

Title: A 24 month longitudinal qualitative study of women’s experience of electromyography biofeedback pelvic floor muscle training (PFMT) and PFMT alone for urinary incontinence: adherence, outcome and context

Authors: Bugge C, Hay-Smith EJC, Kovandzic M, Grant A, Taylor A, Hagen S, McClurg D, Dean S for the OPAL Trial Team

Aims of study: To investigate women’s experiences of electromyography (EMG) biofeedback PFMT and pelvic floor muscle training (PFMT) alone for stress or mixed urinary incontinence (UI) to explain the contextual factors that influence intervention adherence and outcome within a randomised controlled trial.

Study design, materials and methods: The study design was a two-tailed, longitudinal, qualitative case study (1) carried out in parallel to a randomised controlled trial. The ‘tails’ were the biofeedback PFMT group and PFMT alone group. Following ethical approval, purposive maximum variation sampling (based on difference in treatment centre, UI type, and therapist type) was used to invite a subsample of women, who had consented to the trial, to take part in the case study. Interested women were sent written information about, and asked to consent to, the case study specifically. The data from each recruited women formed one case. Women were interviewed at baseline, six, 12 and 24 months after randomisation. Interviews were semi-structured, digitally recorded and transcribed. Where possible, baseline and six month interviews were face to face and either at the participant’s home or in the clinic, and 12 and 24 month interviews were by telephone. Interviews explored women’s experiences of the social contexts within which they experienced UI, the intervention they received, adherence and outcome. Data analysis followed case study analytic traditions (1) whereby all data from a case were analysed and findings collected together to form a case summary with a focus on understanding a woman’s experience of UI, intervention, adherence and outcome and how these factors interacted. Case summaries within a ‘tail’ were collated, the cases compared, and the two tails were then compared to one another.

Results:

Sample: Forty women, 20 per group, were recruited as planned; 24 had data at all four time points (10 biofeedback PFMT and 14 PFMT alone), with 2856 minutes of interview data recorded. There was a wide age range in both groups (20 to 76 years). Eleven women had stress UI and 29 Mixed UI with similar proportions in the groups. Six women were treated in community clinics, 16 in University hospitals and 18 in District General Hospitals with similar proportions in the groups. Most women were treated by specialist women’s health physiotherapists (n=36) and four by continence nurses.

Table 1: Case study examples of variation in adherence by treatment group and across time

	Receiving Active Treatment		Post Treatment Maintenance	
	Biofeedback PFMT	PFMT alone	Biofeedback PFMT	PFMT alone
Good Adherence	Case 27: uses biofeedback every couple of days and has exercised consistently with no breaks.	Case 14: undertakes PFMT ‘religiously’	Case 17: PFMT at least daily	Case 38: PFMT at least daily
Moderate adherence	Case 39: very good adherence for first couple of months then more ad hoc.	Case 24: does PFMT ‘most of the time’	Case 1: tried for 3x a day but doesn’t always manage – does short pulses and not long holds	Case 36: does PFMT when symptoms return
No / minimal adherence	Case 2: maybe exercises once a week	Case 19: does PFMT irregularly	Case 32: does not do PFMT at all	Case 15: does not do PFMT at all

Adherence: Adherence varied considerably between individual women. There were examples of women who had good adherence throughout the two-year follow up, those who adhered to some extent, and those who did not adhere well at any point (Table 1). Patterns of adherence to PFMT were similar between the biofeedback PFMT and PFMT alone groups. Intervention adherence varied over time as a result of multiple contextual factors. Most women maintained belief in their ability (self-efficacy) to restart PFMT exercise after a break; for instance:

“I don’t feel like I need to go back and see a doctor or, you know, see a nurse or anything, I feel like if it got bad again I could, you know, I’ve got these exercises to fall back on” [Case 27, 24 month interview, biofeedback PFMT group].

Outcome: As with adherence there was considerable variation in UI symptom outcome at the 24 month follow up (Table 2). There were women who were ‘cured’ or ‘almost cured’; those with some improvement; and those with no improvement or / worsening symptoms.

Table 2: Case study examples of variance in UI outcomes at 24 months by treatment group

Nature of outcome	Biofeedback PFMT	PFMT
Good outcome	Case 27 was almost cured with few stress UI symptoms at 24 months, some occasional urgency persisted.	Case 20 was almost cured with her stress symptoms gone completely and urgency only occurring occasionally.
Intermediate outcome	Case 17’s symptoms were not gone but were much improved e.g. she makes it to the toilet most of the time	Case 36 continued to have UI symptoms but they were better than before she started in the trial e.g. she had more time to get to the toilet
Poor outcome	Case 32’s UI symptoms were worse at 24 months than when she started in the trial	Case 24’s symptoms were the same or worse at 24 months than when she started in the trial.

Context: Contextual factors influenced adherence in many ways. Key facilitators of adherence were: a desire to improve and prevent deterioration of UI symptoms and the influence of the treating therapist. For instance:

“that’s what I’m hoping...to stop the leaking, maybe be able to go back to yoga and not feel like I’m worrying about leaking or whatever” [Case 27, baseline interview, biofeedback PFMT group]

“[therapist name] is, is a very good therapist, that made a big difference” [Case 36, six month interview, PFMT alone group].

Key barriers to adherence were: (lack of) time in the context of women’s busy lives and life taking over. For instance:

“I haven’t really had an awful lot of time to concentrate of exercises and stuff like that, just because we’ve been so busy ... our business is still just really extremely, extremely busy” [Case 15, 24 month interview, PFMT alone group].

Interpretation of results: There is an interaction between the context within which women live their lives, their desire and ability to maintain longer-term PFMT adherence (with or without biofeedback) and their UI outcomes. Women greatly value the input of therapists, and face difficult personal choices about life priorities, balancing these with PFMT adherence and UI outcome. For clinicians, recognition of, and shared decision-making that includes, consideration of this complexity is necessary along with specific attention to problem solving and action planning for relapse management.

Concluding message: Adherence to PFMT (with or without biofeedback) and outcome are influenced by contextual factors in women’s lives. Even with considerable value placed on, and learning from, therapist input, women need to create an achievable balance in order to maintain adherence.

Submitted separately

Category: Quality of Life / Patient and Caregiver Experiences

Disclosures and Funding: This trial is registered with the ISRCTN (number 57756448). The OPAL Trial was funded by the NIHR Health Technology Assessment programme (project number 11/71/03). The views expressed are those of the researchers and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care. SD's position is partly supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care South West Peninsula at the Royal Devon and Exeter NHS Foundation Trust.

Ethical approval: Ethical approval for all aspects of the study was granted by the West of Scotland Research Ethics Committee 4 on 13th March 2013 (reference number 13/WS/0048).

Reference

1. Yin KR. *Case Study Research: Design and Methods*. 2009 4th ed. Thousand Oaks: SAGE Publications