

# Effectiveness of an urinary incontinence program for Chinese elderly women in a community setting

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<b>Registration date</b> 11/07/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/08/2014	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Involuntary urinary leakage is a very common problem, especially amongst elderly women. The primary aim of this study was to study the effect of a new comprehensive conservative treatment program in elderly woman with involuntary urinary leakage.

### Who can participate?

Chinese women aged 65 years or older with a clinical diagnosis of stress, urge or mixed urinary incontinence.

### What does the study involve?

Participants were randomly allocated to either the intervention group or the control group. The intervention group attended a standardised comprehensive treatment program, which lasted for 12 weeks. A 30-minute individual training session was given at the same time of the day, once weekly for the first 4 weeks and then once every fortnight for the remaining 8 weeks. The three major components of the program were education, pelvic floor muscle training and bladder training. The control group only received an educational pamphlet with information about management of urinary incontinence. Participants were given an appointment for a follow-up visit in 12 weeks.

### What are the possible benefits and risks of participating?

There are minimal reported risks in previous studies with a similar nature. However, subjects with an unreported latex allergy might suffer an allergic reaction.

### Where is the study run from?

Hong Kong Polytechnic University (Hong Kong).

### When is the study starting and how long is it expected to run for?

This study was carried out between September 2006 and August 2007.

Who is funding the study?

This study was jointly funded by the Hong Kong Polytechnic University and the Department of Health (Hong Kong).

Who is the main contact?

Dr Nicola Mok

Department of Rehabilitation Sciences, Hong Kong Polytechnic University

## Contact information

### Type(s)

Scientific

### Contact name

Dr Nicola Mok

### Contact details

Department of Rehabilitation Sciences

Hong Kong Polytechnic University

Hung Hom

Hong Kong

N/A

## Additional identifiers

## Study information

### Scientific Title

Effectiveness of an urinary continence physiotherapy program (UCPP) for Chinese elderly women in a community setting: a randomised controlled trial

### Study objectives

A comprehensive program consisting of education, behavioural modification, and specific therapeutic exercise is more effective than education alone in the management of urinary incontinence in the Chinese elderly female population

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

1. Departmental Research Committee, Department of Rehabilitation Sciences, Hong Kong Polytechnic University, 09/02/2007

2. Ethics Committee, Department of Health, The Government of the Hong Kong Special Administrative Region of the People's Republic of China, 28/11/2006, ref: L/M 376/2006 in DHHQ /5030/5/5

### Study design

Single-centre randomised single-blind interventional clinical trial

### Primary study design

Interventional

## **Study type(s)**

Treatment

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

Urinary incontinence in elderly women

## **Interventions**

Trial period: 12 weeks

Intervention:

1. A 30-minute individual training session was given at the same time of the day, once weekly for the first 4 weeks and then once every fortnight for the remaining 8 weeks
2. A total of eight treatment sessions were given to each recipient
3. Three major components in the UCPP:
  - 3.1. Education, includes anatomy of the pelvic floor muscle and urinary tract, urinary continence mechanism and bladder care
  - 3.2. Pelvic floor muscle training (PFMT) with the aid of vaginal palpation. PFMT included Kegel exercise program and neuromuscular re-education (the knack)
  - 3.3. Bladder training (BT). BT involved strategies to increase the time interval between voids by a combination of progressive void schedules, urge suppression, distraction, self-monitoring and reinforcement.
4. For the control group, only an educational pamphlet with information about management of urinary incontinence was given at the baseline.
5. Participants were given an appointment for a follow-up visit in 12 weeks.

Joint Sponsor details:

Department of Health

The Government of the Hong Kong Special Administrative Region of the People's Republic of China

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

1. The number of urinary incontinence (UI) episodes in the last 7 days (UI7)
2. Subjective perception of improvement was assessed with a 10 cm Visual Analogue Scale (VAS), with 0 being 'no improvement' to 10 being 'complete relief' at the end of the intervention period

## **Key secondary outcome(s)**

1. Subjects satisfaction with treatment, assessed by a 10 cm VAS, with 0 being 'totally dissatisfied' and 10 being 'totally satisfied'
2. Quality of life - assessed by the Incontinence Impact Questionnaire (IIQ) Chinese version

## **Completion date**

31/12/2007

# Eligibility

## Key inclusion criteria

1. Chinese females, aged 65 years or older
2. Had clinical diagnosis of stress, urge or mixed urinary incontinence by a medical practitioner, with reference to a guideline (Lagro-Janssen et al 1991)

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Senior

## Sex

Female

## Key exclusion criteria

1. Concurrent active urinary tract infection
2. On diuretic medication
3. Co-existing bladder pathology or dysfunction due to genitourinary fistula, tumor, pelvic irradiation, neurological or other chronic conditions (e.g. diabetes mellitus, Parkinsons disease)
4. Previous anti-incontinence surgery
5. Significant cognitive impairment (assessed by the Cantonese Version of Mini-Mental State Examination Score (CMMSE))
6. Obesity (body mass index > 30 kg/m<sup>2</sup>)
7. Use of concomitant treatments during the trial

## Date of first enrolment

09/02/2007

## Date of final enrolment

31/12/2007

# Locations

## Countries of recruitment

Hong Kong

## Study participating centre

Department of Rehabilitation Sciences

Hung Hom

Hong Kong

N/A

# Sponsor information

## Organisation

Department of Rehabilitation Sciences (Hong Kong)

## ROR

<https://ror.org/0030zas98>

# Funder(s)

## Funder type

University/education

## Funder Name

Hong Kong Polytechnic University (Hong Kong)

## Alternative Name(s)

The Hong Kong Polytechnic University, , Hong Kong PolyU, Government Trade School, Hong Kong Technical College, Hong Kong Polytechnic, , , Hēunggóng Léihgūng Daaihohk, PolyU, HKPU

## Funding Body Type

Government organisation

## Funding Body Subtype

Universities (academic only)

## Location

Hong Kong

# Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary