Self-Monitoring and Pelvic Floor Muscle Exercises to Treat Urinary Incontinence

Jean E. Kincade
Molly C. Dougherty
Jan Busby-Whitehead
John R. Carlson
William B. Nix
Dwan T. Kelsey
Fay C. Smith
Georgia S. Hunter
Amy D. Rix

Urinary incontinence (UI) is a common, chronic condition among women. Treatment of UI can involve behavioral techniques, pharmacological strategies, or surgical intervention. Clinically, treatment strategies should start with the simplest and least invasive measures. To overcome the deficiencies in previous research and provide definitive information for clinical practice, a randomized clinical trial is currently underway. This clinical trial uses a pretest-posttest design to first determine the effectiveness of self-monitoring techniques before subjects are randomized into one of two treatment groups or an attentional control group with a 1-year followup. The study design, sampling plan, and interventions used in an ongoing clinical trial to assess the effectiveness of self-monitoring and efficacy of biofeedback to treat UI in women are described. Innovative techniques to assess adherence to the pelvic muscle exercise protocol are addressed.

Jean E. Kincade, PhD, RN, is a Research Associate Professor, School of Medicine Program on Aging, and School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, NC.

Molly C. Dougherty, PhD, RN, FAAN, is a Professor, School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, NC.

Jan Busby-Whitehead, MD, is a Professor and Chief of the Division of Geriatric Medicine, and Director, School of Medicine Program on Aging, University of North Carolina at Chapel Hill, Chapel Hill, NC.

John R. Carlson, MS, is a Research Associate Professor, School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, NC.

William B. Nix, BMET, BA, is a Lab Manager, Biobehavioral Lab, School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, NC.

Dwan T. Kelsey, MSN, ANP, is an Adult Nurse Practitioner, Cary Health and Rehab, Cary, NC.

Fay C. Smith, MSN, RN, FNC-BC, is a Research Instructor and Family Nurse Practitioner, School of Medicine Program on Aging, School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, NC.

Georgia S. Hunter, BA, is a Project Manager and Research Instructor, School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, NC.

Amy D. Rix, BA, is a Research Assistant II, School of Medicine Program on Aging, University of North Carolina at Chapel Hill, Chapel Hill, NC.

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However, no study has systematically measured their combined impact on improving UI until recent research by Dougherty and colleagues (1998, 2002). These researchers found that after practicing several easy-to-use self-monitoring strategies, many women with mild-to-moderate UI improved sufficiently and did not wish to engage in further treatment. Further evidence of the effectiveness of these techniques might justify a self-monitoring phase in clinical trials of UI treatments before randomization to intervention groups.

**Problem Statement**

PFM exercises are recommended as the treatment of choice for motivated, cognitively intact, community-dwelling women (Fantl et al., 1996). PFM exercises can be taught with or without the use of biofeedback. Although both techniques are effective in improving UI, findings have been conflicting as to which method is superior (Burgio, Robinson, & Engel, 1986; Burns, Pranikoff, Nochajski, Desotelle, & Harwood, 1990; Burns et al., 1993; Burton, Pearce, Burgio, Engel, & Whitehead, 1988; Shepherd, Montgomery, & Anderson, 1983; Sherman, Davis, & Wong, 1997). The question of whether teaching PFM exercises using biofeedback is more efficacious than teaching PFM exercises alone is important for several reasons. Expensive equipment is required to provide biofeedback and personnel must be specially trained to use it. Some women find biofeedback monitoring devices (vaginal probes, rectal probes, and/or surface electrodes) uncomfortable and invasive. Insurance companies require clear evidence that the use of biofeedback produces improvement in UI significant enough to warrant reimbursement. Thus, because PFM exercises alone are less invasive, use minimal or no equipment, cost less, and may improve or cure many women with UI, biofeedback is justified only if it can be shown to be more efficacious than PFM exercises alone.

However, some women who are enrolled in interventions that teach PFM exercises do not improve with treatment. The question is then raised, is their lack of improvement because PFM exercise is an inappropriate treatment or are the exercises not being performed according to the recommended protocol? When adherence to the treatment protocol was measured, individuals who had higher levels of adherence showed the most improvement (Alewijnse, Mesters, Metsmakers, & van den Borne, 2003; Bo & Talseth, 1996; Lagro-Janssen, Debruyne, Smits, & Van Weel, 1992; O’Brien, Austin, Sethi, & O’Boyle, 1991; Sand et al., 1995; Wells, Brink, Diokno, Wolfe, & Gilles, 1991). Monitoring intervention activities often depends on paper-and-pencil records kept at home (Alewijnse et al., 2003; Bo & Talseth, 1996; Wells et al., 1991) or attendance at intervention sessions (O’Brien et al., 1991). But advances in data recording technology now permit the use of methods that provide more detailed and accurate information.

