Effectiveness of Behavioral Therapy to Treat Incontinence in Homebound Older Adults

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OBJECTIVES: To examine the (1) short-term effectiveness of behavioral therapies in homebound older adults and (2) characteristics of responders and nonresponders to the therapies.

DESIGN: Prospective, controlled clinical trial with crossover design.

SETTING: Adults aged 60 and older with urinary incontinence and who met Health Care Financing Administration criteria for being homebound were referred to the study by homecare nurses from two large Medicare-approved home health agencies in a large metropolitan county in southwestern Pennsylvania.

MEASURES: Structured continence and medical history, OARS Physical and Instrumental Activities of Daily Living scales, Folstein Mini-Mental State Examination Score, Clock Drawing Test, Geriatric Depression Scale, Performance-Based Toileting Assessment, bladder diaries, and physical examination.

RESULTS: One hundred five subjects were randomized to biofeedback-assisted pelvic floor muscle training (53 to the treatment group and 52 to the control groups). Control subjects with complete pre- and post-control data (n = 45) experienced a median 6.4% reduction in urinary accidents in contrast to a median 75.0% reduction in subjects with complete pre- and post-treatment data (n = 48, $P < .001$). Following the control phase, subjects crossed over to the treatment protocol. Eighty-five subjects completed treatment, achieving a median 73.9% reduction in UI. Exercise adherence was the most consistent predictor of responsiveness to the behavioral therapy.

CONCLUSIONS: Clinically significant reductions in urinary incontinence are achievable with behavioral therapies in many cognitively intact homebound older adults despite high levels of co-morbidity and functional impairment. J Am Geriatr Soc 47:309–318, 1999.

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Key words: urinary incontinence; behavioral therapy; homebound older adults

Urinary incontinence (UI) affects an estimated 13 to 53% of homebound older adults.[1–4] Hu estimated that the direct costs associated with UI totaled $23.6 billion in 1995, and indirect costs were $4.2 billion.[5] Costs related specifically to homebound older adults were last examined by Ruther in 1986 when UI was reported to be among the 10 leading principal diagnoses of persons receiving home health agency (HHA) services, with total Medicare charges of $52 million, and it was the most costly diagnosis at $2603 per person served.[4] Kramer and colleagues reported that among homebound older adults, UI was so difficult to manage that it was identified as a separate group in their system of 16 Quality Indicator Groups designed to measure outcomes of home health care.[6] Despite its high prevalence and cost, research on UI among homebound individuals has been limited.[7–9]

Behavioral therapies have been shown to be effective in reducing or eliminating UI in non-homebound older persons living in the community.[10–14] In an uncontrolled study examining the effectiveness of biofeedback-assisted pelvic floor muscle training for homebound older adults, Rose et al. reported a mean 79% reduction in UI.[8] Pelvic floor muscle training can be expected to improve continence by strengthening the striated urogenital sphincter, thereby enhancing its ability to constrict the urethral lumen, improving support of the proximal urethra, and inhibiting detrusor contractions.[15,16]

We examined the effectiveness of behavioral therapies in homebound older adults. In addition, we identified characteristics of short-term responders and nonresponders to the therapies.

METHODS AND DESIGN

This prospective controlled clinical trial had two arms, one for the treatment of cognitively intact (Folstein Mini-Mental State Examination (MMSE) score ≥ 24)) and one for cognitively impaired subjects (MMSE < 24). Within each arm, subjects were randomized to a control or treatment group. Subjects in the treatment group were treated with behavioral therapies delivered during 8 weekly in-home visits by a nurse practitioner. After completion of an 8-week obser-

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vation period, control subjects crossed over to the treatment protocol. Figure 1 presents an overview of the study design. This report focuses on the effectiveness of behavioral therapies among cognitively intact homebound subjects.

Sample

Individuals with urinary incontinence were identified by nurses from two large HHAs in southwestern Pennsylvania, and willing individuals were referred to the study for evaluation. Six hundred fifty-eight individuals were referred to the study over a period of 4 years. A research nurse called all referred individuals to explain the study in greater detail, to confirm urinary incontinence, and to assess initial eligibility. Following telephone screening, eligible persons were scheduled for an in-home assessment. To be eligible for the study, individuals had to be 60 years of age or older, meet Health Care Financing Administration criteria for being homebound (i.e., need assistance to leave their home, require considerable and taxing effort to leave home, have a medical condition that contraindicated leaving their home, and generally, leave home only for short period and for medical reasons), understand and speak English, report at least two urinary accidents per week, and report incontinence persisting for at least 3 months. During the in-home assessment, which was performed by one of two study nurse practitioners (NP), data were collected to characterize subjects' UI, to identify potentially correctable problems that may have contributed to incontinence or impacted on its successful treatment, and to identify individuals who were inappropriate for the behavioral therapy. Individuals were excluded from this arm of the study if they had Folstein MMSE scores less than 24, had severe pelvic prolapse (cystocele, rectocele, or uterine prolapse extending through the vaginal introitus when bearing down), had a terminal illness, had a post-void residual greater than 100 mL, were unable to toilet independently and had no caregiver willing and able to assist with toileting, had fewer than an average of two urinary accidents per week documented in baseline bladder diaries, or were unable to provide satisfactory self-report bladder diary data after three attempts. Potentially correctable problems that could have contributed to UI or impacted on its response to the intervention (e.g., hyperglycemia, urinary tract infections, constipation, and environmental barriers) were evaluated and treated before randomization. Data were also collected to characterize responders and nonresponders to the behavioral interventions.

