

Physical therapy for urinary incontinence in postmenopausal women with osteoporosis or low bone density: a randomized controlled trial

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Abstract

Objective: To assess the effectiveness of 12 weekly physical therapy sessions for urinary incontinence (UI) compared with a control intervention, for reducing the number of UI episodes measured with the 7-day bladder diary, at 3 months and 1 year postrandomization.

Methods: A single parallel-group randomized controlled trial was conducted at one outpatient public health center, in postmenopausal women aged 55 years and over with osteoporosis or low bone density and UI. Women were randomized to physical therapy (PT) for UI or osteoporosis education. The primary outcome measure was number of leakage episodes on the 7-day bladder diary, assessed at baseline, after treatment and at 1 year. The secondary outcome measures included the pad test and disease-specific quality of life and self-efficacy questionnaires assessed at the same timepoints.

Results: Forty-eight women participated (24 per group). Two participants dropped out of each group and one participant was deceased before 3-month follow-up. Intention-to-treat analysis was undertaken. At 3 months and 1 year, there was a statistically significant difference in the number of leakage episodes on the 7-day bladder diary (3 mo: $P = 0.04$; 1 y: $P = 0.01$) in favor of the PT group. The effect size was 0.34 at 1 year. There were no harms reported.

Conclusions: After a 12-week course of PT once per week for UI, PT group participants had a 75% reduction in weekly median number of leakage episodes, whereas the control group's condition had no improvement. At 1 year, the PT group participants maintained this improvement, whereas the control group's incontinence worsened.

Urinary incontinence (UI), defined by the International Continence Society as any involuntary leakage, engenders significant medical and social problems for all age groups,¹ but its impact is most detrimental to older women. Not only is it a top health priority for this demographic of the population,² it is also related to reduced physical activity, increased risk of falls, and is the second leading cause of admissions to long-term care.³ Although not an intrinsic outcome of ageing, prevalence and severity increase with age.^{4,5} Reported prevalence for weekly UI in older women ranges from 21% to 28%,⁶⁻¹⁰ and is even higher in women with osteoporosis.⁸

A recent study of women attending an osteoporosis clinic over a 1-year period found that almost 40% of all women (163/412) reported urinary leakages one or more times per week, and a high prevalence of UI was accompanied by urgency.⁸ These findings were echoed by another study that also found an association between self-reported osteoporosis and disposable pad use (odds ratio [OR] 2.01).¹¹

Physical activity is a crucial component of osteoporosis treatments. It is not only important to preserve bone mass (grade B recommendation),^{12,13} it also reduces falls in adult women (grade A recommendation).^{14,15} Furthermore, UI accompanied with urgency is an independent risk factor for falls and low-trauma fractures in older women.¹⁶ Therefore, physical activity should be prescribed for all women with low bone density or osteoporosis. The co-occurring presence of UI, which can significantly limit a woman's ability to be physically active, makes prescription of physical activity more difficult.¹⁷ Therefore, UI needs to be addressed in this subpopulation.

The mechanism by which UI prevalence is increased in women with osteoporosis is not well understood. One of the main hypotheses for this increased prevalence, however, is the possible sustained increase in intra-abdominal pressure due to changes in spinal curvature and/or spinal compression fracture in this subpopulation, pushing down on the pelvic floor muscle and eventually weakening it. In a cohort study on continent women, Sapsford et al¹⁸ showed a significant reduction in pelvic floor muscle training electromyographic activity in the slump-sitting position compared with the tall-sitting position. Therefore, spine position could influence the pelvic floor muscle function and render the rehabilitation more difficult.

Previous studies investigating physical therapy and pelvic floor muscle-training (PFMT) in older women reported favorable results in reducing the severity of UI and changes in muscle morphology.¹⁹⁻²¹ However, no previous study has investigated whether a specific physical therapy treatment protocol, including PFMT, is effective in older women with osteoporosis and UI.

Knowing whether physical therapy is effective in curing or reducing the severity of UI in this population is important if physicians and other healthcare professionals are to provide evidence-based treatment options to women with osteoporosis and UI, as well as reducing the burden of this condition and preventing risk of falls.

For these reasons, a randomized controlled trial (RCT) was undertaken to assess the effectiveness of a proven 12-session, 3-month physical therapy UI intervention on this

population: postmenopausal women, aged 55 years and older, with osteoporosis or low bone density, and stress, urge, or mixed UI. We hypothesized that the physical therapy group would have a statistically significant reduction in the number of leakage episodes as measured using the 7-day bladder diary, our primary outcome measure, as compared with a control group receiving only osteoporosis education. The number of leakage episodes (7-d diary) is considered one of the most reliable measures of success for incontinence treatment and has been widely used in this type of research.^{21,22} Participants were also followed up at 1-year postrandomization.

