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

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

<sup>1</sup>Nursing, Midwifery and Allied Health Professions Research Unit, Glasgow Caledonian University, Glasgow, UK

<sup>2</sup>Faculty of Health Sciences and Sport, University of Stirling, Stirling, UK <sup>3</sup>University of Exeter Medical School, Exeter, UK

<sup>4</sup>Rehabilitation Teaching and Research Unit, University of Otago, Dunedin, New Zealand

<sup>5</sup>Institute of Applied Health Sciences, University of Aberdeen, Aberdeen, UK <sup>6</sup>NHS Ayrshire and Arran, Kilmarnock, UK

<sup>7</sup>School of Health and Life Sciences, Glasgow Caledonian University, Glasgow, UK <sup>8</sup>Health Services Research Unit, University of Aberdeen, Aberdeen, UK

<sup>9</sup>School of Nursing and Midwifery, Robert Gordon University, Aberdeen, UK <sup>10</sup>Queen Elizabeth University Hospital, NHS Greater Glasgow and Clyde, Glasgow, UK

<sup>11</sup>Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, University of Aberdeen, Aberdeen, UK

<sup>12</sup>Edinburgh Clinical Trials Unit, University of Edinburgh, Edinburgh, UK

\*Corresponding author hagen@gcu.ac.uk

**Declared competing interests of authors:** Sarah G Dean reports funding from University College London for consultancy work as part of an expert panel in the behaviour change technique taxonomy development, Medical Research Council-funded project (2012–2015) outside the submitted work. Mohamed Abdel-Fattah reports having been, in the past, a speaker, consultant and surgical trainer for Astellas Pharma Inc. (Tokyo, Japan), Bard Medical Division (Covington, GA, USA), Pfizer Inc. (New York, NY, USA), American Medical Systems Inc. (Minnetonka, MN, USA) and Coloplast Ltd (Peterborough, UK). At that time, he was reimbursed travel expenses, received limited personal honorariums for some work, and, on occasions, received sponsorship towards attending scientific conferences. He has received a research grant from Coloplast, managed by the or

received assistance University of Aberdeen. A limited number of his trainees attended pharmaceuticalsponsored educational/leadership workshops and/towards presenting their research work in scientific conferences. He was also the chairperson of the Scottish Pelvic Floor Network, which, at the time (up to 2014), received sponsorship from various industrial companies to exhibit in annual meetings and surgical workshops. In addition, he receives travel sponsorship from numerous national and international conferences and non-profit organisations when invited as guest speaker and/or expert surgeon. Wael Agur reports non-financial support from Astellas Pharma; personal fees from Johnson & Johnson (New Brunswick, NJ, USA) – Ethicon Endoscopy; personal fees from Specialty European Pharma Ltd/Contura Ltd (London, UK); personal fees and non-financial support from the Chief Scientist Office (Edinburgh, UK), NHS Research Scotland and NHS Ayrshire & Arran; grants from the National Institute for Health Research (NIHR); grants from the University of Stirling; personal fees from London Medical Education Academy (London, UK); personal fees from the Central Legal Office, NHS Scotland; personal fees from various law firms acting on behalf of mesh manufacturers, patient claimants and defendant clinicians in Scotland, England, Wales, Northern Ireland, the Republic of Ireland, USA and Australia; personal fees from Oaklaw Consultancy Ltd (Kilmarnock, UK) (dealing with medicolegal consultancy through a third party – Medico-legal Administration Service). Karen L Guerrero reports personal speaker fees, outside the submitted work, and educational bursaries from Contura Ltd to attend continuing professional development meetings. She is also course director/faculty member for Glasgow Urogynaecology/NHS Education Scotland courses/training days and meetings and NHS/Deanery Educational courses, which have had industry sponsorship. In addition, she is Treasurer for the UK Continence Society, the British Society of Urogynaecology Educational Committee Chair elect, Secretary of the Scottish Pelvic Floor Network and sits on the Royal College of Obstetricians and Gynaecologists subspecialty training committee. All of these associations/charities have meetings supported by industry. Furthermore, she is co-grant holder for several NIHR grants. John Norrie reports grants from the University of Aberdeen, and the University of Edinburgh during the conduct of the study; and declares membership of the following NIHR boards: Cardiopulmonary Resuscitation Decision-making Committee (2016), Health Technology Assessment (HTA) Commissioning Board (2010–16), HTA Commissioning Sub-Board (Expression of Interest) (2016–19), HTA Funding Boards Policy Group (2016–19), HTA General Board (2016–19), HTA Post-Board funding teleconference (2016–19), NIHR Clinical Trials Unit Standing Advisory Committee (2018–present), NIHR HTA and Efficacy and Mechanism Evaluation Editorial Board (2014–19) and the Pre-exposure Prophylaxis Impact Review Panel (2017–present).

