

**Characteristics predictive of successful pelvic floor muscle training outcomes among
women with stress urinary incontinence**

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A thesis submitted to the
Faculty of Graduate and Postdoctoral Studies
in fulfillment of the requirements for:
Masters of Science Degree in Human Kinetics

School of Human Kinetics
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ACKNOWLEDGEMENT

I would like to thank my thesis supervisor, Dr. Linda McLean for the opportunity to work in the Motor Function Measurement Laboratory (MFM Lab) at the University of Ottawa. I have thoroughly enjoyed my time working and learning in the lab and look forward to my future projects with Dr. McLean and colleagues as a PhD student. Linda, thank you for your knowledge, guidance, and advice throughout this thesis and thank you for providing me with many opportunities to collaborate on other projects in the lab and to travel to several conferences to present projects. I would also like to thank my committee members, Dr. Ryan Graham and Dr. Tony Carlsen for their valuable perspective and expertise in the evaluation of my thesis.

Thank you to the Canadian Institute of Health Research (CIHR) for funding the main project under Dr. Linda McLean and thank you to the Queen Elizabeth II Graduate Scholarship in Science and Technology for providing me with the time and resources to concentrate solely on my thesis work.

I would also like to thank my colleagues in the MFM Lab for their knowledge, insight, and support during my thesis work. You have truly made my experience at the University of Ottawa unforgettable. Thank you Cat and Marie-Eve!

Finally, I would like to thank my friends, family, and boyfriend for their love and support during this Master's program. I would not have been able to remain optimistic and sane without you. Thank you Mom, Dad, Shawna, Matt, Gram, Poppa, and Trigger for all of your support and kind words while I completed my thesis project.

ABSTRACT

Physiotherapist-supervised pelvic floor muscle (PFM) training is the recommended first-line treatment for women with stress urinary incontinence (SUI); however, only up to 50% of women are cured with this treatment. The primary objective of this study was to develop a predictive model of successful physiotherapy intervention outcomes among women with SUI using predictors that are accessible to clinicians. The secondary objective of this study was to run a preliminary investigation of morphologic differences between women with SUI who were cured with a physiotherapy intervention and those who were not cured, using a subset of ultrasound imaging data. Seventy-nine women with SUI were assessed at baseline on measures of demographic data (i.e. age, body mass index, etc.), 3-day bladder diary, 30-minute standardized pad test, clinical assessments of PFM strength and tone, and transperineal ultrasound assessments of PFM morphology. Women then attended a 12-week physiotherapy intervention and returned for a follow-up assessment. The multivariate logistic regression model was significant ($p < .001$) with two predictors: baseline ICIQ-FLUTS UI subscale (SUI severity; $p = .01$) and parity ($p = .06$). A significant ROC curve for the ICIQ-FLUTS UI subscale ($p < .01$) predicts physiotherapy intervention outcomes with 55.6% sensitivity and 80.8% specificity at a cut-off score of 7.50. Women most likely to be cured with a physiotherapy intervention were those with lower scores on the ICIQ-FLUTS UI subscale and those who have given birth to fewer children. Significant differences were found in a subset of data between women with SUI who are cured with the physiotherapy intervention and women who are not cured on morphologic measures in standing of bladder neck height at peak cough ($p = .03$), descent of the bladder neck during maximal Valsalva maneuver (MVM; $p = .04$), levator hiatus circumference at rest ($p = .03$) and at maximal voluntary contraction in both standing and supine (MVC; $p = .01$; $p = .03$). Variables that were trending towards significance included bladder neck height in standing at rest, levator plate length (LPL) at maximal excursion during a cough and MVM in standing, and mid-urethral wall cross-sectional area. These significant differences indicate potential value in using ultrasound imaging outcomes as predictors of a cure with physiotherapy intervention in future models, and a combination of demographic, clinical, and morphologic variables may build a more robust predictive model.

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CHAPTER 1: INTRODUCTION

1.1 PROBLEM STATEMENT

Urinary incontinence (UI) is highly prevalent among women; affecting up to 50% of the female population (Markland, Richter, Fwu, Eggers, & Kusek, 2011). A recent projection model for the United States forecasts that with the aging population, the number of UI cases will increase by 55% — from 18.3 million women in 2010 to 28.4 million women in 2050 (Wu, Hundley, Fulton, & Myers, 2009); similar trends may be expected for Canada.

UI bears a large economic burden to the healthcare system and to the affected individuals. Approximately \$8.5 billion CAD is spent annually on direct (e.g. diagnosis, treatment, routine care, etc.) and indirect (e.g. decreased productivity, days off work, etc.) costs associated with UI (The Canadian Continence Foundation, 2014). Individuals with UI spend \$1400 to \$2100 annually on routine management products (i.e. incontinence pads/diapers, extra laundry costs, etc.; The Canadian Continence Foundation, 2014). Moreover, these costs increase with the frequency and severity of incontinence incidents (Subak et al., 2006). UI also adds approximately \$3.84 billion annually in care costs to the Canadian Health Care System in family physician visits, treatments (both conservative and surgical), and long-term management, as well as admittance to long-term care facilities (The Canadian Continence Foundation, 2014). Indirect costs also have a large impact on the Canadian labour force, with approximately 11.5 million person-days of lost work and over \$2.5 billion lost due to the decrease in productivity and job efficiency (The Canadian Continence Foundation, 2014). These numbers may be even greater as UI is often under-reported (Norton & Brubaker, 2006).

UI has three major subtypes: stress urinary incontinence (SUI), urge urinary incontinence (UUI), and mixed urinary incontinence (MUI). The most commonly diagnosed subtype is SUI,

which comprises up to 61% of female cases globally (Reynolds, 2011). SUI is defined by the International Continence Society (ICS) as “the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing” (Abrams et al., 2003, p. 38). Women with SUI show marked decreases in their quality of life (Minassian, Sun, Yan, Clarke, & Stewart, 2015; Tennstedt et al., 2007), reductions in social interactions and physical activities (Brown & Miller, 2001; Fultz et al., 2003; Xu, Liu, Qu, Chen, & Wang, 2016), and impaired sexual function (Su, Sun, & Jiann, 2015; Tennstedt et al., 2007). The major risk factors for SUI include aging, pregnancy, lifestyle habits, and race (Perera, Kirthinanda, Wijeratne, & Wickramarachchi, 2014). Women who are most at risk for developing SUI include those who are over 50 years of age (Perera et al., 2014), have had one or more pregnancies and have delivered larger babies vaginally (Gyhagen, Bullarbo, Nielsen, & Milsom, 2013; Viktrup, Lose, Rolff, & Barfoed, 1992)—especially with a long, active labor (Allen, Hosker, Smith, & Warrell, 1991), have a history of urological and/or gynaecological surgery (Skoner, Thompson, & Caron, 1994), have a family history of UI (Hannestad, Lie, Rortveit, & Hunskaar, 2004), are heavy smokers (Hannestad, Rortveit, Daltveit, & Hunskaar, 2003), are obese (Sampselle, Harlow, Skurnick, Brubaker, & Bondarenko, 2002), and/or who have participated in high impact physical activities (Bø, 2004; Hunskaar et al., 2000). Modifiable risk factors such as obesity and smoking suggest that SUI may be more prevalent among women who have other diseases: diabetes, lung and/or heart disease (Tannenbaum, Gray, Hoffstetter, & Cardozo, 2013).

Many women with UI delay seeking treatment. This is often due to embarrassment, lack of knowledge, and/or not having time or resources to attend to it (Perera et al., 2014). Women are often embarrassed by their leakage episodes and use maladaptive coping techniques—including avoidance—in which they attempt to conceal their leakages and avoid situations that

may lead to leakages (Xu et al., 2016). Moreover, women often feel embarrassed to consult with a doctor about urine leakages (Perera et al., 2014). When women do consult their physician, only 46% of physicians report that they clearly understand incontinence and just 40% of physicians have an organized plan for treating it (Swanson, Skelly, Hutchison, & Kaczorowski, 2002). Many women also believe that UI is a normal part of aging, a natural result of having delivered babies, and/or do not realize that UI is treatable (Perera et al., 2014); this lack of knowledge further leads to delays in treatment seeking. Other women simply attribute their delay in treatment seeking to being too busy with family priorities, as they are often more concerned about the well-being of their family members than about to their own problem (Perera et al., 2014). With the wide variation in knowledge, treatments, and comfort levels among women and their physicians, it is important to establish a standard of care to provide individuals with recommendations around the most efficient and effective treatment pathways for their given situation.

Current treatment options for women with SUI include surgical management, physiotherapist-supervised PFM training, and other conservative treatments (e.g. pessaries, injectable urethral bulking agents, etc.). There is level I evidence to support PFM training in the management of SUI (Dumoulin, Hay-Smith, & Mac Habée-Séguin, 2014) and this approach comes with minimal risk. As such, the International Continence Society recommends physiotherapy as the first-line treatment for women with SUI. However, only up to 56% of women with mild to moderate SUI are cured with this treatment (Dumoulin et al., 2014). The development of a predictive model that describes clinically accessible variables that predict the success or failure of PFM training would help to streamline treatment options for women with

SUI: improving treatment pathways, accessibility to treatment, and reducing costs for both the affected individuals and the Canadian healthcare system.

Four studies to date have investigated the characteristics predictive of success or failure with PFM training among women with SUI. They have mainly focused on demographic predictors including major risk factors (e.g. age, body mass index (BMI), parity, etc.) and clinical variables including PFM strength and endurance, urethral hypermobility, and incontinence severity. These studies have suggested that high BMI, urethral hypermobility, previous pelvic surgery, strong PFMs at initial assessment (Truijen, Wyndaele, & Weyler, 2001), greater SUI severity, and chronic use of psychotropic medications are predictive of failure with a physiotherapy intervention (Cammu, Van Nysten, Blockeel, Kaufman, & Amy, 2004). Predictors of successful PFM training outcomes among women with SUI have included lower pre-treatment PFM passive force and higher pre-treatment PFM endurance as measured by a dynamometer (Dumoulin, Bourbonnais, Morin, Gravel, & Lemieux, 2010), and reduced bladder neck support as measured by urethra-vesical height on magnetic resonance images (MRIs) (Dumoulin, Tang, Pontbriand-Drolet, Madill, & Morin, 2017).

The majority of studies modeling success or failure with PFM training to cure SUI have been retrospective investigations; only one study has involved a prospective analysis (Dumoulin et al., 2017). Each of the four studies defined success with a physiotherapy intervention differently, with varying degrees of subjective and objective measures used to define a cure. All studies used multivariate logistic regression models; however, two of these models were based on small sample sizes and large numbers of variables (Dumoulin et al., 2010; Truijen et al., 2001), which may have resulted in over specification (Babyak, 2004). None of the studies

validated their model using statistical verification techniques or novel samples, which leaves overall model fit unknown. The current study will address some of these limitations.

1.2 PURPOSE

This study involves a prospective investigation into the predictors associated with successful outcomes of physiotherapist-supervised PFM training among women with SUI. Through predictive modeling, we may improve accessibility to treatment for those who will benefit the most and we may reduce the cost of SUI to both affected individuals and the Canadian healthcare system. The primary objective was to generate a predictive model of successful physiotherapy outcomes for the management of SUI in women using predictors that are easily accessible to clinicians. The secondary objective was to identify potential morphologic predictors, using a subset of ultrasound image data acquired concurrently with the clinical data used to meet the primary objective, to determine which features may improve the model. Specifically, predictors from ultrasound image data may help to build a more robust prediction of treatment success among women with SUI.

CHAPTER 2: LITERATURE REVIEW

2.1 NORMAL CONTINENCE FUNCTION

The human female continence system is well designed to prevent the leakage of urine by resisting rises in intra-abdominal pressure. To accomplish this, the urinary continence system utilizes two features: lower urinary tract support and sphincteric action (DeLancey, 1990). The support system of the lower urinary tract is comprised of the arcus tendineus fasciae pelvis (ATFP), levator ani muscles of the pelvic floor, and the endopelvic fasciae surrounding the urethra and vagina (DeLancey, 1988; DeLancey, 1990). These anatomical features create a floor

upon which the pelvic organs rest and muscular support within that floor can actively resist challenges to support. Further, the connective tissues keep the urethra fixed in a position between the anterior vaginal wall and the pubic symphysis such that, during increases in intra-abdominal pressure, the downward forces generate closure of the urethra through compression. Sphincteric function within the urinary continence system is accomplished by the striated muscle, smooth muscle, and vascular plexus of the urethra (Ashton-Miller & DeLancey, 2007), which contribute to two urethral sphincters: the internal (proximal) sphincter and the external sphincter (DeLancey, 1990). The smooth muscle of the urethra lies within the striated muscle and is circular in configuration. Smooth muscle contraction causes involuntary constriction of the urethra to prevent urine leakage (DeLancey, 1990). The striated muscle forms the outer layer of the urethra—attaching near the vaginal wall—and is arranged in both circular and longitudinal fiber orientations, allowing the striated muscle to maintain constant tone and provide voluntary closure to prevent urine leakages (DeLancey, 1990). The submucosa of the urethra is also lined with a vascular plexus, which helps create a hermetic seal within the urethra and aids in the maintenance of continence during rest (McBride, Li, & Gutman, 2003). Under stress (e.g. forces caused by physical exertion, coughing, etc.), the internal and external sphincters and the PFMs contract to increase urethral closure pressure (DeLancey, Gosling, Creed, Dixon, Delmas, & Landon, 2002); the endopelvic fasciae, ATRP, anterior vaginal wall, and levator ani muscles hold their position, which allows the urethra to be compressed against their hammock-like support (DeLancey, 1994a). Collectively, these mechanisms act to maintain higher pressures within the urethra than those in the bladder and thus they prevent urine leakage.

2.2 PATHOPHYSIOLOGY OF SUI

Early research into the pathophysiology of SUI focused on the loss of structural support and stabilization of the pelvic organs. Researchers proposed hypotheses involving loose tissues at the vesical neck of the bladder (Kelly & Dumm, 1998), the loosening of urethral supports (Bonney, 1923), and the loss of the urethrovesical angle (Jeffcoate & Roberts, 1952); all supporting the idea that a loss of support was responsible for the development of SUI. Enhorning (1961) further proposed that part of the urethra was considered intraabdominal—sitting above the pelvic floor—and that urethral descent below the pelvic floor prevented the effective pressure transmission from the abdomen to the urethra, resulting in reduced urethral closure pressure and consequently SUI. Theories such as these became the empirical basis for surgical interventions for the treatment of SUI, such as the Marshal, Marchetti, and Krantz operation (MMK); the successes of which were attributed to the restoration of the posterior urethrovesical angle by elevating and securing the urethra and vesical neck (Marshall, Marchetti, & Krantz, 1949). However, women with SUI—whose urethral support had been enhanced through surgery—showed no differences in urethral closure pressure even though they experienced some alleviation of their symptoms (Koelle, Windisch, Doerfler, Marth, & Kropshofer, 2006), which suggests that loss of bladder and urethral support may be part of a larger model of SUI pathophysiology.

Closure of the urethra to prevent urine leakage is enhanced by its optimal position between the pubic symphysis and the pelvic floor. When the urethra moves out of this location during dynamic tasks, the expected transmission of intra-abdominal pressure to the urethra cannot occur and urine leakage may result. This “urethral hypermobility” is thought to be associated with damage to the pelvic floor connective tissues that can occur with vaginal

childbirth (Shek & Dietz, 2008) but can also occur as a result of trauma due to high impact activities (Bø, 2004) or straining experienced through chronic coughing (Perera et al., 2014). These exposures lead to paravaginal defects in the ATRP (e.g. ATRP detachment from the ischial spine), which can also alter urethral supports and the synergy between connective tissue support and PFMs, which work together to effectively transmit pressure and prevent leakage (DeLancey, 2002). Urethral hypermobility has traditionally been measured through a clinical Q-tip test (Crystle, Charme, & Copeland, 1971). During this test, an applicator stick (Q-tip) is inserted into the urethra up to the bladder neck, and while the woman completes a straining task in the lithotomy position, the angle of the applicator stick is recorded relative to the horizontal (Crystle et al., 1971; Karram & Bhatia, 1988). Generally, a woman is considered to have urethral hypermobility when the Q-tip angle changes by 30 degrees or more (Caputo & Bension, 1993). However, the Q-tip test may be inaccurate, as the position of the applicator stick is not standardized and the 30 degree or greater angle is an arbitrary cut-off. When validated against ultrasound imaging, the Q-tip test was found to have a 22% false-positive rate (Caputo & Bension, 1993). More recently, urethral trajectory and acceleration have been measured using ultrasound imaging during functional tasks, and differences in urethral displacement between women with and without SUI have been demonstrated (Cassadó et al., 2006; Peng, Jones, & Constantinou, 2006). A recent retrospective analysis found that women with SUI generated lower urethral closure pressure on urodynamics and demonstrated more urethral mobility than their continent counterparts (Właźlak, Surkont, Shek, & Dietz, 2015). Together, these results suggest that there is a functional relationship between the urethral support structures and urethral closure pressure. However, as noted above, sphincteric function also contributes to urethral closure pressure (DeLancey, 1994a; Fantl, Hurt, Bump, Dunn, & Choi, 1986; Peng et al., 2006).

The urethral sphincter further enhances urethral closure through active constriction both at rest and during active resistance to rises in intra-abdominal pressure (Ashton-Miller & DeLancey, 2007; McBride et al., 2003). During a rise in intra-abdominal pressure, the striated urethral sphincter muscle is recruited to enhance closure pressure within the urethra to maintain continence. The urethral sphincter is innervated by the pudendal nerve (Ashton-Miller & DeLancey, 2007) and is prone to damage during vaginal delivery (Allen et al., 1991). During vaginal childbirth, the pudendal nerve experiences strain of up to 33%, which is beyond the normal strain threshold known to cause permanent damage in appendicular nerves (Ashton-Miller & DeLancey, 2007). Damage to the innervation of the striated urethral sphincter may lead to poorly timed sphincteric constriction and a lack of proper closure to prevent leakage (Ashton-Miller & DeLancey, 2007). Furthermore, the bladder and urethral tissues contain estrogen receptors, making them susceptible to hormone levels (Iosif, Batra, Ek, & Åstedt, 1981). Lower levels of estrogen are associated with decreased urethral vascularization and urogenital atrophy (Endo et al., 2000; Robinson & Cardozo, 2003). Estrogen therapies in conjunction with phenylpropanolamine have shown reductions in SUI symptoms among women, such that the maximal urethral closure pressure (Beisland, Fossberg, Moer, & Sander, 1985; Hilton, Tweddell, & Mayne, 1990) and urethral vascularization (Endo et al., 2000) both improve. However, estrogen therapy does not appear to provide a complete cure of SUI symptoms (Fantl, Cardozo, McLish, & The Hormones and Urogenital Therapy Committee, 1994).

The pelvic floor is a fibromuscular layer running from the pubic symphysis to the coccyx and sacrum (Raizada & Mittal, 2008). Passive support of the pelvic organs is provided through the connective tissues, while active resistance to pelvic organ descent is induced in response to rises in intra-abdominal pressure is provided through the PFMs (DeLancey, 1994b). The PFMs

may also play a role in urethral closure through their synergistic contraction with the striated urethral sphincter muscle, which has been demonstrated during voluntary PFM contractions and coughs (Bø, Stien, Kulseng-Hanssen, & Kristofferson, 1994). Damage to the pelvic floor—through denervation of the PFMs—and PFM weakness have been assumed by some to be the main causes of SUI because of the successful reduction of symptoms associated with PFM training (Dumoulin et al., 2014). Further, SUI is associated with events that can cause trauma to the PFMs: childbirth (Snooks, Swash, Mathers, & Henry, 1990; Stoker et al., 2003), chronic coughing (Perera et al., 2014), and high impact exercise (Bø, 2004). If the PFMs or their connective tissue attachments are damaged, they may not be capable of aiding in urethral compression during rises in intra-abdominal pressure, as the urethra is no longer held in an optimal position to be compressed between the anterior vaginal wall and the pubic symphysis (DeLancey, 2002). Trauma to the PFM attachments may concurrently damage the pelvic nerve resulting in ineffective contractions of both the PFMs themselves and the urethral sphincters (Allen et al., 1991; Smith, Hosker, & Warrell, 1989). Interestingly, PFM avulsion has not been associated with increased urethral mobility nor with SUI (Dietz, Kirby, Shek, & Bedwell, 2009; Shek, Pirpiris, & Dietz, 2010). It is not currently clear why PFM training cures women with SUI (Dumoulin et al., 2014); the mechanism may be compensatory or the effect of concurrent strengthening of the urethral sphincters (McLean et al., 2013; Madill, Pontbriand-Drolet, Tang, & Dumoulin, 2015).

The lack of clarity around the pathophysiology of SUI may be related to the fact that there are several different defects that may contribute, alone or in combination, to the failure of the continence mechanism. Potential contributing defects include pelvic organ support, urethral stabilization, urethral sphincter function, and possibly PFM strength and/or motor control.

2.3 MAIN TREATMENTS FOR SUI

The two most common treatments available for women with SUI include surgery and physiotherapist-supervised PFM training. Within Canada, the most regularly performed surgical procedures for SUI include colposuspension and midurethral sling insertions. The target of these surgical treatments is to re-establish urethral support. Sling procedures have cure rates of 63-77% and colposuspension procedures have cure rates similarly ranging from 51-73% (Asicioglu et al., 2014; Ward & Hilton, 2004). However, Digesu, Robinson, Cardozo, & Khullar (2009) found that not all women with SUI experience successful treatment outcomes with surgery, noting an association between smaller urethral sphincter volumes and surgical treatment failure. This suggests that a one-size-fits-all approach to enhance urethral support does not generate optimal outcomes when women present with urethral sphincter insufficiency (DeLancey et al., 2008; DeLancey & Morgan, 2007). These surgeries also carry significant risk for complications including bladder perforation, urgency, voiding difficulties, and detrusor instability (Lapitan & Cody, 2012). Furthermore, a recent study by Welk, Al-Hothi, & Winick-Ng (2015) found that ten years after a mid-urethral sling (mesh) insertion to alleviate SUI, 1 in 30 women required a correction or removal of the mesh due to pain and/or erosion. More research is required to further understand the long-term outlook for surgical treatments for SUI.

An alternative to surgery for SUI is PFM training. The target of this type of treatment is to improve strength, power, endurance, and/or motor control of the PFMs. As noted above, PFM training cures up to 56% of women with SUI with few reported adverse effects (Dumoulin et al., 2014). Physiotherapist-supervised PFM training reduces urine leakage (Bø, Talseth, & Holme, 1999), which has long been attributed to PFM hypertrophy and consequent improvement in PFM strength (Bø et al., 1999). Recent evidence suggests that PFM training goes beyond PFM

hypertrophy, displaying improvements in motor control (i.e. urethral stability) and sphincter hypertrophy (McLean et al., 2013). Furthermore, the long-term outlook for lasting results from PFM training to treat SUI is favourable, with a 66% chance of improvements lasting at least 10 years if the training was initially successful in treating SUI (Cammu, Van Nysten, & Amy, 2001). Currently, PFM training is recommended as the first-line treatment for SUI; however, PFM training cures only half of the women who undertake this treatment (Dumoulin et al., 2014). Further, physiotherapy treatment can be expensive, time-consuming, and is generally not covered by provincial health insurance in Canada. Determining which women will benefit the most from PFM training may be helpful in streamlining treatment options for women with SUI: saving them time and money spent on potentially ineffective treatments.

A recent study on the cost-effectiveness of surgical treatment and physiotherapy for women with SUI favoured surgical interventions over physiotherapy (Labrie et al., 2013). Through a multicenter randomized controlled trial, Labrie et al. (2013) found that ninety percent of the women in the surgical group reported improvement and only 64.4% of the women in the physiotherapy group reported improvement. However, women enrolled in the trial were permitted to cross-over to the surgical group from the physiotherapy group if both the woman and the treating physiotherapist determined that no improvement was being seen, which may have biased the outcomes (Welk, 2014). Moreover, many of these women were allowed to crossover from physiotherapy to surgery after 7.4 ± 4.4 treatment sessions, which is shorter than the recommended duration of PFM training needed to be effective (Dumoulin et al., 2014; Fritel & Dumoulin, 2013). The results of this study may have implications for the treatment of women with SUI, but further research into the long-term economic impact of both treatments should be investigated, particularly considering recent findings around the complications associated with

surgical repair (Lapitan & Cody, 2012) and the need for revisions (Welk et al., 2015). Moreover, the development of a predictive model to determine prospectively which women with SUI will benefit from a physiotherapy treatment may help us optimize treatment pathways.

2.4 PREVIOUS INVESTIGATIONS OF PREDICTIVE CHARACTERISTICS OF SUCCESSFUL OUTCOMES AMONG WOMEN WITH SUI

As noted previously, four studies have examined the characteristics predictive of success or failure with PFM training in women with SUI. Truijen, Wyndaele, & Weyler (2001) investigated 104 women with SUI who had previously completed conservative treatment, including PFM training. The women were assessed using recall procedures as well as chart audits to retrieve clinical and urodynamic data. Truijen et al. (2001) defined treatment success as the disappearance of incontinence symptoms or the loss of only a few drops of urine on heavy straining: thirty-seven out of 104 women reached this definition of treatment success. Using a predictive multivariate logistic regression analysis Truijen et al. (2001) examined age, parity, body mass index (BMI), regular constipation, urethral hypermobility, hysterectomy, previous pelvic surgery, detrusor instability, and the presence of rectocele and cystocele as predictors of success or failure with conservative treatment. They found high BMI, urethral hypermobility, previous pelvic surgery, and strong PFMs at initial assessment were predictive of failure with conservative treatment.

In 2004 Cammu, Van Nysten, Blockeel, Kaufman, & Amy observed 447 women with SUI from an outpatient clinic in Belgium. All of the women received individual PFM training delivered by the same physiotherapist. Cammu et al. (2004) defined a woman as cured or failed based on a Likert-scale of the women's perception of the success of the physiotherapy intervention on their SUI symptoms, the number of incontinence pads they were using after

completing the intervention, and whether or not they went on to have surgery after the intervention. They defined women as not having been cured by the treatment if they used protective pads after physiotherapy, if they went on to have surgery, and/or if they selected statements on a questionnaire suggesting that their condition was unchanged or had worsened. Of the 447 women included in the study, 221 women were deemed cured with physiotherapy, consistent with a 50% cure rate. Twenty-two predictors were selected for inclusion in the model, but only three strongly predicted failure with the physiotherapy intervention: having ≥ 2 leakages per day prior to treatment, chronic use of psychotropic medications, and a positive stress test result at cough prior to treatment. However, even with these three significant predictors, only 15% of the variance in the data was accounted for by the model, suggesting that other important variables may generate a stronger prediction.

Dumoulin, Bourbonnais, Morin, Gravel, & Lemieux (2010) examined physiotherapy outcomes among 57 women with SUI. Using a standardized 20-minute pad test, a pad weight gain of $<2\text{g}$ defined treatment success: forty-two of the 57 women met this definition of successful treatment outcome. In a multivariate logistic regression model, Dumoulin et al. (2010) use dynamometric outcomes including passive force generated during lengthening of the PFM and paravaginal tissues, maximum voluntary contraction (MVC) force generated by voluntary contraction of the PFM, rate of force development during a PFM MVC, and PFM endurance—estimated by the area under a force-time curve during a 90-second maximal effort contraction. They found low pre-treatment passive PFM forces and high pre-treatment PFM endurance were predictive of successful PFM training outcomes in the treatment of SUI. However, this model accounted for only 23% (Cox and Snell R^2) and 34% (Nagelkerke R^2) of

the variance in these data, again indicating that other significant variables may not have been considered.

More recently, Dumoulin and colleagues (Dumoulin et al., 2017) created a predictive model of PFM training success using a sample of 40 women with SUI or MUI who were 60 years and older. In their modelling a cure was defined as a combined score of a 50% post-treatment reduction in both the mean number of UI episodes in a 3-day bladder diary and Incontinence Impact Questionnaire (IIQ) score (Shumaker, Wyman, Uebersax, McClish, & Fantl, 1994; Van der Vaart, De Leeuw, Roovers, & Heintz, 2003). Using this definition, twenty-five of the 40 women were deemed improved after completing a 12-week physiotherapy intervention. Using magnetic resonance imaging (MRI) to gather several ($n = 8$) morphometric measures of the female pelvic floor, Dumoulin et al. (2017) found two strong predictors of treatment success: height of the urethrovesical junction at rest and urethrovesical junction approximation on straining. These two predictors accounted for 42% (Cox and Snell R^2) and 58% (Nagelkerke R^2) of the variance in the model. Using a ROC curve, Dumoulin et al. (2017) determined a cut-off of 11.4mm in the resting urethrovesical height suggesting that women who are most likely to benefit from a physiotherapy intervention for SUI treatment had resting urethrovesical heights higher than the cut-off.

Currently available models predicting the success or failure of physiotherapy outcomes among women with SUI are summarized in Table 2.2.1. Three of the four studies used retrospective data, presumably to attempt to create a database large enough to support multiple predictors. Moreover, each study used a different definition of success with PFM training. All studies used multivariate logistic regression models, but two of these model were based on small sample sizes (e.g. 50 women) and large numbers of predictors (e.g. 7 predictors), which may

have led to model over-specification (Babyak, 2004). None of these models were further validated using statistical verification techniques or new datasets, which leaves a gap in our confidence that the model will fit a new sample. Studies to date have focused on demographic and clinical data or have used specialized data (e.g. dynamometry and MRI) that are not available in most settings. If morphologic data can be acquired using ultrasound imaging as opposed to MRI, a predictive model using a combination of demographic and clinical data in conjunction with relevant ultrasound features has the potential to generate a more complete and robust model of success with PFM training.

Table 2.2.1. Summary of the variables found to contribute significantly to the prediction of success or failure with physiotherapy to treat women with SUI.

Authors	Year	n	Predictors included in final model	OR	<i>p</i> values
Truijen, Wyndaele & Weyler	2001	104	BMI	1.14	.04
			Urethral hypermobility	2.54	.00
			Previous pelvic surgery	7.99	.01
			Right Levator strength	1.47	.09
			Left Levator strength	1.57	.06
Cammu, Van Bylen, Blockeel, Kaufman & Amy	2004	447	Leakages prior to treatment	.65	.00
			Chronic use of psychometric medications	.42	.00
			Positive stress test result at cough	.63	.04
			Pre-treatment PFM passive force	.50	.00
Dumoulin, Bourbonnais, Morin, Gravel & Lemieux	2010	57	Pre-treatment PFM endurance	1.02	.02
			Height of UV junction at rest	1.35	.01
Dumoulin, Tang, Pontbriand-Drolet, Madill & Morin	2017	40	UV approximation on straining	1.26	.08

*Note. Body mass index (BMI); odds ratio (OR); urethrovesical (UV); bolded values denote significance at the $p \leq .05$; shaded rows denote models predicting failure with physiotherapy intervention among women with SUI.

2.5 CONCLUSION

The female continence mechanism appears to rely on redundancy, such that women are well protected against the involuntary leakage of urine. Damage to the continence mechanisms does appear to occur, however, and multiple, concurrent failures related to trauma, age, and lifestyle factors may be responsible for the development of SUI symptoms. The limited information available on which to base treatment decisions can result in access to care being time-consuming and expensive. Developing a predictive model of successful outcomes of physiotherapist-supervised PFM training among women with SUI may help to create a more efficient treatment pathway for women. This may help both women and the healthcare system to save time and money by directing women who are most likely to benefit from a physiotherapy intervention right to physiotherapy and directing those who are least likely to benefit away from physiotherapy in favour of other potential treatments. The study presented in this thesis will move us toward our ultimate goal of predicting which women are best suited to physiotherapy as an intervention for SUI.

CHAPTER 3: METHODS

3.1 ETHICS

Research ethics board approval was received from the University of Ottawa (Appendix A), Queen's University (Appendix B), The Ottawa Hospital (Appendix C), The Monfort Hospital (Appendix D), and the University of Calgary prior to initiating recruitment at each site. Data collection for this study was embedded in a randomized controlled trial (RCT) investigating the effects of perioperative physiotherapist-supervised PFM training on surgical outcomes for

women with SUI. In addition, women were recruited specifically to participate in PFM training for the purposes of this study.

3.2 PARTICIPANTS

Women over the age of 18 (both nulliparous and parous) who reported symptoms of SUI and were on a surgical waitlist for a mid-urethral sling procedure (transvaginal tape [TVT] or transvaginal tape obturator approach [TVT-O]), or beginning physiotherapy treatment for SUI were recruited from the Kingston General Hospital, the Ottawa Hospital, the Montfort Hospital, the Foothills Hospital in Calgary, and local physiotherapy clinics in Ottawa and Kingston, ON. All volunteers were provided with a study flyer by their surgeon/physiotherapist and provided consent to be contacted by study staff. Those who agreed to be contacted were screened for eligibility over the telephone. Women were accepted into the study if they had predominant symptoms of SUI, with or without urge incontinence and nocturia. Women were excluded from the study if they had fecal incontinence, were on medications known to increase or relieve incontinence (Morrison et al., 2002), had neurological impairments involving the central nervous system or sacral nerves (Nickell & Boone, 1996), had connective tissue disorders (Norton, 1993), had known detrusor muscle instability (Jung et al., 1999) or had undergone previous surgery to alleviate SUI. Women were also excluded if they had known pelvic organ prolapse greater than POP-Q stage II (Persu, Chapple, Cauni, Gutue, & Geavlete, 2011), due to the difficulty of visualizing the necessary landmarks and their motion for ultrasound image analysis. Moreover, women with prolapse are more likely to require a surgery that may be more extensive than a mid-urethral sling insertion, which was a requirement of the RCT.

3.3 PROCEDURES

Women who were deemed eligible through telephone screening (Appendix E) and who agreed to participate in the study were mailed or e-mailed copies of the study information, consent form (Appendix F), a demographic and medical history questionnaire (Appendix G), a 3-day bladder diary (Appendix H), the International Consultation on Incontinence Modular Questionnaire (ICIQ-FLUTS; Abrams, Avery, Gardener, & Donovan, 2006), and the SF-36 Health Related Quality of Life Questionnaire (Shumaker et al., 1994). Women received instruction by phone from the study recruitment officer regarding the completion of the bladder diary and questionnaires. Women were asked to bring all of the completed questionnaires with them to their baseline assessment scheduled by the recruitment officer at a predetermined location (e.g. Pelvic Floor Laboratory at Queen's University in Kingston, the Shirley Greenberg Women's Health Center at the Ottawa Hospital, the Motor Function Measurement Lab on Lees Campus of the University of Ottawa, or EFW Radiology in Calgary, Alberta).

On arrival at the baseline assessment, after the participant provided informed consent, a second eligibility screening was completed. Eligibility at this visit depended on three criteria: review and scoring of the 3-day bladder diary, amount of urine leakage on a standardized pad test, and a physical assessment. The physiotherapist first reviewed the 3-day bladder diary in which participants recorded the frequency of voiding, the number of urine leakage episodes, and the events surrounding the leakage episodes in order to determine the severity of incontinence (Richter et al., 2005). The bladder diary is a reliable tool for recording urine leakage episodes (Wyman, Choi, Harkins, Wilson, & Fantl, 1988) and reduces recall bias when reporting these occurrences (Verbrugge, 1980). If there was no reported urine leakage in the diary then women were thanked for their participation and withdrawn from the study. Otherwise, the number of

leakage episodes attributed to stress events, urge events, and unknown events, as well as the estimated volume of leakage (small, moderate, large) were recorded.

Women who remained eligible based on the bladder diary outcome were asked to complete a standardized 30-minute pad test. The pad test is highly sensitive and specific to the diagnosis of UI (Krhut et al., 2016). In preparation for this test, participants were asked to empty their bladder two hours prior to their scheduled baseline assessment and then drink 500mL of water. Women were also asked to avoid more than one caffeinated beverage on the day of their appointment. The study physiotherapist used trans-abdominal ultrasound imaging to estimate bladder volume and to ensure that it was between 300-500mL(Krhut et al., 2016); upon confirmation that their bladder volume was within this range women completed the pad test under the guidance of the study physiotherapist. Women whose bladder volumes were under 300mL were asked to drink 350mL of water and to wait 30 minutes. Bladder volume was measured again and once it was within the predetermined range they began the pad test. The study physiotherapist provided women with a pre-weighed incontinence pad to attach to their undergarments. Women then completed a standardized activity circuit: 15 sit-to-stands, 10 vigorous coughs, 15 jumping jacks, running on the spot for 1 minute, bending at the waist to pick up a small object 10 times, washing their hands in running water for 1 minute, and walking/climbing up one flight of stairs and down one flight of stairs. Women were then asked to remove the pad, to empty their bladders in the nearby washroom facilities and to return the pad to the physiotherapist to be re-weighed. If the pad weight gain was less than 2g the participant was excluded, but if the pad weight gain was greater than or equal to 2g, this was considered a secondary confirmation of urine leakage and the participant continued in the study.

Women who remained eligible after the pad test next underwent a pelvic floor muscle examination performed by the study physiotherapist. The assessment included palpation to identify the presence of obvious pelvic masses, as well as sensory and reflex testing; women who displayed evidence of pelvic mass(es) or neurologic defects were thanked for their participation, withdrawn from the study, and advised to follow up their regular healthcare provider. No women were excluded based on these criteria. Women who remained eligible after the screening underwent an evaluation of their PFM strength and tone. PFM strength was assessed digitally using the Modified Oxford Scale (MOS), with scores ranging from 0 (*no trace of contraction*) to 5 (*strong muscle contraction*). The MOS has demonstrated strong validity and good test-retest reliability when performed by the same physiotherapist (Laycock & Jerwood, 2001). PFM tone was assessed digitally, using the -3 (*very hypotonic*) to +3 (*very hypertonic*) grading scale described by Reissing, Brown, Lord, Binik, & Khalifé (2005).

Next, women underwent a 2-dimensional (2-D) and 3-dimensional (3-D) ultrasound assessment of their pelvic structures using a GE Voluson-*i* ultrasound system (GE Healthcare, Canada). Women began in the lithotomy position and were told that urine or gas leakage during testing was normal and not to hold back if they felt it happening. Static transperineal ultrasound images of the urethra were collected using a mechanical sector endoprobe (7.5 MHz probe) with a view angle of 100 degrees in the sagittal plane and 360 degrees in the axial plane. The probe was covered with ultrasound gel, a condom was stretched over the probe, and more gel was applied over the condom. The entire length of the urethra was visualized in the mid-sagittal plane with the probe tip located at the external urethral meatus. Using the protocol described by McLean et al. (2013), three 3-D volume images of the urethra were obtained. Next a curvilinear probe (6.5-10MHz) was applied transperineally as described by Dietz, Shek, & Clarke (2005) to

record 3-D volumes of the levator hiatus. First, 2-D images were optimized in the mid-sagittal plane and then in 3-D mode, the imaging plane was optimized to visualize the levator hiatus before 3-D volumes of the levator hiatus were rendered. Rendered volumes of the levator hiatus were acquired with the PFMs at rest (relaxed), during three repetitions of a MVC—during which encouragement was provided and continued until there was no further elevation of the anorectal angle (ARA)—and during three repetitions of a maximal effort Valsalva maneuver (MVM)—during which encouragement was provided and continued until there was no further descent of the bladder neck, approximately 10s (Orejuela, Shek, & Dietz, 2012). Using the same 3-D curvilinear ultrasound transducer, 2-D video clips of the pelvic structures (keeping the bladder, urethra, anorectal angle, and pubic symphysis visible within the acquisition frame at all times wherever possible) were acquired in the mid-sagittal plane while women remained relaxed, and while they performed three repetitions of a MVM and three repetitions of a maximal effort cough.

Women then moved to a standing position with their knees slightly flexed. The ultrasound probe was held by the physiotherapist in a mid-sagittal orientation to acquire transperineal images again with the bladder, urethra, ARA, and pubic symphysis visible within the acquisition frame. Women were asked to complete three MVMs held over 10 seconds with continued verbal encouragement to relax the PFMs and to bear down further (participants were corrected if they contracted their PFMs), as well as to assess the position of the pelvic organs at rest and at maximal excursion. The mobility of the urethra and bladder were measured during coughing by asking women to perform three repetitions of a single-barrel maximum effort cough. This concluded the data acquisition session. The entire procedure took approximately 1.5 hours to complete and upon completion all participants received a PFM training handout to

take home (Appendix I). Women recruited into the RCT were then randomized to either the control group (home exercises only) or the physiotherapist-supervised PFM training group using a secure online computer-based randomization program. Participant randomization was stratified based on hospital site with permuted blocks of random size. The participants recruited from the physiotherapy clinics were not randomized and were recruited solely into the physiotherapy group. The study physiotherapist remained blinded to the group assignment of the participant at all assessment visits, but participant blinding was not possible. See Figure 3.1 for a summary of recruitment and participation statistics

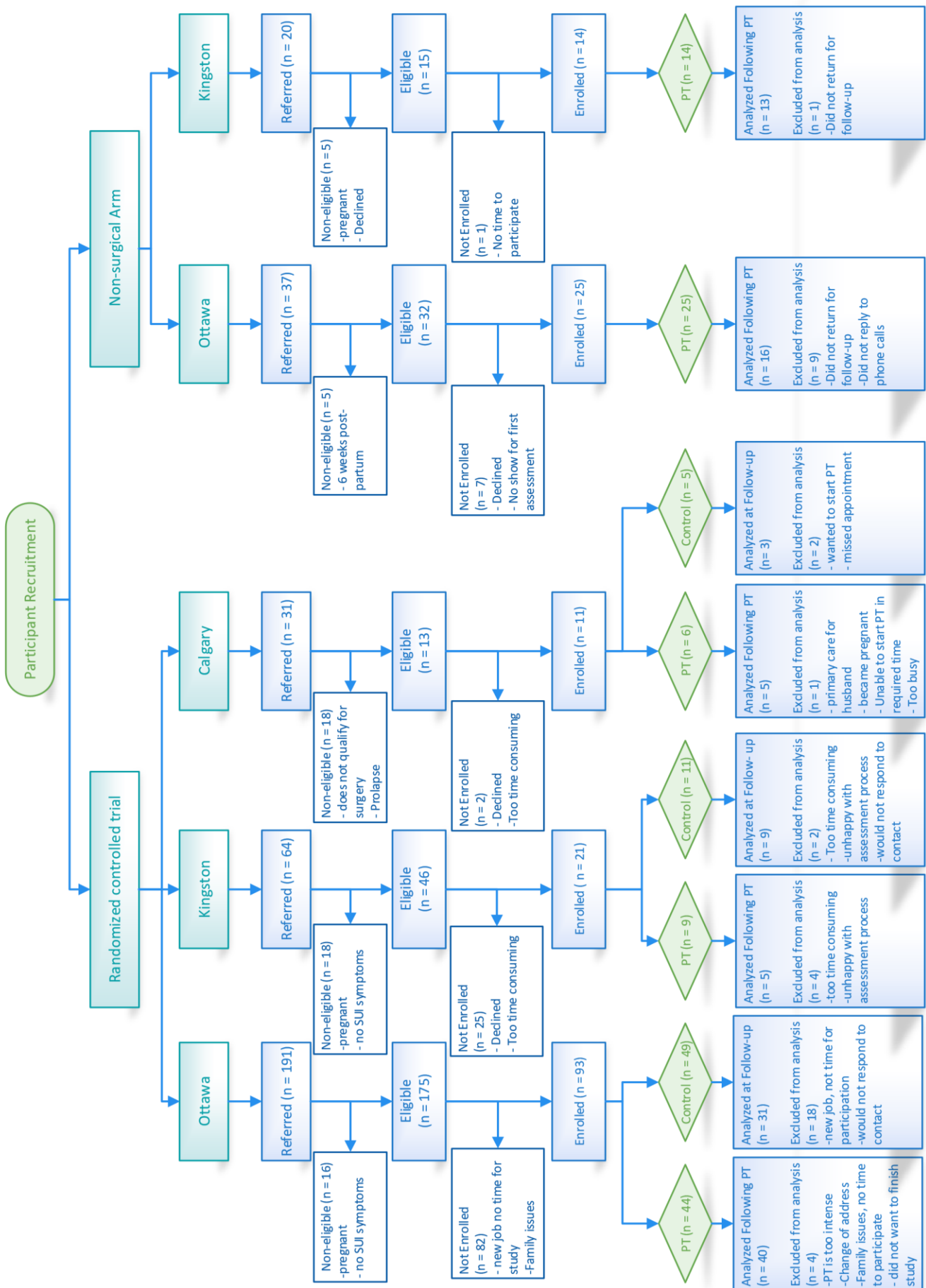


Figure 3.1. CONSORT flow diagram of full RCT study.

3.4 PHYSIOTHERAPY INTERVENTION

Women randomized to the physiotherapy group and those who were recruited specifically by the local physiotherapists to enter the physiotherapy cohort attended 6 physiotherapy sessions over a 12-week period: one session per week for the first three weeks, one session every two weeks for the next two weeks, and one session four weeks later. Treatment was provided by six local physiotherapists with post-graduate training in pelvic floor assessment and UI management. Women attended physiotherapy clinics based on geographic convenience to their home or work. On their first visit women learned to perform a proper PFM contraction using manual palpation and biofeedback to improve the quality of the contraction. Participants learned PFM training exercises including MVCs and “The Knack” in which they practiced contracting their PFMs before tasks that generate a rise in intra-abdominal pressure (e.g. a cough or postural perturbation; Miller, Ashton-Miller, & DeLancey, 1998). The physiotherapist advised women to complete a series of prescribed PFM exercises daily. The exercises included a minimum of three sets of 10 maximum effort voluntary PFM contractions followed by a complete relaxation after each contraction. The physical therapists prescribed other exercises deemed appropriate for the participant’s situation. At each subsequent session, the physiotherapist reviewed and reinforced a proper PFM contraction, assessed the participant’s PFM strength using the Modified Oxford Scale (Laycock & Jerwood, 2001), reviewed “The Knack” (Miller et al., 1998), provided performance feedback, and progressed the exercises according to a standardized protocol (Appendix J). Each physiotherapy session lasted 30 to 45 minutes. Within two weeks after completing the 12-week physiotherapy intervention, women

returned to the laboratory for a second evaluation using the same protocol as the baseline assessment.

3.5 OUTCOME VARIABLES

A cure with PFM training was defined as a pad weight gain of less than 2g during the standardized pad test (Dumoulin et al., 2010) and three or fewer leakage episodes reported in the 3-day bladder diary at the second assessment. Demographic variables of interest were factors known to place women at a higher risk for SUI, including age, parity, BMI, menopausal status, smoking status, hormonal contraception use, hormonal replacement for menopause symptoms use, whether or not women has had a hysterectomy, and SUI severity as determined through the pad test and the ICIQ-FLUTS. Clinical variables of interest included baseline PFM strength and baseline PFM tone.

3.6 ULTRASOUND IMAGE PROCESSING

Ultrasound image and video analyses were performed offline using ImageJ (NIH, Bethesda) and volume analyses were performed offline using 4D View® software (GE Healthcare, Canada). All image and volume analyses were performed by research assistants blinded to clinical data and information about group assignment or visit number. For all outcomes, the median value recorded from the three trials of each task was retained for analysis.

3.6.1 LEVATOR HIATUS MEASURES

Levator hiatus outcomes were generated following the protocol described by Dietz et al. (2005). The area and circumference of the levator hiatus was defined by the region bordered by the pubic symphysis, the inferior pubic rami, and the pubovisceral muscle (See Figure 3.2).

Levator ani muscle thickness was measured at two locations on both the left and right sides as per Dietz et al. (2005) and averaged.

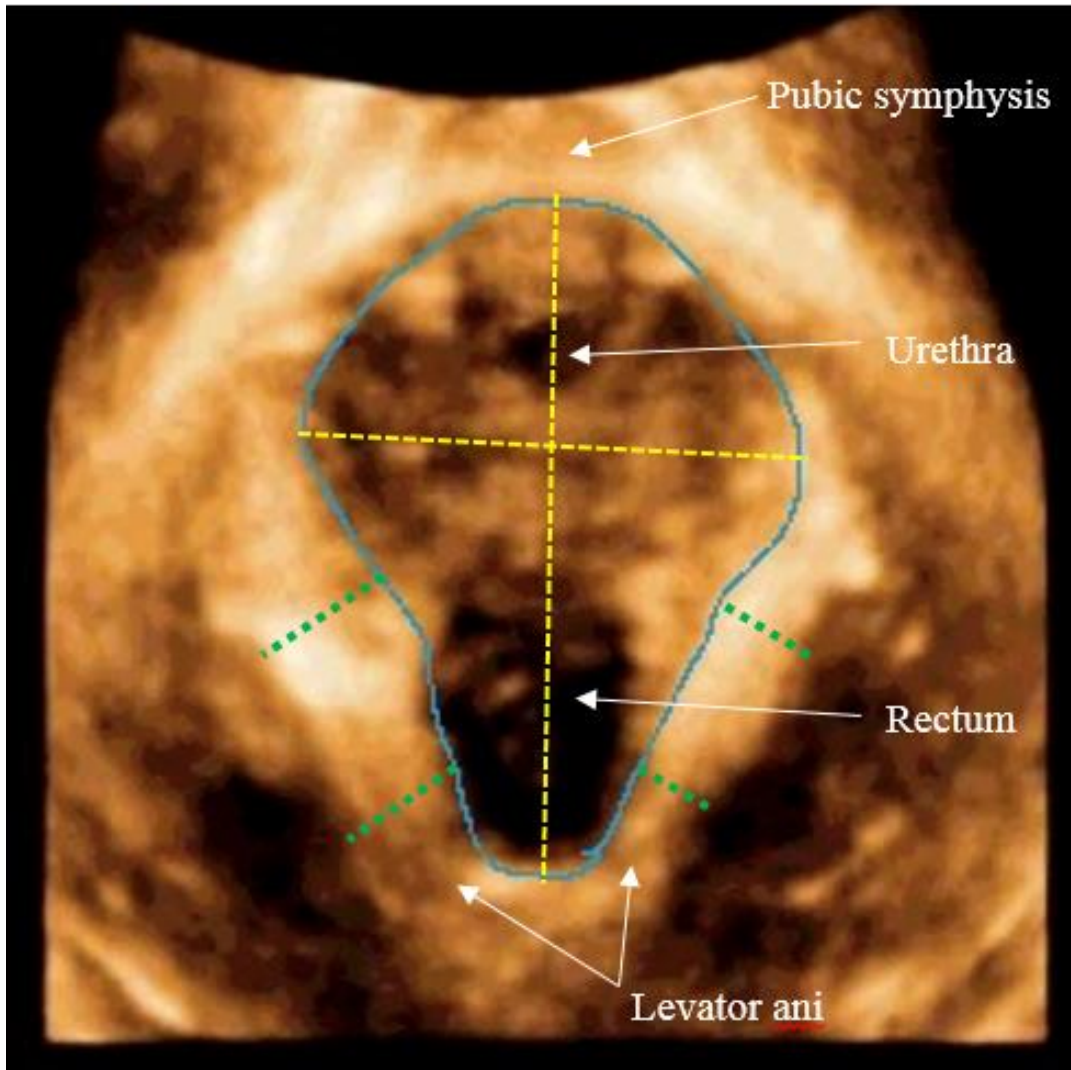


Figure 3.2 Levator Hiatus rendered in 4D View@; blue line denotes the measure of area and circumference; green dashes denote the measures of muscle thickness; yellow dashes denote the anteroposterior and mediolateral diameters.

3.6.2 LEVATOR PLATE LENGTH

Sagittal plane cineloops in both supine and standing were used to analyze the levator plate length (LPL) at rest, peak length on maximal effort cough and Valsalva, and minimum length on MVC, as well as the amount of change in LPL during the three tasks. Research assistants measured the LPL from the most infero-posterior point on the pubic symphysis to the apex of the ARA following protocols described by Majida et al. (2009; See Figure 3.3). Changes in LPL were determined as changes from the initial resting position to the peak excursion of the ARA on MVC, MVM, and cough on all three trials.

3.6.3 BLADDER NECK NET DISPLACEMENT

Bladder neck resting position and excursion during cough, MVC, and MVM were measured following the protocols described by Dietz (2004), such that the x and y coordinates of the most anterior point of the bladder neck were determined at rest and at the point of maximal excursion of each of the three trials of each task. The net excursion was calculated as a vectorless measure (Dietz, 2004; Majida et al., 2009).

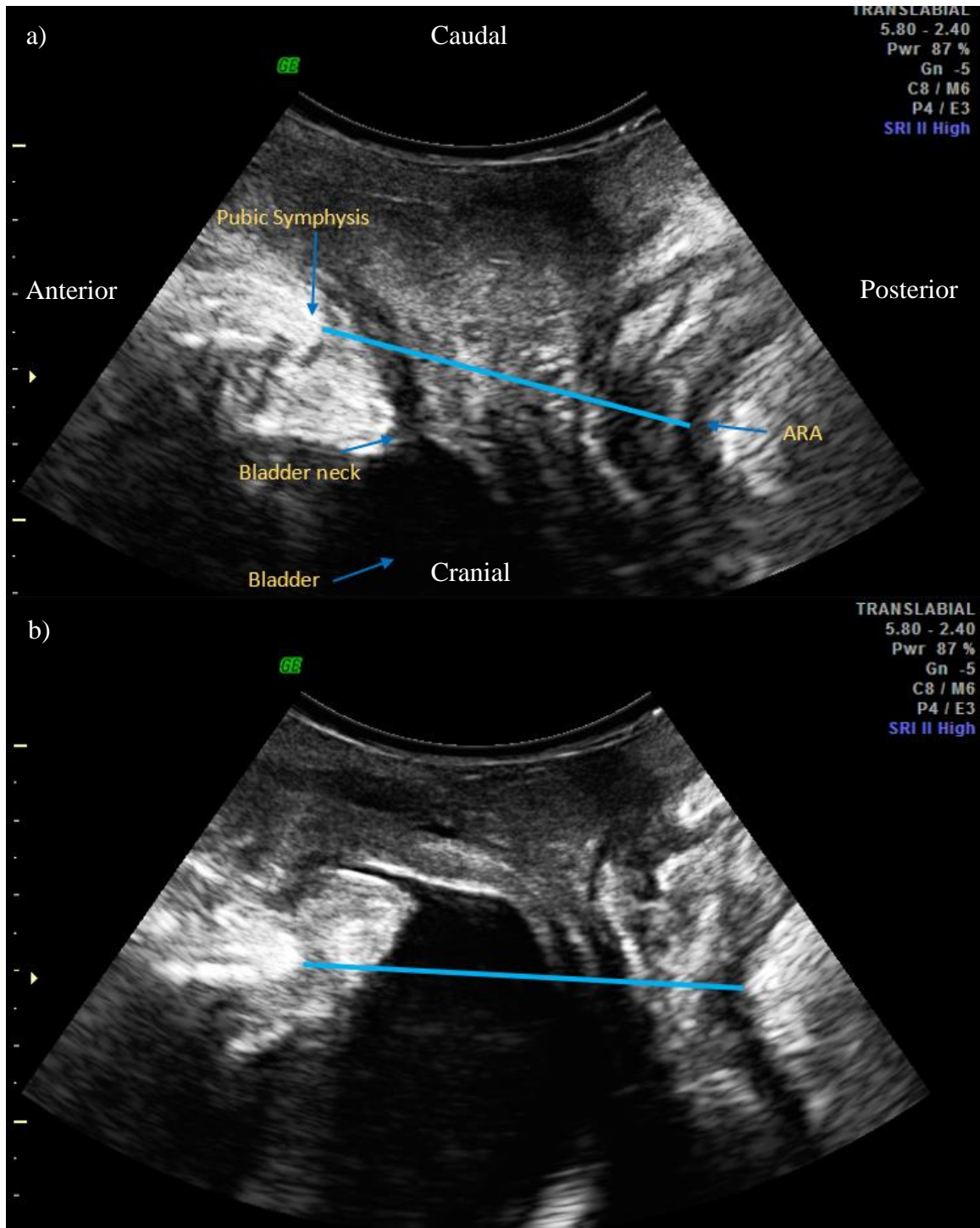


Figure 3.3. LPL measured in ImageJ while PFMs are a) rest and b) at peak MVM in standing; blue line denotes the LPL.

3.6.4 BLADDER NECK POSITION AT REST AND DESCENT RELATIVE TO THE LEVATOR PLATE

Bladder neck position at rest and descent of the bladder neck during each task were measured by calculating the length of a perpendicular line drawn from the anterior wall of the urethra at the point where it meets the bladder to the levator plate line, drawn from the most infero-posterior point on pubic symphysis to the most acute point of the ARA (see Figure 3.4). The change in bladder neck height was measured from the initial position to the point of maximal rise or descent during each of the three tasks (cough, MVC, MVM; Dietz, 2004; Dietz et al., 2005; Shek & Dietz, 2008). Bladder neck position was recorded as positive if it was above the levator plate line and negative if it was below it.

