Basic versus biofeedback-mediated intensive pelvic floor muscle training for women with urinary incontinence: the OPAL RCT

Suzanne Hagen,[1]* Carol Bugge,[2] Sarah G Dean,[3] Andrew Elders,[1] Jean Hay-Smith,[4] Mary Kilonzo,[5] Doreen McClurg,[1] Mohamed Abdel-Fattah,[5] Wael Agur,[6] Federico Andreis,[2] Joanne Booth,[7] Maria Dimitrova,[5] Nicola Gillespie,[1] Cathryn Glazener,[8] Aileen Grant,[9] Karen L Guerrero,[10] Lorna Henderson,[11] Marija Kovandzic,[2] Alison McDonald,[11] John Norrie,[12] Nicole Sergenson,[1] Susan Stratton,[1] Anne Taylor[2] and Louise R Williams[1]

[1]Nursing, Midwifery and Allied Health Professions Research Unit, Glasgow Caledonian University, Glasgow, UK
[2]Faculty of Health Sciences and Sport, University of Stirling, Stirling, UK
[3]University of Exeter Medical School, Exeter, UK
[4]Rehabilitation Teaching and Research Unit, University of Otago, Dunedin, New Zealand
[5]Institute of Applied Health Sciences, University of Aberdeen, Aberdeen, UK
[6]NHS Ayrshire and Arran, Kilmarnock, UK
[7]School of Health and Life Sciences, Glasgow Caledonian University, Glasgow, UK
[8]Health Services Research Unit, University of Aberdeen, Aberdeen, UK
[9]School of Nursing and Midwifery, Robert Gordon University, Aberdeen, UK
[10]Queen Elizabeth University Hospital, NHS Greater Glasgow and Clyde, Glasgow, UK
[11]Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, University of Aberdeen, Aberdeen, UK
[12]Edinburgh Clinical Trials Unit, University of Edinburgh, Edinburgh, UK

*Corresponding author hagen@gcu.ac.uk

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Scientific summary

The OPAL RCT

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Scientific summary

Background

Urinary incontinence (accidental urine leakage) is a distressing problem that affects around one in three women. The main types of urinary incontinence are stress (involuntary urine leakage associated with exertion or effort, or with sneezing or coughing), urgency (involuntary urine leakage accompanied by, or immediately preceding, a compelling desire to pass urine) and mixed (combined stress and urgency), with stress being the most common. Current UK guidelines recommend that women with urinary incontinence are offered at least 3 months of pelvic floor muscle training. There is evidence that pelvic floor muscle training is effective in treating urinary incontinence; however, it is not clear how intensively women have to exercise their pelvic floor muscles to give the maximum sustained improvement in symptoms, and how to enable women to achieve this. Electromyography biofeedback is an adjunct to pelvic floor muscle training that may help women exercise more intensively for longer and, thus, may improve continence outcomes when compared with pelvic floor muscle training alone.

The need for a definitive trial of biofeedback as an intensifier of pelvic floor muscle training is supported by the current evidence base. The Cochrane systematic review of biofeedback-assisted pelvic floor muscle training for women with urinary incontinence (Herderschee R, Hay-Smith EJ, Herbison GP, Roovers JP, Heineman MJ. Feedback or biofeedback to augment pelvic floor muscle training for urinary incontinence in women. *Cochrane Database Syst Rev* 2011;**7**:CD009252) found that biofeedback-assisted pelvic floor muscle training appeared to offer benefit over basic pelvic floor muscle training; however, this effect may have been confounded by the greater amount of health professional contact in the biofeedback groups within trials. Thus, a trial in which women in both groups have similar amounts of contact is needed to allow firm conclusions to be drawn about biofeedback as an intensifier of pelvic floor muscle training in its own right.

The Optimal Pelvic floor muscle training for Adherence Long-term (OPAL) trial was designed to address this gap by answering a pragmatic question concerned with the clinical effectiveness and cost-effectiveness of electromyography biofeedback-mediated intensive pelvic floor muscle training (biofeedback pelvic floor muscle training) compared with pelvic floor muscle training alone (basic pelvic floor muscle training) for the treatment of stress or mixed female urinary incontinence.

