Effectiveness of pelvic floor muscle training with and without electromyographic biofeedback for urinary incontinence in women: multicentre randomised controlled trial

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ABSTRACT

OBJECTIVE

To assess the effectiveness of pelvic floor muscle training (PFMT) plus electromyographic biofeedback or PFMT alone for stress or mixed urinary incontinence in women.

DESIGN

Parallel group randomised controlled trial.

SETTING

23 community and secondary care centres providing continence care in Scotland and England.

PARTICIPANTS

600 women aged 18 and older, newly presenting with stress or mixed urinary incontinence between February 2014 and July 2016: 300 were randomised to PFMT plus electromyographic biofeedback and 300 to PFMT alone.

INTERVENTIONS

Participants in both groups were offered six appointments with a continence therapist over 16 weeks. Participants in the biofeedback PFMT group received supervised PFMT and a home PFMT programme, incorporating electromyographic biofeedback during clinic appointments and at home. The PFMT group received supervised PFMT and a home PFMT programme. PFMT programmes were progressed over the appointments.

MAIN OUTCOME MEASURES

The primary outcome was self-reported severity of urinary incontinence (International Consultation on Incontinence Questionnaire-urinary incontinence short form (ICIQ-UI SF), range 0 to 21, higher scores indicating greater severity) at 24 months. Secondary outcomes were cure or improvement, other pelvic floor symptoms, condition specific quality of life, women's perception of improvement, pelvic floor muscle function, uptake of other urinary incontinence treatment, PFMT self-efficacy, adherence, intervention costs, and quality adjusted life years.

RESULTS

Mean ICIQ-UI SF scores at 24 months were 8.2 (SD 5.1, n=225) in the biofeedback PFMT group and 8.5 (SD 4.9, n=235) in the PFMT group (mean difference −0.09, 95% confidence interval −0.92 to 0.75, P=0.84). Biofeedback PFMT had similar costs (mean difference £121 ($154; €133), −£409 to £651, P=0.64) and quality adjusted life years (−0.04, −0.12 to 0.04, P=0.28) to PFMT. 48 participants reported an adverse event: for 23 this was related or possibly related to the interventions.

CONCLUSIONS

At 24 months no evidence was found of any important difference in severity of urinary incontinence between PFMT plus electromyographic biofeedback and PFMT alone groups. Routine use of electromyographic biofeedback with PFMT should not be recommended. Other ways of maximising the effects of PFMT should be investigated.

TRIAL REGISTRATION

ISRCTN57756448.

WHAT IS ALREADY KNOWN ON THIS TOPIC

The 2011 Cochrane review assessing the benefit of adding feedback to PFMT for female urinary incontinence included 16 trials, but seven reported more PFMT supervision in the biofeedback group

The results differed depending on whether trial groups had comparable PFMT programmes; it was concluded that biofeedback might provide benefit but further research was needed

Since then a meta-analysis including 11 trials concluded no benefit from adding biofeedback to PFMT, whereas two subsequent small single centre trials found some benefit of biofeedback immediately post-treatment

WHAT THIS STUDY ADDS

This trial did not show a statistically significant or clinically important difference in severity of urinary incontinence at 24 months between women randomised to electromyographic biofeedback PFMT or to PFMT alone

This trial confirms that routine use of electromyographic biofeedback with PFMT for women with stress or mixed urinary incontinence does not provide additional benefit

Introduction

Urinary incontinence, defined as involuntary urine leakage,[1] is a distressing, socially restricting condition that affects about one in three women. Urinary incontinence is categorised into three subcategories: stress urinary incontinence, the most common type, concerns urine leakage associated with physical exertion, coughing, and sneezing; urgency urinary incontinence involves a sudden need to pass urine, which is preceded or accompanied by urine leakage; and mixed urinary incontinence involves both stress and urgency urinary incontinence. Regular and progressive pelvic floor muscle training (PFMT) for three months is currently recommended in the United Kingdom for stress and mixed urinary incontinence[2] to

improve pelvic floor muscle function and its role in the continence mechanism.[3] Cochrane review evidence shows effectiveness of PFMT for urinary incontinence.[4]

Adjuncts commonly used clinically to increase the effects of PFMT include electromyographic biofeedback, weighted vaginal cones, and electrical stimulation. Electromyographic biofeedback uses a vaginal probe to capture the electrical activity of the pelvic floor muscles, which is displayed on a screen. Used in tandem with PFMT, electromyographic biofeedback aims to facilitate teaching of the correct contraction technique and home exercise programme. Additionally, biofeedback allows women to visualise the activity of their pelvic floor muscles while exercising, potentially motivating them and enhancing adherence to the prescribed exercises.

A Cochrane review synthesised the evidence for the benefit of PFMT with device mediated biofeedback over PFMT alone and although it seemed biofeedback might be more effective than PFMT alone, many comparisons were confounded.[5] Alternative plausible explanations were that participants receiving biofeedback had longer treatment times, more therapist contact, and different PFMT programmes. It was therefore unclear whether biofeedback provided additional benefit over PFMT alone. In this trial (OPAL, Optimal PFMT for Adherence Long term), we assessed whether PFMT plus electromyographic biofeedback in the clinic and at home would be more effective than PFMT alone for reducing the severity of incontinence in women with stress or mixed urinary incontinence.

Methods

Study design and participants

Our multicentre, parallel group randomised controlled trial was conducted in 23 UK centres providing continence care, with participant recruitment between February 2014 and July 2016.[6] All the centres used electromyographic biofeedback to varying degrees before the trial. Women aged 18 years or older and newly presenting with clinically diagnosed stress or mixed urinary incontinence and urine leakage as the primary problem were potentially eligible for inclusion. We excluded participants who had urgency urinary incontinence alone, a prolapse greater than stage II on examination (>1cm below the hymen on straining), were unable to contract pelvic floor muscles on digital examination when requested, had received formal instruction on PFMT in the preceding year (this was originally three years but was changed on 1 June 2015), were pregnant or had given birth in the past six months (this was originally one year but was changed on 1 June 2015), were receiving treatment for pelvic cancer, had neurological disease, could not provide informed consent because of cognitive impairment, were allergic or sensitive to nickel (this was added on 1 June 2015), or were participating in other urinary incontinence research. We originally excluded women who were using antimuscarinic drugs but removed this criterion before the start of recruitment (4 February 2014) because this is a common treatment for women with mixed urinary incontinence. All participants gave verbal and written informed consent.