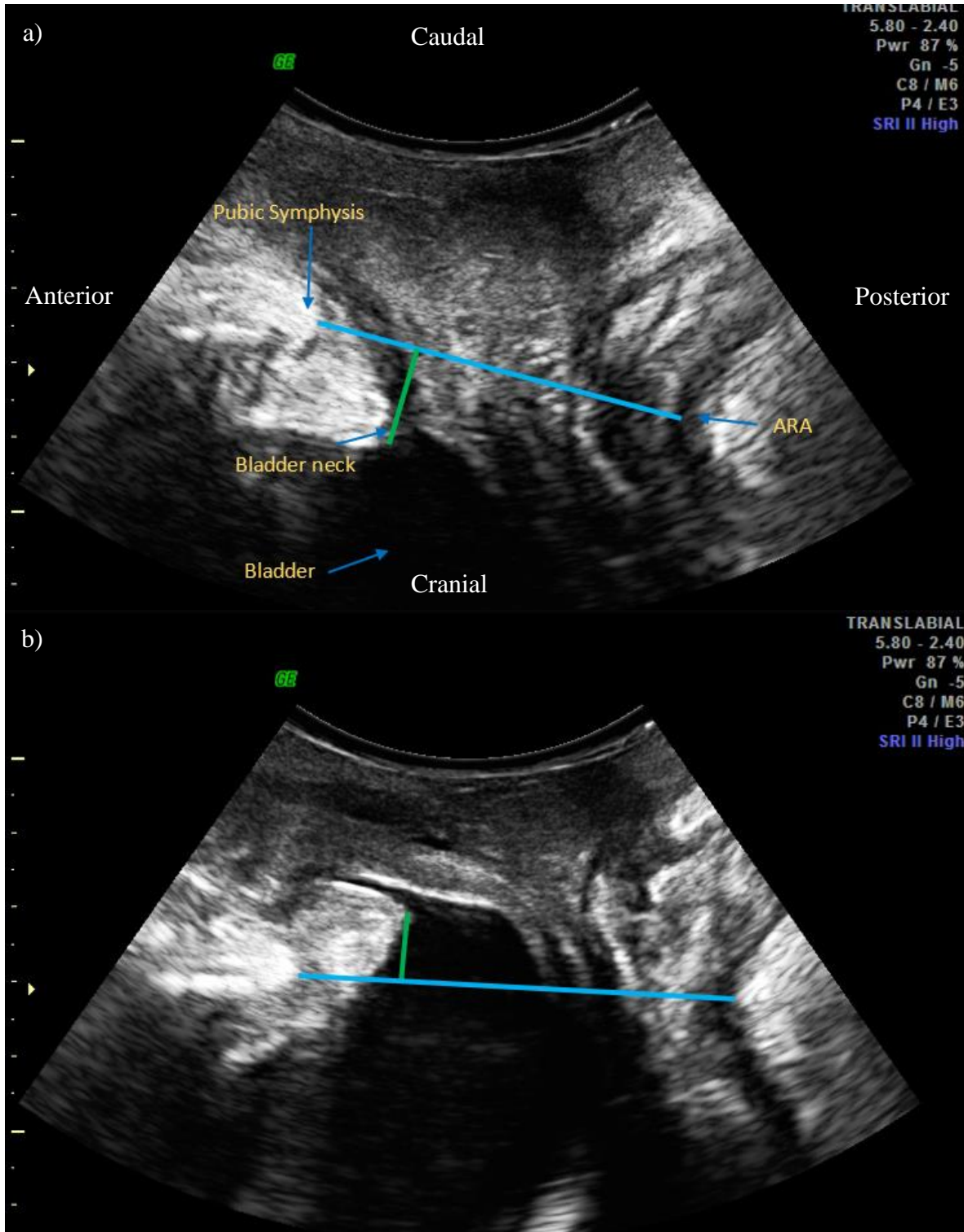


Figure 3.4. Bladder neck height relative to the levator plate in ImageJ a) at rest and b) at peak MVM in standing. The blue line denotes the levator plate and the green line denotes the height of the bladder neck.

3.6.5 URETHRAL CROSS-SECTIONAL AREA

Urethral cross-sectional area was measured following protocols previously described by McLean et al. (2013) and Toozs-Hobson, Khullar, & Cardozo (2001). The length of the urethra was identified by points marked at the bladder neck and the external meatus. Based on the total urethral length, the mid-point of the urethra was identified and a tomographic slice of the urethra was used to measure the cross-sectional area. Care was taken to rotate the sagittal plane image to ensure that the cross-sectional area was computed perpendicular to the path of the urethra in the sagittal and axial planes. The cross-sectional area of the urethral wall (including the external urethral sphincter) was determined by subtracting the area bordered by the hypoechoic longitudinal smooth muscle of the urethra from the external border of the hyperechoic urethral wall (See Figure 3.5).

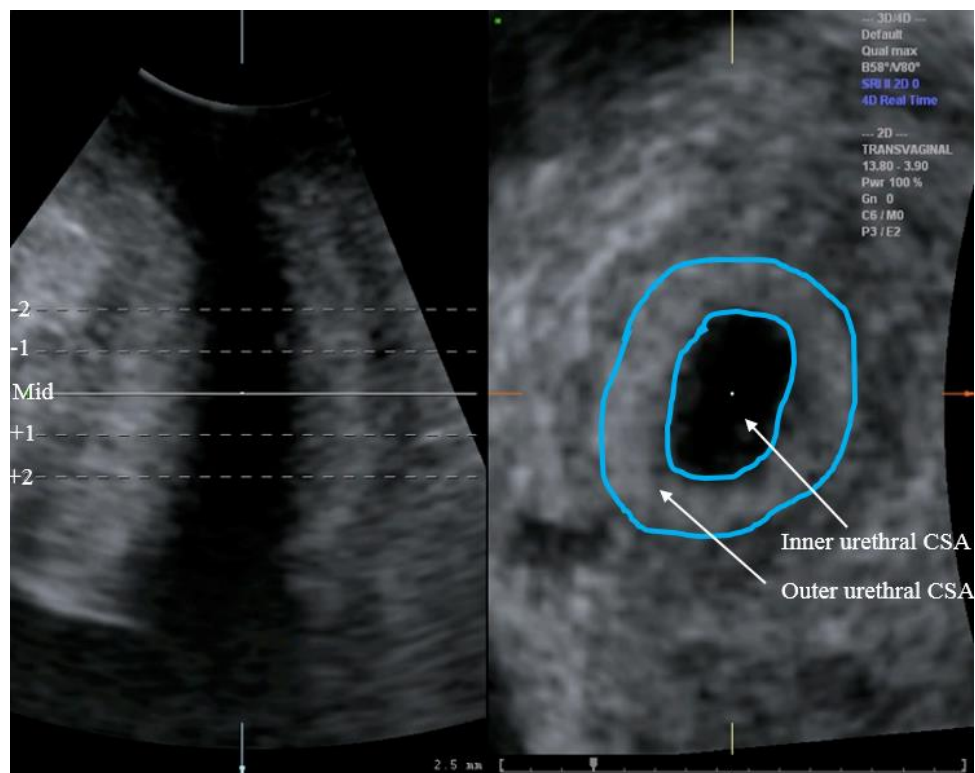


Figure 3.5. Urethral wall cross-sectional area (CSA) in 4D View®.

3.7 DATA ANALYSIS

All statistical analyses were conducted using SPSS version 21. For the predictive model, generated using demographic and clinical data, all variables were tested for normality using the Kolmogorov-Smirnov test. Group differences (i.e. cured vs not cured with physiotherapy intervention) were tested using univariate *t*-tests when the data were normally distributed and using the Mann-Whitney-U test when they were not. Group differences in categorical data were tested using Chi-Square analyses and Fisher's Exact test. These tests were used a-priori to statistical modeling to determine which outcomes would be entered as potential predictors of the dependent variable (e.g. response to treatment). Variables with a p-value of .05 or smaller were entered into the model. The remaining predictors were screened for linearity of the logit and multicollinearity to further refine the model. Variables that did not demonstrate linearity of the logit and variables with multicollinearity were removed, keeping only the ones with the strongest capacity to predict group differences. The model was tested for goodness of fit with the Hosmer-Lemeshow goodness-of-fit test and the overall model was assessed for statistical significance using a Global Likelihood Ratio test. Variables that did not significantly add to the variance accounted for by the model were removed from the model. The revised model was considered exploratory and bootstrap validation based on 1000 samples with replacement was used to assess and correct for model optimism (Steyerberg et al., 2001). Odds ratios were used to describe the independent associations of each predictor and the outcome. The diagnostic ability of the model was assessed using the ROC curve by plotting the sensitivity against the specificity for increasing model probabilities of treatment success (Hanley & McNeil, 1982).

To evaluate the potential predictive capacity of morphological variables derived from the ultrasound image data, a sub-set of data for each ultrasound image outcome was generated and

tested for normality using the Shapiro-Wilk test, as the majority of samples contained 50 or fewer women at the time that this thesis was written. Depending on the data distribution, either a univariate t -test or a Mann-Whitney U test was used to investigate the differences between women with SUI who were cured with a physiotherapy intervention and those who were not. Significance levels were set at $\alpha \leq .05$, yet variables that were trending towards significance ($p \leq .10$) were also identified as being of potential value in the future model. Significance level adjustments were not used to correct for Type I error as this was an exploratory analysis of group differences and any variable that demonstrated a trend towards differing between the women who were deemed to be cured with physiotherapy and those who were not cured may be of value in future modeling.

CHAPTER 4: RESULTS

Ninety-eight women with a mean age of 50 years completed the study. Nineteen datasets were excluded from the analysis because of missing data (i.e. if a participant did not complete the questionnaire and/or participant did not complete the follow-up assessment; Figure 3.1). Of the 79 women with complete datasets, 27 women met the cure criteria and 52 women did not meet cure criteria for this study. See Table 4.1 for demographic characteristics.

Table 4.1. Demographic characteristics of women with SUI at baseline (n = 79).

Demographics	Mean ± SD
Age (years)	50 ± 10
BMI (kg/m ²)	27.78 ± 6.21
Parity	2 ± 1
Baseline Pad Test (g)	20.69 ± 19.69
Baseline 3-Day Bladder Diary (leakage episodes attributed to stress)	8 ± 6
Baseline ICIQ-FLUTS UI Subscale (scores from 0 – 20)	10 ± 4
Baseline PFM Strength (scale from 0 – 5)	3 ± 1
Baseline tone (scale from -3 to +3)	0 ± 1

*Note. Body mass index (BMI); urinary incontinence (UI); stress urinary incontinence (SUI); pelvic floor muscle (PFM); international consultation on incontinence modular questionnaire – female lower urinary tract symptoms (ICIQ-FLUTS).

4.1 PREDICTIVE MODELING WITH DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

The analyses revealed significant univariate differences ($p \leq .05$) between women who were considered cured and those not cured for the following variables: baseline ICIQ-FLUTS UI subscale score, baseline pad test, parity, and baseline PFM tone (Table 4.2 and Table 4.3).

Women who were cured had lower scores on the ICIQ-FLUTS UI subscale, had smaller amounts

of urine leakage on the pad test, and had had fewer babies than women who were not cured.

Although PFM tone was considered significantly different between the groups, both groups had similar median tone. Women who were cured with PFM training tended ($p = .09$) to have stronger PFMs at baseline when assessed through manual palpation.

Table 4.2. Univariate analyses of potential demographic predictors of successful physiotherapy outcomes among women with SUI.

Potential Predictors with normal distribution	Mean \pm SD				<i>Student-t</i>	<i>p</i>
	n	Cured	n	Not Cured		
Age (years)	26	49 \pm 10	52	51 \pm 10	-.75	.46
Baseline ICIQ-FLUTS UI Subscale (scores from 0-20)	27	8 \pm 4	52	11 \pm 3	-3.03	.00
Potential Predictors with non-normal distribution	Median (Interquartile Range)				Mann-Whitney U	<i>p</i>
	n	Cured	n	Not Cured		
Parity	27	2 (2)	52	2 (1)	498	.03
BMI (kg/m ²)	27	27.13 (9.46)	52	26.53 (6.70)	683	.84
Birthweight of heaviest child delivered vaginally (kg)	21	3.50 (1.00)	47	4.0 (1.50)	405	.22
Number of vaginal deliveries	16	2 (0)	45	2 (1)	272.5	.12
Number of C-sections	7	1 (1)	3	2 (0)	6.50	.31
Use of vacuum during delivery	2	1 (0)	4	1 (0.75)	3.00	.48
Baseline Pad Test (g)	27	4.00 (9.78)	52	27.62 (29.99)	277	.00
Baseline PFM Strength (scale from 0 – 5)	27	4 (1)	52	3 (1)	550	.09
Baseline PFM Tone (scale from -3 to +3)	27	1 (1)	52	0 (1)	498	.03
Baseline ICIQ-FLUTS Filling Subscale (scale from 0 – 16)	27	3 (3)	52	4 (3)	611.50	.34
Baseline ICIQ-FLUTS Voiding Subscale (scale from 0 – 12)	27	1 (3)	52	2 (3)	671	.74

*Note. The shaded area denotes parametric testing and the white area denotes non-parametric testing; body mass index (BMI); pelvic floor muscle (PFM); international consultation on incontinence modular questionnaire – female lower urinary tract symptoms (ICIQ-FLUTS).

Table 4.3. Potential categorical predictors of successful physiotherapy outcomes among women with SUI.

Categorical Predictors		Frequencies		Totals	χ^2 values	<i>p</i>
		Cured	Not Cured			
Menopause	Yes	12 (15.2%)	27 (34.2%)	39 (49.4%)	.40	.53
	No	15 (19%)	25 (31.6%)	40 (50.6%)		
Use of forceps during delivery	Yes	2 (7.4%)	4 (7.7%)	6 (7.6%)	.02	.96
	No	25 (31.6%)	48 (60.8%)	73 (92.4%)		
Smoking	Yes	2 (2.5%)	7 (8.9%)	9 (11.4%)	.65	.42
	No	25 (31.6%)	45 (57%)	70 (88.6%)		
Hormonal Contraception*	Yes	3 (7.5%)	6 (15%)	9 (22.5%)	.09	.77
	No	12 (30%)	19 (47.2%)	31 (77.5%)		
Hormone Replacement to Treat Menopausal Symptoms*	Yes	1 (2.6%)	6 (15.4%)	7 (17.9%)	1.09	.30
	No	11 (28.8%)	21 (53.8%)	32 (82.1%)		
Hysterectomy Y(N)	Yes	3 (3.8%)	6 (7.6%)	9 (11.4%)	.00	.96
	No	24 (30.4%)	46 (58.2%)	70 (88.6%)		

*Note. Women using hormonal contraception were pre-menopausal and were not included among the women using hormone replacement to treat menopausal symptoms; number of women (percent of total).

Based on the univariate analyses, five variables were included in the main multivariate logistic regression model: ICIQ-FLUTS UI subscale scores (SUI severity), parity, PFM strength, and PFM tone. All demonstrated significant differences on the univariate analyses except for PFM strength, which demonstrated a trend ($p = .09$), yet this variable was retained based on Truijen et al. (2001) who found that pre-treatment PFM strength was a significant predictor in the success of PFM training to cure SUI.

These predictors were tested for linearity of the logit and multicollinearity. Baseline pad test scores violated the assumption of linearity of the logit, therefore, it was removed and severity of SUI at baseline was represented by the ICIQ-FLUTS UI subscale only. The multivariate logistic regression model was significant ($p < .001$) with two predictors: baseline ICIQ-FLUTS UI (SUI severity) and parity; accounting for 14.8% (Cox & Snell R^2) and 20.4% (Nagelkerke R^2) of the outcome variability. Interactions between predictors were tested but were

not found to be significant. The predictive model accurately classified 72.2% of the women in this study as either cured or not cured; only 22 women were misclassified. The Hosmer and Lemeshow Goodness-of-fit test ($\chi^2 = 3.10, df = 8, p = .93$) indicated that the model fit the data well and the Global Likelihood Ratio indicated a model that is sometimes useful (+LR = 2.51, -LR = 0.45). Baseline tone (Block $\chi^2 = 2.97, df = 1, p = .09$) and baseline strength (Block $\chi^2 = .04, df = 1, p = .85$) were removed from the model due to poor contribution to model fit. With the two remaining predictors, the model was bootstrapped based on 1000 samples with replacement to correct for model optimism. Baseline ICIQ-FLUTS UI for SUI severity ($p = .01$) was a significantly stronger predictor based on the bootstrapped samples, such that women with SUI who had lower scores were more likely to be cured by the physiotherapy intervention. Parity ($p = .06$) was close to significance and indicated that women with SUI who had given birth to fewer children were more likely to be cured by the physiotherapy intervention. Table 4.4 displays the regression coefficients, odds ratios, and confidence intervals for this model.

Table 4.4. Odds ratios and confidence intervals of demographic and clinical predictors of physiotherapy outcomes among women with SUI.

Predictors	B	OR	95% Confidence Intervals		<i>p</i>
			Lower	Upper	
Constant	2.16	8.65			.02
Baseline ICIQ-FLUTS UI (scored 0 – 20)	-.21	.81	.69	.95	.00
Parity	-.41	.67	.43	1.02	.06

*Note. Odds ratio (OR); bolded values are significant ($p \leq .05$); international consultation on incontinence modular questionnaire – female lower urinary tract symptoms (ICIQ-FLUTS).

The diagnostic ability of the significant predictor, ICIQ-FLUTS UI subscale, was assessed using an ROC curve. The area under the curve for baseline ICIQ-FLUTS UI (SUI severity) was $.69 \pm .07$ (95% CI: .56-.82; $p < .01$) as shown in Figure 4.1. A cut-off point of 7.50 predicts physiotherapy intervention outcomes with 55.6% sensitivity and 80.8% specificity, such

that women with SUI who have a score of 7.50 or less on the ICIQ-FLUTS UI subscale are most likely to respond to a physiotherapy intervention.

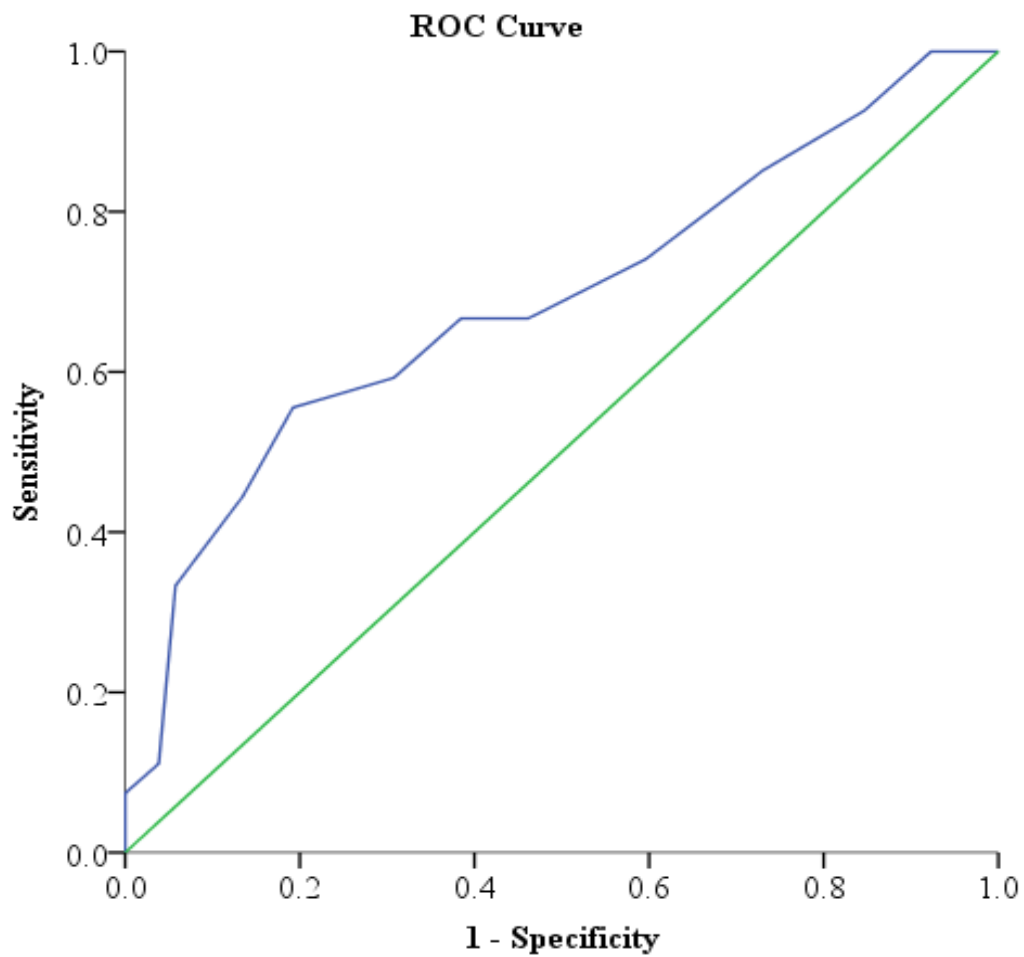


Figure 4.1. Receiver operating characteristic (ROC) curve for baseline ICIQ-FLUTS UI as a predictor of physiotherapy intervention among women with SUI.

4.2 MORPHOLOGICAL CHARACTERISTICS DERIVED THROUGH ULTRASOUND IMAGING

The subset analyses revealed significant differences between women with SUI who were cured with the physiotherapy intervention and those who were not cured based on five outcomes: the height of the bladder neck at the peak of a cough in standing ($p = .03$) and descent of the bladder neck during MVM in standing ($p = .04$); levator hiatus circumference in standing at rest ($p = .03$), in standing during MVC ($p = .01$), and in supine during MVC ($p = .03$). Women who were cured with the physiotherapy intervention were more likely to have a higher bladder position at the peak of a cough, more descent of the bladder neck while performing a MVM in standing, and smaller levator hiatus circumference in standing while at rest, and in both supine and standing during MVC. Four variables demonstrated trends toward being significantly different between groups: the height of the bladder neck at rest, LPL in standing when at the peak of a cough and when at the end of a MVM, as well as the cross-sectional area of the mid-urethra (Table 4.6 and Table 4.6). Women who were cured with the physiotherapy intervention tended to have a higher bladder neck height at rest in standing, had shorter LPLs at both the peak of a cough and the end of a MVM when performed in standing, and displayed larger cross-sectional area of their mid-urethral walls.

Table 4.5. Parametric analyses of potential morphological predictors of successful physiotherapy outcomes among women with SUI.

Outcome Measure	Position & Task	Mean \pm SD				<i>Student-t</i>	<i>p</i>
		n	Cured	n	Not Cured		
Change in BN Height (mm)	Supine Cough	13	10.58 \pm 6.36	37	11.13 \pm 5.28	-.31	.76
	Standing Cough	12	9.56 \pm 2.96	32	8.41 \pm 4.00	.91	.37
	Supine MVM	11	10.95 \pm 4.39	32	12.92 \pm 6.61	-.92	.36
	Standing MVM	9	10.26 \pm 3.96	30	6.33 \pm 5.28	2.16	.04

Height of BN	Supine Rest	19	20.75 ± 5.65	41	21.17 ± 5.30	-.28	.78
	Standing Rest	15	16.65 ± 6.31	36	13.70 ± 5.01	1.77	.08
	Supine Cough	17	10.42 ± 6.40	42	9.93 ± 4.52	.04	.74
LPL (mm)	Supine Rest	24	52.26 ± 7.51	46	52.25 ± 7.40	.01	.99
	Standing Rest	15	54.84 ± 8.20	38	55.79 ± 8.54	-.37	.71
	Supine Cough	18	49.93 ± 8.85	45	53.67 ± 9.81	-1.41	.16
	Standing Cough	18	53.24 ± 8.59	36	57.66 ± 8.46	-1.80	.08
	Supine MVC	19	44.52 ± 8.07	45	47.07 ± 7.60	-1.20	.23
	Supine MVM	16	50.71 ± 9.04	38	53.64 ± 9.67	-1.04	.31
	Standing MVM	14	56.25 ± 10.34	35	61.83 ± 9.35	-1.83	.08
BN Excursion (mm)	Supine Cough	14	12.35 ± 5.73	43	13.55 ± 5.56	-.70	.49
	Standing Cough	16	12.87 ± 12.21	37	11.61 ± 5.10	.53	.60
	Supine MVM	12	14.02 ± 4.57	40	14.46 ± 6.92	-.26	.80
	Standing MVM	13	12.56 ± 4.21	33	13.21 ± 5.55	-.38	.70
LH ML Thickness (mm)	Supine Rest	10	.78 ± .18	31	.79 ± .18	-.12	.90
LH Area (mm ²)	Standing Rest	10	16.37 ± 3.76	31	17.74 ± 4.84	-.82	.42
	Supine MVC	10	11.14 ± 3.41	32	12.61 ± 2.46	-1.50	.14
	Standing MVC	10	13.69 ± 3.11	30	15.74 ± 4.35	-1.37	.18
LH Circumference (mm)	Supine Rest	10	14.48 ± 2.07	31	15.18 ± 1.60	-1.12	.27
	Standing Rest	10	15.53 ± 1.59	31	16.93 ± 1.67	-2.32	.03
	Supine MVC	10	12.52 ± 1.78	32	13.99 ± 1.79	-2.27	.03
Urethral Length (mm)	Supine Rest	8	3.49 ± .67	31	3.36 ± .59	.55	.58
Urethral CSA (mm ²)	Supine Rest	8	1.33 ± .25	31	1.20 ± .17	1.82	.08

*Note. Samples sizes vary depending on ultrasound outcome measure as not all data are processed at this time; bladder neck (BN); levator plate length (LPL); levator hiatus (LH); medio-lateral (ML); maximal Valsalva maneuver (MVM); maximal voluntary contraction (MVC); cross-sectional area (CSA); bolded values denote significant results or those that are close to significance.

Table 4.6. Non-parametric analyses of morphological predictors of successful physiotherapy outcomes among women with SUI.

Outcome Measure	Position & Task	Median (Interquartile Range)				Mann-Whitney U	<i>p</i>
		n	Cured	n	Not Cured		
Change in BN Height (mm)	Supine MVC	12	3.45 (4.03)	40	2.19 (3.80)	207	.47
Height of BN (mm)	Standing Cough	12	9.57 (11.90)	32	4.51 (5.24)	111	.03
	Supine MVC	11	26.26 (14.74)	40	23.68 (11.20)	213	.87
	Supine MVM	13	10.94 (8.63)	35	5.87 (6.20)	163	.14
	Standing MVM	10	7.74 (2.66)	31	4.52 (5.73)	140	.65
BN Excursion (mm)	Supine MVC	11	5.76 (4.65)	40	4.39 (4.42)	198	.61
LH ML Thickness (mm)	Standing Rest	10	.78 (.18)	31	.83 (.28)	154	.98
	Supine MVC	10	.70 (.28)	32	.77 (.19)	154.5	.87
	Standing MVC	10	.81 (.28)	30	.79 (.21)	138	.71
LH Area (mm ²)	Supine Rest	10	12.49 (4.49)	31	13.85 (3.69)	131	.47
LH Circumference (mm)	Standing MVC	10	14.09 (2.91)	30	15.86 (2.16)	72	.01
Change in LPL (mm)	Supine Cough	18	3.02 (3.82)	45	2.57 (4.52)	375	.65
	Standing Cough	14	2.15 (2.49)	34	2.56 (3.83)	232	.89
	Supine MVC	22	6.26 (7.57)	46	5.26 (6.70)	391	.13
	Supine MVM	16	1.70 (2.68)	40	2.51 (5.38)	260.50	.28
	Standing MVM	11	3.43 (4.78)	34	4.67 (7.60)	180.50	.86

*Note. levator hiatus (LH); medio-lateral (ML); maximal Valsalva maneuver (MVM); maximal voluntary contraction (MVC); levator plate length (LPL); bolded values denote significant results or those that are close to significance.

CHAPTER 5: DISCUSSION

The first objective of this work was to determine whether demographic and/or clinical variables could be used to predict successful outcomes of physiotherapist-supervised PFM training for the management of SUI in women. Of the 79 complete datasets used in the predictive model, 27 women (34%) were deemed to have been cured through the intervention. One variable was identified as being predictive of cure with PFM training: severity of incontinence, as measured by the baseline ICIQ-FLUTS UI subscale. This variable was a strong predictor of physiotherapy treatment success, whereby women with lower scores on the ICIQ-FLUTS UI subscale—indicating lower symptom severity—benefitted the most from the PFM training intervention. Although parity was not a significant predictor of success with PFM training, there was a trend suggesting that women who had delivered fewer babies may be more likely to benefit from the physiotherapy intervention. This finding may be related to morphologic damage sustained during pregnancy and delivery.

Our second objective, was to analyze a subset of ultrasound images to date to determine which, if any, features of urogenital morphology or kinematics may be useful in the improvement of our capacity to predict which women with SUI are most likely to be cured with PFM training. Using univariate analyses, subsets of women who were cured with the physiotherapy intervention had a higher bladder neck position at the peak of a cough (i.e. their bladder neck did not descend as much during the cough), had more change in bladder neck position during MVM in standing (i.e. were able to generate bladder neck descent during bearing down maneuvers), had smaller levator hiatus circumferences at rest in standing (i.e. the levator hiatus was smaller when under gravitational load) and at peak MVC in both supine and standing (i.e. were able to voluntarily constrict the levator hiatus to a larger extent) compared to subsets of

women who were not cured. Other variables also showed trends towards being significantly different between subsets of women who succeeded with the physiotherapy intervention and subsets who did not. These included the height of the bladder neck relative to the levator plate line at rest, the length of the levator plate at peak cough in standing and at peak MVM in standing, and cross-sectional area of the mid-urethral wall. This analysis will help to guide further development of the predictive model, whereby we will next complete image analysis of these variables from our full dataset and use them to refine our predictive model of physiotherapy treatment success.

5.1 DEFINING CURE IN WOMEN WITH STRESS URINARY INCONTINENCE

With the relatively stringent cure definition used in this study, 27 out of 79 (34%) women were considered cured with the physiotherapy intervention. Past research evaluating the success of physiotherapy treatment among women with SUI has shown cure rates from 36% to 74% (Cammu et al., 2004; Dumoulin et al., 2010, 2014, 2017; Truijen et al., 2001). The cure rate among women with SUI in our study is lower than those previously reported, and may be attributed to two features of our experimental design: our definition of a cure with the PFM training intervention and the characteristics of our recruited sample.