METHODS

Participants

Community-dwelling postmenopausal women with osteoporosis or low bone density and UI were recruited from an osteoporosis clinic or the waitlist of a continence clinic at a public women's health center providing outpatient care. A brief, standardized screening questionnaire was completed by all women attending the clinic. Postmenopausal women with osteoporosis or low bone density, who also reported symptoms of UI, were invited to be screened in greater detail by the research assistant using a standardized protocol, to determine their eligibility for the study.

Inclusion and exclusion criteria

To participate, women were required to be postmenopausal with osteoporosis or low bone density, defined by a T score of -2.0 or lower for the lumbar spine or hip, or a history of a nontraumatic hip, vertebral, wrist, or rib fracture; 55 years and over; have symptoms of stress, urge, or mixed UI for at least the past 3 months and at least two UI episodes in 3 days (self-reported); able to communicate in English (both written and verbal); and willing to give written consent to participate. T-score reflects the number of standard deviations (SDs) above or below the mean bone mineral density for young normal adults; low bone density is associated with a score between -1.0 and -2.5, and osteoporosis with a score of -2.5 or lower²³).

The determination of UI type was based on answers to two standardized questions: Do you ever leak when you sneeze, cough, laugh, lift, bend forward, stand up from a sitting or lying position, walk, or run quickly? When you have a strong urge to go to the toilet, do you ever leak any urine before you can get to the toilet, for example, when you arrive home, or when you get up in the morning, or during the night? To be eligible for further screening, women had to answer yes to at least one or both questions.

Exclusion criteria included previous treatments or workshops on incontinence in the past 5 years; previous UI surgeries (except for those who had had anti-incontinence surgery at least 20 y previously); fecal incontinence; continuous urine leakage; a current urinary tract infection;

perineal pain or genital prolapse likely to interfere with the PFM assessment and treatment; previous pelvic irradiation; hormone therapy, use of vaginal estrogen, or an unstable hormone dose within the previous 6 months²⁴; use of concomitant treatments for UI during the trial period; severe mobility impairments requiring the use of mobility aids (that would make going to the toilet difficult); use of high-dose diuretics or medications to improve bladder control; history of radiation for pelvic organ cancers; score of less than 24 on the Mini Mental State Exam (MMSE)²⁵; any other medical problem likely to interfere with treatment and evaluation (serious cardiovascular disease, ongoing cancer treatments, neurological conditions, psychiatric conditions); and individuals performing a Valsalva manoeuvre in lieu of PFM contraction.

Design

A single, parallel-group, RCT was conducted at the BC Women's Health Center in Vancouver, Canada, between September 2006 and April 2011. Computer-generated random-block assignment was used to randomly allocate participants to the experimental (physical therapy) or control (osteoporosis education and follow-up) groups. Allocation concealment was assured through the use of opaque, sequentially numbered, sealed envelopes. The research assistant revealed group assignments to the participants after completing their baseline measurement session. Each participant was assigned a number code corresponding to their group assignment, as per the computer-generated randomization. Physical therapists and participants allocated to the physical therapy group were aware of their allocated arm. Outcome assessors, data analysts, and the data collection and analysis team were blinded to group allocations. Participants were asked not to mention their group assignment to the evaluators.

On the basis of the expected mean frequency of UI episodes in the two groups (6.19 episodes per week [mean] in control and 3.3 episodes per week [mean] in treated group) reported in a previous PFMT versus control RCT in aging women by Burns et al,²⁶ and 25% attrition, a sample size of 48 participants was required to achieve 80% power to detect a difference between the two groups.

All participants were sent a bladder diary to be completed for 7 consecutive days before each assessment session (pre, post, and 1 y). The bladder diary (frequency and volume chart) is a recommended method for assessing urinary symptoms²⁷ and a reliable method for determining the frequency of incontinent episodes.²² A bladder diary was collected from each participant at the start of each of the three assessment sessions.

Additionally, two preweighed absorbent perineal pads (24-h pad test²⁸) with instructions were sent before and collected at each assessment session. The pad test, a reliable measure of urine loss in 24 hours,²⁷ is recommended by the International Continence Society.²⁹ "Mild" incontinence is 1.3 to 20 g, "moderate" is 21 to 74 g, and "severe" incontinence is 75 g or more.²⁸ A research assistant contacted participants more than 7 days before each assessment to remind them of the bladder diary and 24-hour pad test, and to answer any related questions.