Randomisation and masking

The Centre for Healthcare Randomised Trials, University of Aberdeen, carried out the web based randomisation, with participants assigned in a ratio of 1:1 to either PFMT with clinic and home electromyographic biofeedback or PFMT alone. Randomisation was minimised by urinary incontinence type (stress *v* mixed), recruiting centre, age (<50 *v* ≥50 years), and severity of urinary incontinence (International Consultation on Incontinence Questionnaire-urinary incontinence short form (ICIQ-UI SF) score of <13 *v* ≥13).[7] Group allocation was relayed to participants by letter and to the trial office and recruiting centre by email. Participants, therapists delivering the intervention, and research staff could not be masked to group allocation. However, clinicians performing the six month pelvic floor muscle assessment were masked.

Procedures

Participants in both groups were offered six face-to-face appointments (weeks 0, 1, 3, 6, 10, and 15; 60 minutes for the first appointment and 30 minutes for subsequent appointments) with a therapist (an experienced physiotherapist, nurse, or other continence clinician) who had received training in intervention delivery. The therapist assessed the pelvic floor muscles, taught the correct technique for exercise, prescribed an individualised PFMT programme to be followed at home (aiming for three sets of exercises daily, recorded in an exercise diary), and used behaviour change techniques[8] embedded in the protocols to encourage adherence.[6] Bladder and bowel management information and lifestyle advice were provided as necessary. For participants in the biofeedback and PFMT group, electromyographic biofeedback was integrated with PFMT during the appointments. In addition, participants in this group were given the same biofeedback device as used during appointments for their home use with a prescribed programme, along with information on operating, cleaning, and output interpretation. The devices stored usage information and the participants recorded the use of the biofeedback device in their exercise diaries. We selected the electromyographic biofeedback device most used in the UK national health service at the time of the trial, and all centres were provided with an adequate supply of this device. By standardising and protocolising the PFMT delivered in both groups we ensured that all participants had the same treatment other than the addition of the electromyographic biofeedback.

For each participant, the therapist recorded age, body mass index, number of births and delivery type, and urinary incontinence type and severity (using two ICIQ-UI SF questions relating to frequency and volume of leakage). The women used a bladder diary to record baseline urine leakage over three days. At

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each appointment, therapists recorded the findings of clinical assessment, treatment plan, prescribed PFMT programme, and participant's adherence. Participants completed questionnaires at baseline and at 6, 12, and 24 months. A clinician not involved in treatment delivery and masked to group allocation carried out a pelvic floor muscle assessment at six months.

Outcomes

The primary outcome was severity of urinary incontinence (ICIQ-UI SF)[9] at 24 months. The ICIQ-UI SF score ranges from 0 to 21 and is the weighted sum of three items addressing urinary incontinence frequency ("how often do you leak urine?" 0=never to 5=all the time), leakage quantity ("how much urine do you usually leak?" 0=none to 6=a large amount), and interference with everyday life (0=not at all to 10=a great deal). Higher scores reflect greater severity.

Secondary outcomes were cure (never or none responses to ICIQ-UI SF frequency or quantity items) and improvement in urinary incontinence (reduction in ICIQ-UI SF score of ≥3 points),[10] the Patient Global Impression of Improvement, measuring participants' perceptions of their urine leakage (1=very much better to 7=very much worse),[11] uptake of urinary incontinence treatment (surgical or non-surgical), the International Consultation on Incontinence Questionnaire-female lower urinary tract symptoms (12 items, three subscales: filling (0-15), voiding (0-12), and incontinence (0-20), higher scores worse),[12] the International Consultation on Incontinence Questionnaire-lower urinary tract symptoms quality of life (19 items, total ranging from 19 to 76, higher scores worse),[13] the EuroQol-5 dimension-3 level (EQ-5D-3L) questionnaire (range −0.594 to 1) and EQ-5D visual analogue scale (range 0 to 100, higher scores better),[14] the pelvic organ prolapse symptom score (POP-SS; seven items, total ranging from 0 to 28, higher scores worse),[15] an early non-validated version of the International Consultation on Incontinence Questionnaire-bowel short form (six items: difficulty emptying, urgency, leakage, frequency of defecation, stool consistency, and interference with everyday life, each scored individually), the Oxford classification for pelvic floor muscle strength (0=no contraction to 5=strong contraction),[16] the International Continence Society classification for pelvic floor muscle relaxation (absent, partial, complete) and contraction (absent, weak, normal, strong),[17] the Pelvic Floor Muscle Exercise Self-Efficacy scale (17 items, total ranging from 17 to 85, higher scores greater self-efficacy),[18] adherence to the home programme (PFMT with or without biofeedback as appropriate) recorded by the therapist at each appointment (programme followed, yes or no), and, if missing, ascertained from participant exercise diaries and biofeedback unit data, and adherence to PFMT longer term self-reported in follow-up questionnaires. To quantify urine leakage, participants were originally asked to complete and return a three day bladder diary along with their 24 month questionnaire: this was stopped because of poor response, with initially only a few participants returning diaries or questionnaires, which affected the completeness of the primary outcome data.

We recorded all adverse and serious adverse events, with details of seriousness, relatedness to the interventions, and whether expected (as prespecified in the trial protocol).

