COMPARING THE EFFECTIVENESS OF PELVIC FLOOR MUSCLE TRAINING AND ACUPUNCTURE FOR THE TREATMENT OF URINARY INCONTINENCE AND THE IMPACT ON HEALTH-RELATED QUALITY OF LIFE FOR NON-HOMEBOUND WOMEN ≥ 50 YEARS OF AGE: A SECONDARY ANALYSIS

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COMPARING THE EFFECTIVENESS OF PELVIC FLOOR MUSCLE TRAINING AND ACUPUNCTURE FOR THE TREATMENT OF URINARY INCONTINENCE AND THE IMPACT ON HEALTH-RELATED QUALITY OF LIFE FOR NON-HOMEBOUND WOMEN ≥ 50 YEARS OF AGE: A SECONDARY ANALYSIS

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Background: Urinary incontinence (UI) is a common, chronic health condition. In 2001, it was estimated 20 million Americans experience UI. Incontinence has been shown to negatively impact health-related quality of life (HRQoL).

Objectives: The aims of this study of community-dwelling women, ≥50 years of age were to: 1) compare the effectiveness PFMT and acupuncture in reducing urinary incontinence, 2) compare their impact on HRQoL, 3) compare subject satisfaction with progress following the intervention phase of each study, 4) compare the treatment burden of each intervention, and 5) examine the relationship between the changes in UI and HRQoL.

Method: This secondary analysis used data from two independent RCTs. One study examined the effectiveness of PFMT in reducing UI in homebound and non-homebound men and women age 60 years and older. The second examined the efficacy of acupuncture in treating UI in women ≥ 25 years.

Sample: Two-hundred fifteen women age 50 years were included in the analysis, 148 (69%) from the PFMT study and 67 (31%) from the acupuncture study.

Measures: Baseline and post-intervention bladder diaries provided data to calculate the reduction in urinary continence. Physical and Mental Health Component scores from the SF-36 (v1.0) were used to measure HRQoL. The Patient Satisfaction Questionnaire provided data regarding satisfaction with progress and treatment burden.

Results: After controlling for group differences, PFMT ($M = 56.6\%$) was more effective than acupuncture ($M = 26.0\%$, $p = .01$) in reducing UI. There were no significant differences in the changes in SF-36 component scores between the groups. A higher proportion of women in the PFMT group were satisfied with their progress than in the acupuncture group ($p < .001$). There were no significant differences in self-reported treatment burden, which was low in both groups. Reduction in UI did not contribute significantly to the variability in the SF-36 component scores.

Conclusion: PFMT was more effective in the short-term treatment of UI in this analysis and should continue to be recommended as first-line therapy for UI. There is not enough evidence at this time to support acupuncture for the treatment of UI in non-homebound women 50 years of age and older.

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1.0 INTRODUCTION

When people think of chronic disorders, urinary incontinence (UI) is not a disorder that comes to mind. However, urinary incontinence is one of the most common health problems experienced by people worldwide (Ko, Swu-Jane, Salmon, & Bron, 2005; Minassian, Drutz, & Al-Badr, 2003). Urinary incontinence is defined as the complaint of any involuntary leakage of urine (Abrams et al., 2002). Many people do not seek treatment for urinary incontinence thinking it is a natural part of aging or there is no treatment for it (Hagglund and Wadensten 2007; Shaw, Tansey et al. 2001). Clinical and epidemiological studies of adults with urinary incontinence have shown incontinence has a significant negative impact on quality of life (Bergstrom, Carlsson et al., 2000; Sari and Khorshid, 2009; Wyman, Fantl et al., 1997). This is often manifested by those with urinary incontinence isolating themselves from family and friends for fear of embarrassment and experiencing symptoms and signs of depression (Melville, Delaney et al., 2005). The symptoms of urinary incontinence seriously impact the physical, psychological, and social lives of those who experience this problem (Harkins, Elliott et al., 2006). Although urinary incontinence is not a life threatening disorder, it has been shown to disrupt the lives of an estimated 20% of middle-age to older adult women (Thom, 1998). Women may restrict activities such as shopping and socializing for fear of embarrassment (Hagglund and Wadensten, 2007; Harkins, Elliott et al., 2006). The management of urinary incontinence can place an increased emotional, physical, and economic burden on caregivers of those who experience UI (Mathur, Browning et al., 2010).

Until recently, the subject of urinary incontinence has rarely been discussed on the national level although urinary incontinence has been a growing worldwide health concern (Minassian et al., 2003). In 2010, the Fourth International Consultation on Incontinence Recommendations of the International Scientific Committee reviewed and updated guidelines related to treatments and recommendations for urinary incontinence. These guidelines can be found at http://onlinelibrary.wiley.com/doi/10.1002/nau.20870/pdf . It is also important for the population in general to be aware of the psychological, social, and economic burden of urinary incontinence. Removing the stigma associated with being incontinent would allow more people to take advantage of the best treatment options available to them.

1.1 BACKGROUND

Urinary incontinence has plagued people since the beginning of time. The earliest written reports of urinary incontinence can be traced back to the Egyptian manuscripts from the 2nd millennium BC (Bitschai and Brodney, 1956; Wershur, 1970). In 2007, the NIH Consensus Statement (http://consensus.nih.gov/2007/incontinencestatement.htm) estimated that 20 million Americans experience urinary incontinence (Landefeld et al., 2008). The incidence (rate of occurrence of new cases) of UI in women ranges from 10-58% per year while in men the incidence of UI ranges from 3-11% per year (Hunskaar, Lose, & Voss, 2003). The overall prevalence (measure of the total number of cases of UI in the population) of UI is low in young women, peaks around the time of menopause and steadily rises after the age of 60 years (Nitti 2001). Table 1 is a summary of studies that examined the prevalence of urinary incontinence. One study estimated approximately 44% of middle-age and post-menopausal women experience some degree of UI (Kinchen, Lee et al., 2007), while other studies reported up to 50% of women 60 years of age and older experiencing at least one episode of UI per week (Swanson, Kaczorowski et al., 2005; Thom, 1998). In 2007, the National Institutes of Health State-of-the-Science Conference Statement on Prevention of Fecal and Urinary Incontinence in Adults reported the prevalence of urinary incontinence in women living in the community increases with age and was estimated to vary from 19% for women younger than 45 years to 29% in those age 80 years or older (Landefeld et al., 2008). The rate appears to plateau from age 50 to age 70 years but then again increases for women after 70 years of age. In published research studies, the estimated prevalence rates vary from 15 to 51% in community-dwelling populations (Andersson, Johansson et al., 2004; Hunskaar, Lose et al., 2003; Kinchen, Lee et al., 2007; Markland, Richter et al., 2011; Melville, Delaney et al., 2005; Minassian, Stewart et al., 2008; Shaw, Das Gupta et al., 2006; Stoddart, Donovan et al., 2001; Swanson, Kaczorowski et al., 2005; Waetjen, Liao et al., 2006). There is wide variability in the estimated prevalence rates of UI reported (Andersson et al., 2004; Anger, Saigal, Litwin & the Urologic Diseases of American Project, 2006). This is attributed to the various definitions of UI used as well as the different populations included in each study (Anger et al., 2006; Thom, 1998). All studies in Table 1 included community-dwelling adults. Several studies examined gender differences and a few examined the prevalence rates of urge, stress, and mixed incontinence. For most of the studies, urinary incontinence was defined as any urine leakage while some went on to say any urinary leakage within a defined period of time. Using data from the National Health and Nutrition Examination Survey (NHANES) between the years of 2001-2008, Markland et al. (2011) reported that the age standardized prevalence of UI increased in both men and women in the United States. The trend revealed a linear upward progression across both genders over the eight-year period of time that the data were collected. This trend is expected to continue as the U.S. population ages in the coming years.

Table 1: Summary of studies examining prevalence of Urinary Incontinence (UI)

Study	Definition of UI	Setting	Prevalence (%)
Andersson, Johansson, Garpenhot, and Nilsson (2004)	Any leakage	Community-dwelling women postal survey using a12-item questionnaire n = 15,360	19
Anger, Saigal, Litwin, and the Urologic Diseases of America Project (2006)	Any involuntary urine leakage in the past 12 months	NHANES 2001-2004 Women >20 years of age n = 4,229	38
Hunskaar, Lose, and Voss (2003)	Any leakage or involuntary loss of urine in the preceding 30 days	Women $\geq$18 years in France, Germany, Spain and the UK via postal survey n = 17,080	35
Jolleys (1988)	Leakage of urine at least two times per week	Rural community-dwelling women in England n = 833	41
Kinchen, Lee, Fireman, Hunkeler, Nehemiah, and Curtire (2007)	Involuntary leakage of urine in the past 7 days	Women (>20 years of age) Participants of managed health care plan at Kaiser Permanente in Northern California from 1997-2003) n = 3,344	44
Markland, Richter, Fwu, Eggers, and Kussek (2011)	Urine leakage during physical activity, before reaching the toilet, and during nonphysical activity	Adults 20 years old or older 2001 to 2008 cycles of the NHANES n = 17,850	Prevalence increased 49.5% in 2001-2002 53.4% in 2007-2008 (p_{trend} = .01)

Table 1 (cont.)

Study	Definition of UI	Setting	Prevalence (%)
Melville, Delaney, Newton, and Katon (2005)	Leakage of any amount that occurred at least monthly	Community-dwelling women in the State of Washington n = 3,536	45
Minassian, Stewart, and Wood (2008)	Any involuntary leakage of urine.	NHANES 2001-2002 Adult women n = 2,875	49.2
Shaw, Das Gupta, Bushnell, Assassa, Abrams, Wagg, Mayne, Hardwick, and Martin (2006)	Any urine leakage in the preceding 30 day period	Cross-sectional survey of women from primary care practices in West Yorkshire, London, Glasgow and Leicestershire n = 3,273	45.7 SUI[a] 21.5 UUI[b] 3 .5 MUI[c] 20.7
Stoddart, Donovan, Whitley, Sharp, and Harvey (2001)	Reported leaking urine in the last month	Community-living elderly (equal numbers of men and women, aged 65 to 74 years and over 75 years) in 11 general practices in a British city n = 2,000	31 (women) 23 (men)
Swanson, Kaczorowski, Skelly, and Finkelstein (2005)	Any urine leakage during the previous month	Women 45 years and older n = 602	51.3
Waetjen, Liao, Johnson, Sampselle, Sternfield, Harlow, and Gold for the Study of Women's Health Across the Nation (2006)	Any involuntary loss of urine	Women 40-55 years of age (mean age 45.8, SD 2.7 years) Study of Women's Health Across the Nation (SWAN) A community-based, prospective cohort study of women from five different racial/ethnic groups from seven clinical sites (Boston, MA; Chicago, IL; Detroit, MI; Los Angeles, CA; Newark, NJ; Pittsburgh, PA; and Oakland, CA) 3,302 per site n = 16,065	46.7

[a] stress urinary incontinence
[b] urge urinary incontinence
[c] mixed urinary incontinence

1.1.1 Types of Urinary Incontinence

The three most commonly recognized types of chronic urinary incontinence are urge, stress, and mixed incontinence. Urge urinary incontinence (UUI) is the complaint of involuntary leakage accompanied by or immediately preceded by an urge to urinate. UUI is also generally accompanied by a more frequent need to urinate and awakening during the night to urinate (nocturia). Urge incontinence occurs when involuntary detrusor contractions increase intra-vesical pressure to a level higher than outlet pressure.

