

## LONG TERM EFFECT OF PELVIC FLOOR MUSCLE TRAINING FOR FEMALE STRESS AND MIXED URINARY INCONTINENCE- A SYSTEMATIC REVIEW

### Hypothesis / aims of study

Today there is level 1, grade A evidence that pelvic floor muscle training (PFMT) is effective in treatment of stress urinary (SUI) and mixed urinary incontinence (MUI), and PFMT is recommended as first line treatment for these conditions (1,2,3). There has, however, been scant focus on systematically literature search, analysis and report of long term follow-up studies, and the evidence for long term effect has been questioned (1,2,3). The aim of the present systematic review was to evaluate the long term effect of PFMT for female SUI and MUI with predominately SUI symptoms.

### Study design, materials and methods

Computerized search on PubMed was undertaken with the following search strategy: pelvic floor AND (urinary incontinence OR stress urinary incontinence) AND (training OR exercise OR physical activity) AND (follow-up OR long term). The search result was limited using the following limits: humans, female, clinical trial, English and adults. In addition, computerized search on Physiotherapy Evidence Database (PEDro), hand search of reference lists from recent systematic reviews on PFMT (1,2,3) and abstract from the International Continence Society (ICS) and International Urogynecology Association (IUGA) annual meetings from 1990 to 2010 was undertaken. Inclusion criteria were 1. studies on SUI and MUI with predominately SUI symptoms using PFMT with or without biofeedback as the intervention, 2. studies with a randomized controlled trial design (RCT), non-randomized studies with a control group or pre- and post-test designs without a control group, 3. a follow-up period of  $\geq$  one year. Exclusion criteria were studies using electrical stimulation alone and studies during pregnancy and in the six months postpartum period. The following data were extracted using preset forms: original study design, original intervention, short term effect, length of long term follow-up period, follow-up intervention if any, long-term outcome measures, losses to follow-up, adherence to PFMT during the follow-up period and the reported long term effect.

### Results

Eighteen studies met the inclusion criteria (1100 women). Statistical meta-analysis was not performed due to huge heterogeneity in interventions, outcome and loss to follow-up. The follow-up period ranged between 1 and 15 years. Nine of the studies were originally RCTs or studies with a non-randomized control group, and 9 studies were long term follow-up studies after a pre-post test design without control group. Most long-term studies were based on postal questionnaires with 6 studies using interview and/or clinical or urodynamic assessment. Ten studies reported surgery rates during the follow-up period as outcome. Only two studies provided a follow-up intervention, consisting of incitements or training sessions for the patients with one study offering monthly group training classes. Losses to follow-up during the long term follow-period ranged between 0 and 39%. Long term adherence to PFMT in the follow-up period varied between 10% and 70%. Four studies reported that the initial success rate on SUI and MUI was maintained at long term follow-up. Another five studies reported long-term success based on short term classification of responders to training, all reporting that long-term effect was better maintained in responders compared to non-responders. The long term success based on responders to the original trial varied between 41% and 85%. Mean surgery rate during the follow-up period ranging from 1-15 years (mean 5.3 years) was 27.6% (95% CI: 12.7-42.4).

### Interpretation of results

To date there is no available quality assessment protocol for critical appraisal of long term follow-up studies. Decrease of effect is expected after cessation of any regular training protocol. As for long-term follow-up of surgery studies, the long term effect of PFMT is difficult to assess across studies due to huge heterogeneity of outcome measures, losses to follow-up, adherence to training during the follow-up period and whether the results are analyzed according to short term success or failure. Most original studies are small and due to loss to follow-up, long term studies often are underpowered which make a statistical comparison between the original randomized groups unsuitable. In addition, in most studies, the original control groups have received PFMT or other treatments after cessation of the short term study. This kind of co-intervention biases the long term results. Interestingly, high satisfaction rates and few patients opting for surgery have been found without any incitements for training in the follow-up period. Future long term studies should report adherence to training during the follow-up period and separate between the originally cured and non-cured patients. There is need for a high quality RCT randomizing short term responders to no incitements and different dosages of PFMT in the follow-up period. Use of validated questionnaires including quality of life and surgery rate are recommended for future long term studies on PFMT.

### Concluding message

When the results were analysed based on short term effect, long term success rate could reach 85% without incitements. A mean surgery rate of 27.6% (95% CI: 12.7-42.4) was found in mean 5.3 years (range 1-15) following cessation of PFMT. There is a need for future RCTs comparing different training dosages after cessation of short term study interventions.

### References

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<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>NONE</b>