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Effectiveness of Prompted Voiding in Treating Urinary Incontinence in Cognitively Impaired Homebound Older Adults

Sandra Engberg, PhD, CRNP, Susan M. Sereika, PhD, B. Joan McDowell, PhD, CRNP, FAAN, Elizabeth Weber, MSN, CRNP, and Isabel Brodak, BSN, RN

Sandra Engberg, PhD, CRNP, is Assistant Professor at University of Pittsburgh School of Nursing, Pittsburgh, Pennsylvania.

Susan M. Sereika, PhD, is Associate Professor at University of Pittsburgh School of Nursing and Graduate School of Public Health, Pittsburgh, Pennsylvania.

B. Joan McDowell, PhD, CRNP, FAAN, is Associate Professor at University of Pittsburgh School of Nursing, Pittsburgh, Pennsylvania.

Elizabeth Weber, MSN, CRNP, is Nurse Practitioner at Late Life Depression Clinic, Western Psychiatric Institute and Clinic, Pittsburgh, Pennsylvania.

Isabel Brodak, BSN, RN, is a Senior Research Specialist at the University of Pittsburgh School of Nursing, Pittsburgh, Pennsylvania.

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Reprint requests: Sandra Engberg, PhD, CRNP, University of Pittsburgh School of Nursing, 462 Victoria Building, University of Pittsburgh, Pittsburgh, PA 15261; e-mail: sje1@pitt.edu.

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Objective: The objective of this study was to examine the short-term effectiveness of prompted voiding (PV) in cognitively impaired homebound older adults.
Design: This was a prospective, controlled exploratory study with a cross-over design where usual care controls crossed-over to the intervention following an 8-week observation period.
Setting: Adults aged 60 years and older with urinary incontinence and who met Center for Medicare and Medicaid Services criteria for being homebound were referred to the study by home care nurses from 2 large Medicare-approved home health agencies in a large metropolitan county in southwestern Pennsylvania. Nineteen cognitively impaired older adults were randomly assigned to either the PV intervention or a usual care attention control group.
Measures: Measures used included structured continence and medical histories, Older American Research and Service Physical and Instrumental Activities of Daily Living scales, Folstein Mini Mental State Examination, Clock Drawing Test, Geriatric Depression Scale, Performance-Based Toileting Assessment, bladder diaries, and physical examination.
Results: Nineteen subjects were randomly assigned to a PV (n = 9) or delayed attention-control group (n = 10). Treatment subjects with complete pretreatment and posttreatment data (n = 6) experienced a mean 60% reduction in daytime incontinent episodes compared with a mean 37% reduction among control subjects (n = 10). Following the control phase, subjects crossed over to the treatment protocol. A total of 15 subjects completed the PV protocol. Among all subjects completing the treatment protocol, there was a 22% reduction in daytime incontinent episodes compared with true baseline (immediately following the control phase for those crossing over from the control group).
Conclusions: The PV intervention resulted in clinically significant reductions in urinary incontinence for many of the participants, which may be achievable for many cognitively impaired homebound older adults. (J WOCN 2002;29:252-65.)

An estimated 1.75 million older adults received home health services during 1996.[1] The prevalence of urinary incontinence (UI) among homebound older adults is estimated at 13% to 53%.[2-5] In a study of caregivers (n = 184) of community-dwelling older adults with dementia, 38% reported that their care recipient was incontinent of urine. The investigators also reported that although UI was rarely the primary reason for nursing home placement, it played an important role in most decisions to institutionalize care recipients who were admitted to a nursing home during the study.[6]

Prompted voiding (PV) is one of the most common behavioral approaches for managing UI in cognitively impaired persons. PV combines regular caregiver-delivered prompts to toilet with positive feedback for appropriate toileting. The goals of this intervention are to (1) decrease the number of incontinent episodes, (2) increase awareness of bladder function, and (3) increase self-initiated toileting.[7]

LITERATURE REVIEW

The effectiveness of PV has been evaluated primarily in nursing home settings, where studies reported a 12% to 62% reduction in the mean percentage of pad checks that showed wet pads.[8-14] Poor staff adherence to the prescribed prompting schedule is often cited as a major barrier to the effective implementation of a PV protocol in long-term care settings.

Only one previous study was found that examined the effectiveness of PV in community-dwelling older adults. Atkins and Mathews[15] examined the effective-

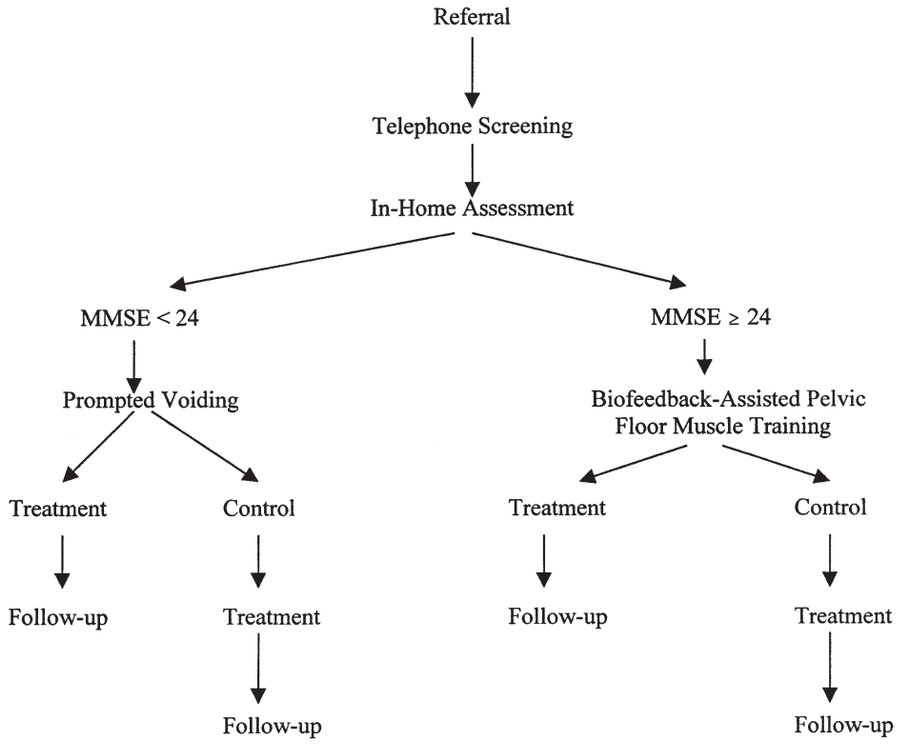

Figure 1. Study diagram.

ness of PV in 2 older adults with Alzheimer's disease. The caregiver of the first subject (A) was instructed to prompt the subject every 2 hours. After 6 days, the prompting interval was changed to every hour. The second subject (B) was placed on an hourly prompting schedule initially, and this schedule was maintained throughout the study. Response to the intervention was measured by pad weight test (grams of urine lost during a 24-hour period). On the 2-hour prompting schedule, subject A's average urine loss per 24 hours decreased by 22% relative to baseline; when the prompting interval changed to hourly, there was an average 69% reduction in urine loss compared with baseline. Subject B experienced an average 55% reduction in urine loss with hourly prompting. This study was small and uncontrolled, and the 1-hour prompting intervals may pose a significant caregiver burden.

