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# Physiotherapists and prolapse: who's doing what, how and why?

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### Abstract

This paper reviews currently available research evidence that supports physiotherapy practice in relation to the treatment of pelvic organ prolapse (POP), in particular the use of pelvic floor muscle (PFM) training. Evidence from Cochrane systematic reviews, a physiotherapy practice survey, and a number of interlinked randomized controlled trials and satellite studies is presented. There is insufficient research evidence to inform physiotherapy practice regarding the use of PFM training for women with POP. However, specialist physiotherapists in the UK are routinely treating women with prolapse, and specifically, they are using the methods of PFM training that are recognized as effective in the treatment of urinary incontinence. Research is now underway to provide rigorous evidence regarding the effectiveness of interventions for this population. The important issue of the standardization of outcome measures for the profession is also being addressed.

*Keywords:* evidence base, pelvic floor muscle training, pessary, prolapse, Pelvic Organ Prolapse – Quantification (POP-Q) system.

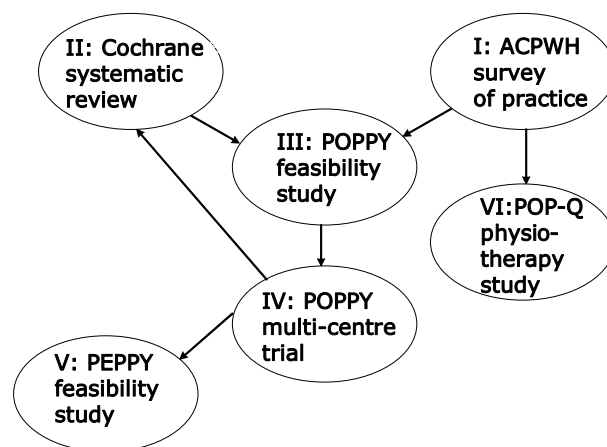
### Introduction

Most physiotherapists who specialize in obstetrics and gynaecology are experienced in delivering pelvic floor muscle (PFM) training (PFMT). There is strong evidence to support the use of this therapy in the treatment of urinary incontinence, but what treatment should physiotherapists be offering women with pelvic organ prolapse (POP)? The present paper describes the research evidence to support the use of PFMT for prolapse, with particular emphasis on a programme of work ongoing at the Nursing, Midwifery and Allied Health Professions (NMAHP) Research Unit, Glasgow Caledonian University, Glasgow, UK (see Fig. 1).

### Background

Prolapse is a common female condition that has been defined by the International Consultation on Incontinence as 'the symptomatic descent of

one or more of the anterior wall, the posterior vaginal wall and the apex of the vagina (cervix/uterus) or vault (cuff) after hysterectomy' (Abrams *et al.* 2005). The exact prevalence of the condition is difficult to estimate; however, in one



**Figure 1.** Overview of the research programme investigating physiotherapy and prolapse at the Nursing, Midwifery and Allied Health Professions Research Unit, Glasgow Caledonian University, Glasgow, UK.

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study of over 27 000 postmenopausal women over 50 years of age, 40% of subjects were found to have some degree of prolapse (Hendrix *et al.* 2002). Confirmed risk factors for prolapse include increased age, Body Mass Index and parity; race, family history, vaginal delivery and constipation are also known to have an influence (Doshani *et al.* 2007). The idea that PFMT might have a role to play in treating prolapse is not new. Baden & Walker (1992) commented on the possibility that the 'patient may experience relief of symptoms', that such exercises 'may strengthen muscles and prepare patient for normal function after surgery', and that 'if POP reduces by a PFM contraction this is a good indicator for Kegels' (i.e. if contracting the PFMs lifts the prolapse, then PFM exercises may be helpful).

The three main options for treatment are surgical repair, vaginal pessary and PFMT. There are three Cochrane systematic reviews summarizing the evidence for these modalities (Adams *et al.* 2004; Hagen *et al.* 2006a; Maher *et al.* 2007), and these conclude that the research evidence for such interventions needs to be strengthened by findings from rigorous randomized controlled trials (RCTs).

