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**Abstract Reproduction Form B-1**

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| Title (type in CAPITAL LETTERS) | RANDOMIZED CONTROLLED TRIAL ON THE EFFECT OF PELVIC FLOOR MUSCLE TRAINING ON QUALITY OF LIFE AND SEX-LIFE IN GENUINE STRESS INCONTINENT WOMEN |

**AIMS OF STUDY**

Randomized controlled trials have demonstrated that pelvic floor muscle training is more effective than no treatment and more effective than both electrical stimulation and vaginal cones in treatment of genuine stress incontinence (GSI). In a former published study we reported the results of such training on pelvic floor muscle function and strength, urodynamic variables, and urinary leakage. WHO has developed a system for outcome measures in rehabilitation studies, named the International Classification of Impairment, Disability, and Handicap/Participation (ICIDH). According to this system pelvic floor muscle strength and urinary leakage can be classified at the impairment and disability levels, respectively. Interference with quality of life, lifestyle, and sex-life are classified at the Handicap/Participation level. The aim of the present study was to compare the effect of pelvic floor muscle training with an untreated control group on quality of life, lifestyle, and sexlife in women with GSI.

**METHODS**

Thirty women with clinically and urodynamically proven GSI were randomized to the control group and 29 to the training group after stratification on degree of leakage measured by a provocative pad test with standardized bladder volume. Background variables for the two groups are given in Table 1:

Table 1: Background variables for the training and control groups before treatment. Mean and SD. No significant differences at baseline.

|                      | Training   | Control    |
|----------------------|------------|------------|
| Mean age             | 49.6(10)   | 51.7(8.8)  |
| BMI                  | 25.1(2.8)  | 25.8(3.7)  |
| Parity               | 2.3(0.8)   | 2.4(0.9)   |
| Duration of symptoms | 10.2(7.7)  | 9.9(7.8)   |
| Stress pad test      | 38.6(34.7) | 51.4(48.2) |

The training group was asked to perform 8-12 close to maximum contractions in 3 series per day. In addition they were exercising 45 minutes in groups once a week with an experienced physical therapist. They met the physical therapist once a month for individual assessment of pelvic floor muscle strength and motivation for training. The intervention period was 6 months. The control group had no contact during the intervention period, but were offered the opportunity to use the Continence Guard (Coloplast A/S). The Bristol Female Lower Urinary Tract Symptoms (B-FLUTS) questionnaire was used to assess impact on quality of life and sex-life before and after treatment. Those women using the Continence guard answered two questionnaires, one that applied for the condition without the guard and another with use of the guard. The present results are reported without the guard. Wilcoxon two-sample rank test corrected for ties was used to compare the groups before and after treatment. Results are reported as frequencies and positive findings are grouped together ("a little, somewhat, a lot" or "a bit of a problem, quite a problem, a serious problem"). Significance level was set to 5%.

**RESULTS**

There were four drop outs in the training group, two due to causes outside the intervention and two due to lack of motivation. There were no drop outs in the control group. Table 2 shows the differences between groups after the 6 months treatment period. There were no significant differences in any variables before the treatment period.

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Table 2: Number of women with a little, some, and much problems in quality of life and sex-life variables after 6 months intervention measured by The Bristol Female Lower Urinary Tract Symptoms questionnaire.

|  | Training | Control | p-value |
|--|----------|---------|---------|
| Sex-life spoilt by UI  | 3        | 12      | .03     |
| Problem with sex-life spoilt by UI   | 2        | 11      | .02     |
| Problem with pain in intercourse   | 2        | 7       | .10     |
| UI with intercourse  | 2        | 10      | .02     |
| Problems because avoiding places and situations                            | 5        | 7       | .54     |
| Problem with interference of social life                                   | 1        | 12      | <.01    |
| Problems with physical activity  | 10       | 23      | <.01    |
| Overall interference with life   | 14       | 23      | <.01    |
| Unsatisfied if you had to spend the rest of your life with symptoms as now | 5        | 10      | <.01    |

**CONCLUSIONS**

The results of the present study demonstrated a significant positive response from pelvic floor muscle training on quality of life and sex-life variables compared with an untreated control group. Although this sample of women had quite severe GSI, it did not make many women avoid places and situations in general. However, participation in physical activity was greatly interfered and improved after treatment. Very few studies have evaluated the effect of pelvic floor muscle training on sex-life. The results of this study should be interpreted with caution. The questions about sex-life is asked in a broad manner, and the results can not give any detailed knowledge on how and why the strength training may affect female sexuality. Further studies are under planning in this area.

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