normally distributed data and Spearman rho (rho) for not normally distributed data. Interim analyses were not performed, and because of the low dropout, we did not perform per protocol analyses. Intention-to-treat analyses were used and baseline values were carried forward for the 1 woman who dropped out in each group. *P* values $< .05$ were considered statistically significant.

RESULTS

One hundred forty-five women with POP were recruited to the trial from November 2005–April 2008. The flowchart (Figure) presents the numbers and reasons for exclusion. Of the 109 participants, 59 were randomly allocated to intensive PFMT and 50 to the control group. One woman in each group dropped out because of motivation problems (PFMT group) and urinary incontinence surgery offered at another hospital (control group).

Baseline

The mean age of the 109 participants was 48.9 years (SD ± 11.8) and 19 were classified as POP stage I, 65 as stage II, and 24 as stage III. One was not classified, as she was not able to perform a Valsalva maneuver during POP-Q. However, her POP-Q values at rest and the ultrasound imaging confirmed that she had POP stage I or greater. Table 1 presents background variables. There were no statistical differences between groups regarding age, parity, stage of POP, proportion of women with positive values for any POP-Q measure, or outcome measures at baseline, except that 43 of 59 women in the PFMT group compared with 26 of 50 women in the control group had prolapse symptoms ($P = .024$). Twelve of the 44 postmenopausal women received hormone/estrogen replacement therapy.

Adherence, adverse effects

Women in the PFMT group adhered with 89% (161.2 ± 26.8) of the prescribed home exercises and 86% (15.5 ± 3.2) of the PT training sessions. Five (10%) of the women in the control group reported that they had performed more PFMT than they did before baseline. No adverse effects were reported.

POP stage

Table 2 shows the change in POP stages between groups and within each stage of POP. Significantly more women in the PFMT compared with control group improved 1 POP-Q stage (11 [19%] vs 4 [8%]; $P = .035$). Within the PFMT group, the number of women improving 1 stage on POP-Q increased with increasing degree of POP (0% for stage I POP, 16.7% for stage II POP, 35.7% for stage III POP) ($P = .034$). Subgroup analyses of the 40 women with prolapse below the hymen (positive values for 1 or more POP-Q measures) demonstrated no statistically significant differences between groups in changing stage of POP ($P = .406$). Five of the 25 women in the PFMT group with prolapse below the hymen vs 3 of the 15 controls improved 1 stage of POP, and 0% vs 20% worsened 1 stage of POP. The same subgroup analyses showed that 7 of the 25 women in the PFMT group elevated the most depending organ to or above the hymen.

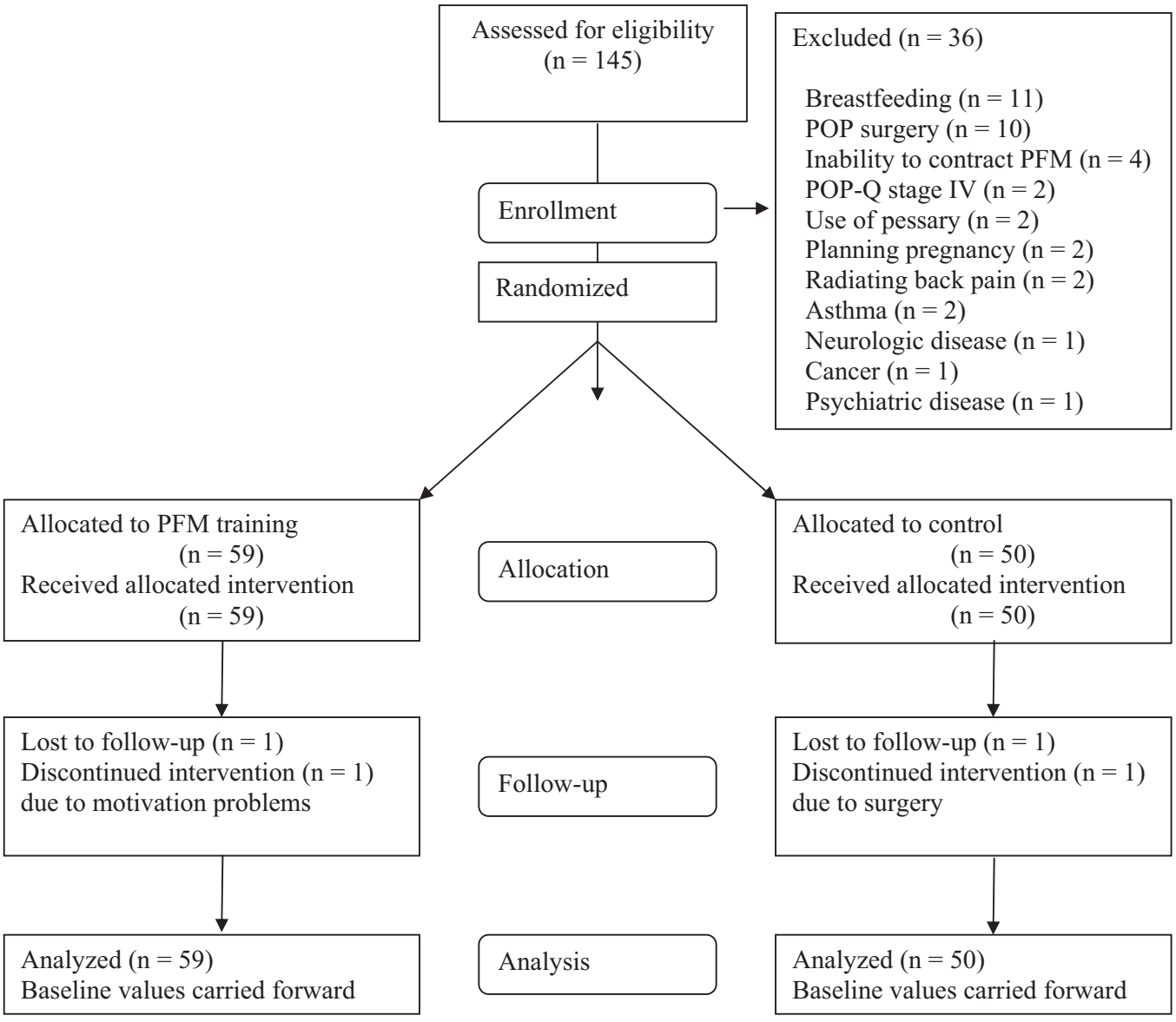
Position of bladder and rectum

The number of paired ultrasound volumes (pre- and posttest) was 94 (47 PFMT, 47 controls) for position of the bladder (bladder neck) and 74 (36 PFMT, 38 controls) for position of the rectum (rectal ampulla). The main reason for exclusion of ultrasound images was poor image quality. At 6 months, women in the PFMT group had a significantly greater cranial elevation of the bladder (2.3 mm vs −0.6 mm; difference: 3.0 mm; 95% CI, 1.5–4.4; $P < .001$) and rectum (4.4 mm vs −1.1 mm; difference: 5.5 mm; 95% CI, 1.4–7.3; $P = .022$) compared with women in the control group. The calculated effect size was 0.79 for elevation of the bladder and 0.63 for the rectum.

Symptoms

Table 3 shows improvement in prolapse, bladder, and bowel symptoms and bother for women who had this symptom at baseline. All women, except the 2 dropouts filled out the 6-month posttest questionnaires. Also, after adjusting for baseline values, women in the PFMT group had significantly reduced frequency ($P = .015$) and bother ($P = .04$) of prolapse symptoms compared with women in the control group. Urinary symptoms based on the ICIQ-UI-SF ($n = 102$) gave an effect size of 0.62 in favor of the PFMT group (difference: 2.40; 95% CI, 0.90–3.80; $P = .002$). Subgroup analyses of the 40 women with prolapse below the hymen demonstrated a reduction in frequency of prolapse

FIGURE
Flowchart of participants through each stage of the randomized controlled trial



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symptoms in 56% (14/25) of the PFMT group compared with 15% in the control group ($P = .008$; χ^2).

PFM function

The PFMT group had significantly greater improvement than the control group in PFM strength (13.1 cmH_2O; 95% CI, 10.6–15.5 vs 1.1 cmH_2O; 95% CI, 0.4–2.7; $P < .001$) and endurance (107 cmH_2O sec; 95% CI, 77.0–36.4 vs 8 cmH_2O sec; 95% CI, −7.4 to 24.1; $P < .001$). The effect size for muscle strength and endurance was 1.21 and 0.96, respectively. There were no differences in change of vaginal resting pressure between groups ($P = .122$). There were positive correlations between increased PFM strength and a cranial elevation of the bladder ($r = 0.23$; $n = 94$; $P = .024$) and rectum ($r = 0.27$; $n = 74$; $P = .019$). No significant correlations between increase in PFM strength and change in POP-Q values or prolapse symptoms were found.

Comment

This is a full-scale RCT using validated outcome measures to demonstrate that PFMT can improve severity of prolapse and reduce prolapse (vaginal bulging and/or heaviness), bladder (SUI, urge urinary incontinence), and bowel symptoms (flatus, loose fecal incontinence). No significant changes between groups were demonstrated for problems with emptying bowel and solid fecal incontinence.

A major strength of the current study is that all the primary outcomes are consistent in favor of PFMT. Other strengths are inclusion of women with all types of POP; stages I, II, and III prolapse;

randomization; blinding of primary outcome assessors; use of POP-Q; ultrasound imaging and validated questionnaires; standardized training protocol; low dropout rate; and high adherence to the training protocol. Possible limitations are differences between groups in prolapse symptoms at baseline, different amount of time spent by the PT between groups, and a relatively small sample size.

The differences in prolapse symptoms at baseline between groups may overestimate the subjectively improvement rate because of the "regression to the mean."[33] However, improvement in POP symptoms has been adjusted for baseline values. The difference between groups in time spent with the PT is unlikely to affect objective anatomic measures. In addition, in another RCT controlling for a possible attention effect in physical therapy, there was no effect on measured urinary leakage in the control group that received back massage.[34] Only 22% of the participants had POP stage III. Hence, the results may therefore not be generalizable to women with more severe POP. Research in the area of POP has suffered from the lack of a standardized definition of POP, and POP can be defined as stage ≥I or stage ≥II. In addition, some research groups suggest including both physical findings and bothersome symptoms in the definition of POP. The reasons for including POP stage I and asymptomatic women were that they, per definition, had POP,[20,35] and the wish to assess the effect of PFMT as a secondary prevention strategy (treat asymptomatic women with POP).[36] The study was not powered to do subgroup analyses and caution must be taken about the results of such analyses. The 109 participants in an RCT may, by some, be considered as a small sample size. However, the current trial was based on an a priori power calculation.

To our knowledge, only 1 previous study evaluated the effect of PFMT using the POP-Q grading system, but this was a pilot study and complete POP-Q data were missing from 27 of the 47 participants.[18] Our data support a study that found greater improvement in prolapse after PFMT in elderly Thai women with severe vaginal wall prolapse compared

TABLE 1
Background and outcome variables in the PFMT and control group before treatment

