A Prospective MultiCentre Randomized Controlled Trial comparing clinician assisted Pelvic Floor Exercises with the PeriCoach™ system assisted Pelvic Floor Exercises in the management of female stress urinary incontinence

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Introduction & Objectives:
Urinary incontinence is a complex disorder. This complicates the search for effective treatments, though pelvic floor muscle exercises (PFME) form the mainstay of conservative treatment. Incontinence has a negative effect on women's quality of life and is a source of social embarrassment. The PeriCoach™ system (PC) comprises a novel vaginal sensor device, web portal and smartphone app to assist with motivation and adherence to PFME. The device provides biofeefback by detecting pelvic floor muscle activity during guided exercise, and transmits this data to a smartphone or tablet via Bluetooth, which is subsequently available in a secure database. The aim of this study was to evaluate the efficacy of the PC in females with stress, or mixed (predominantly stress) urinary incontinence and the impact on quality of life with its use.

Methods:
This was a pragmatic multicentre randomised controlled trial with sites across Australia. Ethics approval was gained from the Human Research Ethics committee at each site. A recruitment target of 100 women aged ≥18 years who met inclusion criteria were screened before randomization to PFME/PC or standard PFME. All women were trained in PFME and asked to perform 2-3 sets daily, sets varied by site based on practitioner assessment. The PFME/PC group was also trained in device use. Both groups received treatment for 20 weeks. Participants in the PFME/PC group were encouraged to use the PC at least once daily. The primary endpoint was ≥30% reduction in leakage in 24hr pad weigh test at weeks 4 and 20. Secondary endpoints included Incontinence Quality of Life (IQOL), Prolapse/Incontinence Sexual Questionnaire IUGA Revised (PISQ-IR), and PFM strength change. Change from baseline was compared using a Mixed ANOVA with group (PFME vs PFME/PC), week (4,20) and their interaction effects in the model. N (%) of subjects with 1-point increase in PFM strength was compared.

Results:
Enrolment concluded with 51 women randomized and available for analysis. Pad Weight data showed improvement in favour of PFME/PC group, though lacking power for significant difference. For IQOL, subjects in PFME/PC reported improved quality of life compared to the PFME group (p=0.0154). Subscales of IQOL were all in a favourable direction for PFME/PC with Psychosocial Impact highly significant (p=0.0165) and Social Embarrassment borderline (p=0.0520). The PISQ-IR presented statistically significant satisfaction in favour of PFME/PC (p=0.0061). PFM strength change of ≥1 point on the Modified Oxford, and 30% reduction in pad weight were statistically significant for both groups (p<0.0001; 56% vs 62% and 37% vs 56% both in favor of PFME/PC) though with no statistically sig difference between groups.

	Pad Weight Change from baseline		IQOL Change from baseline *		PISQ-IR Change from baseline for sexually active subjects *	
	LS Mean	SE	LS Mean	SE	LS Mean	SE
PFME Wk4	7.40	1.92	5.73	2.56	NA	NA
PFME Wk 20	6.18	2.07	10.85	2.67	-2.46	1.06
Peri W4	7.60	2.02	11.50	2.67	NA	NA
Peri Wk 20	4.96	2.19	18.67	2.83	1.71	0.92

* Statistically significant p-value for the group effect.

Conclusions:
PeriCoach, a novel biofeedback system for assisting patients to perform and adhere to PFME was studied in women with stress incontinence, and its effectiveness as compared to clinician-guided unassisted PFME. A clear advantage in quality of life scores and sexual satisfaction is evident for subjects using the PeriCoach device. Both groups showed similar improvement in leakage and PFM strength.