Statistical analysis

Analyses were prespecified (www.journalslibrary.nihr.ac.uk/programmes/hta/117103/#/). As no published long term data on our primary outcome measure were available, we based our sample size calculation on studies reporting baseline ICIQ-UI SF scores for women with stress and mixed urinary incontinence.[19 20] Assuming a higher standard deviation of 10 at 24 months to reflect the long follow-up, we estimated that 234 participants in each group would provide 90% power at a 5% level of significance (two sided) to detect a between group difference of 3 points in the ICIQ-UI SF score, which was considered meaningful (eg, change from leaking urine once a day to never). No minimal clinically important difference had been published for a similar population at the outset of the trial (only for older women, mean age 72 years)[10]; however, subsequently an ICIQ-UI SF minimal clinically important difference of 2.5 points was reported in a study of younger women.[21] We aimed to recruit 300 participants in each group, allowing for 22% loss to follow-up.

Participant characteristics at baseline were summarised with counts (percentages) for dichotomous and categorical variables and means (standard deviations) for continuous variables. We analysed primary and secondary outcomes by intention to treat, using a 5% level of significance. The mean difference between groups in ICIQ-UI SF at 24 months was estimated using a linear mixed model adjusted for minimisation factors, therapist type (physiotherapist or other), and baseline score, with recruiting centre as a random effect.

The potential effects of missing observations in the primary outcome were assessed in a multiple imputation model and a repeated measures model, both assuming that observations were missing at random. Additionally, we fitted pattern mixture models assuming observations were missing not at random, but were higher or lower than the imputed values by 2.5 points (the minimal clinically important difference)[21] for all missing observations, and for each trial group separately.

In both groups we defined protocol fidelity (compliance) as being met if PFMT was initially taught with verbal feedback from vaginal palpation and home exercises prescribed during at least one appointment, along with instruction on device use in the biofeedback group. We investigated the influence of non-compliance using complier average causal effect models in two sensitivity analyses of the primary outcome, assuming that a participant's treatment

was protocol compliant or non-compliant, when compliance status was indeterminable.

For analysis of secondary outcomes, we used appropriate generalised linear models (linear mixed models for continuous outcomes, binary logistic regression for dichotomous outcomes, and ordinal logistic regression for ordered categorical outcomes), adjusted for minimisation variables, therapist type, and baseline score if measured. We prespecified several subgroup analyses for the primary outcome measure, with a stricter 1% level of significance: incontinence type (stress or mixed urinary incontinence), age (<50 or ≥50), therapist (physiotherapist or other), and baseline urinary incontinence severity (ICIQ-UI SF score <13 (mild or moderate) or ≥13 (severe)).[7]

We assessed linearity and normality of error distribution assumptions through residual plots. When ordinal models were fitted, we examined the proportional odds assumption using a Brant test.

A within trial economic analysis was undertaken to estimate quality adjusted life years using responses to the EQ-5D-3L, and healthcare use reported in participant questionnaires, valued using published sources, with costs and quality adjusted life years discounted at the recommended rate of 3.5%.

Statistical analyses were undertaken using Stata SE version 14.1 (StataCorp, College Station, TX). The trial was overseen by a trial steering committee and data monitoring and ethics committee.

Patient and public involvement

A patient representative was a trial co-investigator, a member of the project management group, and involved from the grant writing stage through publication of the protocol to completion and the writing up of the results. In addition, she worked closely with the trial team on the best ways of communicating with participants during the recruitment and follow-up stages. An additional patient representative was an independent member of the trial steering committee. Involvement of these individuals provided the opportunity for patients to influence all aspects of the research, including the design and logistics of implementing the research. The trial was undertaken in response to a commissioned call from the funders, which was informed by a James Lind Alliance priority setting exercise, thus patients also informed the research question.

Results

Between 27 February 2014 and 8 July 2016, 687 women in 23 centres were invited to participate in the trial. Of these women, 600 were randomised: 300 in the PFMT plus electromyographic biofeedback group and 300 in the PFMT along group (fig 1). Participant personal characteristics and pelvic floor symptoms were similar between the groups at trial entry (table 1).

After randomisation, five participants in the biofeedback PFMT group and two in the PFMT group withdrew consent to their data being used, leaving 295 and 298 participants included in the analysis, respectively (fig 1).

The proportion of participants who responded at six months was 74.0% (n=444/600), at 12 months was 84.0% (n=504/600), and at 24 months was 78.0% (n=468/600). Overall, 53.5% (n=321/600) of women attended the six month blinded pelvic floor muscle assessment, and successful masking was recorded in 93.5% (n=300/321). A similar proportion of women responded in both groups (fig 1).

One hundred and ninety eight participants (67.1%) in the biofeedback PFMT group and 192 (64.4%) in the PFMT group attended four or more appointments. The mean number of appointments attended was similar between the groups; the total time spent in appointments was longer for the biofeedback PFMT group (table 2). The intervention in both groups was delivered mostly by physiotherapists (table 2).

The primary outcome, ICIQ-UI SF score at 24 months, was not statistically significantly different between the groups (mean difference −0.09, 95% confidence interval −0.92 to 0.75, P=0.84), with similarly no differences at six and 12 months (table 3); the width of all confidence intervals was less than 2.5, indicating no clinically important differences between the groups.

The results of the sensitivity analyses of the primary outcome to examine the effect of missing data (assuming missing at random) supported those of the primary intention-to-treat analyses (multiple imputation: mean difference −0.11, 95% confidence interval −0.95 to 0.74; repeated measures model: −0.08, −0.86 to 0.70). Similarly, sensitivity analyses assuming missing not at random and addressing non-compliance did not alter the conclusions (see supplementary file).

None of the prespecified subgroup analyses (type of urinary incontinence, age, baseline severity of urinary incontinence, therapist type) of the primary outcome revealed any statistically significant treatment by subgroup interactions (fig 2).

