

PILOT-TESTING OF A THEORY-BASED PELVIC FLOOR TRAINING INTERVENTION FOR RADICAL PROSTATECTOMY PATIENTS

Hypothesis / aims of study. Three approaches to pelvic floor training (PFT) for radical prostatectomy (RP) patients were compared to determine their differential effects on pelvic floor muscle strength, uncertainty in illness, self-efficacy for pelvic floor muscle exercise (PFME), quality of life (QoL), and the frequency, volume, and distress associated with urinary incontinence (UI). We hypothesized more favourable outcomes among patients who received either the *basic* or *enhanced* version of a theory-based PFT intervention than among patients who received only the *usual* PFT provided at the study site.

Study design, materials and methods. The Theory of Unpleasant Symptoms [1] guided conceptualization of this pilot randomized clinical trial. The Theory of Uncertainty in Illness [2] guided identification of content for the PFT intervention, and Social Cognitive Theory [3] guided intervention delivery. Eligible patients resided within 50 miles of the study site, an academic medical centre, and were English-speaking, age 50+ years, recovering from recent RP, and newly incontinent of urine (any amount). Following informed consent and enrollment, participants were randomly assigned via sealed envelope technique to receive either *usual*, *basic* or *enhanced* PFT. All participants received routine brief verbal and written post-operative instructions to perform PFME from their clinician at the study site. The *usual* PFT group received no further instruction. The *basic* PFT group received one additional PFT session and three weekly phone calls from a trained nurse interventionist aimed at reducing uncertainties of the UI symptom experience and building PFME self-efficacy. The *enhanced* PFT group received four additional biofeedback-enhanced PFT sessions and four weekly phone calls from the nurse interventionist toward the same ends. Data were collected from each participant during post-operative months 1 (baseline), 3, 6, and 9. Outcome measures included: urine stream interruption test (pelvic floor muscle strength); Mishel Uncertainty in Illness Scale (uncertainty in illness); Broome Pelvic Muscle Self-Efficacy Scale (PFME self-efficacy); 3-day bladder diary (UI frequency); 24-hour pad test (UI volume); Male Urogenital Distress Inventory (UI distress); and Male Urinary Symptom Impact Questionnaire (QoL). All measures demonstrated acceptable levels of reliability and validity. Repeated measures analysis of variance was used to determine differences within and between *usual*, *basic*, and *enhanced* PFT groups in each of the specified outcomes.

Results. Participants (N=54) were 50-72 years old (M=59.5, SD=6.3) and predominantly white (79.6%), married (81.5%), employed (72.3%), and college educated (61.1%). The majority had Gleason scores < 7 (85.1%), robotic RPs (70.4%), preservation of both neurovascular bundles (70.8%), and negative surgical margins (67.3%). There were no study-related serious adverse events. No significant differences among groups were found in baseline measures of outcome variables. Findings for UI volume on the 24-hour pad test, the most robust outcome measure, suggest that both *basic* and *enhanced* PFT conferred an advantage in recovery of bladder control compared to *usual* PFT. Large, statistically significant declines in UI volume occurred within all groups over the first nine post-operative months ($\eta^2=.41$; $p<.001$); however, the decline over time was significantly steeper for both *basic* and *enhanced* PFT groups compared to the *usual* PFT group ($p<.05$) and the size of this difference was large ($\eta^2=.18$; observed power =.76). Small to moderate differences ($\eta^2=.01$ - .07) in all other outcomes at each data collection point and over time also favoured *basic* and *enhanced* PFT over *usual* PFT, however the observed power (<.54) was inadequate to test for statistically significant differences at a type I error rate of .05.

Interpretation of results. Findings from this study suggest that the *basic* PFT intervention is sufficient to significantly accelerate improvement in UI volume compared to *usual* PFT. The *basic* PFT intervention may also accelerate improvements in pelvic floor muscle strength, uncertainty in illness, PFME self-efficacy, UI frequency, UI distress, and QoL compared to *usual* PFT, although the observed power was inadequate for hypothesis testing with inferential statistics.

Concluding message: RP patients may benefit from a theory-based PFT intervention that reduces uncertainties of the UI symptom experience and builds PFME self-efficacy. Furthermore, the basic level of this intervention may be sufficient to produce beneficial effects. A full-scale randomized clinical trial is warranted.

References

1. Lenz ER, Pugh LC, Milligan RA et al. The middle-range theory of unpleasant symptoms: An update. *ANS Adv Nurs Sci*. 1997;19:14-27
2. Mishel MH. Reconceptualization of the uncertainty in illness theory. *Image J Nurs Sch*. 1990;22(4):256-262
3. Bandura A. *Self-Efficacy. The Exercise of Control*. New York: W.H. Freeman and Company, 1997

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Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Institutional Review Board for the Protection of Human Subjects, Rutgers University, New Brunswick, NJ, USA Institutional Review Board, University of Medicine and Dentistry of New Jersey, New Brunswick, NJ, USA
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes