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Dumoulin C[1], Sran M[2], Lieblich P[2], Wilson P[2]
***1.** University of Montreal, **2.** BC Women's Hospital & Health Centre*

PHYSIOTHERAPY SIGNIFICANTLY REDUCES LEAKAGE IN POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS AND URINARY INCONTINENCE: RESULT OF A PARALLEL RANDOMISED CONTROLLED TRIAL

Hypothesis / aims of study
To evaluate the effectiveness of individual physiotherapy treatments (PT) in reducing urine leakage in postmenopausal, urinary incontinent women with osteoporosis or low bone density, immediately after intervention and at one year in comparison to a control group (Co). We hypothesised that participants receiving physiotherapy would have a significant reduction in the severity of urinary incontinence (UI) after intervention, and that these results would be maintained at one year.

Study design, materials and methods
The study was a parallel randomized controlled trial conducted between November 2006 and March 2011. Postmenopausal women, aged 55 and older, with low bone density or osteoporosis were recruited. Low bone mineral density (BMD) was defined as a total hip, femoral neck or lumbar spine BMD of at least 2 standard deviations below typical peak BMD, or a history of fragility fracture. To be eligible, women had to have had symptoms of stress, urgency or mixed UI for at least 3 consecutive months previous and a minimum of 2 UI episodes in 3 days; be able to communicate in English; and consent to participate. Women were excluded if they had been treated for UI within the past 5 years; had scores of less than 24 on the Mini Mental State Exam; and/or had any other medical problems likely to interfere with the evaluation and intervention.
Women were randomly allocated to either a physiotherapy treatment or a control group.
Randomization was computer-generated, with allocation concealment by opaque sequentially numbered sealed envelope. The process was independent of all clinical collaborators.
Participants in the physiotherapy treatment group received a weekly 30-minute individual pelvic-floor-muscle (PFM) physiotherapy session for 12 weeks and had a daily home PFM exercise programme. The physiotherapy treatment included education, PFM training with biofeedback, motor-control learning exercises, functional use of PFM, urgency control techniques, bladder training, dietary recommendations/changes and, where necessary, constipation management. Control group participants joined a 3-hour group education session on osteoporosis, which included information on physical activity, diet, and medications for prevention and management of osteoporosis. The group education session was taught by a physiotherapist, dietician and a nurse clinician, all of whom were staff of the health centre's osteoporosis clinic. Control group participants who could not attend the group session, due to scheduling conflicts, were given a one-on-one phone or in-person session with the physiotherapist and/or dietician in which specific bone-health content and questions were addressed. Additionally, all control-group participants received follow-up phone calls (total: 1hour) to discuss the education session and any other questions related to osteoporosis and bone health.
The main outcome measure was the frequency of urine leakage per week; measured using the 7-day diary. Other outcome measures included the amount of leakage per day using the 24-hour pad test, the impact of urine leakage using the Urogenital Distress Inventory (UDI) and PFM function measurements using dynamometry. Intention-to-treat analysis was undertaken; the value at last observation was carried forward. Outcome assessors were blinded to the treatment group assignment; and the data analyst (PI) was blinded to subject's group assignment. Finally, the participants and physiotherapists were asked not to mention their group assignment to either the evaluators or data analyst.
A priori power calculation was performed to determine the sample size. Based on the expected mean frequency of UI episodes in the two groups (1), we needed a total sample size of 48 participants to achieve 80% power to detect a difference between groups. Baseline, post-intervention and one year follow-up between-group differences were analyzed using the non-parametric Mann-Whitney U test. Further, within each group, baseline, post-intervention and one-year follow-up data were compared using a non-parametric Friedman rank test and if significant, post hoc comparisons were calculated to compare paired outcome. Two-sided P values < 0.05 were considered significant. All analyses were performed using SPSS 18.

Results
Of those who were eligible, 71% (48/67) agreed to participate in the study; they had a mean age of 66.6 years (range: 55-84), mean BMI of 23.9 (19.1-34.5) and mean parity of 1.7 (0-5); 24 were randomized into each group. There were no significant demographic differences between the two groups. There were no significant differences between the groups at baseline for any outcome measures. Immediately after the physiotherapy treatment, there was a significant difference between groups, favouring the physiotherapy group, in terms of leakage episodes per week [PT median 2.00 (inter-quartile range 0.00-6.00); Co 5.50 (2.00-24.50); U=182.00, p=0.04], total UDI scores[PT 11.00 (4.25-18.75); Co 16.50 (13.25-2.75); U=386.50, p=0.04] and PFM maximal strength (Newton) [PT 3.48 (2.16-5.21); Co 1.81 (1.04-3.38); U=70.50, p = 0.006]. There was no significant difference between groups for the 24-hour pad test [PT 3.50 (2.00-8.50); Co 5.00 (2.25-21.75); U=232.00, p =ns].
At 1 year (46/48 participants had completed the study), there was a significant difference between the groups, again favouring the physiotherapy group, in terms of the number of leakage episodes [PT 2.50 (0.00-6.00); Co 7.50 (1.00-23.00); U= 171.00, p=0.04], 24-hour pad test [PT 2.50 (0.75-3.50); Co 4.00 (2.00-16.50); U=148.50, p=0.01], and UDI score [PT 10.00 (5.50-16.25); Co 16.00 (10.00-24.50); U=361.00, p=0.03]. There was no significant difference between groups for PFM maximal strength [PT 2.51 (1.57-4.34); 2.55 (1.06-3.78); U=83.50, p=ns]. Adverse events were not found in either group.
Over the one year study period, the physiotherapy group showed significant changes in leakage episodes [$X^2(2) = 19.18$; p =0.000], pad tests scores [$X^2(2) = 22.59$; p =0.000], and UDI scores [$X^2(2) = 14.48$ p=0.001], but no significant change for PFM maximal strength, although the score almost reached significance [$X^2(2) = 4.67$; p =0.057]. Leakage episodes changed from baseline to post-physiotherapy treatment [T= 1.07 (p = 0.002)] and from baseline to one year [T= 1.00 (p = 0.004)], but not from post-physiotherapy to one year [T=

-0.07 (p = 1.00)]. Pad test scores changed from baseline to one year [T= 1.25 (p = 0.001)] but did not reach significance from baseline to post-physiotherapy [T= 0.66 (p = 0.086)] nor from post-physiotherapy to one year [T= 0.59 (p = 0.15)]. UDI scores changed from baseline to post-physiotherapy [T= 0.75 (p = 0.039)] and from baseline to one year [T= 1.02 (p = 0.002)] but did not change from post-physiotherapy to one year [T= .273 (p = 1.00)]. Finally, there were no significant changes in the outcomes for the control group over the one year study period.

Interpretation of results

Our results show that women with osteoporosis can significantly reduce UI through a short (12-week) course of physiotherapy treatment. Further, results appear to be maintained after one year. Given the high prevalence of UI in women with osteoporosis (2) and the higher risk of falls, fractures and limits on physical activity in women with UI, physiotherapy should be routinely prescribed for women with osteoporosis and UI.

Concluding message

Pelvic floor physiotherapy reduces the number of leakage episodes, quantity of leakage and the impact of urine leakage in postmenopausal women with osteoporosis. Additionally, it increases PFM strength immediately after treatment. Symptom reduction is maintained one year later.

References

1. Journal of Gerontology 1993;48(4):167-174.
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Specify source of funding or grant	**BC Women's Health Research Institute, Doris Winterbottom Research Award**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ClinicalTrials.gov NCT00323245**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**The study was approved by the the UBC Children´s & Women´s Health Centre of BC Ethics Review Board.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**