Based on responses to the ICIQ-UI SF, the number of women with cure at 24 months was not statistically significantly different between the biofeedback PFMT and PFMT groups (7.9% *v* 8.4%, odds ratio 0.90, 95% confidence interval 0.46 to 1.78, P=0.77) (table 4). Similarly, no statistically significant difference was found in the percentage of women who improved (60.0% *v* 62.6%, 0.89, 0.61 to 1.32, P=0.57) (table 4). Participants' perceptions of improvement, captured by the Patient Global Impression of Improvement instrument, showed no statistically significant difference between the groups at 24 months: 41.0% and 38.1% reported that their symptoms were "very much better" or "much better" (1.12, 0.76 to 1.63, P=0.57) (table 4). Responses to the question "How often do you leak urine?" were similar between the groups at the 24 month follow-up, the most common response being "about once a week or less often" (30.3% biofeedback PFMT *v* 30.4% PFMT) (see supplementary file).

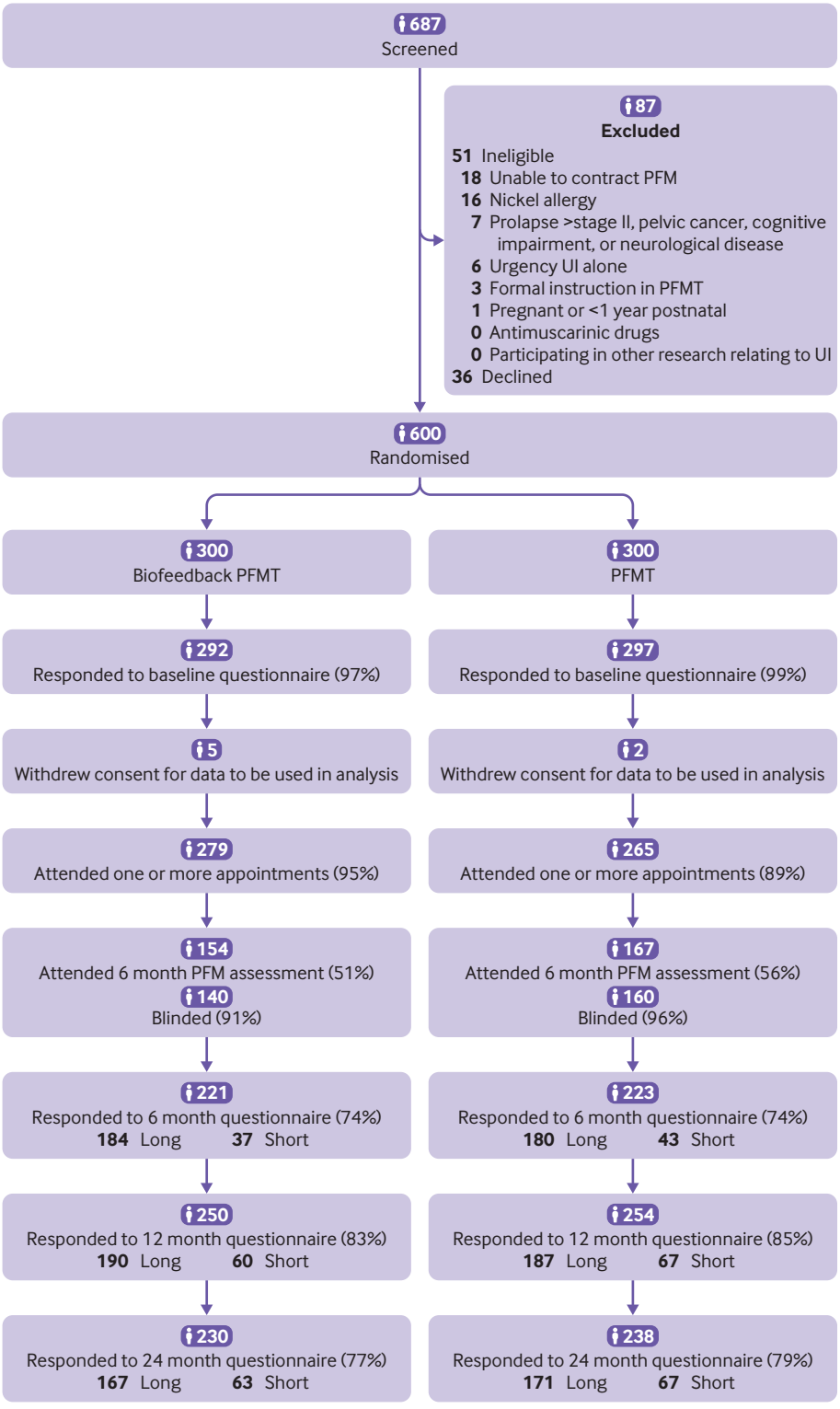

Fig 1 | Trial profile. Short=shortened version of questionnaire, including the International Consultation on Incontinence Questionnaire-urinary incontinence short form, the EuroQol-5 dimension-3 level questionnaire, and questions about adherence to pelvic floor muscle training (PFMT) and uptake of urinary incontinence (UI) treatment, offered at the reminder stage; Long=full version of questionnaire. PFM=pelvic floor muscles

Lower urinary tract symptoms were not statistically significantly different between groups at 24 months on any of the subscale scores of filling, voiding, or incontinence (table 5). Quality of life related to lower urinary tract symptoms was not significantly different between groups at 24 months, measured either by the overall International Consultation on Incontinence Questionnaire-lower urinary tract symptoms quality of

Table 1 | Baseline characteristics of participants assigned to pelvic floor muscle training (PFMT) with electromyographic biofeedback or to PFMT alone. Values are numbers (percentages) unless stated otherwise

Characteristics	Biofeedback PFMT	PFMT
No of women, mean (SD) age (years)	300, 48.2 (11.6)	300, 47.3 (11.4)
No of women, mean (SD) body mass index	290, 28.6 (5.9)	287, 28.3 (6.2)
No of births:	n=298	n=289
0	21 (7.0)	12 (4.2)
1	40 (13.4)	60 (20.8)
2	116 (38.9)	122 (42.2)
3	83 (27.9)	63 (21.8)
≥4	38 (12.8)	32 (11.1)
Type of incontinence:	n=300	n=300
Stress	116 (38.7)	116 (38.7)
Mixed (stress more troublesome)	108 (36.0)	109 (36.2)
Mixed (stress and urgency equally troublesome)	42 (14.0)	42 (14.0)
Mixed (urgency more troublesome)	34 (11.3)	33 (11.2)
No of women, mean (SD) ICIQ-UI SF*	291, 12.5 (4.1)	294, 12.3 (3.7)
ICIQ-UI SF severity*:	n=291	n=294
Mild or moderate (<13)	140 (48.1)	149 (50.7)
Severe (≥13)	151 (51.9)	145 (49.3)
No of women, mean (SD) No of daily episodes of incontinence†	207, 2.4 (2.8)	208, 2.2 (2.8)
No of women, mean (SD) POP-SS	274, 6.4 (5.7)	286, 6.7 (5.6)
Difficulty emptying bowels:	n=289	n=296
Never	85 (29.4)	79 (26.7)
Occasionally	101 (34.9)	94 (31.8)
Sometimes	68 (23.5)	83 (28.0)
Most of the time	25 (8.7)	26 (8.8)
All of the time	10 (3.5)	14 (4.7)

ICIQ-UI SF=International Consultation on Incontinence Questionnaire-urinary incontinence short form; POP-SS=pelvic organ prolapse symptom score.
*ICIQ-UI SF as reported in the participant's baseline questionnaire, rather than the web based randomisation system, which was used for the purpose of minimisation.
†Based on three day bladder diary.

life score or by its separate scale for interference due to urinary symptoms (table 5).

Blinded assessment of pelvic floor muscles at six months showed that 8.5% (n=13) of women in the biofeedback PFMT group and 6.0% (n=10) in the PFMT group had the maximum contraction strength, with no statistically significant difference between the groups (1.28, 0.86 to 1.89, P=0.22) (table 6). Contraction endurance and number of repetitions to muscle fatigue were also similar between groups (table 6).

Prolapse symptom severity (POP-SS score) was not statistically significantly different between the biofeedback PFMT (mean 4.5 (SD 5.0)) and PFMT (mean 4.9 (SD 5.0)) groups at 24 months (mean difference −0.6, 95% confidence interval −1.51 to 0.30, P=0.19). Bowel symptoms at 24 months were similar between groups (see supplementary file).

A statistically significant difference in overall score for PFMT self-efficacy favoured biofeedback PFMT: mean 63.1 (SD 11.6) biofeedback PFMT *v* 60.9 (SD 12.0) PFMT (mean difference 2.36, 95% confidence interval 0.04 to 4.68, P=0.05).

Evidence suggested that the prescribed home programme was followed in at least one period between appointments in 78.3% (220/281) of participants in the biofeedback PFMT group and 81.1% (241/297) in the PFMT group (odds ratio 0.71, 95% confidence interval 0.43 to 1.16, P=0.17). At 24 months, the proportion of participants who reported exercising two or three times a week (as recommended for maintenance) was 49.1% (85/173) in the biofeedback PFMT group and 42.6% (80/188) in the PFMT group (1.20, 0.83 to 1.74, P=0.33, post hoc analysis).

Forty eight participants reported adverse events (34 biofeedback PFMT, 14 PFMT), of whom 23 (21 biofeedback PFMT, 2 PFMT) had an event related or possibly related to the trial interventions. All but four of these events (two in each group) were expected. Only one event was related to the interventions: a nickel allergy in a participant in the biofeedback PFMT group, who discontinued with the intervention. In addition, eight serious adverse events were reported (6 biofeedback PFMT, 2 PFMT). All were unrelated to the interventions and unexpected.

Table 2 | Appointment attendance in participants assigned to pelvic floor muscle training (PFMT) with electromyographic biofeedback or to PFMT alone, and therapist type. Values are numbers (percentages) unless stated otherwise

Attendance and therapist type	Biofeedback PFMT (n=295)	PFMT (n=298)
No of appointments attended:		
0	16 (5.4)	33 (11.1)
1	20 (6.8)	18 (6.0)
2	24 (8.1)	22 (7.4)
3	37 (12.5)	33 (11.1)
4	33 (11.2)	22 (7.4)
5	56 (19.0)	64 (21.5)
6	109 (36.9)	106 (35.6)
Mean (SD) total No of appointments	4.2 (1.9)	4 (2.1)
Mean (SD) total duration of appointments (mins)	176 (84)	152 (78)
Type of therapist:		
Physiotherapist	256 (86.8)	247 (82.9)
Nurse	17 (5.8)	11 (3.7)
Other and mixture	6 (2.0)	7 (2.3)
No therapist	16 (5.4)	33 (11.1)

Table 3 | Summary of International Consultation on Incontinence Questionnaire-urinary incontinence short form (ICIQ-UI SF) responses of participants assigned to pelvic floor muscle training (PFMT) with electromyographic biofeedback or to PFMT alone, and differences between groups

Time point	No of women, mean (SD)		Mean difference* (95% CI)
	Biofeedback PFMT	PFMT	
Baseline	291, 12.5 (4.1)	294, 12.3 (3.7)	–
Follow-up (months):			
6	221, 9.0 (5.0)	221, 8.8 (4.5)	0.39 (−0.33 to 1.12)
12	249, 9.1 (4.9)	252, 8.7 (5.0)	0.57 (−0.17 to 1.31)
24	225, 8.2 (5.1)	235, 8.5 (4.9)	−0.09 (−0.92 to 0.75)

*Linear mixed models adjusted for minimisation variables, therapist type, and baseline ICIQ-UI SF.

Similar proportions of women reported receiving urinary incontinence surgery at each follow-up. Uptake of further non-surgical urinary incontinence care or treatment was also comparable between groups (table 7).