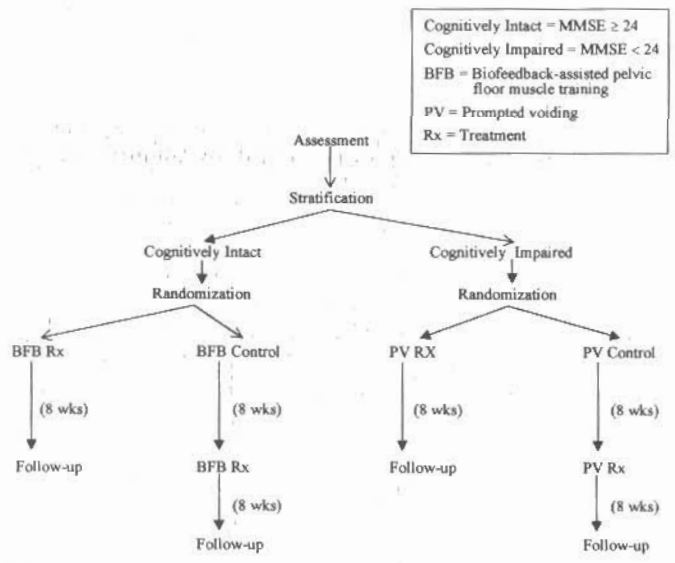

Figure 1. Study design.

Measures and Procedures

A comprehensive continence history and a focused medical history and physical examination were performed by the NPs. The physical exam included a pelvic exam in women, a rectal exam in both men and women, and abdominal and neurologic exams. Post-void residual urine was measured in all subjects by bladder ultrasound. The laboratory evaluation included urinalysis, blood sugar, electrolytes, BUN, and creatinine. Functional ability was measured using the Older Americans Research and Service (OARS) Instrumental (added year 2 of the study) and Physical Activities of Daily Living (ADL) scales.[17] Affective symptoms were measured by the Geriatric Depression Scale (GDS).[18] The Performance-Based Toileting Assessment was utilized to measure toileting ability.[19] The MMSE and Clock Drawing Test were administered to assess cognitive function.[20,21] Subjects completed 2 weeks of baseline bladder diaries describing the number, type, and volume of incontinent episodes. Accidents were defined as large if they soaked a subject's pad or outside clothing and small if they dampened the pad or undergarments. Subjects were also asked to describe the circumstances of each accident, e.g., with urgency or during coughing, sneezing, or changing position. A small number of subjects (n = 7) were unable to provide this detailed bladder diary data. These subjects were given simplified bladder diaries in which they were asked to check the times of large and small accidents in prerecorded 2-hour blocks. Three subjects were blind and were, thus, unable to complete written bladder diaries. These individuals placed a coin in a jar each time they had an incontinent episode. This procedure was more successful than our earlier attempt to have subjects use a voice recorder to document urinary accidents. The instruments utilized to collect data, as well as the assessment protocol, were described in greater detail in earlier articles.[9,22]

After baseline assessment, eligible subjects were randomized to a control or treatment group. Stratified randomization with permuted blocks was used to randomize subjects. Prior to randomization, subjects were stratified according to three key characteristics: cognitive ability (MMSE $\geq$ 24 vs MMSE $<$ 24), toileting skills (dependent on or independent of human assistance), and severity of UI (mild: $<$5 accidents/week; moderate: 5–10 accidents/week; severe: $>$10 accidents/week). An MMSE score less than 24 was selected to classify cognitive ability because scores lower than this are generally considered abnormal and indicative of cognitive dysfunction.[23] The stratified randomization was used to ensure that the treatment and control groups were comparable before intervention on key characteristics known to influence treatment efficacy in other older populations. There was no attempt to equalize the size of the groups based on characteristics or to recruit subjects with specific characteristics. A computer-generated randomization routine was used to blind the NP therapist to future group assignment.

Subjects assigned to the control group were visited by the NP every 1 to 2 weeks to provide social interaction (attention control). This was done to evaluate the effect of socialization alone on outcome. Control visits lasted approximately 35

minutes (in contrast to 40 to 60 minutes for treatment visits). No discussion of UI or its treatment occurred during these visits. Since subjects were homebound with high levels of co-morbidity and had recently been seen regularly by a home care nurse for other medical problems, avoiding discussions on urinary incontinence was relatively easy. On the few occasions that subjects raised the issue of incontinence, the conversation was easily redirected to another topic. Subjects were not asked to keep bladder diaries during the control phase of the study. After 8 weeks of the attention control condition, subjects completed 2 weeks of bladder diaries and crossed-over to the treatment protocol.

