

Project Title

Efficacy of Biofeedback to Treat UI in Women (Wake Women's Project) and Effectiveness of Self-Monitoring to Treat UI in Women (Nash Women's Project)

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I. Introduction

Biofeedback Study. The Agency for Health Care Policy and Research (AHCPR) Clinical Practice Guidelines recommend pelvic floor muscle exercises (PFM exercises) for stress UI and PFM exercises augmented with biofeedback for stress, mixed or urge UI as the treatment of choice for motivated, cognitively intact, community-dwelling women (Fantl et al., 1996). However, very few studies have looked at whether the improvement in UI is greater if PFM exercises are performed with biofeedback than without biofeedback and the findings of these studies are conflicting (Burgio, Robinson, & Engel, 1986; Burns, Prankoff, Nochajski, Desotelle, & Harwood, 1990; Burns et al., 1993; Burton, Pearce, Burgio, Engel, & Whitehead, 1988; Shepherd, Montgomery, & Anderson, 1983; Sherman, Davis, & Wong, 1997).

In addition, this is the first study to include a self-monitoring phase before randomization into the clinical trial of biofeedback to treat UI. Initially subjects will be randomized into a 3-week waiting period followed by 3 weeks of self-monitoring or self-monitoring only. If, after self-monitoring, subjects no longer meet the clinical trial criterion for urine loss they will be followed for one year to determine if the improvement can be maintained.

Self-Monitoring Study. Self-monitoring techniques, defined as factors such as timing and amount of fluid intake, caffeine consumption, and avoidance of constipation, have been recognized as important UI management strategies (Fantl et al, 1996; Wyman, 1992; Wyman, Fantl, McClish, Bump, & The Incontinence Program for Women Research Group, 1998). However, no study has measured their impact on improving UI until recent research by Dougherty and her colleagues (Dougherty et al., 1998). They found that after practicing these easy-to-use techniques (called self-monitoring) that many women with mild to moderate UI had improved sufficiently so that they did not wish to engage in further treatment. This study follows women to measure the effect of self-monitoring over 1 year.

The specific aims of Biofeedback Study are:

1. For women who do not respond to self-monitoring, to compare the efficacy of PFM exercises augmented with biofeedback (PFME/B) to PFM exercises without biofeedback (PFME) over one year in treating women who have persistent stress or mixed UI, as assessed by grams of urine loss, number of UI episodes, quality of life for UI, and subjective assessment of progress/improvement.
2. For women who do not respond to self-monitoring, to compare the efficacy of PFME/B or PFME to a attentional control group (C) over one year in treating women who have persistent stress or mixed UI, as assessed by grams of urine loss, number of UI episodes, quality of life for UI, and subjective assessment of progress/improvement.
3. To compare adherence to the treatment for women in the three groups.

The specific aims of the Self-Monitoring Study are:

1. To measure the effect of self-monitoring over 1 year on urine loss, UI episodes, quality of life for UI, and subjective assessment of progress.
2. To compare the effectiveness of self-monitoring to a waiting period (non-treatment control) group on urine loss, UI episodes, quality of life for UI, and subjective assessment of progress.

The secondary aims of this project are:

- 1a. To determine the stability of urine loss and UI episodes over a short waiting period.
- 1b. After the waiting period, to follow women with remission to determine recurrence of UI over 1 year.

- Using data from both the Biofeedback Study and the Self-Monitoring Study, to compare the effectiveness of self-monitoring after one year with pelvic floor muscle exercises without biofeedback, with pelvic floor muscle exercises augmented with biofeedback, and with an attentional control group.

II. Methods

A. Overall Study Design

Biofeedback Study. After the clinic visit subjects are randomized into a 3-week waiting period followed by 3-weeks of self-monitoring vs. self-monitoring only. If after 3 weeks of self-monitoring the subjects do not meet the biofeedback study inclusion criterion for urine loss, they are followed at 3, 6 and 12-months (*i.e., they are now subjects in the Self-Monitoring Study.* If they still meet the study criterion for urine loss they are randomized into one of three groups (two treatment and one attentional control). After treatment they are followed at 2 weeks, 6 months and 12 months. Data are collected at baseline (clinic screening visit), after self-monitoring, 2 weeks after the intervention, and at 6 months and 12 months after the intervention. Data collected at each of these times include grams of urine loss using the pad test, number of UI episodes using bladder diaries, and quality of life for UI; subjective assessment of progress/improvement is first measured after self-monitoring or waiting period (depending on their group randomization). PFM assessment is done only at baseline and 2 weeks after the intervention; the Broome Pelvic Muscle Self-Efficacy Scale is administered to the PFME and PFME/B groups at the urodynamic clinic visit, 2-week, 6 and 12-month follow-up. Information about adherence to the protocol is collected during the 8-week intervention, 2 weeks after the intervention and at 6 and 12 months after the intervention. The study design is depicted in Figure 1.