**Purpose**

To overcome the deficiencies in previous research and provide definitive information for clinical practice, a randomized clinical trial is currently underway. This clinical trial uses a pretest-posttest design to first determine the effectiveness of self-monitoring techniques before subjects are randomized into one of two treatment groups or an attentional control group with a 1-year follow-up. To monitor adherence to practice of PFM exercises at home, a simple hand-held logger was developed (Nix, Kincade, & Dougherty, 2002).

The purpose of this article is to describe the study design, sampling plan, and interventions used in an ongoing clinical trial to assess the effectiveness of self-monitoring and the efficacy of biofeedback to treat UI in women. An innovative technique to assess adherence to the PFM exercise protocol using a hand-held logger will also be presented.

**Overview of Sample and Study Design**

**Sample size calculations.** The target population for this study was women 18 years of age and older living in Wake, Durham, and surrounding counties in central North Carolina. Number of episodes of urine loss, the mostly widely reported outcome in past clinical trials, was used to calculate sample size. Using the methods of Muller and Barton (1989), 84 subjects in each group were needed to achieve power of 0.90 when Type I error was constrained to 0.05 in a one-tailed comparison between the two treatment groups. Since 20% attrition was predicted, 105 subjects were needed in each of the three groups. One hundred and one subjects (age = 33 to 92 years, mean = 56, SD = 12.7) were randomized into the PFM exercise with biofeedback (PFME/BIO) group, 106 subjects (age = 19 to 84 years, mean = 52.8, SD = 13.1) into the PFM exercise without biofeedback (PFME) group, and 93 subjects (age = 24 to 87 years, mean = 53.1, SD = 13.7) into the Attentional Control group. There was a total sample size of 300 (age = 19 to 92 years, mean = 54, SD = 13.2). No significant difference in age was seen among the three groups (F [2, 297] = 1.78, p = 0.1699).

**Screening and sample criteria.** The study was approved by the University of North Carolina at Chapel Hill School of Nursing Institutional Review Board. To obtain the sample, a community-based outreach strategy was used that employed a variety of mechanisms (for example, placing posters with tear off tabs in public bathrooms, exhibits at health fairs, advertisements in local newspapers, and radio advertisements). Women who called in response to the advertising were asked several screening questions (telephone screen) to determine initial eligibility for the study. Screening inclusion criteria included: (a) live indepen-
dently in the community (noninstitutionalized), (b) no diagnosis of bladder cancer or kidney disease, (c) no prior treatment of UI using biofeedback, (d) no urinary catheter, (e) available to participate in the study for at least 1 year, and (f) not currently pregnant. If these screening inclusion criteria were met, an appointment was then made to meet either with the principal investigator (JEK) or one of the research nurses. Informed consent was obtained at that visit and the subject was given bladder diaries, incontinence pads, and the quality of life questionnaire. A return appointment was made for a clinic visit to conduct a history and physical examination.

Additional inclusion criteria were determined at the clinic visit including: (a) involuntary urine loss of an average of 1 gram or more over 2 days per pad test, (b) a negative urine test for bacteria (using a Bacturcult® Sacks Biologicals, Evans City, PA), and (c) post-void residual of 100 cc or more over 2 days per pad test, (d) a negative urine test for bacteria, (e) available to participate under controlled conditions in the community (noninstitutionalized), (b) no diagnosis of bladder cancer or kidney disease, (c) no prior treatment of UI using biofeedback, (d) no urinary catheter, (e) available to participate in the study for at least 1 year, and (f) not currently pregnant. If these screening inclusion criteria were met, an appointment was then made to meet either with the principal investigator (JEK) or one of the research nurses. Informed consent was obtained at that visit and the subject was given bladder diaries, incontinence pads, and the quality of life questionnaire. A return appointment was made for a clinic visit to conduct a history and physical examination.

Eligible women were then stratified according to amount of urine loss (50 grams or less, 51-250 grams, 251 grams or more) and randomized into the three groups (PFME, PFME/BIO, Attentional Control). Figure 1 shows a diagram of the study design, randomization, data collected, and data collection time frame.

Instrument/procedure. The instruments used to collect data on outcome measures are described below. Data were collected on all subjects at each of the time points and all subjects received a history and physical examination and underwent urodynamic testing (see Figure 1).