RESEARCH QUESTIONS/AIMS

This exploratory study examined the short-term effectiveness of PV in cognitively impaired homebound older adults. The primary purpose of this study was to compare reductions in daytime incontinent episodes of treatment and control subjects. Secondarily, we compared treatment and control subjects in relation to: (1) reductions in the frequency of incontinent episodes during both the day and night, (2) reductions in the daytime percent wet (proportion of voids that were incontinent), (3) reductions in day and night percent wet, and (4) changes in self-initiated toileting. It was hypothesized that subjects randomly assigned to the treatment group would have a greater reduction in (1) daytime incontinent episodes (wet pads), (2) both daytime and nighttime incontinent episodes, (3) daytime percent wet (the proportion of voids that were a result of incontinence), and (4) both daytime and nighttime percent wet than those randomly assigned to the control group.

METHODS

Design

This was one strata (arm) of a larger experimental study examining the effectiveness of behavioral therapy in treating UI among homebound older adults. The parent study was conducted in 2 strata, one for the treatment of cognitively impaired individuals as measured by a Mini Mental State Examination (MMSE) score less than 24 and one for cognitively intact persons (MMSE ≥24). Pelvic floor muscle exercise taught with biofeedback was used to treat UI in the cognitively intact subjects, and PV was used for the subjects who were cognitively impaired. In each stratum, subjects were randomly assigned to either an attention control or treatment group. After completing an 8-week observation period, subjects in the control group crossed over to the treatment protocol. Figure 1 shows the design of the study. The findings for subjects in the cognitively intact strata were presented in an ear-

Prompted voiding is one of the most common behavioral approaches for managing UI in cognitively impaired persons.

Directions: **Place a line through the appropriate response. For example, if he/she was wet when you prompted him/her, put a line through YES and if he/she was dry, put it through NO.**

TIME OF PROMPTING	WAS HE/SHE WET?	DID HE/SHE GO TO THE BATHROOM?	DID HE/SHE VOID IN THE TOILET?	TIME OF OTHER URINARY ACCIDENTS	TIMES HE/SHE WENT TO TOILET ON HIS/HER OWN	DID HE/SHE VOID IN THE TOILET?	WAS HE/SHE WET?
	YES NO	YES NO	YES NO			YES NO	YES NO
	YES NO	YES NO	YES NO			YES NO	YES NO
	YES NO	YES NO	YES NO			YES NO	YES NO
	YES NO	YES NO	YES NO			YES NO	YES NO
	YES NO	YES NO	YES NO			YES NO	YES NO
	YES NO	YES NO	YES NO			YES NO	YES NO

Was this a typical day? Yes ___ No ___ Comment: _____

_____ Did he/she take any medications that he/she does not take regularly? No ___ Yes ___ Name: _____

Figure 2. Prompted voiding bladder diary.

lier article.[16] This report will focus on the effectiveness of the PV intervention in the cognitively impaired sample.

Subjects and Setting

Nurses from 2 large home health agencies in southwestern Pennsylvania identified patients in their caseloads with UI and referred those who were willing to be contacted by the study staff to the overall study. A research nurse called referred persons or their caregivers to explain the study in greater detail and to screen for initial eligibility. To be eligible at telephone screening, individuals had to meet the following criteria: (1) be 60 years or older, (2) meet Center for Medicare and Medicaid Services criteria for being homebound (ie, needing assistance and requiring considerable and taxing effort to leave home or having a condition that contraindicates leaving home and leaving home only for short periods and primarily for medical reasons), (3) understand and speak English, (4) report at least 2 incontinent episodes per week, and (5) report incontinence persisting for at least 3 months. In addition, cognitively impaired individuals had to have a full-time caregiver. Following telephone screening, individuals and their caregivers who were eligible and willing were scheduled for an in-home assessment. The in-home assessment was conducted by one of two study nurse practitioners (NPs) who collected data to identify persons who were inappropriate for the promoted voiding protocol. The NPs also identified potentially correctable problems that may have contributed to incontinence or affected its successful treatment and characterized subjects' medical, functional, and continence characteristics. Cognitively impaired subjects were excluded from the study if (1) they had a terminal illness; (2) they had a postvoid residual volume (PVR) greater than 100 mL; (3) their caregiver was unable or unwilling to provide toileting assistance, complete bladder diaries, or implement the PV protocol; or (4) fewer than an average of 2 incontinent episodes per week were documented in the baseline bladder diary. Potentially correctable problems that could have contributed to UI or affected response to the PV intervention (eg, prostate enlargement or nodule, hyperglycemia, urinary tract infection, and constipation) were evaluated and treated by either the study NPs (urinary tract infection and constipation) or the individual's primary care provider prior to randomization.

The study was approved by the University of Pittsburgh Institutional Review Board. Informed consent for subject participation in the study was obtained from each subject's family member or legal representative (in situations where the caregiver was not a family member). Each subject's caregiver was also asked to participate in the study by providing demographic information and completing caregiving questionnaires, including the Philadelphia Geriatric Center Caregiving Appraisal Scales. Caregivers' consent was also obtained from those who agreed to complete the demographic and caregiving questionnaires.

