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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OPAL

optimising pelvic floor exercises to achieve longterm benefits

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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Aims

To investigate fidelity to intervention delivery, dose and uptake in a randomised controlled trial (RCT).

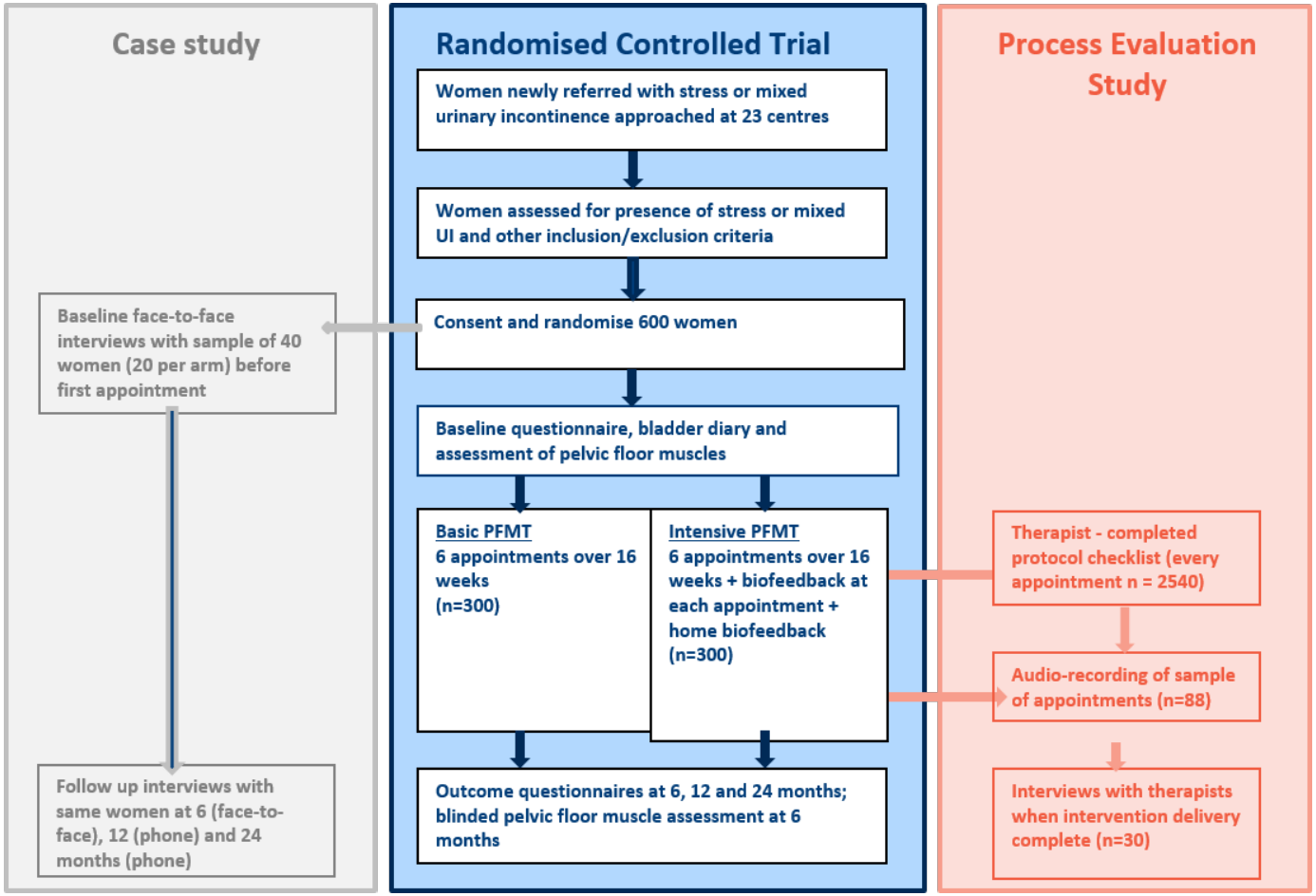
The RCT compares electromyography biofeedback-assisted pelvic floor muscle training (BF-PFMT) versus PFMT alone (PFMT).

The process evaluation asks:

What happens clinically in intervention delivery compared with the trial protocol?

and

Helps explain trial results.



Design

A mixed methods process evaluation study parallel to a RCT:

- 600 women with stress or mixed urinary incontinence
- Randomised to BF-PFMT or PFMT
- 6 appointments offered in each group

Both interventions included Behaviour Change Techniques (BCTs) to support:

- PFMT delivery
- exercise adherence
- BF use

Multiple data sources: appointment checklists and audio-recordings, exercise diaries, therapist interviews.