Bladder diary. A 3-day bladder diary was used. For 3 consecutive 24-hour periods, the subject recorded fluid (including type and amount), voids, and UI episodes (including activity when episode occurred). There has been ongoing discussion among researchers about the appropriate length of time research subjects should complete a bladder diary as an outcome measure. Some researchers recommend a 7-day bladder diary because of good reproducibility and, in social terms, a week represents a full variety of activities (Abrams & Klevmark, 1996; Wyman, Choi, Harkins, Wilson, & Fantl, 1988). The disadvantage of a 7-day bladder diary is that some subjects find it tedious and become less accurate by the end of the period (Abrams & Klevmark, 1996). The Standardization Committee of the International Continence Society recommended that one outcome measure in UI research should be a voiding diary kept a minimum of 3 days (Lose et al., 1998). Nygaard and Holcomb (2000) found, on a 7-day bladder diary, the number of UI episodes between the first 3 and last 4 diary days and the number of voids between the first 3 and last 4 diary days were highly correlated (0.887 and 0.908 respectively). Results from the bladder diary are also improved by: (a) careful instructions to the subject, (b) encouraging the subjects to contact the investigators with questions, and (c) reviewing the bladder diary data with the subjects (Dougherty, Bishop, Mooney, Gimotty, & Williams, 1993; Pfister, 1999). The subjects completed bladder diaries before the clinic-screening visit, after the waiting period, after self-monitoring, 2 weeks following the intervention, and at 6 and 12 months after the intervention (see Figure 1).

Pad test for urine loss. Incontinence pads, which had been weighed in self-sealing plastic bags, were provided to the subjects. Instructions to the subjects were: (a) change pads as frequently as they wished, (b) remove for voiding and defecation, (c) reinsert into bag after use and reseal, and (d) record pad change on bladder diary. Subjects were asked to wear preweighed pads for two consecutive 24-hour periods on Days 2 and 3 when they were completing the bladder diaries. The pads were weighed using a digital scale (Ohaus™ II Balance, Ohaus Corporation, Pine Brook, NJ) under controlled conditions in the University of North Carolina School of Nursing Biobehavioral Lab and the change in pad weights recorded (grams in 24 hours). In recent research, accep-
tance and follow-through of the home pad test were excellent (Dougherty et al., 1993; Dougherty et al., 1998). They reported women of various functional abilities easily followed the instructions. A number of studies have reported that the 48-hour pad test is easy to perform, robust, and reasonably reproducible (Elelund, Bergstrom, Milsom, Norlen, & Rignell, 1988; Versi et al., 1996; Wilson, Mason, Herbison, & Sutherst, 1989). These authors note greater accuracy is attained when pads are weighed by staff (instead of asking women to weigh the pads at home); evaporation loss is minimal within 72 hours and reaches only 4.3% after 1 week; test-retest results on 24-hour pad tests are high (r = 0.9); and there is greater variability in pad test results with larger volume loses. The subjects completed pad tests before the clinic visit, after the waiting period, after self-monitoring, 2 weeks following the intervention, and at 6 and 12 months after the intervention (see Figure 1).

**PFM assessment.** The objective of the PFM assessment was to evaluate the characteristics of the pelvic floor muscles during rest and contraction. The MyoTrac System and Continence Software (Thought Technology, Ltd., Montreal, Quebec, Canada) was used. This is a computerized, dual channel EMG device that measures the electrical activity of the muscles being assessed. After preparing the skin with alcohol, EMG sensors were placed 1 cm lateral of each side of the anus and connected to channel 1. Abdominal sensors were placed on the right external abdominal oblique muscle and connected to channel 2. The position of one electrode was about 10 cm to 15 cm lateral to the umbilicus. The second electrode was inferior to the first, just medial to the anterior superior iliac spine.

After the integrity of the recording system was observed, resting baseline measures were obtained over 30 seconds. The subject was then coached through a series of four 10-second contractions of the pelvic floor muscles. Each contraction was followed by 15-second rest period. The average of the four contractions was calculated in microvolts and adjusted for the baseline resting (deviation from resting). During the recording, the nurse, but not the subject, was able to observe the computer screen as the subject's observation of her performance might constitute biofeedback and bias the measurement.