Instruments

The 2 study NPs collected a comprehensive continence and medical history from the subject and caregiver. The physical examination included an abdominal and neurologic examination, rectal examination, and, in women, a pelvic examination. Bladder ultrasound was used to assess PVR. Other laboratory evaluations included a urinalysis,

blood sugar, electrolytes, blood urea nitrogen, and creatinine. The Older Americans Research and Service (OARS) instrumental (IADL) and physical (PADL) activities of daily living scales were used to evaluate functional ability. The OARS scales measure the amount of assistance needed (ie, no help needed, some help required, or completely dependent) to perform a number of physical activities (eg, bathing, dressing, eating, grooming, getting in and out of bed, walking, and toileting) and instrumental activities (eg, using the telephone, going places, shopping, preparing meals, doing housework, taking medications, and handling money) of daily living. The subjects' caregivers answered the OARS questions in relation to the amount of assistance subjects required. The OARS IADL scale has test-retest reliability of 0.71.[17] The PADL scale had an inter-rater reliability of 0.87.[18] The 15-item Geriatric Depression Scale (GDS-15) was administered to evaluate depressive symptoms. The GDS-15 asks about the presence or absence of 15 symptoms over the preceding "few weeks." Scores range from 0 to 15, with scores between 0 and 4 considered normal, those between 5 and 9 suggesting mild depression symptoms, and scores of 10 or higher suggesting severe depression. The GDS has a reported Cronbach's α of .94, split-half reliability of 0.94, and test-retest reliability of 0.85.[19] Controversy exists about the reliability and validity of the GDS in persons with dementia, with some studies suggesting that it continues to be useful in this population and others finding that its utility is reduced. Current research suggests that the GDS is reliable and valid for persons with MMSE scores of 15 or higher.[20,21] Two tests, the MMSE and the Clock Drawing Test, were used to assess cognitive function. The MMSE has test-retest reliability coefficients of 0.84 to 0.90, sensitivities of 0.81 to 0.87, and specificities of 0.80 to 0.82 in diagnosing dementia.[22-25] Sunderland et al[26] reported highly significant inter-rater reliability for Clock Drawing Test scores in Alzheimer's patients, and Shulman and colleagues[27] reported that Clock Drawing scores were correlated significantly with MMSE scores. The Performance Based Toileting Assessment was administered to determine the amount of time in minutes that subjects required to traverse 15 ft and prepare to toilet. Burgio and colleagues reported inter-rater agreement rates of 100% within 3 seconds on the time required to walk 15 ft and 92.3% on the total time required to walk 15 ft, undress, and position to void in a sample of adult day care participants.[28]

Subjects' caregivers completed a 2-week bladder diary in which they documented subject- and caregiver-initiated toileting, voids in the toilet, and incontinent episodes (Figure 2). If the caregiver had difficulty completing the bladder diary, he or she was reinstructed and the diary was repeated. Caregivers were given up to 3 opportunities to provide adequate bladder diary data at baseline. If the third attempt was still inadequate, the subject was excluded from the study.

The Philadelphia Geriatric Center Caregiving Appraisal Scales were administered to participating caregivers to assess their perceived caregiving burden, caregiving satisfaction, caregiving impact, and caregiving mastery. The maximum scores on the subscales vary (25 for caregiver satisfaction, 30 for caregiving impact and mastery, and 55 for subjective caregiving burden). Higher scores on each of the subscales denote more favorable caregiving appraisal. Cronbach's α on the subscale vary from .67 (caregiving satisfaction) to .65 (subjective burden).[29]

Procedures

After baseline assessment, eligible subjects were randomly assigned to a control or treatment group with use of a computerized minimization algorithm. Prior to randomization, subjects were stratified according to 2 key characteristics previously shown to affect response to behavioral therapies, ability to toilet independently (independent versus dependent on the caregiver for physical assistance during toileting), and severity of UI (mild, <5 incontinent episodes/week; moderate, 5 to 10 incontinent episodes/week; and severe, >10 incontinent episodes/week). At the completion of the baseline assessment, the NP called the project office to get the subject's randomized group assignment based on the aforementioned characteristics.

The 2 NPs visited subjects assigned to the control group every 1 to 2 weeks for socialization (attention control). The control visits lasted approximately 35 minutes. Although subjects and their caregivers were aware that they were in a study examining the effectiveness of a voiding program for UI, there was no discussion of UI or its treatment with the caregiver or subject during the control visits. After 8 weeks of attention control, the caregiver repeated the 2-week bladder diary, and the subject crossed over to the PV treatment protocol.

Treatment consisted of 8 weekly sessions conducted in the subjects' homes by NPs skilled in the delivery of behavioral therapies for UI. The behavioral therapy consisted of PV. Caregivers were instructed to do the following:

1. Approach the subject every 2 hours during waking hours and ask if he or she was wet or dry.
2. Check the subject to see if his or her undergarment or pad was wet or dry.
3. Give the subject feedback on the correctness of his or her response and praise the subject if dry.
4. Ask the subject if he or she would like to use the toilet.
5. If the subject's response was yes, toilet him or her. If the response was no, the caregiver was

Prompted voiding combines regular caregiver delivered prompts to toilet with positive feedback for appropriate toileting.

The Philadelphia Geriatric Center Caregiving Appraisal Scales were administered to participating caregivers to assess their perceived caregiving burden, caregiving satisfaction, caregiving impact, and caregiving mastery.

instructed to encourage the subject to toilet, but not to force him or her to do so.
6. Provide toileting assistance as needed.
7. Provide positive feedback for appropriate toileting.

Initially, all subjects were prompted every 2 hours. If the subject self-initiated toileting, the prompting time was adjusted accordingly. The NP evaluated response to treatment during the weekly visits, and the prompted schedule was individualized based on the findings in the weekly bladder diaries. If the subject was dry on 80% of the 2-hour prompts, the interval was increased to every 3 hours. If the subject had a time of day (often in the morning) when he or she was consistently wet on the 2-hour interval, an extra prompt was added. No caregiver was asked to prompt a subject hourly throughout the day. No behavioral intervention was provided during the night.

In addition to the prompted voiding intervention, caregivers were encouraged to eliminate caffeine from the care recipient's diet. If the subject had enuresis, the caregiver was encouraged to limit fluids in the evening and to treat dependent edema by having the subject elevate his/her legs for several hours in the late afternoon or early evening.

Both NPs followed the prompted voiding protocol. However, behavioral therapies are, by their very nature, individualized to the needs of the patient. For this reason, it was not possible to totally standardize the information provided to subjects.

Caregivers kept bladder diaries throughout treatment phase in which they recorded subject-initiated toileting, caregiver prompts, subjects' responses to the prompts, and other incontinent episodes (Figure 1). The diary was kept for 12 to 16 hours per day (from the time the care recipient arose in the morning until he or she retired at night). The caregiver was also asked to record whether the subject's pad was wet or dry upon arising in the morning. During the weekly visits, the NP reviewed the diary with the caregiver, offered suggestions as indicated, and used the findings to adjust the prompting schedule.

At the end of the treatment, subjects were reassessed. This assessment included evaluation of cognitive function (MMSE and Clock Drawing Test), affective function (GDS), and toileting ability (Burgio Performance Based Toileting Assessment). Caregivers completed a 2-week posttreatment bladder diary. The caregiver was given a written summary of long-term treatment recommendations.