In the biofeedback PFMT group, the mean cost for each participant, taking into account the intervention cost and continence related healthcare (hospital, primary care, prescribed drugs) during 24 months of follow-up was £1261 ($1605; €1374) (SD £1333) compared with £1118 (SD £1294) for the PFMT group (mean difference £121, 95% confidence interval −£409 to £651, P=0.64). The mean quality adjusted life years for biofeedback PFMT was 1.57 (SD 0.49) and for PFMT was 1.62 (SD 0.46) (−0.04, −0.12 to 0.04, P=0.28). On average, biofeedback PFMT cost more than PFMT, and quality adjusted life years were lower, although the differences between groups were not statistically significant.

Discussion

Our findings did not show a statistically significant or clinically important difference in severity of urinary incontinence at 24 months between women randomised to electromyographic biofeedback (in the clinic and at home) PFMT or to PFMT alone. These findings remained in subgroup analyses irrespective of urinary incontinence type, age, severity, or therapist type, and sensitivity analyses showed our primary outcome analysis was robust to missing data and non-compliance. Across all secondary urinary outcomes (cure or improvement, other lower urinary tract symptoms, condition specific quality of life, patient perception of urinary incontinence improvement) at the 24 month follow-up, a consistent pattern of no difference between groups was observed. Other clinically focused secondary outcomes (pelvic floor muscle function, prolapse symptoms, and uptake of other urinary incontinence treatment) did not show any statistically significant differences between groups. Improvement in urinary incontinence was observed in both trial groups, with 8% of women in each group reporting cure and 60% in the biofeedback PFMT group and 63% in the PFMT group reporting improvement at 24 months. This degree of improvement is consistent with the recently updated Cochrane

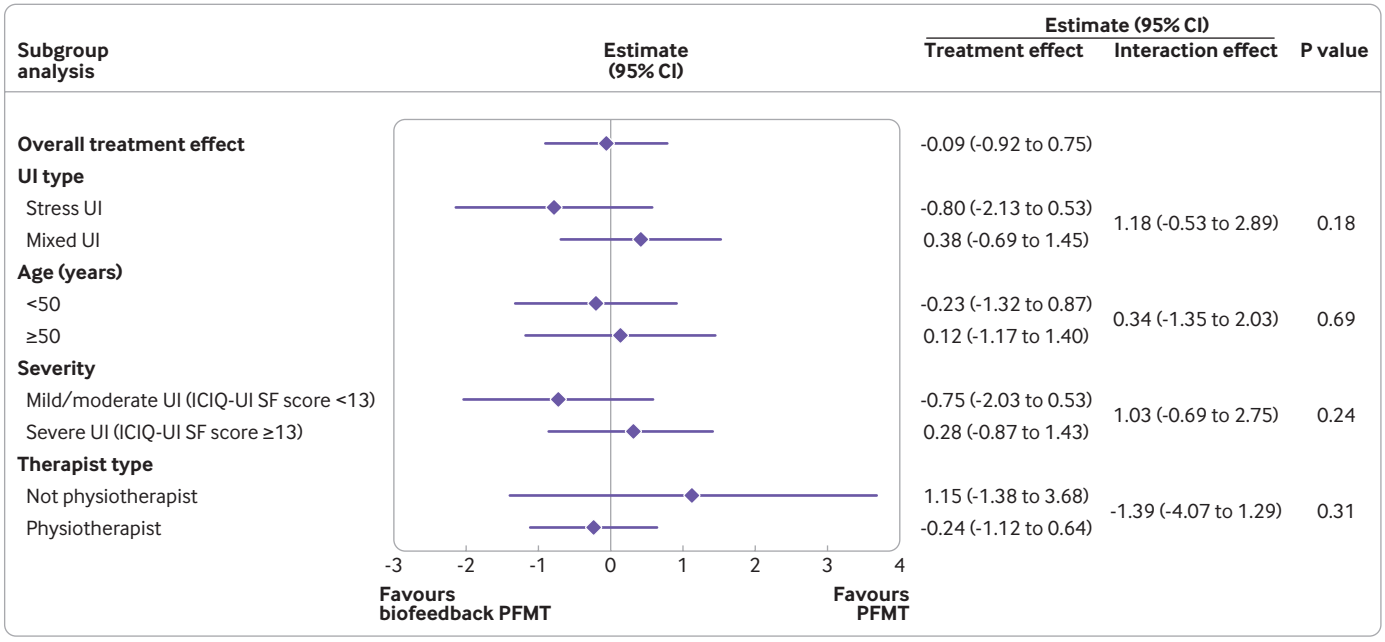

Fig 2 | Summary of subgroup analyses of primary outcome (International Consultation on Incontinence Questionnaire-urinary incontinence short form (ICIQ-UI SF) response at 24 months). PFMT=pelvic floor muscle training

Table 4 | Cure and improvement of urinary incontinence in participants assigned to pelvic floor muscle training (PFMT) with electromyographic biofeedback or to PFMT alone

Outcome at follow-up	No with outcome/No in group (%)		Odds ratio* (95% CI)
	Biofeedback PFMT	PFMT	
Cure†:			
6 months	12/221 (5.4)	13/223 (5.8)	–
12 months	16/250 (6.4)	22/253 (8.7)	–
24 months	18/229 (7.9)	20/238 (8.4)	0.90 (0.46 to 1.78)
Improvement‡:			
6 months	129/221 (58.4)	133/221 (60.2)	–
12 months	148/249 (59.4)	163/252 (64.7)	–
24 months	135/225 (60.0)	147/235 (62.6)	0.89 (0.61 to 1.32)
"Very much better" or "much better"§:			
6 months	96/219 (43.8)	85/221 (38.5)	–
12 months	101/249 (40.6)	92/250 (36.8)	–
24 months	93/227 (41.0)	90/236 (38.1)	1.12 (0.76 to 1.63)

*Between group differences only estimated at 24 months.
†Negative response to both "how often do you leak urine?" and "how much urine do you usually leak?"
‡Reduction in International Consultation on Incontinence Questionnaire-urinary incontinence short form of ≥3 points from baseline.
§Patient Global Impression of Improvement instrument.

review comparing PFMT with no treatment or inactive control.[4] Our findings indicate that supervised and protocolised PFMT, with or without electromyographic biofeedback, provides benefit, supporting the current grade A recommendation for PFMT as an effective treatment for urinary incontinence.[22] We observed greater PFMT self-efficacy in the biofeedback PFMT group, supporting the hypothesised effect of biofeedback. The group difference, however, was small and clinical significance uncertain. Further investigation into the role of self-efficacy is required. The findings of the economic analysis suggest that both interventions resulted in similar overall costs and quality of life over the follow-up period.

Strengths and limitations of this study

One of the trial's strengths was its large sample size, which was more than double that of the largest previous biofeedback trial,[23] and large enough to detect a clinically important between group difference

Table 5 | Lower urinary tract symptoms in participants assigned to pelvic floor muscle training (PFMT) with electromyographic biofeedback or to PFMT alone

	No of women, mean (SD)		Mean difference* (95% CI)
	Biofeedback PFMT	PFMT	
ICIQ-FLUTS			
Filling score (range 0-15):			
Baseline	289, 5.0 (2.8)	297, 4.8 (2.6)	
6 months	183, 3.7 (2.7)	176, 3.4 (2.3)	
12 months	187, 3.8 (2.7)	186, 3.6 (2.4)	
24 months	167, 3.4 (2.6)	168, 3.5 (2.3)	−0.19 (−0.61 to 0.24)
Voiding score (range 0-12):			
Baseline	292, 2.0 (2.0)	294, 2.0 (2.1)	
6 months	182, 1.6 (1.8)	179, 1.4 (1.8)	
12 months	188, 1.5 (1.9)	186, 1.5 (1.8)	
24 months	165, 1.6 (1.8)	169, 1.6 (1.8)	0.04 (−0.30 to 0.38)
Incontinence score (range 0-20):			
Baseline	290, 9.8 (3.6)	294, 9.3 (3.4)	
6 months	182, 7.1 (4.0)	178, 6.6 (3.8)	
12 months	188, 7.1 (3.9)	182, 6.6 (4.1)	
24 months	164, 7.0 (4.3)	169, 6.5 (4.0)	0.20 (−0.58 to 0.98)
ICIQ-LUTSqol			
Overall (range 19-76):			
Baseline	292, 43.5 (12.3)	297, 42.3 (12.1)	
6 months	183, 36.2 (13.2)	176, 35.7 (11.9)	
12 months	189, 35.7 (13.3)	184, 34.7 (12.1)	
24 months	164, 34.3 (12.4)	169, 34.3 (12.5)	−0.81 (−3.03 to 1.41)
Interference scale (range 0-10):			
Baseline	288, 7.4 (2.6)	288, 7.6 (2.5)	
6 months	183, 4.3 (3.1)	177, 4.3 (2.8)	
12 months	189, 4.0 (3.1)	184, 3.9 (3.0)	
24 months	163, 3.8 (3.1)	169, 3.7 (2.9)	0.26 (−0.33 to 0.85)

ICIQ-FLUTS=International Consultation on Incontinence Questionnaire-female lower urinary tract symptoms; ICIQ-LUTSqol=International Consultation on Incontinence Questionnaire-lower urinary tract symptoms quality of life.
*Between group differences only estimated at 24 months.

Table 6 | Pelvic floor muscle assessment at baseline and six months (blinded) in participants assigned to pelvic floor muscle training (PFMT) with electromyographic biofeedback or PFMT alone. Values are numbers (percentages) unless stated otherwise

Pelvic floor muscle assessment	Biofeedback PFMT	PFMT
Oxford scale: slow contraction strength		
Baseline:	n=300	n=300
1	34 (11.3)	31 (10.3)
2	115 (38.3)	111 (37.0)
3	128 (42.7)	134 (44.7)
4	22 (7.3)	24 (8.0)
5	1 (0.3)	0 (0.0)
Six months:	n=153	n=166
1	4 (2.6)	3 (1.8)
2	25 (16.3)	23 (13.9)
3	57 (37.3)	74 (44.6)
4	54 (35.3)	56 (33.7)
5	13 (8.5)	10 (6.0)
No of women, mean (SD) contraction endurance*:		
Baseline	264, 6.48 (3.00)	250, 6.35 (3.13)
6 months	152, 8.72 (2.26)	166, 8.54 (2.48)
No of women, mean (SD) No of slow contractions†:		
Baseline	263, 6.03 (2.44)	249, 5.77 (2.41)
6 months	151, 7.42 (2.62)	165, 7.55 (2.59)

*Length of hold (seconds).
†Repetitions to fatigue.

if one existed. The study therefore provides robust results to inform clinical practice. We recruited participants from various outpatient and community settings, and the two groups were highly comparable at baseline, increasing the generalisability of our findings. We standardised intervention delivery as far as possible, with therapists receiving face-to-face training from clinical research team members along with a comprehensive intervention manual. Importantly, unlike previous trials, both groups received the same PFMT intervention making this a fair test of the benefits of adding electromyographic biofeedback. We achieved high questionnaire return rates (78% at 24 months) reducing the risk of attrition bias. Furthermore, our estimates of the treatment effect were robust to sensitivity analyses. We were unable to mask group allocation from participants, therapists, or researchers and consequently there was a potential risk of detection bias. Participants might have perceived their allocated treatment as being better or worse than that allocated to the other group. However, as adherence to appointments and home PFMT was similar for both groups, group allocation does not seem to have influenced women's engagement. Masking of therapists was achieved in 93% of the six month PFM assessments, and results relating to these assessments showed no group differences. The attendance rate for these assessments was, however, lower than the questionnaire return rate, albeit similar between groups (51% in the biofeedback PFMT group, 55% in the PFMT group). We excluded women who were unable to contract their pelvic floor muscles based on guidance that such women should be offered biofeedback.[2] Consequently, conclusions cannot be drawn about this subpopulation. Newer devices have become available since the trial started, which utilise, for example, Bluetooth technology; however, the basic mechanism of biofeedback (giving a visual or auditory signal of an invisible physiological process) is the same regardless of the device type, and thus findings can be extrapolated.