Baseline measurement

The baseline assessment (duration 1.5-h) included collecting the 7-day bladder diary,^{21,22} the 24-hour pad test,^{27,29} and the following three questionnaires: the Urogenital Distress Inventory (UDI), the Incontinence Impact Questionnaire (IIQ), and the Geriatric Self-Perceived Efficacy questionnaire. The UDI documents the symptoms and the degree to which UI-associated symptoms are troubling (bothersome, hence distressing), with a total score ranging from 0 to 300. Higher scores indicate more symptom bother.³⁰ The IIQ evaluates the quality-of-life impact of UI around the themes of physical activity, travel, social relationships, and emotional health using a score ranging from 0 to 400. A high score indicates greater quality-of-life impact of UI.³¹ The Geriatric Self-perceived Efficacy questionnaire assesses self-efficacy to prevent unwanted urine loss, with higher scores indicating higher self-efficacy.³² Vaginal palpation and observations during contractions were used by the assessing physical therapist to determine each woman's ability to perform a PFM contraction.³³ All participants were instructed to record their home PFMT and/or other exercises (control group) in a diary provided by the research assistant.

Intervention

Physical therapy (experimental) group

Subsequent to the baseline measurement, the physical therapy group received 12 individual sessions (first session was 60 min, subsequent sessions 30 min) of physical therapy for UI over 12 weeks (once per week) at the health center from a trained physical therapist. The sessions included evaluation by manual digital palpation using the PERFECT Scheme ³⁴ (session 1 only); education on the causes of incontinence, conservative treatment, management of constipation, and urge control techniques; PFM retraining using electromyography (EMG) biofeedback; motor control exercises; functional PFM exercises; bladder habit retraining; dietary recommendations/changes (as needed); and audio tapes for home use. This is the standard physical therapy care for women in the continence clinic at the participating center. Intervention protocol details and progression are described in Table 1.

TABLE 1	Physical therapy	group	protocol
Week 1 (60 min)	Week 2 (30 min)	Week 3 (30 min)	
Education	PFMT diary checked	PFMT and TA exercise diary checked	
Determination of problem and treatment plan	Previous week problems/concerns were discussed	Incontinence episodes: frequency, reviewed and advised	
Review bladder diary	Incontinence episodes, and frequency was discussed and advice given	Continued education	
Anatomy of pelvic floor muscles	Education, including urge suppression techniques was continued. Bladder retraining initiated as required	Reassessed pelvic floor muscles digitally in lying and standing and transversus abdominis exs	
Pathophysiology of urinary incontinence	Constipation prevention (increased fiber and fluid intake) and evacuation techniques taught	Assessed using EMG biofeedback in crook lying if participant able to tolerate sensor. EMG used as teaching tool	
Risk factors for incontinence	Assessment of pelvic floor muscles and progression as appropriate	Progressed pelvic floor exercises as appropriate and included some PFM exercises in standing if able	
Education regarding bladder irritants	Ensured they were doing the knack		
Digital assessment of pelvic floor muscles	Assessed transversus abdominis muscle and daily home exercises given. These were recorded on exercise diary as well		
PFM exs taught including fast MVC and slow MVC for endurance			
Printed education handouts for home use			
Functional integration of PFM "The Knack" was taught			
Continence Clinic exercise CD given for home use			
Recording in PFMT diary demonstrated			
Wk 4 (30 min)	Wk 5 (30 min)	Wk 6 to 12 (30 min)	
Reviewed exercise diary and encouraged adherence	Reviewed exercise diary and encouraged adherence	The protocol remained the same for these weeks and pelvic floor exercises continued to be progressed.	
Asked re. incontinence episodes and reviewed how to manage /prevent these	Asked re. incontinence episodes as before	Crowns may be introduced (Pelvic floor muscles contracted 100% (MVC), dropped to 50% to 70%, up to 100%, and repeated these as much as women able to do without loss of coordination.	
Manually reassessed PFM and TA and progress PFMT to standing	Reassess using EMG biofeedback	Steps also done at this stage depending on assessment.	
Reviewed urge suppression techniques and the knack	Continued training using EMG	Exercises were done with increasing difficulty, for example, when walking, lunging, squatting.	
Reviewed use of bladder irritants and encouraged decreasing these	Progressed exercises if appropriate	Aim was to do 10,10-s MVC holds and 30 fast contractions in any position.	
Reviewed frequency of constipation and management strategies	Reviewed integration of the knack into daily activities		
	Reviewed use of urge suppression techniques		

CD, compact disc; EMG, electromyography; MVC, maximal voluntary contractions; PFM, pelvic floor muscles; PFMT, pelvic floor muscle-training; TA, transversus abdominis.