Data Analysis

SPSS for Windows, version 10.0 (SPSS, Inc, Chicago, Ill), was used for data analysis. Data were analyzed descriptively by using frequency counts and percentages and, where appropriate, means, medians, ranges, and standard deviations. The initial effectiveness of the prompted voiding was assessed by comparing continence for the 2 weeks following the last control or treatment visit to the 2-week baseline period. The percent reduction in the average daily frequency of incontinent episodes was calculated with use of the following formula:

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

Reduction in percent wet (the proportion of voids that were incontinent) was calculated as:

$$\text{reduction in \% wet} = \frac{\%\ \text{wet}_{\text{baseline}} - \%\ \text{wet}_{\text{post-treatment/control}}}{\%\ \text{wet}_{\text{baseline}}} \times 100$$

When the study was initiated, caregivers were asked to check the care recipient's pad for wetness every 2 hours. We found, however, that despite instructions to only check the pad for wetness, caregivers also toileted care recipients. Subsequently, we changed the instructions, asking caregivers to check care recipients according to their normal schedule and to document the findings in a baseline bladder diary. There was a significant difference in the number of pad checks done at baseline and posttreatment (mean = 2.94; $P < .001$), whereas there was no significant difference in the number of toilets (mean = 0.24; $P = .67$). Consequently, the proportion of incontinent voids rather than the proportion of wet pad checks was used to calculate the percent of the time subjects were wet. The change in self-initiated toileting was calculated by subtracting the number of self-initiated toilets per day at baseline from the number at the completion of treatment or control.

For subjects completing the treatment phase of the study, the number of incontinent episodes per day and percent wet at true baseline (baseline bladder diaries for subjects randomized to the treatment group and postcontrol diaries for those randomized to the control group) were compared with the 2-week period following completion of the treatment phase of the study.

Exploratory data analysis revealed that all of the outcome variables met the assumption of normality except percent reduction in daytime wet for all treated subjects. Examination of the data revealed one outlier who had a large increase in daytime percent wet. Sensitivity analyses were performed after excluding this subject. The measures of distribution (ie, skewness, kurtosis) improved. Subsequently, responsiveness to the intervention was analyzed with and without this subject's values.

Both parametric and nonparametric statistics were used to compare pretreatment and posttreatment/control continence levels. The Student *t* test

Table 1. Demographic and co-morbid characteristics of randomized subjects (n = 19)

Characteristic	Overall (n = 19)	Control (n = 10)	Treatment (n = 9)	Test statistic, *P* value, effect size
Age (y)				$t = -0.08$, $P = .94$
Mean (SD)	83.0 (5.7)	82.9 (5.7)	83.1 (6.0)	$d = 0.03$
Range	69.3-91.5	69.3-90.7	71.9-91.6	
Gender (n, %)				$\chi^2 = 0.02$, $P = 1.0$*
Female	13 (68)	7 (70)	6 (67)	$w = 0.04$
Male	6 (32)	3 (30)	3 (33)	
Race (n, %)				$\chi^2 = 0.28$, $P = 1.0$*
White	16 (84)	8 (80)	8 (89)	$w = 0.12$
Nonwhite	3 (16)	2 (20)	1 (11)	
Marital status (n, %)				$\chi^2 = 0.04$, $P = 1.0$*
Married	8 (42)	4 (40)	4 (44)	$w = 0.04$
Not married	11 (58)	6 (60)	5 (56)	
Education (y)				$t = -1.5$, $P = .16$
Mean (SD)	10.7 (3.5)	9.6 (3.2)	11.9 (3.6)	$d = 0.67$
Range	5-16	5-14	7-16	
No. of medical problems				$t = -0.57$, $P = .58$
Mean (SD)	9.4 (2.5)	9.1 (3.0)	9.8 (2.0)	$d = 0.26$
Range	5-14	5-14	6-13	
Heart failure (n, %)	6 (32)	4 (40)	2 (22)	$\chi^2 = 0.69$, $P = .63$*, $w = 0.19$
Diabetes (n, %)	5 (26)	3 (30)	2 (22)	$\chi^2 = 0.15$, $P = 1.0$*, $w = 0.09$
Stroke (n, %)	8 (42)	3 (30)	5 (56)	$\chi^2 = 1.9$, $P = .34$*, $w = 0.32$
Parkinson's disease (n, %)	1 (5)	1 (10)	0	$\chi^2 = 1.1$, $P = 1.0$*, $w = 0.24$
No. of medications				$t = .56$, $P = .58$, $d = 0.26$
Mean (SD)	5.5 (3.0)	5.9 (3.4)	5.1 (2.6)	
Range	2-12	2-12	3-11	
Diuretic (n, %)	9 (47)	5 (50)	4 (44)	$\chi^2 = 0.06$, $P = 1.0$*, $w = 0.06$

*Fisher's exact test.

and Mann-Whitney U test using exact methods for the calculation of *P* values were used to compare baseline characteristics of control and treatment subjects, as well as to compare pretreatment and posttreatment continence levels of treatment and control subjects. The one-sample *t* test was computed to determine whether all subjects completing the treatment protocol (those originally randomized to the treatment group, as well as control subjects who crossed over to the treatment protocol) had an improvement in their continence level relative to their true baseline. Cohen's *d* was used to summarize the size of the observed effects for continuous variables, whereas *w* was used for categorical variables. In the behavior sciences, Cohen's *d* values of 0.20, 0.50, and 0.80 indicate a small, medium, and large effect size, respectively, whereas *w* values of 0.10, 0.30, and 0.50 are viewed as representing small, medium, and large effect size, respectively.[30]

Data comparing control and treatment subjects were analyzed assuming both an "intention-to-treat" approach and, secondarily, for only those completing the protocol as intended. For the intention-to-treat approach, all subjects randomized to each group were included in the outcome analysis even if they did not complete the treatment or control phase. The "last observation carried forward" method was used to replace missing data. With this method, the last bladder diary the subject completed (including the baseline diary if this was the only diary completed) was used as his or her final outcome measure. The completed protocol model included only subjects who completed the treatment or control phase of the study as prescribed.

Caregiver adherence to the prompting schedule during treatment was examined by calculating the percentage of time that the subject either self-initiated toileting or was prompted to toilet by the caregiver within 30 minutes of the prescribed prompting interval. Subject cooperation with caregiver prompting was examined by calculating the average proportion of caregiver prompts that subjects (1) toileted and (2) voided.

RESULTS

Research Subjects

Seven hundred twenty-three persons or their caregivers were referred to the overall study (both the prompted voiding and biofeedback groups).