In addition, a digital measure of pelvic muscle strength was done using a measure developed by Brink, Wells, Sampselle, Tailtie, and Mayer (1994). Each subject was asked to squeeze her perineal muscles around two of the nurse's fingers. Pressure, displacement of vertical plane, and duration were each measured on a scale from 1 to 4. Test-retest scores for pressure, displacement, and duration were r = 0.54, 0.51, and 0.53 respectively and 0.65 for the overall scale (Brink et al., 1994). Interrater reliability between nurses doing the test was r = 0.74, 0.67, and 0.52 for pressure, displacement, and duration (Brink et al., 1994). Construct validity was assessed by correlating the mean score for the digital measure with EMG scores (endurance peak, r = 0.37; endurance area, r = 0.56; and means of four shorter contractions, r = 0.43) (Brink et al., 1994). In the present clinical trial, pelvic muscle strength using both techniques was measured at the clinic visit and 2 weeks after the intervention period (see Figure 1).

**Quality of life for UI.** The Incontinence Impact Questionnaire was used to measure quality of life for UI (Shumaker, Wyman, Uebersax, McElish, & Fantl, 1994). This scale consists of 30 items; 24 refer to the degree to which UI affects a range of activities (for example, shopping, recreation, and entertainment), and 6 refer to the effect of UI on various feelings (for example, fear, frustration, and anger). Factor analysis derived subscales are Physical Activity, Travel, Social Relationships, and Emotional Health. The scale was psychometrically sound (Shumaker et al., 1994). Reliability of the subscales is high, ranging from 0.87 to 0.90. Construct validity is supported by moderate levels of correlation between the scale and commonly used generic measures of health-related quality of life. Item responses are assigned values of 0 (not at all), 1 (slightly), 2 (moderately), and 3 (greatly). To allow for missing responses, the average score of items answered was taken. The average, which ranges from 0 to 3, is multiplied by 33/3 in order for the scores to range from 0 to 100. The authors (Shumaker et al., 1994) reported that omission of a single item had no effect on the total score; omission of two items had only a slight effect, but omission of three or more items invalidated the scale. This scale was administered at the clinic visit, after the waiting period, after self-monitoring, 2 weeks after the intervention, and at 6 and 12 months after the intervention (see Figure 1).

**Subjective assessment of progress/improvement.** In addition to assessing quality of life for UI, subjects were asked to give their perception of their progress with treatment, satisfaction with progress, and perceived improvement. Burgio and colleagues (1998) used a series of three questions to measure the subject's perception of progress/improvement: (a) How would you describe your incontinence since you have started your treatment? (much better, better, about the same, worse); (b) How satisfied are you with the progress of your treatment? (completely, somewhat, not at all satisfied); and (c) Could you rate your improvement since you started your treatment on a scale from 0 to 10, where 0 represents no improvement and 10 represents completely dry? These questions were asked after the waiting period, after self-monitoring, 2 weeks after the intervention, and at 6 and 12 months after the intervention (see Figure 1).
Health history and physical examination. The health history described by Wyman et al. (1988) was modified for the current study. The health history included sections on (a) personal information/demographics; (b) co-morbidities, past illnesses, surgery; (c) medications (prescribed, over-the-counter, supplements); (d) health habits (including bladder); and (e) continence status. The physical examination included abdominal, genital, rectal, and neurologic assessments as described by Walters and Karram (1993). A Bacturcurt test was used to assess for bacteria in the urine and a Chemstrip 9 was used to screen for bilirubin, blood, glucose, leukocytes, ketones, nitrite, pH, protein, and urobilinogen. The nurse practitioner used a bladder scan to determine residual urine after voiding and the subject’s pelvic muscle strength was assessed on examination.

Description of Self-Monitoring

Self-monitoring involved individual counseling about caffeine consumption, amount and timing of fluid intake, frequency of voiding, and constipation (Tomlinson et al., 1999) as well as teaching a simple PFM contraction technique (Quick Kegel) based on research by Miller et al. (1998). Data concerning caffeine, fluid intake, and voiding time were collected from the bladder diaries that the subjects completed before the clinic visit. Information about constipation was collected at the clinic visit. The content of the counseling was determined by this information.

For the subject who averaged a daily intake of more than 2 cups/glasses of caffeinated beverage (12 ounces), counseling was initiated about caffeine reduction. Instruction was given to gradually replace caffeinated beverages (such as coffee, tea, and soft drinks) with non-caffeinated beverages (for example, water, decaffeinated tea, coffee, soft drinks, and juices). Over the course of 3 weeks, the goal was to reduce caffeine intake to 2 or less cups/glasses of caffeinated beverage a day.