Treatment consisted of 8 weekly sessions conducted in subjects' homes by NPs skilled in the delivery of behavioral therapies for urinary incontinence. The behavioral therapy consisted of biofeedback-assisted pelvic floor muscle exercises, urge and stress strategies, and bladder retraining. A portable biofeedback instrument and surface electromyography (EMG) were utilized to teach subjects pelvic floor muscle (PFM) exercises by providing immediate visual and/or auditory feedback of pelvic floor and abdominal muscle activity. Biofeedback was repeated up to four times during treatment depending on the subject's progress. Subjects were instructed to perform the PFM exercises three times a day and to do 10 to 15 exercises at each session. The duration of the relaxation and contraction phases for each exercise was determined by the subject's ability to sustain PFM contractions during baseline assessment of PFM strength. Although the goal was for subjects to be able to contract and relax their pelvic floor muscles for 10 seconds each, most were able to contract their muscles for only 3 to 4 seconds at the beginning of treatment. Subjects were instructed to perform one set of exercises (10–15 exercises) while lying down, one while standing, and one while sitting. Subjects continued to practice the exercises throughout treatment.

Once subjects mastered pelvic floor muscle exercises (usually by the second or third in-home visit), they were taught strategies to prevent involuntary urine loss. Subjects who reported involuntary urine loss following a strong urge to void (urge accidents) were instructed to contract their PFMs three or four times quickly to suppress the urge and prevent involuntary urine loss (urge strategies). Those who reported leaking urine with sudden increases in intra-abdominal pressure (e.g., coughing, sneezing, or changing position-stress accidents) were instructed to tighten their pelvic floor muscles during the activity. Subjects who reported frequent voiding (i.e., on average more often than every 2 hours) were also treated with a bladder retraining protocol.[12]

Subjects completed bladder diaries on an on-going basis throughout treatment. During the weekly treatment visits, the NP reviewed the diaries and adjusted the treatment protocol based on the subject's progress. The treatment protocol is described in greater detail in an earlier publication.[22]

At the end of the treatment protocol, subjects completed 2 weeks of posttreatment bladder diaries. Subjects were given a written summary of long-term treatment recommendations and informed that to maintain their improved posttreatment continence level, they would need to continue to practice the learned behavioral therapies indefinitely. Although no additional intervention was provided after the 8-week treatment protocol, long-term follow-up was conducted every 3 months for 1 year to monitor continence status and adherence to treatment recommendations as well as any intervening changes in physical, cognitive, functional, and affective status.

Data Analysis

The computer program SPSS for Windows (version 8.0) and SAS for Windows (version 6.12) were used for data analysis. Data were analyzed descriptively using frequency counts and marginal proportions and, where appropriate, means, medians, ranges, and standard deviations. The initial effectiveness of the behavioral therapy was assessed by comparing incontinence levels during the 2 weeks following the last treatment visit with the 2-week baseline period. The percent reduction at the end of treatment in the average daily frequency of incontinent episodes was calculated using the following formula:

$$\%\ \text{reduction in frequency} = \frac{\text{frequency of incontinence}_{\text{baseline}} - \text{frequency of incontinence}_{\text{post-treatment}}}{\text{frequency of incontinence}_{\text{baseline}}} \times 100$$

The median percent reduction was utilized to describe and compare the percent reduction in incontinence between control and treatment subjects as well as the pre- and post-treatment levels of subjects completing treatment. Both parametric and nonparametric statistics were used to compare pre- and posttreatment continence levels of treatment and control subjects.

Adherence to the PFM exercise regimen during treatment was examined by calculating the percentage of (1) prescribed exercises that subjects performed each day and (2) treatment visits that subjects were adherent to in the prescribed exercise regimen (i.e, performed at least 80% of the number of prescribed exercises each day during the previous treatment week). The latter method (percentage of adherent treatment visits) was used to allow comparison of exercise and strategy adherence. Adherence to urge and stress strategies was measured by asking subjects if they performed each prescribed strategy always, most of the time, occasionally, rarely, or never during the previous treatment week. Subjects were considered adherent if they reported performing the strategy all or most of the time. The percentages of treatment visits in which subjects adhered to both urge and stress strategies was then calculated. Given the nonnormality of adherence data, the Wilcoxon signed rank test was used to compare adherence percentages for each type of strategy to the adherence rate for PFM exercises.

Baseline characteristics and adherence to the prescribed exercise regimen were examined in an attempt to characterize responders to the intervention (responders: $>0\%$ reduction in incontinent episodes; nonresponders: $\leq 0\%$ reduction). The baseline characteristics examined were gender, age, race, living arrangements, educational level, caregiver status, the need for assistance during ambulation and toileting, the number of medications, including diuretic use, and the number of health problems, as well as the presence of specific diseases (stroke, Parkinson's disease, heart failure, diabetes mellitus), OARS physical ADL scale scores, MMSE scores, GDS scores, the time required to walk 15 feet and prepare to toilet, duration of incontinence, grade 3 stress incontinence (i.e., leaking without physical activity or a preceding sense of

urgency), previous prostate surgery (radical prostatectomy or TURP), baseline accidents, and the number of large and small accidents/day. A number of multivariate procedures (stepwise logistic regression, backward elimination, and all possible subsets regression) were utilized to help identify the best model of characteristics associated with responsiveness. For stepwise procedures, *P* values of .10 and .15 were used for variable entry and retention. A *P* value of .15 was used for variable retention in backward elimination.

