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ORIGINAL ARTICLE

# Lifestyle advice with or without pelvic floor muscle training for pelvic organ prolapse: a randomized controlled trial

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**Abstract**
*Introduction and hypothesis* We evaluated the effect of adding pelvic floor muscle training (PFMT) to a structured lifestyle advice program.
*Methods* This was a single-blinded randomized trial of women with symptomatic pelvic organ prolapse (POP) stage≥II. Participants were randomized to a structured lifestyle advice program with or without PFMT. Both groups received similar lifestyle advice in six separate group sessions. The combined group performed group PFMT after an individual assessment. Primary outcome was a global improvement scale at six-month follow-up. Secondary outcomes were the global scale and objective POP at three-month follow-up, symptoms and quality of life including sexuality, at three and six-month follow-up. A clinically relevant change of symptoms was defined as ≥15 %.
*Results* We included 109 women. Eighty-nine women (82 %) completed three months follow-up; 85 (78 %) completed six-month follow-up. At both follow-ups, significantly more women in the combined group reported improvement in the global scale. At the three-month follow-up, the combined group only had significant improvement of POP symptoms while only the lifestyle advice group had significant improvement of quality of life. Change in objective POP and sexuality was nonsignificant. The symptom score improved 17 % in the combined group and 14 % in the lifestyle advice group ($P$= 0.57). Significantly more women in the lifestyle advice group had sought further treatment at the six-month follow-up.
*Conclusion* Adding PFMT to a structured lifestyle advice program gave superior results in a global scale and for POP symptoms. Overall effect of either intervention barely reached clinical relevance.

**Keywords** Conservative treatment · Lifestyle advice · Pelvic floor muscle training · Pelvic organ prolapse

**Abbreviations**

| | |
|---|---|
| POP | Pelvic organ prolapse |
| HRQoL | Health-related quality of life |
| POP-Q | Pelvic Organ Prolapse Quantification system |
| PFDI-20 | Pelvic Floor Distress Inventory Short Form 20 |
| POPDI-6 | Pelvic Organ Prolapse Distress Inventory-6 |
| CRADI-8 | Colorectal–Anal Distress Inventory-8 |
| UDI-6 | Urinary Distress Inventory-6 |
| PFIQ-7 | Pelvic Floor Impact Questionnaire Short Form-7 |
| UIQ-7 | Urinary Impact Questionnaire-7 |
| CRAIQ-7 | Colorectal–Anal Impact Questionnaire-7 |
| POPIQ-7 | Pelvic Organ Prolapse Impact Questionnaire-7 |
| PISQ-12 | Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 |
| PGI-I | Patient Global Index of Improvement Scale |
| NRS | Numeric Rating Scale |
| PFMT | Pelvic floor muscle training |
| LG | Lifestyle advice group |

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|---|---|
| TLG | Combined pelvic floor muscle training and lifestyle advice group |
| ITT | Intention-to-treat analysis |
| RR | Relative risk |

## Introduction

Symptomatic pelvic organ prolapse (POP) is prevalent and has been found in 2.9–11.4 % of adult women [1, 2]. POP commonly becomes symptomatic when the prolapse reaches to or beyond the hymen (hymenal remnant) in the vaginal opening [3, 4], which corresponds to a POP stage ≥II according to the Pelvic Organ Prolapse Quantification system (POP-Q) [5, 6]. Women with POP stage ≥II often feel or see a bulge in the vaginal opening, and they typically have concurrent bladder, bowel, and/or sexual symptoms [7, 8]. Although lifetime risk of surgical intervention for POP is 12.6 % [9], spontaneous regression is possible [10], and elderly women in particular will prefer conservative treatment [11, 12]. Studies show that individual pelvic floor muscle training (PFMT) can reduce POP symptoms compared with offering lifestyle advice in leaflet form with or without a single instruction [13–17]. A recent well-powered study [13] found a significant improvement in POP symptoms but could not confirm previous findings demonstrating significant improvement in objective POP after PFMT [14–17]. The study offering the most intensive individual PFMT program found increased pelvic floor muscle strength and a higher cranial position of pelvic organs after PFMT but could find no significant correlations between these findings and improved symptoms nor objective POP [16]. Based on existing evidence, PFMT seems to have a positive effect on POP symptoms, while the effect on objective POP seems limited. Thus, subjective improvement could hypothetically be caused by attention from health-care professionals and the lifestyle advice offered with PFMT, and the true impact of PFMT might be questionable.