If the bladder diary indicated that a subject’s average daily fluid intake was less than 1,500 cc or greater than 4,000 cc, counseling was instituted. Modification of fluid intake to a more appropriate 1,800 to 2,400 cc/day was encouraged. For fluid intake less than 1,500 cc/day, an additional 120 cc to 240 cc of water or other non-caffeinated beverage in the morning each day for 1 week was recommended, with an increase of another 120 cc to 240 cc each day during the 2nd week. For a fluid intake greater than 4,000 cc per day, a decrease in fluid intake by 120 cc to 240 cc per day for the first week with an additional decrease of 120 cc to 240 cc per day for the 2nd week was advised (Tomlinson et al., 1999).

For problems with nocturia, the subject was instructed to decrease fluid intake after 6:00 pm and shift intake to mornings and afternoons. In earlier research (Tomlinson et al., 1999), it was noted many older women retired before 9:00 pm. If a subject’s bedtime was before 9:00 pm (as recorded in the bladder diary), restriction of fluids 3 hours before the usual bedtime was recommended. Subjects who indicated daytime voiding intervals of greater than 4 hours were encouraged to void every 3 to 4 hours while awake. Other toileting measures such as voiding when first arising, before leaving

Data Collected:
- a. Quality of Life for UI
- b. Grams of Urine Loss (Pad Test)
- c. Number of UI Episodes, Number of Voids, Amount and Type of Fluid (Bladder Diaries)
- d. Subjective Assessment of Progress/Improvement
- e. Pelvic Muscle Strength

*Baseline, pretest data collected for the Self-Monitoring phase
**Posttest data for the Self-Monitoring phase collected. This is baseline, pretest data for the PFM exercise phase of this study.
***Followup data are posttest data to assess effectiveness of PFM exercise.
the house, and before going to sleep were discussed. Women who had a problem with constipation were instructed on bowel management strategies such as drinking adequate fluids, increasing fiber intake, and establishing a regular time for bowel movements (Tomlinson et al., 1999).

In addition to modifications in caffeine, fluid intake, and bowel habits, all women were taught a simple PFM contraction technique (Quick Kegel). Teaching the Quick Kegel involved a description of the basic physiological and functional properties of the pelvic floor muscles. Digital vaginal palpation was then used to confirm that the subject was contracting the pelvic floor muscles. The subject was taught to contract the pelvic floor muscles quickly while breathing in and out. Activities that triggered urine loss were reviewed and instruction was given to use the Quick Kegel before these activities (for example, coughing, sneezing, getting out of bed, lifting heavy objects, or jumping). The Quick Kegel was also recommended as one technique to calm sudden urges to urinate.

Magnetic notes with reminders about relevant components of self-monitoring (such as fluid intake and Quick Kegel) were provided. Women were encouraged to place these in critical areas such as the bathroom, refrigerator, or other places to stimulate their consistent awareness of self-monitoring techniques. Each subject was also given a small tape recorder and audiotape with key points of self-monitoring instruction. The bladder diary and the history obtained at the clinic visit guided content for self-monitoring instruction (see Table 1).

**Description of Pelvic Floor Muscle Exercises**

PFM exercises taught without biofeedback. PFM exercises were taught to each subject in this group individually using techniques outlined by Sampselle and colleagues (Sampselle et al., 1997) (see Table 2). Recommended protocols for PFM exercise training vary between 4 and 20 weeks, but Dougherty and her colleagues (1993) demonstrated the greatest improvement in PFM strength and in urine loss in the first 8 weeks of a 16-week protocol. Given the previous research on PFM exercise for stress UI, an 8-week monitored PFM exercise program was used in this study.

Sampselle et al. (1997) and Fantl et al. (1996) recommended 30 to 45 contractions a day. A more recent comprehensive review of the literature (Wilson et al., 2002) made a similar recommendation of 24 to 36 contractions per day. To maximize the potential for success, 45 contractions a day were prescribed in this study. It has been postulated that near maximal contractions are the most significant factors in increasing strength. Ideally contractions should be sustained for 6 to 8 seconds to activate both slow and fast-twitch muscle fibers. A 10-second contraction activates slow-twitch fibers first and quickly activates the more fatigable fast-twitch fibers. The activation of slow-twitch fibers probably accounts for the sustained effort. Since the strongest stimulation for strength increase is the intensity of the contraction, the object of training is to recruit

