

# An evaluation of pelvic floor muscle exercises and electrical muscle stimulation in patients with stress incontinence

**Submission date**

01/03/2001

**Recruitment status**

No longer recruiting

**Registration date**

01/03/2001

**Overall study status**

Completed

**Last Edited**

16/01/2009

**Condition category**

Urological and Genital Diseases

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Professor JA Oldham

**Contact details**

Centre for Rehabilitation Science

University of Manchester

Central Manchester Healthcare Trust

Oxford Road

Manchester

United Kingdom

M13 9WL

+44 (0)161 276 6672

jackie.oldham@man.ac.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

AP0813

# Study information

## Scientific Title

An evaluation of pelvic floor muscle exercises and electrical muscle stimulation in patients with stress incontinence: a randomised, double-blind, controlled trial

## Study objectives

To evaluate a new pattern of electrical of electrical stimulation as a treatment for stress incontinence.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised double-blind controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Stress incontinence

## Interventions

Women will be randomly allocated to one of the following groups:

1. Pelvic floor exercises alone
2. The new pattern of electrical stimulation alone
3. Pelvic floor exercises and the new pattern of electrical stimulation

## Intervention Type

Other

## Phase

Not Applicable

### **Primary outcome measure**

Patients were assessed pre, mid and post-treatment using:

1. Digital vaginal assessment of pelvic floor muscle strength using the modified Oxford Grading Scale
2. Assessment of vaginal muscle strength and endurance using the PRS 9300 perineometer (Incare Medical Products, USA)
3. One-hour pad test as recommended by the International Continence Society (ICS)

### **Secondary outcome measures**

The following were only used pre- and post-treatment:

1. Seven-day frequency/volume chart
2. 36-item Short Form Health Survey (SF-36)
3. The Incontinence Impact Questionnaire
4. The Urogenital Distress Inventory

### **Overall study start date**

01/01/2000

### **Completion date**

31/12/2000

## **Eligibility**

### **Key inclusion criteria**

1. Females with stress incontinence between the ages of 18 and 70.

Added 12/01/2009:

2. Urodynamically proven stress incontinence
3. No neurological conditions diagnosed by consultant

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

70 Years

### **Sex**

Female

### **Target number of participants**

Added 12/01/2009: 27

### **Key exclusion criteria**

Added 12/01/2009:

1. Previous electrical stimulation for stress incontinence
2. Prolapse
3. Pregnancy
4. Pacemakers and cardiomyopathy
5. Abnormal urological/gynaecological findings
6. Urinary tract/vaginal infection
7. Recent pelvic floor surgery (within the last six months)

**Date of first enrolment**

01/01/2000

**Date of final enrolment**

31/12/2000

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Centre for Rehabilitation Science**

Manchester

United Kingdom

M13 9WL

## **Sponsor information**

**Organisation**

Action Medical Research (UK)

**Sponsor details**

Vincent House

Horsham West Sussex

United Kingdom

RH12 2DP

**Sponsor type**

Charity

**Website**

<http://www.action.org.uk/>

ROR

<https://ror.org/01wcqa315>

## Funder(s)

### Funder type

Charity

### Funder Name

Action Medical Research (UK)

### Alternative Name(s)

actionmedres, action medical research for children, AMR

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

United Kingdom

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### 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?
<a href="#">Results article</a>	results	01/12/2000		Yes	No