In stress urinary incontinence (SUI), involuntary urine loss is associated with activities that cause a sudden increase in intra-abdominal pressure, e.g., sneezing or coughing. Stress urinary incontinence is often due to damage to the muscles, nerves, and/or connective tissue of the pelvic floor or to the urethral sphincter, which lowers outlet resistance and allows urine leakage when intra-abdominal pressure increases. Three different mechanisms appear to be responsible for stress urinary incontinence: 1) dysfunction in neural control, 2) incomplete closure of the vesical neck, and 3) detachment of the endopelvic fascia. The dysfunction in neural control may inhibit muscle contractions, which allows urine leakage. If there is incomplete closure of the vesical neck, the urethra is not able to constrict adequately, so urine beyond the vesical neck will be expelled. When there is a detachment between the endopelvic fascia and lateral attachments around the vaginal and levator ani musculature, the result is loss of support to these muscles, which allows for urine leakage (DeLancey, 1997).

Mixed urinary incontinence is involuntary leakage of urine associated with urgency and also with an increase in intra-abdominal pressure (Abrams et al., 2010). People who experience urine loss with physical activities (stress incontinence) and following an urge to urinate (urge incontinence) have mixed urinary incontinence.

The prevalence of UUI increases with age, while SUI is more common in younger women (Jackson, Vittinghoff et al., 2004). Minassian et al. (2008) estimated the overall prevalence of stress, urge and mixed urinary incontinence to be 23.7%, 9.9%, and 14.5%, respectively. They found the prevalence of SUI to be the highest in the fifth decade of life, while UUI and mixed UI prevalence increased with age.

1.1.2 Impact of Urinary Incontinence (UI)

The costs associated with UI are not only direct and indirect financial costs but also “human” costs evidenced by the impact of urinary incontinence on psychosocial and physical functioning, and quality of life (Harkins et al., 2006).

1.1.3 Psychological Impact

The psychological impact of UI is reflected in the feeling of embarrassment, guilt, shame and loss of self-esteem that often leads to social isolation. Women may restrict activities, such as shopping and socializing for fear of embarrassment (Hagglund & Wadensten, 2007; Harkins et al., 2006). Botlero, Bell, Urguhart, and Davis (2010) examined the association between UI and psychological well-being in 542 community-dwelling women aged 24-80 years and found there was a significant reduction in the psychological well-being in community-dwelling women who experienced UI ($p <.001$).

Melville et al. (2005) conducted a postal survey of 6,000 women examining the rate of depression in incontinent women. There were 3,536 community-dwelling women between the ages of 30-90 years who completed the survey instruments. They reported the prevalence of urinary incontinence was 42% (n = 1,458). This result is consistent with what has been reported in the general population (Kinchen et al., 2007). They also showed the prevalence of major depression to be 3.7% (n = 129). This finding is also consistent with a Center for Disease and Prevention (CDC) Mortality and Morbidity weekly report (MMWR) dated October 1, 2010, which reported that the prevalence rate for major depression for women in the general population is close to 4%. When comparing the occurrence of depression in women with and without urinary incontinence, Melville and colleagues (2005) found depression was reported by 2.2% of women without urinary incontinence vs. 6.1% of women with urinary incontinence. Breaking it down according to severity and types of urinary incontinence, major depression prevalence rates differed by urinary incontinence severity (2.1% in mild, 5.7% in moderate, and 8.3% in severe) and incontinence type (4.7% in stress and 6.6% in urge/mixed). After controlling for age and co-morbidities, Melville and colleagues (2005) reported that for women with moderate incontinence, the odds of having major depression were increased [OR 2.7, 95% CI (1.1, 6.6)]. For women with severe incontinence the odds of major depression were even higher [OR 3.8, 95% CI (1.6, 9.1)]. Melville et al. (2005) suggested that the relationship between urinary incontinence and major depression is bi-directional meaning that women with symptoms and signs of incontinence are at risk for depression and those with depression experience altered neurotransmitter function, which often leads to uninhibited detrusor contractions resulting in urge incontinence. Table 2 includes the studies related the psychological impact of UI.

1.1.4 Physical risks

Brown et al. (2000) reported that weekly or more frequent urge urinary incontinence was associated with an increased risk of falling OR 1.26, 95% CI [1.14, 1.40]. They also reported that there was no association between SUI and falls. This is substantiated in a systematic review conducted by Chiarelli, McKenzie, and Osmotherly, 2008. The conclusion of this systematic review was that the odds of falling varied with the type of UI. The risk of falling is almost twice as high for people with urge incontinence than for people without UI, OR 1.54, 95% CI [1.41, 1.69]. There is an increased risk of falling for people with stress UI compared to people who do not experience UI, OR 1.11, 95% CI [1.00, 1.23]. There is twice the risk of experiencing a fall for those with mixed UI than those without UI, OR 1.92, 95% CI [1.69, 2.18]. The risk of falling for people with any type of UI is 1.5 times higher than for those without UI, OR 1.45, 95% CI [1.36, 1.54].

Table 2: Studies related to the psychological and psychosocial impact of urinary incontinence (UI)

Study	Sample	Methodology	Results
Botlero, Bell, Urquhart, and Davis (2010)	n = 506 community dwelling women, 20-84 years of age	Survey using the Psychological Well-Being Index (PWBI)	Women with UI had a lower PWBI score (mean 76.9, SD = 16.5) vs. women without UI (mean = 81.6, SD = 15.3; $p < .001$
Brink, Wells, and Diokno (1987)	n = 200 Midwest U.S. women aged 55-90 years	120-item investigator developed form to collect specific data relate to urine-control problems, wetting management, and current and past health	108 (54%) of the 200 women reporting at least 1 episode of UI daily and 74 (37%) of the 200 women with less frequent episodes of UI reported changes in lifestyle due to urinary incontinence ($X^2 = 4.5213$, $p < .05$)
Fultz and Herzog (2000)	n = 1,116 continent and n = 206 incontinent respondents age 40 and older	Self-reports of urinary incontinence via telephone interviews as a supplement to a nationally representative monthly consumer survey	Incontinence and the likelihood of: Depression OR 1.12 (0.74–1.68) Loneliness OR 2.10 (1.38–3.16) Sadness OR 1.15 (0.75–1.73)

Table 2 (cont.)

Study	Sample	Methodology	Results
Melville, Delaney, Newton, and Katon (2005)	n = 3,536 women aged 30-90 years who were enrollees in a large health maintenance organization in Washington state	Postal survey To characterize the degree of incontinence, the Sandvik severity index was used The PRIME-MD Patient Health Questionnaire, 9-item (PHQ-9) was used to diagnose current major depression I-QoL instrument a validated 22-item self-report measure was used to measure incontinence-specific quality of life	The prevalence of urinary incontinence was 42% (n = 1,458). The prevalence of major depression was 2.2% among women without UI versus 6.1% in those with incontinence Women with major depression perceived their incontinence symptoms as significantly more severe than non-depressed women (Patient Incontinence Severity Assessment scores: 2.7 versus 2.0; p < .001) Women with major depression reported significantly lower incontinence-specific quality of life based on the I-QoL Total (65.0 versus 83.5; p <.001), Avoidance and Limiting Behaviors (61.2 versus 77.4; p < .001), Psychosocial Impact (73.3 versus 91.1; p < .001), and Social Embarrassment (53.4 versus 76.7; p < .001) scales
Norton, MacDonald, Sedgwick, and Stanton (1988)	n = 201 women, 16-85 years of age, referred to an outpatient urology clinic in London	Interview & Questionnaire	50-64 years n=59 / 65-85 years n=36 / outcome 36 (60%) / 29 (81%) / avoided going away from home 26 (44%) / 23 (66%) / avoided public transportation 31 (52%) / 20 (56%) / felt odd or different 23 (38%) / 10 (29%) / felt less attractive 24 (41%) / 4 (11%) / avoided sexual activity 16 (27%) / 13 (36%) / avoided friends/family 7 (12%) / 5 (14%) / felt others avoided them

Table 2 (cont.)

Study	Sample	Methodology	Results
Ouslander and Abelson (1990)	n = 199 (164 women; 35 men)	Each participant was asked a series of eight questions related to their perceptions of Ul[a]. The same interviewer asked the questions using a structured interview format.	119 (60%) to 169 (85%) participants reported embarrassment or emotional distress from urinary incontinence 83 (42%) said the incontinence interfered with their lives (reluctant to leave home)
Wyman, Harkins, Choi, Taylor, and Fantl (1987)	n = 69 women participating in a study examining the effects of a behavioral therapy intervention for UI[a]	Incontinence Impact Questionnaire (IIQ) Daily activities include: household chores, leisure and recreational activities, work-related activities, and transportation Social Interaction includes: participation in activities with spouse, family and friends Self-perception includes: perceived impact of UI[a] on physical and mental health and reasons for restricting activities	Outcomes-Impact of UI[a] on: Daily activities 78.1% none or slight 21.9% moderate or severe Social Interaction 86.9% none or slight 12% moderate or severe Self-perception 78.6% none or slight 21.4% moderate or severe Total impact score correlation with severity of UI[a] r = 0.34 for SUI[b] r = 0.21 for UUI[c]

[a] Urinary Incontinence
[b] Stress UI
[c] Urge UI

Having urinary incontinence puts people at risk for skin problems, such as rashes, dermatitis, skin infections, and pressure ulcers from the skin being exposed to urine (Charalambous & Trantafylidis, 2009). The risk for repeated urinary tract infection is also increased with urinary incontinence (Stamm & Raz, 1999).

As noted, when people have urinary incontinence, they often stop participating in normal activities such as exercising and attending social gatherings. Some people experience a negative impact on their work and personal lives. Urge urinary incontinence can interrupt concentration and productivity in the workplace (Fultz, Fisher et al., 2004). Family and friends may not understand or find acceptable behavioral changes that occur to accommodate the incontinence, such as frequent toileting (Charalambous & Trantaflidis, 2009). Sexual intimacy may also be impacted because of the embarrassment caused by urine leakage (Knoepp, Shippey et al., 2010).

1.1.5 Nursing home admissions/caregiver burden

From data collected in a survey study of 7,613 family caregivers in Japan, Gotoh, Yoshikawa, Funaheashi, Kato, and Hattori (2009) reported that urinary incontinence places a significant negative psychological burden on family caregivers. Urinary incontinence is associated with increased nursing home admissions (Holroyd-Leduc & Straus, 2004; Thom, 1998). Morrison and Levy (2006) did a secondary analysis of data from the Thom et al. (1998) study. They reported that 10% of nursing home admissions among elderly men and 6% among elderly women were related to having urinary incontinence.

1.1.6 Quality of life

The World Health Organization Quality of Life (WHOQOL) Group (http://www.cdc.gov/hrqol/concept.htm#six) defined quality of life (QoL) as a broad multi-dimensional concept that subjectively evaluates both positive and negative aspects of life (WHOQOL Group, 1998). Since the 1980's the concept of health-related quality of life (HRQoL) has been defined as those aspects of overall quality of life that can be clearly shown to affect health—either physical or mental (CDC, 2000; McHorney, 1999). The concepts of QoL and HRQoL are often used interchangeably in the literature.

The symptoms of urinary incontinence seriously impact the physical, psychological, and social lives of those who experience urinary incontinence, which often leads to lower levels of well-being and QoL (Wyman, Harkins, & Fantl, 1990). Incontinence has been reported to negatively impact QoL and therefore, effective treatment options should improve QoL for those who experience UI (Corcos, Beaulieu et al., 2002).

There have been a number of studies examining the effect urinary incontinence has on the psychosocial aspects of the lives of those who experience it. Most studies included only women with some including both men and women. Norton and colleagues (1988) reported the rates of interference with social activities varied from as low as 11% for avoiding sexual activity to 81% for avoiding going away from home among the 65-85 year age group in their study. In the 50-64 year age group the rates of interference with social activities varied from 12% who felt others avoided them to 60% who avoided going away from home (Norton, MacDonald et al., 1988). The Wyman et al. (1987) study examined urinary incontinence-specific QoL using the Incontinence Impact Questionnaire (IIQ). In this study, 12% of the participants reported moderate to severe interference in social activities, which includes participation in activities with spouse, family, and friends while 21.9% and 21.4% reported moderate to severe interference with doing daily activities and 21.4% reported moderate to severe impact of UI on their mental and physical health (Wyman, Harkins et al., 1987). In the Ouslander and Abelson (1990) study, 85% of the participants reported a negative psychosocial impact on QoL from UI. The variability in rates reported across the studies may be due to differences in methodology, measurement of the impact of UI, severity of UI, and the length of time the participants lived with UI. Most of the studies collected data as part of a clinical trial and the sample characteristics in these studies may have contributed to the differences in the reported impact of UI on the lives of the participants.