Table 2. Functional characteristics of sample

Characteristic	Overall	Control	Treatment	Test statistic, *P* value, effect size
Assistance needed during toileting (n = 19) n (%)	15 (79)	8 (80)	7 (78)	$\chi^2 = 0.01$, $P = 1.0$* $w = 0.03$
Time to toilet in seconds (n = 17)†		(n = 9)	(n = 8)	$t = 0.42$, $P = .68$, $d = 0.22$
Mean (SD)	53.5 (37.7)	57.2 (36.4)	49.3 (41.2)	
Range	2.0-132.0	22-132	2-130	
MMSE (n = 19)				$t = -0.40$, $P = .70$, $d = 0.19$
Mean (SD)	17.2 (5.4)	16.7 (6.4)	17.7 (4.2)	
Range	4-23	4-23	11-23	
Clock (n = 12)‡		(n = 8)	(n=4)	$t = -0.42$, $P = .69$, $d = 0.26$
Mean (SD)	5.2 (3.3)	4.9 (3.4)	5.8 (3.4)	
Range	1-10	1-10	1-9	
GDS (n = 17)‡		(n=9)	(n=8)	$t = -0.52$, $P = .61$, $d = 0.24$
Mean (SD)	4.1 (2.8)	3.8 (2.9)	4.5 (2.9)	
Range	0-10	0-9	1-10	
OARS Physical ADLS (n = 19)				$t = 0.33$, $P = .75$, $d = 0.16$
Mean (SD)	6.6 (3.0)	6.8 (3.5)	6.3 (2.6)	
Range	1-12	1-12	3-10	
OARS Instrumental ADLS (n = 11)‡		(n = 7)	(n = 4)	$t = -1.5$, $P = .18$, $d = 0.70$
Mean (SD)	1.5 (1.0)	1.3 (1.3)	2.0 (0)	
Range	0-3	0-3	2.0	

*Fisher's exact test.
†Missing on 2 subjects
‡Added after the study was initiated.

A caregiver satisfaction questionnaire was administered at the end of treatment to assess satisfaction with the intervention and outcome.

Three hundred forty-seven were excluded or declined to participate at initial telephone screening. Because this occurred prior to administration of the MMSE (administered during the first in-home assessment visit), cognitive status was unknown for most of these persons. The most common reason that persons were excluded at telephone screening was that they either denied being incontinent of urine or self-reported fewer than 2 incontinent episodes per week (n = 87). Three hundred fifty-one persons or caregivers were potentially eligible and interested in participating in the study at telephone screening and were scheduled for an in-home assessment.

At the time of the in-home assessment, 272 individuals (78% of the 351 persons completing the in-home assessment) were cognitively intact (MMSE 24 or higher). These persons were subsequently evaluated for the pelvic floor muscle exercise strata of the study. Seventy-nine (23%) of those assessed were cognitively impaired (MMSE <24) and were evaluated for possible inclusion in the prompted voiding group. Eight caregivers declined to participate, and 52 potential subjects were excluded. The reasons for exclusion were: absence of a full-time caregiver (n = 24), fewer than 2 incontinent episodes per week (n = 12), a terminal illness or development of a potentially life-threatening illness during assessment (n = 3), inability or unwillingness of the caregiver to complete the bladder diary (n = 4), death of the care recipient (n = 4), PVR >100 mL (n = 2), nursing home admission (n = 2), and uncontrolled hyperglycemia (n = 1).

Nineteen subjects met eligibility criteria and were randomly assigned to the treatment (n = 9) or control (n = 10) group. Table 1 summarizes the demographic characteristics of treatment and control subjects. Overall, subjects tended to be female (68%) and white (84%), with a mean age of 83 years. Levels of comorbidity were high (mean of 9.4 problems in addition to UI), and many subjects had illnesses that could have contributed to their UI or affected their response to treatment (eg, heart failure, diabetes, and stroke). There were no statistically significant differences in the demographic characteristics of control and treatment subjects.

Table 2 summarizes the functional characteristics of the sample. The mean MMSE score was 17.2 and the mean Clock Drawing score was 5.2, indicating moderate cognitive impairment. Subjects were

Table 3. Comparison of continence characteristics of treatment and control subjects

Continence characteristics	Control (n = 10)	Treatment (n = 9)	Test statistic, *P* value, effect size
Baseline daytime incontinent episodes/day			$t = -2.3$, $P = .04$, $d = 1.1$
Mean (SD)	3.1 (1.8)	1.7 (.80)	
Range	1.2-6.6	0.5-3.2	
Baseline all incontinent episodes/day			$t = -2.3$, $P = .04$, $d = 1.1$
Mean (SD)	3.9 (1.9)	2.4 (.82)	
Range	1.7-7.1	1.2 -4.2	
Baseline % wet daytime			$t = -2.8$, $P = .01$, $d = 1.3$
Mean (SD)	32.0 (11.7)	19.4 (7.3)	
Range	13.0-47.0	8.0-34.0	
Baseline % wet (day and night)			$t = -2.7$, $P = .02$, $d = 1.3$
Mean (SD)	36.9 (10.6)	25.4 (7.4)	
Range	16.7-54.4	15.9-39.7	
Baseline self-initiated toilets/day			$t = -0.64$, $P = .53$, $d = 0.31$
Mean (SD)	1.1 (1.0)	1.6 (1.8)	
Range	0-3.0	0-4.5	
Baseline voids/day			$t = 0.34$, $P = .74$, $d = 0.16$
Mean (SD)	6.6 (2.6)	7.0 (1.6)	
Range	3.3-10.5	4.3-9.4	

moderately impaired in their ability to perform physical activities of daily living (mean 6.6 out of a possible 12 points), while they were severely impaired in their ability to perform instrumental activities of daily living (mean 1.5 out of a possible 14 points). Most subjects needed assistance with physical activities (from 37% for eating to 95% for bathing). The only instrumental activity that any caregiver reported that the subject could do independently was use the telephone (n = 4, 21%). Most subjects needed mechanical or human assistance during toileting (n = 15, 79%). They required an average of 53.5 seconds to traverse 15 ft and prepare to toilet. There were no statistically significant differences in the functional characteristics of those randomly assigned to the treatment or control group.

Despite randomization, control subjects tended to have more severe incontinence at baseline than those in the treatment group (Table 3). They had significantly more daytime incontinent episodes ($P = .04$) and both daytime and nighttime incontinent episodes ($P = .04$) than subjects randomly assigned to the treatment group. In addition, a significantly greater proportion of their daytime ($P = .01$) and daytime and nighttime ($P = .02$) voids were incontinent (percent wet). There were no significant differences in the mean number of toiletings that control and treatment subjects self-initiated each day at baseline or in the average number of times they voided each day.