Self-Monitoring Study. After the clinic visit subjects are randomized into a 3-week waiting period followed by 3 weeks of self-monitoring vs. self-monitoring only. After treatment they will be followed at 3 months, 6 months and 12 months. Data to be collected at the clinic visit, after the waiting period, after self-monitoring and at 3, 6, and 12 months include grams of urine loss using the pad test, number of UI episodes using bladder diaries, and quality of life for UI; subjective assessment of progress/improvement will be first measured after the waiting period or self-monitoring (depending on their group randomization); PFM assessment will be done at the clinic visit and after self-monitoring. The study design is depicted in Figure 2.

Intervention

Waiting Period. After the clinical screening visit subjects are randomized into self-monitoring or a 3-week waiting period. Data collected before and after the waiting period include number of UI episodes using bladder diaries, grams of urine loss using the pad test, and quality of life for UI. Subjective assessment of improvement is also assessed after the waiting period.

Self-Monitoring. Self-monitoring involves 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 (Miller, Ashton-Miller & DeLancey, 1998). Information about caffeine and fluid intake, and voiding time is collected from the bladder diaries that the subjects complete before the clinic screening visit. Information about constipation is collected at the clinic screening visit. The content of the counseling is determined by this information.

If the subject indicates that she has an average daily intake of more than 2 cups/glasses of caffeinated beverage, she is counseled about caffeine reduction. She is instructed to gradually replace caffeinated beverages (e.g., coffee, tea, and soft drinks) with non-caffeinated beverages (e.g., water, decaffeinated tea, coffee, soft drinks and juices). Over the course of 3 weeks, her goal is to reduce her caffeine intake to 2 or less cups/glasses of caffeinated beverage a day. She is given an information sheet with lists of non-caffeinated and caffeinated beverages to help her make her choices (Tomlinson et al., 1999).

If the bladder diary indicates that a subject's average daily fluid intake is less than 1,500 cc or greater than 4,000 cc, she receives counseling on this. She is encouraged to modify her fluid intake to a more appropriate 1,800 to 2,400 cc/day. If the subject is drinking less than 1,500 cc/day, she is encouraged to drink an additional 120-240 cc of water or other non-caffeinated beverage in the morning each day for one week, with an increase of another 120-240 cc each day during the second week. If the subject drinks more than 4,000 cc per day, she is encouraged to decrease

her intake by 120-240 cc per day for the first week with an additional decrease of 120-240 cc per day for the second week (Tomlinson et al., 1999).

If a subject consumes fluids after 6 p.m. and has a problem with nocturia, she is instructed to decrease fluid intake after 6 p.m. and shift her intake to mornings and afternoons. In earlier research (Tomlinson et al., 1999), most older women retired before 9 p.m. In the proposed research, if a subject's bedtime is after 9 p.m. (as recorded in the bladder diary), fluid restrictions begin 3 hours before her usual bedtime. Subjects who indicated daytime voiding intervals of greater than 4 hours are encouraged to void every 3-4 hours while awake. Other toileting measures such as voiding when first arising, before leaving the house and before going to sleep are discussed. Women who have a problem with constipation are instructed on bowel management strategies such as taking in adequate fluids, increasing fiber intake and establishing a regular time for bowel movements (Tomlinson et al., 1999).

In addition to modifications in caffeine and fluid intake and bowel habits, all women are taught a simple PFM contraction technique (the knack) (This is now called the Quick Kegel) (Miller et al., 1998). Teaching the Quick Kegel involves a description of the basic physiological and functional properties of the pelvic floor muscles. Digital vaginal palpation is then used to confirm that the subject is contracting the pelvic floor muscles. She is taught to contract the pelvic floor muscles while breathing in and out. This technique can be used to prevent urine loss during an activity that suddenly increases intra-abdominal pressure such as coughing. The knack has been shown to significantly reduce urine loss during a cough in women with mild-to-moderate stress UI, without increasing PFM strength (Miller et al., 1998).