The primary objective of this study was to examine whether PFMT in combination with a structured lifestyle advice program would have better effect on a global improvement scale than a structured lifestyle advice program alone in women with symptomatic POP stage≥II.

## Materials and methods

This study was a single-blinded randomized controlled trial that included women aged ≥18 years with a Pelvic Organ Prolapse Quantification system (POP-Q) of stage≥II and at least one of three symptoms: seeing or feeling a bulge in the vaginal opening, voiding dysfunctions or defecation problems, or feeling vaginal heaviness. Fluency of Danish language was required. Exclusion criteria were dementia; symptomatic neurological disease, including serious back problems; PFMT within the last 2 years; childbirth within the last year; more than one surgical treatment for POP or urinary incontinence. Women with POP stage I were excluded, since they are less likely to have symptoms correlated with POP [3] and are less likely to be offered pessary or surgical treatment.

Women recruited were examined and scored with the POP-Q by the primary investigator. Women who fulfilled inclusion criteria had a standard gynecological examination performed by a gynecologist to exclude differential diagnoses. Postmenopausal women with signs of vaginal atrophy were routinely offered vaginal estrogen.

After inclusion, baseline questionnaires were administered. The women completed questionnaires without help but were offered assistance from the research nurse if they needed it. A research nurse administered randomization envelopes. A statistician not involved in the study provided computer-generated random numbers with stratification for age groups≥60 years. Participants drew one closed envelope each. The primary investigator remained blinded throughout the study.

All participants received six group sessions within 12 weeks. Only participants from the combined PFMT and lifestyle advice group (TLG) received an appointment with a specialized pelvic floor physical therapist for visual and digital assessment of their pelvic floor muscle function and an individual instruction in PFMT before starting group sessions in order to assure that they could perform the PFMT program correctly. Women unable to contract their pelvic floor muscles correctly were offered more individual sessions before starting group training. The lifestyle advice group (LG) was given no information about PFMT during their sessions. TLG and LG group sessions were held on separate days, and the two groups never met.

At the three-month follow-up, the primary investigator repeated the POP-Q examination, remaining blinded to all data. All women completed questionnaires again, including the Patient Global Index of Improvement Scale (PGI-I). At the six-month follow-up, three months after the last group session, questionnaires including the PGI-I were sent to study participants and they were asked whether they sought further treatment.

The study took place at Herlev University Hospital, Copenhagen, Denmark. Participants were recruited by the primary investigator from the hospital waiting list and outpatient clinic, websites, local newspapers, and posters in public places (Fig. 1).

Comprehensive written study information was provided, and all women signed an informed consent before entering the study, which was approved by the Danish Scientific Ethical Committee (H-4-2011-072) and the Danish Data Protection Agency and reported to clinicaltrials.gov (NCT01612637). Data are reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement.

