**PRIZE AWARD: Best Clinical Abstract**

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# A MULTICENTRE RANDOMISED CONTROLLED TRIAL OF A PELVIC FLOOR MUSCLE TRAINING INTERVENTION FOR WOMEN WITH PELVIC ORGAN PROLAPSE

Hypothesis / aims of study

Individualised pelvic floor muscle training (PFMT) for women with pelvic organ prolapse is offered by many physiotherapists, yet clear evidence of its long-term clinical and cost-effectiveness is lacking. A recent trial (1) of 109 women with prolapse (both symptomatic and asymptomatic) found benefits immediately post-treatment from an intensive 6 month programme of PFMT (weekly appointments for 3 months, followed by biweekly appointments for 3 months), in terms of prolapse severity (ultrasound and POP-Q) and symptoms. However, evidence for a PFMT intervention targeting symptomatic women, with fewer supervised sessions which is deliverable within existing national health services is still required. The aim of this trial was to determine the effectiveness and cost-effectiveness of such a PFMT programme.

Study design, materials and methods

This was a parallel group, multicentre randomised controlled trial. Women in the intervention group were randomised to PFMT, delivered by a physiotherapist at 5 appointments over 16 weeks, and lifestyle advice. Women in the control group received a Lifestyle Advice Sheet by post only. Randomisation was by computer allocation using a remote randomisation service. Minimisation variables were: centre, POP-Q stage and motivation for surgery (not considering/considering POP surgery). Women had their prolapse assessed by a gynaecologist (POP-Q system) at baseline and (blinded) 6 months, and completed postal questionnaires at baseline (prior to randomisation) and 6 and 12 months. A 24 month follow-up is underway. The primary outcome was prolapse symptom severity (Pelvic Organ Prolapse Symptom Score – POP-SS) (2) at 12 months. Other key outcomes were prolapse severity (POP-Q), women's perceived change in prolapse, uptake of further treatment and cost-effectiveness. Analysis was by intention-to-treat. Sample size calculations indicated that 253 per group would provide 80% power at the 5% level of significance to detect a different of 2.5 points (SD 8) in the primary outcome measure.

Results

448 new gynaecology outpatients with symptomatic prolapse of POP-Q stage I, II or III were recruited over 30 months from 23 UK centres and 2 international centres (1 women withdrew after randomisation and requested her data not be used: n=447). A further 3 international trial centres, where additional outcomes are being measured, are following up 170 women who will contribute data to a future meta-analysis.

The mean age of participants was 56.8 years (SD 11.5); median number of births was 2; 89% of all births were normal vaginal deliveries and 3% caesarean sections. The most common prolapse type was anterior prolapse (34%), followed by combined anterior/posterior prolapse (24%) and posterior prolapse alone (16%). Stage II prolapse was most common (74%), followed by stage III (15%) and stage I (11%). The mean duration of prolapse symptoms was 25.2 months (SD 40.2). The trial group characteristics were well-balanced at baseline.

Questionnaire response rates were high at 6 month follow-up (84% intervention; 86% control), but lower at 12 months (67% intervention; 65% control). Rates of attendance for 6-month prolapse assessment and POP-Q were good (81% intervention; 82% control). Compliance with the intervention was high: 80% of women attended 4 or 5 physiotherapy sessions.

**Prolapse symptoms:** The POP-SS was significantly lower (fewer, less frequent symptoms) in the intervention group compared to the control group at 6 months (estimate of difference between groups in change from baseline 2.84, 95% CI [2.05, 3.63], p<0.001) and 12 months (estimate 1.52, 95% CI [0.46, 2.59], p=0.005) (Table 1). The most common single symptom reported at baseline was "a feeling of something coming down" (85.8% intervention/87.8% control reported having this symptom at least occasionally); this persisted as the most common symptom at 6 months (72.0% intervention/84.4% control) and 12 months (65.3% intervention/70.8% control).

