

Title: A process evaluation study investigating fidelity and dose of intervention delivery and uptake of pelvic floor muscle training delivered in a randomised controlled trial.

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Hypothesis / aims of study: To investigate fidelity to intervention delivery, dose and uptake in a randomised controlled trial (RCT) comparing EMG biofeedback (BF) assisted pelvic floor muscle training (BF-PFMT) versus PFMT alone (PFMT), both comprising six appointments with a home programme. Investigating what actually happens clinically in intervention delivery compared with the trial protocol (1) is important; this type of study, previously uncommon in PFMT research, helps explain trial results.

Study design, materials and methods: A mixed methods process evaluation (2) study parallel to a RCT. Six hundred women with stress or mixed urinary incontinence were randomised to BF-PFMT or PFMT. Both interventions included Behaviour Change Techniques (BCTs) (3) to support PFMT delivery, adherence and BF. As an adjunctive therapy, BF is a recognised BCT. Data sources were: therapist completed intervention protocol checklists and clinical report forms (CRFs) (6 appointments, potentially 3,600); home exercise diaries (5 per participant, potentially 3,000); appointment audio-recordings (maximum variation sample of 100 different participants across 6 appointments); post-trial interviews with 30 purposively sampled therapists. Analysis comprised: descriptive summaries of quantitative data (checklists; CRFs; diaries); logistic regression models to estimate adjusted odds ratios to compare therapist adherence rates, content analysis of free text diary responses and audio-recordings; Framework Analysis of therapist interviews.

Results: Ninety-three therapists delivered the interventions to 600 participants (300 per group) across 23 trial sites. The proportion of participants attending 6 appointments was 36.9% (BF-PFMT) and 35.6% (PFMT). Therapists returned 2450 (68%) checklists and CRFs; similar proportions were returned between groups across appointments but return decreased from appointment 1 (91%) to appointment 6 (60%), reflecting participant attrition.

Checklist data showed more BCTs were delivered to the BF-PFMT group; who were meant to receive PFMT related BCTs and BF related BCTs, e.g. for appointment one (Table 1) the median number of BCTs delivered was 18 for PFMT (19 available, column one) and 26 for BF-PFMT (28 available, column 4). This pattern was similar across appointments. The median number of BCTs delivered per appointment was less than the number available but pattern of use was consistent with the protocol: the BF-PFMT group received more than the PFMT group.

Table 1: Summary of checklist BCTs reported delivered for appointment one; by trial groups.

	PFMT Group		Biofeedback PFMT Group	
	Column 1	Column 2	Column 3	Column 4
Appointment 1 No. available BCTs	PFMT BCTs 19		Biofeedback only BCTs 9	PFMT BCTs & Biofeedback BCTs 28
No. of checklists	265	279	279	279
No. of BCTs used	18	18	8	26
Median	18	18	9	27
Mode	17-19	15-18	5-9	20-27
IQR				

From the CRFs therapist adherence to teaching PFMT or BF-PFMT (as appropriate) was 88% in each group (OR 0.69, 95% CI 0.33 to 1.42). Adherence to practicing PFMT, and BF if allocated, during appointments was just under 80% in each group (OR 0.89, 95% CI 0.63 to 1.25). Adherence by women to their unsupervised home programme between appointments was around 80% in each group (OR 0.71, 95% CI 0.43 to 1.16).

Overall 1628 exercise diaries were returned (829 BF-PFMT, 799 PFMT). Similar proportions were returned by each group across appointments, but number returned decreased over time as attrition increased. A similar proportion of diaries were signed by participants and their therapist (BCT called 'commitment') in each group. Free text diary entries indicated the most frequently cited reasons for not exercising: time (BF-PFMT=13; PFMT=33); forgetting (BF-PFMT=7; PFMT=24); other physical health reasons (BF-PFMT=25; PFMT=13); menstruation (BF-PFMT=14; PFMT=6).

Eighty-eight audio-recordings were obtained (88% of target). For BCTs that could be assessed (audible) therapists were heard to use fewer BCTs than those available. This was consistent by group and across appointments, although the BF-PFMT group were still heard to receive more BCTs (e.g. for appointment one see Table 2).

Table 2: Summary of audio-recording coding of BCT delivery by group for appointment one.

	PFMT Group	Biofeedback PFMT Group		
	Column 1	Column 2	Column 3	Column 4
Appointment 1 No. available & audible BCTs	PFMT BCTs 17		Biofeedback only BCTs 7	PFMT BCTs & Biofeedback BCTs 24
No. of audios	7	8	8	8
No. of BCTs audible	11	8.5	3	11.5
Median	10	8	2 & 3	15
Mode	9 - 14	5-12	0-7	7-18
Range				

Thirty therapist interviews were conducted; analysis focused on their perceptions of why and how the interventions engaged women and promoted adherence. Therapists' observed that symptoms prompted PFMT but as symptoms improved it became more common to forget PFMT. Women's levels of motivation and commitment influenced engagement; buy-in was linked to time and energy available for competing priorities including their other health conditions. Therapists thought that if women (mistakenly) expected the BF device to stimulate their muscles they were disappointed and somewhat demotivated. BF in itself was considered motivating in less complex cases. Accountability was important, the requirement for regular attendance and knowing they were going to be assessed, meant women worked harder than they would have done on their own; therapists queried if accountability was felt more strongly in the BF-PFMT group because appointments included reviewing the device's data. Therapists noticed many women struggled to fit BF into their daily routine, especially those who were time-constrained, and working mothers in particular: *"how do I fit this into my daily life? - that's the big issue, and you know, we had quite a few conversations about that"*. Therapists questioned if BF would work better if only used in clinic, or if home BF was key; or if BF was only appropriate for those who struggled doing PFMT due to very weak muscles or lack of contraction sensation. Most hypothesised that BF was more suited to goal-orientated women with time and privacy at home to use equipment.

Interpretation of results: Therapists delivered a BF-PFMT intervention that was more intensive than that delivered to the PFMT group. Most women in both groups received BCTs core to delivery of PFMT; no apparent inadvertent 'intensification' of delivery in the PFMT group occurred. These findings indicate that the RCT did achieve what it set out to do: a fair test of whether an 'intensified' intervention (BF-PFMT) could improve women's outcomes over well delivered PFMT intervention. Findings assist in understanding the trial results, which are unlikely to be attributed to a failure of intervention delivery or uptake.

The multiple data sources enable understanding of the experiences of those involved in the RCT and explain minor variations in intervention delivery and uptake within and between trial groups. The work informs future research and clinical practice, particularly benefits of using BCT informed PFMT protocols to clearly describe intervention content, check for fidelity and assist with replication and implementation (2). One previous PFMT trial reported a process evaluation using a single method (qualitative) approach; this current study is therefore unique in using a theoretically informed mixed-methods process evaluation. Limitations include audio-recording data quality; analytical volume and complexity. Further work is underway to ensure full exploration and learning from these datasets.

Key message: This process evaluation demonstrated robust assessment of intervention fidelity and dose providing evidence that the interventions were delivered by therapists and taken up by women. This means the parallel RCT was a fair test of a more (BF-PFMT) versus less (PFMT) intensive intervention and trial results are unlikely attributed to failure of intervention delivery or uptake.

Keywords: pelvic floor, conservative treatment, physiotherapy, rehabilitation.

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