<table>
<thead>
<tr>
<th>Topic</th>
<th>Instruction Given</th>
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<tbody>
<tr>
<td>ALL subjects require counseling about the Quick Kegel.</td>
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<tr>
<td><strong>Caffeine Intake:</strong> Bladder diary indicates caffeine intake of 12 ounces or more in 1 of the 3 days.</td>
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<tr>
<td><strong>Amount of Fluid Intake:</strong> Bladder diary indicates intake of less than 50 ounces (1,500 cc) on at least 1 day.</td>
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<tr>
<td><strong>Amount of Fluid Intake:</strong> Bladder diary indicates intake of more than 133 ounces (4,000 cc) on at least 1 day.</td>
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<tr>
<td><strong>Timing of Fluid Intake:</strong> Bladder diary indicates fluid intake within 3 hours of her normal bedtime on at least 1 day, and bladder diary indicates nocturia twice or more per night.</td>
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<tr>
<td><strong>Frequency of Voiding:</strong> Bladder diary indicates voiding intervals of more than 4 hours on at least 1 day.</td>
<td></td>
</tr>
<tr>
<td><strong>Frequency of Voiding:</strong> Bladder diary indicates voiding intervals of less than 2 hours on at least 1 day.</td>
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<tr>
<td><strong>Constipation:</strong> Subject answers “yes” to one of the following questions on item 26 on clinic questionnaire:</td>
<td></td>
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<tr>
<td>a. Straining on more than one-quarter of bowel movements.</td>
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<tr>
<td>b. Stool frequency less than 3 times per week.</td>
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<tr>
<td>c. Longest period without a bowel movement is more than 7 days.</td>
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<tr>
<td>d. Enemas or laxatives (not fiber or bulk) more than once per month.</td>
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Table 1. Content of Self-Monitoring Instruction
Table 2.
Pelvic Floor Muscle Exercise Instructions

<table>
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<tr>
<th>General Information</th>
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<tbody>
<tr>
<td>• Perform 45 contractions daily</td>
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<tr>
<td>• 10-second contractions</td>
</tr>
<tr>
<td>• 10-second relaxation periods between each one</td>
</tr>
<tr>
<td>• Three groups of 15 contractions each spread out during the day – standing, sitting, lying</td>
</tr>
<tr>
<td>• If weak pelvic floor muscles, contract 2 to 5 seconds, increase up to 10 seconds</td>
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<table>
<thead>
<tr>
<th>Pelvic Floor Muscle Exercise Technique</th>
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<tbody>
<tr>
<td>• Pretend that you are trying to avoid passing gas or a bowel movement by tightening these muscles.</td>
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<tr>
<td>• Bring the same tightening motion forward to the muscles around the vagina.</td>
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<tr>
<td>• Move the contraction up your vagina toward the small of your back.</td>
</tr>
<tr>
<td>• Contract only the pelvic muscles.</td>
</tr>
<tr>
<td>• Do not strain down or tighten your thighs or buttocks.</td>
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<tr>
<td>• Exhale gently and keep your mouth open each time you tighten your muscles.</td>
</tr>
<tr>
<td>• Check with mirror.</td>
</tr>
<tr>
<td>• Check with finger vaginally.</td>
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<tr>
<td>• Interrupt urine stream once weekly.</td>
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</table>

as many motor units as possible including both fast twitch and slow-twitch fibers (Wilson et al., 2002). Thus, the protocol called for 10-second contractions with 10-second relaxation periods between each one (Dougherty, 1998; Sampselle et al., 1997). Women with weak PFM were instructed to contract more briefly (2-5 seconds) and to increase the duration of contractions up to 10 seconds as they gained strength and confidence in their technique.

For a successful PFM exercise program, basic information about the purpose of the muscle training, the anatomy of the pelvic floor, and the characteristics of effective and ineffective contractions were taught. The subjects were instructed how to avoid bearing-down efforts. This was done by having her take a deep breath, hold it and bear down, and note the bulging of the perineum. The correct technique was taught by having the subject pretend to avoid passing intestinal gas and to bring the same tightening motion forward. By placing a hand on her abdomen, the subject was shown how to avoid contracting abdominal muscles.

Women in this study were instructed to perform 45 PFM contractions daily. An audiotape and pamphlet (developed by the Principal Investigator JEK) with instructions were provided to each woman in this group at the first visit to take home. PFM exercise was divided into 15 contraction sets in supine, sitting, and standing positions. Continued use of the Quick Kegel was reinforced. Women were encouraged to incorporate the exercises into their daily routine to improve exercise maintenance.

The PFM exercise group had four treatment visits, at 2-week intervals, which focused on education as described above. Each visit had a specific focus: (a) techniques to identify and isolate the pelvic floor muscles (Sampselle et al., 1997), (b) instructions emphasizing the importance of integrating PFM contractions into daily activities that stimulate urine loss episodes, (c) review and support for progress with PFM exercises at home, and/or (d) emphasis on specific features such as PFM exercise in sitting, standing, and lying positions and the rationale for regular PFM exercise. The PFME group was encouraged to continue the recommendations made to them during the self-monitoring phase as well.