Comparison with other studies

Since this trial commenced several others evaluating biofeedback for the treatment of urinary incontinence have been published. Five are directly comparable, but are smaller single centre trials and have shorter follow-up. One of the studies found no group differences in King's Health Questionnaire parameters (measuring urinary incontinence related quality of life) after 12 weeks when electromyographic biofeedback PFMT was compared with PFMT for women with stress urinary incontinence (n=46).[24] Conversely, another of the studies found between group differences in favour of pressure biofeedback PFMT compared with PFMT in women with stress urinary incontinence on all but one King's Health Questionnaire domain after 12 weeks (n=40).[25] A further trial by the researchers found that women with stress urinary incontinence (n=72) were no more likely to increase the frequency of home exercise after three months, irrespective of whether they had home PFMT with clinic pressure biofeedback, or home and clinic PFMT, and cure did not differ at nine months.[26] Electromyographic biofeedback with PFMT has, however, been found to statistically significantly improve pelvic floor muscle strength compared with PFMT alone for women with stress urinary incontinence (n=49).[27] In a three arm trial in women with stress urinary incontinence (n=53), the addition of electromyographic perineal biofeedback or intravaginal pressure biofeedback to home PFMT were both superior to home PFMT alone for outcomes

Table 7 | Uptake of further treatment for urinary incontinence in participants assigned to pelvic floor muscle training (PFMT) with electromyographic biofeedback or PFMT alone

Further treatment at follow-up	No with event/No in group (%)		Odds ratio (95% CI)
	Biofeedback PFMT	PFMT	
Surgery:			
0-6 months	2/172 (1.2)	3/164 (1.8)	0.56 (0.09 to 3.53)
6-12 months	8/204 (3.9)	11/210 (5.2)	0.63 (0.23 to 1.69)
12-24 months	8/154 (5.2)	12/162 (7.4)	0.62 (0.24 to 1.65)
Non-surgical treatment:			
0-6 months	96/146 (65.8)	107/149 (71.8)	0.77 (0.46 to 1.28)
6-12 months	70/164 (42.7)	74/159 (46.5)	0.90 (0.56 to 1.42)
12-24 months	40/105 (38.1)	42/119 (35.3)	0.65 (0.65 to 2.03)

relating to severity of urinary incontinence, cure or improvement, and pelvic floor muscle strength.[28]

Policy implications and conclusions

Overall, the trial findings are consistent with national guidelines and confirm the recommendation that electromyographic biofeedback should not be routinely offered as part of PFMT.[2]

In this large multicentre trial with long term follow-up of electromyographic biofeedback as an adjunct to PFMT, we found no evidence of benefit from routinely adding biofeedback to PFMT. Supervised PFMT is effective in the management of urinary incontinence, although further research is needed into how to maximise its benefits.

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Contributors: All authors read, commented on, and approved the final manuscript. SH had responsibility overall for the study and manuscript and for delivery of the trial. She conceived the trial and made intellectual input to the study design. AE prepared the statistical analysis plan, delivered and reported the statistical analysis, and supervised the conduct of the trial data analysis. SS was trial manager, responsible for the day-to-day operationalisation and management of the trial. NS managed the trial data. CB conceptualised the case study and process evaluation components of the trial and delivered and reported the qualitative components of the study. SD conceptualised the case study and process evaluation components, developed the trial interventions, and was responsible for delivery and reporting of the process evaluation component of the trial. JH-S conceptualised the case study and process evaluation components and led the development of the PFMT intervention protocol. MK delivered, supervised, and reported the health economics analysis. MD conducted the health economics analysis. MA-F conceived the trial, made intellectual input to the study design, and contributed his expertise in clinical trials and urinary incontinence. WA conceived the trial, made intellectual input to the study design, and was a local principal investigator. JB developed the trial interventions and was a local principal investigator. CG conceived the trial, made intellectual input to the study design, and contributed her expertise in clinical trials and urinary incontinence. KG contributed her expertise in clinical trials and urinary incontinence and was a local principal investigator. AMcD provided senior trial management expertise and support for the trial. JN contributed his expertise in complex intervention trials methodology. LRW was trial manager responsible for management of the trial from June 2018 and drafted material for the manuscript. DMcC conceived the trial, made intellectual input to the study design, contributed to developing the trial interventions, and delivered training and ongoing clinical support to therapists at recruiting centres. SH is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Ethical approval: The West of Scotland Research Ethics Committee 4 (NRS13/UR13) granted ethical approval for the research and any amendments.

Data sharing: Individual participant data collected for this trial, and a data dictionary defining each field in the dataset, will be made available to others; all available data will be de-identified participant data. The protocol, statistical analysis plan, informed consent form, and ethics committee approval are available (https://www.journalslibrary.nihr.ac.uk/programmes/hta/117103/#/). To access data, a request should be submitted to the corresponding author

(s.hagen@gcu.ac.uk) with a scientific proposal including objectives. Written proposals will be assessed by members of the trial steering committee and a decision made about the appropriateness of the request. The data will only be shared after the data sharing agreement is fully executed.

The lead author (SH) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported, that no important aspects of the study have been omitted, and that any discrepancies from the trial as originally planned have been explained.

Dissemination to participants and related patient and public communities: An executive summary of the findings in the format of a newsletter was sent to all trial participants. Once the trial results have been published details will be sent to several charities, patient/public groups, and professional organisations to ask them to disseminate findings to their membership.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Supplementary information: Additional figures and tables showing summary results