Objective

The overall objective of the trial was to evaluate the clinical effectiveness and cost-effectiveness of electromyography biofeedback as an adjunct to pelvic floor muscle training, the latter being the recommended first-line treatment for female urinary incontinence in the UK. We conducted a randomised controlled trial in which electromyography biofeedback was delivered in addition to pelvic floor muscle training as an intensifier (both in clinic and at home), and compared with pelvic floor muscle training alone. We included a process evaluation to identify mediating factors, such as intervention fidelity, that might affect the clinical effectiveness of the intervention, and to establish how these factors influence clinical effectiveness and whether or not they differ between randomised groups. A nested longitudinal qualitative case study was also included to explore women's experiences of the trial interventions, to identify the barriers to and facilitators of adherence, to establish how they influence adherence and to assess whether or not they differ between randomised groups.

Methods

We carried out an individually randomised, multicentre controlled trial in which we compared biofeedback pelvic floor muscle training with basic pelvic floor muscle training for women with stress or mixed urinary incontinence to assess superiority. The allocation ratio was 1 : 1. The allocation was carried out remotely via a web-based automated application, with minimisation by type of urinary incontinence, centre, age and urinary incontinence severity at baseline. A sample size of 600 women was needed to detect a difference of 2.5 points on the primary outcome measure between the groups, with 90% power and 5% significance level, assuming a standard deviation of 10 and allowing for attrition of > 20%.

Participants were recruited from UK centres in community and outpatient care settings, where continence care is usually provided. During the trial recruitment period, women attending for their first continence appointment were identified by the health-care team at each centre. Eligibility was assessed by a clinician who saw the woman at a screening appointment, which included a vaginal examination. The inclusion criteria were being female, being aged ≥ 18 years and newly presenting with stress or mixed urinary incontinence. Women excluded were those with urgency urinary incontinence alone, those who had received formal instruction in pelvic floor muscle training in the previous year, those unable to contract their pelvic floor muscles, those who were pregnant or < 6 months postnatal, those with prolapse greater than stage II, those currently having treatment for pelvic cancer, those with cognitive impairment affecting capacity to give informed consent, those with neurological disease, those with a known nickel allergy or sensitivity and those currently participating in other research relating to their urinary incontinence.

The primary outcome measure was severity of urinary incontinence at 24 months post randomisation, as measured by the validated International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form. Interim follow-ups were conducted at 6 and 12 months. Secondary outcome measures included number of participants who were cured/improved, uptake of other treatment for urinary incontinence, presence of other pelvic floor symptoms (bladder, bowel, prolapse), self-efficacy for and adherence to pelvic floor muscle training, and quality of life. Resource use data were collected by participant self-report at the follow-up time points. The primary health economic outcome measure of cost-effectiveness was incremental cost per quality-adjusted life-year at 24 months.

Participants were offered six appointments with a trained therapist over 16 weeks, during which the trial intervention (biofeedback pelvic floor muscle training or basic pelvic floor muscle training) was delivered. Biofeedback units were provided to participants in the biofeedback pelvic floor muscle training group for home use. A written intervention manual was prepared for the therapists to guide intervention delivery. A checklist was provided for each appointment, detailing the intervention components to be delivered. Behaviour change techniques, both core and optional, were built in to the intervention protocols delivered (e.g. to help participants with goal-setting, action-planning and problem-solving).

As part of the process evaluation, therapists delivering the intervention at each centre were interviewed. In addition, to record their delivery of the intervention, therapists completed an intervention checklist at every appointment with a participant. A selection of appointments from across centres, where therapists were delivering the trial interventions, were audio-recorded. A subset of participants took part in a longitudinal case study and were interviewed at baseline and at 6, 12 and 24 months. These interviews were transcribed and analysed at different levels: within time points, within-case, cross-case and between trial groups. Quantitative descriptive summaries and framework analysis methods were used to analyse these mixed-methods data sets.