Osteoporosis education (control) group

Subsequent to the baseline assessment, identical to that of the experimental group, control group participants received a group osteoporosis education session (3 h), including information on physical activity, diet, and medications used in the prevention and management of osteoporosis. The group education session was taught by a physical therapist, dietician, and a nurse clinician working in the osteoporosis clinic of the health center. If participants could not attend the group session due to scheduling conflicts, they were then given 1:1 phone or inperson sessions, covering the same material and their specific bone-health questions, with the osteoporosis program's physical therapist and/or dietician. All participants in the control group received an additional follow-up phone call to discuss the education session and other questions related to osteoporosis and bone health. One-on-one sessions with the dietician and physical therapist lasted 60 minutes, and follow-up phone calls ranged between 10 and 30 minutes. As a part of the follow-up activities, the control group participants spent 2 to 4 hours with a healthcare professional outside of the assessment sessions.

Assessment after treatment

Follow-up assessments were conducted 13 weeks after the baseline assessment (ie, the week after the final physical therapy session) and at 1 year. All tests were readministered at each assessment.

Participants were either reimbursed for public transit costs or given free parking at the health center for the days they attended the assessment, evaluation, or treatment sessions.

Data analysis

Intention-to-treat analysis was conducted; the value at last observation was carried forward. The Mann-Whitney U test was used to compare the baseline number of leakage episodes, pad test values, age, parity, body mass index (BMI), smoking history, incontinence type (stress, urge, or mixed), and UDI and IIQ data between the two groups. Baseline, 3-month, and 1-year data for the two groups were analyzed with the Mann-Whitney U test, using SPSS statistical software (v.18.0). The level of significance was set at P less than 0.05 a priori. The effect size was calculated ($r = z/\text{square root of } n$). According to Cohen, an effect size of $r = 0.1$ is considered a small effect, an effect size of $r = 0.3$ is considered a medium effect, and an effect size of $r = 0.5$ is considered a large effect.³⁵

RESULTS

Of the 114 women screened for eligibility, 47 were ineligible, 19 eligible candidates declined participation, and 48 were randomized (Fig. 1). Thus, 72% (48/67), of those who were eligible, agreed to participate.

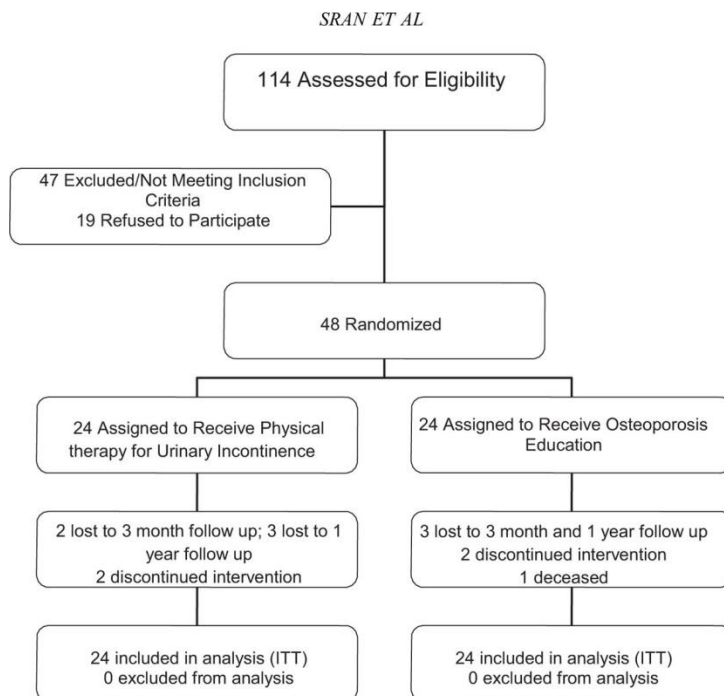


FIG. 1. Flow diagram on a study of postmenopausal women with osteoporosis or low bone density and urinary incontinence, randomly allocated to either a physical therapy group or a control group.

Two physical therapy participants (8.3%) and three control (osteoporosis education) participants (12.5%) were lost to the 3-month follow-up. The physical therapy participants dropped out because of a lack of interest in the PFMT or the time commitment it entailed. The control participants withdrew from the study because they did not want to participate, it required too much commitment, or for reasons unrelated to the study (a death). Additionally, a physical therapy participant did not complete the 1-year follow-up due to the time requirement. Thus, a total of six participants (three per group) were lost to the 1-year follow-up. No participant withdrew or missed follow-up because of adverse effects.

Adherence

In the physical therapy group, 58% (14/24) of participants attended all 12 treatment sessions; 33% (8/24) attended 10 or 11 sessions. In the control group, 38% (8/21) attended the group education session and 62% (13/21) received a 1:1 education session.

At the 3-month follow-up, 33% (8/24) of participants in the physical therapy group had completed 100% of the home exercises, 33% (8/24) completed 70% to 99%, and one participant 50% of the home exercises. Twenty-one percent (5/24) of the participants did not complete, either partially or at all, their exercise diary, although most of them reported doing the exercises some of the time.