Detail	PFMT, n = 59	Control, n = 50
Background variables		
Age, y	49.4 (12.2)	48.3 (11.4)
Postmenopausal, n (%)	26 (44.1)	18 (36.0)
Body mass index, kg/m^2	25.8 (3.8)	26.18 (5.3)
Parity	2.4 (0.8)	2.4 (0.7)
With anterior wall POP, n (%)	54 (93.1)	49 (98.0)
With posterior wall POP, n (%)	46 (79.3)	42 (84.0)
With apical POP, n (%)	47 (81.0)	41 (82.0)
Stage of POP (POP-Q)		
With stage I, n (%)	8 (13.8)	11 (22.0)
With stage II, n (%)	36 (63.8)	29 (58.0)
With stage III, n (%)	14 (22.4)	10 (20.0)
With positive POP-Q value, n (%)	25 (41.3)	15 (30.0)
Ultrasound measurements, vertical resting position of		
Bladder neck, mm	16.7 (9.2)	19.3 (7.2)
Rectal ampulla, mm	10.2 (11.1)	10.9 (12.5)
Symptoms		
With prolapse symptoms, n (%)	43 (72.9)	26 (52.0)
With bladder symptoms, n (%)	51 (86.4)	36 (72.0)
ICIQ-UI-SF	7.4 (5.9)	5.4 (4.7)
With bowel symptoms, n (%)	38 (64.4)	27 (54.0)
PFM function		
PFM strength, cmH_2O	29.8 (18.6)	30.8 (20.2)
PFM endurance, cmH_2O sec	212 (151)	209 (152)
Vaginal resting pressure, cmH_2O	27.0 (7.5)	30.3 (12.1)

Means with standard deviation (SD) are given unless stated otherwise.
ICIQ-UI-SF, International Consultation on Incontinence Urinary Incontinence Short Form questionnaire; *PFM*, plevic floor muscles; *PFMT*, pelvic floor muscle training; *POP*, pelvic organ prolapse; *POP-Q*, Pelvic Organ Prolapse Quantification.
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TABLE 2
Change in stage of pelvic organ prolapse measured with POP-Q

Variable	PFMT	Control
Overall improvement	11/58 (19.0%)	4/50 (8.0%)
Stage I	0/8 (0%)	0/11 (0%)
Stage II	6/36 (16.7%)	1/29 (3.4%)
Stage III	5/14 (35.7%)	3/10 (30.0%)

Numbers with percentages are presented.
PFMT, pelvic floor muscle training; *POP-Q*, Pelvic Organ Prolapse Quantification.
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TABLE 3
Improvement of prolapse, bladder, and bowel symptoms

Variable	PFMT	Control	Difference (%) with 95% CI	P[a]	OR (95% CI)
Improvement in prolapse symptoms; vaginal bulging and/or heaviness					
Reduced frequency	32 (74%)	8 (31%)	43.6 (21.6–65.7)	.000[b]	6.55 (2.23–19.24)
Reduced bother	29 (67%)	11 (42%)	25.1 (1.5–48.7)	.000[b]	2.82 (1.03–7.73)
Improvement in bladder symptoms					
SUI: reduced frequency	29 (74%)	8 (30%)	44.7 (22.7–66.7)	< .001	6.89 (2.30–20.59)
SUI: reduced bother	27 (69%)	8 (30%)	39.6 (17.1–62.1)	.003	5.34 (1.83–15.58)
UUI: reduced frequency	16 (59%)	4 (33%)	25.9 (−6.6 to 58.4)	.042	2.91 (0.70–12.09)
UUI: reduced bother	15 (56%)	3 (25%)	30.6 (−0.3 to 61.4)	.075	3.75 (0.83–16.99)
Improvement in bowel symptoms					
Empty: reduced frequency	15 (60%)	6 (40%)	20.0 (−11.4 to 51.4)	.083	2.25 (0.61–8.31)
Empty: reduced bother	14 (56%)	8 (53%)	2.7 (−29.2 to 34.5)	.700	1.11 (0.31–4.03)
Flatus: reduced frequency	18 (53%)	5 (22%)	31.2 (0.7–55.0)	.002	4.05 (1.22–13.42)
Flatus: reduced bother	16 (47%)	5 (22%)	25.3 (1.5–49.1)	.002	3.20 (0.97–10.60)
LFI: reduced frequency	11 (79%)	1 (10%)	68.6 (40.2–97.0)	.006	[c]
LFI: reduced bother	9 (64%)	0	64.3 (39.2–89.4)	.007	[c]
SFI: reduced frequency	2 (68%)	2 (100%)	−33.3 (−86.7 to 20.0)	> .99	[c]
SFI: reduced bother	2 (68%)	1 (50%)	16.7 (−70.8 to 104.1)	.800	[c]