Mixed methods for analysis

Results: Delivery & Attendance

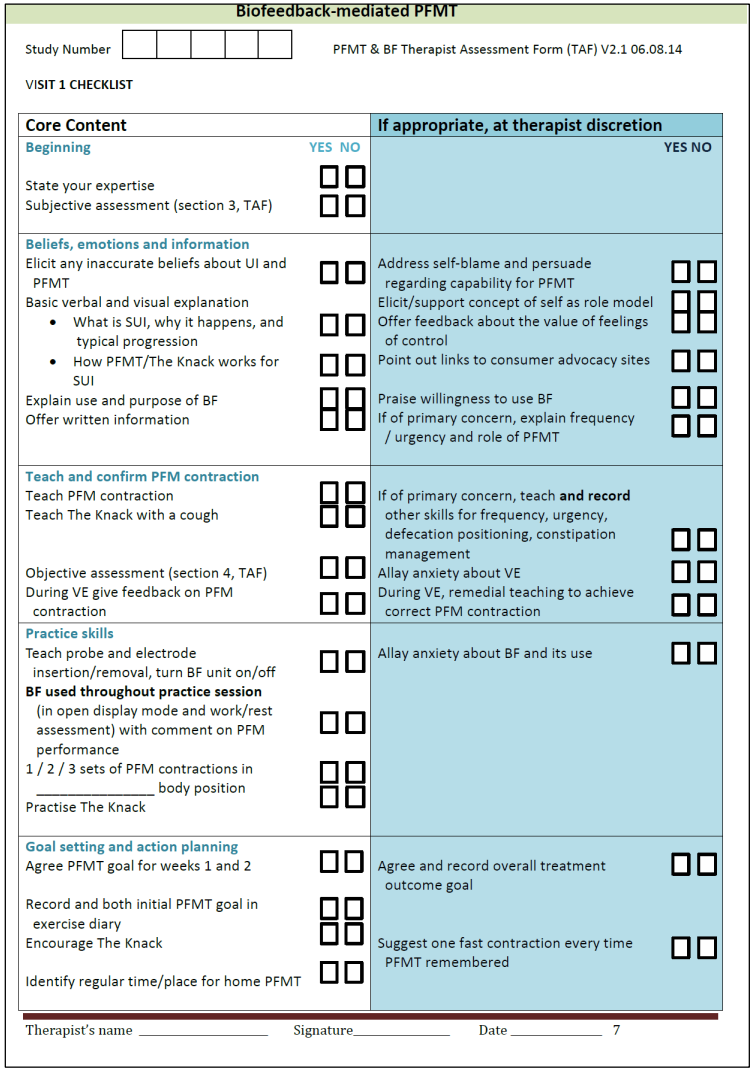
93 therapists delivered the interventions, 300 per group, 23 trial sites.

Attendance at 6 appointments was 36.9% (BF-PFMT) and 35.6% (PFMT).

Results: Checklists (n = 2450, 68%)

2450 (68%) checklists returned (similar proportions between groups across appointments).

Return decreased from appointment 1 (91%) to appointment 6 (60%), reflecting participant attrition.



Biofeedback-mediated PFMT

Study Number ☐☐☐☐☐☐ PFMT & BF Therapist Assessment Form (TAF) V2.1 06.08.14

VISIT 1 CHECKLIST

Core Content	YES	NO	If appropriate, at therapist discretion	YES	NO
Beginning					
State your expertise	☐	☐			
Subjective assessment (section 3, TAF)	☐	☐			
Beliefs, emotions and information					
Elicit any inaccurate beliefs about UI and PFMT	☐	☐	Address self-blame and persuade regarding capability for PFMT	☐	☐
Basic verbal and visual explanation			Elicit/support concept of self as role model	☐	☐
• What is SUI, why it happens, and typical progression	☐	☐	Offer feedback about the value of feelings of control	☐	☐
• How PFMT/The Knack works for SUI	☐	☐	Point out links to consumer advocacy sites	☐	☐
Explain use and purpose of BF	☐	☐	Praise willingness to use BF	☐	☐
Offer written information	☐	☐	If of primary concern, explain frequency / urgency and role of PFMT	☐	☐
Teach and confirm PFM contraction					
Teach PFM contraction	☐	☐	If of primary concern, teach **and record** other skills for frequency, urgency, defecation positioning, constipation management	☐	☐
Teach The Knack with a cough	☐	☐			
Objective assessment (section 4, TAF)	☐	☐	Allay anxiety about VE	☐	☐
During VE give feedback on PFM contraction	☐	☐	During VE, remedial teaching to achieve correct PFM contraction	☐	☐
Practice skills					
Teach probe and electrode insertion/removal, turn BF unit on/off	☐	☐	Allay anxiety about BF and its use	☐	☐
BF used throughout practice session (in open display mode and work/rest assessment) with comment on PFM performance	☐	☐			
1 / 2 / 3 sets of PFM contractions in _____ body position	☐	☐			
Practise The Knack	☐	☐			
Goal setting and action planning					
Agree PFMT goal for weeks 1 and 2	☐	☐	Agree and record overall treatment outcome goal	☐	☐
Record and both initial PFMT goal in exercise diary	☐	☐			
Encourage The Knack	☐	☐	Suggest one fast contraction every time PFMT remembered	☐	☐
Identify regular time/place for home PFMT	☐	☐			