### Research on physiotherapy and prolapse

Four completed and two ongoing studies on physiotherapy and prolapse are described below.

#### *What is current practice amongst specialist physiotherapists? A survey of ACPWH members*

In 2002, a survey of members of ACPWH (Fig. 1: I) was undertaken by Hagen *et al.* (2004) in order to establish what was current practice with regard to treating prolapse in the UK. A response rate of 71% ( $n=364$ ) was obtained, including replies from women's health physiotherapists with a range of clinical experience. Ninety-two per cent of respondents were treating women with prolapse. Almost all (>96%) reported using the core elements of PFMT (i.e. explanation of anatomy and physiology, verbal explanation of PFMT technique, and vaginal examination to check technique), and most reported providing a leaflet (88%), employing biofeedback (83%) and using electrical stimulation (76%). As expected, because of the limited evidence base, the majority of respondents (79%) reported that they had no guidelines to direct their practice. The most commonly used out-

come measures were patient-reported symptoms (97%), PFM strength (94%) and quality of life (84%). Use of prolapse grading systems was less common (44%). Encouragingly, more than 80% of respondents expressed an interest in being involved in a future multicentre trial of PFMT for prolapse that would improve the evidence base for practice.

In conclusion, PFMT was widely practised by UK physiotherapists for treatment of prolapse. A need was identified for evidence and evidence-based clinical guidelines, as well as for standardized referral guidelines to ensure consistent access to PFMT. Respondents were keen to be involved in a future RCT to address the evidence gap.

#### *What evidence currently exists to support practice? Results from a Cochrane systematic review*

Randomized controlled trials relating to PFMT for treatment of prolapse are lacking (Hagen *et al.* 2006a) (Fig. 1: II). To date, only one reasonably sized trial has been published (Piya-Anant *et al.* 2003), and unfortunately, this had some significant limitations.

Piya-Anant *et al.* (2003) described a trial of PFM exercises and advice on reducing constipation in an elderly population in Thailand. All women aged over 60 years who were living within 10 km of the hospital where the study was conducted were originally assessed for the presence of anterior wall POP. Clusters of women defined by postcode area were then randomized to either an intervention ( $n=330$ ) or a control group ( $n=324$ ). The success of the intervention in preventing the worsening of anterior wall prolapse was assessed. This cluster RCT included 654 women. Follow-up was conducted at 6, 12 and 24 months.

It was not stated whether women without prolapse were excluded; however, the numbers presented in the study would suggest that they were not. Piya-Anant *et al.* (2003) did not report clearly who provided the intervention (only that women attended a clinic), the method of randomization, the method of prolapse assessment, or how the assessor was blinded to previous assessment results and the participants' group status. There was insufficient detail about women lost to follow-up. At the 6-month follow-up, there were no significant differences between the intervention and control groups with regard to the number of women with worsened prolapse for either women classified initially with mild

prolapse or those categorized as severe cases. For women who had mild prolapse at the outset, those in the intervention group were less likely to have worse prolapse at the 12-month follow-up than those in the control group ( $P < 0.05$ ). By the 24-month follow-up, this difference between groups was no longer evident. For women who were initially classified with severe prolapse, there was no difference between the intervention and control groups at the 12-month follow-up (no figures reported). However, women in the intervention group were less likely to have worse prolapse at the 24-month follow-up (28%) than those in the control group (72%) (Piya-Anant *et al.* 2003).

The evidence considered in the above review is insufficient in order to judge the value of conservative management of POP. It was concluded that a large, rigorous trial of PFMT using standardized measures of prolapse severity and symptoms is needed in women with confirmed prolapse.

#### *Providing evidence for practice: the POPPY feasibility study and multicentre trial*

Given the lack of RCTs in this area, Hagen *et al.* (2006b) conducted a feasibility study, the Pelvic Organ Prolapse Physiotherapy (POPPY) study, for a RCT of a PFMT intervention in 47 women with symptomatic stage I or II prolapse in two UK centres.