Magnetic notes with reminders about relevant components of self-monitoring (e.g., fluid intake, the Quick Kegel) and an audiotape are provided. Women are encouraged to place these in critical areas such as the bathroom, refrigerator or other places to stimulate their consistent awareness of self-monitoring techniques.

PFME Taught Without Biofeedback. (*Biofeedback Study only*) PFM exercise are taught using techniques outlined by Sampselle and her colleagues (1997). Protocols for PFM exercise training vary between 4 and 20 weeks, but Dougherty et al. (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, we are using an 8-week monitored PFM exercise program.

Sampselle et al. (1997) and Fantl et al. (1996) recommend 30-45 contractions a day. To maximize the potential for success, we prescribe 45 contractions a day. The protocol calls for 10-second contractions with 10-second relaxation periods between each one. Women with weak PFM are instructed to contract more briefly (2-5 seconds) and to increase the duration of contractions up to 10 seconds as they gain 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 will be taught during clinic visits. The subject are taught how to avoid bearing-down efforts. This is done by having her take a deep breath, hold it and bear down, and note the bulging of the perineum. The correct technique is taught by having the subject pretend that she is trying to avoid passing intestinal gas and to bring the same tightening motion forward. By having her place her hand on her abdomen she can avoid contracting her abdominal muscles.

It is postulated that 10-second contractions recruit Type I fibers and Type II fibers. A 10-second contraction probably activates Type I fibers first and quickly activates the more fatigable Type II fibers. The activation of Type I fibers probably accounts for the sustained effort. This would suggest that 3- to 6-second contractions would be more effective in training Type II fibers. However, differential results from shorter contractions have not been clearly demonstrated (Dougherty, 1998). A 10 second relaxation period is most commonly recommended after each contraction (Dougherty, 1998; Sampselle et al., 1997).

Women are instructed to perform 45 PFM contractions daily. Written instructions and an audiotape are provided to each woman for use in performing PFM exercise. PFM exercise are divided into 15 contraction sets in supine, sitting, and standing positions, and continued use of the knack (Miller et al., 1998) is reinforced.

The PFME group has four clinic visits (to parallel the PFM/B group's visits) that focus on education as described above. Each visit has a specific focus, for example (a) techniques to identify and isolate the pelvic floor muscles

(Sampselle et al., 1997), (b) review and support for progress with PFM exercises at home, and/or (c) emphasis on specific features such as PFM exercise in sitting, standing and lying positions and the rationale for regular PFM exercise. The PFME group are also encouraged to continue the recommendations made to them during the self-monitoring phase.

PFM Exercise Taught Using Biofeedback. (*Biofeedback Study only*) The rationale for teaching PFM exercise with biofeedback is that: (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, and (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 is provided. The rationale for biofeedback enhancement of PFM exercise is explained at the first PFM/B visit.

A computerized integrated biofeedback system with dual channel EMG is used. After preparing the skin with alcohol, EMG sensors are placed 1 cm from each side of the anus and connected to channel 1. Abdominal sensors are placed on the right external abdominal oblique muscle. The position of one electrode is about 10–15-cm lateral to the umbilicus. The second electrode is inferior to the first, just medial to the anterior superior iliac spine.

A resting baseline measure is obtained over 1–3 minutes. The subject is coached through three PFM contractions of 10 seconds duration (if EMG amplitude falls to 1/3, the subject is coached to relax). An event marker on the tracing denotes the cue to begin and end each contraction. Each contraction is followed by a 15-second relaxation period. The nurse and subject observe and discuss the abdominal and PFM tracing. Features that the nurse uses to guide the biofeedback session include:

1. The characteristics of the abdominal and pelvic floor muscles during the resting baseline.
2. The time from when the subject was cued to contract to the time of the maximum amplitude of contraction.
3. The time from when the subject was cued to relax to the time EMG measures returned to baseline.
4. The maximum amplitude recorded on each channel during the contraction.
5. The characteristics of the PFM contraction over 10 seconds.
6. The degree of relaxation of the abdominal muscles during a PFM contraction.

