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

Submission date
30/06/2011

Recruitment status
No longer recruiting

Registration date
11/07/2011

Overall study status
Completed

Last Edited
14/08/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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Contact information

Type(s)
Scientific

Contact name
Dr Nicola Mok

Contact details
Department of Rehabilitation Sciences
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N/A

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
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 measure
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

Secondary outcome measures
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

Overall study start date
09/02/2007

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

Age group
Senior

Sex
Female

Target number of participants
55

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/m2)
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)

Sponsor details
Hong Kong Polytechnic University
Hung Hom
Hong Kong
N/A

Sponsor type
University/education

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, PolyU, HKPU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Hong Kong

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