

IS THE APPARENT EFFECTIVENESS OF BIOFEEDBACK CONFOUNDED BY THE EFFECT OF CONTACT WITH A HEALTH CARE PROFESSIONAL? FINDINGS OF A COCHRANE SYSTEMATIC REVIEW.

Hypothesis / aims of study

The objective of this systematic review was to determine whether feedback or biofeedback adds further benefit to pelvic floor muscle training for women with urinary incontinence. A secondary object was to compare the effectiveness of different forms of feedback or biofeedback.

Among the most common first line therapies for women with uncomplicated urinary incontinence (UI) is pelvic floor muscle training (PFM) training. There is currently no consensus about the optimal type of PFM training, and this lack of knowledge is the main priority for incontinence research [1]. This priority was identified during the development of a methodology (using the James Lind criteria) to choose and prioritise important research questions in UI through consensus between patients and clinicians.

In clinical practice, PFM training is often combined with feedback (often biofeedback (BF)) to help women learn how to contract the muscles or to modulate this contraction or encourage training performance. A recent systematic review of conservative therapies for women with stress UI stated that "There is clear evidence that PFM training plus BF was effective" (page xi) [2]. Feedback and BF are also used to assist with training PFM for women with mixed UI, urgency UI, and overactive bladder syndrome; this review was completed to investigate the effectiveness of these adjuncts to PFM training in women with all types of UI.

Study design, materials and methods

The systematic review methods were consistent with best practice [3]. Reports of trials were sought through electronic and hand searching. Trials were independently assessed for eligibility and risk of bias. Data were extracted by two reviewers and cross-checked. Disagreements were resolved by discussion with a third reviewer. Where appropriate data were meta-analysed, and when this was not appropriate a narrative synthesis was used. The primary outcomes of interest were incontinence specific quality of life, and the women's perceptions of cure or improvement in UI symptoms. Secondary outcomes included leakage episodes, and PFM function. For each outcome data were sub-grouped according to whether there was a difference in the type of PFM training between the trial arms being compared.

Studies were eligible for inclusion if they were randomised controlled trials (RCTs) in women with UI (regardless of cause) in which two or more treatment arms included a programme of repeated voluntary PFM contractions taught by a health professional, with one or more of these arms also using feedback or BF as an adjunct to training. The purpose of the PFM training did not matter; this could be for strengthening, fatigue resistance or using a contraction to counter a rise in intra-abdominal pressure or urgency (through suppressing a detrusor muscle contraction). Feedback was defined as a clinician mediated method of giving information about a voluntary PFM contraction back to the woman performing the contraction (such as verbal feedback from observation or palpation during a contraction). In contrast, BF was the use of an instrument or device to record the biological signals (e.g. squeeze pressure, electrical activity, movement) during a voluntary PFM contraction and present this information back to the woman in auditory or visual form.

Results

Of the 528 records found in the electronic search 250 were immediately excluded for failure to meet the inclusion criteria. From the 278 records retrieved 33 studies were potentially eligible, and 24 trials (total of 1583 women) were included. Sixteen of the 24 included trials compared PFM training with BF versus PFM training, which is the comparison presented here. The trials recruited participants with stress UI only (10 studies), stress or mixed UI (three), urgency UI only (one neuropathic, one idiopathic) and urgency or mixed UI (one).

There was no statistically significant difference in rates of cure reported by women between BF and no BF groups (risk ratio (RR) 1.18, 95% confidence interval (CI) 0.82 to 1.70, five trials). However, twice as many women in the BF group reported cure or improvement (RR 1.42, 95% CI 1.19 to 1.69, seven trials). The subgroup analysis (based on whether the PFMT programmes were the same in both treatment arms or not) showed that the rate of cure was not statistically significantly different in either subgroup. However, for cure/improvement the effect was not consistent (BF with PFMT the same in both arms RR 1.13, 95% CI 0.87 to 1.47, two trials; BF with PFMT different in both arms RR 1.61, 95% CI 1.28 to 2.02, 5 trials).

For quality of life a pooled analysis was not appropriate because of differences in measurement instruments and the different ways in which results were reported. The effect estimates in two separate studies did not demonstrate between BF and no BF groups. However, an overall effect could not be excluded because data could not be combined,

One other meta-analysis was possible. The overall summary statistic showed fewer leakage episodes in women receiving BF although this difference comprised around one fewer leakage episodes every eight days, which questions the clinical relevance of this outcome (weighted mean difference (WMD) -0.12, 95% CI -0.22 to -0.01, eight trials). There was a consistent pattern of no difference in PFM function measures and pad tests.

No difference in the pattern of effect by type of UI was observed. BF given once or twice appeared to be as effective, or more effective than BF given more often.

Interpretation of results

Based on the available data, BF as an addition to PFMT may benefit women with SUI, MUI or UI. Some caution is needed in interpreting these data as another plausible explanation for the effect is that women who receive more contact with a health professional do better. However, it could be argued that the use of BF as an adjunct to PFMT inherently changes the amount, content and quality of attention from the health professional,

If BF is used as an adjunct to PFMT there is some evidence to suggest that it is as effective to use BF once or twice as it is to use it more often, or repeatedly at home. There is too little evidence available to indicate whether the approach matters (e.g. vaginal or anal devices measuring pressure or electrical activity, or ultrasound). Thus, equipment availability and the preferences of women and therapist are likely to dictate choice.

Concluding message

Biofeedback provides additional benefit to pelvic floor muscle training in women with urinary incontinence but the observed effect could well be related to another variable such as the amount of health professional contact rather than the biofeedback per se.

References

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2. Imamura M, Abrams P, Bain C, Buckley B, Cardozo L, et al.. Systematic review and economic modelling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence. *Health Technol Assess* 2010;14(40).
3. <http://www.cochrane.org/training/cochrane-handbook>

<i>Specify source of funding or grant</i>	None
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	NONE