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A MULTICENTRE RANDOMISED CONTROLLED TRIAL OF A PELVIC FLOOR MUSCLE TRAINING INTERVENTION FOR THE PREVENTION OF PELVIC ORGAN PROLAPSE: 3 YEAR FOLLOW-UP

Hypothesis / aims of study

Pelvic floor muscle training (PFMT) for the treatment of pelvic organ prolapse is offered by many physiotherapists, and there is evidence from well-conducted trials of its benefit, in terms of reducing prolapse severity (1) and improving symptoms (1,2). It has been hypothesised that PFMT could also prevent prolapse from developing through the same mechanism of increasing hypertrophy and functional recruitment of the muscles to support the pelvic organs. The PREVPROL randomised controlled trial (RCT) found that at 2 year follow-up PFMT was effective in reducing prolapse symptoms in a non-clinical population of women who had not sought treatment for prolapse (3). We now report on 3 year follow-up of the trial participants.

Study design, materials and methods

This was a multicentre, multinational RCT of PFMT versus control (lifestyle advice leaflet) for the secondary prevention of prolapse symptoms. Women, who had not sought treatment for prolapse, but had stage I, II or III prolapse on exam were recruited from an existing cohort.

Intervention group women were offered one-to-one PFMT (5 physiotherapy appointments over 16 weeks), followed by Pilates-based classes, including PFMT. Classes were led by a physiotherapist trained in Pilates and were carried out in 6 week blocks; each woman was offered two 6 week blocks, with one class per week. An exercise DVD was provided for home use. Women were offered a one-to-one physiotherapy annual review appointment at 1 and 2 years after randomisation. The control group received only a Lifestyle Advice Leaflet by post.

Randomisation was by computer allocation, minimising on centre, POP-Q stage, delivery mode history and parity. Postal questionnaires were administered at baseline, 1, 2 and 3 years post-randomisation. The primary outcome was prolapse symptom severity (POP-SS). Secondary outcomes at 3 years were uptake of prolapse treatment, women's perceived health benefit, and cost-effectiveness. Analysis was by intention-to-treat. POP-SS scores were compared using repeated measures mixed models. Other continuous outcomes were analysed using analysis of covariance and binary/ordinal outcomes were analysed using logistic/ordinal regression. All analyses adjusted for age, minimisation variables and baseline measurements. Sample size calculations indicated that 200 per group would provide 99% power at a 5% significance level (two-sided) to detect a difference of 3 in POP-SS scores between groups. This was achieved across the UK and New Zealand centres.

Results

337 UK women were randomised and 335 included in the analysis. Mean age was 47.1 (SD 4.5) and median parity 2 (range 1-11). Questionnaire response rate was 77% at 1 year, 86% at 2 year and 70% at 3 year follow-up. By year 3, 82/118 (69%) in the intervention group reported they had done pelvic floor muscle exercises in the last 4 weeks, compared to 70/139 (50%) in the control group (OR=2.2, 95% CI 1.3 to 3.7, p=0.003). Frequency of exercise, number of contractions per day and length of hold were also significantly higher in the latter.

Previously we reported a significantly lower POP-SS score in the intervention group compared to the control group at 1 year (effect size -0.94, 95% CI -1.53 to -0.34, p=0.002) and 2 years (effect size -0.90, 95% CI -1.56 to -0.23, p=0.008), indicating fewer symptoms. There was, however, no difference at 3 years (Table 1).

There were significantly fewer women in the intervention group who had received treatment for prolapse symptoms within 3 years, and in particular there were significantly fewer GP consultations and physiotherapy referrals in the intervention group (Table 2).

Table 1: Prolapse symptoms reported in baseline, Year 1, 2 and 3 questionnaires

	Intervention				Control				Effect size at 3 yrs (95% CI), p value
POP-SS*	Baseline N=167	Year 1 N=129	Year 2 N=133	Year 3 N=118	Baseline N=168	Year 1 N=140	Year 2 N=156	Year 3 N=139	
Mean (SD)	4.4 (4.8)	3.2 (3.5)	3.2 (3.4)	3.6 (4.1)	4.1 (3.9)	4.2 (3.9)	4.6 (4.6)	4.0 (4.3)	-0.08 (-0.86 to 0.70),p=0.834
Median (range)	3 (0-26)	2 (0-19)	2 (0-22)	2 (0-24)	3 (0-17)	3 (0-17)	3 (0-27)	2 (0-18)	