At 1 year, 78% (18/23) of the physical therapy participants continued to do the PFM exercises; 67% (12/18) did so regularly (daily to three times a week) and 33% (6/18) occasionally (less than three times a week). Moreover, at the 1-year follow-up, 95% (19/20) of physical therapy participants responded “yes” to the question: Are you using the techniques that you were taught to control your urge to void?

Baseline: group comparison

Baseline characteristics of participants in both groups are presented in Table 2. At baseline, there were no significant differences between groups for age, parity, BMI, smoking, type or severity of incontinence, or self-perceived efficacy (Table 2). Noteworthy, the three participants with BMI values over 30 were all randomly allocated to the physical therapy group.

TABLE 2 Baseline characteristics for the two groups, including type and severity of incontinence and between-group differences

Baseline characteristics	Physical therapy group (n = 24)	Control group (n = 24)	P
Age (y), mean (SD)	66.17 (6.66)	67.13 (8.38)	0.663 ^T
Body mass index (kg/m ²), mean (SD)	24.69 (3.93)	23.08 (2.03)	0.085 ^T
Parity, mean (SD)	1.35 (1.15)	2.05 (1.47)	0.084 ^T
Smoker (previous or current) % (n)	35 % (8)	48% (11)	0.50 ^C
Type of incontinence (symptoms)			
Stress only % (n)	12.50 (3)	12.50 (3)	0.734 ^C
Urge only % (n)	20.83 (5)	12.50 (3)	
Mixed stress and urge % (n)	66.67 (16)	75.00 (18)	
Severity of incontinence	Median (25th-75th percentiles)		
Episodes/week	8.00 (4.00-10.50)	5.50 (2.25-16.75)	0.741 ^M
24-h pad test (g)	6.50 (3.00-25.50)	5.50 (2.25-15.00)	0.733 ^M
Urogenital Distress Inventory (UDI), total score	113.07 (75.85-137.41)	98.49 (87.50-137.41)	0.845 ^M
Incontinence impact	53.06 (23.33-88.13)	46.39 (14.38-91.46)	0.959 ^M
Questionnaire (IIQ) total score			
Self-perceived efficacy score	0.51 (0.38-0.68)	0.45 (0.29-0.70)	0.529 ^M

Statistical tests used for each analysis have been identified in the table as superscript alphabets: T, Student's *t* tests; C, chi-square test; M, Mann-Whitney *U* test. Significance level was established at $P < 0.05$.

Three-month follow-up: between-group differences

At 3 months, there was a statistically significant difference in the number of leakage episodes on the 7-day bladder diary ($P = 0.044$, effect size = 0.29), the UDI ($P = 0.021$), the IIQ ($P = 0.018$), and the self-perceived efficacy ($P = 0.007$) score in favor of the physical therapy group (Table 3). Although the values for the pad test were lower for the physical therapy group, the difference did not reach significance.

TABLE 3 Median, 25th, and 75th percentiles, and between-group differences at 3 months (postintervention)

3 mo (postintervention)	Physical therapy group (n = 24)	Control group (n = 24)	P
Bladder diary # of leakage episodes	2.00 (0.00-6.00)	5.50 (2.00-24.25)	0.044 ^a
Pad test (weight, g)	3.50 (2.00-8.50)	5.00 (2.25-21.75)	0.246
UDI total score	62.88 (34.37-103.98)	92.80 (79.36-130.68)	0.021 ^a
IIQ total score	9.72 (0.00-36.19)	44.58 (11.25-94.93)	0.018 ^a
Self-perceived efficacy	0.72 (0.50-0.83)	0.47 (0.38-0.61)	0.007 ^a

Data are presented as median (25th-75th percentiles).
IIQ, Incontinence Impact Questionnaire; UDI, Urogenital Distress Inventory.
Significance level was established at ^a $P < 0.05$.

One-year follow-up: between-group differences

One year after randomization, there was a statistically significant difference in the number of leakage episodes on the 7-day bladder diary ($P = 0.018$; effect size = 0.34), the amount of leakage on the 24-hour pad test ($P = 0.011$), and the impact of UI as measured by the UDI ($P = 0.026$) in favor of the physical therapy group (Table 4). Further, there was also a trend toward significance in IIQ and self-perceived efficacy results at 1 year, in favor of the physical therapy group ($P = 0.082$ and $P = 0.081$, respectively).

TABLE 4 Median, 25th and 75th percentiles, and between-group differences at 1 year (Mann-Whitney U test)

One year	Physical therapy group (n = 24)	Control group (n = 24)	P
Bladder diary # of leakage episodes	2.00 (0.00-5.75)	7.50 (1.00-23.00)	0.018 ^a
Pad test (weight, g)	2.50 (1.00-3.75)	4.00 (2.00-16.50)	0.011 ^a
UDI total score	66.29 (30.50-90.91)	81.82 (68.00-139.49)	0.026 ^a
IIQ total score	6.95 (0.00-26.39)	17.23 (4.52-73.27)	0.082
Self-perceived efficacy	0.64 (0.51-0.76)	0.53 (0.38-0.75)	0.081

Data are presented as median (25th-75th percentiles).