Published December 2020 DOI: 10.3310/hta24700

DOI: 10.3310/hta24700

## **Plain English summary**

The OPAL RCT Health Technology Assessment 2020; Vol. 24: No. 70

NIHR Journals Library www.journalslibrary.nihr.ac.uk

# **Plain English summary**

U rinary incontinence (accidental leakage of urine) is a common and embarrassing problem for women. Pregnancy and childbirth may contribute by leading to less muscle support and bladder control. Pelvic floor exercises and 'biofeedback' equipment (a device that lets women see the muscles working as they exercise) are often used in treatment. There is good evidence that exercises (for the pelvic floor) can help, but less evidence about whether or not adding biofeedback provides better results.

This trial compared pelvic floor exercises alone with pelvic floor exercises plus biofeedback. Six hundred women with urinary incontinence participated. Three hundred women were randomly assigned to the exercise group and 300 women were randomised to the exercise plus biofeedback group. Each woman had an equal chance of being in either group. Women were offered six appointments with a therapist over 16 weeks to receive their allocated treatment.

After 2 years, there was no difference between the groups in the severity of women's urinary incontinence. Women in both groups varied in how much exercise they managed to do. Some managed to exercise consistently over the 2 years and others less so. There were many factors (other than the treatment received) that affected a woman's ability to exercise. Notably, women viewed the therapists' input very positively. The therapists reported some problems fitting biofeedback into the appointments, but, overall, they delivered both treatments as intended. Women carried out exercises at home and many in the biofeedback pelvic floor muscle training group also used biofeedback at home; however, for both groups, time issues, forgetting and other health problems affected their adherence. There were no serious complications related to either treatment.

Overall, exercise plus biofeedback was not significantly more expensive than exercise alone and the quality of life associated with exercise plus biofeedback was not better than the quality of life for exercise alone.

In summary, exercises plus biofeedback was no better than exercise alone. The findings do not support using biofeedback routinely as part of pelvic floor exercise treatment for women with urinary incontinence.

© Queen's Printer and Controller of HMSO 2020. This work was produced by Hagen et al. under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

### **Health Technology Assessment**

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 3.370

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, the Cochrane Library and Clarivate Analytics Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

#### Criteria for inclusion in the Health Technology Assessment journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

#### **HTA programme**

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

#### This report

The research reported in this issue of the journal was funded by the HTA programme as project number 11/71/03. The contractual start date was in September 2013. The draft report began editorial review in December 2018 and was accepted for publication in May 2019. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care.

© Queen's Printer and Controller of HMSO 2020. This work was produced by Hagen *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

### **NIHR Journals Library Editor-in-Chief**

Professor Ken Stein Professor of Public Health, University of Exeter Medical School, UK

### **NIHR Journals Library Editors**

**Professor John Powell** Chair of HTA and EME Editorial Board and Editor-in-Chief of HTA and EME journals. Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK, and Professor of Digital Health Care, Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

**Professor Andrée Le May** Chair of NIHR Journals Library Editorial Group (HS&DR, PGfAR, PHR journals) and Editor-in-Chief of HS&DR, PGfAR, PHR journals

**Professor Matthias Beck** Professor of Management, Cork University Business School, Department of Management and Marketing, University College Cork, Ireland

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin Senior Scientific Advisor, Wessex Institute, UK

Dr Peter Davidson Consultant Advisor, Wessex Institute, University of Southampton, UK

Ms Tara Lamont Senior Scientific Adviser (Evidence Use), Wessex Institute, University of Southampton, UK

**Dr Catriona McDaid** Senior Research Fellow, York Trials Unit, Department of Health Sciences, University of York, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Emeritus Professor of Wellbeing Research, University of Winchester, UK

Professor John Norrie Chair in Medical Statistics, University of Edinburgh, UK

**Professor James Raftery** Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professor of Child Health Research, UCL Great Ormond Street Institute of Child Health, UK

Professor Jonathan Ross Professor of Sexual Health and HIV, University Hospital Birmingham, UK

**Professor Helen Snooks** Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Professor Ken Stein Professor of Public Health, University of Exeter Medical School, UK

**Professor Jim Thornton** Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Professor Martin Underwood Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, UK

Please visit the website for a list of editors: www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: journals.library@nihr.ac.uk