Study protocol

Effects of High Intensity Focused Electromagnetic Therapy with Pelvic Floor Muscle Training on Urine Leakage and Quality of Life in Primipara or Multipara Women with Stress Urinary Incontinence: A Pilot for Randomised Controlled Trial

Objectives

This study aimed to evaluate the impact of High-Intensity-Focused-Electromagnetic-Therapy (HIFEM) combined with Pelvic-Floor-Muscle-Training (PFMT) versus PFMT alone on urine leakage and quality of life in Primipara or Multipara women with stress urinary incontinence.

Method

Ethical committee approval

This study protocol was approved by the Ethics Committee of Hong Kong Metropolitan University (reference number: N&HS00004).

Sample size calculation

The sample size was determined based on the observations of the primary outcome (the 1-hour pad test) in a previous study. Using version 3.1.9.4 of the G*Power statistical software, a minimum sample size of 42 (21 per arm) was established. The a priori power analysis utilized an estimated effect size of 0.9, with a 95% confidence interval ($\alpha \leqslant 0.05$), statistical power of 80%, and a 1:1 allocation ratio. Anticipating a 20% dropout rate, the calculated size was adjusted to 50 subjects (25 per group).

Participants

Ambulatory and community-dwelling primipara or multipara women aged $\geqslant$ 30 years with Stress Urinary Incontinence (SUI) symptoms confirmed by the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF) were recruited if they agreed not to seek any other form of treatment for SUI during the study. Those with contraindications for High-Intensity Focused Electromagnetic Therapy (HIFEM) were excluded. Other exclusion criteria included prior surgery for incontinence, use of medications for bladder dysfunction or diuretics, hormone therapy, urgent or mixed urinary incontinence, incontinence associated with a neurological condition, inability to perform voluntary pelvic floor muscle contractions, cognitive impairment or dementia, major neurological disorders (such as stroke, cerebral palsy, and multiple sclerosis), inability to carry out the treatment or evaluation, and uncontrolled hypertension.

Procedure

Interventions: Subjects were randomized into two treatment groups. The experimental group received both HIFEM and Pelvic Floor Muscle Training (PFMT), while the control group received only PFMT. The treatment continued for 6 weeks.

HIFEM: HIFEM stimulation was administered using an Emsella instrument (manufactured by BTL Industry Inc., Boston, MA) according to the manufacturer's protocol. The frequency ranged between 50 and 60 Hz, and the intensity was set as high as the patient could tolerate, typically up to 100%.

The PFMT protocol followed guidelines outlined in a previous study. Participants were instructed to perform 5 rapid contractions over a span of 3 seconds, followed by 10 prolonged contractions, each lasting between 3 to 8 seconds, with 10-second intervals for relaxation in

between, all while in a crook-lying position.

Measurements
Evaluations conducted at baseline and after the six-week intervention. Measurements included the 1-hour Pad Test, the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF), and sonography to assess bladder neck movement.

1-hour pad test: The total amount of urine leakage was measured by weighing the pad after performing several standardized activities over the course of an hour.

ICIQ-UI-SF: The ICIQ-UI-SF was used to assess the frequency and severity of SUI and its impact on quality of life. The scores from these items provide an overall score ranging from 0 to 20, with higher scores indicating greater severity of urinary incontinence and a more significant impact on quality of life.

Bladder neck movement: Bladder neck movement was measured using an ultrasound scanner. The ultrasound scanner is a Clarius C3 HD3 (Clarius Mobile Health, Vancouver, Canada).

Statistical analysis
All data were analyzed using IBM SPSS Statistics for Windows, Version 26.0 (Armonk, NY: IBM Corp). A two-way repeated measures ANOVA was employed with the outcome metrics, both pre- and post-intervention.