The intervention consisted of five physiotherapy appointments over a 16-week period (appointments at weeks 0, 2, 6, 11 and 16), and an individually prescribed daily PFM exercise programme. At the first appointment, a one-hour consultation, a standardized history was taken from the subject, and a subjective prolapse assessment and internal PFM assessment (using the PERFECT scheme; Laycock & Jerwood 2001) were both carried out. Anatomy and function of the PFMs were taught, and types of prolapse were described using diagrams and a model pelvis. Women were also taught how to correctly contract their PFMs and how to counterbrace against increases in intra-abdominal pressure ('the Knack'; Miller *et al.* 1998). An individualized home exercise programme was prescribed and women were encouraged to perform six sets of exercises daily; an exercise diary was used to record compliance. A standardized lifestyle advice sheet was given to the subjects, and where appropriate, tailored lifestyle advice was given on ways of reducing intra-abdominal pressure (e.g. advice on weight loss, chronic

**Table 1.** Change in Pelvic Organ Prolapse – Quantification (POP-Q) severity from baseline to 20-week assessment [ $n$  (%): (PFMT) pelvic floor muscle training

Change in POP-Q stage*	PFMT (total $n=11$ )	Control (total $n=9$ )
+2 stages	0 (0)	0 (0)
+1 stage	1 (9)	3 (33)
No change	5 (45)	6 (67)
– 1 stage	4 (36)	0 (0)
– 2 stages	1 (9)	0 (0)

\*Positive and negative values indicate worsened and improved stages of prolapse, respectively.

cough, heavy lifting and general exercise to maximize the effects of the PFMT). Symptom changes, lifestyle advice compliance and changes in PFMs, assessed by vaginal examination, were recorded at each subsequent 30-min consultation, and the content of the home exercise programme adjusted accordingly.

Women in the control group received only the lifestyle advice sheet, which was posted to them at home; there was no planned contact with a physiotherapist or other healthcare professional regarding prolapse in this group.

Outcome measures included: blinded prolapse assessment using the Pelvic Organ Prolapse – Quantification (POP-Q) system (Bump *et al.* 1996); prolapse-related symptom severity and quality of life assessment via postal questionnaires; and PFM strength (Modified Oxford Grading Scale), in the intervention group only. A POP-Q assessment was carried out by gynaecologists prior to randomization and at 20 weeks post-randomization. Questionnaires were completed by women at baseline, and at 20 and 26 weeks post-randomization. Twenty-three women were randomized to PFMT and 24 women to the control group.

Women in the intervention group were more likely than controls to have an improvement in prolapse stage (Fisher's exact test,  $P=0.038$ ) (Table 1).

There was a significant difference between the intervention and control group in the change in prolapse symptom score from baseline to the 26-week follow-up; women in the intervention group reported a significantly greater improvement in symptoms than controls post-intervention (unpaired  $t$ -test =  $-2.298$ ,  $P=0.021$ ) (Table 2).

There were significant differences between the groups at both follow-up time points in perceived improvement in prolapse ( $\chi^2$  test, 20 weeks:  $\chi^2=11.465$ , d.f. = 1,  $P=0.001$ ;  $\chi^2$  test, 26

**Table 2.** Change in prolapse symptom score: (SD) standard deviation; and (PFMT) pelvic floor muscle training\*

Time from Baseline (weeks)	Group	Number	Mean	SD	Unpaired <i>t</i> -test <i>P</i> -value
20	PFMT	17	-1.94	4.8	0.094
	Control	20	0.40	3.0	
26	PFMT	17	-3.47	5.4	0.031
	Control	20	-0.10	2.9	

\*Sum of seven symptom questions: (minimum) 0=no symptoms; and (maximum) 28=all symptoms present all the time.

