

A COMMUNITY INTERVENTION STUDY OF FEMALE PELVIC FLOOR CONDITION AND KNOWLEDGE OF PELVIC FLOOR EXERCISES: PART 2 RANDOMISED CONTROLLED TRIAL OF PELVIC FLOOR MUSCLE TRAINING IN WOMEN WITH A WEAK PELVIC FLOOR.

Hypothesis / aims of study

The condition of the pelvic floor has been intimately implicated in the development of stress urinary incontinence and pelvic floor muscle training (PFMT) has been shown to be effective in its prevention and treatment. It is known that the pelvic floor muscles can be difficult to identify for individual women and that supervision is required to enable them to do pelvic floor exercises properly. Also, it has been shown that 30% of women asked to do so are unable to contract their pelvic floor correctly and that a quarter of women were using a technique that could potentially promote incontinence. Even in fit, nulliparous, young women one in ten could not contract the pelvic floor to any extent. Simple verbal or written instruction was not adequate preparation for PFMT. However, once learnt properly pelvic floor exercises produced favourable results that persist in many women for at least 10 years (1), and it has been shown that nurses with limited training could effectively provide effective PFMT (2).

The aims of the first part of this study were to 1. find the proportion of women of different ages who are unable to contract the pelvic floor and to identify the condition of the pelvic floor in the population 2. explore and identify the relative importance of various factors relating to an inability to contract the pelvic floor. The aim of part 2 was to evaluate the effectiveness of an educational programme for pelvic floor exercises delivered by a pelvic floor specialist or by a short course-trained nurse.

Study design, materials and methods

This was a nested design comprising a prospective cohort study together with a controlled trial intervention after baseline assessment in the cohort study for a defined at-risk group (modified Oxford score 2 or less). The study took place within primary and secondary care settings, usually when women attended for procedures that included vaginal examination (e.g. cervical smears). Details of health and background were recorded, and validated questionnaires on general health (SF 36), incontinence (Bristol Female Lower Urinary Tract Symptoms) and sexual function were given for home completion.

Pelvic floor muscle function was assessed using vaginal squeeze pressure (perineometry), and was the primary outcome for the trial. The modified Oxford Grading System of vaginal palpation (3) was also used to assess and monitor correct contraction of the pelvic floor.

Practice Nurses were trained using a short course designed specifically for the study. It involved a theoretical and practical introduction together with further supervision and instruction at their surgeries from the pelvic floor specialist. It covered both pelvic floor assessment and the teaching of pelvic floor exercises. Women identified as having a weak pelvic floor were invited to enter part 2 of the study and were randomly allocated to either 1. control group (no treatment) 2. supervised PFMT by a Practice Nurse or 3. supervised PFMT by a Specialist Nurse. Over a three month period the exercise subjects were given the pelvic floor education programme to develop an ability to contract the pelvic floor and then to develop the strength and endurance of pelvic floor contractions. After the initial training each exercise subject was seen monthly. After 3 months the condition of the pelvic floor muscles were assessed again in all the trial subjects. Using information from previous studies the mean value of perineometry for a weak pelvic floor was taken to be around 7 cm water and strengthened measures to be 10 and 12, with a common standard deviation of 7. A sample size of 50 would give a power of 80% to detect a contrast between the highest and the other two measures. To allow for a 30% dropout rate (found in previous behaviour intervention studies) this figure needed to be raised to 65 per group, or a total of 195.

Results

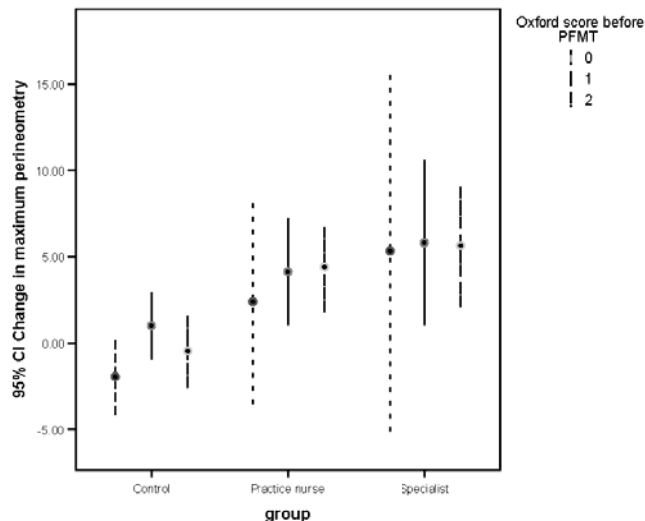
For part one 764 women from 11 General Practices were assessed. Forty per cent were found to have weak pelvic floor muscles (modified Oxford score 2 or less). Two hundred and forty of these were randomised to one of the three groups (75 control, 84 Practice nurse, 81 Specialist). The mean baseline maximum perineometry was 13.8cm H₂O (SD 8.6).

Table 1: Change in maximum perineometry

group	Mean	Std. Deviation	N	Minimum	Maximum
Control	-0.13	5.00	56	-12.7	11.3
Practice nurse	4.10	6.23	50	-7.7	26.7
Specialist	5.67	9.35	53	-13.0	47.0
Total	3.14	7.47	159	-13.0	47.0

Both treatment groups showed a significant increase in pelvic floor strength compared with Controls ($p < 0.01$ both groups). The difference between the Practice Nurse and Specialist groups was not significant ($p = 0.32$).

Figure 1: Change in maximum perineometry by initial Oxford score and group



As can be seen in figure 1, there was improvement in PFM strength irrespective of the initial Oxford score. By the end of the study 51% in the Practice Nurse group and 56% in the Specialist group had an Oxford score of 3 or more compared with 18% in the Control group. The change in Oxford score was significant between the Control and two treatment groups ($p < 0.01$).

Interpretation of results

After 3 months of supervised PFMT women with weak pelvic floor muscles were able to show a significant increase in strength. Differences between that achieved by Practice Nurses and the Specialist Nurse were comparable. Some of those with initial Oxford score of 0 were shown to have improved in strength, possibly because they were scored 0 when they were unable to perform a correct contraction at the first visit. The subjects were recruited from a general population and were not necessarily symptomatic.

Concluding message

The short course trained nurse is quite capable of providing supervised PFMT and can assist women in the general population to achieve an objective improvement in pelvic floor strength.

References

- (1) BJU Int (2000) 85(6): 655-658.
- (2) BMJ (1991) 303: 1308-12.
- (3) Physiotherapy (2001) 87: 631-642.

FUNDING: Wellbeing of Women (RCOG)

CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the Plymouth Local Research Ethics Committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.