HRQoL appears to be impacted by the extent the incontinence is bothersome to the individual (Gil, Somerville, Chichowski & Savitski, 2008). The more bothersome the women felt the UI was the more likely they were to seek surgical intervention. It has only been in recent years that researchers have started examining the degree of bother expressed by the individuals as it relates to QoL reported. When examining the different types of urinary incontinence, Dedicacao, Haddad, Saldanha, and Driusso (2009) found among women with mixed UI, the negative impact of urinary incontinence on QoL and lifestyle was greater than for women who experienced other types of urinary incontinence. Urinary incontinence is a barrier to good physical health and social well-being, which may also impact the perceived QoL one experiences (Charalambous & Trantafylidis, 2009).

Time and activity pattern were areas examined by Fultz et al. (2004) in relation to UI. They found that women changed activities and the length of time they participated in activities due to their incontinence. The activities that women chose not to participate in were physical activities as opposed to cognitive activities. This result was felt to be due to fear of embarrassment and fear of odor. Women in this study reported fewer hours of work, fewer hours spent walking, and fewer hours spent on house cleaning. They were more likely to read and watch TV than to go shopping, show physical affection toward others, or attend religious services. Women with urinary incontinence who felt the need to change their activities also perceived a lower quality of life.

1.1.7 Economic impact

Thom, Nygaard, and Calhoun (2005) reported that in the 1990's for Medicare beneficiaries, the cost for UI doubled from $128.1 million in 1992 to $234.4 million in 1998. The increase was attributed to an increase in outpatient costs, which increased from $25.4 million or 9.1% of total costs in 1992 to $329 million or 27.3% of total costs in 2000 in this group (Thom et al., 2005). Direct cost includes resources used to diagnose, treat, and care for incontinence and the cost of rehabilitation. Other direct costs related to infections, fall injuries, hospitalizations, etc. that are associated with urinary incontinence (Hu et al., 2004). The direct cost for UI in community-dwelling women $\geq$65 years of age is at least $8.6 billion annually (Wilson, Brown, Shin, Luc, & Subak, 2001). Urinary incontinence is associated with increased nursing home admissions (Holroyd-Leduc, Mehta, & Covinsky, 2004; Thom, 1998). Using a cost-of-illness analysis, Morrison and Levy (2006) showed nursing home admissions were either the single largest direct cost among community-dwelling adults with UI (28% of the $14.2 billion cost) or the second largest direct cost following routine care (22% of the $10.8 billion total direct cost of UI).

Indirect cost includes the cost of care giving by family members or others who care for the incontinent person, loss of productivity both at work and at home.

1.2 TREATMENT OPTIONS

Healthcare professionals have been slow to educate their patients about bladder health and the fact that incontinence is never normal (Lukacz et al., 2011). Treatment of urinary incontinence is dependent on the type of incontinence and other health conditions the person is experiencing. Treatment methods include pharmacologic measures, surgical interventions, and behavioral interventions (Kincade et al., 2005). Although a variety of interventions exist, the most commonly used interventions for urge urinary incontinence (UUI) are pharmacotherapy and behavioral therapy. For stress urinary incontinence (SUI), the most common interventions are surgical interventions and behavioral therapy.

1.2.1 Medication to treat urinary incontinence

Pharmacotherapy, specifically anticholinergic medications, have been widely used for urge incontinence (Herbison, Ellis, & Moore, 2003; Kafri et al., 2008; Lilley, 2001). The most recognized of these medicines are oxybutynin (Ditropan) and tolterodine (Detrol). Anticholinergic medications work by relaxing the smooth muscle of the bladder. They do this by inhibiting parasympathetic nerve impulses and selectively blocking the binding of the neurotransmitter acetylcholine to its receptors (Lilley, 2001). The parasympathetic system is responsible for contraction of the detrusor muscle during normal bladder emptying. Activation of the parasympathetic nervous system results in contraction of the bladder. Anticholinergic medications work by inhibiting parasympathetic cholinergic mediation of detrusor contractions, thereby reducing or delaying involuntary bladder contractions which may also help increase capacity (Lilley, 2001). Burgio, Locher, and Goode (2000) compared behavioral therapy vs. drug therapy for UUI. They found that women who used medication alone to treat UUI reported a mean percent reduction of 69% (SD = 37.2%) in incontinent episodes. Unfortunately, these medications are associated with a significant risk of side effects, particularly dry mouth and constipation (Burgio et al., 2008; Herbison et al., 2003).

1.2.2 Surgical interventions

Surgery may be the treatment of choice for stress incontinence when there is prolapse or hypermobility of the bladder neck and urethra. Surgery works to restore these structures to their anatomically correct positions to provide better support for the muscles of the pelvic floor (DeLancey et al., 2008). Tension-free vaginal tape procedures and other urethral sling procedures are the most widely used surgical interventions for pure stress incontinence (Harding and Thorpe, 2008; Serati et al., 2012). In a study of 90 community-dwelling women living in Norway, Nilsson, Kuuva, Falconer, Rezapour, and Ulmsten (2001) examined the long-term benefits of a tension-free vaginal tape procedure for stress urinary incontinence and found the procedure met the criteria for cure or significant improvement for 95% of the women. This result was similar to findings in other studies of the same procedure (Olsson and Kroon, 1999; Ulmsten, Johnson et al., 1999). In November of 2011, the American Urological Associations

(AUA) commenting on their 2009 guidelines for the surgical management of stress urinary incontinence http://www.renalandurologynews.com/risk-factor-for-sui-reoperation-identified/article/210888/ conveyed that “synthetic slings are an appropriate treatment choice for women with stress incontinence, with similar efficacy but less morbidity than conventional non-mesh sling techniques (Charlow, 2011). The AUA stated these procedures are safe and effective if performed by adequately trained professionals.

1.2.3 Behavioral interventions

Behavioral techniques have been used to manage urinary incontinence. Behavioral management offers many advantages, such as being non-invasive and having limited side effects and are, thus, a good first line treatment for UI. They are appropriate for use in older adults who may not be appropriate candidates for surgery or drug therapy. The disadvantages of behavioral therapy include requiring the person to be actively engaged and to maintain motivation to remain adherent to the prescribed regimen.

Behavioral therapies used for urge incontinence include fluid management, electrical stimulation, timed voiding, bladder retraining, and pelvic floor muscle training with and without biofeedback (Diokno et al., 2010; Doggweilier-Wiygul, & Selhorn, 2002). Re-establishing control over bladder functioning is the aim of bladder training. Bladder retraining encourages the individual to lengthen the time between voids by learning to suppress bladder instability and diminish urgency. The individual is asked to void by the clock rather in response to the urge to urinate in an attempt to restore normal bladder function. Jarvis and Millar (1980) and Pengelly and Booth (1980) examined the efficacy of bladder retraining for the treatment of overactive bladder (OAB) and detrusor instability, respectively. These studies reported a 47-78% cure rate. Cure rate is defined as having no UI episodes in a 3-7 day period as noted in a bladder diary. Fantl and colleagues (1991) reported that the women in their study with detrusor instability and genuine stress UI reported a ≥50% reduction in incontinent episodes using bladder retraining.

The most widely used behavioral intervention for urinary incontinence is the use of pelvic floor muscle (PFM) exercises (Burgio, Robinson, & Engel, 1986; Tran, Levin, & Mousa, 2009). This treatment was initially reported by Kegel in 1948 as a way to improve intra-urethral pressure and reduce stress urinary incontinence for pregnant women (Abrams et al., 2002; Kincade et al., 2005). The goal is to increase the strength and coordination of the pelvic floor muscles (Abrams et al., 2002). The individuals may also be instructed to do a simple quick contraction of their pelvic floor muscles during activities associated with involuntary urine loss (e.g., coughing). This technique is sometimes referred to as 'the knack' (Miller, Perlicchini et al., 2001). The object of this maneuver is to learn to contract the pelvic floor muscles and increase urethral closure pressure during increases in intra-abdominal pressure (Bo, 2004; McDowell et al., 1999; Sari & Khorshid, 2009). PFMT has been recommended as a first line treatment for urge and mixed incontinence (Kafri et al., 2008). While the short-term effectiveness of pelvic floor muscle training (PFMT) has been well documented for reducing urge and stress UI, adherence to the prescribed regimen over the long-term has been problematic (Dougherty, Bishop, Mooney, Gimotty, & Bradford, 1993; McDowell et al., 1999). Biofeedback has been used to augment PFMT and has been shown to be effective in helping to reduce UI by helping to teach pelvic floor muscle exercises (PFME), bladder inhibition and abdominal relaxation (Burgio et al., 2002; Burgio et al., 1986; McDowell et al., 1999). Biofeedback permits the individual to observe the results of their attempt to contract and relax their pelvic floor muscles (Burgio et al., 1986).

1.2.4 Acupuncture

Acupuncture is a novel intervention that may be effective for the treatment of urinary incontinence (Bergstrom et al., 2000; Emmons & Otto, 2005; Engberg, Cohen & Sereika, 2009; Philp, Shah & Worth, 1988). According to traditional Chinese medicine, energy flowing through pathways throughout the body influences the internal organs of the body and their surrounding structures (Pomeranz, 2003). Energy from these pathways leaves the structures at various points (i.e., acupuncture points). These points serve as access routes to the deeper circulatory channels within the body. Very fine needles are inserted at the access points or meridians and activate the body's natural energy (qi) to initiate the healing process (Pomeranz, 2003). Each meridian corresponds to a different organ system. It is believed that an imbalance in the flow of qi throughout a meridian is responsible for disease. The Western view of acupuncture is that it stimulates the release of neurotransmitters via nerve impulses to the brain and influences the autonomic nervous system (Kaptchuk, 2002). The side effects and risk associated with acupuncture have been reported as being very low (Kaptchuk, 2002). When the treatments are administered by properly trained practitioners using sterile disposable needles the side effects such as infections and/or punctured organs are minimal according to the U.S. Food and Drug Administration (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=880.5580).

1.3 CURRENT RECOMMENDATIONS

Once lifestyle changes such as weight reduction, decreased caffeine usage, modifying fluid intake, smoking cessation, and managing constipation have been addressed, the first line treatment recommendation for urinary incontinence has been non-pharmacological interventions (Mathur et al., 2010). It is advised that the intervention be given 8-12 weeks before assessing its effectiveness (Abrams et al., 2010). The most common interventions have been categorized into 3 groups: 1) non-pharmacological/behavioral, 2) pharmacological, and 3) surgical (invasive). It has been suggested that the most bothersome symptom (urgency, frequency, stress incontinence, etc.) should be addressed first (Holroyd-Leduc & Straus, 2004). If the non-pharmacological interventions are not successful for people with UUI, a trial of anti-cholinergic medication would follow (Mathur et al., 2010). The 4th International Consultation on Incontinence in 2009 recommended that treatment should be based on the severity of incontinence, what the individual wants, and what is known to be effective and safe for the type of incontinence experienced (Abrams, Andersson et al., 2010). The most common treatment interventions are outlined in Table 3.