PFM exercise taught using biofeedback. The rationale for teaching PFM exercise with biofeedback include (a) weak muscles give off limited proprioceptive sensations needed to gauge the effectiveness of the contraction; (b) when pelvic floor muscles are weak, there is a strong tendency to substitute abdominal and gluteal contraction which gives faulty feedback for the desired contraction; (c) when PFM exercises are performed inaccurately, there is no change in muscle function which reduces motivation; and (d) effective training improves the PFM coordination needed to counteract sudden increases in abdominal pressure (Dougherty, 1998; Tries & Eisman, 1995).

Basic information about the purpose of PFM training, the anatomy of the pelvic floor muscles, and the characteristics of effective and ineffective contractions were individually taught to each subject in this study group. The rationale for biofeedback enhancement of PFM exercise was explained at the first treatment visit.

The MyoTrac 3TM EMG System and Continence Software (Thought Technology, Ltd., Montreal, Quebec, Canada) was used for the biofeedback training. The sensors were placed in the same manner as when pelvic muscle strength was measured.

A resting baseline measure was obtained over 1 to 3 minutes. The subject was coached through three PFM contractions of 10 seconds duration (if EMG amplitude fell to 1/3, the subject was coached to relax). An event marker on the tracing denoted the cue to begin and end each contraction. Each contraction was followed by a 10-second relaxation period. The nurse and subject observed and discussed the abdominal and PFM tracing.
Features that the nurse used to guide the biofeedback session included:

- Characteristics of the abdominal and pelvic floor muscles during the resting baseline.
- Time from when the subject was cued to contract to the time of the maximum amplitude of contraction.
- Time from when the subject was cued to relax to the time EMG measures returned to baseline.
- Maximum amplitude recorded on each channel during the contraction.
- Characteristics of the PFM contraction over 10 seconds.
- Degree of relaxation of the abdominal muscles during a PFM contraction.

While observing the EMG tracings, the subject was guided with goals that were individualized based on her performance. Representative goals were to reinforce abdominal and PFM performance that resulted in:

- Greater amplitude and duration of PFM strength and tone.
- Relaxation of abdominal and gluteal muscles during PFM contractions.
- Shaping PFM contractions with short response latency (time from cue to maximum amplitude).
- Shaping PFM contractions toward immediate recovery to baseline after PFM contraction ends.
- Carrying out PFM contractions with biofeedback while sitting, standing, bending, and coughing to mimic daily activities that result in UI.

The overall goal of biofeedback was to optimize PFM responses that mediate bladder control. Four biofeedback sessions, every 2 weeks, were carried out over the 8-week period of PFM exercise training. The PFM exercise training at home for the PFM exercise with biofeedback group was the same as for the PFM exercise alone group. The biofeedback group was also encouraged to continue the recommendations made to them during the self-monitoring phase. Women in this group were also given the same pamphlet, at the first visit, as the PFM exercise alone group and an audiotape for home practice.

**Attentional Control Group**

The attentional control group was designed to provide the subjects in this group with the same data collection procedures and the same number and duration of nurse contacts as the treatment groups, but without any information about managing UI. There is evidence that data collection procedures, clinic visits, and nurse contact may improve UI without additional intervention (Burgio et al., 1998; Fantl et al., 1991; Nygaard, Kreder, Lepic, Fountain, & Rhomberg, 1996; Wells et al., 1991). Keeping time and attention constant across all three groups controlled for the effects of the therapeutic relationship the nurse developed with the subjects in the PFME and PFME/BIO groups.

After randomization, subjects in the attentional control group made four clinic visits, 2 weeks apart, over an 8-week period. At each clinic visit, the subject’s self-monitoring recommendations were reviewed, questions answered, and additional suggestions made. Following this, each subject was given information on a topic related to the theme, “Maintenance of a Healthy Life Style.” The four topics were (a) Tips to Manage Stress in Your Life, (b) Guidelines for a Healthy Diet, (c) Sleep: Are You Getting Enough? and (d) The Sun and Your Skin: What Can You Do to Protect Yourself? Both verbal information and a pamphlet were given to the subject at each visit and questions were answered. At the end of the four sessions, each subject was given an audiotape summarizing the information. The principal investigator developed the information for the pamphlets and the audiotape.