Sixteen caregivers consented to participate in the study, 8 from the treatment group and 8 from the control group. Eleven of the caregivers were women and 5 were men. Their average age was 65.2 years (SD = 12.0 years). Seven were spouses of the care recipient, 6 were daughters, and 3 were sons. All lived with the care recipient. Eleven (73%) reported providing care for 10 or more hours per day. They had been caring for this person for an average of 4.6 years (SD = 3.7 years, range = 1 to 15 years). Seven of the caregivers (44%) rated their physical health as excellent or good, whereas 9 (56%) rated their health as fair or poor. Nine (56%) rated their emotional health as excellent or good, and 7 (44%) believed that their emotional health was only fair or poor. Caregivers were asked how much strain they experienced in relation to a number of dimensions of their care recipients' incontinence or the care they provided in relation to it. About half of the caregivers indicated that they experienced some or a great deal of strain in relation to (1) the care recipient leaking urine on his or her clothing (50%), (2) odor from the incontinence (56%), (3) changing wet bed linen (44%), (4) changing the care recipient's pad or clothing (50%), (4) toileting the care recipient (53%) and (5) the cost of briefs/pads (53%). Scores on the Caregiving Appraisal Scales revealed that, on average, the caregivers believed that caring for the subjects (1) quite frequently had a negative impact on their lives (mean score per item = 2.3 out of 5), (2) was sometimes a burden (mean = 3.3), (3) sometimes experienced a sense of satisfaction (mean = 3.2) and (4) sometimes felt a sense of caregiving mastery (mean = 3.3). When the characteristics and responses of the caregivers of treatment and control subjects were compared, caregivers of control subjects had been providing care for a significantly

Although the sample in this study was small, clinically significant reductions in urinary incontinence were achieved for many of the participants despite high levels of co-morbidity and functional impairment.

longer period (mean of 6.5 years, SD = 4.1) than caregivers of treatment subjects (mean = 2.6 years, SD = 1.7, P = .03, d = 1.3). There were no other statistically significant differences between the 2 groups, although the effect sizes were moderate for Impact (d = 0.62), Caregiving Satisfaction (d = .65), and Caregiving Mastery (d = .61) scales of the Caregiving Appraisal questionnaire.

Outcome by Random Assignment

Six of the nine subjects randomly assigned to the treatment group completed this phase of the study, and all 10 of those randomly assigned to the control group completed the control phase. Three of the 9 subjects randomly assigned to the treatment group dropped out or were excluded during the treatment phase (death of the subject, n = 2; deterioration in caregiver health, n = 1). There were no significant differences in the characteristics of subjects who dropped out and those who remained in the study.

Table 4 compares the reduction in incontinent episodes, percent wet, and changes in self-initiated toileting for the control and treatment subjects. When data were analyzed using an intention-to-treat approach, treatment subjects had a mean 50% decrease in daytime incontinent episodes compared with a mean 37% decrease for control subjects (P = .24). Daytime percent wet decreased an average of 43%, while it decreased a mean 35% among control subjects (P = .33). When using the per-protocol approach, treatment subjects had a mean 60% decrease in daytime incontinent episodes compared with a mean 37% for control subjects (P = .12, d = 0.64). Treatment subjects had a 55% decrease in all incontinent episodes (day and night) compared with a 27% reduction among control subjects (P = .04, d = 0.97). Thus, the only hypothesis that was supported was that subjects randomly assigned to the treatment groups would have a greater reduction in both daytime and nighttime incontinent episodes than those randomly assigned to the control group. The effect size for daytime incontinent episodes was, however, moderate, suggesting that had the sample been larger, the difference may have been statistically significant. Five treatment subjects had a 50% or greater reduction in daytime incontinent episodes. Two subjects (33%) were completely dry during the day at the end of treatment; one continued to have occasional episodes of enuresis, while the other was dry both day and night. There was no statistically significant difference in the change in self-initiated toileting for treatment and control subjects.

Outcome for All Subjects Completing Treatment

At the completion of the control phase of the study, subjects randomly assigned to the control group crossed over to the treatment protocol. To control for the changes in UI that occurred during the control phase of the study, their postcontrol bladder diary was used as the baseline diary (true baseline) in evaluating treatment efficacy. When data were combined for all subjects completing treatment (n = 15), the mean number of daytime incontinent episodes decreased from 2.2 per day (SD = 1.4) at true baseline (baseline for those assigned to the treatment protocol and postcontrol for those assigned to the control group) to 1.8 (SD = 1.6) posttreatment (22% reduction, t = 1.8, P =.04, d = 0.47). Response to the intervention was variable. Ten subjects (67%) improved (2% to 100% decrease in daytime incontinent episodes), whereas 5 (33%) had an increase in daytime incontinent episodes during treatment (18% to 48% increase). Although the sample was too small to determine the characteristics of subjects who did not respond to the intervention, three of those who had an increase in their incontinence during treatment had a deterioration in their health status, and for one, caregiver adherence to the prescribed prompting schedule was only 72%. The total number of incontinent episodes per day decreased from a mean of 2.8 (SD = 1.5) to 2.4 (SD = 1.7) following treatment (19% reduction, t = 1.7, P =.06, d = 0.44). There was no significant change in the percent wet during the day (8%, P = .34) or during the day and night (7%, P = .33). Although not statistically significant, the number of self-initiated toilets increased from an average of 2.0 (SD = 2.3) at true baseline to 3.3 (SD = 3.4) posttreatment (t = 1.12, P = .26, d = 0.32).

One subject experienced a marked deterioration in health and functional ability during the treatment phase of the study and was not toileting at all by the end of treatment. This subject experienced a 187% increase in daytime percent wet compared with postcontrol and a 145% increase in both day and night percent wet. When this subject was excluded from the data analysis, the remaining subjects completing treatment experienced a 21% decrease in daytime percent wet (t = 1.8, P = .05, d = 0.48), and a 17% decrease in day and night percent wet (t = 1.6, P = .07, d = 0.42). Daytime incontinent episodes decreased a mean of 0.47 episodes per day (25% reduction, t = 2.1, P = .03, d = 0.55), while there was a mean decrease of 0.55 in total incontinent episodes (day and night) per day (21% reduction, t = 1.9, P = .04, d = 0.51).

Adherence to the Prompted Voiding Intervention

Bladder diary data were used to assess caregiver adherence to the prescribed prompting protocol at each treatment visit. Caregivers were adherent to the prescribed interval on average 89% of the time (SD = 10.4, range = 71% to 100%). Subject cooperation with caregiver prompting was assessed by ex-

Positive caregiver response to the intervention further supports its potential benefit in community-based clinical practice.