With the subject observing the EMG tracings of her performance, she is guided with goals that are individualized based on her performance. Representative goals are to reinforce abdominal and PFM performance that result in:

1. Greater amplitude and duration of PFM strength and tone.
2. Relaxation of abdominal and gluteal muscles during PFM contractions.
3. Shaping PFM contractions with short response latency (time from cue to maximum amplitude).
4. Shaping PFM contractions toward immediate recovery to baseline after PFM contraction ends.
5. 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 is to optimize PFM responses that mediate bladder control. Four biofeedback sessions are carried out over the 8 week-period of PFM exercise training. The PFM exercise training at home for the PFME/B group is the same as for the PFME group. The PFME/B group is also encouraged to continue the recommendations made to them during the self-monitoring phase.

Attentional Control Group. (*Biofeedback Study only*) The rationale for including an attentional control group is to take into account the potential effects of data collection procedures, therapist contact and clinic visits that could produce therapeutic effects without additional intervention. Also, any influences (e.g., community education programs, media campaigns) that are external to this study affects all groups.

After randomization, subjects in the attentional control group make four clinic visits over the 8-week intervention period. At each clinic visit, the subject's self-monitoring recommendations are reviewed, questions answered and additional suggestions made. Following this, each subject is given information on a topic related to the theme: "Maintenance of a Healthy Life Style." The four topics are: "The Sun and Your Skin: What Can You Do To Protect Yourself?", "Tips to Help You Manage Stress in Your Life," "Guidelines for a Healthy Diet," and "Sleep: Are You Getting Enough?" Both verbal information, an audiotape, and pamphlets are given to the subject and questions are answered.

B. Subjects

The target sample size for the Self-Monitoring Study is 201. These are noninstitutionalized women 18 years of age and older who have stress, mixed, or urge UI and are expected to have generally good health status. In order to achieve a final sample size of 252 for the Biofeedback Study and allow for 20% attrition, 315 women 18 years of age and older will be randomized into the three groups. They are noninstitutionalized women who have stress or mixed UI and are expected to have generally good health status.

Inclusion Criteria:

- Eighteen years or older
- Do not live in an institution
- Involuntary urine loss on at least one of two days of 1 gram or more
- Negative urine test for bacteria

Exclusion Criteria:

- Diagnosis of bladder cancer or kidney disease
- Prior treatment of UI using biofeedback
- Urinary catheter
- Available to participate in the study for less than 1 year
- Post void residual of 100 cc or more
- Pure urge UI (Biofeedback Study only)
- Unable or unwilling to keep bladder diaries
- Pregnant

C. Setting

The target population for the Biofeedback Study is women 18 years of age and older who live in Wake and surrounding counties. The target population for the Self-Monitoring study is women 18 years of age and older who live in Nash and surrounding counties. Subjects will be recruited from the community using a community-based outreach network that utilizes a menu of mechanisms through which potential subjects will be identified. (This recruitment process is described in Section E below).

D. Data Collection Methods

The instruments that are being used to collect data on outcome measures are described below. In addition to outcomes, other measures include the health history and physical examination, and urodynamic testing.

Bladder Diary. (Note: This was changed to a 3-day bladder diary based on new research by Nygaard & Holcombe, 2000). A 7-day bladder diary is used to measure UI episodes. Wyman, Choi, Harkins, Wilson, & Fantl (1988) found a 0.92 correlation in UI episodes on bladder diaries recorded in 2 consecutive weeks. Throughout the day and night for 7 days, the subjects will note fluid intake (including amount and type), voids, incontinence episodes, and urges to void not accompanied by voids or incontinence. Spearman's Rank correlation coefficient ($n=60$) on UI episodes assessed at baseline and after a 1-month no-treatment period was 0.59 (Dougherty et al., 1992). Results from the bladder diary were improved by (a) careful instructions to the subject; (b) contacting the subject during the week to discuss her experiences and answer questions; and (c) reviewing the diary with the subject and tallying the results of interest in the presence of the subject. *In the Biofeedback Study* bladder diaries are completed by the subjects 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. In the Self-Monitoring Study bladder diaries are completed by the subject before the screening visit, after the waiting period, after self-monitoring, and at 3, 6, and 12 months after the intervention.

