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IS BIOFEEDBACK AUGMENTED PELVIC FLOOR MUSCLE TRAINING MORE EFFECTIVE THAN PELVIC FLOOR MUSCLE TRAINING ALONE FOR URINARY INCONTINENCE IN WOMEN? A SYSTEMATIC REVIEW WITH META-ANALYSIS

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HYPOTHESIS / AIMS OF STUDY
The Committee on Conservative Management from the 7th International Consultation on Incontinence stated that the benefit of adding biofeedback to pelvic floor muscle training remains unclear [1]. A meta-analysis was not presented. We are updating the 2011 Cochrane review of feedback and biofeedback augmented pelvic floor muscle training (PFMT) for women with urinary incontinence [2]. Our aim is to incorporate the data from all eligible trials comparing biofeedback augmented PFMT versus PFMT alone, and to meta-analyse the data to increase the power and accuracy in estimating effect. The decision to use biofeedback in clinical settings should be based primarily on whether it is an effective adjunct to PFMT or not.

The Cochrane review update investigates the effectiveness of feedback, biofeedback, the combination of feedback and biofeedback, and one type of biofeedback versus another. This abstract addresses only the effectiveness of biofeedback augmented PFMT versus PFMT alone for the treatment of UI in women.

STUDY DESIGN, MATERIALS AND METHODS
Systematic review methods were according to the Cochrane Handbook for Systematic Reviews of Interventions [3]. The previous review was, as per Cochrane practice, the published protocol for the update [2].

Eligible trials were (quasi) randomised controlled, in women with UI. Interventions were PFMT with or without feedback (from digital palpation) or biofeedback. Biofeedback collected a biological signal (e.g. squeeze pressure) during a voluntary pelvic floor muscle contraction and simultaneously presented this in auditory or visual form (or both). We excluded trials in women with neurological conditions, pregnant or postpartum women (<6 months from delivery).

The Cochrane Incontinence Specialised Registry (containing trials identified from: Cochrane Central Register of Controlled Trials, MEDLINE, CINAHL and handsearching) was last searched in July 2022. Records were screened in Covidence. Two reviewers independently: screened titles and abstracts, and full text of all potentially eligible studies; extracted included study data onto a template updated from the previous review and assessed risk of bias using the Cochrane Risk of Bias tool (version 1). Any disagreements in these processes were resolved through discussion.

Incontinence quality of life (QoL) meta-analysis used the standardised mean difference (SMD) and inverse variance weighted method. SMD was necessary to pool data from any one of the nine incontinence QoL instruments rated A or A+ (based on psychometric properties) by the 6th International Consultation on Incontinence. In the forest plot a negative value favours PFMT with biofeedback.

Meta-analysis of leakage episodes (converted to 'per 24 hours' by division by the relevant period of reporting) used the mean difference and inverse variance weighted method. A negative value favours PFMT with biofeedback.

Meta-regression was used for subgroup analysis. First, for trials with low risk of bias (random sequence generation and adequate allocation concealment) or higher risk of bias. Second, for trials in women with stress (or stress predominant) UI or other diagnostic groupings.

In the forest plots, trials were ordered by descending effect size. Statistical heterogeneity was assessed by visual examination of the forest plots, Chi squared test for heterogeneity ($P < 0.10$), and I-squared statistic. R version 4.2.2; library 'meta' and function 'metacont' were used for the analyses.

RESULTS
From 2611 records screened, 119 studies progressed to full-text screening. Forty-one were included, 11 were ongoing (potentially eligible) studies, and 67 excluded. Exclusions were for study design (n = 6), population (n = 4), the intervention (n = 24), wrong comparison (n = 32), and 1 trial that was registered but not conducted.

Of the 41 included studies included for analysis, 33 trials (2216 women) compared biofeedback augmented PFMT versus PFMT alone. All remaining results pertain to these 33 trials.

In 26/33 trials women had stress or stress predominant UI, and average ages in all but two trials were 40 to 60 years. Biofeedback: used a variety of biological signals (electrical, pressure) collected by a vaginal, anal or perineal sensor; was offered in clinic, home, or both; and offered once only in clinic up to recommended daily use at home. All PFMT programmes included voluntary pelvic floor muscle contractions although the programmes varied considerably between trials, and in 12 trials the biofeedback group had more supervision of their PFMT. Trialists measured heterogenous outcomes and used heterogeneous measures for the same outcome. Only 22/33 trials measured incontinence QoL using one of the pre-specified measures, and only 16/33 measured leakage episodes. Regarding risk of bias, nine were low, 22 had some concerns and two were high risk.