*POP-SS score, 0=no symptoms, 28 = all symptoms all the time

Table 2: Treatment received for prolapse symptoms within 3 years

	In Year 1		**In Year 2**		**In Year 3**		**Within 3 years**		
	Interv. n/N(%)	Control n/N(%)	Interv. n/N(%)	Control n/N(%)	Interv. n/N(%)	Control n/N(%)	Interv. n/N(%)	Control n/N(%)	Odds ratio (95% CI), p-value
Any treatment	5/130 (3.8%)	13/140 (9.3%)	9/137 (6.6%)	16/152 (10.5%)	7/117 (6.0%)	25/139 (18.0%)	8/102 (7.8%)	31/127 (24.4%)	**0.27 (0.12 to 0.61), p=0.002**
Surgery	0/127 (0.0%)	1/134 (0.7%)	0/136 (0.0%)	1/148 (0.7%)	1/114 (0.9%)	3/131 (2.3%)	0/93 (0.0%)	3/114 (2.6%)	n/a
Pessary	0/130 (0.0%)	0/140 (0.0%)	0/137 (0.0%)	2/151 (1.3%)	0/117 (0.0%)	0/137 (0.0%)	0/97 (0.0%)	2/123 (1.6%)	n/a
Physio referral	1/125 (0.8%)	5/134 (3.7%)	3/135 (2.2%)	8/147 (5.4%)	0/114 (0.0%)	7/131 (5.3%)	1/91 (1.1%)	11/112 (9.8%)	**0.14 (0.02 to 0.77), p=0.024**
Practice nurse	0/127 (0.0%)	1/137 (0.7%)	4/134 (3.0%)	6/149 (4.0%)	0/117 (0.0%)	3/137 (2.2%)	2/95 (2.1%)	7/118 (5.9%)	0.35 (0.08 to 1.52), p=0.163
Contin. Nurse	1/123 (0.8%)	1/130 (0.8%)	2/134 (1.5%)	1/146 (0.7%)	0/111 (0.0%)	3/130 (2.3%)	0/88 (0.0%)	3/108 (2.8%)	n/a
GP	3/127 (2.4%)	8/140 (5.7%)	7/132 (5.3%)	17/152 (11.2%)	6/116 (5.2%)	19/139 (13.7%)	7/89 (7.9%)	27/123 (22.0%)	**0.31 (0.13 to 0.72), p=0.007**
Gynae-cologist	0/111 (0.0%)	2/124 (1.6%)	2/147 (1.4%)	3/159 (1.9%)	0/117 (0.0%)	3/138 (2.2%)	2/101 (2.0%)	6/121 (5.0%)	0.31 (0.09 to 1.79), p=0.233
Other reason	1/111 (0.9%)	2/124 (1.6%)	0/147 (0.0%)	1/159 (0.6%)	0/117 (0.0%)	0/138 (0.0%)	1/101 (1.0%)	1/121 (1.7%)	0.88 (0.11 to 6.91), p=0.903
No reason	1/111 (0.9%)	0/124 (0.0%)	4/147 (2.7%)	0/159 (0.0%)	1/117 (0.9%)	0/138 (0.0%)	2/101 (2.0%)	0/121 (0.0%)	n/a

Women in the intervention group were more likely to say their health was better compared to control women (27% vs 13%, OR=3.10, 95% CI 1.76 to 5.45, p<0.001). The incremental cost of the intervention was £518 and the cost per QALY was £25,700 at year 3.

Interpretation of results

Prolapse symptoms reported at 3 years were not significantly less in women who had the PFMT intervention; symptom benefit was achieved only in the first two years. This was despite women in the intervention group being more likely to report doing pelvic floor muscle exercises, more frequently and intensively, in the last 4 weeks and being more likely to say they felt better due to the study. However controls were more likely to have received additional prolapse treatment which may have improved their symptoms. The economic analysis indicated that PFMT could be cost-effective (3 year cost per QALY was below the threshold set by UK National Institute for Health and Care Clinical Excellence).

Concluding message

The results provide evidence that at 3 years post-PFMT intervention prolapse symptoms were not significantly better compared to symptoms in women who had not received PFMT. Strategies to maintain symptom benefit from PFMT need to be explored.

References

1. Brækken IH, Memona Majida PT, Engh ME, Bø K. Morphological Changes After Pelvic Floor Muscle Training Measured by 3 Dimensional Ultrasonography: A Randomized Controlled Trial. Journal of Obstetrics & Gynaecology 2010 Feb;105(2),Part 1:317-324.
2. Hagen S, Stark D, Glazener C, Dickson S, Barry S, Elders A, et al. Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): a multicentre randomised controlled trial. Lancet 2014; 383:796-806
3. Hagen S, Glazener C, McClurg D, Macarthur C, Herbison P, Wilson D, Toozs-Hobson P, Bain C, Hay-Smith J, Collins M, Elders A. A multicentre randomised controlled trial of a pelvic floor muscle training intervention for the prevention of pelvic organ prolapse (PREVPROL). Neurourology and Urodynamics 2014;33:852-853.

Disclosures

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