Table 1. Pelvic Organ Prolapse Symptom Score (POP-SS) at baseline, 6 and 12 months

| **POP-SS*: mean (SD)** | **Baseline** | **6 months** | **12 months** |
|---|---|---|---|
| Intervention | 10.04 (6.00) n=224 | 6.56 (5.09) n=188 | 5.74 (4.89) n=145 |
| Control | 9.51 (5.64) n=222 | 9.17 (5.81) n=189 | 7.04 (5.43) n=139 |

** POP-SS score, 0=no symptoms, 28 = all 7 symptoms all the time*

**Prolapse severity:** Change in prolapse stage from baseline to 6-month follow-up showed a marginally significant difference between trial groups (Mann Whitney test p=0.052): 20% in the intervention group had an improved stage versus 12% in the control group. The majority of women in both groups had no change in their prolapse stage (Table 2).

Table 2. Change in POP-Q severity from baseline to 6 month assessment

| | **Intervention (n=168)** | **Control (n=171)** |
|---|---|---|
| +2 stages | 2 (1%) | 2 (1%) |
| +1 stages | 20 (12%) | 28 (16%) |

| | | |
|---|---|---|
| no change | 113 (67%) | 120 (70%) |
| -1 stage | 32 (19%) | 21 (12%) |
| -2 stage | 1 (1%) | 0 |

**Uptake of further treatment:** By 12 months, a significantly greater proportion of control women (55%) reported they had received further treatment for prolapse compared to the intervention women (30%) (difference estimate 25%, p<0.001). Control women were significantly more likely than intervention women to report referral to physiotherapy. Rates for receiving other treatments were similar.

**Self-reported change:** Intervention group women were significantly more likely than control group women to report their prolapse felt better compared to the start of the study, both at 6 months (52% intervention vs 17% control) (p<0.001) and 12 months (57% vs 45%) (p=0.012).

**Pelvic floor muscle function:** In the intervention group (n=143, those who attended the 5$^{th}$ appointment), there was a significant increase in contraction strength from baseline on the modified Oxford scale (mean increase 0.6, 95% CI [0.5, 0.7], p<0.001).

**Cost-effectiveness:** The net cost of the intervention, taking into account the cost of further treatment received/avoided, was £127 per woman. This cost is set against an average decrease in POP-SS at 12 months of 1.52, which represents a clinically important change in symptoms for women (3).

Interpretation of results

The intervention was found to be effective: compared to the control group, women's prolapse symptoms were less frequent in the PFMT group at 6 and 12 months, they were more likely to report their prolapse felt better, and less likely to seek further treatment. There was a tendency for more improvement in POP-Q stage in the intervention group, although this was only marginally significant. The average improvement in the POP-SS was associated with a cost of £127 per woman. Assuming intervention women gained 10% on their quality of life for a year as a result of the intervention, it is estimated that the cost per quality adjusted life year gained is around £16K. This level of cost per QALY is commonly accepted by organisations such as National Institute for Health and Clinical Excellence.

Concluding message

There is now sufficient evidence to conclude that PFMT is effective and cost-effective in reducing prolapse symptoms and should be recommended as first-line management for prolapse.

References


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| ***Specify source of funding or grant*** | **Chief Scientist Office, Scotland** |
| ***Is this a clinical trial?*** | **Yes** |
| ***Is this study registered in a public clinical trials registry?*** | **Yes** |
| ***Specify Name of Public Registry, Registration Number*** | **Current Controlled Trials** |
| ***Is this a Randomised Controlled Trial (RCT)?*** | **Yes** |
| ***What were the subjects in the study?*** | **HUMAN** |
| ***Was this study approved by an ethics committee?*** | **Yes** |
| ***Specify Name of Ethics Committee*** | **Scotland A Research Ethics Committee** |
| ***Was the Declaration of Helsinki followed?*** | **Yes** |
| ***Was informed consent obtained from the patients?*** | **Yes** |