IIQ, Incontinence Impact Questionnaire; UDI, Urogenital Distress Inventory.

Significance level was established at ^a $P < 0.05$.

Contamination

One control group participant had two physical therapy treatments for UI just after the 3-month follow-up assessment because she wanted to be in the physical therapy group, but had been randomized to the control group. There was some improvement in her UDI and IIQ results at 1 year, but both the number of leakage episodes and pad weight worsened at 1 year. Another control group participant attended an UI education class between the baseline and 3-month follow-up period. According to the participant, this was by mistake, as she had been recruited through the clinic's waitlist and had already been scheduled for the session and forgot about the study protocol. The participant's results at 1 year were either similar to or worse than baseline for all measures.

Adverse events

No participant reported adverse events related to either intervention, the assessments, or outcome measures presented in this study. All participants were sent the study results by mail. All control group participants were given the opportunity to access physical therapy treatment through the center's continence clinic.

DISCUSSION

The PFM training has been shown to be effective in the treatment of UI compared with no treatment.³⁶ Our study is the first RCT in a group of women with osteoporosis or low bone density, a population with a high UI prevalence. After a 12-week physical therapy program for UI, participants had a 75% reduction in the median number of weekly leakage episodes, whereas the control group's condition had no improvement: physical therapy group (8.00 [4.00-10.50] to 2.00 [0.00-6.00]) versus control group (5.50 [2.25-16.75] to 5.50 [2.00-24.25]). At 1 year, physical therapy participants maintained this improvement, whereas the control participants' incontinence worsened, with the number of weekly leakage episodes increasing 50% from baseline: physical therapy group 8.00 (4.00-10.50) to 2.00 (0.00-5.75) versus control group 5.50 (2.25-16.75) to 7.50 (1.00-23.00). Other measures of incontinence severity, including the pad test, self-perceived efficacy, UDI, and IIQ, showed statistically significant improvements

in the short term for the physical therapy group. In the long term, the pad test and the UDI were statistically different between the two groups, favoring the treatment group. The self-perceived efficacy was lower at 1 year in the treatment group and higher in the control group, making the difference between the two groups nonsignificant. Finally, the impact of UI on quality of life was less in the control group, making the difference between the two groups nonsignificant.

Our results are in agreement with the previously published trials investigating the efficacy of PFMT for UI treatment in women aged 60 and above. As in our study, the studies by Burns et al 37 and Pereira et al 38 compared individual PFMT sessions, delivered by a professional, to a control group. Burns et al focused on women with predominant SUI. The treatment group received an individual (1:1) 8-week PFMT with a nurse; the control group received no treatment.³⁷ In the treatment group, women had 54% fewer urinary leakages on a 1-week bladder diary at the end of the study; the control group had a 9% increase in urinary leakages.³⁷ This improvement in the treatment group and deterioration in the control group also mirrors our study's results. Pereira et al targeted women with SUI; the intervention included a 6-week individual PFMT with a physical therapist (1-h sessions, twice weekly); the control group received no treatment.³⁸ There was an 89.3% reduction in urinary loss as measured by the 1-hour pad test in the treatment group compared with a 5.94% reduction in the control group.³⁸ Thus, these results, which were deemed significant, also concur with those of our study.

The strength of our study resides in the use of multiple, validated, and reliable UI outcome measures, investigating both the amount and number of leakage episodes in addition to disease-specific quality-of-life questionnaires. Moreover, a unique aspect of our intervention was the individualized progression in exercise training, with exercises being individualized to each participant's ability, rather than that of the group (ie, group approaches often require each participant to perform the same number of repetitions and at the same intensity, regardless of ability or the quality of their contraction).

Study limitations are primarily age-related. The mean age of participants in the two groups was 66.17 (6.66) and 67.13 (8.38) years of age, respectively; as a result, exercise adherence was reasonably high, with many participants performing the PFM exercises on a routine basis. Whether a significantly older population would adhere to or have the same results remains unknown, but a previous study of women aged 70 and above, who did not have osteoporosis or low bone density, also found positive results for exercise adherence.¹⁹ Moreover, as this study is the first one assessing PFMT in women with osteoporosis or low bone density, our sample size was limited. A larger RCT should be conducted on this subpopulation (wide range of ages) to generalize our study results.