RESULTS

Three hundred sixty-six (55.6%) of the 658 individuals referred to the study agreed to and were eligible for in-home assessment. Sixty-six (10.0%) declined to be assessed, and 226 (34.3%) were ineligible after telephone screening. The most common reasons for ineligibility were denied being incontinent (n = 64, 28.3%), self-reporting fewer than two accidents/week on average (n = 26, 11.5%), admission to a long-term care setting (n = 18, 8.0%), and not homebound (n = 13, 5.7%). Two hundred eighty-nine persons (79.0%) who completed the in-home assessment were cognitively intact (MMSE ≥ 24), whereas 77 (21.0%) were cognitively impaired (MMSE < 24). Following in-home assessment, 62 individuals (18.0% of those assessed) declined to participate, and 176 (48.1%) were ineligible. The most common reasons for ineligibility of the cognitively intact subjects were inability or unwillingness to provide adequate self-report bladder diary data (n = 52, 29.5%) and less than an average of two accidents per week documented in baseline bladder diaries (n = 27, 15.3%).

One hundred five cognitively intact individuals (15.9% of referred individuals and 28.9% of those assessed) were randomized to either the treatment (n = 53) or control (n = 52) protocol. Table 1 summarized the demographic characteristics of randomized subjects. The sample was predominately female (n = 95, 90.5%) and white (n = 98, 93.3%). Their mean age was 76.8 years (SD = 7.2). Fifty (47.6%) subjects lived alone, and 70 (66.7%) reported having neither a part-time nor a full-time caregiver.

Levels of comorbidity were high, with subjects reporting an average of 8.3 medical problems (SD = 3.3) (Table 1). Twenty-eight subjects (26.7%) had a previous stoke, 24.8% had diabetes mellitus, 16.2% had heart failure, and 5.7% had Parkinson's disease. Subjects took 0 to 14 prescription medications per day (mean = 5.0), and 41 (39.0%) were taking a diuretic. The only significant differences between the treatment and control subjects at baseline were the number of medications (mean = 5.7 for control subjects vs 4.3 for treatment subjects, *P* = .02).

Functional limitations were common among the subjects. Half (n = 56, 53.3%) of the subjects used an assistive device or required human assistance during ambulation. Subjects required an average of 31.8 seconds to traverse 15 feet and prepare to toilet and an average of 44.5 seconds (SD = 35.6 seconds, range = 2.0–342.0 seconds) to get from their usual location to the toilet. Subjects were mildly impaired in their ability to perform physical activities of daily living as measured by the OARS physical ADL scale (mean score = 10.1 of a possible score of 12; SD = 1.9; range = 0–12). They were more impaired in the ability to perform instrumental activities of daily living (mean score = 8.5 of 14 possible points; SD = 3.8; range = 0–14). Higher scores on both ADL measures reflect greater independence. The mean score on the GDS was 4.7 (SD = 3.3; range = 0–13). Forty-eight subjects (45.7%) had scores indicating clinically significant depressive symptoms (GDS ≥ 5). By design, all subjects were cognitively intact. The mean MMSE was 28.2 (SD = 1.4), and the mean Clock Drawing Test score was 9.0 of a possible score of 10 (SD = 1.5; range = 4–10) (higher scores indicate better cognitive function). Subjects randomized to the control group has significantly lower instrumental ADL scores than those randomized to the treatment group (mean = 7.1 vs 8.5, *P* = .03). Otherwise, the differences in the functional status of control and treatment subjects were not statistically significant.

Subjects had been incontinent for an average of 7.0 years (range = .2–52.5 years) at the time of referral to the study. Baseline bladder diary data were used to characterize subjects' incontinence. Subjects recorded an average of 3.9 accidents per day (SD = 3.6; range = .1–18.1). Most subjects (n = 76, 72.4%) had severe incontinence (>10 accidents/week). Data on the size of urinary accidents were available for 104 subjects. These individuals reported an average of 1.4 large accidents per day (SD = 2.2; range = 0–12.9). Ninety-five subjects recorded voids in the toilet and information describing the circumstances of their accidents. The types of accidents were derived from subjects' documentation of the antecedents associated with incontinent episodes. Ninety-one of these individuals (95.8%) reported urge accidents, either alone (n = 43) or in combination with stress accidents (n = 48). Subjects reported an average or 2.3 urge (SD = 2.3; range = 0–11.9), 0.8 stress (SD = 2.3; range = 0–15.4), and 0.1 other (accidents that could not be clearly defined as urge or stress) (SD = 0.4; range = 0–2.9) accidents per day. They reported an average of 0.2 episodes of enuresis per night (SD = 0.4; range = 0–2.3). They recorded an average of 11.2 voids per day (SD = 9.2; range = 3.2–91.9) and 1.9 episodes of nocturia (SD = 1.5; range = 0–8.2). There were no statistically significant differences in incontinence characteristics of control and treatment subjects.