Table 3: Interventions for the two most common types of urinary incontinence (UI)

	Type of Urinary Incontinence	
Intervention	Stress Urinary Incontinence (SUI)	Urge Urinary Incontinence (UUI)
Non-Pharmacological/ behavioral	Pelvic Floor Muscle training Bladder training Timed/prompted voiding	Pelvic Floor Muscle training Bladder training Timed/prompted voiding
Pharmacological		Anti-cholinergics/anti-muscarinics Tolterodine Oxybutynin
Surgical	Bulking agents (collagen, autologous fat, silicone beads, etc.) Open retropubic colposuspension Sling procedures TVT procedures	Botulism toxins Neuromodulation Bladder augmentation

While each of the incontinence management options may be effective for many people, there are limitations associated with each of them. For example, PFME has been shown to be safe and effective for both SUI and UUI. This intervention, however, requires active participation by the individual over the long term (Burgio et al., 2008; Castro et al., 2008). Maintaining motivation to continue to follow the prescribed regimen has been shown to be difficult and long-term adherence may be problematic (Burgio et al., 2008; Burgio et al., 1998; McDowell et al., 1999). While, pharmacological interventions are widely used by women to manage their urge incontinence, long-term adherence is often a problem due to the unacceptable side effects (Burgio, Kraus et al., 2008; Gopal, Haynes et al., 2008). The most common side effect is dry mouth, but blurry vision, headache, dizziness, urinary retention, and nausea have also been reported (Burgio et al., 2008). Gopal et al., (2008) reported that most women stop their prescribed medication within 4-5 months (median 4.7 months). Choosing one intervention over another can be a difficult choice as each has advantages and disadvantages. Individuals must be given all the necessary information about each potential treatment in order to make a truly informed decision. Finding alternative treatment options for urinary incontinence is important as no one treatment option will work for everyone.

1.4 PROBLEM STATEMENT

There have been no studies comparing PFMT vs. acupuncture for the treatment of UI or comparing the impact they have on QOL. Biofeedback-taught PFME were found to be effective for treating UI in previous studies (Burgio et al., 2002; Burns et al., 1993; Castro et al., 2008; McDowell et al., 1999). There is no risk to the individual doing the PFM exercises making this option an ideal first line treatment for many people with UI. It has been documented, however, that adherence to the prescribed regimen for doing the exercises is often problematic (Burgio et al., 2008; Burgio et al., 1998; McDowell et al., 1999).

Acupuncture for the treatment of UI has not received much attention to date but may provide an alternative treatment option for people who experience UI (Emmons and Otto, 2005; Engberg, Cohen et al., 2009). As noted previously, there are several small studies that have suggested acupuncture might be an effective alternative treatment for urinary incontinence (Bergstrom et al., 2000; Kelleher, Filshie, Burton, Khuller, & Cardozo, 1994; Philp, Shah, & Worth, 1988). If there is evidence to support this, acupuncture would be another tool to add to the arsenal of non-pharmacological interventions to treat UI. Acupuncture has limited side effects and therefore may be a safe, alternative treatment option for women who are not surgical candidates or who have failed other options.

When examining an intervention as a treatment option, in addition to examining its impact on the health problem being treated, it is also important to study the impact it has on QoL. Healthcare providers regularly ask their patients about their symptoms and how those symptoms affect their lives. Measuring QoL via questionnaire or interview is a more formal way of quantifying the impact of treatment on important aspects of a person's life such as physical functioning, interference with work, social life, self-esteem, body image, feelings, etc.

1.5 SPECIFIC AIMS

The aims of this study of non-homebound, community-dwelling women 50 years of age and older are to: 1) compare the short-term effectiveness of PFMT and acupuncture in reducing urinary incontinence, 2) compare the impact of PFMT and acupuncture on general HRQoL, 3) compare the satisfaction with progress (reduction in UI) reported by the women in each study group following treatment, 4) compare the treatment burden of the women in each study related to the intervention received, and 5) examine the association between change in UI and HRQoL immediately following treatment.

1.6 RESEARCH QUESTIONS

Research Question #1. Among non-homebound women age 50 years and older, what is the comparative effectiveness of pelvic floor muscle training (PFMT) and acupuncture in reducing episodes of UI?

Research Question #2. Among non-homebound women age 50 years and older, what is the comparative effectiveness of PFMT and acupuncture in improving general HRQoL?

Research Question #3. Among non-homebound women age 50 years and older, is there a significant difference in the satisfaction with progress reported by women in the PFMT group compared with women in the acupuncture group?

Research Question #4. Among non-homebound women age 50 years and older, is there a significant difference in treatment burden experienced by women in the PFMT study compared with women in the acupuncture study?

Research Question #5. Among non-homebound women age 50 years and older, what is the association between change in UI and change in HRQoL?

1.7 OPERATIONAL DEFINITIONS

Urinary Incontinence is defined as any involuntary urine leakage (Abrams et al., 2002). For this secondary analysis, data collected from a 7-day paper/pencil diary in the PFMT study and a 7-

day electronic bladder diary in the acupuncture study were used to measure the number of incontinent episodes.

Satisfaction with progress is defined as the degree to which the progress achieved has met the patient's outcome expectation. Data related to satisfaction with progress (reduction in urinary incontinent episodes) from pre- to post-treatment were collected from the Patient Satisfaction instrument.

Treatment burden is defined as the degree of work necessary, as perceived by the subject, to acquire knowledge of interventions, to attend intervention and follow-up sessions, to make behavioral and lifestyle changes, as well as travel to study sites. For this study, these data were collected from the Patient Satisfaction instrument at the immediate post-intervention visit.

Quality of Life (QoL)/Health-related Quality of Life (HRQoL) is defined using the World Health Organization (WHO) as "those attributes valued by patients including their resultant comfort or sense of well-being; the extent to which they were able to maintain reasonable physical, emotional and intellectual function; the degree to which they retain their ability to participate in valued activities within the family, in the workplace and in the community." In this study, HRQoL was measured by the Physical and Mental Health Component scores from Medical Outcomes Study Short Form version 1 (MOS-SF 36v1).

Middle-age is defined as 50-65 years of age.

Older adult is defined as $\geq$ 65 years of age.

2.0 CONCEPTUAL MODEL AND LITERATURE REVIEW

2.1 PROPOSED OPERANT PATHWAYS

To understand urinary incontinence it is first important to understand the structures in the lower urinary tract and the role they play in maintaining continence. These structures include the bladder, urethra, and pelvic floor muscles. The urinary bladder is a hollow muscular sac responsible for storing urine for prolonged periods of time. There are three layers that make up the bladder wall. The central layer known as the detrusor muscle is important to the micturition process as it allows for the bladder to stretch during filling and contract when it's time to urinate (Heuther, 2002). The function of the bladder is to fill, store and empty urine. During the filling phase the detrusor muscle relaxes to allow for the bladder to expand to store urine while keeping intravesical pressure low (Ashton-Miller & DeLancey, 2007). The urethra, a thin muscular tube, extends from the neck of the urinary bladder to its external opening, the urethral meatus. During bladder filling, contraction of the sphincter muscles at the neck of the bladder and urethra maintain urethral closure (Ashton-Miller & DeLancey, 2007). Relaxation of the sphincters allows the bladder to empty during micturition. The internal sphincter is not under voluntary control (DeLancey & Ashton-Miller, 2004). The external sphincter, on the other hand, is under voluntary control and can voluntarily relax to facilitate emptying of the bladder or contract to prevent urine from leaking when abdominal pressure is increased, such as when one coughs, sneezes or laughs (DeLancey & Ashton-Miller, 2004). The pelvic floor muscles serve to support and protect the organs and structures that make up the pelvic floor (Ashton-Miller & DeLancey, 2007). These muscles are under voluntary control by the nervous system and are important in maintaining continence.

The nervous system plays a major role in the micturition process. Lower urinary tract function is dependent upon complex interactions between the brain, spinal cord, and peripheral nervous system, and lower urinary tract structures (Fowler, Griffiths, & DeGroat, 2008). Voluntary control of lower urinary tract function is dependent on input from both autonomic and somatic neural pathways. Autonomic input comes from both the sympathetic and parasympathetic divisions. Sympathetic nerves release noradrenaline leading to relaxation of the bladder and contraction of the bladder neck and proximal urethra (internal sphincter). Sympathetic stimulation keeps bladder pressure low and the urethra closed during filling and storage. Parasympathetic nerves release (1) acetylcholine, which acts through muscarinic receptors to cause the detrusor muscle to contract and (2) nitric oxide, which inhibits contraction of the internal sphincter. Concurrent contraction of the detrusor muscle and relaxation of the internal sphincter allows the bladder to empty (Fowler, et al., 2008). Somatic fibers in the pudendal nerve innervate the striated muscle (external sphincter) of the external urethral and release acetylcholine causing the external sphincter to contract increasing urethral closure pressure (Fowler et al., 2008). The sympathetic fibers innervating the bladder arise from the thoracolumbar section of the spinal cord and innervate the bladder and proximal urethra via the hypogastric nerve. The parasympathetic fibers arise from the sacral cord and travel to the bladder via the pelvic nerve. Somatic nerves also arise from the sacral section of the spinal cord. Sensory information related to bladder filling is carried to the spinal cord by the hypogastric and pelvic nerves, while input from the bladder neck and urethra are transmitted by the hypogastric and pudendal nerves (Fowler et al., 2008).

Animal and human studies suggest that numerous areas in the brain are involved in bladder control. Based on the results of these studies, including functional MRI studies in humans, it is postulated that afferent impulses from the bladder are received in the periaqueductal grey (PAG) cells in the midbrain, which relays them to the thalamus, insula, anterior cingulate gyrus (ACG), and frontal lobes. There are extensive connections between the ACG and prefrontal cortex and these two areas are thought to be important in determining how much attention one pays to afferent signals from the bladder and responds to them including determining when it is socially appropriate to void (Fowler et al., 2008). Once the decision is made to void, efferent impulses are sent to the pontine micturition center (PMC). The PMC, in turn, sends efferent signals to the sacral cord activating parasympathetic outflow. As a result, the detrusor muscle contracts and intravesical pressure increases. At the same time, the urethral smooth muscle relaxes allowing urine to flow into the urethra and the bladder to empty (Fowler et al., 2008). Any interruption in the neuromuscular pathway appears to place a person at increased risk for urinary incontinence.

Griffiths, Tadic, Schaefer, and Resnick (2007) reported that urge incontinence with detrusor over-activity may be due to an abnormality in the afferent signals from the bladder or abnormal activation within the brain when afferent signals are received. Griffiths and colleagues (2007) used fMRI to explore the possibility of supra-spinal bladder control during urine storage. Their findings suggest that the insular responses to bladder filling decrease with age. This may predispose the older adults to decreased bladder control and urge urinary incontinence.

When examining individuals with urge urinary incontinence, Tadic, Griffiths, and colleagues (2010) used the fMRI to study the interactions between regions of the brain and bladder control. Their exploratory study showed that in women with normal bladder function the connections between the right insula (RI) and ACG with the other areas of the brain are inhibitory and are effective in maintaining bladder control. In women with urge incontinence, these connections are shifted to other ancillary areas in an attempt to maintain bladder control when the bladder is full (Tadic, Griffiths, Schaefer, Cheng, & Resnick, 2010; Tadic, Griffiths, Schaefer, & Resnick, 2007).

Stress incontinence is associated with inadequate urethra sphincter closure which may be related to sphincter dysfunction or a problem with the support system of the anterior vaginal wall and connective tissue that attach to the pelvic bones through the levator ani muscle and tendinous arch of the pelvic fascia (Ashton-Miller & DeLancey, 2007; DeLancey et al., 2008). These structures make up the urethral support system. All of these structures interact to maintain pelvic support and continence (DeLancey & Ashton-Miller, 2004). When coughing occurs, there is downward pressure from the abdominal muscles causing the muscles to press against the supportive layer of the endopelvic fascia, the vagina, and the levator ani muscles (DeLancey & Ashton-Miller, 2004). When there is an abnormality in the supportive structures, stress urinary incontinence may occur (DeLancey et al., 2008). In addition, when the urethral sphincter cannot accommodate the increase in bladder pressure from the sudden increase in abdominal pressure, such as during times of coughing, sneezing, etc. stress urinary incontinence may occur (DeLancey & Ashton-Miller, 2004). Therefore, stress incontinence may occur from weakened pelvic muscles that support the bladder and urethra or because the urethral sphincter is not working correctly (DeLancey et al., 2008).