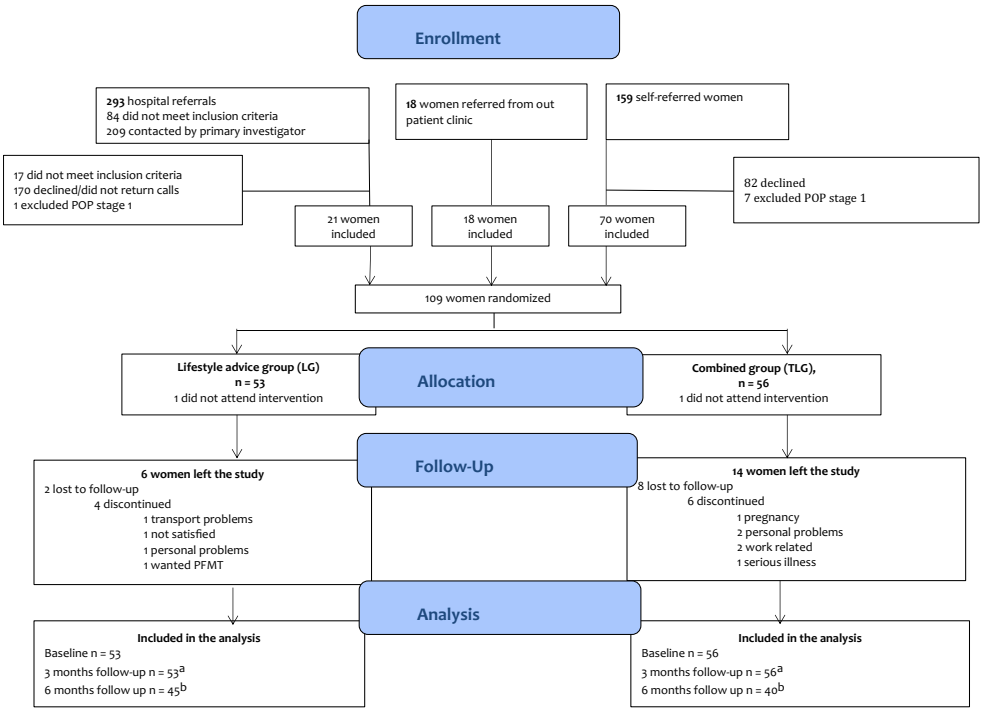


**Fig. 1** Consolidated Standards of Reporting Trials (CONSORT) flow diagram describing the trial process. *GP* general practitioner, *POP* pelvic organ prolapse. **a** Analysis was performed as intention to treat, with baseline scores carried forward; **b** three-month follow-up scores were carried forward in women who had sought further treatment

## Outcome measures

Primary outcome was the Patient Global Index of Improvement Scale (PGI-I) [18, 19] at six-month follow-up, three months after the final group session. Secondary outcomes were POP-Q [6] performed at baseline and at three-month follow-up, the PGI-I at three-month follow-up, the Pelvic Floor Distress Inventory Short Form-20 (PFDI-20), the Pelvic Floor Impact Questionnaire Short Form-7 (PFIQ-7) [20], and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) completed at baseline and at three- and six-month follow-up [21]. Women receiving PFMT reported bother from PFMT in their training diaries using the Numeric Rating Scale (NRS) ranging from 0 to 10. A higher number indicated more bother.

The PFDI-20 contains 20 items divided into three subscales revealing bladder [Urinary Distress Inventory-6 (UDI-6)], bowel [Colorectal–Anal Distress Inventory-8 (CRADI-8)], and prolapse [Pelvic Organ Prolapse Distress Inventory-6 (POPDI-6)] symptoms, as well as bother. Each item can be scored on a scale from 0 to 4; a higher score indicates greater bother. The PFIQ-7 reveals health-related quality of life (HRQoL) regarding pelvic floor disorders, with items divided into three subscales revealing effect of HRQoL related to bladder [Urinary Impact Questionnaire-7 (UIQ-7)], bowel [Colorectal–Anal Impact Questionnaire-7 (CRAIQ-7)] and POP [Pelvic Organ Prolapse Impact Questionnaire-7 (POPIQ-7)] symptoms. Each item is scored from 0 to 3, with a higher score indicating a greater impact on HRQoL. Total and subscale scores can be calculated from PFDI-20 and PFIQ-7. Subscale scores range from 0 to 100 and total scores from 0 to 300, where higher scores indicate increased symptoms, bother, and negative impact on HRQoL. The PISQ-12 has 12 items on sexual problems in relation to pelvic floor disorders. Each item is scored from 0 to 4, with a lower score indicating a greater impact. Only single-item scores were analyzed in this study.

## Interventions

### *Lifestyle advice sessions*

Both groups received an identical lifestyle advice program. The primary investigator developed six PowerPoint teaching modules lasting 45–60 min each. Specialized pelvic floor physical therapists were instructed in teaching the group sessions and carried out those sessions independent of the primary investigator. Subjects for the six group sessions were based on known POP-promoting factors, such as straining, constipation, being overweight, and heavy lifting [22]. The following subjects were presented: introduction to POP and how to reduce pressure on the pelvic floor; bladder function and POP; bowel function and POP and how to improve micturition and defecation technique; diet, weight loss, and POP; QoL and POP and impact of POP on body image and sexuality; sports and POP and

how to increase level of activity without increasing pressure on the pelvic floor. The women were offered handouts during the sessions, bladder and bowel dairies, and encouraged to try out any lifestyle advice that they found relevant for their specific POP-related symptoms.

