

## 🏆 Best Clinical Abstract (Joint)

393

Hagen S<sup>1</sup>, Glazener C<sup>2</sup>, McClurg D<sup>1</sup>, Macarthur C<sup>3</sup>, Herbison P<sup>4</sup>, Wilson D<sup>4</sup>, Tooze-Hobson P<sup>5</sup>, Bain C<sup>6</sup>, Hay-Smith J<sup>4</sup>, Collins M<sup>7</sup>, Elders A<sup>2</sup>

1. NMAHP Research Unit, Glasgow, 2. Health Services Research Unit, Aberdeen, 3. University of Birmingham, 4. Dunedin School of Medicine, University of Otago, 5. Birmingham Women's Hospital, 6. Aberdeen Royal Infirmary, 7. Yunus Centre, Glasgow Caledonian University

### A MULTICENTRE RANDOMISED CONTROLLED TRIAL OF A PELVIC FLOOR MUSCLE TRAINING INTERVENTION FOR THE PREVENTION OF PELVIC ORGAN PROLAPSE (PREVPROL)

#### 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. This randomised controlled trial (RCT) aimed to determine clinical and cost-effectiveness of PFMT to prevent prolapse symptoms and the need for prolapse treatment.

#### Study design, materials and methods

This was a multicentre, multinational RCT of PFMT versus control (lifestyle advice leaflet) for the prevention of prolapse symptoms. Women already involved in a longitudinal study of pelvic floor dysfunction after childbirth, who did not have prolapse symptoms which had caused them to seek treatment, were identified. Those who had agreed to a prolapse examination at the 12 year follow-up, and had not previously sought treatment for prolapse, were invited to take part. Women with POP-Q stage 0 or IV on examination were excluded.

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 and 2 years post randomisation. The primary outcome was prolapse symptom severity (Pelvic Organ Prolapse Symptom Score-POP-SS) (3) at 2 years. Secondary outcomes were prolapse-related quality of life, uptake of prolapse treatment, symptoms of urinary incontinence, anorectal or sexual dysfunction, 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 (if applicable) 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.

#### Results

407 women were randomised. Mean age was 46.6 (SD 4.6) and median parity 2 (range 1-11). Questionnaire response rate was 81% at 1 year and 86% at 2 year follow-up. Non-responders at 2 years were younger and had a higher baseline POP-SS. 78% attended 3 or more of the 5 appointments offered. Attendance at annual review appointments was 52% and 46% at year 1 and year 2 respectively, and uptake of classes in the UK was 33% and 17% at 1<sup>st</sup> and 2<sup>nd</sup> block respectively. By year 2, 77% in the intervention group reported they had done pelvic floor muscle exercises in the last 4 weeks. This was significantly higher than for the control group (53%) (OR=2.94, 95% CI 1.82 to 4.74, p<0.001).

There was a significantly lower POP-SS score at 2 years in the intervention group compared to the control group (effect size - 0.90, 95% CI -1.56 to -0.23, p=0.008), indicating fewer symptoms. In addition, the difference at 1 year was also significant in favour of the intervention group (effect size -0.94, 95% CI -1.53 to -0.34, p=0.002) (Table 1).

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

POP-SS*	Intervention			Control			Effect size (95% CI)	
	Baseline N=206	Year 1 N=159	Year 2 N=161	Baseline N=199	Year 1 N=164	Year 2 N=180	Year 1	Year 2
Mean (SD)	4.4 (4.5)	3.2 (3.5)	3.2 (3.4)	3.9 (3.7)	3.9 (3.7)	4.2 (4.4)	-0.94 (-1.53 to -0.34)	-0.90 (-1.56 to -0.23)
Median (range)	3 (0-26)	2 (0-19)	2 (0-22)	3 (0-17)	3 (0-17)	3 (0-27)		

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

There were no significant differences at 2 years between the groups in terms of how much interference they experienced as a result of prolapse in any of the domains (physical activity, social activity, personal hygiene or everyday life). There were no significant differences between groups in the uptake of treatment for prolapse (Table 2).

Table 2: Treatment received for prolapse symptoms at Year 2

	Intervention n/N (%)	Control n/N (%)
--	----------------------	-----------------

Surgery	0/163 (0.0%)	1/171 (0.6%)
Pessary	0/164 (0.0%)	1/175 (0.6%)
Physiotherapy referral	4/161 (2.5%)	7/173 (4.0%)
Practice nurse	4/162 (2.5%)	7/170 (4.1%)
Continence nurse	2/160 (1.2%)	1/169 (0.6%)
GP	9/159 (5.7%)	17/176 (9.7%)
Other	10/147 (6.8%)	10/159 (6.3%)

No significant difference was found between groups in the percentage who experienced urine leakage at 2 years. Neither was there a significant difference between the groups in the ICIQ-UI short form score, or the number of pads used weekly. Faecal urgency and incontinence were not significantly different between the groups at 2 years. Neither was interference associated with anorectal symptoms. The rates of sexual inactivity due to prolapse and prolapse interference with sex life were not significantly different between groups at 2 years. Women in the intervention group were more likely to say their health was better compared to control women (OR=7.01, 95% CI 3.87 to 12.71,  $p<0.001$ ). The incremental cost of the intervention was £518 and the cost per QALY was £17,267 at year 1. At year 2, the incremental cost of the intervention was £518 and the cost per QALY was £51,800.

#### Interpretation of results

Prolapse symptoms were less at 2 years in those women who were randomised to the PFMT intervention. The control group POP-SS mean score had stayed similar over the study time-points, whereas the intervention group score had decreased (indicating fewer symptoms). At 2 years, women in the intervention group were more likely to report doing pelvic floor muscle exercises in the last 4 weeks and more likely to say their health felt better due to the study. Although there were no significant differences between the groups in relation to the other symptoms, in general the results were in the direction of the intervention group having better scores compared to the control group. The economic analysis suggests that such an intervention could be cost-effective (the cost per QALY ranged from £17,267 in year 1 to £51,800 in year 2); however, the economic implications of this result will be affected by any savings which might be expected as a result of reduced use of healthcare for prolapse symptoms in the intervention group in the coming years. We are undertaking 3 and 4 year follow-up to determine if there are long-term benefits.

#### Concluding message

The results provide good evidence that PFMT can be effective in reducing prolapse symptoms in a non-clinical population of women who had not sought treatment for prolapse. This is important information for physiotherapists, gynaecologists, and women generally. They can use it to make decisions about preventative strategies that they might use. Cost-effectiveness will be fully assessed at future follow-up.

#### References

1. Braekken IH, Majida M, Engh ME, Bø K. Morphological changes after pelvic floor muscle training measured by 3-dimensional ultrasonography: a randomized controlled trial. *Obstet Gynecol.* 2010 Feb;115:317-24
2. Hagen S, Stark D, Glazener C, Dickson S, Barry S, Elders A, Frawley H, Galea MP, Logan J, McDonald A, McPherson G, Moore KH, Norrie J, Walker A, Wilson D; POPPY Trial Collaborators. Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): a multicentre randomised controlled trial. *Lancet.* 2014 Mar 1;383(9919):796-806.
3. Hagen S, Glazener C, Sinclair L, Stark D, Bugge C. Psychometric properties of the pelvic organ prolapse symptom score. *BJOG.* 2009 Jan;116(1):25-31.

#### Disclosures

**Funding:** Wellbeing of Women; New Zealand Continence Association; Dean's Bequest Fund of Dunedin School of Medicine  
**Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov, NCT01171846 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Scotland REC A, reference 10/MRE00/53; Lower South Regional Ethics Committee, Ministry of Health, Dunedin **Helsinki:** Yes  
**Informed Consent:** Yes