Chancellor and Yoshimura (2004) examined the neural connection for stress urinary incontinence. One mechanism related to stress urinary incontinence they reported is known as the guarding reflex. The guarding reflex occurs when there is an increase in bladder volume. This reflex involves activation of the stretch-sensitive receptors in the bladder wall, which send afferent signals to the sacral spinal cord. This, in turn, activates the pudendal efferent pathway that stimulates contraction of the external urethral sphincter, which helps to maintain outlet resistance and urinary continence (Chancellor & Yoshimura, 2004). Bladder stretching also activates the sympathetic reflex path, which causes inhibition of bladder activity and internal urethral sphincter contraction maintaining continence (Chancellor & Yoshimura, 2004; DeLancey et al., 2008). If there is a sudden increase in abdominal pressure as with coughing or sneezing and there is an interruption in the neuronal pathways, stress incontinence is likely to occur (Chancellor & Yoshimura, 2004; DeLancey et al., 2008).

2.1.1 Pelvic Floor Muscle Training (PFMT)

PFME involves repetitive contraction and relaxation of the pelvic floor muscles in an attempt to strengthen the muscles (Bo, 2004). PFME are believed to improve periurethral muscle strength and to give better support for the structures of the pelvic floor including the urinary sphincters (Burgio et al., 1986; Marques, Stothers, & Macnab, 2010). All of the structures work together to maintain continence. The voluntary contractions of the pelvic floor muscles stabilize the vesical neck during increases in abdominal pressure. Adding biofeedback may help women isolate their pelvic floor muscles by allowing them to visualize when they are doing their exercises correctly.

Biofeedback also works to improve the intensity of the muscle contractions, which may also help to improve both stress and urge urinary incontinence by helping to maintain or increase adequate urethral sphincter closure pressure (Burgio et al., 2002). Women may be taught to contract their pelvic floor muscles at the first feeling of urgency in an attempt to delay the urgency sensation and ward of urine leakage. They may also be taught to contract the pelvic floor muscles prior to activities that cause them to experience stress urinary incontinence thus avoiding urine leakage (Burgio et al., 2002; McDowell et al., 1999).

2.1.2 Acupuncture

Explaining the mechanism whereby acupuncture works for chronic health problems overall has been perplexing for Western Medicine. There has been increasing evidence, however, that nervous system dysfunction is an important factor for urinary incontinence (Fowler et al., 2008; Jabs & Stanton, 2001; Jung et al., 1999). It is therefore postulated by Western practitioners that acupuncture alters brain chemistry by changing the release of neurotransmitters affecting the parts of the central nervous system (CNS) related to sensation and involuntary body functions through autonomic regulation (Emmons & Otto, 2005) and by activating neural impulses, which in turn causes changes in the neural blood flow and the release of neurotransmitters and neurohormones and possibly endogenous opioids (Shen, 2001). Hui et al. (2000) used functional MRI, which demonstrated changes in specific areas of the brain during acupuncture. Acupuncture may modify abnormal afferent impulses from the bladder to the spinal cord resulting in activation of the inhibition reflex to control detrusor contractions. Bergstrom et al.

(2000) and Philp et al. (1988) suggested that acupuncture may work by increasing levels of endogenous opioids, which may work to stabilize abnormal detrusor instability.

2.2 PROPOSED CONCEPTUAL MODEL

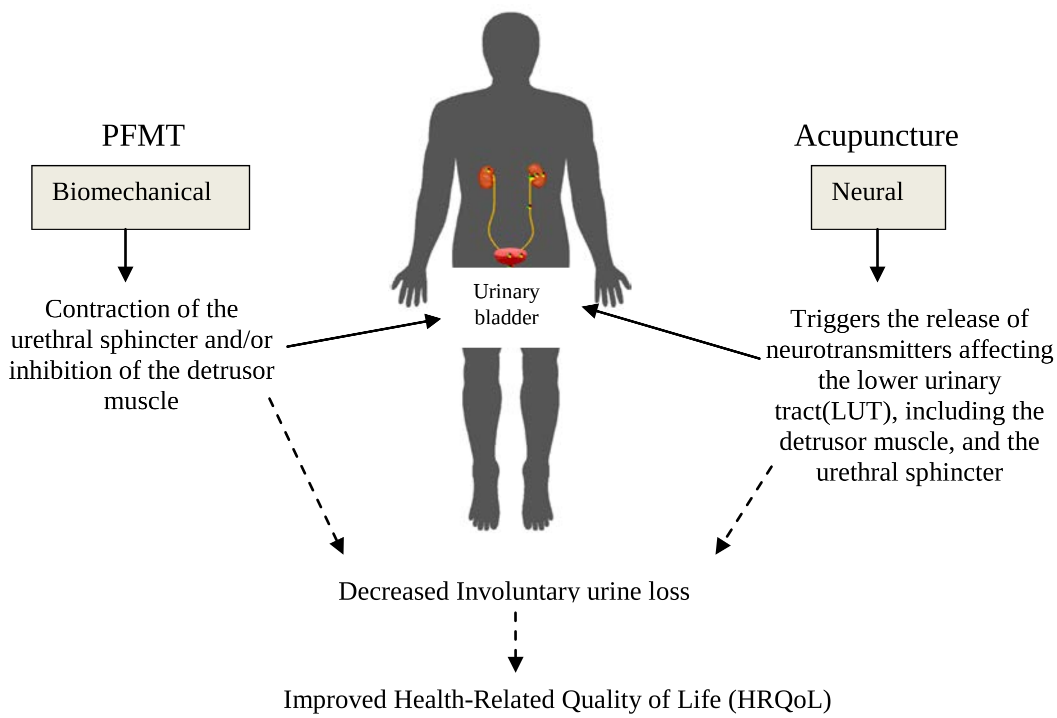

Figure 1: Proposed Conceptual Model

- Biofeedback as an adjunct to pelvic floor muscle exercises allows for better isolation of the structures comprising the pelvic floor. This has been shown to provide support to the structures of the pelvic floor and to strengthen contractions of the pelvic floor muscles increasing urethral closure pressure. Teaching patients to actively use their pelvic floor muscles to increase urethral closure pressure (SUI) or suppress detrusor contractions (UUI) can reduce involuntary urine loss (UI).

- Acupuncture uses needles to stimulate the release of neurotransmitters, which may reduce UI by inhibiting abnormal detrusor contractions (UI) or stimulate contraction of the urethral sphincter (SUI).

- It is hypothesized that a reduction in episodes of urinary incontinence regardless of the intervention used improves health-related quality of life.

2.3 LITERATURE REVIEW

An extensive literature search was conducted using the PubMed version of OVID Medline along with EBSCOhost and CINAHL. One search utilized the key words: stress urinary incontinence or urge urinary incontinence or pelvic floor muscle exercises or Kegels, or acupuncture. Another search included urinary incontinence combined with pelvic floor muscle exercises or Kegels or behavioral therapy or acupuncture. A third search included the same key words noted above combined with quality of life or health-related quality of life. Another search using the key words comparative effectiveness research or health policy or patient-centered outcomes or affordable health care act and/or Institute of Medicine. The searches were limited to studies published in English and conducted on humans, specifically adult females. The search was conducted through March 2012. Articles were excluded if participants did not experience urinary incontinence, were diagnosed with bladder cancer, or the women were pregnant. Studies using a combination of interventions (drug and PFMT, etc.) were not included. A brief narrative summary of the literature followed by a tabular presentation of more detailed information about the studies reviewed follows. See Tables 4-6.

2.3.1 Pelvic Floor Muscle Studies

Seven studies that examined the use of PFM exercises as an intervention to treat UI were included in this review. These studies included community-dwelling and homebound women between the ages of 24-95 years of age. Overall, the studies examining PFMT in this target population reported a decrease in UI episodes ranging from 39%-82%. Five of the studies examined the impact of PFMT with and without biofeedback (Burgio et al., 1998; Burns et al., 1993; McDowell et al., 1999, Perrin, Dauphinee, Corcos, Hanley, & Kuchel, 2005; Sari & Khorshid, 2009). One study examined PFME without biofeedback (Sari & Khorshid, 2009). Of the seven studies, four examined the impact of PFME on SUI, UUI, and mixed UI (Burns et al., 1993; McDowell et al., 1999; Perrin et al., 2005, Sari & Khorshid, 2009). There were two studies that examined the impact of PFMT on only SUI (Burgio et al., 1986, Castro et al., 2008) and one that examined UUI only (Burgio et al., 2002). All studies reviewed had differing prescriptions for the PFME, which varied from 45 to 200 repetitions per day. Outcomes from these seven randomized controlled trials (RCTs) identified are reported in Table 4.

Table 4: Studies reporting the effect of pelvic floor muscle training (PFMT) on urinary incontinence (UI)

Authors	Date	Sample	Intervention	Primary Outcome % change in number of UI episodes (mean)
Burgio, Robinson, and Engel	1986	Community-dwelling women $\geq$19 years of age with stress urinary incontinence (SUI) n = 13	Biofeedback-taught PFMT[b] (only abstract available)	$\geq$60%
Burgio, Goode, Locher, Umlauf, Roth, Richter,… Lloyd, et al.	2002	Community-dwelling women with urge urinary incontinence (UUI) 55-92 years of age n = 73	PFME[a] Urge suppression strategies 45 exercises q day (sets of 15 ex 3 x q day). Duration of contraction to increase to a max of 10 seconds with resting period = to contract period PFME* practiced lying, sitting, standing Practice stream interruption once a day 8 weeks (4 clinic visits at two week intervals) of biofeedback-behavioral therapy	63.1%
Burns, Pranikoff, Nochajski, Hadley, Levy, and Ory	1993	Community-dwelling women with SUI, UUI, and mixed UI >55 years of age n = 83 (PFME* only n = 43) (PFME* with BFT[c] n = 40)	Group 1: PFME[a] with one weekly biofeedback session x 8 weeks (each session 1 hour) Group 2: PFME[a] only 4 sets of 20 (10 quick and 10 sustained) exercises to increase by 10 per set over 4 weeks until a daily maximum of 200 exercises was attained	61% PFME[a] with BFT[c] 54% PFME[a] only

[a] Pelvic Floor Muscle Exercise
[b] Pelvic Floor Muscle Training
[c] Biofeedback Taught Exercise

Table 4 (cont.)