*Combined therapy and lifestyle advice sessions*

Along with the lifestyle advice sessions, the TLG performed group PFMT with focus on conscious precontractions before an increased intra-abdominal pressure (Knack training) [23, 24]. Home training was based on generally accepted training principles and was to be performed 5 days a week [25]. Each participant had an individually adjusted home training program comprising of three sets of up to ten sustained (10-s) pelvic floor muscle contractions. They were instructed on contracting with as much effort as possible while maintaining normal respiration. The physical therapists teaching the TLG had access to results of the initial pelvic floor muscle function assessment of women in the TLG. The home training program was verbally adjusted during group PFMT when a woman expressed ease with her program. Progression of the home training program included increasing effort, number of contractions, length of each contraction, and load on the pelvic floor in varying body positions. They were additionally taught to do Knack training during their everyday activities. Participants in the TLG filled in a training dairy, and they reported bother related to the home training in the NRS.

### Statistics

Descriptive statistics were used to describe baseline data. Both parametric and nonparametric statistics were used to analyze questionnaire scores. Since analyses showed similar results, we only reported results from parametric analyses in order to be comparable with other studies. Nonparametric statistics were used for single-item analyses. Categorical data were analyzed with chi-square test, and relative risk (RR) was calculated for improvement on the PGI-I. Three- and six-month follow-up analyses were done using intention to treat (ITT) with last observation carried forward (LOCF). Univariate and multivariate forward logistic regression analyses ($P$ value $\leq 0.20$, $\geq 80$ % data completeness) were performed to find possible baseline predictors of improvement (dichotomized) at three-month follow-up. Level of significance was set at $P$ 0.05 for all statistical tests and results are reported as two-sided. All analyses were performed with SPSS version 22.0 (SPSS Inc., Chicago, IL. USA).

### Sample size

Sample size was based on the PGI-I and the PFDI-20 to determine the minimal clinically relevant difference, defined as a change ≥15 % [20]. With a power of 80 % at a 5 % significance level, we needed to enroll 45 women in each arm. To compensate for possible dropouts, we recruited 54 women in each arm.

## Results

### Baseline

Between October 2012 and December 2013, 109 women with POP were enrolled and randomized: 62 (57 %) had stage II and 47 (43 %) had stage III. Of the 109 women, 96 (88 %) had prolapse of the anterior compartment, 70 (64 %) had prolapse of the posterior compartment, and 64 (59 %) had prolapse of more than one compartment. None had isolated prolapse of the middle compartment. Anterior and posterior POP at or beyond the hymen was found in 78 (72 %) and 58 (53 %) women, respectively (Table 1).

Thirty-nine women (36 %) were recruited from hospital referral lists or the outpatient clinic. Seventy women (64 %) were self-referred (Fig. 1). Women recruited from referral lists or the outpatient clinic had a higher POP-Q score ($P$=0.037) but were otherwise comparable with self-referred women. Fifty-three women (49 %) were randomized to the LG and 56 to the TLG (51 %). At baseline, the two groups were comparable in all scores and reported moderate symptoms and bother on the PFDI-20, with no significant differences between groups (Table 2).

In the TLG, two women required three individual sessions to learn to perform PFMT correctly. Single-item analysis of the baseline questionnaire revealed that 87 (80 %) women reported seeing or feeling a bulge, 77 (71 %) had pelvic heaviness, 66 (61 %) experienced urinary frequency, and 63 (58 %) had fecal urgency. Fifty-eight women (53 %) reported incomplete bladder emptying and/or bowel movement, 57 (53 %) reported urinary urgency, while 54 (51 %) had flatus incontinence. PFIQ-7 scores indicated a low impact on HRQoL (Table 2), and 33 %, 57 %, and 44 % scored no impact on the UIQ-7, CRAIQ-7, and POPIQ-7 at baseline, respectively. According to total baseline PFIQ-7 scores, 18 % indicated no impact on HRQoL. PISQ-12 item response rate ranged from 92 (84 %) to 72 (66 %). Nonresponders indicated lack of partner or no active sex life. Responders reported moderate to low impact on sexual function (data not shown).

