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A study comparing pelvic floor muscle exercises with and without the use of computer feedback for women with urine leakage (OPAL)

Submission date
19/12/2013

Recruitment status
No longer recruiting

Registration date
10/01/2014

Overall study status
Completed

Last Edited
10/12/2020

Condition category
Urological and Genital Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Urinary leakage is a common and often distressing problem for women. There is good evidence that pelvic floor muscle exercises can cure or reduce leakage but it is unclear as to how intensely these exercises need to be undertaken. Sometimes a technique called 'electromyography' (EMG) biofeedback is used to help a woman perform the exercises. However, it is uncertain whether using this technique makes the exercises more effective. This study aims to find out whether doing pelvic floor muscle exercises with biofeedback is any more effective than doing exercises without biofeedback.

Who can participate?
Women 18 years of age or above, presenting with a new episode of stress or mixed urinary incontinence (UI).

What does the study involve?
All participants will be asked to attend 6 appointments over 16 weeks with a continence physiotherapist or nurse. At the first scheduled appointment the continence physiotherapist or nurse will ask some questions, look at the participant's bladder diary (which will have been sent to them in advance), and a routine vaginal assessment will be undertaken. If they are eligible and interested in the study then a Researcher will give them information about the study and answer any questions they may have. Providing the woman is still interested they will be given a consent form and a questionnaire to complete, after which they will be randomly allocated to one of two groups. Participants in one group will be taught how to do pelvic floor muscle exercises and will be given a home exercise programme. Participants in the other group will, in addition, receive EMG biofeedback at clinic and will be provided with a small handheld EMG biofeedback unit to help with undertaking the exercises at home. The EMG biofeedback uses a vaginal device called a Periform which in the clinic is connected to a computer screen that displays the contraction of the muscles as a line graph. At the next and subsequent appointments the continence physiotherapist or nurse will assess their condition and discuss their treatment goals and exercise plan. They will educate the participant on how to do pelvic floor muscle exercises. The continence physiotherapist or nurse will discuss possible reasons for their urinary leakage and

lifestyle changes they may be able to make which could also help. During these appointments their progress will be monitored and exercise plan adjusted accordingly. Some treatment appointments may be audio recorded to find out if the treatment is being delivered as intended. A small number of women will also be interviewed. A separate Information Leaflet will be given to those selected for Interview. Questionnaires will be sent to the participant for completion at 6, 12 and 24 months into the study. They will also be asked to attend for a follow-up vaginal assessment at 6 months. They will be asked to complete a bladder diary over 3 days at the start and end of the study. This will involve keeping a record of liquids they drink, the number of times they go to the toilet or have an accident and how much urine they pass.

What are the possible benefits and risks of participating?
We do not anticipate any risks from being involved in the study. All the materials and techniques are already being used in the NHS. Participation in the study is therefore only to help us evaluate these procedures and should not involve any additional risk. Some people may feel uncomfortable with vaginal examinations but these would be undertaken as part of routine care. Should the participant decide that this is something they do not wish to have, this will be respected, although they will not be able to take part in the study. This will also not affect the treatment they will receive. Some of the questions may seem invasive but the information is important to us.

Where is the study run from?
The research is being carried out by a group of experienced doctors, nurses, physiotherapists and researchers from a number of different organisations:
1. Nursing, Midwifery and Allied Health Professions Research Unit, Glasgow Caledonian University (lead organisation)
2. The University of Stirling
3. Health Services Research Unit, University of Aberdeen
4. Centre for Healthcare Randomised Trials, University of Aberdeen
5. The University of Exeter
6. The University of Otago, New Zealand
7. NHS Greater Glasgow & Clyde
8. NHS Grampian
9. NHS Ayrshire and Arran
The Trial Office is located in the NMAHP Research Unit, Glasgow Caledonian University. The Clinical Trials Unit involved with the trial (CHaRT) is based at the University of Aberdeen. The qualitative researchers are based at University of Stirling.

When is the study starting and how long is it expected to run for?
The study started in September 2013 and will run until May 2018. Participant recruitment is due to start in February 2014.

Who is funding the study?
The study is funded by the National Institute for Health Research, UK.