Despite our participants having a concomitant affliction of osteoporosis or low bone density, our results support the findings of previous physical therapy studies on PFMT in older women with UI. Similar to a previous study in women without osteoporosis,³⁷ participants in the physical therapy group showed dramatic improvements in continence status, whereas UI symptoms

among nontreatment control group participants worsened, underscoring the need for an intervention.

CONCLUSIONS

Our results suggest that incontinence in older women with osteoporosis and UI can be effectively treated using this conservative physical therapy protocol. Given the negative impact of UI on physical activity levels and the importance of physical activity to improving bone density, our results should be used by physicians and other healthcare providers to educate clients with osteoporosis and UI: they can effectively reduce or cure their incontinence with this PFMT. Many women believe there is nothing they can do, that UI is a normal part of aging for which the only options are costly drugs or invasive surgeries. Healthcare providers need to take an active role in educating women with osteoporosis or low bone density on how they can regain continence, especially given the high and expected rise in prevalence of these concomitant conditions given the aging baby-boomer population. Healthcare professionals and clients must also acknowledge that reasonable adherence to the training program is necessary to gain results.

REFERENCES

1. Milsom I, Altman D, Cartwright R. Epidemiology of urinary incontinence (UI) and other lower urinary tract symptoms (LUTS), pelvic organ prolapse (POP) and anal incontinence (AI). In: Abrams CL, Khoury SP, et al., eds. *Incontinence, 5th International Consultation on Incontinence*. ICUD: Paris; 2012:15–107.
2. Tannenbaum C, Mayo N. Women's health priorities and perceptions of care: a survey to identify opportunities for improving preventative health care delivery for older women. *Age Ageing* 2003; 32:626–635.
3. Thom DH, Haan MN, Van Den Eeden SK. Medically recognized urinary incontinence and risks of hospitalization, nursing home admission and mortality. *Age Ageing* 1997; 26:367–374.
4. Minassian VA, Stewart WF, Wood GC. Urinary incontinence in women: variation in prevalence estimates and risk factors. *Obstet Gynecol* 2008; 111 (2 pt 1):324–331.
5. Herschorn S, Gajewski J, Schulz J, Corcos J. A population-based study of urinary symptoms and incontinence: the Canadian Urinary Bladder Survey. *BJU Int* 2008; 101:52–58.
6. Brown JS, Grady D, Ouslander JG, Herzog AR, Varner RE, Posner SF. Prevalence of urinary incontinence and associated risk factors in postmenopausal women. *Heart & Estrogen/Progestin Replacement Study (HERS) Research Group*. *Obstet Gynecol* 1999; 94:66–70.

7. Temml C, Haidinger G, Schmidbauer J, Schatzl G, Madersbacher S. Urinary incontinence in both sexes: prevalence rates and impact on quality of life and sexual life. *Neurourol Urodyn* 2000; 19:259–271.
8. Sran MM. Prevalence of urinary incontinence in women with osteoporosis. *J Obstet Gynaecol Can* 2009; 31:434–439.
9. Hannestad YS, Rortveit G, Sandvik H, Hunskaar S. A community-based epidemiological survey of female urinary incontinence: The Norwegian EPINCONT Study. *J Clin Epidemiol* 2000; 53:1150–1157.
10. Wetle T, Scherr P, Branch LG, et al. Difficulty with holding urine among older persons in a geographically defined community: prevalence and correlates. *J Am Geriatr Soc* 1995; 43:349–355.
11. Johnson TM II, Kincade JE, Bernard SL, Busby-Whitehead J, DeFriesse GH. Self-care practices used by older men and women to manage urinary incontinence: results from the national follow-up survey on self-care and aging. *J Am Geriatr Soc* 2000; 48:894–902.
12. Papaioannou A, Morin S, Cheung AM, et al. 2010 clinical practice guidelines for the diagnosis and management of osteoporosis in Canada: summary. *CMAJ* 2010; 182:1864–1873.
13. St James M, Carroll S. A meta-analysis of impact exercise on postmenopausal bone loss: the case for mixed loading exercise programmes. *Br J Sports Med* 2009; 43:898–908.
14. Robertson MC, Campbell AJ, Gardner MM, Devlin N. Preventing injuries in older people by preventing falls: a meta-analysis of individual-level data. *J Am Geriatr Soc* 2002; 50:905–911.
15. Sherrington C, Tiedemann A, Fairhall N, Close JC, Lord SR. Exercise to prevent falls in older adults: an updated meta-analysis and best practice recommendations. *N South Wales Public Health Bull* 2011; 22:78–83.
16. Boele van Hensbroek P, van Dijk N, van Breda GF, et al. The CAREFALL Triage instrument identifying risk factors for recurrent falls in elderly patients. *Am J Emerg Med* 2009; 27:23–36.
17. Nygaard I, Girts T, Fultz NH, Kinchen K, Pohl G, Sternfeld B. Is urinary incontinence a barrier to exercise in women? *Obstet Gynecol* 2005; 106:307–314.
18. Sapsford RR, Richardson CA, Maher CF, Hodges PW. Pelvic floor muscle activity in different sitting postures in continent and incontinent women. *Arch Phys Med Rehabil* 2008; 89:1741–1747.
19. Kim H, Suzuki T, Yoshida Y, Yoshida H. Effectiveness of multidimensional exercises for the treatment of stress urinary incontinence in elderly community-dwelling Japanese women: a randomized, controlled, crossover trial. *J Am Geriatr Soc* 2007; 55:1932–1939.