Of the 52 subjects who were randomized to the control group, five individuals (9.6%) dropped out during the control phase of the study (withdrew n = 1; indwelling catheter inserted n = 2; serious illness n = 1; death n = 1), and postcontrol bladder diary data were missing or inadequate for two additional subjects. For the remaining 45 subjects, who provided complete pre- and postcontrol bladder diary data, the observed number of incontinent episodes decreased from 4.1 at baseline to 3.5 post-control (Table 2). The median improvement in UI during the control phase was 6.4%.

Of the 53 subjects randomized to the treatment group, 48 (90.6%) completed the treatment phase of the study and provided adequate posttreatment bladder diary data. They reported a mean 4.0 accidents per day at baseline and 1.8 accidents/day at the end of treatment. The median percent improvement for treatment subjects was 75.0%. Compared with control subjects, treatment subjects experienced a significantly greater reduction in urinary accidents per day (*P* = <.001). These findings were robust to the inclusion and exclusion of outliers and to various types of analyses.

A total of 85 subjects had complete posttreatment bladder diary data (Table 3). This included subjects who crossed over from control to treatment. A total of 15 subjects (5 randomized to the treatment group and 10 crossed-over control subjects) were lost during this phase of the study (withdrew n = 2; catheter inserted n = 1; moved out of the

Table 1. Demographic Characteristics of Randomized Subjects

Characteristics	Overall (n = 105)	Control (n = 52)	Treatment (n = 53)	Test Statistic *P* Value
Age (years)				
Mean	76.8	77.3	76.4	$t(103) = 0.62$, $P = .54$
SD	7.2	7.8	6.6	
Median	76.7	77.2	75.3	
Range	60.5–96.9	60.5–96.9	63.48–93.0	
Gender				
Female	95 (90.5)	47 (90.4)	48 (90.6)	$\chi^2(1) = 0.001$, $P = .98$
Male	10 (9.5)	5 (59.6)	5 (9.4)	($p_{FE} = 1.00$)
Race				
White	98 (93.3)	48 (92.3)	50 (94.3)	$\chi^2(1) = 0.17$, $P = .68$
Nonwhite	7 (6.7)	4 (7.7)	3 (5.7)	($p_{FE} = .72$)
Marital status				
Married	37 (35.6)	19 (36.5)	18 (34.6)	$\chi^2(1) = 0.04$, $P = .84$
Not married	67 (64.4)	33 (63.5)	34 (65.4)	
Living arrangements				
Alone	50 (47.6)	24 (46.2)	26 (49.1)	$\chi^2(1) = 0.09$, $P = .77$
With others	55 (52.4)	28 (53.8)	27 (50.9)	
Education (years)				
Mean	12.1	12.3	11.9	$t(103) = 0.60$, $P = .55$
SD	3.3	3.2	3.4	
Median	12.0	12.0	12.0	
Range	2–20	5–20	2–18	
Caregiver requirements				
Yes	35 (33.3)	17 (32.7)	18 (34.0)	$\chi^2(1) = 0.02$, $P = .89$
No	70 (66.7)	35 (67.3)	35 (66.0)	
Number of medical problems				
Mean	8.3	8.7	8.0	$t(103) = 1.09$, $P = .28$
SD	3.3	3.1	3.4	
Median	8.0	8.0	7.0	
Range	1–16	1–16	1–15	
Heart failure	17 (16.2)	11 (21.2)	6 (11.3)	$\chi^2(1) = 1.87$, $P = .17$
Diabetes	26 (24.8)	15 (28.8)	11 (20.8)	$\chi^2(1) = 0.92$, $P = .34$
Parkinson's disease	6 (5.7)	2 (3.8)	4 (7.5)	$\chi^2(1) = 0.67$, $P = .41$ ($p_{FE} = .68$)
Stroke	28 (26.7)	15 (28.8)	13 (24.5)	$\chi^2(1) = 0.25$, $P = .62$
Neurological disorders	34 (32.4)	16 (30.8)	18 (34.0)	$\chi^2(1) = 0.12$, $P = .73$
Number of medications				
Mean	5.0	5.7	4.3	$t(103) = 2.46$, $P = .02$
SD	3.0	3.1	2.8	
Median	4.0	5.0	4.0	
Range	0–14	1–13	0–14	
Diuretics	41 (39.0)	20 (38.5)	21 (39.6)	$\chi^2(1) = 0.02$, $P = .90$

area n = 1; change in anti-incontinence medication n = 1; inability to provide adequate self-report bladder diary n = 2; deterioration in health n = 7; death n = 1).

Among the 85 subjects completing treatment, the average number of accidents per day decreased from 4.0 before treatment to 1.7 after treatment ($P < .001$), with a median 73.9% reduction in incontinent episodes. Twenty-eight subjects 32.9%) had less than a 50% reduction in UI during treatment. The majority (n = 57, 67.1%), however, experienced a 50% or greater reduction, with 13 subjects (15.3%) becoming totally continent by the end of treatment. Table 3 summarizes the change in the mean and median number of accidents (total and by subtype), voids, and episodes of nocturia at the end of treatment relative to baseline. There was a reduction in all types of accidents, with significant reductions in all types of accidents except enuresis, which occurred at a very low rate at baseline. There was a median 73.9% reduction (mean = 38.3%) in all accidents, a median 91.8% decrease in large accidents (mean = 59.0%), and a median 77.6% decrease in small accidents (mean = 38.7%). Urge accidents decreased by a median 82.1% (mean = 56.2%), and stress accidents decreased a median 100.0% (mean = 49.5%).