For incontinence QoL, 11 trials randomised 1169 women with data suitable for analysis (Figure 1). There was no statistical evidence of a difference, with modest evidence of unexplained heterogeneity (I-squared 43% and formal test of heterogeneity P = 0.062). Two studies (Hagen 2020, Weinstein 2022) contributed 39% and 26% of the information respectively. Meta-regression by risk of bias found a SMD of -0.06 (95% CI -0.19 to 0.08, 4 trials, 842 women) in the low risk of bias trials, and SMD -0.09 (95% CI -0.32 to 0.13, 7 trials, 327 women) in the trials at greater risk of bias. Meta-regression by diagnostic group found a SMD of -0.09 (95% CI -0.25 to 0.06, 8 trials, 650 women) in women with stress UI, and SMD -0.04 (95% CI -0.21 to 0.14, 3 trials, 519 women).

For leakage episodes 11 trials randomised 721 women with data suitable for analysis (Figure 2). There was statistical evidence of a difference, favouring biofeedback augmented PFMT, with no evidence of unexplained heterogeneity.

Twelve trials assessed adverse events, eight reporting none. Adverse events (1 each) were urinary tract infection and vaginal irritation with PFMT alone, and yeast infection, vaginal pain with device insertion, vaginal itching and blisters with biofeedback.

INTERPRETATION OF RESULTS
No statistically significant difference in incontinence QoL was found between biofeedback and non-biofeedback groups. Of the two trials that contributed 67% of the information between them, the point estimates favoured PFMT alone in one (Hagen 2020, 40%) and biofeedback in the other (Weinstein 2022, 27%). The moderate unexplained heterogeneity was not explained by risk of bias, or diagnostic grouping. For risk of bias the effect size was similar in low and higher risk of bias studies, neither of which was statistically significant. While the effect estimate for the 'other' diagnostic group favoured biofeedback more than the stress UI grouping, neither was statistically significant. In Figure 1, the confidence limits are from -0.18 (favouring PFMT with biofeedback) to 0.05 (favouring PFMT alone). Therefore, if on the scale of measurement, a standard deviation of about -0.2 reflects a clinically important difference, the meta-analysis lacks power to exclude a clinically important difference.

A statistically significant difference was found, favouring biofeedback, for leakage episodes in 24 hours. There was no evidence of unexplained heterogeneity and therefore no meta-regression was performed. Clinically, the point estimate of -0.25 is a difference between groups of one fewer leakage episodes in four days.

Adverse events were few, and none were serious.

The findings apply, principally, to women of mid-age or more, with symptoms of stress or stress predominant UI.

CONCLUDING MESSAGE

Rather than an unclear effect, it seems there may be no statistically significant effect of biofeedback augmented PFMT on incontinence QoL compared to PFMT alone. While there may be statistically fewer leakage episodes in the biofeedback group, the difference (about one fewer leakage episodes every four days) may be insufficient for this to be observed as a difference in incontinence QoL.

FIGURE 1

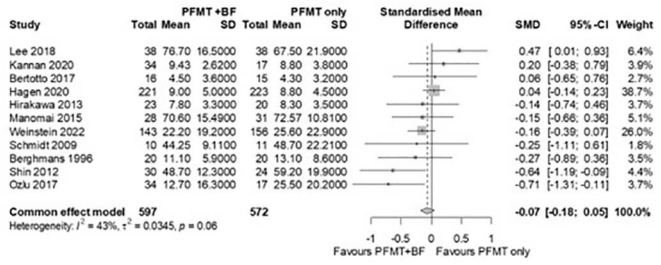

Figure 1. Meta-analysis – standardised mean difference (95% CI) for incontinence quality of life

FIGURE 2

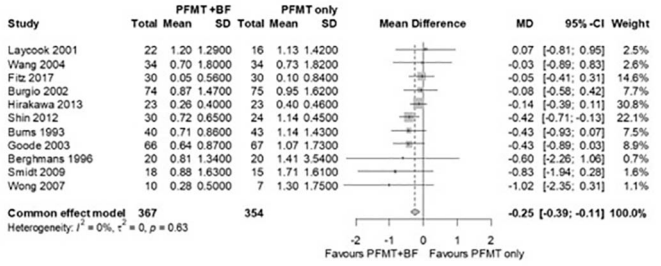

Figure 2. Meta-analysis – mean difference (95% CI) for leakage episodes in 24 hours

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