### Three-month follow-up

Eighty-nine women completed the follow-up (82 %) (Fig. 1); 14 (25 %) in the TLG and six (11 %) in the LG left the study before the three-month follow-up. These women were younger ($P$=0.004), reported more effect on bowel HRQoL ($P$= 0.053) and more bother related to urinary incontinence during

**Table 1** Baseline characteristics

| Variable | Lifestyle advice | Lifestyle advice+PFMT | Total | *P* value |
|---|---|---|---|---|
| Baseline characteristics | | | | |
| Number of women | 53 | 56 | 109 | |
| Age, years [mean (range)] | 58 (34–79) | 60 (33–79) | 60 (33–79) | 0.77 |
| BMI [mean (range)], kg/m$^2$ | 25 (20–36) | 24 (19–37) | 25 (19–37) | 0.46 |
| Surgery, [*n* (%)] | 7 (13) | 9 (16) | 16 (15) | 0.67 |
| Referred/self-referred, [*n* (%)] | 20/33 (38 / 62) | 19/37 (34 / 66) | 39/70 (36 /64) | 0.68 |
| Parity [mean (range)] | 2 (1–4) | 2 (1–9) | 2 (1–9) | 0.07 |
| Working [*n* (%)] | 33 (62) | 31 (55) | 64 (59) | 0.60 |
| Objective POP at baseline, [*n* (%)] | | | | |
| POP-Q stage II/III | 29/24 (55/45) | 33/23 (59 /41) | 62/47 (57 /43) | 0.66 |
| Anterior | 47 (89) | 49 (88) | 96 (88) | 0.40 |
| Posterior | 34 (64) | 36 (64) | 70 (64) | 0.10 |
| Combined | 32 (61) | 32 (57) | 64 (59) | 0.73 |
| Anterior ≥0 cm | 38 (71) | 40 (71) | 78 (72) | 0.80 |
| Posterior ≥0 cm | 28 (53) | 30 (54) | 58 (53) | 0.79 |

*BMI* body mass index, *POP* pelvic organ prolapse, *POP-Q* Pelvic Organ Prolapse Quantification system, *PFMT* pelvic floor muscle training

sexual intercourse (*P*=0.027). Women in both the LG and the TLG attended a median of five group sessions (0–6). Nine women (16 %) in the TLG compared with one (2 %) in the LG reported being much better or very much better on the PGI-I, resulting in an RR of 8.5 [95 % confidence interval (CI) 1.1–66.0, *P*=0.017] of improvement for those in the TLG. Overall, 29 women (51 %) in the TLG compared with 11 (21 %) in the LG reported improvement, giving a RR of 2.5 (95 % CI 1.4–4.5, *P*=0.001) (Table 3). Regression analyses showed no significant associations between self-reported improvement on the PGI-I and baseline data, including PFDI-20 and PFIQ-7 total and subscale scores or POP stage (data not shown).

No significant differences in PFDI-20 total or subscale scores were found between groups (Table 2). Both groups had significant improvement on bladder and bowel subscales,

**Table 2** Between-group differences in symptom and quality of life scores at baseline, three-month and six-month follow-up presented as mean (SD)

| Questionnairer | Baseline | | | Three-month follow-up[b] | | | Six-month follow-up[c] | | |
|---|---|---|---|---|---|---|---|---|---|
| | LG (*n* = 53)[a] | TLG (*n* = 56)[a] | *P* value | LG (*n* = 53)[a] | TLG (*n* = 56)[a] | *P* value | LG (*n* = 45)[a] | TLG (*n* = 40)[a] | *P* value |
| Symptom and bother | | | | | | | | | |
| POPDI-6[d] | 30.3 (19.6) | 37.2 (24.4) | 0.11 | 29.3 (17.0) | 30.6 (23.0) | 0.74 | 27.3 (15.4) | 27.5 (21.3) | 0.96 |
| CRADI-8[d] | 24.2 (18.5) | 24.6 (21.3) | 0.93 | 19.0 (16.7) | 20.5 (18.0) | 0.65 | 17.0 (13.6) | 21.7 (19.6) | 0.20 |
| UDI-6[d] | 32.3 (22.6) | 29.6 (23.2) | 0.53 | 26.4 (21.0) | 24.7 (22.0) | 0.68 | 20.4 (17.5) | 23.4 (20.9) | 0.47 |
| PFDI-20[d] | 87.0 (46.3) | 91.3 (59.7) | 0.67 | 74.6 (39.5) | 75.7 (55.2) | 0.90 | 64.7 (32.7) | 72.6 (51.8) | 0.40 |
| Quality of life | | | | | | | | | |
| UIQ-7[d] | 18.3 (20.6) | 12.7 (18.3) | 0.13 | 13.7 (18.0) | 11.5 (17.9) | 0.52 | 9.6 (15.5) | 11.1 (17.1) | 0.68 |
| CRAIQ-7[d] | 8.15 (16.0) | 10.0 (18.6) | 0.59 | 5.7 (14.8) | 10.2 (18.5) | 0.16 | 2.0 (4.8) | 7.3 (14.7) | 0.037 |
| POPIQ-7[d] | 12.2 (19.8) | 13.8 (18.8) | 0.67 | 9.3 (17.4) | 12.0 (18.9) | 0.45 | 9.0 (17.8) | 10.0 (17.6) | 0.79 |
| PFIQ-7[d] | 37.8 (45.1) | 36.4 (47.0) | 0.87 | 28.7 (38.3) | 33.8 (48.0) | 0.55 | 20.7 30.3) | 29.0 (43.2) | 0.31 |