We compared the median percent reduction of subjects who were able to provide detailed bladder diary data with data of those who were not. Subjects who completed accident-only diaries (n = 7) achieved only a median 24.3%

Table 2. Reduction in Urinary Incontinence in Subjects Randomized to Control (n = 45) and Treatment (n = 48) Groups, with Complete Posttreatment Bladder Diary Data

Continence Characteristics	Control (n = 45)	Treatment (n = 48)	Test Statistic P Value
Baseline accidents/day			
Mean	4.1	4.0	$t(91) = 0.24$, $P = .813$
SD	3.8	3.5	$z = -.18$, $P = .857$
Median	2.6	3.3	
Range	0.1–15.4	0.3–18.1	
Postintervention accidents/day			
Mean	3.5	1.8	$t(91) = 2.91$, $P = .006$
SD	3.0	2.9	$z = -4.06$, $P < .001$
Median	2.7	0.7	
Range	0.1–11.1	0.0–14.1	
Percent reduction in accidents/day			
Mean	−48.0	60.6	$t(93) = -3.02$, $P = .004$
SD	239.1	35.1	$z = -5.31$, $P < .001$
Median	6.4	75.0	
Range	−1525.0–88.0	−21.4–100.0	

reduction in UI compared with to a median 78.5% reduction among those who completed diaries describing the circumstances of their accidents as well as the number of voids (n = 78; $P = .02$).

At each treatment visit, subjects were queried about the number of exercises they performed each day and how often they performed urge and stress strategies. Self-reported adherence rates during treatment were high (97%) during treatment for the number of prescribed exercises per day. Urge strategies were prescribed for 85 subjects. Among these subjects, the median percentage adherent to the prescribed exercise regimen (i.e., performed at least 80% of prescribed number of exercises each day) was 100% (mean = 76.9%; SD = 31.4). This was significantly higher than the median percentage adherence of 75.0% for urge strategies (mean = 76.6%; SD = 30.8; $P = .02$). Stress strategies were prescribed for 44 subjects. Among these subjects, the median percentage adherent to the exercise regimen was 92.9% (mean = 77.7%; SD = 36.2%), whereas the median percentage adherent to stress strategies was significantly lower at 55.0% (mean = 53/1%; SD = 36.2; $P < .001$).

As illustrated in Table 4, stepwise linear regression identified gender, use of an assistive device when ambulating, and performing at least 30 exercises/day during the 8 weeks of treatment as significant predictors of the percentage change in incontinence after behavioral therapy. Male gender and the use of an assistive device were associated negatively with the percentage change in incontinence following treatment, whereas performing at least 30 exercises per day, on average, during treatment was associated positively with the percentage change in incontinence following treatment. These results suggest that percentage change in urinary incontinence during treatment was less for male subjects and for those patients requiring assistive devices and was enhanced when subjects performed the minimum number of exercises (at least 30) during treatment.

When adherence to exercise and number of exercises performed was limited to performance at the beginning of treatment, a somewhat different predictive model resulted. Gender, number of years of education, caregiver requirements, and the number of exercises performed during the first week of treatment were now identified as significant predictors of the percentage change in urinary incontinence after behavioral therapy (Table 4). Negative predictors of percentage change in urinary incontinence following treatment included gender and number of years of education, suggesting that the percentage change in posttreatment urinary incontinence decreased for men and as the number of years of education increased. Positive predictors included caregiver requirements and number of exercises performed during the first week of treatment. Subjects performing more exercises early in treatment tended to demonstrate greater changes in incontinence, whereas subjects having partial caregiver requirements appeared to have a greater percentage change in urinary incontinence compared with subjects requiring no or full-time caregivers.

Table 5 summarizes the results of conducting stepwise logistic regression to identify predictors of improvement in urinary incontinence following treatment. When considering the number of exercises performed and the adherence to exercise recommendations throughout treatment, three predictor variables were identified: living alone, depressive symptomatology (as measured by the Geriatric Depression Scale), and performing, on average, at least 30 exercises per day throughout treatment. Living with someone, lower scores on the GDS, and performing the minimum number of exercises per day (≥30) during treatment recommendation placed subjects at increased odds for demonstrating improvement in their urinary incontinence at the conclusion of treatment.

