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A FEASIBILITY STUDY FOR A RANDOMISED CONTROLLED TRIAL OF PELVIC FLOOR MUSCLE TRAINING COMBINED WITH VAGINAL PESSARY FOR WOMEN WITH PELVIC ORGAN PROLAPSE

Hypothesis / aims of study
Pelvic floor muscle training (PFMT) and vaginal pessaries (support devices) are commonly used to treat pelvic organ prolapse. Each of these treatments may be effective individually but there is no evidence to assess whether a combination of treatments is more effective than a pessary alone. It is hypothesised that undertaking PFMT with a pessary in place may reduce stretching on pelvic support structures and thus optimise pelvic floor muscle changes. This could lead to improvements in prolapse symptoms and quality of life beyond that expected from a pessary alone. The aim of this study was to determine the feasibility of conducting a randomised controlled trial (RCT) of the effectiveness of a PFMT intervention in conjunction with pessary management versus pessary management alone for women with prolapse.
Study design, materials and methods
Four centres recruited new gynaecology outpatient attendees with symptomatic prolapse of POP-Q stage I-IV, who were being fitted with a pessary. Women were randomised to either: 1) PFMT (5 appointments over 16 weeks with a specialist women's health physiotherapist) in conjunction with pessary management (intervention group), or; 2) pessary management alone (control group). Women had their pessary removed 6 months after randomisation and vaginal symptoms assessed. At 7 months women had a gynaecology review appointment to re-assess their prolapse and discuss further treatment. Participants received postal questionnaires at baseline (2 weeks after pessary fitted), 6 and 7 months post-randomisation, and recorded symptoms in a diary for 1 month after removal of the pessary. Key outcomes measured were prolapse symptoms (POP-SS)(1), prolapse-related quality of life, prolapse severity (POP-Q)(2), and further prolapse treatment received/expected at 7 month follow-up.
Results
A total of 66 women were approached; 24 were ineligible or unwilling to participate. Of the 42 eligible women, 11 did not successfully retain their pessary so became ineligible. A further 15 women subsequently decided not to take part. The remaining 16 women were randomised (8 intervention, 8 control). The mean age of randomised women was 63.1 years (SD 14.3), compared to 70.5 years (SD 13.6) for non-randomised women. The majority of women had prolapse involving the anterior vaginal wall. 25% had stage I, 50% stage II, and 25% stage III prolapse. 14 women had a ring pessary, 1 woman a shelf and 1 a soft portex pessary fitted. The groups were comparable at baseline. Compliance with the intervention was good: 75% of intervention women attended 4 or 5 appointments.

The mean POP-SS score (Table 1) was highest in both groups at 7 months, indicating worse symptoms after pessary removal for a month. The mean score was higher in the control group compared to the intervention group at 6 months, but the reverse was true at 7 months.

Table 1. Pelvic organ prolapse symptom score (POP-SS) at baseline, 6 and 7 months

*POP-SS **		Baseline	6 months	7 months
Intervention	N Mean (SD)	7 4.57 (3.87)	8 5.38 (4.72)	4 14.50 (5.46)
Control	N Mean (SD)	8 3.00 (2.20)	7 8.57 (9.65)	3 12.67 (9.24)

** Prolapse symptom score, 0=none, 28 = all symptoms all the time*

Women were asked how much their prolapse symptoms interfered with their everyday life at baseline, 6 and 7 months (Table 2). There was an indication that prolapse was more bothersome after the pessary had been removed in both the intervention and control groups.

Table 2. Prolapse-related quality of life scores in baseline, 6 and 7 month questionnaires

How prolapse interferes with everyday life*		Baseline	6 months	7 months
Intervention	Mean (SD)	2.00 (2.56) n=8	1.88 (2.54) n=8	4.33 (3.62) n=6
Control	Mean (SD)	1.00 (1.41) n=8	2.29 (3.68) n=7	4.00 (3.61) n=3

** scored from 0 (not at all) to 10 (a great deal)*

Women in the intervention group had their pelvic floor muscles assessed digitally during the physiotherapy sessions (Table 3). There was a significant increase in strength (modified Oxford scale) from the first to the last appointment.

Table 3. Pelvic floor muscle strength in intervention group women

Pelvic Floor Muscle Strength (Intervention)	Mean	N*	SD	Z statistic#	Asymp.P value
Fast contraction strength 1st appointment	2.43	7	0.84	-2.388	0.017
Fast contraction strength last appointment	4.86	7	3.38		
Slow contraction strength 1st appointment	2.57	7	0.79	-2.264	0.024

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Slow contraction strength last appointment	3.43	7	0.45	.	

** 1 woman declined pelvic floor assessment at last appointment*; *[#] Wilcoxon signed ranks test*

The change in prolapse stage from baseline to 7 months (1 month after pessary removal) was examined (Table 4). Comparable changes were observed in the intervention and control group. The exception was one intervention group woman whose prolapse stage improved from stage III to stage I. However this woman was planning to have prolapse surgery at the end of the study therefore we assume that her prolapse was still bothersome.

Table 4. Change* in POP-Q severity stage from baseline to 7 month assessment

Change* in POP-Q severity	Intervention (n=6)	Control (n=3)
+2 stages	0	0
+1 stages	2 (33%)	2 (66%)
no change in stage	3 (50%)	1 (33%)
-1 stage	0	0
-2 stage	1 (17%)	0

** A negative value indicates an improvement at 6 months*

Some women still required further treatment for prolapse, 1 woman (intervention group) expected to have surgery; 2 (1 intervention, 1 control) expected referral to a dietician; 1 (control group) had received oestrogen treatment.

Interpretation of results

In terms of feasibility, recruiting to the study proved difficult. Reasons included busy clinics and limited use of pessaries by the recruiting gynaecologists. Women were reluctant to participate, perhaps because they were recruited at a point when the decision to fit a pessary had already been made. Motivation to agree to receive an additional intervention may have been affected. Had recruitment taken place prior to any treatment decisions, uptake may have improved. Older women were less likely to take part; often due to difficulties in attending appointments. Once women were randomised compliance and follow-up was good, suggesting this part of the methodology would be transferrable to a larger trial. Compliance was lower in the control group; comments from some participants suggested that this was because they felt they were “missing out”.

Concluding message

This study has helped us plan a larger study which will tell us how effective a combined treatment for prolapse is when compared to single therapies. Important issues were identified

relating to the feasibility of the trial protocol, and useful pilot data were successfully collected. Funding for a full size multicentre will be sought based on these findings.

References

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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**