*SD* standard deviation, *LG* lifestyle advice group, *TLG* combined pelvic floor muscle training and lifestyle advice group, *POPDI-6* Pelvic Organ Prolapse Distress Inventory–6, *CRADI-8* Colorectal-Anal Distress Inventory–8, *UDI-6* Urinary Distress Inventory–6, *PFDI-20* Pelvic Floor Distress Inventory Short Form 20, *UIQ-7* Urinary Impact Questionnaire-7, *CRAIQ-7* Colorectal-Anal Impact Questionnaire-7, *POPIQ-7* Pelvic Organ Prolapse Impact Questionnaire-7, *PFIQ-7* Pelvic Floor Impact Questionnaire Short Form-7

[a] Number in each group analyzed

[b] Baseline scores carried forward in women that left the study before three months follow-up

[c] Three-month scores carried forward in women who had sought other treatment

[d] Data analyzed with unpaired samples *t* test

**Table 3** Distribution and between-group differences in global scores (PGI-1) at the three- and six-month follow-up

| Questionnaire | Three-month follow-up[b] ($n$ = 109) | | | Six-month follow-up[c] ($n$ = 85) | | |
|---|---|---|---|---|---|---|
| | LG (53)[a] | TLG (56)[a] | $P$ value | LG (44)[a,d] | TLG (40)[a] | $P$ value |
| Very much better | 0 (0 %) | 3 (5 %) | 0.003 | 0 (0 %) | 1 (3 %) | 0.02 |
| Much better | 1 (2 %) | 6 (11 %) | | 3 (6 %) | 5 (13 %) | |
| Little better | 10 (19 %) | 20 (36 %) | | 6 (14 %) | 16 (40 %) | |
| No change | 36 (68 %) | 21 (37 %) | | 29 (66 %) | 12 (30 %) | |
| Little worse | 6 (11 %) | 6 (11 %) | | 6 (14 %) | 6 (15 %) | |
| Much worse | 0 (0 %) | 0 (0 %) | | 0 (0 %) | 0 (0 %) | |

*PGI-I* Patient Global Index of Improvement scale, *LG* lifestyle advice group, *TLG* combined pelvic floor muscle training and lifestyle advice group

[a] Mann–Whitney *U* test

[b] Dropouts before three months follow-up recorded as "no change"

[c] Three-month scores carried forward in women who had sought further treatment

[d] One woman did not answer these questions

but only the TLG had significant improvement on the POP subscale (POPDI-6, $P$=0.001) (Table 4). The TLG had a mean improvement on PFDI-20 total score of 15.6 (SD 29.5), corresponding to a 17 % improvement; the LG improved by a mean of 12.4 (SD 30.3), corresponding to a 14 % improvement. The between-group difference was 3.2 (95 % CI −7.9 to 14.3, $P$=0.57).

Single-item analyses of the PFDI-20 revealed that only the TLG had significant improvement in pelvic heaviness ($P$=0.032), feeling or seeing a bulge ($P$=0.009), urinary frequency ($P$=0.039), and small amount of leakage ($P$=0.027). Only the LG reported significant reduction in straining in relation to bowel movements ($P$=0.015). Both groups had significant improvement concerning flatus incontinence and voiding difficulties. No significant between-group differences were found in the PFIQ-7 total or subscales scores at three-month follow-up (Table 2). Only the LG had significant improvement in PFIQ-7 total score due to improvement in the bladder subscale (Table 4). None of the women obtained significant improvement in the PISQ-12 (data not shown). POP-Q stage did not improve significantly in either groups (Table 4), and there was no significant between-group differences in referred versus self-referred women in any three-month follow-up scores. Thirty-one of the 42 women completing the TLG handed in their training dairies (74 %); 11 women reported bother in relation to PFMT, which was low, with a median NRS of 2 (0–5) in 85 (11 %) of 805 times of reported training.

