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Broad Category: Female Stress Urinary Incontinence

Title: Effectiveness and cost-effectiveness of biofeedback-assisted pelvic floor muscle training for female urinary incontinence: a multicentre randomised controlled trial

Hypothesis/aims of study
Urinary incontinence (UI) is a common, distressing condition affecting approximately a third of women (1). Current national guidelines (2) recommend a minimum of 3 months PFMT for women with UI. The addition of electromyography (EMG) biofeedback may support women's exercise motivation and performance, potentially improving their continence compared with PFMT alone, but may have greater costs associated with it (3). This study aimed to determine the effectiveness and cost-effectiveness of EMG biofeedback-assisted pelvic floor muscle training (biofeedback PFMT) compared to pelvic floor muscle training alone (PFMT) for female stress or mixed urinary incontinence (SUI, MUI).

Study design, materials and methods
A multicentre, parallel group, randomised controlled trial compared biofeedback PFMT with PFMT alone in terms of UI severity at 2 years. There were two parallel studies (not reported here): a mixed methods process evaluation and a longitudinal qualitative case study. Recruitment to the trial took place between February 2014 and July 2016 at 23 community and outpatient care centres. Women 18 years or older with a new diagnosis of stress or mixed UI, who were able to contract their pelvic floor muscle, were eligible to participate. Excluded were women who had received PFMT within the past year, had urgency UI or prolapse greater than stage II, were pregnant or less than 6 months postnatal, undergoing treatment for pelvic cancer, had cognitive impairment, a neurological disease, or a known nickel intolerance, or were participating in other UI research.

Participants were randomly assigned (1:1) via remote computer allocation (minimised by type of UI, centre, age <50/≥50 years, and UI severity) to the biofeedback PFMT or PFMT group. All participants received an individually tailored PFMT programme and were offered six therapist appointments over 16 weeks. The biofeedback PFMT group additionally received biofeedback during appointments and were given a biofeedback unit for home use. Recognised Behaviour Change Techniques were incorporated into the PFMT protocols delivered for both groups. Outcome data were collected via questionnaire at 6 months, 1 and 2 years. Primary outcome: International Consultation on Incontinence Questionnaire UI Short Form (ICIQ-UI SF) score at 2 years. Secondary outcomes included: ICIQ-UI SF at 6 months and 1 year, global impression of improvement (PGI-I), uptake of other UI treatment, and pelvic floor muscle function (blinded assessment at 6 months). Primary health economic outcome: incremental cost per quality-adjusted-life-year (QALY) gained at 2 years based on EQ-5D-3L. Blinding of participants, treating therapists and researchers to group allocation was not possible. Participants completed diaries to record their home PFMT and biofeedback use.

The primary analysis was by intention-to-treat, with participants' observed data analysed according to their randomised group. Group differences in ICIQ-UI SF scores at 2 years were assessed using a linear mixed model adjusting for minimisation variables, therapist type (physiotherapist/other therapist) and baseline score. Centre was fitted as a random effect. Secondary outcomes were analysed similarly using appropriate generalised linear models. A sample size of 468 (234 per group) was needed to detect a difference of 3 points on the ICIQ-UI SF between the groups with 90% power and a 5% level of significance, assuming a standard deviation of 10. We aimed to randomise 600 women to allow for over 20 % dropout. Sensitivity analyses were conducted to examine the effect of missing data and non-compliance. The exploratory subgroup analyses by age (<50/≥50 years), UI type and severity (ICIQ-UI SF score <13/≥ 13), and type of therapist used a stricter 1% significance level.

Results
600 women were randomised, 300 per group. The mean age of participants was 47.7 years (SD 11.5), and 61.3% had mixed (stress and urgency) UI. The trial group characteristics were

well balanced at baseline. Adherence (fully explored in the process evaluation) was comparable between groups in terms of appointment attendance and undertaking the home programme.

Questionnaire response rates at 6 months, 1 and 2 years were 74%, 83%, 77% and 74%, 85%, 79% for the biofeedback PFMT and PFMT groups respectively. Primary outcome data were available for 460 participants (225 biofeedback PFMT and 235 PFMT). There was no significant difference between the groups in the ICIQ-UI SF score at 2 years (mean for biofeedback PFMT 8.2 (SD 5.1) and PFMT 8.5 (SD 4.9); mean difference -0.09, 95% CI -0.92 to 0.75) (Table). The results of planned sensitivity analyses of the primary outcome measure produced very similar findings under different assumptions about non-compliance with the intervention and missing data (results not shown). There were no significant subgroup effects: the difference between groups did not appear to differ by age, UI type, UI severity or therapist type (results not shown). There were no differences between groups in the ICIQ-UI SF score at 6 months (mean difference 0.39, 95% CI -0.33 to 1.12) and 1 year (mean difference 0.57, 95% CI -0.17 to 1.31) (see Table).

Table. ICIQ-UI Short Form Score by group, at baseline, 6 months, 1 and 2 years

	ICIQ-UI Short Form score*					
	Biofeedback PFMT			**PFMT alone**		
	N	Mean	SD	N	Mean	SD
Baseline	291	12.5	4.1	294	12.3	3.7
6 months	221	9.0	5.0	221	8.8	4.5
1 year	249	9.1	4.9	252	8.7	5.0
2 year	225	8.2	5.1	235	8.5	4.9

** ICIQ-UI SF range 0 to 21, with higher scores indicating more severe incontinence*

Participant reported improvement: At 2 years there was no significant difference between groups in the PGI-I score (OR 1.14, 95% CI 0.75 to 1.72), with 41% (biofeedback PFMT) and 38% (PFMT) reporting they were “very much better” or “much better”.
Exercise adherence: At 2 years, the proportion exercising at least once a week was 52.0% in the biofeedback PFMT group and 46.3% in the PFMT group.
Pelvic floor muscle contraction strength: There was no difference between the groups in the Oxford Score for slow contraction strength at 6 months (OR 1.28, 95% CI 0.86 to 1.89, p=0.22), with 43.8% (biofeedback PFMT) and 39.7% (PFMT) scoring 4 or 5 out of 6.
Uptake of further treatment: By 2 years, similar proportions of women had received surgery for UI (12.3% biofeedback PFMT, 9.3% PFMT, OR 1.25, 95% CI 0.35 to 4.46). Uptake of further non-surgical care/treatment for UI was also comparable between groups (81.7% biofeedback PFMT, 79.7% PFMT, OR 1.35, 95% CI 0.54 to 3.41)
Cost-effectiveness: Biofeedback PFMT was not significantly more expensive than PFMT alone and did not generate significantly higher QALYs. The incremental cost-effectiveness ratio (ICER) was £56,617. The probability that biofeedback PFMT would be cost-effective was 48% and 49% at £20,000 and £30,000 thresholds for willingness to pay (WTP) for a QALY.

Interpretation of results
We found no evidence of a difference between biofeedback PFMT and PFMT for UI severity at 2 years, nor any difference in secondary outcome. The ICER indicated that Biofeedback PFMT would not be considered to be cost-effective at society’s WTP upper threshold of £30,000. Symptoms of UI were no better for women who had received biofeedback. Around half of participants were exercising weekly at 2 years regardless of trial group.

Concluding message
There is no evidence from this trial that the addition of EMG biofeedback to a robust protocolised programme of PFMT (including behaviour change techniques) offers benefit in terms of long-term continence outcomes. Other methods of encouraging long-term practice of PFMT to maximise its benefits should be investigated.

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