Authors	Date	Sample	Intervention	% change in number of UI episodes (mean)
Castro, Arruda, Zanetti, Santos, Sartori, and Girao	2008	Community-dwelling women with urodynamic diagnosed (SUI) without detrusor over-activity (DO) Mean age 56.2 (SD 12.5) n = 26	PFME[a]: three 45 minutes exercise/classes/week for 6 months supervised by physiotherapist Pelvic Floor Muscle Contractions (PFMC) taught by trained physiotherapist Set: 5 voluntary pelvic floor muscle contraction (VPFMC) with 10 sec hold, 10 VPFMC with 5 sec hold, 20 VPFMC with 2 sec hold, 20 VPFMC with 1 sec hold, 5 contractions with cough	75%
McDowell, Engberg, Sereika, Donovan, Jubeck, Weber, and Engberg	1999	Cognitively intact homebound older adults with high levels of co-morbid functional impairment (90.5% women) Mean age 76.8 years (SD 7.2) n = 48	8 weeks of PFMT[b], Urge/stress strategies and bladder retraining. PFM exercise 3 x q d with 10-15 reps at each session goal to hold 10 seconds To do one set lying down, standing, and sitting	(Median) 75%
Perrin, Dauphinee, Corcos, Hanley, and Kuchel	2005	Community-dwelling women with SUI and mixed UI on a wait list for incontinence surgery. Mean age >75 years n = 5	PFMT[b] with BT[c] 6 treatments of 1-1.5 hours each over 6-9wks Urge suppression strategies PFME regimen increased from 5 to 10 to 15 contractions/set 3 x q d (15/set) Sustained contractions starting with 2 sec to 5 sec to 10 sec with 15 sec rest period Performed lying, sitting, and standing	39.16%
Sari and Khorshid	2009	Community-dwelling women with SUI or mixed UI living in Izmir, Turkey. Mean age 41.82 (SD 8.65) years n = 17	3 sets of fast and slow contractions completely daily in the supine, sitting, and standing positions 30 contractions/set. Muscle training including quick flick exercises (1-2-s contractions), followed by sustained (5-s) contractions With sustained contractions increasing time by 1 s/week for 5 weeks to a max of 10 s at week 6. Each contraction was followed by a relaxation period equal to the sustained contraction time Digital palpation to ensure awareness of the position of levator ani and to assess correct PFM contraction Use the “knack” to contract the pelvic floor voluntarily before any sudden rise in abdominal pressure	82%

[a] Pelvic Floor Muscle Exercise [b] Pelvic Floor Muscle Training [c] Behavioral Training

2.3.2 Acupuncture studies

Three studies were identified that examined the effectiveness of acupuncture for the treatment of UI (Bergstrom et al., 2000; Emmons & Otto, 2005; Engberg et al., 2009). One of the three studies in Table 5 used the pad test (g) to determine a reduction in urine leakage (Bergstrom et al., 2000). One study focused on treatment for overactive bladder and reported the impact of acupuncture on urge incontinence (Emmons & Otto, 2005). Two studies examined acupuncture for the treatment of UUI and/or SUI (Bergstrom et al., 2000; Engberg et al., 2009). All reported a reduction in UI episodes from 43% to 75% following acupuncture treatment. See Table 5 for more details of these studies.

Table 5: Acupuncture studies

Author	Year	Sample	Intervention	Mean % change in UI
Bergstrom, Carlsson, Lindholm, and Widengren	2000	Community-dwelling women with urge urinary incontinence (UUI) and mixed UI Mean age 76.4 years (range 66-82) n = 15	12 acupuncture treatment sessions over 6 weeks (twice weekly) 4 needles first treatment-increased until 14 needles Needles in place for 25 minutes and stimulated 2 x during each session	48 hour pad test post treatment Baseline mean (grams) = 121 Discharge mean (grams) = 69 43% change (mean) in grams of urine lost
Emmons and Otto	2005	Community-dwelling women with overactive bladder (OAB) and UUI $\geq$18 years of age n = 85	Four 30 minute acupuncture sessions 1 session/week x 4 weeks 7 needles	Mean number of incontinent episodes/3 days ($\pm$SD*) Pre-treatment 6.3 ($\pm$7.3) Post-treatment 2.6 ($\pm$3.1) % change (mean) = 59% (UUI)
Engberg, Cohen, and Sereika	2009	Community-dwelling women with self-reported stress urinary incontinence (SUI), UUI or mixed UI - 2 or more times/week for at least 3 months 40-70 years of age n = 9 (4 in the treatment group)	Twelve-30 min acupuncture sessions (2 q week x 6 weeks) Needles in place for 25 minutes and stimulated 2 x during each session. 12 needles	% Mean (SD*) — % Median 1 week 63.30 (34.55) — 65.99 4 week 67.47 (39.93) — 75.76

*standard deviation

2.3.3 Quality of life

Across the studies reviewed, an improvement in the severity of urinary incontinence was associated with an improvement in overall QoL scores ranging from 25-44%. Also, quality of life was not consistently defined or measured. Throughout the literature, quality of life has included general QoL, HRQoL and disease-specific QoL often used interchangeably. A variety of instruments were used to measure quality of life, i.e., Incontinence-Quality of Life (I-QOL), SF-36, Incontinence Impact Questionnaire (IIQ), King's Health Questionnaire (KHQ), Norwegian Quality of Life Scale (QoLS-N), Bristol Female Lower Urinary Tract Symptoms (B-FLUTS), and Urinary Distress Inventory (UDI) making it difficult to compare findings. When percentages were not given, the following equation was used to calculate % change in all QoL scores (either general health related QoL or UI-specific QoL). Unless otherwise noted, the percentages given are based on the mean scores. When medians were used, the median values were placed into the equation for the mean values.

$$\left(\frac{\text{Post-intervention (mean) score-Baseline (mean) score}}{\text{Baseline (mean) score}} \right) *100 = \text{\% change in QoL}$$

Ten studies examining QoL following PFMT were identified. Table 6 lists the individual studies. Three of these studies examined the impact of PFMT training on general HRQoL (Balmforth et al., 2006; Bo et al., 2000, Tibaek et al., 2004). Balmforth et al. (2006) only examined general HRQoL using the King's Health Questionnaire and reported significant changes in six of the nine subscales. Two of the studies (Bo et al., 2000; Tibaek et al., 2004) examined the impact of PFMT on both general HRQoL and incontinence-specific HRQoL. Bo et al. (2000) used the Norwegian version of the QoL Scale (QOLS-N) to compare the impact of PFMT relative to a no treatment control group and reported that there was no significant change in post-intervention general HRQoL between the groups (p=.15) or within the PFMT intervention group (p-value not reported). In contrast, significantly fewer women in the PFMT group reported that UI interfered with social life and physical activity compared with the control subjects. Tibaek et al. (2004) used the SF-36 to measure general HRQoL and the Incontinence Impact Questionnaire (IIQ) to measure UI-specific QoL and reported no significant change in either general HRQoL or UI-specific QoL (p = .147 and p = .374, respectively) following PFMT. The remaining seven studies examined only UI-specific QoL (Castro et al., 2008; Goode et al., 2006; Kafri et al., 2007, Kashanian et al., 2011; Perrin et al., 2005; Sari & Khorshid, 2009; Vaughn et al., 2011). The studies used a variety of questionnaires to measure the impact of PFMT on UI-specific QoL and all but one reported that there was a significant improvement in QoL scores. The other study, a small pilot study with five subjects, reported a 51% improvement in IIQ scores, but did not examine the change to determine if it was statistically significant (Perrin et al., 2005).

Three studies examined changes in quality of life in women whose UI was treated with acupuncture (Bergstrom et al., 2000, Emmons & Otto, 2005; Engberg et al., 2009), Two of the three acupuncture studies reported significant improvements in urinary incontinence-specific quality of life reporting a 29-52% improvement measured by IIQ scores (Emmons & Otto, 2005; Bergstrom et al., 2000). The third acupuncture study (Engberg et al., 2009) showed a modest improvement (12.3%) in UI-specific QoL at 1 week post acupuncture treatment. This study also showed a small improvement in general HRQoL based on the SF-36 Physical (4.5%) and Mental

Health Component (7.8%) scores. The sample size, however, was small in this pilot study and only 4 women received the acupuncture intervention.

Table 6: Studies examining quality of life (QoL) after intervention for urinary incontinence (UI)

Authors	Year	Sample	Intervention and Measure	Quality of Life (QoL) Outcome % change in mean QoL scores representing improvement post-intervention
Balmforth, Mantle, Bimead, and Cardozo	2006	Women from a tertiary urogynecology clinic with urodynamic confirmed SUI[a]. Mean age 49.5 years. n = 97 (84 completed the program)	Intervention: 14 week intensive PFMT[b] and behavioral modification program (behavior modification included: fluid management, diet/bowel management, Exercise) General HRQoL Measure: King's Health Questionnaire (KHQ)	<u>KHQ subscales (all improved):</u> Gen. health perception:3.2%, p = .413 Condition impact = 78%, p < .001 Role limitations = 47.8%, p < .001 Physical limitations = 28.6%, p <. 001 Social limitations = 41.2%, p = .009 Personal relationships = 15.2%, p = .736 Emotions = 20.6%, p = .006 Sleep/energy = 13.4%, p = .023 Severity measures = 7.0%, p = .321
Bo, Talseth, and Vinshes	2000	Community-dwelling women with clinically and urodynamic proven genuine SUI* Mean age: 49.6 (SD 10) Treatment n = 59 (25 in the PFMT[b] group)	Intervention: PFMT[b] General QoL Measure: Norwegian version of the Quality of Life Scale (QoLS-N) Incontinence-specific QoL Measure: Bristol Female Lower Tract Symptoms (B-FLUTS)	<u>QOLS-N</u> The change in general HRQoL was ns within group (no p-value given) or between groups, p = .15. <u>B-FLUTS-PFMT[b] vs. control:</u> Avoiding places/situations:28 vs. 34.4, ns Interference -social activities: 3.7 vs. 40.7, p < .01 Interference-physical activities:43.5 vs. 79.3, p < .01 Interference-with life overall:56.0 vs.82.1, ns Unsatisfied if you had to spending the rest of your life with symptoms as they are now: 4.0 vs. 37.9, ns
Castro, Arruda, Zanetti, Santos, Santorie, and Girao	2008	Community-dwelling women, mean age 56.2 years n = 118 with 26 in PFMT[b] group	Intervention: PFMT[b] QoL Measure: I-Qol	Total I-QoL = 28.3% improvement at 6 months post-intervention, p <.001

[a] stress urinary incontinence
[b] pelvic floor muscle training

Table 6 (cont.)

Authors	Year	Sample	Intervention and Measure	Quality of Life (QoL) Outcome % change in mean QoL scores representing improvement post-intervention
Goode, Burgio, Locher, Roth, Umlauf, Richter, Varner, and Lloyd	2006	Community-dwelling women ages 40-78 (mean age 57 years) with SUI[a] or Mixed UI n = 200 (66 in the PFMT[b] group)	Intervention: PFMT[b] Incontinence-specific QoL: IIQ	Total IIQ = 38% improvement, p<.001 Physical subscale = 36% improvement post intervention (2 weeks post-intervention) Social subscale = 41% improvement Emotional subscale = 35% improvement
Kafri, Langer, Dvir, and Katz-Leurer	2007	Community-dwelling women, >18 years of age having urge incontinence and urodynamic confirmed overactive bladder. n = 55 (20 PFMT[b] group).	Intervention: PFMT[b] QoL Measure: I-QoL	Total I-QOL = 21% improvement at 3 months post-intervention, p < .01
Kashanian, Ali, Mazeni, and Bahasadri	2011	Community-dwelling women living in Tehran, Iran Mean age 41.6 years. n = 85 (46 in the PFMT[b] group).	Intervention: PFMT[b] Incontinence-specific QoL: I-QoL, Incontinence Impact Questionnaire (IIQ) and Urinary Distress Inventory (UDI)	Total I-QoL = 23% improvement at 1 month (4 months from beginning the study), p < .001 Total IIQ = 31% improvement at 1 month (4 months from beginning the study), p < .001 UDI = 32% improvement at 1 month (4 months from beginning the study), p < .001
Perrin, Dauphinee, Corcos, Hanley, and Kuchel	2005	Community-dwelling women Mean age ≥75 years on a wait list for incontinence surgery. n = 5	Intervention: PFMT[b] QoL Measure: Incontinence Impact Questionnaire (IIQ)	Total Incontinence Impact Questionnaire (IIQ) Score = 51%

[a] stress urinary incontinence
[b] pelvic floor muscle training

Table 6 (cont.)