### Six-month follow-up

Eighty-five women (78 %) returned the questionnaires. Significantly more women in the TLG reported improvement in the PGI-I ($P$=0.003) (Table 3). Thirty women (68 %) in the LG compared with 11 (28 %) in the TLG had sought further treatment ($P$=<0.001). Twenty-four women in the LG compared with three in the TLG had sought PFMT ($P$<0.001). Two women in the LG and four in the TLG had received a pessary ($P$=0.30). Three women in the LG and two in the TLG had received surgery ($P$=0.79). Four women in the LG and two in the TLG had received a nonspecified conservative treatment ($P$=0.77): three in the LG together with a specified treatment. Between-group analyses showed no significant differences in PFDI-20 scores, while the LG had lower bother in the bowel subscale of the PFIQ-7 (CRAIQ-7, $P$=0.037) (Table 2). Women who had sought further treatment had significantly greater POP stage in the anterior compartment ($P$=0.029), and greater impact on bladder-related HRQoL (UIQ-7, $P$=0.046) at baseline and at the three-month follow-up (UIQ-7, $P$=0.037). Five women had subsequent POP surgery; besides having more anterior POP ($P$=0.017), they reported more prolapse symptoms (POPDI-6, $P$=0.008) and greater effect of POP-related HRQoL (POPIQ-7, $P$=0.019) at the three-month follow-up. No significant difference in uptake of further treatment was found between referred and self-referred women or between women with or without previous POP surgery.

## Discussion

When offered a combined program of lifestyle advice and PFMT, significantly more women considered themselves improved on the global scale at both three- and six-month follow-up. They also showed significant improvement in POP symptoms on paired tests. However, this improvement was not reflected in additional reduction of symptoms, better HRQoL, reduction of sexual problems, or improvement in POP-Q scores. Compared with earlier studies on PFMT and lifestyle advice, our results do not convincingly favor PFMT. The major difference between these studies and our study was the design. We used an identical lifestyle advice program in both groups with the same number of sessions and the same

**Table 4** Paired test between baseline scores and the three-month follow-up

| Questionnaire | LG (53)[a] | | | TLG (56)[a] | | |
|---|---|---|---|---|---|---|
| | Baseline | Three-month follow-up | *P* value | Baseline | Three-month follow-up | *P* value |
| Symptoms and bother[b] | | | | | | |
| POPDI-6 | 30.3 (19.6) | 29.3 (17.0) | 0.56 | 37.2 (24.6) | 30.6 (23.0) | 0.001 |
| CRADI-8 | 24.2 (18.5) | 19.0 (16.7) | 0.011 | 24.6 (21.3) | 20.5 (18.0) | 0.009 |
| UDI-6 | 32.4 (22.6) | 26.4 (21.0) | 0.002 | 29.6 (23.2) | 24.6 (22.0) | 0.003 |
| PFDI-20 | 87.0 (46.3) | 74.6 (39.5) | 0.004 | 91.3 (59.7) | 75.7 (55.2) | <0.001 |
| Quality of life[b] | | | | | | |
| UIQ-7 | 18.3 (20.6) | 13.1 (17.1) | 0.014 | 12.9 (18.4) | 11.5 (17.9) | 0.24 |
| CRAIQ-7 | 8.15 (16.0) | 5.6 (14.8) | 0.073 | 10.1 (18.7) | 10.2 (18.5) | 0.95 |
| POPIQ-7 | 11.9 (19.8) | 9.5 (17.6) | 0.12 | 13.1 (18.2) | 12.0 (18.9) | 0.49 |
| PFIQ-7 | 37.9 (45.6) | 28.3 (38.5) | 0.011 | 36.1 (47.5) | 33.8 (48.0) | 0.42 |
| POP-Q [b] | | | | | | |
| POP-Q total score[c] | +2.5 (0.5) | +2.4 (0.5) | 0.21 | +2.4 (0.5) | +2.3 (0.5) | 0.10 |

