

Dr. Mary Jane Minkin
Summary of Clinical Study¹ for The Myself[®] Trainer

Urinary incontinence is a major health problem impacting millions of Americans. Incontinence poses an immense economic burden, in terms of direct health care costs. It also impacts quality of life; some experts say that it is only second to depression as the leading cause of decreased quality of life.

Urge incontinence is often addressed pharmacologically; stress incontinence surgically. However, the Agency for Healthcare Research and Quality has recommended behavioral methods as a first course for treatment of Urinary Incontinence. First advocated by Dr. Arnold Kegel in 1948 for restoration of the perineal muscles, so called “Kegel” exercises, or progressive resistance exercises, are now recommended for both men and women with stress, urge and mixed incontinence. Physicians often find that many women are not correctly doing Kegel exercises. Also, patient compliance with prescribed biofeedback type approaches can be problematic.

To that end, a personal trainer was devised, with a pneumatic sensor to measure pelvic muscle contractions and provide immediate feedback. Software was also installed to guide the patient through preset protocols. The patients were asked to perform 5 minute sessions three times a day for 16 weeks. Three resistance levels were built in to the device. Patients were also provided what was termed a “winks” session for quick contractions. Daily recording was done in a journal.

55 healthy women with bothersome incontinence, ages ranging from 25-81 years, with a mean age of 54, were recruited for the clinical trial. 44 completed the 16 week project. The group consisted of women with stress (7), urge (8) and mixed (29) incontinence. Women actually averaged 2 sessions per day; 14 did one session a day; 7 performed 3 sessions a day.

At the end of the 16 week trial, 43% of the women were dry; 39 % noted a greater than 50% reduction in leaks per day. The group mean for leaks per day was 2.9 initially; at the end of 16 weeks, the figure decreased to 1.1. Voids per day for the group were initially 10.8; this decreased to 8.1 in 16 weeks. Women who could do the three sessions per day trended towards greater improvement.

Most importantly, there were no complications in the women in this study. All medications used for treatment of urge incontinence carry the potential side effects of dry mouth, constipation, and possible CNS effects. Any surgical approach for patients with stress incontinence carries the risk of bleeding, infection, and bladder and bowel damage. This biofeedback device has none of these risks.

To most clinicians, it would make sense to approach any patient with significant incontinence with a non invasive strategy, and proceeding with more intervention if symptoms were not adequately alleviated.

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She is lead author or coauthor of articles in numerous peer-reviewed journals, including *Obstetrics and Gynecology* and *Journal of Reproductive Medicine*, as well as coauthor of *A Woman's guide to Sexual Health* (Yale University Press, 2005) and *A Woman's Guide to Menopause and Perimenopause* (Yale University Press, 2005). Dr. Minkin is a recipient of the Irving Friedman Award, given by Yale School of Medicine's Department of Obstetrics, Gynecology and Reproductive Sciences, for excellence in clinical abilities and patient care, and has been awarded the Resident's Teaching Award three times for best community attending physician.

¹ Smith et al. A Self-directed Home Biofeedback System for Women with Symptoms of Stress, Urge and Mixed Incontinence. *Journal of Wound, Ostomy and Continence Nursing*. 2000; 27: 239-246.

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