Authors	Year	Sample	Intervention and Measure	Quality of Life (QoL) Outcome % change in mean QoL scores representing improvement post-intervention
Sari and Khorshid	2009	Community-dwelling women with SUI or mixed UI living in Izmir, Turkey. Mean age 41.82 (SD 8.65) years n = 17	Intervention: Pelvic Floor Muscle Exercise (PFME) Incontinence-specific QoL: Incontinence specific-quality of life I-QoL (3 domains)	Total Incontinence-Quality of Life (I-QoL) = 29%, p = .01 Significant improvement in all three I-QoL domains: 1) Avoidance/limiting behaviors = 25% 2) Psychosocial impact domain = 39% 3) Social embarrassment domain = 48%
Tibaek, Jensen, Lindskov, and Jensen	2004	Clinical sample of women from a University Hospital in Sweden, post-ischemic stroke with primarily urge and mixed UI Mean age (treatment group) = 59 years (min 56-max 72) n = 24 (12 in PFMT group; 12 control group)	Intervention: Pelvic Floor Muscle Training (PFMT) General QoL measure: SF-36 Incontinence-specific QoL: IIQ	SF-36 no significant change in scores pre-to post-treatment, p = .147 IIQ: no significant change in scores pre to post-treatment, p = .374.
Vaughn, Juncos, Burgio, Goode, Wolf and Johnson	2011	Uncontrolled pilot study of participants with Parkinson Disease, mean age of 66.5, recruited from a movement disorders clinic (15 (90%) were male) n = 20 (17 completed the study)	Intervention: PFMT using computer-assisted EMG biofeedback Incontinence-specific QoL: International Consultation on Incontinence Questionnaire for overactive bladder (ICIQ-OAB)	ICIQ-OAB = 23.1% improvement, p = .002
Bergstrom, Carlsson, Lindholm, and Widengren	2000	Community-dwelling women Mean age 76.4 years (range 66-82) n = 15	Intervention: Acupuncture Incontinence-specific QoL: Incontinence Quality of Life Index (I-QoLI).	Total I-QoLI = 34% change in medians at 3 months (Mdn change 41 to 55), p = .001

Table 6 (cont.)

Authors	Year	Sample	Intervention and Measure	Quality of Life (QoL) Outcome % change in mean QoL scores representing improvement post-intervention
Emmons and Otto	2005	Community-dwelling women ≥18 years of age n = 85	Intervention: Acupuncture Incontinence-specific QoL: IIQ and Urinary Distress Inventory (UDI)	IIQ Total = 52%, p = .004 UDI = 57%
Engberg, Cohen, and Sereika	2009	Community-dwelling women 40-70 years of age n = 9 (4 in the intervention group)	Intervention: Acupuncture General HRQoL: Medical Outcomes Study-SF-36 (SF-36); UI-specific QoL: IIQ and UDI	Based on the medians for the four scores below: SF-36 Physical Component = 4.5% SF-36 Mental Health Comp = 7.8% IIQ Total = 12.3% UDI Total = 13.5%

2.3.4 Limitations

There are a few studies examining the impact of PFMT or acupuncture on general HRQoL and none focusing on older women. There are no published studies comparing the impact of these interventions, PFMT and acupuncture, on either incontinence frequency or HRQoL.

2.3.5 Discussion

This proposed secondary analysis will address the gaps in the literature and add to the body of knowledge in regard to treatment interventions for middle-aged and older women who experience UI. There have been no studies comparing the effectiveness of PFMT and acupuncture for the treatment of urinary incontinence. While acupuncture has been shown to be an effective treatment option for many chronic disorders, there are very few studies examining the use of acupuncture to treat urinary incontinence. Middle-aged and older women have not been the focus of many UI studies to date (Sampselle, 2003). The majority of studies have been on women of child-bearing age even though the prevalence of UI has been reported to increase with age (Waetjen et al., 2006). Since there is no one intervention that will work for everyone, it is important to identify effective and safe interventions to treat urinary incontinence and at the same time improve the HRQoL for middle-aged and older women who experience urinary incontinence.

3.0 RESEARCH DESIGN AND METHODS

3.1 STUDY DESIGN

3.1.1 Comparative Effectiveness Research (CER)

Since 2007, there has been an increased focus on decision-making by clinicians and their patients (Sox & Greenfield, 2009). As a result, the Institute of Medicine called for a national initiative of research to help promote better decision-making about interventions to treat health conditions (Sox & Greenfield, 2009). As noted, there are many treatment options available for urinary incontinence but practical information that can guide health care choices for individual patients is often entwined with uncertainty on the part of the clinician and the patient (Conway & Clancy, 2009). It is important for both clinicians and patients to know which interventions work and which work better on average for certain subgroups of patients (Conway & Clancy, 2009; Horn & Gassaway, 2010; Luce et al., 2009). With the passage of the American Recovery and Reinvestment Act of 2009, the stage was set for comparative effectiveness research (Sox, 2010).

Comparative effectiveness research (CER) provides evidence related to the effectiveness, harms, and benefits of different treatment options so consumers or stakeholders can make truly informed decisions about the care they give or receive with the ultimate outcome of seeing an improvement in quality of life (Sox & Greenfield, 2009). CER is defined by the Institute of Medicine in its report published on June 30, 2009 (http://www.nap.edu/openbook.php?record_id=12648&page=29) as:

> "…the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers and policy makers to make informed decisions that will improve health care at both the individual and population levels."

Systematic reviews use data from two broad research categories, i.e., observational studies and randomized control trials to summarize the empirical evidence, which has helped policy-makers formulate practice guidelines to date (Concato, Peduzzi, Huang, O'Leary, & Kupersmith, 2010; Horn & Gassaway, 2010; Sox & Greenfield, 2009). In recent years, large databases from diverse populations have been compiled in an attempt to use information to mimic real-life experience (Berger, Mamdani, Atkins, & Johnson, 2009; Concato et al., 2010; Horn & Gassaway, 2010). It is important for researchers to choose the right method to address the research question(s) and the choice should be driven by policy goals (Teutsch, Berger, & Weinstein, 2005). Quite often using RCTs is most appropriate when examining treatment options related to benefit-risk-cost assessment (Teutsch et al., 2005). This is the direction of the current study, which is examining data collected from two prior randomized controlled trials (RCTs) to compare the effectiveness of PFMT and acupuncture for the treatment of UI as well as to examine the impact on HRQoL for women with urge and/or stress UI. The information gained from this study will add to the body of knowledge and may help assist patients, clinicians, and policy makers in making decisions related to treatment options.

This study was a secondary analysis of data collected during two independent, randomized controlled trials. One of the studies examined the efficacy of a relapse prevention intervention in maintaining improvements in UI following a PFMT intervention for homebound and non-homebound women $\geq$ 60 years of age. The PFMT study was a longitudinal, randomized controlled trial with repeated assessments at baseline [prior to the PFMT intervention (pre-intervention)], immediate post-intervention, following the relapse intervention (for subjects randomized to the relapse intervention) and at 3, 6, 9, and 12 months post-intervention. All subjects received PFMT once a week for six weeks. Following the initial PFMT, subjects were randomly assigned to a 4-month relapse prevention therapy designed to promote continued adherence to the PFMT regimen or to a traditional follow-up group with no additional intervention. Eligible non-homebound, female participants who received the PFMT intervention were included in this secondary analysis. Surface electromyography (EMG) was utilized to teach subjects how to contract and relax their PFMs and to provide visual and/or auditory feedback on their performance. They were asked to do the pelvic floor muscle exercise (PFME) three times a day with 10-15 repetitions at each session. They were asked to do one session while lying down, standing, and sitting. The initial duration of contraction and relaxation for each repetition was based on the baseline assessment of PFM strength. Subjects were instructed to gradually increase the duration of PFM contraction and relaxation with a goal of 10 seconds each. Subjects with urge UI (UUI) were taught urge suppression strategies, i.e., 3-4 quick PFM contractions to suppress urgency and prevent involuntary urine loss. For stress UI (SUI), participants were instructed to contract their PFMs during the activities associated with involuntary urine loss.

The second study examined the efficacy of acupuncture for the treatment of UI in non-homebound women $\geq$ 25 years of age. The acupuncture study was a longitudinal, double-blinded, randomized controlled trial with repeated assessment of non-homebound women to examine the short-term and long-term efficacy of acupuncture for the treatment of UI. With equal allocation, women were randomized to either a true or sham acupuncture group. The sham acupuncture was performed using a non-penetrating needle (Park, White, Stevinson, Ernst, & Martin, 2002). Women randomized to the sham acupuncture group were eligible to crossover and receive the true acupuncture following the 4-week post-treatment assessment. Subjects initially randomized to the acupuncture group were blinded to their group assignment; crossover subjects were not. Eligible women, who were at least 50 years of age and received the true acupuncture, as either their initial treatment or after crossing over following sham acupuncture, were included in the current study. Acupuncture was performed by a single acupuncturist licensed by the Commonwealth of Pennsylvania. Subjects were in prone position on a treatment table or seated in a massage chair during the treatment sessions. The specific acupuncture protocol was a modification of the protocol used by Bergstrom et al. (2000). Subjects received 12 acupuncture treatments over 6 weeks; treatments occurred twice a week. Each treatment session lasted 45 to 60 minutes. The acupuncture needles (12 total) were inserted bilaterally at the following acupuncture points: two leg points (KI-3 and SP-6), and BL-23, 31, 32, and 33 (paraspinal points from L2 to mid-sacrum). These points were selected by Bergstrom et al. (2000) so that acupuncture points would correspond to segmental innervation of the bladder. For the extremity points a 30 mm 32 gauge needle was inserted to a depth of 20-30 mm. For the paraspinal points a 40 mm 32 gauge needle was inserted to a depth of 30-40 mm. Needles were manually inserted and manipulated until the subject experienced the de-qi sensation (i.e., the sensation of the tissue grabbing onto the needle, or a feeling of numbness, heaviness or slight pain that spreads around the needle). They remained in place for 25 minutes and stimulated by manual manipulation by the acupuncturist twice during each treatment to regain the de-qi feeling. Baseline data (pre-intervention) and 1 week post-intervention data on incontinence severity and HRQoL were used for this analysis.

3.1.2 Sample

For this secondary analysis, the sample included 148 non-homebound women who were $\geq$ 60 years of age from the PFMT study and 67 women, $\geq$ 50 years of age, who received the true acupuncture either initially or following crossover. This yielded a total sample size of 215. We chose a minimum age of 50 years from the acupuncture study in an attempt to make the two intervention groups more comparable relative to age. Since the focus of both studies was persistent urinary incontinence, to be eligible to participate in both studies, women had to have experienced UI for at least three months and reported experiencing at least two incontinent episodes per week both verbally and as documented in a bladder diary. All women received the intervention in their respective study. There were four women who participated in both studies. The PFMT data for these four women were used in this analysis but not their acupuncture data to keep the samples independent and to avoid the effects from the PFMT intervention confounding the effect of the acupuncture intervention. See Table 7 for more details related to the exclusion criteria for each study sample and the secondary analysis.

Table 7: Exclusion Criteria for the studies in this analysis

PFMT Study	Acupuncture Study	Secondary Analysis
Symptomatic urinary tract infection (UTI)	Symptomatic urinary tract infection (UTI)	Men
Fecal impaction	Fecal impaction	Homebound women
Probable Grade 3 stress urinary incontinence (SUI)	Probable Grade 2 stress urinary incontinence (SUI)	$\leq$ 50 years of age
Inability to hear telephone conversation	Inability to hear telephone conversation	
Post void residual (PVR) >100 ml	Post void residual (PVR) >200 ml	
Glycosuria	Glycosuria	
Hematuria	Hematuria	
Mini Mental Status Exam (MMSE) < 24	Mini Mental Status Exam (MMSE) < 24	
Unable or unwilling to complete bladder diaries after two attempts	Unable or unwilling to complete bladder diaries after two attempts	
Unable to toilet independently	Unable to toilet independently	
Indwelling or intermittent catheter	Indwelling or intermittent catheter	
Severe pelvic organ prolapsed (POP)	Severe pelvic organ prolapsed (POP)	
Terminal illness	Terminal illness	
Enlarged Prostate	Men	
	Being homebound	
	<25 years of age	
	History of sacral nerve modulation	
	History of pelvic cancer	
	History of augmentation cystoplasty	
	Current use of cholinesterase inhibitor	
	History of neurological illness (Parkinson's, MS, etc.)	
	Concurrent treatment with anti-muscarinic or anticholinergic medication—not willing to stop it for at least two weeks prior to baseline visit	
	Unable to contact after 3 attempts	
	Using oral corticosteroids	
	History of urethral diverticulum	
	Previous acupuncture for any reason	
	Inability to complete the 48 hour pad test after two attempts	
	Diuretic or hypertension (HTN) medication	
	Plan to move away from Allegheny County within the year	
	Plan to get pregnant within the year	

3.1.3 Sample size justification

Since the total and study (i.e., treatment group) sample sizes were fixed as existing data were used for this investigation, the sample size software PASS v11 (Hintz, 2011) was used to estimate the smallest detectable effect size given the analysis planned at a desired power of .80 for two-sided hypothesis testing at a significance level of .05.

