Nursing, Midwifery and Allied Health Professions Research Unit

Comparing effectiveness and cost-effectiveness of basic versus biofeedback-mediated intensive pelvic floor muscle training for female urinary incontinence

OPAL
optimising pelvic floor exercises to achieve longterm benefits

Background:

Urinary incontinence (UI), accidental urine leakage, affects approximately 1 in 3 women, and has the following main types: stress (SUI), urgency (UUI) and mixed (MUI) (both stress and urgency). There is strong evidence for the effectiveness of pelvic floor muscle training (PFMT) for SUI and MUI, and current UK guidelines recommend a supervised PFMT programme of at least 3 months. However, it is unclear what level of intensity of PFMT is required and how women are best enabled to achieve optimal results.

Electromyography (EMG) biofeedback is an adjunct to PFMT, which, by enabling women to 'see', their pelvic floor muscles exercising, could prove beneficial for long-term outcomes of PFMT compared with PFMT without biofeedback. The OPAL (Optimal PFMT Adherence Long-term) trial was conducted to investigate the effectiveness and cost-effectiveness of PFMT with biofeedback, compared with PFMT alone, for treatment of SUI and MUI in women.

Aims and objectives:

The OPAL trial aimed to evaluate how effective and cost-effective the addition of EMG biofeedback to PFMT is for treatment of female stress or mixed UI.

Objectives were to conduct:

- a parallel-group randomised controlled trial comparing two groups: 1) biofeedback mediated PFMT or 2) PFMT alone
- a process evaluation to identify factors which potentially impact on intervention effectiveness, how these factors impact on effectiveness and any group differences
- a qualitative case study in a sub-group of participants, exploring their experiences, barriers/facilitators to adherence, how these influence adherence, and group differences

Methods:

Women aged 18 years or older, diagnosed with SUI or MUI and with UI as the presenting complaint were potentially eligible. Excluded were women: with urgency UI alone; who had received PFMT instruction in past year; unable to contract pelvic floor muscles; pregnant or <6 months postnatal; with prolapse >stage II; receiving pelvic cancer treatment; unable to consent due to cognitive impairment; with a neurological disease; intolerant to nickel; already participating in UI research.

Women were recruited and randomly assigned (1:1) to group via the web-based randomisation service provided by the Centre for Healthcare Randomised Trials (CHaRT) at the University of Aberdeen. Intervention masking was not possible for participants, therapists or trial staff, but clinicians performing the 6-month assessment were masked to group allocation.

Both groups of women were offered PFMT over a 16-week period with 6 therapist appointments. Women were taught to contract and relax their pelvic floor muscles and were given an individually tailored PFMT exercise programme which was progressed over time. The biofeedback group additionally had the use of biofeedback incorporated into their appointments and were given a biofeedback unit for home use.

The primary outcome was severity of UI symptoms captured on the International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-SF) at 24 months.

Secondary outcomes included: UI cure/improvement, other urinary and pelvic floor symptoms, UI-specific quality of life, self-efficacy for PFMT, global impression of improvement in UI, adherence to exercise, uptake of other UI treatment, and pelvic floor muscle function. The primary health economic outcome was incremental cost per quality-adjusted-life-year gained at 24 months.

Findings:

From February 2014 to July 2016, 600 women were recruited from 23 UK centres (15 in Scotland, 8 in England). Follow up was completed in June 2018. The final report was submitted to the funder in December 2018 and is currently under peer review. Publications relating to the trial findings are in preparation.

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OPAL investigator team:
NMAHP RU Glasgow Caledonian University: Professor Suzanne Hagen (Chief Investigator), Professor Doreen McClurg, Andrew Elders
University of Otago: Jean Hay-Smith
University of Stirling: Carol Bugge
University of Exeter: Sarah Dean
NHS Greater Glasgow and Clyde: Karen Guerrero
University of Aberdeen: Mohamed Abdel-fattah, Charis Glazener, Mary Kilonzo
CHaRT: Lorna Henderson, Alison McDonald, Gladys McPherson
University of Edinburgh: John Norrie
Consumer Advisor: Lyndsay Wilson

OPAL trial researchers:
Trial Managers (NMAHP RU Glasgow Caledonian University): Susan Stratton, Louise Williams
Data Co-ordinators (NMAHP RU Glasgow Caledonian University): Nicole Sergenson, Lisa Wotherspoon, Nicola Gillespie
Qualitative Researchers (University of Stirling): Anne Taylor, Aileen Grant, Marija Kovandzic, Federico Andreis

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www.nmahp-ru.ac.uk

Contact details:

General contact Stirling:
Unit 13 Scion House
University of Stirling Innovation Park
Stirling
FK9 4NF

01786 466341

nmahp.ru@stir.ac.uk

General contact GCU:
6th floor Govan Mbeki Building
Glasgow Caledonian University
Cowcaddens Road
Glasgow
G4 0BA

0141 331 8100

nmahpruadmin@gcu.ac.uk

Twitter: @nmahpru