Results

Twenty-three centres agreed to take part in the trial and 687 women were screened for eligibility: a total of 600 women were randomised (300 women to the biofeedback pelvic floor muscle training

group and 300 women to the basic pelvic floor muscle training group). The two randomised groups were comparable at baseline. Follow-up questionnaire return rates were 74% at 6 months, 84% at 12 months and 78% at 24 months. Adherence to the intervention appointments was good: 92% attended at least one appointment (95% biofeedback pelvic floor muscle training, 89% basic pelvic floor muscle training) and 36% attended all six appointments (37% biofeedback pelvic floor muscle training, 36% basic pelvic floor muscle training). The average number of appointments attended was 4.1 (4.2 biofeedback pelvic floor muscle training, 4.0 basic pelvic floor muscle training).

The primary analysis indicated that there was no difference between groups in the severity of urinary incontinence at 24 months (mean difference –0.09, 95% confidence interval –0.92 to 0.75; $p = 0.84$). This finding was robust to sensitivity analysis that investigated assumptions about non-compliance and missing data. There were no significant differences between groups in the primary outcome within the predefined subgroups of type of urinary incontinence, age, baseline severity or type of therapist. There were no significant differences between groups in International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form score at 6 or 12 months.

The analysis of secondary outcomes indicated no significant differences between groups, at any time point, in urinary incontinence cure or improvement, other lower urinary tract symptoms, condition-specific quality of life, participant impression of improvement, uptake of further treatment for urinary incontinence, pelvic floor function, prolapse symptoms or bowel symptoms. The biofeedback pelvic floor muscle training group had statistically significantly better scores for self-efficacy for pelvic floor muscle exercises at 24 months, but the difference was small and unlikely to be clinically significant.

There were 48 participants who had a non-serious adverse event (34 biofeedback pelvic floor muscle training, 14 basic pelvic floor muscle training), of whom 23 (21 biofeedback pelvic floor muscle training, 2 basic pelvic floor muscle training) had a complication related or possibly related to one of the interventions. There were eight serious adverse events (6 biofeedback pelvic floor muscle training, 2 basic pelvic floor muscle training), all of which were unrelated.

The base-case economic analysis concluded that, at 24 months, biofeedback pelvic floor muscle training (£956) was not significantly more expensive than basic pelvic floor muscle training (£906) (mean difference £50, 95% confidence interval –£84 to £184), but neither was it associated with significantly more quality-adjusted life-years (1.567 vs. 1.566, mean difference –0.0009, 95% confidence interval –0.06 to 0.06). The incremental cost-effectiveness ratio of £56,617 per quality-adjusted life-year gained exceeded society's willingness-to-pay threshold of £30,000. Biofeedback pelvic floor muscle training was associated with a 49% chance of being cost-effective if society was willing to pay £30,000 for a quality-adjusted life-year.

The process evaluation had two key findings. First, therapists did deliver a more intensive intervention to the biofeedback pelvic floor muscle training group, despite time pressures. Second, most participants in both groups did receive core behavioural change techniques embedded in the basic pelvic floor muscle training, as intended, but few optional behavioural change techniques were used by therapists in either group.

Women from both groups who were interviewed reported positive experiences of the interventions received. There was variation in adherence and urinary incontinence outcomes in both groups, with no clear differences between groups. Factors that helped women adhere in the short and long term that were similar in both groups were their desire to improve their continence, having the belief that they were able to undertake pelvic floor muscle training and the expectation of what they might achieve in terms of symptoms and quality of life. Adherence was facilitated by the therapists and their input was particularly valued. Having time to undertake pelvic floor muscle training and 'life taking over' were important barriers to short- and long-term adherence.

Conclusions

Implications for health care

- We can be confident in concluding that the addition of biofeedback to pelvic floor muscle training treatment does not improve incontinence severity at 2 years and is unlikely to be cost-effective. Therefore, we think it unlikely that routinely offering this adjunct to pelvic floor muscle training will benefit continence outcomes for women.
- It is feasible for the behaviour change techniques that were embedded in the basic pelvic floor muscle training (which have evidence of effectiveness in other fields) to be used within the context of pelvic floor muscle training for women with urinary incontinence.

Recommendations for research (in priority order)

- Investigate other intensive forms of pelvic floor muscle training to improve continence outcomes (e.g. a pelvic floor muscle training programme with the addition of more health professional support).
- Establish if there is potential for evaluation of newer biofeedback devices in the context of treatment of urinary incontinence.

Trial registration

This trial is registered as ISRCTN57746448.

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This report

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