**Table 3.** Self-reported change in prolapse since the start of the study [*n* (%)]: (PFMT) pelvic floor muscle training

Self-reported change	PFMT group		Control group	
	20 weeks ( <i>n</i> =19)	26 weeks ( <i>n</i> =19)	20 weeks ( <i>n</i> =21)	26 weeks ( <i>n</i> =21)
Same/worse	9 (47)	7 (37)	20 (95)	16 (76)
Better	10 (53)	12 (63)	1 (5)	5 (24)

weeks:  $\chi^2=6.320$ , d.f.=1,  $P=0.012$ ); women in the intervention group were more likely to report that their prolapse was better than at the start of the study (Table 3).

A significant improvement in PFM strength was detected in the intervention group ( $t=-3.09$ , d.f.=14,  $P=0.008$ , 95% confidence interval=0.2, 0.8); the mean improvement was 0.5 (SD=0.6) on the Modified Oxford Grading Scale. However, PFM strength measures were taken by physiotherapists who had knowledge of the women who were in the intervention group, and thus, the results may have been subject to bias in reporting.

The study concluded that a multicentre trial of PFMT for prolapse was feasible and that the methods developed in the feasibility study could be rolled out to more centres. There were indications of a positive effect of PFMT from the pilot data, and the data indicated that an adequately powered trial would require approximately 520 women to give reliable conclusions regarding the effectiveness of PFMT for prolapse.

Based on the feasibility study findings, funding was secured to undertake a multicentre trial (the POPPY trial), which began recruitment in September 2007. Seventeen UK centres have agreed to participate, and each will aim to randomize 36 women to the trial. An additional, separately funded centre in Dunedin, New Zealand, will randomize a further 36 women. Similarly, three centres in Australia (i.e. Melbourne, Adelaide and Sydney) have jointly

obtained funding to undertake trial recruitment with additional PFM assessment in women from two centres.

In order to standardize the physiotherapy intervention, a one-day course, developed and taught by one of the authors, was attended by UK trial intervention physiotherapists prior to the start of the trial. Attendees already had clinical experience in PFMT. Therefore, the course ensured consistency in: teaching of PFM exercises; PFM assessment; lifestyle advice; content of return appointments; use of diaries; and standardized leaflets. The course material that was developed was used to provide equivalent training in the international centres.

A number of changes to the feasibility study protocol were made before embarking on the main trial. Women with stage III prolapse are now eligible for inclusion: in the feasibility study some women with stage III prolapse who were excluded went on to be referred to physiotherapy. Within the PFMT intervention, the number of sets of exercises recommended to women has been changed from six sets to 'at least three sets' daily. This was as a result of comments from the funding committee, who felt that six sets of exercises was unrealistic. Women are followed up with questionnaires at 6 and 12 months after they are randomized. Only a short follow-up period had been possible in the feasibility study.

The UK POPPY trial is scheduled to report its findings in 2010. Another ongoing trial being

carried out by Kari Bø and her colleagues in Norway is scheduled to report later in 2008. This is a single-blind RCT involving 100 women with stage I, II or III prolapse, and evaluating the effects of a PFMT intervention. The intervention spans a 6-month period, with weekly physiotherapy appointments for 3 months, then fortnightly appointments for 3 months, and a structured home training programme.

#### *Pelvic floor muscle training as an adjunct to vaginal pessary: the PEPPY study*

The use of vaginal pessaries is a common gynaecological practice, particularly in women with more severe prolapse who are unsuitable for or unwilling to have surgery. An important question is whether PFMT can be of additional benefit to these women. By reducing the descent of the pelvic organs and the consequent stretching of soft tissue, a pessary may allow the PFMs to be exercised more effectively, leading to increased support in the pelvic area. This in turn may improve the pessary retention rate and effectiveness. A study exploring the feasibility of a trial to answer such a question is now underway: the PEssary Plus Physiotherapy (PEPPY) study. This is a satellite study to POPPY.

Women with prolapse who are not eligible for the UK POPPY trial because they require a pessary will be recruited to a feasibility study in three of the centres. Consenting women will be randomized to have individualized PFMT delivered by a specialist physiotherapist, with their pessary *in situ*, or to have a pessary alone. Women will be followed up at 7 months. This study will provide important information about how feasible and acceptable to women a trial of this kind is, and it will provide data to inform the sample-size calculations for a definitive trial.

