

A prospective multicentre randomised controlled trial of quality of life and sexual satisfaction comparing clinician assisted pelvic floor exercises with PeriCoach assisted pelvic floor exercises in the management of female stress urinary incontinence

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Objectives

Urinary incontinence causes social embarrassment and lack of confidence for sexual engagement (Bo, 1999). PFME done properly develop PFM strength, reducing incontinence and shown to influence sexual dysfunction (de Mendes, 2016). The aim of this study is an interim analysis evaluating sexual satisfaction with relation to use of PeriCoach—a sensor device with Smartphone app to assist performance and compliance of PFME.

Materials & Methods

To date, 47 female patients ≥18 years meeting inclusion criteria undergo baseline screening prior to being randomised to one of two groups: PeriCoach and PFME (PFME/PC) or standard clinician-guided PFME as practiced at each site. All patients are trained to perform PFME as per standard clinic practice. PFME/PC group are also trained on device use. The Sexual Questionnaire (PISQIR IUGA) was collected only at baseline and week 20. Change from baseline to week 20 was analysed and compared between the groups for the sexually active participants (Q7-Q20). Q7-11, 15-20 from Section 2 are presented graphically in Figure 2 (Blue: PFME; Pink: PFME/PC).

Results

Currently 47 patients (mean age 41.2 years) have been randomized between the groups. Of the 38 subjects available at baseline (18 and 20) were sexually active and filled out the questionnaire, with 30 subjects (13 and 17) still active at week 20. The overall sexual satisfaction score increased (p=0.0765) for the PFME/PC, but worsened significantly (0.0273) for the PFME group by week 20. The group effect was highly significant (p=0.0061) when compared change from baseline between the groups in favour of PFME/PC. Also Figure 2, Q8, emotional state manifesting during sexual activity (Translation Protocol PISQ-IR, page 19), showed improved shame and fear score for the PFME/PC. The response data for Q18 also supports this improvement further, with reduced fear scores with relation to fear of urine leakage during sexual activity.

Conclusions

PeriCoach, a novel sensor device for assisting patients to perform and comply with PFME, is being studied in women with stress incontinence. Preliminary data shows that the PeriCoach may offer assistance in early improvement of urinary incontinence for the sexually active subject and increase their overall sexual satisfaction. Results support the PeriCoach use as showing superior sexual satisfaction outcomes when compared with the PFME group, and when looking at the individual question scores, it may indicate that the biofeedback of the PeriCoach leads to improved overall confidence.

Figure 1: Results of sexual satisfaction (PISQIR IUGA)

	LSM (SE)			LSM (SE)		p-value [1]
	Baseline	Week 20	Change	PFME	PFME/PC	
PFME/PC	54.15 (1.070)	55.00 (0.868)	1.71 (0.924)	-2.46 (1.057)	1.71 (0.924)	0.0061
PFME	54.44 (1.128)	52.08 (0.993)	-2.46 (1.057)	P = 0.0273 [2]	P = 0.0756 [2]	
p-value [1]	0.8509	0.0350	0.0061			

[1] from ANOVA comparing the 2 groups; [2] from ANOVA comparing each group to 0

Figure 2: Summary of Q-IUGA-PISQ-IR Response for Sexually Active Subjects Change from Baseline