Pad Test for Urine Loss. Incontinence pads which have been weighed in self-sealing plastic bags are provided to the subject. Instructions are to (a) change pads as frequently as they wish, (b) remove for voiding and defecation, (c) reinsert into bag after use and reseal, and (d) record pad change on bladder diary. Subjects are asked to wear pre-weighed pads for two consecutive 24-hour periods on Days 2 and 3 when they are completing the bladder diaries. The pads are weighed and the change in pad weights recorded (grams in 24 hours). In recent research (Dougherty et al., 1993; Dougherty et al., 1998) acceptance and follow-through of the home pad test were excellent, and instructions were easily followed by women of various functional abilities. A number of studies (Versi et al., 1996; Wilson, Mason, Herbison, & Sutherst, 1989; Elelund, Bergstrom, Milsom, Norlen, & Rignell, 1988) have reported that the 48-hour pad test is easy to perform, robust and reasonably reproducible; 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 one 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. *In the Biofeedback Study* pad tests are completed by the subjects 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. In the *Self-Monitoring Study* pad tests are completed by the subjects before the clinic screening visit, after the waiting period, after self-monitoring, and at 3, 6, and 12 months after the intervention.

PFM Assessment. The objective of the PFM assessment is to evaluate the characteristics of the pelvic floor muscles during rest and contraction. After preparing the skin with alcohol, EMG sensors are placed 1-cm lateral of each side of the anus and connected to channel 1. Abdominal sensors are placed on the right external abdominal oblique muscle and connected to channel 2. The position of one electrode is about 10-15 cm lateral to the umbilicus. The second electrode is inferior to the first, just medial to the anterior superior iliac spine.

After the integrity of the recording system is observed, resting baseline measures is obtained over 1-3 minutes. Then, the subject is coached through a series of ten 10-second contractions of the pelvic floor muscles. Each contraction is followed by 10-second rest period. The nurse investigator observes the EMG tracing of the contraction. If the contraction amplitude falls to 1/3 of the initial amplitude, she cues the subject to relax the pelvic muscle contraction. After 10 seconds, she cues the subject to begin another contraction. EMG characteristics to be recorded during pelvic floor muscle relaxation and contraction are (a) abdominal muscle average, (b) PFM maximum amplitude, and (c) PFM contraction average. During the recording, the nurse, but not the subject, observe the computer screen. (The subject's observation of her performance might constitute biofeedback and bias the biofeedback intervention.) Results obtained at the clinic screening visit and 2 weeks after the intervention period (after self-monitoring for the *Self-Monitoring Study* subjects) will be compared across treatment and control groups.

Quality of Life for UI. The Incontinence Impact Questionnaire (Shumaker, Wyman, Uebersax, McClish, & Fantl, 1994) is used to measure quality of life for UI. This scale consists of 30 items; 24 refer to the degree to which UI affects a range of activities (e.g., shopping, recreation, entertainment), and 6 refer to the effect of UI on various feelings (e.g., fear, frustration, anger). Factor analysis derived subscales are Physical Activity, Travel, Social Relationships, and Emotional Health. The scale was found to be psychometrically robust (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 responded to is taken. The average, which ranges from 0 to 3, is multiplied by 33 1/3 in order for the scores to range from 0 to 100. The authors report that omission of a single item has no effect on the total score; omission of two items has only a slight effect, but omission of three or more items invalidates the scale. In the *Biofeedback Study* this scale are administered before the clinic screening visit, after the waiting period, after self-monitoring, 2 weeks after the intervention and at 6 and 12 months after the intervention. In the *Self-Monitoring Study* this scale is administered before the clinic screening visit, after the waiting period, after self-monitoring, and 3, 6, and 12 months after the intervention.

Subjective Assessment of Progress/Improvement. In addition to assessing quality of life for UI, subjects are asked to give their perception of their progress with treatment, satisfaction with progress and perceived improvement. Burgio and her 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 100%, where 0% represents no improvement and 100% represents completely dry? In the Biofeedback Study these questions are asked after the waiting period, after self-monitoring, 2 weeks after the intervention, and at 6 and 12 months after the intervention. In the Self-Monitoring Study these questions are asked after the waiting period, after self-monitoring and 3, 6, and 12 months after the intervention.

Adherence to Research Protocols. (*Biofeedback Study only*) Adherence to the research protocols is measured in four ways: (a) attendance at the intervention sessions (PFME, PFME/B and C groups), (b) practice of PFM exercises at home during the 8-week intervention (PFME, PFME/B groups), (c) practice of PFM exercises at home during the 12-month follow-up (PFME, PFME/B groups), and (d) practice of self-monitoring recommendations during self-monitoring, during the 8-week intervention and during the 12-month follow-up (PFME, PFME/B and C groups).