Improvement in frequency and bother of prolapse, bladder, and bowel symptoms for women who had the actual problem, based on the questionnaire.[29]
CI, confidence interval; *Empty*, difficult emptying bowel; *Flatus*, flatus leakage; *LFI*, loose fecal incontinence; *OR*, odds ratio; *SFI*, solid fecal incontinence; *SUI*, stress urinary incontinence; *UUI*, urge urinary incontinence.

[a] Analyzed with Mann-Whitney *U* test (4 category scales) unless otherwise specified; [b] Analyzed with ordinal logistic regression analyses; [c] Odds ratios are not performed because of low number having actual problem.

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with milder anterior vaginal wall prolapse.[16] However, this larger trial had major methodologic limitations,[17] and POP-Q was not used.

In addition to improving pelvic support, we found that PFMT reduced the frequency and bother of vaginal bulging and heaviness. A previous pilot study[18] and an RCT of anterior wall prolapse only[19] also demonstrated improvement in prolapse symptoms after PFMT. Although women in our study also showed improvement in all of the bladder symptoms and some of the bowel symptoms, it should be noted that bladder and bowel symptoms can exist without POP[5] and are considered by most research groups as coexisting symptoms, rather than symptoms of POP.

In addition to POP-Q, ultrasound was used to assess severity of prolapse. The bladder neck and rectal ampulla are markers of the position of the bladder and rectum and thus indicate the severity of anterior and posterior compartment prolapse. POP-Q is the recommended gold standard for assessing severity of POP.[20,35] However, POP-Q involves a strenuous Valsalva maneuver not being a normal part of activity of daily living. On the contrary, increased intraabdominal pressure is considered a risk factor for developing prolapse, and women are generally recommended to avoid straining.[37] Hence, ultrasound measurement of the resting position of the bladder and rectum in standing position may be a better way of assessing the effect of PFMT on POP. In the current study, 19% of the PFMT and 8% of the control group improved 1 POP stage. However, only women in the PFMT group significantly elevated the bladder and rectum; the controls did not.

POP seems to progress with increasing age,[2] but it is not known how many millimeters per year the pelvic organs normally descend, and we do not know the long-term effect of this program. The current study demonstrated elevation of the pelvic organs after PFMT, and it is likely to assume that PFMT can be used in prevention of POP. One research group[12] has estimated that 90,000 of American women could be saved from experiencing pelvic floor dysfunction with a 25% prevention rate. Vaginal bulging and heaviness have been shown to be the most discriminatory symptoms in women with POP.[5] Of the symptomatic women in the PFMT group, 74% reported reduced frequency of vaginal bulging and/or heaviness at the 6-month posttest. Hence, the reduction in prolapse symptoms may be considered the most important treatment effect, because these subjective symptoms are the main indication for surgery.[6]

We chose to conduct an explanatory study with an individually supervised training program following evidence-based strength training prescriptions and former PFMT protocols showing positive effect on SUI. Future pragmatic trials are warranted based on the same protocol, and longer follow-up studies are needed to determine if the improvement of prolapse severity and reduced symptoms are sustainable. ■

ACKNOWLEDGMENTS

We thank the physical therapists Vigdis Skøld and Guðrún Ágústa Brandsdóttir, Akershus University Hospital, for excellent help in training some of the participants; Ingar Morten Holme, professor and biostatistician, Norwegian School of Sport Sciences, Department of Sports Medicine, Oslo, Norway, for statistical assistance; Roar Robinson, manual therapist, Msci, Oslo, Norway, for providing an office for the exercise sessions and clinical examinations; and Dr Ingrid Nygaard, professor, Department of Obstetrics and Gynecology, University of Utah School of Medicine, Salt Lake City, UT, for important English revision of the manuscript.

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