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# Inko-Outside multicentre, controlled, randomised, blinded study for the treatment of stress urinary incontinence

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 23/03/2010 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 25/03/2010 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 06/03/2019 | Urological and Genital Diseases | [_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Ruth Maher

**Contact details**
North Georgia College and State University
82 College Circle
Dahlonega, Georgia
United States of America
30597

## Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT01472068

**Protocol serial number**
BMR-09-1008

## Study information

**Scientific Title**

A single-blind multicentre, controlled, randomised, blinded comparative study of three forms of pelvic floor muscle training: kegel exercises (KE), electrical stimulation using external skin-electrodes (ESEX) and electrical stimulation using an intra-vaginal electrode (ESIN), in the treatment of stress urinary incontinence

## Acronym
INKO-OUTSIDE

## Study objectives
Comparison of three forms of pelvic floor muscle training in the treatment of stress urinary incontinence:
1. Kegel exercises (KE)
2. Electrical stimulation using external skin-electrodes (ESEX)
3. Electrical stimulation using an intra-vaginal electrode (ESIN)

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Institutional Review Board (IRB) of North Georgia College & State University

## Primary study design
Interventional

## Study design
Randomised controlled single-blind multicentre trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Stress urinary incontinence

## Interventions
1. 12 weeks of treatment with Inko-Outside (external NMES) and 14 weeks of Kegels
2. 12 weeks of treatment with conventional NMES using an internal probe and 14 weeks of Kegels
3. 26 weeks of Kegels

## Intervention Type
Mixed

## Primary outcome(s)
Change in continence scores compared to baseline:
1. Incontinence impact questionnaire score (IIQ-7)
2. Pelvic Floor Muscle strength as determined by Modified Oxford Scale upon digital palpation:
2.1. Pad usage
2.2. Leaks per week
2.3. Pad weight in provocative tests (cough and jumping jacks)
2.4. Compliance measure on stimulators and on diary for PFMT
3. Number of participants who have gone on to have surgery at 1 year - follow-up phone call

### Key secondary outcome(s)
1. Proportion of group cured (namely, dry at each visit):
2. Proportion of group improved
3. Time to dryness in weeks

Dryness will be defined as dry for 5 consecutive days as reported by subjects on enquiry, and which is subsequently maintained until the end of the study (26 weeks). The status will also be confirmed by provocative tests with cough and jumping jack activities in the clinic. Participants having been declared "dry" will be determined to have relapsed if they have more than 1 leak per week, with normal activities.

### Completion date
01/12/2010

## Eligibility

### Key inclusion criteria
1. Referrals with significant stress urinary incontinence (SUI) (defined as greater than 3 leaks/day or greater than 3 g in cough/jumping jack test) of any ethnic background
2. Pre-screened and cleared by gynaecological/urologist/suitably experienced PT for structural abnormalities (e.g. prolapsed uterus)
3. Body mass index (BMI) less than 40 kg/m^2
4. Non-smoker
5. Greater than 3 months post-partum
6. Females at least 18 and less than 70 years of age
7. Able to comply with either therapy
8. Able and willing to complete all of the study and provide informed written consent prior to entering the study

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Key exclusion criteria
1. Persons contra-indicated for ES
2. Individuals with a history of an underlying neurological condition
3. Individuals with an active implanted medical device, e.g., pacemaker or pump
4. Pregnant women or inadequate precautions to prevent pregnancy
5. Neurological impairment affecting pelvic floor musculature

6. Medication affecting continence
7. Medication for high blood pressure
8. Previous incontinence surgery, hysterectomy, previous gynaecological related surgery
9. Intra-uterine devices (IUDs) or metal implants in the pelvic area, including hip
10. Clinical diagnosis of prolapse
11. Abnormal Pap smear in the previous 6 months

### Date of first enrolment
12/04/2010

### Date of final enrolment
01/12/2010

## Locations

### Countries of recruitment
United Kingdom

Germany

Ireland

United States of America

### Study participating centre
**North Georgia College and State University**
Dahlonega, Georgia
United States of America
30597

## Sponsor information

### Organisation
North Georgia College and State University (USA)

### ROR
https://ror.org/001pe5g24

## Funder(s)

### Funder type
Industry

**Funder Name**
Bio-Medical Research Ltd (UK) - provided devices

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not provided at time of registration