Table 4. Changes in continence characteristics postcontrol/treatment

Characteristics	Control (n = 10)	Treatment*	Test statistic, *P* value, effect size
Intention-to-treat approach			
Percent decrease in daytime incontinent episodes per day posttreatment/control			*t* = 0.74, *P* = .24 (one tail), *d* = 0.34
Mean (SD)	37.3 (34.3)	50.1 (41.3)	Exact *P* value = .27
Range	–32.0-94.0	–4.0-100.0	
Percent reduction in all incontinent episodes/day			*t* = 1.3, *P* = .10 (one tail), *d* = 0.61
Mean (SD)	27.2 (26.1)	47.0 (39.2)	Exact *P* value = .19
Range	–32.0-58.0	–3.0-100.0	
Reduction in daytime % wet			*t* = 0.46, *P* =.33 (one tail), *d* = 0.21
Mean (SD)	34.6 (33.5)	43.1 (46.6)	Exact *P* value = .35
Range	–.15-92.0	–30.0-100	
Reduction in day and night % wet			*t* = 1.1, *P* = .15 (one tail), *d* = 0.53
Mean (SD)	23.0 (22.7)	40.6 (44.3)	Exact *P* value = .20
Range	–15.0-53.0	–26.0-100	
Change in self-initiated toilets/day	n = 9	n = 9	*t* = .65, *P* = .53 (two tail), *d* = 0.33
Mean (SD)	1.9 (2.1)	3.1 (4.8)	Exact *P* value = .50
Range	–1.8-5.8	–2.1-12.6	
Per Protocol			
Percent decrease in daytime incontinent episodes per day posttreatment/control			*t* = 1.2, *P* = .12 (one tail), *d* = 0.64
Mean (SD)	37.3 (34.3)	59.8 (36.9)	Exact *P* value = .10
Range	–.32-94.0	2.0-100.0	
Percent reduction in all incontinent episodes/day			*t* = 1.9, *P* = .04 (one tail), *d* = 0.97
Mean (SD)	27.2 (26.1)	55.2 (33.5)	Exact *P* value = .07
Range	–32.0-58.0	4.0-100.0	
Reduction in daytime % wet			*t* = 0.77, *P* = .23 (one tail), *d* = 0.40
Mean (SD)	34.6 (33.5)	50.2 (48.2)	Exact *P* value = .24
Range	–15.0-92.0	–30.0-100.0	
Reduction in day and night % wet			*t* = 1.4, *P* = .10 (one tail), *d* = 0.72
Mean (SD)	23.3 (22.7)	45.3 (43.3)	Exact *P* value = .12
Range	–15.0-53.0	26.0-100.0	
Change in self-initiated toilets/day	n = 9	n = 6	*t* = .54, *P* = .60 (two tail), *d* = 0.29
Mean (SD)	1.9 (2.1)	2.7 (3.6)	Exact *P* value = .80
Range	–1.8-5.8	–2.1-7.4	

*Intention-to-treat treatment group, n = 9; per protocol treatment group, n = 6.

amining the proportion of prompts that subjects (1) went to the toilet and (2) voided as measured by caregiver documentation in the bladder diary. Subjects responded to caregiver prompts by toileting an average of 76% of the time (SD = 34%, range = 8% to 100%) and by voiding 71% of the time (SD = 31.6, range = 6% to 100%).

Caregiver Satisfaction With the Prompted Voiding Intervention

A caregiver satisfaction questionnaire was administered at the end of treatment to assess satisfaction with the intervention and outcome. Fifteen caregivers (100% of those whose care recipient completed the treatment protocol) completed the

questionnaire. Most caregivers (n = 12, 80%) believed that the persons they were caring for had fewer incontinent episodes than they had prior to treatment, whereas 9 (60%) believed that the incontinent episodes subjects had were smaller. However, only 2 (13%) believed that the care recipient was able to wear less protection. Overall, 12 of the caregivers (80%) believed that their care recipient was better, 2 (13%) thought that they were about the same, and one believed that his/her care recipient was worse than prior to treatment. Caregivers were asked if the intervention had increased their work. Seven (47%) reported that it decreased their work, 3 (20%) reported that their workload had not changed, and 5 (33%) reported that their caregiving workload had increased. As part of this survey, caregivers were asked which aspects of the study were difficult for them. Five (33%) identified keeping the diaries as difficult, whereas only 2 (13%) identified prompting their care recipient as difficult. Overall, 14 (93%) were somewhat or completely satisfied with their care recipient's progress, and all of the caregivers reported that they were comfortable enough with the prompted voiding protocol to continue it indefinitely.

DISCUSSION

In interpreting and generalizing the results of this study, several limitations need to be kept in mind. The small sample size limits generalizability even to similar populations of patients receiving home care services for subacute medical problems. When the study was designed, it was anticipated that prompted voiding subjects would only comprise a small proportion of the total sample. The sample size for the original study was not designed to provide a sufficient sample to detect clinically significant differences in treatment effectiveness for this group. The examination of the effectiveness of the prompted voiding protocol was viewed as more exploratory. Given the requirement for a full-time caregiver who was willing and able to toilet the subject, the duration of the study (average = 15 months) and the requirement that the caregiver complete a daily bladder diary during treatment, as well as the frailty of the potential subjects, we anticipated that both refusal and ineligibility rates would be high. Because cognitive status was not known for most individuals at telephone screening, it is not possible to know how many of those who were excluded or declined to participate were potential candidates for the prompted voiding protocol. Only 24% of the cognitively impaired persons completing the in-home assessment were eligible and willing to participate. In addition, there was a 21% attrition rate (n = 3 subjects, 2 because of death) among subjects entering the study protocol, and all of these individuals were in the treatment group. With only 9 and 10 subjects per group, we had adequate power (.80) to detect only very large differences (d = 1.14) between treatment and control groups at a significance level of .05 (one tailed). When using an intention-to-treat approach to the analysis, effect sizes in this study ranged from 0.21 to 0.61. To have sufficient power (0.80) to detect effects in this range at a significance level of .05, we would have needed anywhere from 34 subjects per group (for an effect size of 0.61) to 281 subject per group (for an effect size of 0.21).

