

LIFESTYLE ADVICES WITH OR WITHOUT PELVIC FLOOR MUSCLE TRAINING FOR WOMEN WITH SYMPTOMATIC STAGE II-III PELVIC ORGAN PROLAPSE, A SINGLE-BLINDED RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

Studies have shown that individual pelvic floor muscle training (PFMT) can reduce symptoms of pelvic organ prolapse (POP) when compared to lifestyle advice given as a single instruction or as an information leaflet (1). While it seems that PFMT has a positive effect on POP symptoms the effect on objective POP is limited. The subjective improvement could hypothetically be caused by the attention from health care professionals and from the lifestyle advice offered in relation to a PFMT program and not from the PFMT itself. The aim of this study was to examine the effect of a structured lifestyle advice program with or without PFMT in women with symptomatic POP stage \geq II.

Study design, materials and methods

This was a single-blinded randomized controlled trial. Women \geq 18 years with POP symptoms and a POP-Q of \geq II were randomized to structured lifestyle advice program with (combined group) or without PFMT (lifestyle advice group). A statistician provided computer generated random numbers with stratification for age groups \geq 60 years and a research nurse performed the randomization. The primary investigator remained blinded to all data throughout the study. Participants received six group sessions within twelve weeks comprising an identical lifestyle advice program. The lifestyle advice group was held naïve of PFMT while the combined group did group PFMT and home training after an assessment and an individual instruction. Externally hired specialized pelvic floor physiotherapists led the group sessions and performed the PFMT instructions.

Primary outcome was the Patient Global Index of Improvement scale (PGI-I) at six months follow-up, three months after the last session. Secondary outcomes were the Pelvic Organ Prolapse Quantification system (POP-Q) performed at baseline and at three-months follow up; The PGI-I at three months follow up; the Pelvic Floor Distress Inventory-short form 20 (PFDI-20); the Pelvic Floor Impact Questionnaire-short form 7 (PFIQ-7) and the Pelvic organ prolapse/urinary incontinence sexual questionnaire (PISQ-12) completed at baseline and at three and six months follow-up. Analyses were performed by intention-to-treat. Sample size calculation was based on the PGI-I and the PFDI-20 and a clinically relevant change was defined as a change greater than or equal to 15% of the PFDI-20 (2). With a power of 80% at a 5% significance level we needed 45 women and we included 54 women in each arm to compensate for possible dropouts.

Table 1: PGI-I scores at three and six months follow-up

	Three months Follow-up*		p value 0.003	Six months Follow-up**		p value 0.02
PGI-I	Lifestyle (n=53)	Combined (n=56)	PGI-I	Lifestyle (n=44)***	Combined (n=40)	
Very much	0 (0%)	3 (5%)		0 (0%)	1 (3%)	
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%)	

*Dropouts set as "no change".

** three months scores carried forward in women that had sought further treatment

*** One woman did not answer these questions

Results

Between October 2012 and December 2013, 109 women were included and randomized. Median age was 60 years (range 33-79). Forty-seven women (43%) had POP stage III and 62 women (57%) had POP stage II. Fifty-six women were randomized to the combined group and fifty-three to the lifestyle advice group. Eighty-nine women (82%) completed three months follow up and 85 women (78%) completed six months follow up. Fourteen women (25%) compared to six (11%) in the lifestyle advice group left before three months follow-up ($p=0.08$). At both three and six months follow-up significantly more women in the combined group indicated improvement in the PGI-I (table 1). At three months follow-up both groups showed significant improvement of their total PFDI-20 score, while only the combined group had significant improvement in the POP symptom subscale (table 2). Improvement of the PFDI-20 total score reached 17% in the combined group and 14% in the lifestyle advice group ($p=0.59$). Significant improvement of PFIQ-7 could only be found in the lifestyle advice group (table 2). Between-group analysis showed no significant differences in any PFDI-20 or PFIQ-7 scores at three months follow-up while the lifestyle advice group had better bowel related quality of life (CRAIQ-7, $p=0.037$) at six months follow-up. The PISQ-12 and objective POP did not improve significantly. The majority of the women in the lifestyle advice group ($p<0.001$) had sought further treatment at six months follow-up, mainly as PFMT.

Table 2: Changes in PFDI-20 and PFIQ-7 scores from baseline to three months follow-up

	Lifestyle advice group(n=53)			Combined group (n=56)		
	Baseline (SD)	3 months follow-up (SD)	p value	Baseline (SD)	3 months follow-up (SD)	p value
Symptoms and bother						
POPDI-6	30.3 (19.6)	29.3 (17.0)	0.563	37.2 (24.4)	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)	0.004	29.6 (23.2)	24.7 (22.0)	0.003
PFDI-20	87.0 (46.3)	74.6 (39.5)	0.005	91.3 (59.7)	75.7 (55.2)	<0.001
Quality of life						
UIQ-7	18.3 (20.6)	13.7 (18.0)	0.014	12.7 (18.3)	10.7 (17.0)	0.241
CRAIQ-7	8.2 (16.0)	5.7 (14.8)	0.073	10.0 (18.6)	10.2 (18.5)	0.947
POPIQ-7	12.3 (19.8)	9.3 (17.4)	0.124	13.8 (18.8)	12.0 (18.9)	0.486
PFIQ-7	38.0 (45.1)	28.8 (37.3)	0.011	36.4 (47.0)	33.8 (48.0)	0.421

Interpretation of results

When adding PFMT to a structured lifestyle advice program more women reported improvement on a global scale but the effect of any of the two interventions barely reached clinical relevance. PFMT gave a small additional improvement of POP related symptoms but it had no effect on quality of life compared to a structured lifestyle advice program alone. No between-group differences could be found at three months follow-up and the difference at six months follow-up was minor. Women offered the combined treatment were less likely to seek further treatment at six months follow-up.

Concluding message

Based on our findings we cannot make strong recommendations about the use of PFMT in women with POP stage II-III. But if a woman wishes for a conservative approach, or if surgery is not an option, our study supports a small positive effect of lifestyle advices alone, or in combination with PFMT

References

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2. Barber MD, Walters MD, Bump RC. Short forms of two condition-specific quality-of-life questionnaires for women with pelvic floor disorders (PFDI-20 and PFIQ-7). *Am J Obstet Gynecol*. 2005 Jul;193(1):103-13. PubMed PMID: 16021067. Epub 2005/07/16. eng.

Disclosures

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