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# A SINGLE BLIND, RANDOMISED, CONTROLLED TRIAL OF PELVIC FLOOR MUSCLE TRAINING WITH HOME ELECTRICAL STIMULATION IN THE TREATMENT OF URODYNAMIC STRESS INCONTINENCE.

## Hypothesis / aims of study

Physiotherapy is established as the mainstay of conservative treatment for urodynamic stress incontinence (USI), with pelvic floor muscle training (PFMT) more effective than no treatment or electrical stimulation (ES) (1).
The purpose of this study was to assess whether home pelvic floor ES in combination with PFMT is more effective than PFMT alone, for the treatment of USI.

## Study design, materials and methods

Women with urodynamic stress incontinence were prospectively recruited from a busy urodynamics clinic in a tertiary referral centre, over a four year period. They all had either a new diagnosis, or had no treatment in the preceeding 6 months. They were randomised into four groups: 1) PFMT + active home ES; 2) PFMT + sham home ES; 3) PFMT alone; 4) deferred treatment and then cross-over into group 1 with reassessment. Initial treatment period was 14 weeks.
All PFMT was undertaken by an experienced physiotherapist and included tailored individual lifestyle advice, with review at weeks 1, 3, 6, 10, and a closing visit at week 14. Home ES was performed using a Unomax stimulator with a Periform intra-vaginal electrode. The sham (inactive ES) system was manufactured to be identical to the active device. Outcome was assessed using a standardised pad test (bladder volume 250mls, half hour exercise program), and condition-specific, validated quality of life questionnaire (Kings Health Questionnaire), at baseline and post-treatment. The investigator was blinded to treatment modality at the time of assessment. Statistical analysis was undertaken using SPSS (v11) on an intention to treat basis.

## Results

A total of 173 women were recruited to the study, and 129 completed treatment.
Demographic baseline data
Kruskal-Wallis test showed no significant difference in age (p=0.116) or baseline pad weight (0.127) between the groups. Data is included where collected prior to withdrawals.

| | **N=** | **Mean age – years (SD)** | **Withdrawals (%)** | **Baseline pad weight– g (SE)** | **Pad weight change– g (SE)** |
|---|---|---|---|---|---|
| **1.PFMT + ES** | 82 | 50.37 (11.46) | 15 (18.3%) | 9.98 (1.56) | -5.74 (1.91) |
| **2.PFMT + sham** | 42 | 51.5 (9.69) | 12 (28.5%) | 10.02(2.61) | -2.01 (2.15) |
| **3.PFMT** | 40 | 46.16 (8.53) | 10(25%) | 11.97 (3.34) | - 9.62 (3.37) |
| **4.No treatment** | 20 | 47.47 (11.46) | 7(35%) | 8.04 (4.93) | 3.65 (1.71) |

Pad weight change
Compared using independent samples t test (assuming unequal variances)

| | **1.PFMT + ES** | **2.PFMT + sham** | **3.PFMT** |
|---|---|---|---|
| **1.PFMT + ES** | | | |
| **2.PFMT + sham** | P=0.199 | | |
| **3.PFMT** | P=0.321 | P=0.063 | |
| **4.No treatment** | **P=0.001** | **P=0.046** | **P=0.001** |

Improvements in quality of life scores across domains of the Kings Health Questionnaire
Wilcoxon Signed Rank Test

| | GHP | II | RL | PL | SL | PR | E | SE | SM |
|---|---|---|---|---|---|---|---|---|---|
| **1.PFMT + ES** | .273 | **.0001** | **.0001** | **.0001** | **.001** | .112 | **.0001** | **.001** | **.007** |
| **2.PFMT + sham** | **.033** | .059 | .224 | .298 | .974 | .234 | .082 | .332 | .470 |
| **3.PFMT** | .248 | **.025** | **.001** | **.015** | **.032** | .268 | **.028** | .307 | .074 |
| **4.No Rx** | .102 | 1.000 | .228 | .680 | 1.000 | .524 | .607 | .681 | .821 |

**Interpretation of results**

These results confirm previously reported findings that PFMT is more effective than no treatment for the treatment of urodynamic stress incontinence. There is no objective evidence that home ES in combination with PFMT confers any additional benefit over PFMT alone. This may be due to poor compliance with home ES.

There was, however, significant subjective improvement across most domains, as assessed by the Kings Health Questionnaire, for the active stimulation group and pelvic floor muscle training groups. This was not mirrored by the sham group, which may be a manifestation of a relatively small sample size.

**Concluding message**

Pelvic floor muscle training is an effective treatment modality for urodynamic stress incontinence. It significantly reduces urine loss when compared with no treatment, and improves quality of life. There is no evidence, however, that the concomitant use of a home electrostimulator device confers any additional benefit.

**References**

1. Single-blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. BMJ 1999; 318(7182):487-93

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