*LG* lifestyle advice group, *TLG* combined pelvic floor muscle training and lifestyle advice group, *POP-Q,* Pelvic Organ Prolapse Quantification system, *POPDI-6* Pelvic Organ Prolapse Distress Inventory-6, *CRADI-8* Colorectal-Anal Distress Inventory–8, *UDI-6* Urinary Distress Inventory–6, *PFDI-20* Pelvic Floor Distress Inventory Short Form-20, *UIQ-7* Urinary Impact Questionnaire-7, *CRAIQ-7* Colorectal-Anal Impact Questionnaire-7, *POPIQ-7* Pelvic Organ Prolapse Impact Questionnaire-7, *PFIQ-7* Pelvic Floor Impact Questionnaire Short Form-7

[a] Baseline scores carried forward in women who left the study before the three-month follow-up

[b] Paired-samples *t* test

[c] Based on the POP-Q system, where POP is described in millimeters, with positive numbers indicating POP beyond the hymen and negative numbers indicating POP above the hymen

amount of attention, except for PFMT, as opposed to comparing a PFMT program with a lifestyle advice leaflet or a single instruction [13–17]. A second important difference was that our proportion of patients with stage III was twice as big as in other studies and that we excluded women with stage I POP [13–17]. Physiologically, there is a large difference between stage I and stage III POP, and this might have influenced the overall effect found in our study.

To ensure that all women received an identical lifestyle advice program, we chose to offer our intervention as group sessions, and participants in the TLG were only offered one individual assessment of their pelvic floor muscle function followed by six group-training sessions. The number of sessions and the home training program was comparable with most other studies [14, 15, 17]; however, adjustments to home training programs could only be via verbal instructions, so it is posible that the PFMT program was not individualized enough to produce a pronounced effect. Furthermore, the large dropout rate in the TLG, particularly among younger women, might have negatively influenced our results.

Only 11 % of women contacted from hospital referral lists accepted recruitment to our study, which may represent a selection bias; women referred by a clinician had more advanced POP but the same moderate level of POP symptoms as the self-referred women. Furthermore, participants were comparable with women with pelvic floor disorders referred to a tertiary center [26], and they had higher PFDI-20 scores than women with stage I-II POP recruited from general practice [27]. We did, however, find low baseline PFIQ-7 scores, implying low impact on HRQoL. This could be a sign of a ceiling effect of PFIQ-7, defined as >15 % scoring no impact on their HRQoL [28]. The PFIQ-7 might overlook important aspects of POP-related HRQoL [26, 29], but perhaps women accepting participation in our study had a lower impact on HRQoL than women declining.

The indications for POP surgery are relative, and many women prefer conservative treatment [11, 12]. When PFMT was compared with watchful waiting, 57 % receiving PFMT considered themselves improved compared with 13 % in the watchful waiting group despite questionable symptom improvement [27]. We found that women receiving the combined treatment were 2.5–8.5 times more likely to consider themselves improved despite not presenting with significantly less symptoms or better HRQoL scores than the LG—except for a significant improvement on POP symptoms in the paired test. This makes us suspect that the positive effect found in the global scale might partly be explained by placebo, and since the majority of the LG sought PFMT after completing the intervention, it is likely that women with POP expect to receive PFMT in a conservative treatment program [13].

A recent Dutch validation of the PFDI-20 and the PFIQ-7 found that a clinically relevant improvement on the PFDI-20 should exceed 22.9 points to account for possible measurement errors and that only a change of 16.3 points could be trusted as a true improvement [26]. We found a reduction in

the PFDI-20 of 15.6 points (17 %) in the TLG and of 12.4 points (14 %) in the LG at the three-month follow-up. The difference between groups was only 3.1 points (95 % CI −8.22 to 14.43). A limitation of our study was that our sample size calculation might have been too optimistic, since both groups reached our predefined smallest relevant change of 15 %. Furthermore, we barely achieved the required number of women at three-month follow-up, and we cannot exclude the possibility that a larger sample would have given a different result [20, 29].

Based on our findings, we cannot make strong recommendations about the use of PFMT in women with POP stage II-III. However, if a woman prefers a conservative approach or if surgery is not an option, our study supports a small positive effect on symptoms related to POP from lifestyle advice alone or in combination with PFMT. Women with advanced POP should be informed that the chance of conservative treatment improving their objective POP is minimal and that relief of objective POP most likely requires pessary or surgical treatment.

In conclusion, adding PFMT to a structured lifestyle advice program gave more perceived improvement on a global scale and of POP symptoms but did not reduce symptoms or improve HRQoL more than lifestyle advice alone. Thus, the treatment effect of either intervention was low and of questionable clinical relevance.

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