Who is the main contact?
Professor Suzanne Hagen (Chief Investigator)
S.hagen@gcu.ac.uk
Susan Stratton, OPAL Trial Manager
susan.stratton@gcu.ac.uk

Study website
https://www.opaltrial.co.uk/

Contact information

Type(s)
Scientific

Contact name
Prof Suzanne Hagen

Contact details
Dept of Psychology
Glasgow Caledonian University
City Campus
70 Cowcaddens Road
Glasgow
United Kingdom
G4 0BA

Additional identifiers

EudraCT/CTIS number
N/A

IRAS number

ClinicalTrials.gov number
N/A

Secondary identifying numbers
HTA 11/71/03, 15841

Study information

Scientific Title
OPAL: a multicentre randomised trial of the effectiveness and cost-effectiveness of basic versus biofeedback-mediated intensive pelvic floor muscle training for female stress or mixed urinary incontinence

Acronym
OPAL

Study objectives
The research objective is to compare two types of pelvic floor muscle training (PFMT), basic and intensive, and establish if intensive PFMT (PFMT with the addition of biofeedback) is more clinically effective and cost-effective after 24 months at reducing incontinence, improving quality of life, reducing need for surgery and other incontinence treatments, improving pelvic floor muscle function and increasing women's confidence and adherence to PFMT

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=15841 and http://www.nets.nihr.ac.uk/projects/hta/117103

Study protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0017/81170/PRO-11-71-03.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Service, 13/03/2013, ref: 13/WS/0048

Study design
Randomised; Interventional and Observational; Design type: Treatment, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Female stress or mixed urinary incontinence

Interventions
1. PFMT intensified with use of electromyography biofeedback both at home and in clinic.
2. Basic PFMT.

Both groups will be seen for six appointments and intervention over a 16 week period. Follow up, with questionnaires at 6,12 & 24 months and interviews for a sub-group of approximately 40 women.

Assessors carrying out the 6-month pelvic floor muscle assessment will be blinded to which group the woman is in.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
International Consultation on Incontinence short form questionnaire (ICIQ-UI SF) measured at baseline, 6, 12 and 24 months

Secondary outcome measures
Urinary outcomes
1. Number of episodes of UI per day, recorded by women in a bladder diary [Locher et al 2001]
2. Impression of global improvement in UI (PGI-I) [Yalcin and Bump 2003]
3. Number of women with UI cured and number with UI improved, derived from the ICIQ-UI ShortForm (cured is a negative response to both 'how often do you leak urine?' and 'how much urine do you usually leak (whether you wear protection or not)?'
4. Uptake of surgery for UI
5. Uptake of other treatment for UI
6. Other urinary symptoms (ICIQ-FLUTS) [Brookes et al 2004]

Quality of life outcomes
1. UI-specific quality of life (Kings Health Questionnaire) [Kelleher et al 1997]
2. General health (EQ-5D-3L) [EuroQol Group]

Pelvic floor related outcomes
1. Prolapse symptoms (POP-SS - Hagen et al 2009)
2. Bowel symptoms (early version of ICIQ Bowel Short Form)
3. Pelvic floor muscle function (Oxford scale - Laycock 2008, ICS method - Messelink et al 2005)
4. Self-efficacy for PFMT (PFME self-efficacy scale) [Chen 2004]
5. Adherence to PFMT (exercise diary/follow-up questionnaire)

Economic outcomes
1. Cost and use of NHS services
2. Cost to the women and their families/carers
3. The incremental costs, QALYs and incremental cost per QALY derived by the economic model.

Overall study start date
01/09/2013

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Women 18 years of age or above, presenting with a new episode of stress or mixed urinary incontinence (UI)
2. Who are willing and eligible to be randomised

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Female

Target number of participants
Planned Sample Size: 600

Total final enrolment
600

Key exclusion criteria
1. Women who have urge UI alone
2. Women who cannot contract their pelvic floor muscles
3. Women who had formal instruction in PFMT in the last three years
4. Women who are pregnant or less than one year postnatal
5. Women who have prolapse greater than stage II, who have pelvic cancer, cognitive impairment or neurological disease

Date of first enrolment
01/02/2014

Date of final enrolment
31/05/2018

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Glasgow Caledonian University
Glasgow
United Kingdom
G4 0BA

Sponsor information

Organisation
Glasgow Caledonian University (UK)

Sponsor details
Dept of Psychology
City Campus
70 Cowcaddens Road
Glasgow

Scotland
United Kingdom
G4 0BA

Sponsor type
University/education

Website
http://www.gcu.ac.uk/

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment (HTA) (UK) 11/71/03

Results and Publications

Publication and dissemination plan
2019 results presented at the International Continence Society conference in August 2019 https://www.ics.org/2019/abstract/489 (added 11/05/2020)

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/02/2019		Yes	No
Protocol article	protocol	19/02/2019		Yes	No
Results article	results	14/10/2020	22/10/2020	Yes	No
Results article	results	01/12/2020	10/12/2020	Yes	No

HRA research summary	28/06/2023	No	No