19

Hagen S[1], Stark D[2], Sinclair L[1], Glazener C[3], Ramsay I[2]
1. NMAHP Research Unit, 2. Southern General Hospital, 3. Health Services Research Unit

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

Hypothesis / aims of study
There is a lack of evidence as to whether pelvic floor muscle training (PFMT) for women with pelvic organ prolapse (POP) is effective yet many physiotherapists offer this treatment. This study aimed to develop the methods and assess the feasibility of a multi-centre randomised controlled trial of PFMT for POP. As part of the study, pilot data were collected to test questionnaires and inform sample size calculations in preparation for undertaking the full multi-centre trial.

Study design, materials and methods
A trial was designed and implemented at two centres where 47 women were recruited: 23 randomised to a 16-week PFMT intervention and 24 randomised to a control group (receiving a lifestyle advice sheet).

Intervention:
The intervention group received an individualised programme of PFMT delivered by a physiotherapist. This consisted of an initial one-hour appointment followed by four 30-minute appointments at weeks 2, 6, 11 and 16. Women were instructed to carry our six sets of exercises daily and to record compliance in an exercise diary. Control group women did not see a study physiotherapist.

Outcome measures:
- prolapse type and severity (blinded POP-Q assessment by physician), at baseline and 20 weeks
- prolapse-related symptom severity and quality of life via postal questionnaires, at baseline, 20 and 26 weeks
- pelvic floor muscle strength assessed at each physiotherapy appointment (Modified Oxford scale) (intervention group only).

Results
The feasibility study identified important issues regarding recruitment, prolapse measurement, and study processes and documentation which will lead to improvements in the main multi-centre trial.

Pilot data indicated that the distribution of prolapse types was similar in the intervention and control groups. The most common type was cystocele (83% and 88% in the intervention and control group respectively).

Analysis of data from the 20 women who had complete POP-Q measurements recorded at both baseline and 20 weeks indicated that the intervention group were more likely to have an improvement in prolapse stage (Fisher's exact test p=0.038) (Table 1).

Table 1 Change in POP-Q severity from baseline to 20-week assessment
(frequency (%))

	Intervention (n=11)	**Control (n=9)**
+2 stages	0 (0)	0 (0)
+1 stages	1 (9)	3 (33)
no change	5 (45)	6 (67)
-1 stage	4 (36)	0 (0)
-2 stage	1 (9)	0 (0)

There was a significant difference between the intervention and control group at 26 week follow-up in change in prolapse symptom score since baseline (Table 2).

Table 2. Change in prolapse symptom score (sum of 7 symptom questions, min. 7=no symptoms, max. 35=all symptoms present all the time)

	Intervention (n=17) Mean (SD)	**Control (n=20) Mean (SD)**
Baseline	16.2 (5.8)	14.6 (4.2)
26 week follow up	12.8 (3.4)	14.5 (4.8)
Difference in change score (baseline – 26 weeks) between intervention & control (mean [95% CI])	3.4 [0.5 to 6.2]	

There was no significant difference between intervention (mean score 2.0 SD 1.5) and control women (mean score 2.1 SD 2.3) with respect to interference with everyday life due to their prolapse.

Women were asked in follow-up questionnaires how their prolapse compared to the start of the study. There were significant differences between the groups at both 20 (p=0.001) and 26 weeks (p=0.024), with greater proportions of intervention women reporting improvement (Table 3).

Table 3 Self-reported change in prolapse since start of study (frequency (%))

	Intervention	**Control**		
	20-week (n=19)	**26-week (n=19)**	**20-week (n=21)**	**26-week (n=21)**
the same/worse	9 (47)	7 (37)	20 (95)	16 (76)
better	10 (53)	12 (63)	1 (5)	5 (24)

Pre- and post-intervention pelvic floor muscle strength measurements were available for 15 out of the 23 intervention women. Based on these data there was evidence of an improvement in muscle strength (Wilcoxon Signed Ranks Test Z=-2.385, p=0.017). The mean change in muscle strength was 0.5 on the Modified Oxford scale.

Interpretation of results

This feasibility study identified important modifications necessary for the success of a larger multi-centre trial. Despite the small sample size there were interesting findings from the analysis of the pilot data. Women in the intervention group had significantly more improvement in prolapse severity and prolapse symptom score, and were significantly more likely to say that their prolapse had improved since the start of the study. There was however no significant difference between groups in overall prolapse-related quality of life.

Concluding message

This study confirmed the feasibility of a multi-centre trial and, even with a small sample size, gave encouraging results regarding the positive effect of PFMT on prolapse and its symptoms. Based on the pilot data it is recommended that a trial of 500 women is needed in order to detect important differences in outcome due to PFMT.

FUNDING: Chief Scientist Office
DISCLOSURES: NONE
CLINICAL TRIAL REGISTRATION: ISRCTN register, clinicaltrials.gov
HUMAN SUBJECTS: This study was approved by the Southern General Hospital and Grampian Research Ethics Committees and followed the Declaration of Helsinki Informed consent was obtained from the patients.