**Measurement of Adherence To Pelvic Floor Muscle Exercises**

Adherence to the PFM exercise protocol was measured using a hand-held logger developed at the University of North Carolina School of Nursing Biobehavioral Lab (Nix et al., 2002). Six components were required to build the logger: (a) a HOBO™ state board (Onset Computer Corporation, Pocasset, MA) with two stereo jack connections and two light emitting diodes to monitor operation conditions; (b) a 3.5 mm stereo jack connected to a female 9 pin serial cable; (c) a software interface (Boxcar™ Onset Computer Corporation, Pocasset, MA), which was designed to initialize, download, and transfer data from the board; (d) a momentary switch connected to the stereo jack; (e) a 3-volt CR-2032 Lithium battery, and (f) a plastic case to house and to protect the board and fit comfortably in the subject’s hand. Each logger cost under $100 to construct (see Figure 2).

Two assessments were done with the loggers before they were used in the study. The first assessment was to demonstrate that all loggers would record data in an identical manner while the second assessment was to determine if the life of the battery was long enough to record the required data. To conduct the first assessment, five loggers were placed in a container that had a handle for simultaneous closure of the momentary switches. The same computer was used to synchronize the loggers and all were initialized for a delayed start so that closure of all the loggers would begin at the same time. A standard protocol was used to simulate a series of contraction durations. The files were exported into Excel and a merged spreadsheet was used to compare deviations in the datasets. All the loggers recorded identical data. A second assessment was to determine how long the battery would last and how many events could be captured. The logger was initialized and 45 daily events were recorded for 30 days. The starting voltage in the battery was 3.19 and the final was 2.89. The testing period required 0.3
volts to record 1,486 events. Given this test, the expected life for the CR-2032 battery in the logger was 10 months.

As described earlier, women randomized into the PFME group and PFME/BIO group were asked to practice 3 sets of 15 contractions each day for 14 consecutive days. This was the time between treatment visits. Contractions were to be held for 10 seconds with 10-second relaxation periods between. The subject was instructed to depress the button on top of the logger while contracting the pelvic floor muscles (closing the circuit) and release the button between contractions (opening the circuit). Figure 3 shows an example of the text file that the logger generates when it is downloaded onto a computer file. The logger recorded the date (column 1), time of day (column 2), and the duration of the contraction and relaxation periods (column 3) indicating whether the circuit was “open” or “closed.” From these data the number and duration of contractions were calculated. These data were converted into a Statistical Analysis System (SAS) file and frequency distributions were run. These frequency distributions were edited to identify and remove invalid data. Data were considered invalid if the circuit was closed five or fewer consecutive times or if the duration that the circuit was closed was 2 seconds or less. These criteria were selected because closing the circuit five or fewer times (even if she was contracting her pelvic floor muscles) was inadequate to improve strength or endurance. Recordings of less than 2 seconds may have been just an accidental depression of the logger, or if it represented a contraction, inadequate to build strength or endurance.

Table 3 is an example of data before and after editing. Using data from the loggers, adherence was measured in two ways: (a) criterion-based adherence (to what extent was the exercise protocol practiced as taught? [3 sets of 15 exercises per day for a 14 day period where each exercise consists of a 10 second contraction followed by a 10 relaxation]) and (b) the actual count of exercises practiced per day.

Conclusions/Implications

Urinary incontinence is a common and costly problem among women that can have a profound impact on quality of life. The study design and the sampling plan of an ongoing clinical trial were reported. Interventions were described in detail and an innovative technique for assessing adherence to the exercise protocol was presented. The PFME intervention was developed from the large body of literature on PFM exercises and may be used by clinicians in their work with women with stress and mixed UI. The PFME/BIO intervention was developed from the biofeedback literature and is supported by PFM exercise research. Clinicians may employ this information when they develop clinical protocols for the use of biofeedback for UI. Although the data from this ongoing trial are not yet available, these protocols are based on sound research and may be confidently employed by clinicians. Advances in technology have permitted the wide application of biofeedback in clinical settings. Yet, one of the ongoing challenges of PFM exercises, as an intervention for UI, is that women often do not continue to do PFM exercises beyond the intervention period. Additionally, there have been few reliable tools to evaluate adherence to PFM exercises. The data logger
represents a significant advance. It may be used with minimal cost to motivate women to do PFM exercises and to stimulate them to continue PFM exercises for the long term.

The information provided in this article permits clinicians to weigh the value of this approach to encourage adherence to a PFM exercise protocol, which is less time-consuming for women than recording in paper-and-pencil logs and is more likely to yield accurate data. Urinary incontinence remains a common problem for women across the adult years. relatively little progress has been made to provide women in need with research-based approaches to manage UI. The approaches described in this article may serve clinicians to bridge the gap between research and practice.

References


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