20. Kim H, Yoshida H, Suzuki T. The effects of multidimensional exercise treatment on community-dwelling elderly Japanese women with stress, urge, and mixed urinary incontinence: a randomized controlled trial. *Int J Nurs Studies* 2011; 48:1165–1172.
21. Madill SJ, Pontbriand-Drolet S, Tang A, Dumoulin C. Effects of PFM rehabilitation on PFM function and morphology in older women. *Neurourol Urodyn* 2013; 32:1086–1095.
22. Locher JL, Goode PS, Roth DL, Worrell RL, Burgio KL. Reliability assessment of the bladder diary for urinary incontinence in older women. *J Gerontol A Biol Sci Med Sci* 2001; 56:M32–M35.
23. Kahlaev N, Pflieger BA. WHO scientific group on the assessment of osteoporosis at primary health care level. Press W, ed. Switzerland; 2004:13 pp.
24. Andersson KE, Chapple CR, Cadozo L, Abrams P, Cardozo L, Khoury S, Wein A, et al. Pharmacological treatment of urinary incontinence. *Incontinence*. France: Health Publication Ltd; 2009. 631–699.
25. Sherburn M, Bird M, Carey M, Bø K, Galea MP. Incontinence improves in older women after intensive pelvic floor muscle training: an assessor-blinded randomized controlled trial. *Neurourol Urodyn* 2011; 30:317–324.
26. Burns PA, Pranikoff K, Nochajski TH, Hadley EC, Levy KJ, Ory MG. A comparison of effectiveness of biofeedback and pelvic muscle exercise treatment of stress incontinence in older community-dwelling women. *J Gerontol* 1993; 48:M167–M174. [Bibliographic Links](#)
27. Groutz A, Blaivas JG, Chaikin DC, et al. Noninvasive outcome measures of urinary incontinence and lower urinary tract symptoms: a multicenter study of micturition diary and pad tests. *J Urol* 2000; 164 (3 pt 1):698–701.
28. O'Sullivan R, Karantanis E, Stevermuer TL, Allen W, Moore KH. Definition of mild, moderate and severe incontinence on the 24-hour pad test. *BJOG* 2004; 111:859–862.
29. Lose G, Fantl JA, Victor A, et al. Outcome measures for research in adult women with symptoms of lower urinary tract dysfunction. *Neurourol Urodyn* 1998; 17:255–262.
30. Hagen S, Hanley J, Capewell A. Test-retest reliability, validity, and sensitivity to change of the urogenital distress inventory and the incontinence impact questionnaire. *Neurourol Urodyn* 2002; 21:534–539.
31. Handa VL, Massof RW. Measuring the severity of stress urinary incontinence using the Incontinence Impact Questionnaire. *Neurourol Urodyn* 2004; 23:27–32.
32. Tannenbaum C, Brouillette J, Michaud J, et al. Responsiveness and clinical utility of the geriatric self-efficacy index for urinary incontinence. *J Am Geriatr Soc* 2009; 57:470–475.

33. Bø K, Kvarstein B, Hagen BB, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: II. Validity of vaginal pressure measurements of pelvic floor muscle strength and the necessity of supplementary methods for control of correct contraction. *Neurourol Urodyn* 1990; 9:479–487.
34. Laycock J, Jerwood D. Pelvic floor muscle assessment: The PERFECT Scheme. *Physiotherapy* 2001; 87:631–642.
35. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Hillsdale, NJ: Lawrence Earlbaum Associates; 1988.
36. Dumoulin C, Hay-Smith EJC, Mac Habée-Séguin G. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database Syst Rev* 2014; 5:CD005654.
37. Burns PA, Pranikoff K, Nochajski T, Desotelle P, Harwood MK. Treatment of stress incontinence with pelvic floor exercises and biofeedback. *J Am Geriatr Soc* 1990; 38:341–344.
38. Pereira VS, Correia GN, Driusso P. Individual and group pelvic floor muscle training versus no treatment in female stress urinary incontinence: a randomized controlled pilot study. *Eur J Obstet Gynecol Reproduct Biol* 2011; 159:465–471.

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