- (a) Attendance at the intervention sessions. Attendance is recorded in each of the three groups and calculated as a percentage of subjects who attended 1, 2, 3 or 4 sessions.
- (b) Practice of PFM exercises at home during the 8-week intervention. Each subject in the PFME and PFME/B groups is given a home monitoring device to take home after the first session. The subject is asked to use the home monitoring device to record the PFM exercises she practices. The home monitoring device automatically records the date the subject records the exercises, the number of exercises practiced and the duration of each PFM contraction. Two measures of adherence will be calculated. The first is the percentage of subjects in each of the treatment groups who practice 100%, 75-99%, 50-74%, 25-49% or less than 25% of the days. In addition, each subject is asked to complete 45 PFM exercises per day. A measure will then be calculated to indicate the percentage of subjects in each of the two treatment groups who completed 45 PFM exercises on 100% of the days, 75-99% of the days, 50-74% of the days, 25-49% of the days, or less than 25% of the days.
- (c) Practice PFM exercises at home during the 12-month follow-up. At 6 and 12 months a home monitoring device is mailed to each subject in the PFME and PFME/B groups along with their bladder diaries, pads and questionnaires. The woman is asked to keep track of her PFM exercises for a week and is asked whether this was typical of what she usually did. The same measures will be calculated as in (b) above.
- (d) Practice self-monitoring recommendations. Practice of self-monitoring is recorded in the bladders that the women complete at a number of times during the study.

Health History and Physical Examination. The health history described by Wyman et al. (1988) was modified for the Nursing Models Project. The health history includes sections on (a) personal information/demographics, (b) health (current and past), (c) medications (prescribed, over-the-counter, supplements), (d) health habits (including bladder), and (e) continence status, and history of treatment of urine loss. The physical examination includes abdominal, genital, rectal and neurologic assessments as described by Walters and Karram (1993). A Bacturcult test is used to assess for bacteria in the urine, MultiStix 10 SG Reagent Strips are used to screen for bilirubin, blood, glucose, leukocytes, ketones, nitrite, PH, protein and urobilinogen, and a bladder scan is used to determine residual urine after voiding.

Urodynamic Testing. (*Biofeedback Study only*) Urodynamic testing is done to screen for pure urge UI. It consists of 2-channel supine water cystometry. The subject is asked to void and then is placed in a lithotomy position. Two 8F sensor lumin microtransducer catheters with filling lumin (one urethral and one rectal) are inserted. The bladder is then be filled with sterile water at a rate of 50 ml/minute to a maximum of 500 ml. Threshold volumes are recorded for first desire to void, strong desire to void, detrusor contraction, cystometric capacity, and urine loss. The criterion for pure urge UI is detrusor contractions of at least 15 cm of water during bladder filling or detrusor contractions of less than 15 cm of water if also associated with urge symptoms in the absence of leaking during heel bouncing, cough, and positional changes. Intrinsic sphincter insufficiency is defined by an open bladder neck at rest or a valsalva or cough leak point pressure of less than 60 cm of water.

D. Data Collection Procedures

1. Recruitment of Subjects and Consent Procedures. Subjects are recruited from the community using a community-based outreach network that utilizes a menu of mechanisms through which potential subjects can be identified. The following are some examples. Presentations are done at various community settings, e.g., senior housing projects and senior centers, to church groups. Exhibits are done at health fairs and in pharmacies. Posters with tear offs are placed in bathrooms in malls, department stores, restaurants, clinics, and sporting events. Interviews are done with local TV channels, radio stations, and newspapers. Ads are placed in local newspapers.

When potential subjects call into the research office in response to our publicity, they are screened by project staff for inclusion into the study. The initial screening interview is conducted by phone. Inclusion criteria that must be met in the initial screen are: (a) female aged 18 years or older and (b) live in their own homes in the community (noninstitutionalized). Exclusion criteria determined in the initial screen include: (a) diagnosis of bladder cancer or kidney disease, (b) prior treatment of UI using biofeedback, (c) a urinary catheter, (d) available to participate in the study for less than one year, and pregnancy. Subjects who meet these inclusion and exclusion criteria make an appointment at the Raleigh Clinic (Biofeedback Study) or Rocky Mount Clinic (Self-Monitoring Study). At that visit the study is explained in detail and she is asked to sign a consent form. She is given bladder diaries, pads, and questionnaires and a return appointment is made for the clinic visit. At the clinic visit the subject asked to sign a "Permission to Contact Physician" for and a "Release of Medical Information" form. The Permission form allows us to notify the indicated physician of the subject's participation in the study. The subject is also show a copy of the content of the letter that will be sent. The Medical Release form authorizes us to send to the physician the subject indicates information about abnormal test findings.