When exercise performance was limited to the first week of treatment, the result was a similar predictive model, which included depressive symptomatology (as measured by the Geriatric Depression Scale), performing, on average, at least 30 exercises per day during the first week of treatment, and functional status based on the OARS Physical ADL Score. Subjects who had lower depressive symptomatology scores and performed at least 30 exercises per day during the first

Table 3. Reduction in Urinary Incontinence in All Subjects Completing Treatment (n = 85)

Incontinence Characteristic	Baseline	Postintervention	Test Statistic, *P* Value
Total accidents/day (n = 85)			
Mean	4.0	1.7	$t(84) = 7.29, P < .001$
SD	3.7	2.6	$z = -6.93, P < .001$
Median	3.2	0.6	
Range	0.1–18.1	0.0–14.1	
Large accidents/day (n = 83)			
Mean	1.3	0.5	$t(82) = 4.16, P < .001$
SD	2.2	1.3	$z = -5.85, P < .001$
Median	0.5	0.0	
Range	0.0–12.9	0.0–9.3	
Small accidents/day (n = 83)			
Mean	2.7	1.2	$t(82) = 5.91, P < .001$
SD	2.6	2.2	$z = -6.05, P < .001$
Median	1.9	0.4	
Range	0.0–13.9	0.0–14.0	
Urge accidents/day (n = 74)			
Mean	2.1	0.9	$t(73) = 5.52, P < .001$
SD	2.0	1.5	$z = -5.66, P < .001$
Median	1.5	0.2	
Range	0.0–8.8	0.0–10.2	
Stress accidents/day (n = 74)			
Mean	0.9	0.3	$t(73) = 2.40, P = .019$
SD	2.5	1.0	$z = -3.30, P < .001$
Median	0.1	0.0	
Range	0.0–15.4	0.0–7.1	
Enuresis accidents/day (n = 74)			
Mean	0.2	0.1	$t(73) = 0.74, P = .461$
SD	0.4	0.4	$z = -0.97, P = .334$
Median	0.0	0.0	
Range	0.0–2.3	0.0–2.2	
Other accidents/day (n = 72)			
Mean	0.4	0.1	$t(71) = 2.67, P = .009$
SD	1.0	0.4	$z = -3.17, P = .002$
Median	0.2	0.0	
Range	0.0–5.9	0.0–2.4	
Voids/day (n = 74)			
Mean	10.4	9.4	$t(73) = 3.61, P < .001$
SD	4.0	2.9	$z = -3.07, P = .002$
Median	9.9	9.0	
Range	3.2–21.5	3.1–20.7	
Nocturia/day (n = 74)			
Mean	2.1	1.6	$t(73) = 3.32, P < .001$
SD	1.6	1.2	$z = -3.24, P < .001$
Median	2.0	1.6	
Range	0.0–8.2	0.0–5.4	

week of treatment were more likely to have improved their incontinence status at the end of treatment. However, the odds of improvement in urinary incontinence appear to decrease with increasing functional status, based on physical ADL scores.

DISCUSSION

Results of this study can be generalized only to similar populations of patients receiving homecare services for subacute medical problems. As expected, given the frailty of the population and the study criteria, ineligibility rates were high. In a clinical practice situation, some of these individuals (e.g., those who could not or would not keep bladder diaries) would probably be treated. At baseline assessment, incontinence was generally severe and had existed for many years. Levels of co-morbidity were high, and functional impairments were common in this sample. It took subjects an average of 31.8 seconds to traverse 15 feet to the toilet and prepare to void in contrast to an average of 6.0 seconds for non-homebound individuals without impaired mobility.[9]

Subjects randomized to treatment achieved a median 75.0% reduction in incontinent episodes in contrast to only 6.4% reduction for the control group. Control subjects were visited every 2 weeks to examine the effect of socialization on

Table 4. Results of Stepwise Linear Regression Modeling of the Percentage Change in Urinary Incontinence After Behavioral Therap

Predictor	Model with Exercise Performance During Treatment	Model with Initial Exercise Performance
Gender (male vs female)	−47.34**	−33.39*
	(17.31)	(16.16)
Number of years of education		−4.79**
		(1.51)
Caregiver requirements (partial vs none, full-time)		30.33*
		(13.28)
Use of assistive devices (yes/no)	−21.18*	
	(10.03)	
Number of exercises performed during the second week of treatment		1.21**
		(0.33)
Performing, on average, at least 30 exercises per week during treatment (yes/no)	38.78**	
	(13.14)	
R^2	.18	.31
R_{adj}^2	.15	.27
S	42.63	39.87

*$.01 \le P < .05$.
**$P < .01$.

Table 5. Results of Stepwise Logistic Regression Modeling of Improvement in Urinary Incontinence After Behavioral Therapy

Predictor	Model with Exercise Performance During Treatment	Model with Initial Exercise Performance
Geriatric Depression Scale	−0.264*	−0.289*
	(0.125)	(.137)
	0.768	0.749
	(0.601, 0.982)	(0.572, 0.980)
OARS Physical ADLs score		−0.979*
		(0.458)
		0.376
		(0.153, 0.922)
Live alone (yes/no)	−1.656	
	(0.897)	
	0.191	
	(0.033, 1.108)	
Performing at least 30 exercises per day during the second week of treatment		2.140*
		(0.896)
		8.498
		(1.469, 49.160)
Performing, on average, at least 30 exercises per day throughout treatment (yes/no)	2.720*	
	(0.857)	
	8.32	
	(1.553, 44.618)	
X_{Model}^2	14.33, $P = .0025$	17.29, $P = .0006$
$X_{H\text{-}L\ GOF}^2$	5.05, $P = .7519$	5.07, $P = .7500$

*$.01 \le P < .05$.
**$P < .01$.

self-reported UI. Socialization seems to have had no effect on the frequency of incontinent episodes reported.

