

CHANGES IN PROLAPSE FOLLOWING PELVIC FLOOR MUSCLE TRAINING: A RANDOMISED CONTROLLED TRIAL.

Hypothesis / aims of study

Evidence for the effect of pelvic floor muscle training (PFMT) on pelvic organ prolapse (POP) symptoms and staging is emerging (1-3), with a few recent trials demonstrating reduction in symptom and POP-Q stage, and some evidence of PFM changes in response to PFMT at six months follow-up (1,2). However little is known of PFM outcomes and POP-Q stage at 12 months follow-up. The aims of this study were to investigate: (a) whether individualised PFMT and lifestyle advice, versus lifestyle advice leaflet alone, was effective in reducing POP symptoms and improving POP stage; and (b) any changes in the PFM of women doing PFMT, as a mechanistic explanation of any clinical benefits.

Study design, materials and methods

This was a parallel group, multicentre (4 Australian sites) randomised trial. Women in the PFMT group received PFMT plus lifestyle advice, delivered by a physiotherapist at 5 appointments over 16 weeks. The Lifestyle Advice group received a postal lifestyle advice sheet and one telephone call from the trial office to ensure it had been received. Randomisation was computer generated with allocation by a remote randomisation service. At baseline prolapse was assessed by a gynaecologist (POP-Q system) and the PFM measures (digital [ICS strength scale] and manometric [Peritron unit, coupled with PhysiologPro software]) by a physiotherapist. Follow-up Pelvic Organ Prolapse Symptom Score (POP-SS (5), POP-Q and PFM measures were taken at 6 and 12 months by blinded gynaecology and physiotherapy assessors. The primary endpoints were PFM manometric strength and endurance, and prolapse symptom severity (POP-SS) at 6 months. POP-Q stage was a secondary outcome. Sample size calculations indicated that 82 participants per group would provide 80% power at the 5% level of significance to detect a mean difference in PFM strength of 7cm H₂O (a 15% change) with a pooled SD of 16cm H₂O. Analysis was by intention to treat. Data were analysed using logistic regression.

Results

168 women with symptomatic POP of stage I, II or III, were recruited. Mean age was 55.9 years (SD 9.9). Anterior prolapse was most common (n=123, 73%), followed by posterior prolapse (n=106, 63%). Stage II prolapse was most common (n=135, 80%), followed by stage III (20, 12%) and stage I (13, 8%). The mean duration of bothersome prolapse symptoms was 5.7 years (SD 5.3) and mean POP-SS at baseline was 10.2 (SD 5.5). The most common symptom reported at baseline was "a feeling of something coming down" (n=57, 34% reported having this symptom at least occasionally), followed by "a feeling that your bowel has not emptied properly" (n=35, 21%).

Sixty-nine of 84 (82.1%) of women attended either 4 or 5 physiotherapy sessions. At 6 months there were 21/168 (12.5%) losses to follow up (12/84 or 14.3% in the PFMT group, and 9/84 or 10.7% in the Lifestyle group), and at 12 months 20/147 or 13.6% losses to follow-up (4/72 or 5.6% in PFMT group, and 16/75 or 21.3% in Lifestyle group).

Prolapse symptoms: The table below shows values of POP-SS at baseline, 6 and 12 months follow-up. POP-SS was significantly lower (fewer, less frequent symptoms) in the PFMT group compared to the Lifestyle group at 6 ($p<0.000$) and 12 months ($p=0.006$).

Table. Pelvic Organ Prolapse Symptom Score (POP-SS*)

Group	Baseline n=168 (100%); mean (95%CI)	6 months n=141 (100%); mean (95% CI)	12 months n=111 (100%); mean (95% CI)
Lifestyle	84 (50%); 9.8 (8.7 – 10.9)	72 (51%); 8.0 (6.8 – 9.1)	54 (49%); 7.5 (6.2 – 8.8)
PFMT**	84 (50%); 10.5 (9.2 – 11.8)	69 (49%); 4.5 (3.7 – 5.4)	57 (51%); 5.1 (4.1 – 6.2)
Between group differences	-0.67 (-0.23 – 1.0)	3.5 (2.0 – 4.9)	2.3 (0.7 – 4.0)

* POP-SS score, 0=no symptoms, 28 = all 7 symptoms all the time; **PFMT=pelvic floor muscle training

Prolapse Stage

There were no overall differences in POP-Q stages between groups at 6 ($p=0.98$) and 12 months ($p=0.90$). There were significant differences in points Ap and Bp in favour of PFMT group at 6 ($p=0.03$, 95% CI -0.79 – -0.03) and 12 months ($p=0.02$, 95% CI -0.86 – -0.08). When analysed relative to the hymen, significant differences emerged for points Ap ($p=0.04$, 95% CI 0.11 – 0.96) and Bp ($p=0.04$, 95% CI 0.13 – 0.96) in favour of PFMT group at 12 months.

Pelvic floor muscle changes

Digital muscle strength was significantly stronger in the PFMT group compared to the Lifestyle group at 6 months (OR 2.2, $p=0.04$, 95% CI 1.04 – 4.79) and stronger but not significant at 12 months (OR 1.87, $p=0.12$, 95% CI 0.85 – 4.15). Total work performed (maximum voluntary contraction held for 30 seconds) was higher in favour of PFMT group at 6 months, of borderline

significance (Coefficient 0.72, $p=0.047$, 95% CI 9.12 – 1494.52). Other manometry findings were non-significant between groups.

Interpretation of results

The physiotherapy-supervised PFMT plus lifestyle advice program tested in this study resulted in clinically and statistically significant improvements in POP symptoms at 6 and 12 months, with magnitude of improvement above the minimum clinically important difference of 1.5 points on the POP-SS. POP-Q stage was not significantly different between PFMT and Lifestyle groups at 6 or 12 months, however analysis of the linear measures showed improvements in the posterior compartment in the PFMT group at 6 and 12 months. Not surprisingly, overall POP-Q stage improvement was not observed on maximum Valsalva as pelvic organ descent is related to connective tissue as well as striated muscle support.

A statistically significant improvement in PFM strength was observed in digital strength testing and to a lesser extent in manometry, however digital testing is a less robust measure of muscle strength for scientific purposes. No previous results using pressure manometry to measure PFM strength in response to a PFMT program in women with POP have been reported. The results of this study support PFMT as a beneficial intervention for women with symptomatic prolapse, with symptom benefit persisting 6 months following cessation of intervention.

Concluding message

This is the first study to investigate PFM strength in a cohort of women with Stage I, II and III symptomatic POP at 6 months following cessation of physiotherapy-supervised PFMT. The intervention tested in this RCT was beneficial immediately following the intervention, and at 6 months post-intervention. The results of this study provide further support for the clinical prescription of PFMT for women with POP.

References

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Disclosures

Funding: National Health and Medical Research Council (NH&MRC) Australia, Project Grant 508925. **Clinical Trial:** Yes **Public Registry:** Yes **Registration Number:** Australian New Zealand Clinical Trials Registry (ANZCTR), Registration Number: 12608000113358. **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** The University of Melbourne, Health Sciences HREC **Helsinki:** Yes **Informed Consent:** Yes