Therapist's name _____ Signature_____ Date _____ 7

Results: Adherence (checklists)

Therapist adherence to teaching PFMT or BF-PFMT (as appropriate) was 88% in each group (adjusted 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 (adjusted OR 0.89, 95% CI 0.63 to 1.25).

Adherence by women to unsupervised home programme was ~ 80% in each group: (adjusted OR 0.71, 95% CI 0.43 to 1.16).

Results: Use of BCTs (checklists)

Median number of BCTs used per appointment less than number available, e.g. appointment 1 had 19 BCTs for PFMT alone, both groups received 18.

More BCTs used for BF-PFMT group than PFMT-alone group (as intended), e.g. appointment 1 had 9 additional BCTs relating to BF, median use was 8.

Overall pattern of BCT use was consistent with protocol.

Results: Use of BCTs (Audios, n = 88; 88% of target)

For BCTs that were audible, therapists used fewer BCTs than those available.

Pattern consistent by group and across appointments; BF-PFMT group were heard to receive more BCTs, as consistent with protocol.

Results: Exercise Diaries

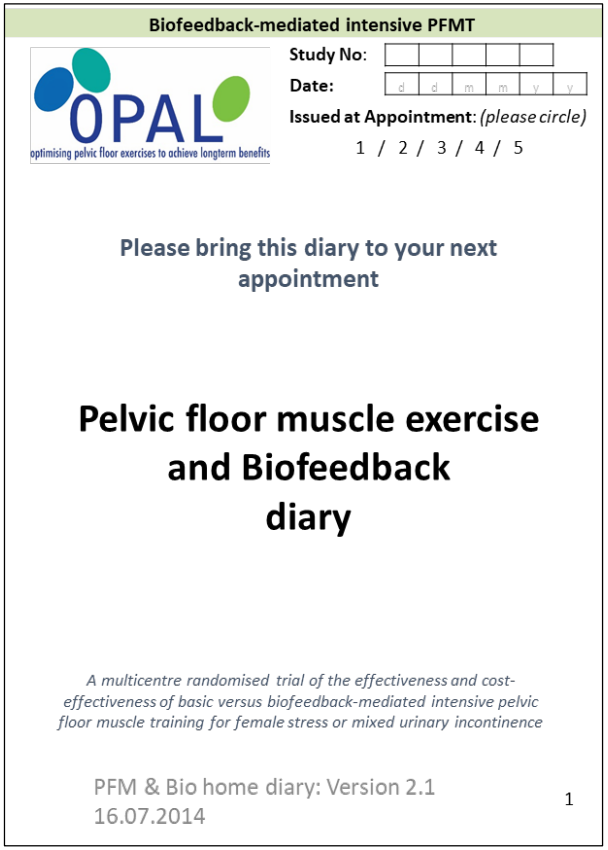
n = 628 returned at least one diary;
total of 829 BF-PFMT, 799 PFMT diaries.

Similar proportions returned by each group across appointments (but decreased as attrition increased).

Similar proportion of diaries signed by participants and therapists
(BCT called 'commitment') in each group.

Reasons for not exercising:

- time
- forgetting
- other physical health reasons
- menstruation



Results: Therapist interviews (n = 30)

Symptoms prompted PFMT but symptom improvement = forget PFMT.

Women's 'buy-in' linked to time and energy available versus competing priorities e.g. other health conditions.

If women (mistakenly) expected BF to stimulate their muscles they were disappointed. BF itself was considered motivating in less complex cases.

Accountability was important (required regular attendance/knowing they were being assessed) meant women worked harder than if on their own; accountability maybe more in BF-PFMT group due to reviewing device data.

Many women struggled to fit BF into a 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"*.

BF possibly more suited to goal-orientated women with time and privacy at home to use equipment.

Key messages

Robust assessment of intervention fidelity and dose.

Interventions were delivered by therapists & taken up by women.

BF-PFMT intervention was more intensive than PFMT alone intervention.

Most women in both groups received BCTs core to delivery of PFMT; no apparent inadvertent ‘intensification’ occurred in the PFMT alone group.

The RCT was a fair test of whether BF could improve women’s outcomes over well delivered PFMT intervention.

Trial results are unlikely due to failure of intervention delivery or uptake.

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Thank you

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