Levels of comorbidity were high and functional impairments were common in this sample. Subjects had an average of 9.4 medical problems in addition to their UI, and many had comorbidities associated with an increased risk for UI (eg, heart failure, diabetes, and/or stroke). Almost half (47%) were taking a diuretic. Most (79%) needed assistance during toileting, and it took subjects an average of 53.5 seconds to traverse 15 ft and prepare to toilet in contrast to an average of 6.0 seconds for nonhomebound persons without impaired mobility.[31]

Despite randomization, subjects in the control group were significantly more incontinent at baseline than were those randomly assigned to the treatment group. Caregivers of control subjects reported that they had been caring for their care recipients for a significantly longer time (mean = 6.5 years) than caregivers of treatment subjects (mean = 2.6 years). Although there were no significant differences in the 2 groups on the demographic and functional measures we collected, it is possible that control subjects were more impaired at baseline than treatment subjects and that this contributed to their being more incontinent than those in the treatment group. However, the measures used to assess UI severity (decrease in percentage of voids that were incontinent and percent decrease in incontinent episodes) take into account the subjects' baseline level of incontinence, so differences observed at baseline should have had no impact on the findings.

Subjects randomly assigned to the treatment group who completed the protocol had a mean 60% reduction in daytime incontinent episodes and a 50% reduction in daytime percent wet compared with a 37% and 35% reduction, respectively, among those randomized to the control group. The percent reduction in wet episodes for treated subjects in this study was comparable to reductions reported among nursing home residents treated with a 1-hour prompted voiding intervention in 2 studies by Schnelle and colleagues[8,9] (50% and 41%, respectively). In the current study, however, control subjects had a much greater reduction in percent wet (35%) compared with the 2% increase and 3% reduction, respectively, reported in the 2 studies of nursing home residents by Schnelle et al. Hu et al[10] reported that nursing home residents treated with a 1-hour prompted voiding protocol

KEY POINTS

- Clinically significant reductions in incontinence may be achievable for many homebound older adults with cognitive impairment.
- Caregivers of homebound, cognitively impaired elders generally respond positively to prompted voiding as a method for managing incontinence and exhibit good adherence to treatment recommendations.
- The intervention can be readily adapted to clinical practice.

reduced their wet episodes by 26% compared with a 0.97% reduction among control subjects. Subjects in this study who were randomized to and completed treatment had an average 60% reduction in incontinent episodes, whereas control subjects had a mean reduction of 37%. In the studies conducted in nursing homes, control subjects' incontinence was essentially unchanged. In contrast, UI improved during the control phase of this study. Unlike other studies, however, study NPs on this project visited control subjects and their caregivers every 2 weeks to provide socialization. Although neither UI nor its treatment were discussed during these visits, it is possible that other health-related information shared during these visits or the experience of keeping a bladder diary at baseline and postcontrol had a positive impact on caregivers' incontinence management and thus decreased subjects' incontinence.

Subjects in this study who were randomized to and completed treatment had a similar change in mean daytime percent wet (50%) to that reported by previous studies examining the effectiveness of a 1- or 2-hour prompted voiding protocol using a one-group pretest-posttest design. These studies reported that nursing home residents had a 12% to 47% reduction in mean percent wet.[11-14]

Among all subjects completing treatment in this study, there was a 22% reduction in daytime incontinent episodes and 19% decrease in both day and night UI. There was essentially no change in percent wet during the day (8% reduction) or day and night (7% reduction). There was, however, one outlier whose health and functional ability deteriorated during treatment to the point that he was unable to toilet by the end of treatment. He experienced a 187% increase in daytime percent wet and 145% increase in both day and night percent wet. When he was excluded from the data set, the remaining subjects completing treatment experienced a 21% decrease in daytime percent wet and a 25% reduction in daytime UI episodes. The fact that control subjects and their caregivers had 8 weeks of interactions with the NPs prior to starting treatment could have contributed to the diminished treatment efficacy observed when the data from both groups were combined after control subjects crossed over to the treatment protocol. Control subjects experienced a mean 37% reduction in daytime incontinence during the control phase of the study, but 5 of the 9 who crossed over to treatment did not experience a further reduction when they completed the treatment. Although the sample was too small to examine characteristics that predicted response to the prompted voiding intervention, 3 of the 5 nonresponders had a deterioration in their health status during treatment, and caregiver adherence to the prompted recommendations was only 72% for the fourth subject.

Caregivers were generally satisfied with the prompted voiding intervention. Most (80%) felt that their care recipient's UI had improved. However, the majority did not indicate that this improvement had resulted in the use of fewer protective garments. This finding is consistent with the finding that although most care recipients had a decrease in UI, only 2 were totally dry at the end of the intervention. Caregiver adherence to the prompting prescription was generally good (mean = 89%). Care recipient's cooperation with caregiver prompting was more variable. They toileted in response to an average of 76% of the caregiver prompts and voided 71% of the times they were prompted. Most caregivers did not believe that the intervention had increased their workload and were satisfied with their care recipient's progress. One of the aspects of participation that we thought might be a burden for caregivers was completing bladder diaries. Four subjects were ineligible to participate in the study because their caregiver was unable or unwilling to complete the diary. None of these caregivers had sensory deficits or difficulty writing that would have interfered with completing the diary. It is not known whether the inadequate diaries reflected inability or unwillingness to provide the requested information. Of the caregivers who completed the study, 33% (n = 5) identified keeping the diaries as a difficult task. Despite the difficulties associated with their use, bladder diaries are not only commonly used to evaluate treatment efficacy for incontinence, but they also provide useful feedback to both the nurse and caregiver. This feedback can allow the nurse to adjust the treatment protocol to maximize potential effectiveness and may improve caregiver adherence to treatment recommendations.

Although the differences in UI observed in treatment and control subjects were not significant, some of the effect sizes in this small exploratory study were moderate. In addition, a number of subjects responded very well to the prompted voiding intervention. In contrast to the experience often reported in nursing home studies, caregiver adherence to the intervention was generally good. The effectiveness of this intervention should be explored in a larger study to provide adequate power and to identify characteristics of individuals most likely to benefit from the intervention. The major barrier to doing this study was recruiting an adequate sample of cognitively impaired persons with caregivers who were willing and able to participate in the study. We recruited almost all of our subjects through home health care agencies. Consequently, in addition to their cognitive impairment, subjects had high levels of medical comorbidity. The combination of significant medical and cognitive problems may have increased caregiver stress and decreased the likelihood that caregivers were willing and able to participate in the research study. Future studies should expand their recruitment strategies to include community-dwelling, cognitively impaired persons who are not receiving home health care services.

CONCLUSIONS

Although the sample in this study was small, clinically significant reductions in urinary incontinence were achieved for many of the participants despite high levels of co-morbidity and functional impairment. Positive caregiver response to the intervention further supports its potential benefit in community-based clinical practice. The intervention can be readily incorporated into clinical practice and provided by home health agencies. Future studies should examine the impact of this intervention in a large sample, which would also permit the identification of the persons most likely to benefit from this behavior intervention.

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