Despite the frailty of the sample, the majority of treated patients (n = 57, 67.1%) achieved a 50% or greater reduction in urinary accidents, with 15% (n = 13) becoming totally continent at the end of treatment. The median percent reduction at the end of treatment was 73.9%.

In order to achieve the aims of our present study and to exclude as few subjects as possible who could have potentially benefited from biofeedback-assisted PFM training, we

simplified our bladder diary and gave participants up to three attempts to provide adequate bladder diary data. Although all subjects had an MMSE of 24 or greater, some could not complete diaries describing their voiding habits and the circumstances of their accidents. These subjects were given check diaries in which they simply checked the times of voids, large and small accidents, and the reasons for accidents in prerecorded 2-hour blocks. Those who had difficulty completing the check diaries were asked to complete accident-only diaries in which they checked only the times of large and small accidents. Those who were unable to complete these diaries were excluded from the study. Although cognitively intact as measured by a MMSE score of 24 or higher, subjects who were able only to complete accident-only diaries were significantly less responsive to the behavioral intervention, achieving only a median 24.3% reduction in urinary accidents. Individuals who are unable to provide ongoing, detailed self-report data about bladder habits may also have difficulty using behavioral interventions effectively to prevent involuntary urine loss.

Reduction in UI was examined in relationship to both the size and type of accidents. There was a median 90% reduction in large accidents, which are the most debilitating and costly to the patient. Although there was a clinically significant reduction in all types of accidents (median 82.1 to 100%), the greatest median reduction was in stress accidents (100%). The mobility problems and prolonged length of time it took subjects to get to the toilet and prepare to void may have made urge accidents somewhat less responsive to the behavioral interventions. In addition subjects were somewhat less adherent in performing urge strategies than in performing their pelvic floor muscle exercises (68–73% vs 97%).

Although adherence rates were lower (51–64%) for stress strategies than for urge strategies (68 to 73%), reductions in stress accidents were greater. It may be that stress accidents are more responsive to strengthening pelvic floor muscles, whereas decreasing urge accidents are more dependent on the timely use of urge strategies.

Studies examining the effectiveness of biofeedback-assisted pelvic floor muscle exercises in community-dwelling older adults have reported a mean 61 to 94% reduction in incontinent episodes.[10,13,24] Rose et al. reported a mean 79% reduction in UI for home health agency subjects in their study.[8] A higher proportion of subjects in their study achieved a clinically significant reduction in UI (≥50%), 83% versus 67.1% in our study. The Rose et al. study[8] was, however, an uncontrolled study, the sample was small, and noncompliant individuals, as well as those with complex medical problems, were excluded. These individuals were not excluded from our study. Although the Rose et al. study[8] did not report the functional characteristics of its subjects, they may have been less functionally impaired than those in our study.

Multiple baseline characteristics, as well as adherence to the prescribed exercise regimen, were examined for their ability to identify those most likely to respond to the behavioral interventions. Responsiveness was modeled as (1) any improvement versus no improvement in UI relative to baseline and (2) the percent change in incontinent episodes relative to baseline and adherence and was measured (1) throughout treatment and (2) for the initial week of treatment only. Adherence to the prescribed exercise regimen was the only consistent significant predictor of responsiveness to the behavioral therapy. Future studies of behavioral therapies for UI should examine the effectiveness of interventions designed to promote pelvic floor muscle exercise adherence.

Rose et al. also examined baseline characteristics in an attempt to identify homebound older adults who were most responsive to behavioral therapy for UI. They failed to identify any subject characteristics that predicted responsiveness.[8] The characteristics they examined were age, gender, bladder capacity, mental status scores, years of education, medication use, past urinary-related surgeries, and the duration of UI. Adherence to the prescribed exercise regimen was not examined.

Quality of life and cost have become two important outcomes in clinical trails research examining the efficacy of interventions. During the fourth year of our study, our aims were expanded to include quality of life as an outcome. We incorporated both a disease-specific measure (the Modified Incontinence Impact Questionnaire[25]) and a general health-related measure (Medical Outcomes Study Short Form-36 (MOS SF-36)[26]). Preliminary data suggest that both the Modified Incontinence Impact Questionnaire and select subscales of the MOS SF-36 may be sensitive to reductions in incontinent episodes.

CONCLUSIONS

Clinically significant reductions in urinary incontinence are achievable with behavioral therapies in many cognitively intact homebound older adults despite high levels of comorbidity and functional impairment. The absence of side effects with these interventions makes them particularly attractive options for this population, many of whom are not candidates for surgical or pharmacologic interventions. The therapies utilized in this study can be incorporated readily into clinical practice and can be provided by home health agencies. Future studies should examine the impact of these interventions on quality of life as well as the cost of providing behavioral treatment of UI to homebound older adults and methods designed to maximize adherence to the prescribed exercise regimen.

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