First, we defined a cure through the physiotherapy intervention as women reporting three or fewer leakage incidents across a three-day bladder diary and no evidence of leakage on a standardized 30-minute pad test after treatment. This definition was selected to capture both subjective reports of SUI symptoms as well as an objective measure of severity recorded in the controlled environment of our laboratory. Combining the subjective and objective aspects of a cure provides a more robust definition (Abrams et al., 2010). However, subjective reports of cure may have biased our cure rate as SUI symptoms and the corresponding distress they may

cause are perceived differently among individuals (Perera et al., 2014; Shaw, 2001); some women may perceive any reduction in leakage amounts/episodes as a treatment success despite still suffering from frequent or large volumes of urine loss (Castro et al., 2008; Lagro-Janssen, Debruyne, Smits, & van Weel, 1991). Women had to satisfy both cure criteria in order to be considered cured, which is more stringent than other studies and may have resulted in a lower cure rate for our study. Specifically, women who subjectively reported more than three leakages in their bladder diary but showed no leakage on a standardized pad test would be considered not cured by our definition. If we had defined our cure using only one criterion, our cure rates would have been higher: based on the standardized pad test results, 40 out of 79 (51%) women would have been considered cured, and based on the bladder diary results, 48 out of 79 (61%) women would have been considered cured, both of which are more in line with the cure rates reported in the literature (See Table 5.7). Previous research has used a variety of definitions of cure based either on a subjective report (Cammu et al., 2004; Dumoulin et al., 2017) or observation (Dumoulin et al., 2010; Truijen et al., 2001), which are similar to those seen in this study when only one cure criterion was used. Including both an objective and subjective measure of a cure made it more difficult to detect women who were cured, but was done to ensure that false positives were minimized. We expect that this approach provided a more accurate estimate of the proportion of women with SUI who were cured with the physiotherapy intervention, yet further research is needed to standardize the definition of cure.

The population from which our sample of women was drawn may have resulted in a larger proportion of women with severe SUI in our sample relative to other studies. More than half of the women in our study (41 of 79) were recruited from surgical waitlists for mid-urethral sling insertions; women who, in collaboration with their surgeon, had decided that their SUI was

severe enough to choose to undergo this surgery despite the known risks. As such, the women in our sample likely had more severe and possibly more long-standing SUI, than the women who participated in other studies. Previous research on predicting success with PFM training has used samples recruited from outpatient clinics (Cammu et al., 2004), through community-based advertising (Dumoulin et al., 2017), and through referrals from gynecologists (Dumoulin et al., 2010), whereby women may have had less severe incontinence as they had not consulted with a surgeon. Based on the outcomes of our study, women who reported less severe SUI were more likely to be cured by the physiotherapy intervention; thus, the samples recruited into other studies may have been more likely to be cured by physiotherapy interventions. Furthermore, both studies by Dumoulin and colleagues focused on specific populations of women: women with persistent postpartum SUI (Dumoulin et al., 2010) and women over the age of 60 years with SUI (Dumoulin et al., 2017). These specific populations may have responded better to a physiotherapy intervention, may have had schedules that allowed them to adhere well to the prescribed treatment (i.e. due to maternity leave, retirement, etc.), and may have been more motivated to complete the physiotherapy treatment as they were self-selected volunteers; all of which may have resulted in higher cure rates. Women studied by Dumoulin et al. (2010) had higher amounts of urine leakage on a standardized pad test than the average amount of leakage seen in this study. However, this may be attributable to the sample of women recruited: women with persistent postpartum SUI were included if they were 45 years old or younger and if it had been three months or more since their delivery and yet they still displayed SUI symptoms that were not present before the delivery. These women may have been more likely to respond to a physiotherapy intervention as pudendal nerve damage is common during vaginal delivery and healing requires adequate time for re-innervation (Allen et al., 1991) and re-learning the ability

to properly contract their PFMs (Dumoulin et al., 2004). Motor learning may have been a key factor in the success of the physiotherapy treatment in this group of women, as their timeline (three months or more after delivery) may have positioned them at a point where re-innervation had occurred, which may have increased their chances of benefitting from PFM training to enhance motor learning and strength. The second study by Dumoulin et al. (2017) involved a sample of women aged 60 years or more and in comparison to the 3-day bladder diary outcomes reported by Dumoulin et al. (2017), our sample of women experienced more frequent urine leakage episodes. This may indicate that Dumoulin et al. (2017) recruited more women with mild to moderate SUI severity compared to our study. In line with the results from our study, whereby women with less severe SUI were more likely to be cured by the physiotherapy intervention, the sample of women recruited by Dumoulin et al. (2017) may have been more likely to benefit from the physiotherapy intervention, and may therefore have generated a higher cure rate. Due to the majority of our recruitment being through referrals from physicians or physiotherapists rather than self-selecting and volunteering to participate, it is not surprising that our cure rate was lower in comparison to the reported cure rates of previous predictive modeling studies. Further, our study supports the recommendation that physiotherapy in the form of PFM training be recommended as a first-line treatment for women with mild to moderate SUI symptoms (Dumoulin et al., 2014).

Table 5.7. Outcome criteria used by previous predictive modeling studies of success with PFM training among women with SUI.

Authors	Year	n	Baseline SUI Severity (% cure)	Cure Criteria	Cure (%)
Truijen et al.	2001	104	Presence of leakage during straining task (detailed information not provided)	Incontinence disappeared or the woman occasionally lost a few drops on straining post-treatment.	36%

Cammu et al.	2004	447	1) Pad use: No pads 67% Not daily pads 53% Daily pads (2>/day) 52% >2 pads/day 28% 2) Mean leakage episodes/day <1 63% 1-<2 59% ≥2 35%	Combined score: 1) Selected statements 1 or 2 on the 5-point scale: Impact of PFM training on incontinence. 2) No longer uses protective pads for incontinence. 3) Did not go to surgery after PFM training.	49%
Dumoulin et al.	2010	57	Pad test (mean ± SD) 34.49g ± 54.76g (detailed information not provided)	A pad weight gain of ≤2g on a standardized 20 minute pad test post-treatment, meaning dry.	74%
Dumoulin et al.	2017	40	1) Mean leakage episodes/day (mean ± SD) 1.89 ± 1.24 65% 2) IIQ scores (mean ± SD) 4.75 ± 2.58 52%	Combined score: 1) Reduction of 50% or more in the mean number of UI episodes per day in a 3-Day Bladder Diary. 2) Reduction of 50% or more in their IIQ impact score.	63%

*Note. Pelvic floor muscle (PFM); urinary incontinence (UI); Incontinence Impact Questionnaire (IIQ).

5.2 DEMOGRAPHIC AND CLINICAL CHARACTERISTICS PREDICTIVE OF CURE

Severity of SUI symptoms (expressed as the score on the ICIQ-FLUTS UI subscale) was a significant predictor of treatment success, such that women with lower scores on the ICIQ-FLUTS UI subscale at baseline were most likely to be cured with physiotherapist-supervised PFM training. The cut-off for predicting that a woman would be successful with a physiotherapy intervention was a score of 7.50 out of 20. Similarly, Cammu, Van Nysten, Blockeel, Kaufman, & Amy (2004) found that having higher SUI severity (as measured by the number of leakages and the number of protective garments used before treatment) was predictive of failure with a physiotherapy intervention. Other studies have reported a similar trend: women with mild to moderate SUI severity respond best to physiotherapist-supervised PFM training, while women

with more severe SUI respond less optimally (Elia & Bergman, 1993; Hahn, Sommar, & Fall, 1991; Mouritsen, Frimodt-Møller, & Møller, 1991; O'Sullivan et al., 2003; Wilson, Samarraï, Deakin, Kolbe, & Brown, 1987). Women with severe SUI may be less likely to respond to physiotherapy interventions due to a confluence of factors. Women with extensive tissue damage, nerve damage, or reduced vascularization may be less likely to benefit from PFM exercise because enhancing PFM strength can only compensate for these deficits to a limited extent (Madill & McLean, 2007). Thus, SUI symptom severity may be an important factor in deciding whether or not a woman should try physiotherapy to cure her SUI symptoms.

Although not a significant predictor in our model, in the univariate analysis, women who were cured with the physiotherapy intervention had lower parity than the women who were not cured. As parity is a risk factor for pelvic floor trauma, the women with higher parity may have experienced more extensive connective tissue or neuromuscular damage to their pelvic floor during pregnancy and delivery, and may have been less likely to be cured by the physiotherapy intervention. In fact, recent studies have reported that parity is associated with an increased risk of the development of SUI, especially with vaginal delivery (Agarwal & Agarwal, 2017) and when instruments are used (forceps/vacuum; Stothers & Friedman, 2011), when babies are large (Gyhagen et al., 2013), and when the active stages of labour are long (Allen et al., 1991). Vaginal childbirth is associated with partial denervation of the pelvic floor (Allen et al., 1991; Snooks et al., 1990), connective tissue damage (DeLancey et al., 2002), and PFM damage (DeLancey et al., 2002; Dietz, 2010). It is not reasonable to expect that a physiotherapy intervention to improve PFM strength would repair severe connective tissue or neuromuscular damage (Madill & McLean, 2007). The subsequent ultrasound imaging data reported here may be a better way to predict treatment success as it can be used to measure the extent of tissue

damage, especially as parity has not been found by others to be predictive of success with physiotherapy treatment for SUI (Cammu et al., 2004; Truijen et al., 2001).

PFM strength was not a significant predictor of success with a physiotherapy intervention among the women with SUI in our study, despite work by Truijen et al. (2001) finding that high pre-treatment PFM strength was predictive of failure. As in the current study, Truijen et al. (2001) used intravaginal digital palpation of the PFMs to determine PFM strength, however, palpation may not be sensitive nor reliable enough for scientific research (Bø & Finckenhagen, 2001; Ferreira et al., 2011). When measured more objectively, using a custom intravaginal dynamometer, Dumoulin et al. (2010) found that PFM strength was not a significant predictor of success with a physiotherapy intervention among women with persistent postpartum SUI. In contrast to both Dumoulin et al. (2010) and Truijen et al. (2001), Bø & Larsen (1992) reported that women with stronger PFMs at baseline were treated successfully with a physiotherapy intervention in comparison to women with weaker PFMs. They postulated that the women who were able to contract their PFMs may have had intact neuromuscular function, whereas the women who were unable to effectively contract their PFMs (Grades 1 and 2 on the MOS) did not; neuromuscular function may be an essential feature for success with a PFM training intervention for SUI (Bø & Larsen, 1992). Interestingly, in line with this hypothesis, ten of the twelve women in this study whose PFM strength scored one or two out of a possible five on the MOS at the baseline assessment were not cured with the physiotherapy intervention, which may reflect inadequate innervation of their PFMs (Bø & Larsen, 1992). In contrast, Truijen et al. (2001) suggested that if PFM strength was already good prior to the physiotherapy intervention, improving PFM strength would do little to improve SUI symptoms. In the current study, of the 38 women with PFM strength classified as four or five on the MOS, approximately half (n = 21)

were not cured. Only two women in our study were classified as a five on the MOS and both women were not cured after the intervention. These women may not have been cured with the physiotherapy intervention as there was no room for PFM strength improvement. There may be an optimal level of baseline PFM strength that can be used to predict success with physiotherapy treatment, but the relationship may not be linear. Perhaps, evidence of intact innervation is required, such that strength must be higher than a grade of one, but that strength must also be lower than a grade of four, such that there is room for improvement to translate into improved continence function. This hypothesis should be tested in future research.

PFM tone was not a significant predictor of successful physiotherapy outcomes for women with SUI in this study. We assessed PFM tone digitally (Reissing et al., 2005) and, using a univariate analysis, found that tone evaluated at the baseline assessment was higher in the women who were cured with the physiotherapy intervention compared to those who were not, yet PFM tone did not contribute significantly to the predictive model. Again using their custom dynamometer, Dumoulin et al. (2010), reported that women with lower resistance to passive stretch of their paravaginal tissues (i.e. lower tone) at baseline were more likely to benefit from a physiotherapy intervention. Differences in results may be attributed to differences between digital assessment of PFM tone and dynamometric assessment as noted above in our discussion of PFM strength (Ferreira et al., 2011), but also may be related to differences in the sample characteristics. More information about passive tissue properties of the PFMs is needed to understand the potential implications of passive tissue properties on the success or failure of physiotherapy interventions for women with SUI.

5.2 THE POTENTIAL ADDED VALUE OF MORPHOLOGICAL CHARACTERISTICS ON PREDICTING CURE

Several morphological variables were significantly different between the women who were cured and those who were not cured of their SUI through physiotherapy intervention. When standing, women who were cured with physiotherapy had higher bladder neck positions during a cough and demonstrated greater change in bladder neck position during MVM. Moreover, during quiet standing, the women who were cured tended to have a higher bladder neck position relative to the levator plate line than women who were not cured. Using morphometric characteristics from MRI to predict the outcome of a physiotherapy intervention in older women, Dumoulin et al. (2017) found that women who had a higher urethrovesical junction height at rest in supine were most likely to be successful with the treatment. MRI and ultrasound imaging differ on their measures of the urethrovesical junction height and the bladder neck position. The height of the urethrovesical junction is determined using two bony landmarks, a line is drawn from the inferior edge of the pubic symphysis to the anterior aspect of the sacrococcygeal joint; the perpendicular distance between this line and the urethrovesical junction is used to determine the amount of bladder neck support. Although similar, on ultrasound imaging, the height of the bladder neck is measured as the perpendicular distance between the anterior aspect of the urethrovesical junction to the levator plate line, which is a line drawn from the postero-inferior edge of the pubic symphysis to the ARA, a non-rigid, deforming structure which moves during dynamic tasks. The ARA is used for this measure as the viewing angle available when using a curvilinear probe and transperineal ultrasound imaging is limited (in our case, to 85 degrees) and it is therefore not possible to visualize both the pubic symphysis and the coccyx on ultrasound images the way the entire pelvis can be seen on MRI. That said,

when these measurements are made at rest they are similar, and it appears that this measure is worth pursuing as it is more clinically accessible than MRI and may be a predictor of successful physiotherapy outcomes among women with SUI. In an earlier study using MRI, asymptomatic women displayed higher bladder neck positions at rest in supine compared to women with SUI and women with prolapse (Hoyte, Schierlitz, Zou, Flesh, & Fielding, 2001). Height of the bladder neck may be indicative of the extent of connective tissue support present within the pelvis and if severe damage is present may not be corrected with physiotherapy (Madill & McLean, 2007). Women who were cured with the physiotherapy intervention also had a larger amount of change in the position of their bladder necks during MVM, while those who were not cured had smaller amounts of change in their bladder neck position. This may be due to the initial resting position of their bladder neck, women who were more likely to be cured with the physiotherapy intervention had higher bladder neck positions at rest, as such the change in bladder neck position may appear larger during this bearing down maneuver; while women whose bladder neck sits lower may not have been able to generate a large amount of change because their bladder neck was already positioned low within their pelvis. Moreover, the women in this study may not have completely relaxed their PFMs during testing for fear the embarrassment of experiencing a urine leakage episode during the assessment in our laboratory, despite our instructions to relax their PFMs and that urine leakage during testing is normal. The women with higher SUI severity may have been more concerned about urine leakages, as they happen more frequently and are larger than the leakages of women with lower severity, as such, they may not have relaxed their PFMs completely during their assessment. The women with lower SUI severity may have been less concerned with urine leakage during testing as their leakage episodes happen less frequently and in smaller amounts, this may have encouraged them

to completely relax their PFMs. Further study is required to understand the relationship between the amounts of change in bladder neck position generated during MVM by women with SUI who are cured with a physiotherapy intervention. A higher bladder neck position at rest and a larger change in position during MVM may be suggestive of better structural support, and may also be linked to a smaller amount of bladder neck descent seen during a cough. Motor control of the PFMs may also be relevant. Performing the knack maneuver as described by Miller, Ashton-Miller, & DeLancey (1998), whereby a woman contracts her PFMs prior to coughing, may reflect good motor control of the PFMs as it can effectively reduce the frequency and severity of urine leakage in women with SUI. Therefore, height of the bladder neck in standing at rest and during MVM and cough may be valuable predictors of successful physiotherapy outcomes among women with SUI. These measures are very accessible as they require only 2-D ultrasound imaging capabilities.

In the current study, several measures of levator hiatus circumference were significantly different between women who were cured with physiotherapy and those who were not cured, such that women who were cured with physiotherapy had smaller levator hiatus circumferences at rest in standing and at peak MVC in both supine and standing. No other studies have reported levator hiatal dimensions as predictors of a cure for women with SUI treated with a physiotherapy intervention, however, larger hiatal dimensions have been linked to both SUI and pelvic organ prolapse (Hoyte et al., 2001; Shek & Dietz, 2009). Vaginal childbirth appears to enlarge the dimensions of the levator hiatus (Shek & Dietz, 2009), presumably through damage to the connective tissue including both microstructural damage and levator avulsion. Since the majority of women in this study were parous ($n = 69/79$), and parity appeared to have some influence on the success of PFM training outcomes, levator hiatus circumference may be

reflective of the extent of connective tissue damage experienced by women during childbirth, whereby a larger hiatal area may reflect impaired support, including support of the bladder and urethra (Hoyte et al., 2001). The women who were cured with the physiotherapy intervention in the current study also had smaller levator hiatus circumferences during MVCs when compared to women who were not cured. This may be indicative of better PFM strength in the women who were cured, either through better motor control, less muscle damage, less denervation, and/or less scar tissue formation in comparison to women who were not cured with the physiotherapy intervention. Damage to the PFMs is two times as likely to be present in women with SUI than asymptomatic women (DeLancey, 2010) and as such, may reduce functional ability of the PFMs to reduce levator hiatal circumference. Better PFM strength may allow women to prevent pelvic organ descent during tasks that increase intra-abdominal pressure. Thus, the extent to which a woman can voluntarily reduce the circumference of her levator hiatus may reflect the integrity of the PFMs, their innervation, and their associated connective tissues; those who can achieve some amount of constriction may consequently respond better to a physiotherapy intervention than those women who demonstrate limited or no reduction in levator hiatus circumferences during MVC. In support of this idea, our data suggest that levator hiatus circumferences may be negatively correlated with baseline PFM strength ($r = -.28, p = .06$), such that as strength increases the hiatal circumference decreases during MVC in both supine and standing. Measures of levator hiatus circumference may be useful in the prediction of successful physiotherapy outcomes among women with SUI.

The women with SUI who were cured with the physiotherapy intervention tended to have shorter LPLs during Valsalva maneuvers than the women who were not cured. When women perform a proper Valsalva maneuver, they must completely relax their pelvic floor (Örnö &

Dietz, 2007), and if they are successful in doing so, the LPL becomes a measure of the capacity of the endopelvic fascia and the PFMs to lengthen (McLean et al., 2013). Women who have damaged connective tissues may be able to lengthen their levator plate more than women whose connective tissues are uninjured. Previous research has indicated that asymptomatic women have significantly shorter LPLs upon straining tasks than women with SUI or prolapse (Hoyte et al., 2001). A physiotherapy intervention aimed at strengthening the PFMs and improving motor control is unlikely to have an impact on shortening or strengthening damaged connective tissues which may explain why women who were not cured with PFM training demonstrated longer LPLs during MVM than those who were cured. This finding is consistent with the finding that the women who were not cured also had bladder neck heights that were lower relative to the levator plate line on MVM, yet LPL on straining and bladder neck descent on straining were not significantly correlated ($r = -.21, p = .17$). Dumoulin et al. (2017) used a measure similar to the LPL derived from MRI, labelling it the H-line; however, this measure was only recorded while women were in supine and they did not find significant differences in the H-line length between women with SUI who were and were not cured with a physiotherapy intervention. Dumoulin et al. (2017) did find significant differences between women with SUI who were cured with a physiotherapy intervention and those who were not cured based on the angle of the levator plate from the pubococcygeal line to the ARA during a straining task, which may reflect a similar phenomenon; however, they did not find that this variable was a significant predictor of success with their physiotherapy intervention.

The women who were cured with the physiotherapy intervention also tended to have shorter LPLs during a coughing task. As noted above, during coughing there is active contraction of the PFMs to resist the sudden rise in intra-abdominal pressure (DeLancey, 1996).

Having a shorter LPL during a cough may reflect that neuromuscular function is intact and that there is adequate motor control, that is, an automatic contraction of the PFM to resist downward pressure of the pelvic organs in response to the rise in intra-abdominal pressure (DeLancey, 1996). Irreparable damage to the pudendal nerve may lead to longstanding poor PFM coordination, which may result in delayed or absent PFM responses to cough (Miller et al., 1998). Interestingly, in our preliminary analysis there was a significant ($r = -.24, p = .05$) negative correlation, such that women with higher PFM strength had shorter LPLs at peak cough. There was also a significant ($r = .44, p = .01$) positive correlation, such that women with shorter LPLs at peak cough had smaller levator hiatus circumferences. Dumoulin et al. (2017) did not analyze coughing tasks with MRI, likely because MRI does not have adequate time resolution to capture rapid changes in landmark motion. As with bladder neck position and motion, measures of the LPL and changes in LPL are relatively simple to acquire and requires only 2-D imaging capabilities. Such 2-D images may provide as much information as the levator hiatal size, which requires 4-dimensional (4-D) imaging and thus more expensive infrastructure and higher levels of skill for acquisition and analysis. In a future predictive model based on morphologic features, we will investigate whether variables derived from 4-D imaging of the levator hiatus can be avoided due to collinearity with variables that are easier to acquire and analyze using 2-D ultrasound imaging.

Lastly, women who were cured with the physiotherapy intervention had larger cross-sectional areas of the urethral wall at baseline compared to those who were not cured. Though we cannot distinguish between connective and muscle tissues embedded within the urethral wall using ultrasound imaging, it is possible to distinguish tissue types with MRI. Using MRI, DeLancey et al. (2007) showed that women with SUI have less striated muscle tissues in the

urethral sphincter than continent women. There is also a known synergistic relationship between the PFMs and the urethral sphincters (Bø & Stien, 1994). The cross-sectional area of the urethral wall may be influenced by denervation and/or muscle atrophy of the striated urethral sphincter as well as by connective tissue thinning. McLean et al. (2013) showed that PFM training enlarges the cross-sectional area of the urethral wall, and this finding was later confirmed in older women by Madill, Pontbriand-Drolet, Tang, & Dumoulin (2015) using MRI, suggesting that PFM training concurrently leads to hypertrophy of the striated urethral sphincter. In the current study, women who were not cured with the physiotherapy intervention tended to have smaller urethral wall cross-sectional areas than those who were cured. Similar to Bø & Larsen's (1992) theory about the PFMs, larger urethral wall cross-sectional areas may indicate intact innervation and consequently, more capacity for hypertrophy of the striated urethral sphincters with treatment (Digesu et al., 2009). A larger urethral wall may also reflect healthy connective tissue of the urethra (DeLancey, 2002; DeLancey et al., 2002). Damage incurred during childbirth may result in smaller urethral cross-sectional area (DeLancey et al., 2007) and may compromise the stiffness of the sub-urethral tissues (DeLancey, 2002). If urethral and para-urethral connective tissue damage is involved in SUI, then a physiotherapy intervention aimed at strengthening the PFMs is less likely to be beneficial. The cross-sectional area of the mid-urethra may be of value in enhancing our capacity to predict successful outcomes with PFM training.

Together, the findings of these univariate analyses of morphologic features generated through ultrasound imaging suggest that some may be significant predictors of treatment outcomes for women with SUI. In the only other study that has investigated the value of urogenital morphology to predict physiotherapy treatment success for women with SUI, the nature of closed MRI limited the information generated to data that could be acquired during

static tasks with women in supine (Dumoulin et al., 2017). In contrast, ultrasound imaging has the capacity to acquire images while women are in both supine and standing and while they perform a variety of dynamic tasks (i.e. coughing, Valsalva maneuvers, MVCs). Our preliminary analysis suggests that images acquired at rest and during tasks performed in standing—allowing the pelvic structures to be visualized while under typical gravitational loading—may be more informative than images acquired in supine, especially as several outcomes were significant or close to being significantly different between women with SUI who were cured and those who were not cured by the intervention. Although the spatial resolution of ultrasound is more limited than MRI and the view angle limits the capacity to base measurements on planes that are generated using non-rigid, deforming landmarks within the image frame, the low cost, ease of use, high time resolution, and versatility of patient positioning afforded by ultrasound imaging may all be important features in generating a robust predictive model of cure with physiotherapy.

5.3 LIMITATIONS AND FUTURE DIRECTIONS

A major challenge when modeling successful physiotherapy intervention outcomes is the precise definition of a cure. In fact, the concept of cure is a challenge in many aspects of clinical research. Cure may be considered the complete absence of a condition or disease state, yet is commonly considered as an improvement in signs or symptoms by at least 50% relative to the pre-intervention state (European Medicines Agency, 1998). We defined cure more stringently than a 50% improvement in symptoms based on the idea that women with more severe incontinence would presumably still be dissatisfied with the treatment if they reduced their urine leakage by 50% yet still leaked significant amounts. For example, improving from 60g of leakage per day to 30g per day, or from six urine leakage episodes per day to three would

presumably leave women with SUI that was still bothersome; however, there is no standard for cure of SUI defined in the literature. As such, the decision to consider no more than one leakage episode per day, on average, as a cure was fairly arbitrary. Using two concurrent criteria for cure resulted in our cure rate being lower than cure rates reported by others, but meant that the women we deemed to be cured through our intervention were more likely to be truly cured. As previously noted, standardized methods for the evaluation of SUI presence and severity are needed and would allow for direct comparisons to be made among studies involving different populations and interventions.

There are several measures used to determine SUI presence and severity in the literature. The standardized 30-minute pad test used in this study was based on a similar pad test used by Dumoulin et al. (2010) as a way to compare our work to previous research. This test is reliable, but is prone to false positives (Papa Petros & Ulmsten, 1992). The more reliable standardized pad test is the twenty-four hour pad test, in which a woman wears the pad for an entire day and the amount of urine leakage is recorded (Ryhammer, Djurhuus, & Laurberg, 1999). However, a full twenty-four hour pad test may be susceptible to high rates of attrition as many women do not want to wear an incontinence pad for that long. To balance our rates of attrition as well as to maintain high reliability, we chose to use the 30-minute pad test. Our main focus was on the SUI leakage episodes with the pad test and the exercise protocol reflects this, including many activities likely to provoke an SUI leakage episode (i.e. jumping jacks, bending down to pick something up off the floor, etc.), however, this protocol also included washing one's hands under water for one minute. This type of activity is more likely to trigger an UUI episode rather than a SUI episode (Hahn & Fall, 1991). This may have affected our pad test results by increasing the amount of urine leakage on the pad test and may not have been completely representative of SUI.

Previous psychometric testing of the 30-minute standardized pad test included the handwashing activity within their protocol and therefore, to maintain fidelity we kept all tasks in the standardized protocol as described in the literature. It may be useful to generate separate pad tests based on study populations—those with SUI, those with UUI, and those with MUI. Lastly, pad tests have been criticized for not reflecting incontinence severity, as it provides a snapshot of a woman’s incontinence severity at one particular session.

Using a bladder diary to record urine leakage episodes and amounts provides us with a better account of the activities surrounding episodes of urine leakages, the frequency of leakage, and an estimate of the amount of urine leakage. Recording urine leakage in this way allowed us to separate out urine leakage associated with stress events from those associated with urge events. However, bladder diary records have been associated with recall bias depending on how the participant decides to complete the entries (i.e. forgets to fill in urine leakage episodes one day; Bright, Drake, & Abrams, 2011). Questionnaires measuring the severity of SUI, such as the ICIQ-FLUTS, provide a more robust representation of the types of activities surrounding urine leakage episodes as well as the frequency and amount of urine leakage. They often provide easy-to-use scoring to create a range of incontinence severity and may, such as the ICIQ-FLUTS, include measures of perceived distress regarding UI symptoms. However, like the bladder diary, questionnaires are also prone to recall bias, as they often ask participant’s to reflect on their symptoms during a period of time, in the case of the ICIQ-FLUTS, over the course of four weeks (Abdelmoteleb, Kamel, & Hashim, 2017). We included both subjective (ICIQ-FLUTS), semi-objective (bladder diary), and objective (pad test) measures of SUI severity in our model to determine which measure of SUI severity may be most valuable in predicting those women with SUI who are cured with physiotherapy intervention. All three variables displayed similar trends,

smaller amounts of leakage, less frequent urine leakage episodes, and lower scores on the ICIQ-FLUTS were more likely to benefit from the physiotherapy intervention. We selected the ICIQ-FLUTS UI subscale as our measure of severity for this study because it did not violate the assumptions of a logistic regression (Fields, 2013) and was not used in our definition of cure. Future research should consider each of these measures of SUI severity to further investigate their potential as predictors of successful physiotherapy intervention outcomes among women with SUI.

The physiotherapy intervention used in this work was twelve weeks in duration, where women attended six one-on-one sessions with a participating physiotherapist over the study duration and were asked to perform a series of home exercises daily. We selected this treatment intensity and duration based on interviews with clinicians about their normal treatment frequency and duration, as well as on our previous work (McLean et al., 2013) through which women reported that weekly physiotherapy sessions were too frequent and thus resulted in higher rates of attrition than is ideal. It is possible, however, that more women would be cured if more frequent physiotherapy visits were incorporated into the protocol. Treatment duration may also be an important factor. We chose to re-assess women after twelve weeks of treatment to allow enough time for both motor control changes and muscle hypertrophy to occur. Others have set the duration of the intervention between 8 and 12 weeks (Cammu et al., 2004; Dumoulin et al., 2010, 2017; Truijen et al., 2001) so the results of our study should be comparable to the literature in this regard. However, there is no standard protocol for PFM training. Recommendations put forth based on a recent review, published after we had begun recruitment, suggested that three sets of exercises per week for eight weeks are needed to see improvements (Ghaderi & Oskouei, 2014) and that there is much variability in exercise prescription in terms of the number of

contractions, contraction speed and duration. In this study, all women received consistent instruction on the performance of three sets of ten MVCs of the PFMs per day for a period of twelve weeks. Our physiotherapy intervention was four weeks longer than the recommendation put forth by Ghaderi & Oskouei (2014), which may have led to higher attrition (see Figure 3.1) yet at the same time, may have allowed adequate time to maximize any benefits derived from the exercises. Rates of attrition from previous modeling studies were not reported for comparison to the current study. Finding the optimal length of physiotherapy treatment and the optimal number of sets/repetitions per week may help to balance treatment success with attrition.

We asked women to perform their PFM exercises daily whereas the recommendation by Ghaderi and Osouei (2014) was that women should perform exercises at home at least three days per week. It is possible that the recommendation to perform the PFM exercise program daily may have resulted in PFM overtraining in some women, which may have resulted in declines in PFM strength, yet this is unlikely to have been a problem for three reasons. Previous RCTs have based their exercise protocol on a recommendation that women perform PFM exercises daily and have demonstrated clear improvements in PFM strength (Bø, 1995) and clear benefits in continence control (Dumoulin et al., 2014; Ghaderi & Oskouei, 2014). Second, it does not appear that women perform their true maximum when they attempt MVCs, and as such, they are training at a submaximal rather than a maximal level that would be high enough to result in overtraining (Madill & McLean, 2007). Lastly, in prescribing daily exercises, we expected that most women would not perform the exercises daily, but that they would perform exercises at least three to four times per week, which would be consistent with the exercise physiology literature (Bø, 1995). This was the case in our previous trial (McLean et al., 2013) and will be determined in future work with this dataset moving forward.

Linked to the frequency of performance of home exercises, adherence to treatment is another factor that is likely to influence treatment success. Lagro-Janssen et al. (1991) noted a significant positive relationship between adherence to the prescribed exercises and the benefit from the treatment. Women's motivation to complete the physiotherapy intervention may be important, as women who are more motivated are more likely to seek out and adhere to treatment (Maclean, Pound, Wolfe, & Rudd, 2002). In the current study, we did not recruit women who were seeking out treatment—instead more than half of the women who participated were referred to the study from surgical waitlists. As such, the women in this study may have been less motivated to perform the exercises—especially since many of them were scheduled for mid-urethral sling insertion at the end of the treatment period. Since we aimed to predict success through features of a clinical evaluation at baseline, we could not include exercise adherence in our analysis, yet exercise adherence would be expected to be an important predictor of success. Some groups have focused on the impact of motivation on successful physiotherapy outcomes, and this work has culminated in the development of the Incontinence Treatment Motivation Questionnaire (Sarma, Hawthorne, Thakkar, Hayes, & Moore, 2009). Future work should investigate motivation at baseline as a potential predictor of treatment success.

Ideally, we would have analyzed all ultrasound imaging outcomes on all participants and included relevant features generated from the ultrasound imaging protocol into the predictive modelling presented here. However, due to the extensive amount of ultrasound image processing and analysis required, this was not practical nor feasible within the time frame of this study and as such, is beyond the scope of this thesis. Instead, the second objective of this thesis was to determine which morphologic outcomes may have predictive value. With this analysis, we can move forward to analyze those images and features captured by the protocol that we have

deemed to have potential relevance to treatment outcomes, which will be the next phase of this research. A combination of demographic and clinical features with the salient morphological features may generate a clinically accessible yet robust model of physiotherapy treatment success with PFM training. In particular, we will investigate the predictive value of the following variables: levator hiatus circumference in standing at rest and MVC, levator hiatus circumference in supine at MVC, LPL at peak MVM and cough in standing, height of the bladder neck in standing at rest, at peak MVM and peak cough, and urethral wall cross-sectional area. As noted above, analysis to eliminate collinear features may further reduce the complexity of image acquisition and analysis needed for predictive modeling. In particular, if features seen on 2-D sagittal plane images are highly correlated with features derived from 3-D rendering, processing time could be cut substantially while not impacting the overall predictive value of the model.

Due to the time-consuming nature of the ultrasound image analyses, automated analysis of 2-D dynamic ultrasound images would further enhance the clinical accessibility of dynamic ultrasound imaging for the purposes of predictive modeling as well as for other applications. We are currently developing such a system in our laboratory (Czyrnyj, Labrosse, & McLean, 2016) which will directly apply to the current modeling aspects of this work. After generating a predictive model that includes relevant demographic, clinical, and morphological variables we plan to validate it using a newly recruited sample of women with SUI.

The present study addressed the limitations of previous research by using prospective data, avoiding model over specification (e.g. 79 participants and 5 predictors), and statistically validating our predictive model using bootstrapping techniques to correct for model optimism (Babyak, 2004). These approaches have reduced the chances of overfitting our model to the data, thereby improving our confidence in model fit and furthering the development of predictive

models for treatment options among women with SUI. However, it should be noted that this model remains limited in its predictive ability as it accounts for only 15% and 20% of the variance in the data. Further, this model is only generalizable to women who do not have significant prolapse evaluated to be greater than a POP-Q stage II. The model is also not generalizable to women who have concurrent fecal incontinence or those who have known neurological impairments. Although this was beyond the scope of the current study, future research should investigate the impact of the treatment in women with these disorders as comorbidities to their SUI.

Physiotherapist-supervised PFM training is the current, first-line treatment recommended for women with SUI; however, it only cures up to 56% of women who complete it (Dumoulin et al., 2014). Creating a statistical model that can accurately predict which women are most likely to be cured through a physiotherapy intervention could help create a more efficient treatment pathway for women with SUI. The policy implications of such a model would see those women most likely to benefit from physiotherapy provided with access to this treatment, while women less likely to benefit from physiotherapy directed to other options. If a predictive model can accurately predict 90% of women who will succeed with a physiotherapy intervention it would provide the necessary evidence to lobby governments and insurance companies to have physiotherapy expenses for those women who are most likely to benefit covered by federal, provincial, or private health insurance. Currently in Canada, physiotherapy in private clinics is not covered by provincial health insurance aside from specific populations (i.e. people over the age of 65 years) which makes inaccessible to many women who suffer with SUI. Further, physiotherapy assessment and treatment for SUI require a physiotherapist with specialized training to work one-on-one with individual clients, which can often increase the cost of

treatment. By creating sensitive and specific cut-off values through predictive modeling, we may influence health policy, while improving the efficiency and effectiveness of physiotherapy interventions for women with SUI.

5.4 CONCLUSION

The results of this study suggest that baseline SUI severity as measured by the ICIQ-FLUTS UI subscale is an important predictor of treatment success regardless of key demographic risk factors for SUI including age, parity, BMI, and smoking history. Further clinical evaluations of PFM strength and PFM tone do not appear to impact treatment outcomes. A preliminary analysis of morphologic features acquired from the same sample using 2-D and 3-D ultrasound imaging suggests that certain features may add to our capacity to predict treatment success. In particular, morphology measured in standing including bladder neck position, levator hiatus circumference, LPL, and changes in these measures during PFM contractions, coughing, and Valsalva maneuvers may indeed be strong predictors of success, along with urethral wall thickness measured in supine. Measures generated through ultrasound imaging may reflect different aspects of continence system morphology and mechanics. Moving forward, these ultrasound features will be tested to determine their contributions to a predictive model of treatment success.

The results presented in this thesis support recommendations that women with mild to moderate SUI as reported on the UI subscale of the ICIQ-FLUTS are most likely to be cured from PFM training. Further, the results suggest that morphological outcomes based on static and dynamic ultrasound imaging of the urogenital structures may be significant predictors of success with PFM training in women with SUI and may generate a more robust model.

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APPENDIX A



File Number: H10-14-18B

Date (mm/dd/yyyy): 02/19/2015

Université d'Ottawa University of Ottawa

Bureau d'éthique et d'intégrité de la recherche

Office of Research Ethics and Integrity

Certificate of Ethics Approval

Health Sciences and Science REB

Principal Investigator / Supervisor / Co-investigator(s) / Student(s)

<u>First Name</u>	<u>Last Name</u>	<u>Affiliation</u>	<u>Role</u>
Linda	McLean	Health Sciences / Others	Principal Investigator
Kevin	Baker	Medicine / Medicine	Co-investigator
Robert	Brison	Medicine / Medicine	Co-investigator
Andrew	Day	Health Sciences / Others	Co-investigator
Marie-Andrée	Harvey	Medicine / Medicine	Co-investigator
Eric	Sauerbrei	Medicine / Medicine	Co-investigator

File Number: H10-14-18B

Type of Project: Professor

Title: Optimizing treatment outcomes for women with stress urinary incontinence through the identification of factors contributing to successful interventions

Approval Date (mm/dd/yyyy)	Expiry Date (mm/dd/yyyy)	Approval Type
02/19/2015	02/18/2016	Ia

(Ia: Approval, Ib: Approval for initial stage only)

Special Conditions / Comments:

N/A

550, rue Cumberland 550 Cumberland Street
 Ottawa (Ontario) K1N 6N5 Canada Ottawa, Ontario K1N 6N5 Canada
 (613) 562-5387 • Téléc./Fax (613) 562-5338
<http://www.recherche.uottawa.ca/deontologie/> <http://www.research.uottawa.ca/ethics/index.html>



File Number: H10-14-18B

Date (mm/dd/yyyy): 02/19/2015

Université d'Ottawa University of Ottawa

Bureau d'éthique et d'intégrité de la recherche

Office of Research Ethics and Integrity

This is to confirm that the University of Ottawa Research Ethics Board identified above, which operates in accordance with the Tri-Council Policy Statement and other applicable laws and regulations in Ontario, has examined and approved the application for ethical approval for the above named research project as of the Ethics Approval Date indicated for the period above and subject to the conditions listed the section above entitled "Special Conditions / Comments".

During the course of the study the protocol may not be modified without prior written approval from the REB except when necessary to remove subjects from immediate endangerment or when the modification(s) pertain to only administrative or logistical components of the study (e.g. change of telephone number). Investigators must also promptly alert the REB of any changes which increase the risk to participant(s), any changes which considerably affect the conduct of the project, all unanticipated and harmful events that occur, and new information that may negatively affect the conduct of the project and safety of the participant(s). Modifications to the project, information/consent documentation, and/or recruitment documentation, should be submitted to this office for approval using the "Modification to research project" form available at:

<http://research.uottawa.ca/ethics/submissions-and-reviews>.

Please submit an annual status report to the Protocol Officer 4 weeks before the above-referenced expiry date to either close the file or request a renewal of ethics approval. This document can be found at: <http://research.uottawa.ca/ethics/submissions-and-reviews>.

If you have any questions, please do not hesitate to contact the Ethics Office at extension 5387 or by e-mail at: ethics@uOttawa.ca.

Germain Zongo

Protocol Officer for Ethics in Research

For Daniel Lagarec, Chair of the Sciences and Health Sciences REB

APPENDIX B



QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD

October 26, 2011

Dr. Linda B McLean
School of Rehabilitation Therapy
Queen's University

Dear Dr. McLean,

Study Title: REH-503-11 Optimizing treatment outcomes for women with stress urinary incontinence through the identification of factors contributing to successful interventions
Co-Investigators: Dr. R. Brison, Mr. A. Day, Dr. E. Saurbrei, Dr. M.A. Harvey, Dr. K. Baker, Mr. K. Varette, Ms. L. Kodiattu
Full Board Meeting Date: September 12, 2011

The members of the Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board have examined the treatment protocol, exercise protocol for controls, compliance log, pad test, bladder diary, confidentiality form, questionnaire 2 – urinary symptoms, questionnaire 3 – vaginal symptoms, release form, references, flyer, medical directive – Dr. Harvey to K. Varette, medical directive - Dr. Harvey to Registered Pelvic Floor Physiotherapists, and the revised information/consent form (Version date: October 2011) for your project (as stated above) and consider it to be ethically acceptable. This approval is valid for one year from the date of the Chair's signature below. Please attend carefully to the following list of ethics requirements you must fulfill over the course of your study: **Reporting of Amendments:** If there are any changes to your study (e.g. consent, protocol, study procedures, etc.), you must submit an amendment to the Research Ethics Board for approval. (see <http://www.queensu.ca/ors/researchethics/REB.html>).

Reporting of Serious Adverse Events: Any unexpected serious adverse event occurring locally must be reported within 2 working days or earlier if required by the study sponsor. All other serious adverse events must be reported within 15 days after becoming aware of the information.

Reporting of Complaints: Any complaints made by participants or persons acting on behalf of participants must be reported to the Research Ethics Board within 7 days of becoming aware of the complaint. Note: All documents supplied to participants must have the contact information for the Research Ethics Board.

Annual Renewal: Prior to the expiration of your approval (which is one year from the date of the Chair's signature below), you will be reminded to submit your renewal form along with any new changes or amendments you wish to make to your study. If there have been no major changes to your protocol, your approval may be renewed for another year. Yours sincerely,

Chair, Research Ethics Board

Study Code: REH-503-11 6006245

Investigators please note that if your trial is registered by the sponsor, you must take responsibility to ensure that the registration information is accurate and complete

The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards as defined by the Tri-Council Policy Statement; Part C Division 5 of the Food and Drug Regulations, OHRP, and U.S DHHS Code of Federal Regulations Title 45, Part 46 and carries out its functions in a manner consistent with Good Clinical Practices.

Federalwide Assurance Number: #FWA00004184, #IRB00001173

Current 2011 membership of the Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board:

Dr. A.F. Clark Emeritus Professor, Department of Biochemistry, Faculty of Health Sciences, Queen's University (Chair)

Dr. H. Abdollah Professor, Department of Medicine, Queen's University

Dr. R. Brison Professor, Department of Emergency Medicine, Queen's University

Dr. M. Evans Community Member

Dr. S. Horgan Manager, Program Evaluation & Health Services Development, Geriatric Psychiatry Service, Providence Care, Mental Health Services, Assistant Professor, Department of Psychiatry

Dr. B. S. Kisilevsky, Professor, School of Nursing, Departments of Psychology and Obstetrics & Gynaecology, Queen's University

Ms. D. Morales, Community Member

Ms. P. Newman, Pharmacist, Clinical Care Specialist and Clinical Lead, Quality and Safety, Pharmacy Services, Kingston General Hospital

Dr. W. Racz Emeritus Professor, Department of Pharmacology & Toxicology, Queen's University

Ms. S. Rohland, Privacy Officer, ICES-Queen's Health Services Research Facility, Research Associate, Division of Cancer Care and Epidemiology, Queen's Cancer Research Institute

Dr. B. Simchison Assistant Professor, Department of Anesthesiology, Queen's University

Dr. A.N. Singh WHO Professor in Psychosomatic Medicine and Psychopharmacology Professor of Psychiatry and Pharmacology, Chair and Head, Division of Psychopharmacology, Queen's University, Director & Chief of Psychiatry, Academic Unit, Quinte Health Care, Belleville General Hospital

Dr. E. Tsai Associate Professor, Department of Paediatrics and Office of Bioethics, Queen's University

Rev. J. Warren Community Member

APPENDIX C



Ottawa Hospital Research Ethics Boards / Conseils d'éthique en recherches

725 Parkdale Avenue, Box 411, Ottawa, Ontario K1Y 4E9 613-798-5555 ext. 14902 Fax: 613-761-4311
<http://www.ohri.ca/ohreb>

December 13, 2011

Dr. Kevin Baker
Ottawa Hospital - Civic Campus
1053 Carling Avenue
CPC, Room 525
Ottawa, ON
K1Y 4E9

Dear Dr. Baker:

Re: Protocol # 2011625-01H Optimizing Treatment Outcomes for Women with Stress Urinary Incontinence through the Identification of Factors Contributing to Successful Interventions

Protocol approval valid until - February 13, 2012

Thank you for the letter of support dated December 6, 2011. I am pleased to inform you that this protocol underwent expedited review by the Ottawa Hospital Research Ethics Board (OHREB) and is approved for two months to begin recruiting English-speaking participants. No changes, amendments or addenda may be made to the protocol or the consent form without the OHREB's review and approval.

Approval is conditional upon the existence of a fully executed agreement, between the Ottawa Hospital Research Institute, Principal Investigator, and Queen's University site.

Approval is for the following:

- COREB Application
- Physiotherapy Treatment Protocol, dated August 2011
- Pad Test
- Case Report Form
- English Bladder Diary
- English Questionnaire Package
- English Pre-Treatment Medical and Bladder and Bowel Function Questionnaire
- English Patient Hand Out on Pelvic Floor Muscle Exercises Given to all Participants
- English Pelvic Floor Muscle Exercises
- English Debriefing Sheet, dated August 2011
- English Telephone Information Sheet
- English Poster
- English Letter of Information, dated November 2011
- English Consent form for Pelvic-Floor Physiotherapy Services, dated November 2011
- French Poster

Upon receipt and review of the French diary, questionnaires, hand outs, scripts, approval may be extended for up to one year and the recruitment of French-speaking participants may begin.

The validation date should be indicated on the bottom of all consent forms and information sheets (see copy attached).

.../2

The Ottawa Hospital Research Ethics Board is constituted in accordance with, and operates in compliance with the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; Health Canada Good Clinical Practice: Consolidated Guideline; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Health Information Protection Act 2004 and its applicable Regulations.

Raphael Saginur, M.D.
Chairman
Ottawa Hospital Research Ethics Board

Encl.

RS/ll



Ottawa Hospital Research Ethics Boards / Conseils d'éthique en recherches

725 Parkdale Avenue, Box 411, Ottawa, Ontario K1Y 4E9 613-798-5555 ext. 14902 Fax: 613-761-4311
<http://www.ohri.ca/ohreb>

March 12, 2012

Dr. Kevin Baker
Ottawa Hospital - Civic Campus
1053 Carling Avenue
CPC, Room 525
Ottawa, ON
K1Y 4E9

Dear Dr. Baker:

Re: Protocol # 2011625-01H Optimizing Treatment Outcomes for Women with Stress Urinary Incontinence through the Identification of Factors Contributing to Successful Interventions

Thank you for the email from Dr. Linda McLean dated March 12, 2012. The French documentation is approved and the recruitment of French-speaking participants may now begin.

Approval is for the following:

- French Bladder Diary
- French Questionnaire Package
- French Patient Hand Out on Pelvic Floor Muscle Exercises Given to all Participants
- French Pelvic Floor Muscle Exercises
- French Debriefing Sheet, dated August 2011
- French Pelvic Floor Muscle Exercise Log
- English Pelvic Floor Muscle Exercise Log
- French Letter of Information, dated November 2011
- French Consent form for Pelvic-Floor Physiotherapy Services, dated November 2011

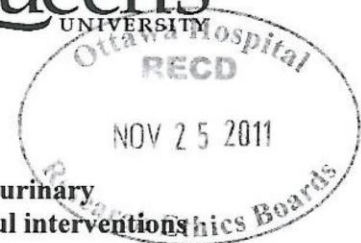
Ethical approval has now been extended to December 12, 2012.

Yours sincerely,

Raphael Saginur, M.D.
Chairman
Ottawa Hospital Research Ethics Board

Encl.

/ll



Consent Form for Pelvic-Floor Physiotherapy Services

Title of the Study: Optimizing treatment outcomes for women with stress urinary incontinence through the identification of factors contributing to successful interventions

Principal Investigator: Linda McLean, PhD, Associate Professor, School of Rehabilitation Therapy, Queen's University.

Local Investigator: Dr. Kevin Baker, Ottawa Hospital

Physiotherapy Services

The physiotherapy evaluations and treatments for the pelvic floor that will be performed over the course of this study are based on current practice standards. You will receive the same type of services if you were to consult a physical therapist in a clinical setting, who has specific training in the evaluation and treatment of incontinence.

Physiotherapy has been shown to have benefits in women with urinary incontinence. There are however, no guarantees that you will see improvements.

The physiotherapist you will be seeing over the course of this study has received post-graduate training in pelvic floor assessment and treatment and has been evaluating and treating women with pelvic floor concerns for over three years.

You should review the general information about what the physiotherapy evaluations and treatments which have been explained to you verbally and in the initial consent form are. You should form your own opinions of whether you feel comfortable working with the physiotherapist, and you should not participate in any aspect of the assessment or treatment sessions if you are uncomfortable with them. If you have any questions or concerns regarding the physiotherapy evaluation and treatment procedures, feel free to let the physiotherapist know so that she can provide clarification and discuss other options with you.

Professional Fees

There is no fee on your part for the services being provided in the context of this research study.

Contacting Your Physiotherapist

You can call _____ (physiotherapist inserts her phone number) to reach your physiotherapist. You may find it easier to reach the physiotherapist by email _____ (physiotherapist inserts her email). If you are unable to reach your physiotherapist, feel free to contact the investigators at _____ or _____ at any time and they will relay the message and make sure your physiotherapist gets in touch with you.



Confidentiality

All personal health information will be kept confidential, unless release is required by law. Representatives of the Ottawa Hospital Research Ethics Board, as well as the Ottawa Hospital Research Institute, may review your original medical records under the supervision of Dr. Baker's staff for audit purposes.

You will not be identifiable in any publications or presentations resulting from this study. No identifying information will leave the Ottawa Hospital. All information which leaves the hospital will be coded with an independent study number.

The link between your name and the independent study number will only be accessible by Dr. McLean and her staff. The link and study files will be stored separately and securely. Both files will be kept for a period of 15 years after the study has been completed. All paper records will be stored in a filing cabinet in a locked office. All electronic records will be stored on a secure database at Queen's University and protected by a user password, again only accessible by Dr. McLean and her staff. At the end of the retention period, all paper records will be shredded, and all electronic records will be deleted.

Participant Rights and Liability: You are free to withdraw from the treatment and the study at any time. You are also free to choose not to undergo any evaluation or treatment component at any time during the course of the study.

Please let the physiotherapist know if you have any questions about this consent form. This copy is for you to keep.

Standard pelvic floor physiotherapy evaluations and/or treatments entail the following:

- Insertion of up to 2 fingers inside the vagina to evaluate the strength and flexibility of the pelvic floor muscles to provide feedback on the quality of contraction to help you gain control and strength of these muscles
- Insertion of 1 finger inside the anus (only during initial evaluation) to evaluate the strength and flexibility of the pelvic floor muscles
- If necessary: the insertion of a single-user vaginal probe for electromyography



The Ottawa Hospital | L'Hôpital d'Ottawa



Consent for Pelvic Floor Physiotherapy Evaluation and Treatment

I _____
(Name of client, please print)

agree to allow _____ provide
(Name of physiotherapist, please print)

pelvic floor physiotherapy evaluations and interventions for the purposes of treatment of my stress urinary incontinence.

I understand the following:

- ✓ The reason for the recommended treatment
- ✓ The goals for the treatment
- ✓ How the treatment will be done
- ✓ What the potential outcome of this treatment is
- ✓ That this consent may be withdrawn at any point in the process

Client Signature: _____ Date: _____

Physiotherapist Signature: _____ Date: _____

Valid until DEC 12 2012



Letter of Information

Title of the Study: Optimizing treatment outcomes for women with stress urinary incontinence through the identification of factors contributing to successful interventions

Principal Investigator: Linda McLean, PhD, Associate Professor, School of Rehabilitation Therapy, Queen's University.

Local Investigator: Dr. Kevin Baker, Ottawa Hospital

Background Information

Pelvic floor exercises can improve the symptoms of stress urinary incontinence (SUI) in a great percentage of women. However, few studies have looked at the reasons why some women improve more so than others when doing the pelvic floor exercises. We also do not know if pelvic floor exercises provide added benefits (better outcomes and fewer complications) to women who undergo trans-vaginal tape (TVT) surgery. This study is looking at how pelvic floor muscle training helps to improve symptoms of SUI in women, and whether or not such training improves surgical outcomes. A research assistant will read this consent form with you and answer any questions you may have. The research ethics boards from Queen's University and the Ottawa Hospital have approved this study.

Purposes of the Study

The study aims to determine the impact of pelvic floor muscle training on the continence system and aims to predict which women with SUI benefit the most from physical therapy. The study also evaluates whether women who undergo physical therapy combined with TVT surgery do better than those who undergo TVT surgery alone. To answer these questions, 400 women in Kingston and Ottawa who are on the waiting list for TVT surgery will take part in the study. Women will be assigned to one of two groups. **The physical therapy group** will undergo six sessions with a physical therapist; **the control group** who will receive information on how to perform exercises at-home.

The study will involve:

Bladder diary

You will receive a 3-day bladder diary by mail or email. A research assistant will explain to you how to fill out this diary. On it, you record the frequency and amount of urine leakage you experience over the course of three typical days. You will need to fill this out before attending the baseline testing.

Baseline Testing

This session will take place at the Pelvic Floor Laboratory at Queen's University in Kingston or at the Shirley Greenberg's Women's Health Center at the Riverside Campus of the Ottawa Hospital. The session will last approximately 2.5 hours. The research assistant will first look at your bladder diary with you. Next, you will perform the 20-minute pad test. The purpose of the test is to determine how severe your symptoms are by measuring the amount of urine leakage



that occurs during the test. You will arrive for this test with a comfortably full bladder, and the size of your bladder will be measured using ultrasound imaging. Then, the research assistant will give you a protective pad to wear in your underwear. You will perform a series of activities, such as walking up and down a flight of stairs, sitting down and standing up. The research assistant will weigh the pad after the test to see how much urine you lose during the test. After the test, you will empty your bladder.

You will next complete a physical examination with the physical therapist research assistant. The physical therapist research assistant will measure your height and weight. He or she will then perform a visual and manual inspection of your pelvic area and pelvic floor reflexes. For the physical screening, you will wear a gown, and you will get into a regular gynecological position. You will have pillows behind your back with your feet rested in heel rests. The physical therapist research assistant will first test your reflexes. Next, he or she will feel your pelvic floor muscles using two gloved fingers inserted into your vagina. He or she will then ask you to contract your muscles to assess their strength. You may ask to stop or to slow the testing down at any time.

At this point, the physical therapist research assistant will decide **if you are eligible** for the study, based on your bladder diary, pad test and physical screening results. You will be ineligible for the study if your bladder diary or pad test do not show that you leak urine. You will also be ineligible if the physical therapist research assistant finds that you have abnormal pelvic floor reflexes. If you are ineligible, the research assistant will tell you why. He or she will answer any questions or concerns you might have, and the testing will end.

If you are eligible to continue, the physical therapist research assistant will use an ultrasound machine to image your pelvic floor while you relax, while you perform pelvic floor muscle contractions, while you bear down, and while you cough. The physical therapist research assistant will give you clear instructions and will help you to practice each task before the ultrasound images are taken. The ultrasound imaging involves placing an ultrasound probe covered in gel over your genital area. The ultrasound will obtain images of your pelvic floor while you are lying down and then while you are standing up. Two different ultrasound heads will be used during the testing. Again, you may ask to stop or to slow the testing down at any time.

Before the end of the baseline testing, you will complete questionnaires on your incontinence symptoms. The questionnaires are expected to take approximately 10 minutes to complete. You will also receive a sheet on how to perform pelvic floor muscle exercises. This will conclude the baseline testing session.

Within one day after the baseline testing session, a research assistant will call your home to let you know **your study group**. This decision is made by a computer program; the investigators have no control over which group you are assigned to. If you are part of the **control group**, you will review the pelvic floor exercise sheet you received from the physical therapist research assistant and you will be re-evaluated in 12 weeks time. If you are part of the **physical therapy group**, you will take part in six treatment sessions with a physical therapist before you are re-evaluated.



Physical Therapy Group:

The physical therapy treatments will take place at a private physiotherapy clinic in Ottawa or Kingston. There are several physiotherapy clinics participating in this study, so that you can choose a clinic that is most convenient to your home or work. A physical therapist with expertise treating women with urinary incontinence will guide you through the sessions. The goals of physical therapy are to increase your pelvic floor muscle strength, endurance and control to decrease your urine leakage. The initial session will consist of education and an evaluation in order to set treatment goals. The treatment consists of 6 sessions over a 12-week period, and includes education, a home exercise program, pelvic floor muscle exercises and, if needed, biofeedback training. The biofeedback involves the insertion of a small measuring probe into your vagina, which shows you how well your muscles are working through an image on a computer screen. A major part of the physical therapy treatment is the pelvic floor muscle exercises that you do on your own every day at home.

Control Group

You will receive a home-based pelvic floor muscle training educational sheet. These exercises are part of the routine standard care that women receive while waiting for surgery. The exercises are very similar to the ones that the women assigned to the physical therapy group receive.

Post-Intervention/ Pre-surgical Testing

You will return to the Pelvic Floor Laboratory at Queen's University in Kingston or at the Shirley Greenberg's Women's Health Center at the Ottawa Hospital Riverside Campus 12 weeks after your initial testing session. We ask you not to reveal to the physical therapy research assistant whether you received physical therapy treatment or not. This pre-surgical testing will unfold exactly as the baseline testing (i.e., bladder diary, pad test, strength evaluation, ultrasound imaging, and questionnaires).

Pre-surgical Physical Therapy Follow up

If you are a participant in the physical therapy group, you will continue your exercise program. You will also visit your physical therapist every three weeks until your surgery date.

If you are a participant in the control group, you will continue doing at-home pelvic floor exercises until your surgery date.

Post-surgical Intervention

If you are a participant in the physical therapy group, you will continue your exercise program starting the day after your surgery. You will visit her physical therapist one week, three weeks and five weeks after your surgery. Your physical therapist will ensure that you are performing your exercises correctly. She will also progress your exercises based on your performance.

If you are a participant in the control group, you will continue your exercises on your own at home.



Post-surgical Testing

You will return to the laboratory 12 weeks after your surgery to be re-evaluated by the research assistant using the bladder diary, questionnaires and the pad test. This post-surgical testing will last 45 minutes.

Long-term follow-up testing

Although your participation in this study will last only until 12 weeks after your surgery, you may be asked undergo a long-term follow up evaluation using the questionnaire and pad test (similar to the post-surgical testing) at 12 months and 2 years after your surgery. Your participation in this study will therefore last 2 years. We anticipate that the entire study will be completed in four years.

Risks

Much like any muscle-training program, pelvic floor muscle exercises can cause muscle soreness or tiredness that might last up to 2 days after starting training. This is actually quite unlikely to occur since most women use their pelvic floor muscles every day and so they are used to contracting. There are no known risks to any of the testing procedures such as ultrasound imaging or physical therapy assessment used in this study.

Benefits

Pelvic floor muscle training is effective at decreasing the symptoms of urinary incontinence in some women, and as such, you might experience an improvement in your symptoms because of your participation.

The results of this study will advance our understanding of the impact of pelvic floor muscle training on surgical outcomes in women with stress urinary incontinence. The study may also allow us to predict which women benefit most from physical therapy in order to help health care professionals make decisions about patient care.

Compensation

You are not paid to participate in this research study.

If you are in the physical therapy group, treatments will be free of charge as long as you participate in this study. You will receive reimbursement for parking fees directly related to this study.

If you are in the control group, you will learn about your pelvic floor muscles. You will learn to contract them correctly during the baseline and pre-surgical testing sessions. You will also receive reimbursement for parking fees directly related to this study.

In the event of a research-related injury or illness, you will receive appropriate medical treatment/care. You are not waiving your legal rights by agreeing to participate in this study. The study doctor and the hospital still have their legal and professional responsibilities.



Alternative Treatment

You do not have to participate in this study to receive physical therapy treatment to help you with your symptoms of urinary incontinence. If you are deemed ineligible to participate or if you choose not to participate, the research assistant will provide you with a list of registered physiotherapists in the Ottawa region who are fully qualified to provide treatment similar to that which you may receive through participating in this study.

Withdrawal from Study

You have the right to withdraw your participation from this study at any time and without providing any reason. If you choose to withdraw from this study, this choice will have no consequence in terms of any future medical, surgical or physiotherapy care you receive at the Ottawa Hospital or at any private physiotherapy clinics.

Confidentiality

All personal health information will be kept confidential, unless release is required by law. Representatives of the Ottawa Hospital Research Ethics Board, as well as the Ottawa Hospital Research Institute, may review your original medical records under the supervision of Dr. Baker's staff for audit purposes.

You will not be identifiable in any publications or presentations resulting from this study. No identifying information will leave the Ottawa Hospital. All information which leaves the hospital will be coded with an independent study number.

The link between your name and the independent study number will only be accessible by Dr. McLean and her staff. The link and study files will be stored separately and securely. Both files will be kept for a period of 15 years after the study has been completed. All paper records will be stored in a filing cabinet in a locked office. All electronic records will be stored on a secure database at Queen's University and protected by a user password, again only accessible by Dr. McLean and her staff. At the end of the retention period, all paper records will be shredded, and all electronic records will be deleted.

Participant Rights

Your participation in this study is voluntary. You may withdraw from this study at any time without affecting your future access to medical care or your position on the surgical waiting list with Dr. Harvey, Johnston or Baker. You are free to choose not to answer any questions. You are free to choose not to undergo any testing, without giving any reason. The researchers may withdraw you from the study for scientific reasons at any time. In this case, they would give you a clear and valid reason. You have the right to obtain copies of any study forms that contain your personal information.



New Information on the Study

The researchers will inform you of any new findings during the study that may affect your desire to continue to participate in this study. At this time, you may have to sign a new consent form.

If at any time, you have further questions or problems you can contact the study investigators:

Linda McLean, BSc (PT), PhD at

Dr. Kevin Baker, MD at

or

The research assistants at the Pelvic Floor Laboratory at 613-929-3991 (Ottawa local) or
(Kingston Local) or :

If you have any questions on the ethical aspects of this study, you can contact the Director of the School of Rehabilitation Therapy Elsie Culham, at

If you have any questions about this study or if you feel that you have experienced a research-related injury, please contact Dr. Linda McLean at or the study physiotherapist at

The Ottawa Hospital Research Ethics Board (OHREB) has reviewed this protocol. The OHREB considers the ethical aspects of all research studies involving human subjects at The Ottawa Hospital. If you have any questions about your rights as a research subject, you may contact the Chairperson of the Ottawa Hospital Research Ethics Board at 613-798-5555, extension 14902.



Consent to Participate in Research

I understand that I am being asked to participate in a research study about the effect of pelvic floor muscle exercise on surgical outcomes in patients undergoing surgery to correct urinary incontinence.

This study has been explained to me by Ms. Lizy Kodiattu or Ms. Kevin Varette.

I have read this 7 page Patient Information Sheet and Consent Form or have had this document read to me. All my questions have been answered to my satisfaction. If I decide at a later stage in the study that I would like to withdraw my consent, I may do so at any time.

I voluntarily agree to participate in this study.

A copy of the signed Information Sheet and/or Consent Form will be provided to me.

Signatures

Participant's Name (Please Print)

Participant's Signature

Date

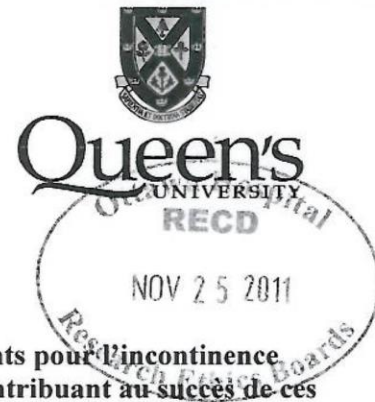
Investigator Statement (or Person Explaining the Consent)

I have carefully explained to the research participant the nature of the above research study. To the best of my knowledge, the research participant signing this consent form understands the nature, demands, risks and benefits involved in participating in this study. I acknowledge my responsibility for the care and well-being of the above research participant, to respect the rights and wishes of the research participant, and to conduct the study according to applicable Good Clinical Practice guidelines and regulations.

Name of Investigator/Delegate (Please Print)

Signature of Investigator/Delegate

Date



Lettre d'information

Titre de l'étude clinique : Optimisation des bienfaits des traitements pour l'incontinence urinaire d'effort chez la femme par l'identification de facteurs contribuant au succès de ces interventions

Chercheuse principale : Linda McLean, PhD, Professeure agrégée, École de réadaptation, Université Queen's.

Chercheur local : Dr. Kevin Baker, Hôpital d'Ottawa,

Description générale

Les exercices du plancher pelvien peuvent améliorer les symptômes de l'incontinence urinaire d'effort (IUE) chez un grand pourcentage de femmes. Par contre, peu d'études ont évalué comment ces exercices aident à améliorer l'IUE et pourquoi les femmes ne bénéficient pas toutes de ces exercices au même niveau. Nous ne savons pas non plus si une combinaison d'exercices de plancher pelvien et de chirurgie par bandelettes vaginales sans tension (TVT) est supérieure à la chirurgie seule. L'étude proposée ici évalue comment les exercices de renforcement du plancher pelvien aident à diminuer les symptômes d'IUE chez les femmes, et si cet entraînement offre une valeur ajoutée aux résultats chirurgicaux. Un assistant de recherche clinique lira avec vous ce formulaire de consentement, décrira en détail les procédures et pourra répondre aux questions que vous pourriez vous poser. Les comités d'éthique de la recherche des deux sites de l'étude (Kingston et Ottawa) ont approuvé ce protocole de recherche.

Buts de l'étude

Le but principal de l'étude est de déterminer l'impact des exercices des muscles du plancher pelvien sur le système de continence chez les femmes souffrant d'IUE, et de déterminer s'il est possible de prédire quelles femmes bénéficieront le plus de ces exercices. L'étude évalue aussi si les femmes qui subissent une chirurgie TVT et qui ont reçu des traitements de physiothérapie péri-opératoires voient une diminution plus importante au niveau de leurs symptômes en comparaison aux femmes qui n'en auront pas reçu. Pour répondre à ces questions, 400 femmes de Kingston et d'Ottawa qui sont sur une liste d'attente pour une chirurgie TVT vont participer à l'étude. Chaque femme sera affectée à un groupe. Les femmes affectées au groupe de physiothérapie recevront un minimum de six séances préopératoires, suivi de trois séances postopératoires avec un physiothérapeute; les femmes affectées au groupe contrôle recevront de l'information pour effectuer des exercices de renforcement du plancher pelvien à la maison.

Le protocole d'étude est composé de :

Calendrier de miction

Vous allez recevoir un calendrier de miction par la poste ou par courriel en même temps que la lettre d'information, suite à l'évaluation téléphonique initiale. Un assistant de recherche vous aura expliqué comment le remplir. Pendant trois jours typiques, vous remplirez le calendrier de



miction en indiquant toute perte d'urinaire non contrôlée. Vous devrez avoir rempli ce calendrier avant la séance d'évaluation initiale.

L'évaluation initiale

Cette rencontre aura lieu au Laboratoire du plancher pelvien à l'Université Queen's à Kingston, ou au Département de physiothérapie de L'Hôpital d'Ottawa, sur le Campus Riverside, en compagnie d'un ou d'une assistante de recherche. La rencontre durera approximativement 2.5 heures. L'assistant de recherche va premièrement discuter de votre calendrier de miction avec vous. Ensuite, vous effectuerez le test de la serviette hygiénique qui dure 20 minutes. Ce test permet de déterminer la sévérité de vos symptômes d'incontinence en mesurant la quantité d'urine relâchée au cours du test. Vous devez vous présenter au test avec la vessie pleine, et la taille de votre vessie sera mesurée par échographie à ultrasons. Ensuite, l'assistant de recherche vous fournira une serviette hygiénique à porter pour le reste du test. Avec votre vessie pleine, vous ferez une série d'activités, comme monter quelques marches d'escalier ou laver vos mains. Une fois le test complété, l'assistant de recherche pèsera la serviette hygiénique pour calculer la quantité d'urine perdue. Vous pourrez alors vider votre vessie complètement.

Par la suite, vous complèterez une évaluation physique. L'évaluation physique inclut une mesure de votre grandeur et poids, de même qu'une évaluation visuelle et manuelle de votre plancher pelvien et de ses réflexes. Pour cela, une robe d'hôpital vous sera fournie et vous vous positionnerez comme pour un examen gynécologique de routine : couchée sur le dos, avec des oreillers placés sous votre dos pour votre confort, vos talons appuyés dans des supports et les jambes supportées par des bandes élastiques au niveau des genoux. L'assistant de recherche utilisera deux doigts gantés insérés dans votre vagin pour toucher les muscles du plancher pelvien. Elle/Il évaluera la force de ces muscles en vous demandant de les contracter. Vous pouvez en tout temps lui demander de ralentir ou de mettre fin au test.

À ce moment-là, l'assistant de recherche décidera **si vous êtes admissible à l'étude**, en se basant sur les résultats de votre calendrier de miction, du test de la serviette hygiénique et de l'évaluation physique. Si ni le test de la serviette hygiénique ni votre journal de miction ne démontrent que vous souffrez d'incontinence urinaire, vous ne pourrez pas participer à l'étude. Vous serez aussi inadmissible si vous avez des réflexes anormaux au niveau du plancher pelvien. Si vous n'êtes pas admissible, l'assistant de recherche vous expliquera pourquoi et répondra aux questions et inquiétudes que vous pourriez avoir, et la rencontre initiale sera terminée.

Si vous êtes admissible, le physiothérapeute assistant de recherche utilisera l'imagerie par ultrasons pour visualiser vos muscles du plancher pelvien. Ceci sera effectué pendant que vous êtes au repos, pendant que vous contractez vos muscles du plancher pelvien, pendant que vous poussez, et pendant que vous tousssez. L'imagerie par ultrasons s'effectue en plaçant une sonde propre couverte d'un condom et ensuite de gel sur la région génitale. Le physiothérapeute assistant de recherche vous donnera des instructions claires et vous aidera à pratiquer chaque tâche avant que les images soient prises. Des images seront acquises alors que vous êtes en position couchée et debout, et deux différents types de sondes seront utilisés. À nouveau, vous pouvez demander en tout temps à l'assistant de recherche de ralentir ou de mettre fin au test.



Avant la fin de l'évaluation initiale, vous allez remplir des questionnaires sur vos symptômes d'incontinence urinaire. Les questionnaires devraient prendre environ 10 minutes à compléter. Finalement et avant de quitter, vous recevrez une feuille sur comment effectuer des exercices de plancher pelvien à la maison et ceci conclura la rencontre.

La journée suivant votre rencontre, un assistant de recherche vous contactera à la maison pour vous faire savoir quel groupe vous a été attribué. Cette décision est prise par un ordinateur; les chercheurs n'ont aucun pouvoir décisionnel sur votre groupe d'affectation. Si vous faites partie du groupe contrôle, vous allez réviser votre feuille d'exercices que vous avez reçue, et vous serez réévaluée 12 semaines plus tard. Si vous faites partie du groupe de physiothérapie, vous prendrez part à six séances de physiothérapie avant d'être réévaluée.

Groupe de physiothérapie :

Les traitements de physiothérapie prendront place dans une clinique privée dans votre ville, soit Ottawa ou Kingston. Plusieurs cliniques de physiothérapie participent à cette étude, alors vous pourrez choisir une clinique près de votre emploi et/ou de votre maison. Une/une physiothérapeute avec de l'expérience pour traiter l'incontinence urinaire chez la femme vous guidera. Les buts de la physiothérapie sont d'augmenter la force, l'endurance et le contrôle de vos muscles pelviens et de diminuer les pertes urinaires incontrôlées. La séance initiale consistera en de l'éducation et une évaluation afin de déterminer les buts des traitements de façon personnalisée. Le traitement consiste en un minimum de six séances sur une période de 12 semaines et inclut de l'éducation, un programme d'exercices à faire à la maison, des exercices de renforcement du plancher pelvien, et, au besoin, du biofeedback. Le biofeedback se fait en insérant une petite sonde dans votre vagin, sonde qui transmet l'image de vos muscles en action à un ordinateur. Les exercices de renforcement du plancher pelvien à faire par vous-même à la maison sont une partie importante des traitements de physiothérapie.

Le groupe contrôle :

Vous allez recevoir de l'éducation sur les exercices que vous avez reçus, et vous serez réévaluée 12 semaines plus tard. Ces exercices font partie du traitement standard que les femmes reçoivent lorsqu'elles attendent pour leur chirurgie TVT. Ces exercices sont très semblables à ceux qui sont effectués par les femmes qui sont affectées au groupe de physiothérapie.

Évaluation post-intervention/ pré-chirurgicale

Douze semaines après votre évaluation initiale, vous reviendrez au Laboratoire du plancher pelvien à l'Université Queen's à Kingston, ou au Département de physiothérapie de L'Hôpital d'Ottawa, sur le Campus Riverside. Nous vous demandons de ne pas révéler votre appartenance au groupe d'intervention (soit contrôle ou physiothérapie) à l'assistant de recherche pour ne pas biaiser les résultats des tests. Cette rencontre est semblable à l'évaluation initiale (c.-à-d., calendrier de miction, test de la serviette, évaluation physique de votre plancher pelvien, imagerie par ultrasons, et questionnaires).



Intervention pré-chirurgicale

Si vous êtes une participante du groupe contrôle, vous continuerez votre programme d'exercices jusqu'à votre date de chirurgie.

Si vous êtes une participante du groupe de physiothérapie, vous continuerez votre programme d'exercices. Vous rencontrerez aussi votre physiothérapeute une fois par trois semaines jusqu'à votre date de chirurgie.

Intervention post-chirurgicale

Si vous êtes une participante du groupe de physiothérapie, vous continuerez votre programme d'exercices dès la journée suivant votre chirurgie. Vous rencontrerez aussi votre physiothérapeute une semaine, trois semaines et cinq semaines après votre chirurgie. Votre physiothérapeute s'assurera que vous effectuez vos exercices correctement et les adaptera selon votre progression.

Si vous êtes une participante du groupe contrôle, vous continuerez votre programme d'exercices à faire à la maison.

Évaluation post-chirurgicale

Douze semaines après votre chirurgie, vous reviendrez pour une rencontre de 45 minutes avec l'assistant de recherche. À cette rencontre, le calendrier de miction, le test de la serviette, et les questionnaires seront utilisés pour évaluer vos symptômes.

Intervention post-chirurgicale (à long-terme)

Même si votre participation à cette étude dure que 12 semaines après votre opération, vous pourriez être demandé d'accomplir une évaluation à long terme utilisant des questionnaires et des test de serviettes sanitaire (ressemblant à l'évaluation post-chirurgicale) 12 mois et 2 ans après votre chirurgie.

Risques et inconvénients

Telle que le programme d'entraînement musculaire, les exercices de plancher pelvien peuvent causé des endolorissement ou fatigue musculaire qui peuvent durée jusqu'à deux jours après avoir commencer l'entraînement. Ceci est peu probable puisque les femmes utilisent leur plancher pelvien chaque jour et sont donc habituées de contracter ce muscle. Il n'y a aucun risque connu associé avec les techniques utilisées telle que la technique d'imagerie d'écographie ou les évaluations de physiothérapie utilisé dans cette étude.

Avantages

L'entraînement du plancher pelvien est effectif à diminuer les symptômes d'incontinence urinaire pour certaines femmes, ainsi, vous pouvez possiblement improuver vos symptômes avec votre participation dans cette étude.



Les résultats de cette étude vont avancer notre compréhension de l'impact de l'entraînement du plancher pelvien après un opération pour les femmes avec de l'incontinence urinaire. Cette étude pourra aussi nous permettre de prédire quelles femmes vont bénéficier le plus de la physiothérapie pour aider les professionnels de la santé de faire des décisions à propos des patients.

Compensation

Vous ne serez pas payée pour participer à cette étude clinique.

Si vous êtes une participante du groupe de physiothérapie, les traitements de physiothérapie décrits dans cette étude seront faits gratuitement tant et aussi longtemps que vous participerez à l'étude. Les frais de stationnement directement reliés à la participation à l'étude vous seront remboursés.

Si vous êtes une participante du groupe contrôle, vous serez informée sur le rôle que jouent vos muscles pelviens. Vous apprendrez comment les recruter lors des séances d'évaluation pré et post-chirurgicales. Les frais de stationnement directement reliés à la participation à l'étude vous seront remboursés.

Dans l'éventualité de blessure ou de maladie relié à cette étude, vous recevrez les soins et traitements médicaux nécessaires. En signant ce formulaire de consentement, vous ne renoncez à aucun de vos droits légaux. Le médecin responsable de l'étude clinique ainsi que l'hôpital sont toujours tenus de respecter leurs responsabilités professionnelles et légales.

Traitement alternatif

Vous ne devez pas participer à cette étude pour vous aidez avec vos symptômes d'incontinence urinaire. Si vous êtes qualifié inéligible de participer ou si vous choisissez de ne pas participer, le ou la chercheur(e) vous fournira une liste de physiothérapeutes enregistrés dans la région d'Ottawa qui sont bien qualifiés de vous fournir un traitement similaire à celui dont vous auriez reçu avec votre participation dans cette étude.

Retrait de votre étude

Vous avez le droit de retirer votre participation dans cette étude à n'importe quelle temps sans fournir de raison. Si vous choisissez de vous retirer de cette étude, ce choix n'aura aucune conséquence en terme de vos futures soins médicaux, chirurgicaux, ou en physiothérapie que vous obtenez à l'Hôpital d'Ottawa ou n'importe quelle autre cliniques privés de physiothérapie.

Confidentialité

Tous les renseignements obtenus seront strictement confidentiels, à moins d'une exception de la loi nous autorisant à les communiquer. Les représentants du Conseil d'éthique en recherches de L'Hôpital d'Ottawa ainsi que l'institut de recherche de l'Hôpital d'Ottawa, peuvent réviser vos records médicaux originaux pour des raisons d'audit sous la supervision des employés de Dr. Baker.



Vous ne serez pas identifiable dans aucune publications ou présentations résultant de cette étude. Aucune information d'identité ne sortira de l'Hôpital d' Ottawa. Tous informations qui sortira de l'hôpital sera masquer par un numéro du participant indépendant de l'études.

Le lien entre votre nom et votre numéro de participant sera accessible uniquement par Dr. McLean et ses employés. Le lien entre votre nom et votre numéro de participant conservé séparément et en toute sécurité. Les deux fichiers seront gardés pour une période de 15 années après avoir complété votre étude. Tous papiers de records seront conservés dans un meuble de classement dans un bureau barré. Tous les records électroniques seront sauvegardés dans une base des données à l'Université Queen's et sera protégé par un mot de passe d'utilisateur seulement accessible par Dr. McLean et ses employés. Lorsque la période de retentions sera terminé, tous records de papier seront déchiquetés et tous records électroniques seront supprimé.

Droits des participantes

Votre participation est volontaire. Vous êtes libre de participer à cette étude et de vous en retirer en tout temps. Si vous décidez de ne pas participer à l'étude ou de vous en retirer, cela n'influera en rien sur la qualité des soins futurs ou votre position sur la liste d'attente des docteurs Harvey, Johnstone ou Baker. Vous êtes libre de choisir de refuser de répondre à certaines questions. Vous êtes aussi libre de choisir de refuser de vous soumettre aux tests, sans avoir à donner de raison. L'équipe de recherche peut décider à tout moment de vous retirer de l'étude, pour des raisons scientifiques. Dans ce cas, l'équipe vous donnera une raison claire et valable pour le faire. Vous avez aussi le droit de recevoir une copie des formulaires de l'étude contenant de l'information vous concernant.

Nouvelles informations à propos de l'étude

Vous serez avertie de toute nouvelle information découverte au cours de l'étude et qui pourrait influencer sur votre décision d'y participer. Vous pourriez devoir signer un nouveau formulaire de consentement

Si vous avez des questions ou des problèmes, vous pouvez contacter en tout temps les chercheurs responsables de l'étude :

Linda McLean, BSc (PT), PhD, au _____

D^{re} Marie-Andree Harvey, MD, au _____

D^r Kevin Baker, MD, au _____

encore

Les assistants de recherche au Laboratoire du plancher pelvien, au _____
ou _____

Si vous avez des questions au sujet de l'étude ou si vous croyez avoir subi une blessure reliée à cette recherche, s'il vous plaît contacter Dr. Linda McLean au _____ ou l'étude des physiothérapeutes au _____



Le Conseil d'éthique en recherches de L'Hôpital d'Ottawa(Ottawa Hospital Research Ethics Board-OHREB) a révisé ce protocole. OHREB considère les aspects éthiques de toutes les études incluant des sujets humains à l'Hôpital d' Ottawa. Si vous des questions au sujet de vos droits en tant que participant humain, vous pouvez contacter le directeur du Conseil d'éthique en recherches de L'Hôpital d'Ottawa, au

Sur les aspects éthiques de cette étude clinique, veuillez contacter le directeur de l'École de réadaptation, au () vous avez des questions sur vos droits en tant que sujet de recherche, veuillez contacter le directeur du Conseil d'éthique en recherches de L'Hôpital d'Ottawa, au



Formulaire de consentement

Titre de l'étude clinique : Optimisation des bienfaits des traitements pour l'incontinence urinaire d'effort chez la femme par l'identification de facteurs contribuant au succès de ces interventions

Je comprends que je suis invitée à participer à une étude clinique sur les effets d'un entraînement pour les muscles du plancher pelvien sur la gestion de l'incontinence urinaire d'effort. J'ai lu les sept pages de la lettre d'information et du formulaire de consentement, et l'étude m'a été expliquée par un assistant de recherche. J'ai eu l'occasion de poser toutes les questions voulues au sujet de l'étude et on y a répondu à ma satisfaction.

En signant ce formulaire de consentement, j'accepte de participer au présent projet de recherche, selon les conditions suivantes :

- Je comprends que je suis demandé de participer à une étude de recherche au sujet des effets d'exercice du plancher pelvien après une chirurgie pour les patients qui vont avoir une chirurgie pour corriger l'incontinence urinaire.
- Cette étude m'a été expliqué par Mme Lizy Kodiattu ou M. Kevin Varette.
- J'ai lu les 7 pages d'information pour les patients et la forme de consentements ou j'ai déjà lu ces documents. Je suis satisfait des réponses obtenues pour mes toutes questions. Si je décides de retirer ma participation plus tard durant l'étude, je peux faire ceci à n'importe quel temps.
- Ma participation est volontaire.
- Une copie de cette lettre d'information signée et/ou du formulaire de consentement me sera fournie.

Signatures

Nom de la participante (en lettre moulées)

Signature de la participante

Date

Déclaration de l'investigateur (ou de la personne expliquant le consentement)

J'ai expliqué soigneusement à la participante de la recherche la nature de l'étude susmentionnée. Pour autant que je sache, la participante apposant sa signature à ce consentement reconnaît la nature, les exigences, les risques et les avantages que comporte sa participation à l'étude. Je reconnais ma responsabilité envers le soin et le bien-être de la participante susmentionnée, le respect des droits et des désirs de ce dernier, et le déroulement de cette étude, conformément aux directives et aux règlements relatifs à la bonne pratique clinique.

Nom du chercheur ou de son délégué
(en lettres moulées)

Signature du chercheur ou de son délégué
(veuillez inscrire la date)

Date de la version : novembre 2011

Valide jusqu'au 12 DEC. 2012

Page 8 de 8



Formulaire de consentement pour services de physiothérapie du plancher pelvien

Titre de l'étude : « Optimisation des bienfaits des traitements pour l'incontinence urinaire à l'effort chez la femme par l'identification de facteurs contribuant au succès de ces interventions »



Chercheuse principale : Linda McLean, PhD, Professeure agrégée, École de réadaptation, Université Queen's.

Chercheur local : Dr. Kevin Baker, Hôpital d'Ottawa

Services de physiothérapie

Les évaluations et traitements de physiothérapie du plancher pelvien dispensés au cours de cette étude clinique sont basés sur les pratiques cliniques actuelles. Vous recevrez le même type de services de physiothérapie que vous recevriez lors d'une consultation avec un physiothérapeute spécialisé dans l'évaluation et le traitement de l'incontinence en clinique privée.

Les avantages de la physiothérapie chez les femmes souffrant d'incontinence ont été démontrés. Il n'y a toutefois aucune certitude ou garantie que vous verrez une amélioration de vos symptômes. La physiothérapeute que vous rencontrerez tout au long de cette étude a reçu une formation spécialisée dans l'évaluation et le traitement des troubles du plancher pelvien.

Il est important que vous passiez en revue le formulaire d'information générale traitant de l'évaluation et des traitements de physiothérapie afin de bien comprendre le déroulement de l'étude. Le processus d'évaluation et les traitements vous ont été expliqués de façon verbale et sont décrits dans le formulaire de consentement initial. Il est primordial que vous soyez confortable à l'idée de travailler avec la physiothérapeute. De plus, vous n'avez aucune obligation de participer aux traitements qui vous gênent ou rendent nerveuse. Si vous avez des questions ou inquiétudes liées aux séances d'évaluation et de traitements de physiothérapie, veuillez en aviser la physiothérapeute qui se fera un plaisir de clarifier l'information pour vous et de discuter des options possibles.

Frais professionnels

Aucun frais ne vous seront facturés pour les services fournis dans le cadre de l'étude clinique.

Contactez votre physiothérapeute

Vous pouvez appeler _____ (inscrire le numéro du physiothérapeute) pour rejoindre votre thérapeute. Il se peut qu'il soit plus pratique et facile de rejoindre votre physiothérapeute par courriel, au _____ (insérer l'adresse courriel du physiothérapeute). Si vous êtes incapable de joindre votre physiothérapeute, ou il est difficile de vous joindre, appelez des chercheurs responsables de l'étude au

(Linda McLean) ou au _____ (Laboratoire du plancher pelvien) à un moment opportun pour vous et ils passeront le message à votre physiothérapeute pour s'assurer que celui-ci entre en communication avec vous.



Confidentialité

Toutes informations de santé personnel sera garder confidentiel, à moins que l'information est requise d'être libéré par la loi. Les représentés du bureau d'éthique en recherche de l'Hôpital d'Ottawa ainsi l'institut de recherche de l'Hôpital d'Ottawa, peuvent révisés vos records médicaux originaux sous la supervision des employés de Dr. Baker pour des raisons d'audit.

Vous ne serez pas identifiable dans aucune publications ou présentations résultant de cette étude. Aucune information d'identité ne sortira de l'Hôpital d' Ottawa. Tous informations qui sortira de l'hôpital sera masquer par un numéro du participant indépendant de l'études.

Le lien entre votre nom et votre numéro de participant sera accessible uniquement par Dr. McLean et ses employés. Le lien entre votre nom et votre numéro de participant conservé séparément et en toute sécurité. Les deux fichiers seront gardés pour une période de 15 années après avoir complété votre étude. Tous papiers de records seront conservés dans un meuble de classement dans un bureau barré. Tous les records électroniques seront sauvegardés dans une base des données à l'Université Queen's et sera protégé par un mot de passe d'utilisateur seulement accessible par Dr. McLean et ses employés. Lorsque la période de retentions sera terminé, tous records de papier seront déchiquetés et tous records électroniques seront supprimé.

Droits et responsabilités de la participante : Vous êtes libre de vous retirer du traitement et de l'étude à tout moment durant l'étude clinique. C'est aussi votre droit de choisir de refuser de participer aux évaluations et traitements ou portions de traitements pendant l'étude.

Veillez informer votre physiothérapeute si vous avez des questions à propos de ce formulaire de consentement et veuillez conserver ce formulaire; il est à vous.

Les évaluations et traitements standards de physiothérapie pour le plancher pelvien comportent :

- L'insertion de 1 ou 2 doigts à l'intérieur du vagin pour mesurer la force et flexibilité des muscles du plancher pelvien, afin d'évaluer la qualité de la contraction du muscle, et ainsi vous aider à améliorer le contrôle et la force de ces muscles
- L'insertion d'un doigt à l'intérieur de l'anus (uniquement lors de l'évaluation initiale) pour évaluer la force et la flexibilité des muscles du plancher pelvien
- L'insertion d'une sonde vaginale pour les séances de traitements utilisant le biofeedback



Consentement pour l'évaluation et le traitement de physiothérapie du plancher pelvien

Je soussignée _____
(Nom de la cliente en lettres moulées)

accepte que _____ (Nom du physiothérapeute en lettres moulées), physiothérapeute, procède à des évaluations et traitements de physiothérapie du plancher pelvien dans le but de traiter mon incontinence urinaire d'effort.

Je comprends :

- ✓ La raison pour le traitement recommandé
- ✓ Les objectifs du traitement
- ✓ De quelle manière le traitement se déroulera
- ✓ Quels sont les résultats potentiels du traitement
- ✓ Que mon consentement peut être retiré à tout moment

Signature de la cliente : _____

Date : _____

Signature du physiothérapeute : _____

Date : _____

Valide jusqu'au 12 DEC, 2012

APPENDIX D

713, chemin Montréal Road, Ottawa, ON K1K 0T2
Tél./Tel.: 613-746-4621 Téléc./Fax: 613-748-4914
hopitalmontfort.com



Un hôpital d'enseignement
affilié à l'Université d'Ottawa
A teaching hospital affiliated
with the University of Ottawa



Avis de renouvellement de l'approbation éthique Comité d'éthique de la recherche (CÉR) de l'Hôpital Montfort

4 octobre 2016

Chercheure principale :

Linda McLean
Queen's University, Kingston, Ontario

Collaborateurs :

Kevin Baker
Ottawa Hospital

Responsable de site Hôpital Montfort

Vincent della Zazzera
Hopital Montfort

Marie-Andrée Harvey
Kingston General Hospital
Queen's University

Andrew Day
Clinical Trials Group for Community Health and
Epidemiology

Robert J Brison
Kingston General Hospital
Clinical Trials Group for Community Health and
Epidemiology

Eric Sauerbrei
Kingston General Hospital
Queen's University Radiology

Titre du projet « Optimizing treatment outcomes for women with stress urinary incontinence through the identification of factors contributing to successful interventions »

Numéro du dossier M-16-07-15

Date de début 4 octobre 2016

Date de fin 24 septembre 2017

Renouvellement : d4

Le Bureau d'éthique de la recherche (BÉR) de l'Hôpital Montfort vous informe que votre demande de renouvellement annuel de l'approbation éthique pour le projet mentionné ci-dessus a été **évaluée et approuvée** par le président du CÉR ou son délégué. Les décisions prises au sujet des dossiers évalués en comité délégué sont ratifiées par le comité lors de sa prochaine réunion plénière.

Le protocole de l'étude ne peut être modifié sans une approbation préalable du CÉR sauf s'il est question de la sécurité immédiate des participants. Le chercheur doit, avant toute utilisation, soumettre pour évaluation et approbation toutes les modifications au protocole et à la documentation destinée aux participants, par exemple, formulaire de consentement et aux outils de recrutement. Vous devez aussi aviser le CÉR

Page 1

immédiatement de tout événement indésirable ou nouvelle information pouvant augmenter le risque ou modifier le cours du projet de recherche.

Votre certificat d'approbation est valide pour les dates de début et de fin mentionnées ci-dessus et vous devriez nous acheminer **quatre semaines avant la date d'échéance de cet avis d'approbation**, un rapport final ou d'étape annuel afin de fermer le dossier ou de faire une demande de renouvellement de l'approbation éthique. Veuillez noter que vous pouvez soumettre votre demande de renouvellement plus tôt que le délai exigé. Toutefois, le CÉR évaluera et émettra le certificat de renouvellement à une date qui ne remonte pas à plus tôt que 30 jours avant la date d'expiration du certificat valide.

Le CÉR de l'Hôpital Montfort est constitué et exerce ses activités d'une manière conforme à la Norme nationale du Canada visant la surveillance de l'éthique de recherches comportant des essais cliniques biomédicaux de l'Office des normes générales du Canada, aux Bonnes pratiques cliniques : directives consolidées, du Conseil international sur l'harmonisation des exigences techniques relatives à l'homologation des produits pharmaceutiques à usage humain (CIH-BPC E6), à la Partie C, Titre 5, du Règlement sur les aliments et drogues et aux règlements applicables, à la partie 4 du Règlement sur les produits de santé naturels; à la partie 3 du Règlement sur les instruments médicaux, au « *Code of Federal Regulations* » des États-Unis, à la Loi ontarienne de 2004 sur la protection des renseignements personnels sur la santé, de même qu'aux lois et règlements applicables en Ontario.

Si vous avez des questions, vous pouvez communiquer avec le bureau d'éthique de la recherche (BÉR) de l'Hôpital Montfort au 613746-4621 poste 2221 ou par courriel à ethique@montfort.on.ca.

Johanne Pomerleau, BSc., LLM

Gestionnaire du bureau d'éthique de la recherche - Hôpital Montfort

APPENDIX E

Telephone Information Sheet

Thank you for your interest in the study.

First I am going to tell you about the purpose of this study, as well as the details of what your participation would entail if you are eligible and choose to participate. If you are still interested after the description of the study, then I will ask you a number of questions to determine your eligibility for the study. This description and screening questionnaire could take about 10-20 minutes, and some of the questions are personal in nature. Is now an appropriate time to complete the interview? Please interrupt me at any time if you have questions.

Can I ask in what city you currently live? On what doctor's waiting list are you? (enter in p.3)
Screen right away for: Will you be living in this same city for the next few months?
Are you able to commute bi-monthly to Kingston or Ottawa (as appropriate)?

The purpose of this study is to determine the effectiveness of pelvic floor muscle training for treating stress urinary incontinence (SUI) and for improving surgical outcomes. We are only including women who have SU and who are waiting for a surgical dates for TVT surgery. We are offering you the opportunity to participate while waiting for surgery and potentially improve your surgical outcomes.

The pelvic floor muscles are the muscles responsible for vaginal, urinary, and anal functioning. Physiotherapy (PT) has shown success in previous studies, however cannot yet predict which women will benefit most from PT. We also do not know whether a combination of surgery and physiotherapy is better than surgery alone, but we suspect it is.

Your participation in the study would start now, while you are waiting for surgery, and would terminate 2 years after your surgery.

First, you will be sent a letter of information about the study, then a bladder diary to fill out. Next, you will come into the Shirley Greenberg women's health center or Pelvic floor lab at riverside campus of the Ottawa hospital or Queen's University campus for a 2 hour baseline testing session to verify your eligibility for the study. During this session, you will complete a "pad test". During the pad test you will wear a protective pad and perform activities that might cause leakage such as going up stairs. You will undergo a physical examination much like a gynecological exam (without the speculum part) to assess the strength of your pelvic floor muscles and to rule out the presence of other conditions that might affect your participation. I will then image your PFM using an ultrasound system (the same use for pre-natal visits). No health risks are posed by any of these techniques. At the end of the session, I will let you know whether you are eligible to continue or not. In other words, if you have symptoms of incontinence you will be eligible to continue; this is very likely since you are on the waiting list for surgery.

After you have finished the baseline testing, you will be assigned to one of 2 groups: a physical therapy group or a control group. The physical therapy consists of 6 45 minute treatment with a physical therapist in your home town. The control group receives information on how to perform pelvic floor muscles exercises at home. 12 weeks later and before your surgery, you will come back for a follow-up testing to reproduce the first session and to see where have been any changes to your status. Then, after your surgery, we have you come in one more time to re-evaluate and to see how you are doing. Lastly, we will do quick follow-up testing 12 months and 2 years after your surgery.

The treatments, the treatment material and your parking costs will be provided to you free of charge. We ask that you avoid any other form of treatment for SUI during the course of the study. This study will shed light on the best management options for women with SUI and hopefully assist women in the future in regaining full continence.

This is the study in a nutshell. Do you have any questions? Are you interested in seeing if you are eligible for participating in the study? **If no, thank them for their time, and ask them to feel free to call back if they change their mind.**

- Currently pregnant or <6 months post-partum
- pelvic mass (es)
- pad test weight gain less than 1g at baseline testing
- no episode of SUI as demonstrated by a 3-day bladder diary
- having received more than 4 sessions of physical therapy in the past 5 years specifically for treating their symptoms of SUI
- detrusor instability as identified by routine urodynamics studies performed as part of the patient evaluation by the urogynaecologist
- prolapse (> POP-Q stage 2)
- are taking medications known to increase or alleviate incontinence
- not willing to cease other treatment for SUI treatment during the course of study
- fecal incontinence (e.g., pessary)
- prior urogynecological surgery
- neurological impairments involving the central nervous system or the sacral nerves or known connective tissue disorders
- major psychiatric conditions which impact significantly with daily functioning and would prevent full participation in the study
- Physical impairment that would prevent the participant from completing the 20-minute pad test (a major study outcome measure)
- in situ devices that would not be suitable for ultrasound testing

Telephone Screening Form

Name: _____ **Date of screening:** _____ (yyyy-mm-dd)

Home #: () - (best time to call:) leave a message? Y N
Cell #: () - (best time to call:) leave a message? Y N
Work #: () - (best time to call:) leave a message? Y N

Mailing address OR fax # (only if necessary) to send the bladder diary and LOI before the first session:

Email address: _____

Recruitment Source: MAH [1] J [2] Baker [3]

Interested in finding out if they are eligible? Y [1] N [0] If no, reason _____

Interested in participating? Y [1] N [0] If no, reason _____

Availability _____

**Let them know that someone will contact them a few days before their appointments to let them know the details of where to go and what to bring:*

How do you want to be reminded of you appointments?

- Email**
- Phone msg**
- No reminder**

Bookings:

Pre-intervention session: _____ (yyyy-mm-dd) _____ (00:00)

Eligible for study? Y[1] N [0]

If no, why? _____

Post-intervention session: _____ (yyyy-mm-dd) _____ (00:00)

Post-surgical session: _____ (yyyy-mm-dd) _____ (00:00)

Follow-up 1 session: _____ (yyyy-mm-dd) _____ (00:00)

12 mos

Follow-up 2 session: _____ (yyyy-mm-dd) _____ (00:00)

2 yrs

Initial telephone screening (not stored with the contact sheet for confidentiality) ID _____

1. What language do you prefer: English or French? E[1] F [2]
2. Which city do you live in? _____ study site: Ottawa [1] Kingston [2]
3. Living in this same city for the next few months? Y [1] N [2]
4. Able weekly commute to Ottawa/Kingston? Y [1] N [2]

*To determine if you are eligible to participate in the study we will need to ask you some questions about your medical history. Is that okay?

5. How old are you? _____ (* not eligible if under 18) DOB: _____(yyyy-mm)
6. Are you currently pregnant or are you trying to become pregnant? Y *[1] N [2]
7. When was your last pregnancy? _____(yyyy-mm) (* not eligible if less than 6 months)
8. Are you currently suffering from any medical (neurological, etc.), pain or psychiatric conditions? Y* [1] N [2] If yes:
a)With what condition(s) have you been diagnosed? (If unsure of eligibility ask questions about how long they've had this diagnosis, severity of condition)
Cardiovascular/vascular (e.g., angina, heart attack, transient ischemic attack, stroke, etc)

Respiratory (e.g., asthma, chronic obstructive pulmonary disease, emphysema, etc)

Gastrointestinal/renal (e.g., irritable bowel syndrome, interstitial cystitis, etc) _____

Musculoskeletal/rheumatological (e.g., fibromyalgia, arthritis, etc) _____

Endocrinological (e.g., hypothyroidism, diabetes, etc) _____

Gynecological (e.g., endometriosis, pelvic inflammatory disease, recurrent yeast infections, etc)

Psychiatric (e.g., depression) _____

Connective tissue disorder * _____

Chronic pain conditions _____

b) Do you think this/these condition(s) prevent you from participating in the study?
Y* [1] N [2] Details: _____

c) Do you have balance problems? Y* [1] N [2]

d) Do you use a walking aid? Y* [1] N [2]

e) Have you fallen in the last year? Y* [1] N [2] If yes, how many times? _____

f) Is your fitness level allow you to walk for over 20 minutes comfortably? Y [1] N [2] *

9. Are you currently taking any medication or analgesics for the conditions named above (i.e., pain medication)? Y [1] N [2] if yes, which ones:?

10. Have you ever had surgery (specifically urogynecological)? Y [1] * N [0]

If yes, which ones you have had.

- | | | | |
|-----------------------|-----|------------------|-----|
| Partial Hysterectomy | O 1 | Ovariectomy | O 5 |
| Complete hysterectomy | O 2 | Colposuspension: | O 6 |
| TVT | O 3 | Others _____ | O 7 |
| Tubal Ligation | O 4 | None | O 8 |

11. Do you have any episodes of urine leakage? Y [1] N*[0]

a. How often? _____/day _____/month

b. When do they **most often** occur?

- | | | | | | |
|----------|----|------------|----|-----------------|----|
| Coughing | O1 | Laughing | O2 | Key in the door | O3 |
| Lifting | O4 | Pants down | O5 | Sneezing | O6 |
| Run/jump | O7 | Sex | O8 | Other _____ | O9 |

c. When did you first start having symptoms of SUI? _____(yyyy)

d. If any, what treatments that you have tried?

- | | | | | |
|--------------------------------------|----|---------------------------|----|----------|
| Changing voiding habits
creams | O1 | Physical Therapy** | O2 | Hormone |
| Prescription medication
injection | O3 | Alternative medicine | O5 | Collagen |
| | O4 | | O6 | |

Pessary
treatment O9
Other:

O7 Surgery

O8 Other medical

None

O10

If they have undergone physiotherapy treatments for your SUI

What do you mean by physiotherapy?

For how many sessions did you take part in physiotherapy treatment?
_____ (* ineligible if more than 4 sessions)

When did you undergo this treatment? _____ yyyy (*ineligible if less than 5 years)

- e. Are you currently undergoing any treatment specifically for your SUI?
Y [1] * N [0] If yes, which one(s)?

- f. Would you be willing to stop this treatment for the length of the study? Y [1] N [0]* If prescription meds, will need to **consult family MD**
- g. Do you ever have urge incontinence whereby you cannot make it to the bathroom and your entire bladder (not just a couple of drops) empties? Y [1] * N [0] If yes, is that a bigger problem than your stress incontinence? Y [1] * N [0]
- h. Are you aware whether you have an overactive bladder (peeing over 15 times a day for small amounts) as diagnosed by a doctor? Y* [1] N [0] **Suspected [2]**
12. Do you currently have episodes of fecal incontinence?
Y* [1] N [0] Details: (frequency, duration)_____
13. Are you aware whether you have a pelvic organ descent? (prolapsus) Y* [1] N [0]
If yes, does it bulge out of your vagina if you strain? Y* [1] N [0]
14. Do you have any devices in your abdomen that would prevent you from undergoing ultrasound testing? Y* [1] N [0]
15. For future reference, would like to be offered to participate in other studies in the lab?
Y [1] N [2]

ELIGIBLE FOR BASELINE TESTING? Y [1] N* [2] (enter info on p.1)

If no

Explain, thank them for their time, provided them with information on how to solve the above-mentioned problems, if applicable. Refer to resources in their area, offer to email information/educational material.

If yes:

- explain and mail, fax or email their consent form and bladder diary
- explain the details for the PAD TEST (wear loose clothing)
- water consumption before the testing
- make sure they have appropriate contact information for each site
- remind them they will end up in 1 of 2 intervention groups
- Importance of informing us if they ever move
- book baseline testing and remind them they will receive an email/phone call before the testing to remind them of the appointment and to bring their bladder diary.

Thank you!

APPENDIX F



uOttawa



Ottawa Hospital
Research Institute
Institut de recherche
de l'Hôpital d'Ottawa

PARTICIPANT INFORMED CONSENT FORM



Title of the Study: Optimizing treatment outcomes for women with stress urinary incontinence through the identification of factors contributing to successful interventions

Local Site Principal Investigator: Dr. Kevin Baker
Shirley E. Greenberg Women's Health Centre

1967 Riverside Dr. Riverside Campus

The Ottawa Hospital (TOH), Ottawa, ON K1H 7W9

Principal Investigator: Dr. Linda Mclean, PhD, Full Professor
School of Rehabilitation Sciences
University of Ottawa

Funding Agency: Canadian Institutes of Health Research (CIHR)

Why am I being given this form?

You are being asked to participate in this research study because you are planning to receive pelvic floor therapy for your stress urinary incontinence (SUI).

Why is this study being done?

Pelvic floor exercises can improve the symptoms of stress urinary incontinence (SUI) in a great percentage of women. However, few studies have looked at the reasons why some women improve more than others when doing the pelvic floor exercises. This study is looking at how pelvic floor muscle training helps to improve symptoms of SUI in women, with the goal of more effectively identifying those women with SUI who will benefit from pelvic floor therapy.

Participation in this study is voluntary. Please read this Participant Informed Consent Form carefully before you decide if you would like to participate. Ask the study team as many questions as you like. We encourage you to discuss your options with family, friends or your healthcare team. The research ethics boards from Queen's University and The Ottawa Hospital have approved this study.

The study aims to determine the impact of pelvic floor muscle training on the continence system and aims to predict which women with SUI benefit the most from physical therapy.

To answer this question, data will be collected from women with SUI in several cities, including Ottawa, who are seeing a physical therapist for their SUI.

How is the study designed?

Participants in the study will undergo six physiotherapy sessions during a 12-week period with a physiotherapist who specializes in pelvic floor muscle training. Participants will undergo an evaluation with the study physiotherapist before and after the 12-week treatment period.

What is expected of me?

Once you agree to participate in the study and have signed the Participant Information Consent Form, the following study procedures will be conducted:

Bladder diary and Questionnaires

You will receive a three-day bladder diary and a series of questionnaires about your symptoms and your general health by mail or email. A research assistant will explain them to you. The most difficult questionnaire is the bladder diary, and the research assistant will explain in detail how to complete it. On it, you record the frequency and amount of urine leakage you experience over the course of three typical days. You will complete this diary and the questionnaires before attending the baseline testing.

Baseline Testing

This session will take place at Dr. Linda McLean's Motor Function Measurement Laboratory at the Lees Campus of the University of Ottawa, Ottawa, Ontario. The research assistant will first look at your bladder diary with you. Next, you will complete the 20minute pad test. The purpose of this test is to determine how severe your symptoms are by measuring the amount of urine leakage that occurs during the test. You will arrive for this test with a comfortably full bladder, and the size of your bladder will be measured using ultrasound imaging. Then, the research assistant will give you a protective pad to wear in your underwear. You will perform a series of activities, such as walking up and down a flight of stairs, sitting down and standing up. The research assistant will weigh the pad after the test to see how much urine you lost during the test. After the test, you will empty your bladder in a nearby toilet facility.

You will next complete a physical examination with the physical therapist research assistant. The physical therapist research assistant will measure your height and weight. He or she will then perform a visual and manual inspection of your pelvic area and pelvic floor reflexes. For the physical screening, you will wear a gown, and you will be asked to get into a regular gynecological position. You will have pillows behind your back with your feet rested in heel rests. The physical therapist research assistant will first test your reflexes. Next, he or she will feel your pelvic floor muscles using two gloved fingers inserted into your vagina. He or she will then ask you to contract your muscles to assess their strength. You may ask to stop or to slow the testing down at any time.

At this point, the physical therapist research assistant will decide **if you are eligible** for the study, based on your bladder diary, pad test and physical screening results. You will be ineligible for the study if your bladder diary or pad test do not show that you leak urine. You will also be ineligible if the physical therapist research assistant finds that you have abnormal pelvic floor reflexes. If you are ineligible, the research assistant will tell you why. Any questions or concerns you might have will be answered, and the testing will end.

If you are eligible to continue, the physical therapist research assistant will then use an ultrasound machine to image your pelvic floor while you relax, while you perform pelvic floor muscle contractions, while you bear down, and while you cough. The physical therapist research assistant will give you clear instructions and will help you to practice each task before the ultrasound images are taken. The ultrasound imaging involves placing an ultrasound probe covered in gel over your genital area. The ultrasound will obtain images of your pelvic floor while you are lying down and then while you are standing up. Two different ultrasound heads will be used during the testing. Again, you may ask to stop or to slow the testing down at any time. This will conclude the baseline testing session, which will last approximately two hours.

Physical Therapy:

The physical therapy treatments will take place at the private physiotherapy clinic in Ottawa that referred you to this study. You will be seen by the same physical therapist, with expertise treating women with urinary incontinence, that you would see should you not enroll in this study. The goals of physical therapy are to increase your pelvic floor muscle strength, endurance and control to decrease your urine leakage. The initial session will consist of education and an evaluation in order to set treatment goals. The treatment consists of six sessions over a 12-week period, and includes education, a home exercise program, pelvic floor muscle exercises and, if needed, biofeedback training. The biofeedback involves the insertion of a small measuring probe into your vagina, which shows you how well your muscles are working through an image on a computer screen. A major part of the physical therapy treatment is the pelvic floor muscle exercises that you do on your own every day at home.

Post-Intervention Testing

You will return to the Pelvic Floor Laboratory at the Lees Campus of the University of Ottawa 12 weeks after your initial testing session, after undergoing the physical therapy protocol. This assessment will

unfold exactly as the baseline testing (i.e., bladder diary, questionnaires, pad test, strength evaluation, and ultrasound imaging).

Long-term Follow-up Testing

You will return to the laboratory 12 weeks after your post-intervention testing to be re-evaluated by the research assistant. You will complete the bladder diary and the questionnaires before coming and the only testing performed during this visit will be the pad test. This session will last 45 minutes or less.

What are the potential risks I may experience?

Much like any muscle-training program, pelvic floor muscle exercises can cause muscle soreness or tiredness that might last up to two days after starting training. This is actually quite unlikely to occur since most women use their pelvic floor muscles every day and so they are used to contracting. There are no known risks to any of the testing procedures such as ultrasound imaging or physical therapy assessment used in this study.

Can I expect to benefit from participating in this research study?

Pelvic floor muscle training is effective at decreasing the symptoms of urinary incontinence in some women, and as such, you might experience an improvement in your symptoms with the physiotherapy treatment. Participating in this study provides you with additional consultation (pad test, bladder diary and ultrasound results) and training- the findings from this assessment will be shared with you and with your physiotherapist if you ask us to.

The results of this study may allow us to predict which women benefit most from physical therapy in order to help health care professionals make decisions about patient care.

Do I have to participate? What alternatives do I have?

Your participation in this study is voluntary. You may withdraw from this study at any time without affecting your future access to physiotherapy or any medical care.. You are free to choose not to answer any questions. You are free to refuse to undergo any testing, without giving any reason. The researchers may withdraw you from the study for scientific reasons at any time. In this case, they would give you a clear and valid reason. You have the right to obtain copies of any study forms that contain your personal information.

As a participant in this study, you have the right to an environment in which you feel comfortable. As such, you may request that a third person be present in the evaluation room during any or all assessment procedures. To this end, you are welcome to bring a friend or family member with you, or, if you would prefer, the study team can provide you with a third person to be present in the room. We will always have a research assistant available in the general laboratory space outside of the assessment room and she can step into the room at your request, at any time.

Alternative Treatment

You do not have to participate in this study to receive physical therapy treatment to help you with your symptoms of urinary incontinence. If you are deemed ineligible to participate or if you choose not to participate, you can still see the same registered physiotherapist that referred you to our study, and you will receive the same level of care.

What compensation will I receive if I am injured or become ill in this study?

In the event of a study-related injury or illness, you will be provided with appropriate medical treatment and care. You are not waiving any of your legal rights by agreeing to participate in this study.

Will I be paid for my participation or will there be any additional costs to me? You are not paid to participate in this research study.

You will receive reimbursement for parking fees directly related to this study and the study team will pay for your physiotherapy treatments.

How is my personal information being protected?

All personal health information will be kept confidential, unless release is required by law.

You will not be identifiable in any publications or presentations resulting from this study. No identifying information will leave The University of Ottawa. There will be one electronic password-protected file that links your name to your participant number, which will only be accessible by Dr. McLean and her staff at the university. That file will be stored on a secure server. All other information will be coded with an independent study number. All electronic records will be stored in a secure database and protected by a user password, again only accessible by Dr. McLean and her staff. All paper records will be stored in a locked file and/or office. All files will be kept for a period of 15 years after the study has been completed. At the end of the retention period, all paper records will be disposed of in confidential waste or shredded, and all electronic records will be deleted.

Do the investigators have any conflicts of interest?

There are no conflicts of interest to declare related to this study.

What are my responsibilities as a study participant?

It is important to remember the following things during this study:

- Ask the research staff if you have any questions or concerns.
- Tell the research staff if anything about your health has changed.
- Please contact study staff if you experience any side effects, even if you are unsure whether it has anything to do with this study.

Will I be informed about any new information that might affect my decision to continue participating?

The researchers will inform you of any new findings during the study that may affect your desire to continue to participate in this study. At this time, you may have to sign a new consent form.

Who do I contact if I have any further questions?

If you have any questions about this study or if you feel that you have experienced a research-related injury, please contact Dr. Linda McLean at _____ or

or Dr. Kevin Baker at _____, or the study physiotherapist at _____

If you have any questions on the ethical aspects of this study, you can contact the Director of the School of Rehabilitation Sciences, University of Ottawa, Dr. Paulette Guitard at _____.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed this protocol. The Board considers the ethical aspects of all research studies involving human subjects at The Ottawa Hospital. If you have any questions about your rights as a study participant, you may contact the Chairperson at _____.



Consent to Participate in Research

I understand that I am being asked to participate in a research study entitled “**Optimizing treatment outcomes for women with stress urinary incontinence through the identification of factors contributing to successful interventions**”. This study is about the effect of pelvic floor therapy on the symptoms of stress urinary incontinence.

This study has been explained to me by Dr. McLean’s physical therapist research assistant. I have read, or have had it read to me, each page of this Participant Informed Consent Form. All my questions have been answered to my satisfaction. If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.

I voluntarily agree to participate in this study.

I will be given a copy of this signed Participant Informed Consent Form.

Participant’s Printed Name Participant’s Signature Date

Investigator or Delegate Statement

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

Investigator/Delegate’s Printed Name Investigator/Delegate’s Signature Date

Assistance Declaration

Was the participant assisted during the consent process? Yes No

- The consent form was read to the participant/substitute decision-maker, and the person signing below attests that the study was accurately explained to, and apparently understood by, and consent was freely given by the participant/substitute decision-maker.
- The person signing below acted as a translator for the participant/substitute decision-maker during the consent process. He/she attests that they have accurately translated the information for the

participant/substitute decision-maker, and believe that the participant/substitute decisionmaker has understood the information translated.

Name of Person Assisting (Print)	Signature	Date
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APPENDIX G

BASELINE DEMOGRAPHICS

STUDY ID : _____

DATE: _____

AGE : _____

Please answer the questions on your EDUCATION AND WORK STATUS:

1. What is the highest level of formal education you have received ?

Some High School (1)

High School or Trade school (2)

College or Undergraduate (3)

Graduate or Professional School Degree (4)

Other (5)

2. What is your current employment Status ?

Employed Full time (1)

Employed Part time (2)

Student (3)

Retired (4)

Unemployed (5)

ON Disability (6)

Full Time parenting (7) Other (8)

3. Describe your Occupation

(1) Sedentary

(2) Active

(3) Mix

Medical and bladder and bowel function questionnaire

Date completed: _____ (yy/mm/dd) ID: _____

Please answer these questions as best you can.

Check the most appropriate answers in the circle beside.

If you have questions, write them down and we will address them on the day of testing.

Now please answer the questions on your bowel and bladder function:

1. How often do you feel that you empty your bladder completely when you urinate?

- 1 Always (100% of the time)
- 2 Almost always (90% of the time or more)
- 3 Often (more than 50% of the time)
- 4 Half of the time (about 50% of the time)
- 5 Sometimes (less than 50% of the time)
- 6 Rarely (10% of the time or less)
- 7 Never (0% of the time)

2. Do you have the urge to urinate not long after you have been ?

No (0) Yes(1)

3. How is the flow most times?

- Weak (1)
- Moderate (2)
- Strong (3)

4. Can you voluntarily stop the flow of urine?

- Not at all (0)
- Partially (1)
- Completely(2)

5. Have you regularly practised to stop the flow of urine as an exercise?

- No(0)
- Yes(1)

6. Do you have a loss of drops of urine after you have finished urinating?

- No(0)
- Yes(1)

7. Do you feel a tissue bulge / protrusion at the vaginal opening?

- No (0)
- Yes (1)

8. Do you have urgency of stool (difficulty holding in stool but no involuntary loss of stool)?

- No(0)

Yes (1)

If yes, how often is it urgent when you have to go to the bathroom for a bowel movement (i.e. you have to go right away)?

- 1 Always (100% of the time)
- 2 Almost always (90% of the time or more)
- 3 Often (more than 50% of the time)
- 4 Half of the time (about 50% of the time)
- 5 Sometimes (less than 50% of the time)
- 6 Rarely (10% of the time or less)
- 7 Never (0% of the time)

9. How often do you feel that you have to force or push to evacuate your bowel?

- 1 Always (100% of the time)
- 2 Almost always (90% of the time or more)
- 3 Often (more than 50% of the time)
- 4 Half of the time (about 50% of the time)
- 5 Sometimes (less than 50% of the time)
- 6 Rarely (10% of the time or less)
- 7 Never (0% of the time)

10. How often do feel that you did not empty your bowel completely?

- 1 Always (100% of the time)
- 2 Almost always (90% of the time or more)
- 3 Often (more than 50% of the time)
- 4 Half of the time (about 50% of the time)
- 5 Sometimes (less than 50% of the time)
- 6 Rarely (10% of the time or less)
- 7 Never (0% of the time)

11. How often do you have to assist yourself in the passage of stools?

- 1 Always (100% of the time)
- 2 Almost always (90% of the time or more)
- 3 Often (more than 50% of the time)
- 4 Half of the time (about 50% of the time)
- 5 Sometimes (less than 50% of the time)
- 6 Rarely (10% of the time or less)
- 7 Never (0% of the time)

12. Do you have a lot of bloating or gas or problems with bloating or gas?

No (0) yes (1)

13. Are you able to prevent the passage of gas? (** Negative answer **)

No (0)

Yes (1)

14. Would you say that you have chronic constipation problems?

No (0)

Yes (1)

15. Do you have haemorrhoids and /or anal fissure?

No (0)

Yes (1)

Don't know (2)

If yes , Are they painful?

No (0)

Yes (1)

Now please answer the questions on your gynecological history:

1. Have you had or are you currently experiencing menopause?

No (0) Yes (1)

If not menopausal: Do you take hormonal contraceptives?

No (0) Yes (1)

If menopausal: Are you on hormonal replacement therapy?

No (0) Yes (1)

2. Have you ever given birth?

No(0) Yes (1)

If yes, how many pregnancies? _____

Were they all vaginal/natural deliveries?

No(0) Yes(1)

Any complications during delivery?

No(0) Yes(1)

If Yes -- prolonged Labour

Vaccum ,Forceps

C.sections

How many live births?: _____

Birth wt. of the largest child:_____

ANY STDs? Yes O1No O2

If yes:

Chlamydia O1 Trichomoniasis O8

Gerdnerella vaginalis O2 Bladder/urinary infections O9

Genital Warts or HPV O3 Interstitial cystitis O10

Gonorrhea O4 Pelvic inflamatory disease O11

Genital herpes O5 Endometriosis O12

HIV/AIDS O6 Vaginal infections O13
Syphilis O7 Other _____ O14

Have you had a Hysterectomy?
No (0) Yes (1)

Now please answer the questions on your fitness level, diet and stress level:

1. Do you currently engage in physical activity? Yes O1 No O2
If yes, what type? _____
How often? _____ / per week

2. Do you consider that you have healthy eating habits (e.g. fiber, fruits and vegetables, balanced diet, etc.)?
Yes O1 No O2 If no, specify: _____

3. Do you smoke ? Yes O1 No O2 If yes, how many cigarettes per day? _____ Since when? _____
If yes, are you thinking or have you attempted to stop? Yes O1 No O2
Details: _____

4. On average, how much stress have you experienced over the last week on a scale of 0 (not stressed at all) to 10 (most stressed ever)? _____ /10
Details: _____

5. What is/are your favorite leisure activities (name 1 to 3)?

APPENDIX H

Bladder Diary

start 3 days prior to appt.

DAY 1 DATE _____

<u>Time</u>	<u>leakage -Amount</u> (S/M/L)	<u>Activity</u>

<u>Day 2</u>		
<u>Time</u>	<u>leakage -Amount</u> (S/M/L)	<u>Activity</u>

APPENDIX I

Participants are instructed to practice the following pelvic floor muscle (PFM) exercises lying down, sitting and standing to gain control of PFMs in different positions and circumstances which are more representative of daily activities. BUT, to begin with: try lying down or half-lying down and half sitting with pillows supporting your back, with knees bent and hips relaxed.

Cues: To perform a contraction of the PFMs, “tighten” or “squeeze” as if you are trying to hold urine or restrict the passage of gas. Think of the muscles “drawing in and up” as they contract. To perform a proper relaxation of your PFMs, concentrate on “letting go” completely of the contraction, “relaxing” and “not doing anything at all”.

PFM Exercise	Goal	Instructions	Parameters
1. “The Basic Contract-Relax”	<ul style="list-style-type: none"> - Identification and awareness of PFMs - Identification of the contrast between contraction & relaxation of PFMs 	<ul style="list-style-type: none"> - A maximal voluntary contraction followed by a complete relaxation of the PFMs which needs to be at least twice as long as the contraction phase to allow full relaxation 	<ul style="list-style-type: none"> - Contraction held 2 seconds, relaxation for a minimum of 4 seconds - 1 set = 10 repetitions of contraction and full relaxation - 2 sets/day
2. The “Wave”	<ul style="list-style-type: none"> - Increase awareness of PFMs - Isolation of different regions of the pelvic floor - Isolation of PFMs vs. other muscles such as your abdominals, gluts, hip adductors 	<ul style="list-style-type: none"> - A contraction of one section of PFMs at a time, beginning by contracting at the anus, then the vagina, and then the urethra. Then, do the reverse, by beginning at the urethra, vagina, and then anus. - Thus, the movement is like a wave going back and forth. 	<ul style="list-style-type: none"> - Contractions at each section are held for 2 seconds, followed by a relaxation of 4 seconds before moving on to another section. - The start direction is unimportant, but each direction of movement from front to back, or back to front is repeated 5 times. - 1 set = a total of 10 contractions at each section (anus, vagina, urethra) - 2 sets/day
3. The “Elevator”	<ul style="list-style-type: none"> - Increase control of contraction and relaxation of the PFMs 	<ul style="list-style-type: none"> - A gradual contraction and a gradual relaxation of all sections of the PFMs at the same time. - Imagine that the PFMs are like an elevator going up from the ground-floor (GF) to the 3rd, where the GF is complete relaxation and 3rd floor is maximal contraction. - Try to contract/go up one floor at a time to the 3rd, and relax/go down one floor at a time to the GF. 	<ul style="list-style-type: none"> - Each contraction step up or relaxation step down is held for one slow count, about 2 seconds, including the 3rd floor. - Each ground-floor relaxation is held 5 seconds - 1 set = going up and down the 3 floors 5 times - 2 sets/day

<p>4. “Rapid Contract-Relax”</p>	<p>- Increase control of complete relaxation after a quick contraction</p>	<p>- A series of quick contractions with a prompt and complete relaxation between each contraction. - The emphasis is on the relaxation, and trying to attain the best relaxation as promptly as possible. - Before contracting, try to completely relax, thus the duration of the contractions will be much quicker than the duration of the relaxations.</p>	<p>- Each contraction is held for about 1 second, and relaxations depend on how quickly the participant can relax fully. - 1 series = 5 quick contractions and relaxations - 1 set = 5 series, with 10 seconds of rest between each series - 2 sets/day</p>
<p>5. “The Squeeze” (ie., maximum voluntary contraction)</p>	<p>- Increase strength and build muscle mass</p>	<p>- A series of strong sustained contractions. - The emphasis is on contracting the urethra, vaginal and anal opening simultaneously. - Special attention given to avoiding contraction of the buttocks and thighs. - Rest period must be respected between sets to allow for muscular recovery.</p>	<p>- Each maximal contraction is held for 5 seconds. - 1 series = 5 contractions for 5 seconds, with 10 seconds rest in between contractions - 1 set = 3 series, with 2 minutes of rest between each series - 5 sets/day</p>
<p>6. “The Knack”</p>	<p>- Increase motor control and speed in a functional setting. - To “Reset” the lost contraction reflex before an increase in intra-abdominal pressure to prevent leakage.</p>	<p>- The instruction is to contract the PFM before lifting, pushing, sneezing, laughing, etc.</p>	<p>- Every occurrence. Varies accordingly. -For the purpose of an exercise, try contracting the PFM and holding them on while you cough, then relax. -Repeat this 10 times with a 15 second rest between coughs -3 sets/day</p>
<p>7. The “Marathon”</p>	<p>- Increase endurance</p>	<p>- The instruction is to hold the PFM contraction as long as possible.</p>	<p>- Each contraction is held for as long as possible (at least 10 seconds to start) until the patient can do 45 seconds. - 1 set = 3 contractions - 3 sets/day</p>

Hand-out on Pelvic Floor Muscle Exercises given to all participants after baseline testing

Helpful Instructions for Doing Kegel Exercises: Kegel exercises are frequently discussed in childbirth classes or written about in magazine articles. Unfortunately, because pelvic muscles are hidden from view, it is difficult to know if you are doing them correctly. Some tips that can help you find the right muscles include:

- Try to stop your urinary stream. If you succeed then you have identified the right muscles to exercise. This is a learning tool. Do not stop your urine frequently as there is concern that this may create problems with bladder emptying.
- Imagine you are going to pass gas, then, squeeze the muscles that would prevent that gas from escaping from your rectum. Exercising the muscles around the rectum will also strengthen those around the vagina and under the bladder.
- Use a hand mirror to look at your vaginal opening and the perineum (the muscle wall between the vagina and rectum). You should see the perineum lift up when you contract your pelvic muscles.
- While lying or sitting, place one finger inside your vagina. Squeeze as if you were trying to stop urine from coming out. You should feel your finger lifted and squeezed if you are correctly contracting your pelvic muscles.
- Do not hold your breath while exercising.
- Remember not to tighten your stomach and back muscles or squeeze your legs together. These should be relaxed as you isolate and contract *just* your pelvic muscles.
- You don't have to do this alone! If you are just not sure that you are doing the exercises correctly ask your doctor or their nurse at a pelvic exam to check if your squeeze is working the right muscles.
- GET A PERSONAL TRAINER FOR YOUR PELVIC FLOOR! Ask your doctor for a referral to a physical therapist with expertise in pelvic floor muscle rehabilitation. They are trained to evaluate your back and abdominal strength, your gait and your posture. These all effect how your pelvic muscles work.

Recommended Routine

- Start by pulling in and holding a pelvic muscle squeeze for 3 seconds then relax for an equal amount of time (3seconds).
- Do this for 10 repetitions three times a day
- Increase your contraction hold by 1 second each week until you are contracting for a 10 second squeeze.
- Remember to rest and breathe between contractions.
- When you start, do the exercises while lying down. As you get stronger; do an exercise set sitting and standing.

APPENDIX J

PHYSIOTHERAPY (PT) TREATMENT PROTOCOL

Note: Participants are informed in written form and verbally of their right to have a person of their choice also present during PT sessions. Prior to treatment, before each treatment session, the therapist will discuss with the participant treatment components and the plan of treatment for the session and obtain verbal consent from the participant. The participant is also asked to hand in a weekly exercise log, if they have not done so, they are asked to complete one based on what they remember doing in the past week.

GUIDELINES:

- The following protocol outlines the different PT treatment components, goals, descriptions, and the parameters, and the documents related to treatment that will be used.

TREATMENT SPECIFICATIONS:

- Number of treatment sessions: 6 sessions
- Treatment frequency: one session/week X 2 weeks, 1 session/2 weeks X 8 weeks
- Total treatment time: 10 -12 weeks (assuming each participant will have two weeks where a scheduled visit is either not possible or cancelled)
- Expected duration of each session: First session 1 hour, subsequent sessions 30-45 minutes

TREATMENT COMPONENTS:

Each session will involve three components:

- 1. Education*
- 2. Review of previous exercise and reassessment of PFM strength*
- 3. Progression of the exercise program.*

1. Education

Education is provided by the treating physiotherapist in order to inform, situate and involve the participant in their care. The education that will be provided is listed below in point form.

- 1) Functional anatomy: Explain the functioning and anatomy of pelvic floor muscles (PFMs) using educational tools (drawings, 3D pelvis anatomical model), including explaining their role in vaginal, urinary, and anal functioning (canister; diaphragm, PFMs - breathing, lumbopelvic stability, abdominal muscle co-ordination etc.). Continence mechanism; impact of intra-abdominal pressure
- 2) Different types of UI: urge, stress, mixed.
- 3) Types of prolapse
- 4) Prevalence of SUI (approx. 40% of women in general population) and prolapse (even more common)
- 5) SUI = Not normal aging process
- 6) The importance of improving strength and motor control of PFMs.
- 7) Two support systems: fascia and muscles

- 8) Goals of physiotherapy: The main goal is to decrease occurrence of urine leakage by increasing strength, awareness and control of their PFMs with active PFM exercises (i.e. Kegel exercises), biomechanics, educate and provide information, help the patient gain control over the condition.
- 9) Physiotherapy treatment components: education, bladder diary, active PFM exercises (i.e. Kegel exercises; speed, endurance, strength and graded contractions), biofeedback PRN, manual stimulation/feedback PRN, proprioception and myofascial techniques if appropriate, at-home program including log diary to control and increase compliance and recommendations on bladder training, posture assessment, lombo-pelvic assessment, breathing assessment, etc., combined PFMEs with ADLs, functional act..
- 10) Expected outcomes: so far studies show a success rate ranging from 40-80% amongst women who undergo physiotherapy treatment.
- 11) Provide information on possible causes of SUI – tied to anatomy, and prolapse (surgery, birth, bad voiding habits, overweight, straining, etc.).
- 12) Bowel habits: bowel routine, avoiding straining, nutritional advice
- 13) Bladder training:
 - Avoid high impact activities. – suggest alternatives, waiting to see if problems improves... progressive return
 - Solutions to avoid straining (evacuation (handout) and constipation protocol, resources if applicable)
 - Lifestyle choice: amount of water drank daily, before bed, etc.
 - Weight reduction – if applicable – mention correlation weight and Pelvic organ prolapse and SUI and offer resources
 - Scheduled voiding (retraining frequency) – provide pamphlet, postponing 10-15min. – if applicable
 - Types of liquids and bladder irritants
 - Avoid exercises before and during voiding
- 14) Discuss adherence/compliance, and importance of exercises and motivation, etc. PT as a coach. Stress importance of honesty about exercise frequency and intensity- mention that this is an important study outcome! Stress importance of attending treatment even if participant has not done the exercises.
- 15) Postures during work and activities of daily living – stress importance of posture and proper biomechanics to avoid high intra-abdominal pressure

Once the treatment is initiated, the physiotherapist asks for **feedback** from the participants on the home exercises and reviews their log diary to look at **progression** by observing how many times exercises were performed, if they were done to completion. Tied with progression based on manual assessment during treatment- objective assessment.

The therapist and the participant discuss and formulate goals for the each treatment session based on the progression of the participants so far.

At all sessions the therapist will enquire about and address patient's questions and concerns.

Total education time at 1st session: 20 min.

Total education time at subsequent sessions: 5-10 min.

Note: educating, answering questions posed and addressing concerns is continuously done through-out treatment sessions even during other components listed below.

2. Re-assessment and review of previously prescribed exercises

- 1) Home exercise program and weekly log reviewed (Appendix 6). If participant forgets to bring the log, review their weekly exercise activities at that visit.
- 2) The therapist watches the patient perform her PFM exercises– using palpation and observation she ensures that the patient is performing the exercises properly. (See below; for exercise prescription)
- 3) Assessment of PFM strength, tone and endurance [88]

3. Pelvic floor muscle (PFM) exercises

Note: Research into the prescription of PFM exercises is limited at this point despite the fact that several RCTs have found that PFM exercises are beneficial to relieve symptoms of SUI [7]). Despite the fact that in most studies of PFM exercise, the prescription exceeds the parameters that are recommended for other skeletal muscles, these parameters have been found to be beneficial for women with SUI. In particular, women are encouraged to perform three sets of maximal effort contractions three times per day and to perform these exercises daily. In other skeletal muscles, such a prescription would result in overtraining and strength losses. The fact that this prescription works for the PFMs may have a lot to do with the fact that women do not seem to be able to contract their PFMs maximally using voluntary contractions [109], and that most women will not actually perform the exercises daily even though that is what is prescribed.

Guidelines: Participants are instructed to practice three of the following PFM exercises to improve the strength, endurance and motor control of her PFMs in different positions and circumstances every day. All participants begin all exercises in the supine or crook-lying position and each exercise is progressed from supine to reclined sitting to sitting and then to standing. At the first treatment session, all participants begin with exercise 0 to ensure that they learn a proper PFM contraction (approximately 50% of women cannot perform a proper PFM contraction with verbal instruction and will require some form of biofeedback) and then they are prescribed exercises 1, 2 and 3 in the first week. They will be instructed to perform 2 sets of 10 repetitions of each exercise daily, and to progress to a reclined sitting and a sitting position over the course of the week if they are finding that the exercises are easy to perform and are going well. At their next visit, the PT will assess their performance of the exercises in supine and then in sitting to ensure that they are being performed properly and will then progress the exercises accordingly. At the first session, the participant will also learn “the Knack” (Exercise 6; Miller et al.) and will be instructed to contract their PFMs throughout their day whenever they are about to change positions, cough, sneeze or laugh. They will be encouraged to continue this behaviour indefinitely.

Throughout the 12 weeks of treatment, participants will continue to perform exercise 1, the basic contract-relax, for two sets per day. This exercise may be progressed to being performed in


different positions or during different tasks (e.g. Exercises 8, 9, 10). All participants will progress to exercise 4 once they can perform two sets of ten repetitions of exercise 1, since a quick contraction is thought to be very important functionally. Exercise 4 can also be progressed to functional positions (Exercises 8, 9, 10) once the participant has mastered the ability to perform 2 sets of 10 repetitions in supine. All participants will be progressed to exercise 7 to develop some endurance in their PFM contraction, and, again, once they can perform exercise 7 with a 45 second hold, they may progress to performing this exercise during functional tasks. It is expected that by the end of the 12 week physiotherapy program, all participants will be performing exercises 1, 4, and 7 daily in the sitting and/or standing position, and they will be advised to continue to practice these exercises until their surgery, to begin them again after their surgery and to continue to practice them until 5 weeks after their surgery. At that point they will be advised that they can perform the exercises 2 or 3 days per week to maintain their status. There are three guiding principles to exercise prescription and progression. The first guiding principle is that the patient has to be reasonably challenged based on their progress. E.g. If patient can perform 4 good rapid contractions over 10 seconds.


Exercise of the week: Perform 5 contractions over 10 seconds. The second guiding principle is that a participant will not perform any exercises if they are prescribed too many, so a maximum of three PFM exercises along with some form of cardiovascular or postural training will be prescribed each week. The PFM exercises should take no longer than 10 minutes to perform. The endurance and postural correction exercises will be prescribed above and beyond that, but the participant will be instructed to focus first and foremost on the PFM exercises. A third guiding principle is that a participant will not perform exercises if they perceive them to be too easy or not to be necessary. As such, the participant will discuss their perception of the exercises with the therapist and exercises will be prescribed to maximize the likelihood that they will be performed.

Progression: Progress can be considered an increase in number of repetitions or sets, a change in position, or the addition of a functional activity to be performed concurrently with the PFM exercise. Progression of the exercises is prescribed on an individual basis and is based on the participant's strength as assessed at the start of each treatment session as well as based on their feedback and demonstrated performance of the exercises prescribed in the previous week.

Cues: To perform a contraction of their PFMs, participants are instructed to "tighten" "pull" "lift" or "squeeze" as if they were trying to hold urine or avoid the passage of gas. To perform a relaxation of their PFMs, they are instructed to "let go" completely of the contraction, "relax" and "not do anything at all".

Exercise	Goals	Instructions/Details	Parameters
0.Initiation PFME	- To feel the PFM lifting motion in supine and then in standing	- Instructed to stand over a chair's armrest and to lift the PFMs and feel the change in pressure in standing	- 1 set = 10 reps
1. "The basic Contract-Relax" - this exercise will be prescribed to all participants	- Identification of PFMs - Identification of the contrast between contraction & relaxation of PFMs	- A maximal voluntary contraction followed by a complete relaxation of their PFMs which needs to be at least twice as long as the contraction phase to allow full relaxation - Variance: focus can be put on contraction or relaxation or both	- Contraction held 2 seconds, relaxation for a minimum of 2 seconds - 1 set = 10 repetitions of contraction and full relaxation - 3 sets/day
2. The "Wave" -this exercise will be prescribed if the participant is not able to achieve a strong PFM contraction and has poor awareness of her PFMs..	↑ awareness of PFMs - Isolation of different regions of the pelvic floor - Isolation of PFMs vs. other muscles such as abdominals, gluteals, hip adductors	- A contraction focusing on one region of the PFMs at a time, beginning by focusing on contracting around the anus, then the vagina, and then the urethra. Then, do the reverse, by beginning at the urethra, vagina, and then anus. - Thus, the movement is like a wave going back and forth. (admittedly women cannot actually contract separate regions individually but the process helps them to become aware of the sensation of the PFMs contracting)	- Contractions at each section are held for 2 seconds, followed by a relaxation of 4 seconds before moving on to another section. - The start direction is unimportant, but each direction of movement from front to back, or back to front is repeated 5 times. - 1 set = a total of 10 contractions at each section (anus, vagina, urethra) - 2 sets/day
3. The "Elevator" - this exercise will be prescribed if the participant can initiate the contraction but has difficulty generating a strong contraction, or does not relax the PFMs well after contraction	- ↑ control of contraction and relaxation PFMs	- A gradual contraction and a gradual relaxation of the PFMs. - Women are asked to imagine that their PFMs are like an elevator going up from the ground-floor (GF) to the 3 rd , where the GF is complete relaxation and 3 rd floor is maximal contraction. - They are asked to contract/go up one floor at a time to the 3 rd , and relax/go down one floor at a time to the GF.	- Each contraction step up or relaxation step down is held for one slow count, about 2 seconds, including the 3 rd floor. - Each ground-floor relaxation is held 5 seconds - 1 set = going up and down the 3 floors 5 times - 2 sets/day ** can be used to retrain relaxation in certain cases
4. "Quickies" -this exercise will be prescribed to all participants after they have mastered exercise 1.	- ↑ control of full relaxation after a quick contraction - allow efficient response to prevent leakage effectively	- A series of quick contractions with a prompt and complete relaxation between each contraction. - The emphasis is on the relaxation, and trying to attain	- Each contraction is held for about 1 second, & relaxations depend on how quickly the participant can relax fully. - 1 repetition = 5 quick contractions and relaxations

	<ul style="list-style-type: none"> - increase motor control and speed - leading to THE KNACK exercise 	<p>the best relaxation as promptly as possible.</p> <ul style="list-style-type: none"> - Before contracting, the participant must fully relax, thus the contractions will be much quicker than the duration of relaxations. 	<ul style="list-style-type: none"> - 1 set = 5 repetitions, with 10 seconds of rest between each set - 2 sets/day
<p>5. “The squeeze” (ie., maximum voluntary contraction + extra squeeze)</p> <p>-this exercise will be prescribed to participants who do not reach maximal contraction OR for whom “the knack” is not effective in reducing urine loss.</p>	<ul style="list-style-type: none"> - ↑ strength and build muscle mass - work in inner range of PFMs 	<ul style="list-style-type: none"> - A series of strong maximal contractions held for 5s followed by a 5s extra contraction – called peaks or ROOF (if using the elevator analogy). - The emphasis is on contracting the urethra, vaginal and anal opening simultaneously. - Special attention given to avoiding contraction of the buttocks and thighs. - Rest period must be respected between sets to avoid for muscular recovery. 	<ul style="list-style-type: none"> - Each contraction is held for about 5 second and if possible, up to 5 peaks are added to the contraction. - 1 series = 5 contractions or 5 seconds, with 10 seconds rest in between contractions - 1 set = 3 series, with 2 minute of rest between each series - 5 sets/day
<p>6. “The knack”</p> <p>-this exercise will be prescribed to all women as a behaviour modification but may also be prescribed as a specific strengthening exercise if the women is not remembering to perform a pre-contraction before activities that increase intra-abdominal pressure</p>	<ul style="list-style-type: none"> - ↑ motor control and speed in a functional setting. - To “Reset” the required automatic contraction that occurs before an increase in intra-abdominal pressure to prevent leakage. 	<ul style="list-style-type: none"> - The patient is instructed to contract their PFMs before lifting, pushing, sneezing, laughing, etc. 	<ul style="list-style-type: none"> - Attempted in supine than in standing. - Performed at every occurrence of increase IAP pressure. Included in ADLs. - Instructed to attempt it by pretending to cough. - 1 set = 5 times - 2 sets/day
<p>7. The “marathon”</p> <p>-this exercise will be prescribed to all women after they have mastered exercise 1.</p>	<ul style="list-style-type: none"> - ↑ endurance 	<ul style="list-style-type: none"> - The patient is instructed to hold the contraction as long as possible (starting at 10 seconds, and building up to 45 seconds by the end of the treatment). 	<ul style="list-style-type: none"> - Each contraction is held for as long as possible (at least 10 seconds to start) until the patient can do 45 seconds. - 1 set = 3 contractions - 3 sets/day
<p>8. PFM during sit-to-stand</p> 	<ul style="list-style-type: none"> - PFM contraction during a task (ie, getting up from toilet to avoid post-voiding dribbling) 	<ul style="list-style-type: none"> - As demonstrated. -Patient instructed to try to contract PFM and keep contraction while standing up. - Can be performed at the toilet after voiding. 	<ul style="list-style-type: none"> -Progression of basic exercises (1-7) as appropriate.

<p>9. PFM during squat</p> 	<p>-To help the patient develop PFM control in an abducted position.</p>	<p>Variance: less deep, hands on waist, hands on chair for support, etc.</p>	<p>- Progression of basic exercises (1-7) as appropriate.</p>
<p>10.. PFM + abdominal and lower extremity exercises</p>	<p>-Exercises usually performed in half sitting or supine that combines all muscle groups for core strengthening.</p>	<p>-Instructed to contract PFMs and Transversus Abdominus while supine with knees bent and to let one leg open out while holding the contraction. -Progressed to active straight leg raise while holding,</p>	<p>-Progression of exercises 1-7 as appropriate.</p>
<p>11. General cardiovascular conditioning walking, swimming, etc.</p>	<p>Exercise prescribed for all participants based on their initial activity level</p>		<p>- instructed to perform a fast paced walk beginning at 20 minutes per day and to progress to longer duration or faster speed depending on the participant's progress.</p>

ADDITIONAL THERAPEUTIC TECHNIQUES EMPLOYED DURING TREATMENT:

1. *Manual therapy techniques – performed on 1st treatment and then as appropriate*

Goals: Increase proprioception/awareness of the PFMs, mobilise PFMs and soft tissue (fascia and skin) by increasing circulation, stimulate and facilitate PFM contractions, strengthen the PFMs, help with relaxation, desensitize and release tension.

Guidelines: All manual techniques are performed by the physiotherapist with 1 or 2 gloved and lubricated (for intra-vaginal techniques) fingers. The use of 1 or 2 fingers depends on the participant's level of comfort. Not all manual techniques need to be used with all participants, techniques are chosen based on participant findings upon assessment.

1. *Manual resistance*

Goal: Offer resistance to levator ani muscles to help address specific weakness in the pelvic floor in order to build strength and increase proprioception.

Description: Moderate to high pressure is applied using one or two fingers (more pressure is applied with two fingers), inside the vagina on PFMs anywhere points of weakness if found. Resistance is offered for 5 seconds while the patient contracts.

Progression: Amount of pressure applied can be gradually increased according to the participant's level of comfort and strength.

2. *Proprioceptive stimulation / “Tapping”*

Goal: To increase PFM awareness/proprioception in individuals who are having difficulty learning a proper PFM contraction

Description: Gentle tapping is done inside the vagina on PFMs, after which the participant can then be asked to perform a PFM where she feels the tapping. The tapping can also be done externally, for example over the central perineal tendon.

3. *Proprioceptive neuromuscular stimulation*

Goal: To increase PFM awareness/proprioception and facilitate PFM contractions in individuals who cannot generate adequate force or cannot initiate the contraction

Description: A quick, light stretch is performed on PFMs to elicit involuntary reflex contractions which may allow the participant to better perceive PFMs contractions.

2. *Biofeedback and exercises – performed as needed. This approach is used to begin exercises if the initial strength grade is 0 or 1 out of 5.*

Biofeedback is performed for all patients at the initial assessment - using the ultrasound system. For all weeks where the participant still scores a grade of 0 or 1 out of 5, an electromyography (EMG) biofeedback system is used to allow the participant and the physiotherapist to visualize the quality and duration of PFM contraction and relaxation.

Goal: Assist in pelvic floor muscle retraining, increase control of the PFMs.

Description:

- The US probe is lubricated with a gel-like, water-based, conductive lubricant, covered with a condom and with more gel. It is applied over the lower abdomen such that the bladder base is visible. Patients are instructed to elevate the bladder base, by watching the imaging screen.
- Instruction and encouragement are provided as necessary by the physiotherapist throughout the entire biofeedback session. This may include concurrent digital palpation and pressure feedback if necessary.