FOCUSED QUESTION
What is the effect of retraining diaphragmatic, deep abdominal, and pelvic floor muscle (PFM) coordinated function in a graded, multi-stage, supervised exercise program compared to PFM retraining alone in a self-monitored one-stage exercise program on urinary leakage in women with stress incontinence?


CLINICAL BOTTOM LINE:
Recent studies have focused on the relationship of the pelvic floor muscles (PFM) and abdominal muscles, but the effectiveness of the coordination of these muscles to treat stress and mixed urinary incontinence had yet to be supported. This study emphasizes the coordination of these muscles to maintain the stress continence mechanism, unlike previous approaches, which focused on strengthening a specific muscle. This exercise program could be taught by observation and chest and abdominal palpation, which may be appealing for women who are uncomfortable with vaginal palpation, which is a common method used in PFM strengthening programs.

Some limitations of this study include inconsistencies with timing and the site in which the intervention took place between the control and treatment groups. Although the study presented with these intervention biases, based on the statistically significant results, it is an effective method in treating stress and mixed urinary incontinence symptoms in women rather than just PFM exercises alone. After the 4-month intervention, there was a 96.7% cured/improved rate in the experimental group. There was also a significantly lower amount of leakage and number of leaks in the experimental group, but not in the control group. Lastly, the experimental group experienced an improvement in more aspects of quality of life than the control group. This new approach shows promise as an alternative treatment for women with urinary incontinence.

RESEARCH OBJECTIVE(S)
List study objectives.

This study was conducted to “investigate the effect of treating women with stress or mixed urinary incontinence (SUI or MUI) by diaphragmatic, deep abdominal and PFM retraining” (p. 273).
DESIGN TYPE AND LEVEL OF EVIDENCE:

Level I: Randomized controlled trial

Limitations (appropriateness of study design):
Was the study design type appropriate for the knowledge level about this topic? Circle yes or no, and if no, explain.

YES/NO

SAMPLE SELECTION

How were subjects selected to participate? Please describe.

Female volunteers were recruited through a newspaper advertisement. The women then answered two standardized questions about urinary incontinence (UI). The first question was for SUI and the second was for urge UI. “Women who answered ‘yes’ to the first question only and who answered ‘yes’ to both questions were categorized as SUI and mixed UI (MUI) and were recruited for the study” (p. 274).

Inclusion Criteria

- 18–65 years of age
- Had at least one episode of SUI symptom during the previous month

Exclusion Criteria

- Pregnant or less than 3 months postpartum
- Systemic neuromuscular disease
- Previous surgery or intensive pelvic floor muscle training (PFMT) for UI
- Severe low back pain or pelvic pain
- Undergoing concurrent treatment for UI or low back pain
- Radial hysterectomy
- Ongoing urinary tract infections

SAMPLE CHARACTERISTICS

N=70

<table>
<thead>
<tr>
<th>% Dropouts</th>
<th>6 (8.6%)</th>
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<tbody>
<tr>
<td>#/ (%) Male</td>
<td>0%</td>
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<tr>
<td>#/ (%) Female</td>
<td>70/100%</td>
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Ethnicity | Not reported (NR) |

Disease/disability diagnosis | Stress or mixed urinary incontinence (SUI or MUI) |
Check appropriate group:

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<th>Study Group</th>
<th>Description</th>
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**INTERVENTION(S) AND CONTROL GROUPS**

*Add groups if necessary*

**Group 1**

**Brief Description**
Experimental (training) group; 31 women; participated in 5-stage exercise regimen

The 5-stage exercise regimen that the experimental group engaged in with direct supervision for monitoring of progression was: “1) Diaphragmatic breathing; 2) tonic activation of transversus abdominis (TrA) and PFM; 3) muscle strengthening of TrA, PFM, and internal obliques; 4) functional expiratory patterns like coughing and sneezing; and 5) impact activities such as running and jumping” (p. 275).

**Setting**
Clinic (Women’s Health Laboratory) and home

**Who Delivered?**
Physical therapist during clinical visits and participant during home exercises

**Frequency?**
2x/month

**Duration?**
4 months

**Group 2**

**Brief Description**
Control group; 33 women; performed self-monitored PFM exercises

The control group was a self-monitored exercise program. “Participants in the control group received oral instructions and usual information, consisting of introduction for urinary incontinence, PFM exercise, and bladder hygiene” (p. 275).

**Setting**
Home

**Who Delivered?**
Participant; physical therapist provided initial, oral instruction for PFM exercises

**Frequency?**
2x (1st evaluation and 2nd evaluation)

**Duration?**
4 months

**Intervention Biases:** *Circle yes or no and explain, if needed.*

**Contamination**

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**Co-intervention**

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Timing

**YES/NO**
The control and experimental groups were not told how long or how often to complete the prescribed home exercise plans.

Site

**YES/NO**
Experimental group received intervention at home and in the clinic while the control group only completed pelvic floor muscle exercises at home.

Use of different therapists to provide intervention

**YES/NO**

**MEASURES AND OUTCOMES**
Complete for each relevant measure when answering the evidence-based question:

Name of measure, what outcome was measured, whether the measure is reliable and valid (as reported in article – yes/no/NR [not reported]), and how frequently the measure was used.

- **4-point Likert scale** (worse, unchanged, improved, cured) was used as a self-reported improvement measure.
- Validity and reliability: No psychometric properties reported
- This measurement was only used one time, at the time of the second evaluation.

Name of measure, what outcome was measured, whether the measure is reliable and valid (as reported in article – yes/no/NR [not reported]), and how frequently the measure was used.

- **3-day voiding diary**: This was completed by the participants of the study to record voiding events, urgency and urinary leak, and described amount of leakage. The average number of voiding and leaks per day were calculated and used for analysis. The diary was only used as an outcome measure; the researchers encouraged the study participants of both control and experimental groups to not record during the intervention period.
- Test–retest reliability: Concordance correlation coefficient = 0.83–0.86
- Validity: No psychometric properties reported
- The diary was completed two times, at first evaluation and second evaluation (after 4 months).

Name of measure, what outcome was measured, whether the measure is reliable and valid (as reported in article – yes/no/NR [not reported]), and how frequently the measure was used.

- **The Symptom Impact Index** was used to measure the impact of UI on quality of life.
- Test-retest reliability: 0.87–0.91; good
- Validity: No psychometric properties reported
- This self-report measure was given two times, at the first evaluation and second evaluation (after 4 months).
Name of measure, what outcome was measured, whether the measure is reliable and valid (as reported in article – yes/no/NR [not reported]), and how frequently the measure was used.

- 20-minute pad test was used to measure the amount of leakage
  - The participant’s bladder was filled with 250 mL of water and asked to do various exercises for 20 minutes. After the 20 minutes, the pre-weighed perineal pad was weighed to determine the amount of leakage.
- Reliability and validity: No psychometric properties reported
- This test was conducted twice, at the first evaluation and second evaluation (after 4 months).

Name of measure, what outcome was measured, whether the measure is reliable and valid (as reported in article – yes/no/NR [not reported]), and how frequently the measure was used.

- Pelvic floor muscle function test was used to look at muscle strength and endurance. The test was conducted with the participant in a bent knee position. Measurements were recorded using a manometer.
- Test–retest reliability: Intraclass correlation coefficient was 0.95; good
- Validity: No psychometric properties reported
- This test was conducted twice, at the first evaluation and second evaluation (after 4 months).

Measurement Biases

Were the evaluators blind to treatment status? *Circle yes or no, and if no, explain.*

**YES/NO**

Recall or memory bias. *Circle yes or no, and if yes, explain.*

**YES/NO**

Others (list and explain):

RESULTS

List results of outcomes relevant to answering the focused question.

Include statistical significance where appropriate (*p* < 0.05)

Include effect size if reported

- At the first evaluation, there was no difference in any outcome variable between the two groups.
- When comparing the Likert scale scores, more members of the experimental group showed a statistically significant value for cured or improved symptoms than those of the control group. Of the 31 participants in the experimental group, 96.7% noted their symptoms as being cured or improved, with a *p*-value of 0.002. Of the 33 participants in the control group, 66.6% reported their symptoms as being cured or improved.
- Analysis of data from the Symptom Impact Index revealed a significant decrease in
“number of worries” for both the experimental ($p < 0.001$) and control group ($p = 0.002$). There was also a significant improvement for both experimental ($p < 0.001$) and control groups ($p = 0.002$) for “avoiding activities due to worrying about leaking.” The experimental group showed a statistically significant improvement in “activities affected” and “avoiding activity due to needing a toilet” compared to those values of the control group. The values for “activities affected” for the experimental group was $p < 0.001$, and $p = 0.104$ for the control group. For the “avoiding activity due to needing a toilet,” the value for the experimental group was $p < 0.001$ and $p = 0.085$ for the control group.

- When comparing the two groups, there was no significant difference after intervention in either amount of leakage (0.346) and number of leaks (0.473). However, when looking at the groups individually, the experimental group showed statistically significant improvement during the 20-minute pad leakage test ($p = 0.006$), while the control group did not ($p = 0.233$). Through analysis of the 3-day diary, it was found that participants of the experimental group also had significantly reduced the amount of leaks per day ($p = 0.042$). These results suggest that the study lacked power and the treatment effect size was weak.
- After comparing baseline results between the two groups of the pelvic floor muscle function test, it was noted that there were no statistically significant changes for maximal vaginal squeeze pressure ($p = 0.643$) and holding time ($p = 0.753$).

Was this study adequately powered (large enough to show a difference)? *Circle yes or no, and if no, explain.*

**YES/NO** Sample size was set at 30 subjects per group to provide a power of 80%, meaning the effect size was very weak.

Were appropriate analytic methods used? *Circle yes or no, and if no, explain.*

**YES/NO**

Were statistics appropriately reported (in written or table format)? *Circle yes or no, and if no, explain.*

**YES/NO**

**CONCLUSIONS**

State the authors’ conclusions that are applicable to answering the evidence-based question.

The authors state that after the 4-month intervention program, they concluded that the suggested exercise program of retraining diaphragmatic, deep abdominal, and PFM coordinated function improves symptoms and quality of life for women with SUI and MUI. The authors also suggest that the proposed intervention can be utilized as a treatment for women with UI who cannot accept vaginal palpation therapy.
This work is based on the evidence-based literature review completed by Taylor Campbell, MOTS, and Robin Steed, PhD, LOTR, Faculty Advisor, Louisiana State University Health Sciences Center.


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