#### *Measuring outcomes of physiotherapy for prolapse using the Pelvic Organ Prolapse – Quantification system*

Physiotherapists do not routinely use a standardized outcome measure when treating women with prolapse (Hagen *et al.* 2004). The use of the POP-Q system (Bump *et al.* 1996) by physiotherapists would facilitate recording of prolapse type and severity, and thus, allow the effect of physiotherapy to be clearly demonstrated in clinical practice and research.

A study was undertaken in one Scottish gynaecology department to determine the feasibility, inter- and intra-rater reliability of physiotherapists using the POP-Q system (Stark *et al.* 2007).

Examiner	Stage	Physiotherapist					Total
		0	I	II	III	IV	
Gynaecologist	0	0	1	0	0	0	1
	I	2	7	3	0	0	12
	II	1	8	12	0	0	21
	III	0	0	4	6	1	11
	IV	0	0	0	0	0	0
Total		3	16	19	6	1	45

**Figure 2.** Agreement about Pelvic Organ Prolapse – Quantification (POP-Q) stage between gynaecologist and physiotherapist.

Six physiotherapists and two consultant gynaecologists took part in the study, participating in a standardized POP-Q training programme including theoretical and practical training. Women were recruited from gynaecology and urogynaecology clinics. Two POP-Q examinations were performed by study staff at the first clinic visit, one by the gynaecologist and one by a physiotherapist. Women attended the clinic one week later, when two further POP-Q examinations were performed, one by the same physiotherapist as the week before and one by a second study physiotherapist. The examination order at each clinic was randomized. The chaperone nurse timed each examination, and women were asked to complete a short questionnaire regarding their experience of each examination.

The primary outcome measures were the agreement between the examiners about POP-Q stage, comparison of the duration of examination by different examiners and the questionnaire responses of the women. Agreement about POP-Q stage was assessed between pairs of examiners using the weighted kappa statistic.

Forty-five women were recruited (median age=59 years, age range=32–87 years). The presenting complaint was: POP ( $n=22$ ); urinary incontinence ( $n=15$ ); other ( $n=7$ ); or not reported ( $n=1$ ).

Agreement about POP-Q stage between the gynaecologist and physiotherapist was substantial (Fig. 2), with a weighted kappa statistic of 0.63. Weighted kappa was 0.67 for inter-rater agreement between two different physiotherapists, and 0.71 for intra-rater reliability for repeated examinations by a single physiotherapist.

The duration of the examination was significantly shorter for gynaecologists [mean  $\pm$  standard deviation (SD)=171  $\pm$  51 s] compared with physiotherapists (mean  $\pm$  SD=224  $\pm$  52 s)

for the same examinations (difference: mean  $\pm$  SD = 53  $\pm$  73 s;  $P < 0.01$ , paired *t*-test).

There was no difference between gynaecologists and physiotherapists in the reported experience of the participants during the examinations. All subjects who expressed an opinion reported both that the examination itself and the time taken to conduct the examination were acceptable. Participants predominantly rated the levels of discomfort as none or mild, and there were few differences between the ratings given to gynaecologists and physiotherapists.

The feasibility and acceptability of physiotherapists using the POP-Q in a clinical situation was confirmed. The kappa statistics indicated a substantial agreement between the raters, demonstrating the reliability of physiotherapists using the POP-Q.

The POP-Q is a feasible and reliable measure for use by physiotherapists. Its use both as a research tool and in clinical practice to assess physiotherapy interventions would be a useful development for the profession. Multi-professional communication would be improved via the application of a common standardized measurement system.

## Conclusions

Evidence is urgently needed to support physiotherapy practice in this clinical area. Physiotherapists across the UK are already treating women with prolapse, but are doing so on the basis of very little evidence. We do not yet know which women might benefit from PFMT or what benefits it might confer. Work is underway to rectify this position and research will soon be available to direct practice, ultimately facilitating the best-possible outcomes for women with this condition.

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