2. Inducements. Biofeedback Study. Each subject will be paid \$10 for each set of complete data at baseline (clinic screening visit), after the waiting period, and after self-monitoring, and \$20 for each set of complete data for the three follow-up visits after the intervention. Subjects in all three intervention groups receive \$10 Wal-Mart gift card at each of the 4 visits during the intervention. In addition, after each subject in all three groups has completed the 12-month data collection point, she will receive a copy of preliminary results and subjects in the attentional control group will receive verbal and written PFM exercise instructions.

Self-Monitoring Study. Each subject will be paid \$10 for each set of complete data at the clinic screening visit, after the waiting period, and after self-monitoring and \$20 for each set of complete data for the three follow-up contacts after completion of self-monitoring.

F Risk/Benefit

1. Risks. Biofeedback Study. Risks are expected to be minimal. A catheter is inserted into the bladder during urodynamic testing. Some women report moderate discomfort with urinary catheterization, for others it is painless. Urinary catheterization involves a small risk (1-3%) of inflammation or urinary tract infection. All women are given prophylactic antibiotics before and after urodynamic testing. All women are asked about allergies at the clinic visit when a history and physical exam is done. A protocol for antibiotic administration was written by Ellen Wells, MD. The subjects do not incur any costs for antibiotics. The Macrobid has been obtained free of charge from Proctor & Gamble. Dr. Wells writes a prescription for other antibiotics and the subject is reimbursed by the project. To minimize the probability of urinary tract infections the specially trained project nurse adhere rigidly to accepted antiseptic technique in all procedures related to urodynamics. In addition, because the women are discussing UI, undergoing physical examination is part of the screening and having skin electrodes placed during the intervention, they may experience some psychological distress and embarrassment.

A specially trained and experienced nurse conduct the screening and interventions. She is supervised by two experienced physicians to whom any health-related problems or concerns are referred.

The subjects can withdraw from the study at any time. No names appear on the data collection forms. Names and identification numbers are kept in a locked file cabinet separate from the data collection forms.

Self-Monitoring Study. Because women are discussing UI and undergoing a physical examination they may experience some psychological distress and embarrassment. A specially trained and experienced nurse conducts the screening and interventions. The subjects can withdraw from the study at any time. No names appear on the data collection forms. Names and identification numbers are kept in a locked file cabinet separate from the data collection forms.

2. Benefits. As discussed previously, the risks to subjects are expected to be minimal. However, there are both immediate and long-term benefits to current subjects and to other women with incontinence. The majority of subjects who participate in the study are expected to show at least some improvement in their incontinence. In terms of long-term benefits, this study addresses the efficacy of biofeedback in the treatment of UI. This question is an important one for several reasons. Additional, expensive equipment is required for biofeedback and personnel have to be specially trained in its use. Some women may find the monitoring devices (vaginal probes, rectal probes

and/or surface electrodes) to be uncomfortable and invasive. Insurance companies require clear evidence that the use of biofeedback produces incremental improvement to UI great enough to warrant reimbursement. Therefore, biofeedback may be contradicted unless it can be show to be more efficacious than PFM exercises alone. This study has long-term implications for the costs of treatment of UI and insurance reimbursement for biofeedback.

2. Illegal Activities or Deception. None

E. Investigator's Assurance Statement

As Principal Investigator, I have read the University of North Carolina at Chapel Hill, School of Nursing, IRB guidelines governing the use of human subjects in research activities and I agree to abide by them. I agree to a continuing exchange of information with the IRB including the occurrence of any previously undesirable or serious adverse effects or complications during data collection. I also agree to submit an ADDENDUM seeking IRB approval before instituting any significant changes or additions to the project and a brief progress report at the annual review period. A copy of the signed consent form for each subject will be retained in the files of the PI.

Signature of Principal Investigator

Date

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