Aim#1 and #2: For each of these study aims analysis of covariance (ANCOVA) will be applied, where the means for percentage reduction in the frequency of UI (Aim #1) and percentage change in the physical and mental component scores of the SF-36 as measures of HRQoL (Aim #2) from pre-invention to post-intervention for the two treatment groups (148 for the PFMT study and 67 for the acupuncture study) will be compared, controlling for two covariates (age and duration of UI). When conducting ANCOVA, an effect size index which may be used is f, which is calculated as the ratio of standard deviation of the group means (σ_m) to the standard deviation with a group (σ), which is assumed to be the same for all groups (i.e., the standard deviation of the subjects); this index is related to the noncentrality parameter. For a two-group ANCOVA, the smallest detectable effect size (f) was estimated to be 0.191, 0.183, and 0.166 (i.e., small to medium effect sizes from a behavioral science perspective [Cohen, 1988]) if small (R^2=0.01), medium (R^2=0.09) and large (R^2=0.25) proportions of variability were explained by the two covariates in the outcome variables of interest, respectively.

Aim #3: To address this aim sample sizes of 134 for the PFMT study and 67 for the acupuncture study were available for analysis. Differences in the treatment group proportions for satisfaction with progress (in terms of the reduction in frequency of UI post-intervention) of

0.2190 or greater may be detected with at least .80 power when using the Fisher's exact test with the two-tailed significance level set at .05.

Aim #4: As for Aim #3, group sample sizes of 134 for the PFMT study and 67 for the acupuncture study were available for analysis for this study aim. A standardized difference of group means (*d*) as small as 0.42 (i.e., near medium from a behavioral science perspective) may be detected with at least .80 power when comparing treatment group means of the burden of the intervention using independent samples *t*-test at a significance level of .05 for two-sided hypothesis testing.

Aim #5: To examine the association between the percentage change in the frequency of UI episodes from pre- to post-intervention and percentage change in HRQoL from pre- to post-intervention, multivariate linear regression analyses will be performed considering the mental and physical component summaries of the SF-36 simultaneously, followed by an examination of each component summaries individually using multiple linear regression. For these analyses, the effect size of interest is R^2(Tested|Controlled), the proportion of variance in the outcome variables explained by the predictor(s) of interest (i.e., to be tested) controlling a set of covariates. With a total sample size of 215, an R^2(Tested|Controlled) as small as 0.027 (i.e., small from a behavioral science perspective) attributed to one predictor variable to be tested (i.e., percentage change in the frequency of UI episodes from pre- to post-intervention) and a set of 5 covariates to be controlled (age, duration of UI, severe depressive symptomatology [based on self-report using screening instruments for depressive symptoms], intervention, level of education) explaining 25% of the variability in the outcome (i.e., R^2[Controlled]) with .80 power with a significance level of .05 for two-sided hypothesis testing using a partial F-test.

3.1.4 Measures

Table 8: Variables and Data Collection Instruments

Variable	CV/IV/DV	Level	Instrument
Sociodemographics			Sociodemographic questionnaire
Age (years)	CV	Ratio	
Level of education ($\leq$ HS or > HS)	CV	Nominal	
Marital status (Single/widowed/separated/divorced, or married/living with a significant other)	CV	Nominal	
Income meets basic needs (Yes/No)	CV	Nominal	
Duration of urinary incontinence (years)	CV	Ratio	
Severity of urinary incontinence (mean # of weekly accidents at baseline)	DV	Ratio	Pencil/paper diary * Electronic bladder diaries**
Treatment Burden	DV	Ordinal	Patient Satisfaction Instrument
Satisfaction	DV	Ordinal	Patient Satisfaction Instrument
Depression symptoms (severe depressive symptoms) (Yes/No)	CV	Nominal	Geriatric Depressive Scale (GDS)* Center for Epidemiologic Studies-Depressive Scale (CES-D)**
Change in Urinary Incontinence post-intervention	DV Aim 1 IV Aim 5	Ratio	Pencil/paper diary* Electronic diary (PDA)**
Health-related quality of life (HRQoL) (Physical and Mental Health Components and subscales)	DV Aim 2 DV Aim 5	Ratio	Medical Outcome Study-Short Form (SF-36v1)

*PFMT group ** Acupuncture group
CV = covariate; IV = independent variable; DV = dependent variable

3.1.5 Instruments

Bladder diaries have been shown to be a reliable and valid way to collect data related to the everyday occurrences of UI. They were used in the two primary studies (paper/pencil in the PFMT study and electronic PDA diaries in the acupuncture study) to collect data related to the number and frequency of UI episodes as well as severity of UI. In a study done by Locher, Goode, Roth, Warrell, and Burgio (2001), it was reported that for women with urge incontinence, a five-day bladder diary achieved internal consistency (α = .90) and for women with stress incontinence that same level was achieved after 7 days. The 7-day diary has been used in other studies and has been reported as being reliable for collecting this type of data (Locher et al., 2000; Wyman, Choi, Harkins, Wilson, & Fantl, 1988). Quinn, Goka and Richardson (2003) compared UI-related data collected using a paper and electronic bladder diary and the findings were similar. However, they did not do a statistical comparison. Data from the bladder diaries will be used to calculate the mean number of accidents per day pre- and 1 week post-intervention for each group as a measure of UI.

The Medical Outcome Study-Short Form (SF-36) is widely accepted as an inexpensive, brief assessment of general HRQoL. The SF-36 contains items (questions) about limitations in normal role activities due to physical or psychological distress. The items are answered on a Likert scale. Each item is scored and transformed to a scale from 0-100. The scores for the items to be included in each subscale are then averaged to obtain the 8 subscale scores. Scores for the 8 subscales are used to calculate the two summary component scores (Ware, Shah, Kosinski, & Gandek, 1993). All scales and the component scores are positively scored so that higher scores represent better HRQoL (Ware et al., 1993). It has been reported that this measure of HRQoL has a median relative precision of 0.93 for the component scores. (McHorney, 1994) and for the 8 dimensions, a median relative precision of .76 (Ware et al., 1993). The internal consistency (Cronbach’s alpha) for this instrument when used in both younger and older community-based samples has exceeded 0.8 except for the social functioning subscale which was .79 for both samples (Hayes & Morales., 2001; Walters, Munro, & Brazier, 2001). In this study, Cronbach’s alpha was .75 for the Physical Health Component score and .70 for the Mental Health Component score.

The Geriatric Depression Scale (GDS) is often used in older adults as a general measure of depressive symptoms. The internal reliability of this instrument was assessed in the parent

PFMT study and was reported to be 0.80. The GDS was administered at baseline to examine the affective status of the subjects prior to treatment. Using the cut-off value of $\geq$11 (Yesavage, 1983) to indicate significant depressive symptoms, recoding of data into two categories (1 = significant depressive symptomatology and 0 = little or no depressive symptomatology) was accomplished to allow comparison of depression status at baseline between the two study samples.

The Center for Epidemiologic Studies-Depression (CES-D) scale was used to measure depressive symptoms in the parent acupuncture study. This instrument is a commonly used measure of depressive symptoms. An internal reliability of Cronbach's alpha = 0.85 was reported in the general population obtained by probability sampling from households in Missouri and Maryland, which consisted of Caucasian men and women, >18 years of age living in the community (Radloff, 1977). For the present study of women 50 years of age and older who were in the acupuncture study, internal reliability was estimated to be Cronbach's alpha = .78. This tool administered at baseline for women in the acupuncture study. Scores were re-coded by using the established cut-off value of $\geq$ 16 (Radloff, 1977) to indicate significant depressive symptomatology. The data were recoded into 1= significant depressive symptomatology vs. 0 = little or no depressive symptomology for comparison of significant depressive symptoms measured by the GDS in the PFMT study.

The Patient Satisfaction Questionnaire was used to collect data related to satisfaction with the progress following each intervention and the perceived treatment burden the subject experienced while being in the intervention phase of each study. This instrument has been used by the PI in a previous PFMT study to collect data related to satisfaction with progress after treatment. The questionnaire was sensitive to change in continence status in that study. Subjects who indicated they were completely satisfied with their progress had a median 82.7% reduction in UI, while those who reported they were somewhat or not satisfied had a median 52.2% reduction ($p = .07$). The subjects indicated level of satisfaction with their progress following each intervention by choosing 1 (completely satisfied), 2 (somewhat satisfaction) or 3 (not at all satisfied). There was one item related to satisfaction on this instrument and therefore internal consistency could not be checked.

Burden scores expressed as a percentage of possible points were calculated for subjects in each study. Although the same instrument, the Patient Satisfaction Questionnaire, was used to collect data related to burden, there a different number of items with different response options in the two studies. There were 4 items measuring burden for the PFMT study. However, one item asked subjects how difficult it was for subjects to postpone voiding until the scheduled time and was only applicable for subjects with urinary frequency. Thus, the number of relevant items was either 3 or 4. The valid responses were 1 = yes, 2 = no. These responses were re-coded to 0 = no, 1 = yes and scores were totaled to yield a total possible score of 0 to 3 or 0 to 4. This score was then converted to a score ranging from 0-100 using the following equation:

$$(\text{total burden score}/\text{total possible score}) * 100$$

For the acupuncture group, there were four items with responses on a Likert scale ranging from 1 (not at all difficult) to 10 (extremely difficult). The scores were recoded to a scale of 0-9 with 0 indicating “not difficult” to 9 indicating “extremely difficult.” After transformation of the individual items, the scores of the four items were summated to obtain a total burden score ranging from 0-36, with 36 indicating “extremely difficult.” This score was then converted to a score ranging from 0-100 using the following equation:

$$(\text{total burden score}/\text{total possible score}) * 100$$

Adjustments in the scoring of the responses were made to allow for comparison of burden between the groups. Cronbach's alpha could not be determined for the PFMT study due to the low number of items after two items of the four items were removed from this analysis due to redundancy. For the acupuncture study, there was good internal consistency (reliability): Cronbach's alpha = .71.

3.2 DATA ANALYSIS PLAN

The statistical analysis was performed using the IBM SPSS Statistics 20.0.0, Release version 20.0.0 (IBM SPSS, Inc., 2011, Chicago, IL, www.spss.com). Preliminary information from the exploratory data analysis was used to describe the univariate and bivariate data distributions. Means, standard deviations, and minimum-maximum values were reported for continuous variables (age, years of incontinence, and incontinent episodes at baseline). Medians are reported for variable description when means were not appropriate (e.g., non-normal distributions of the variable(s), ordinally scaled variables) with interquartile ranges to describe variability. Frequencies (percentages) were reported for categorical variables (race, income able to meet basic needs, marital status, level of education, depressive symptomatology). Reporting of central tendency measures were as follows: for ordinal and/or skewed interval data, the medians were reported, and for normally distributed interval/ratio data, the means were reported.

Data were examined for missing values and/or aberrant (out of range) values. The pattern of missingness and extent of missing data were examined. There was <10% of data missing in the PFMT study. The missing data were identified as being missing completely at random (MCAR) based on looking at the descriptive stats and tabulated patterns and confirmed by Little's MCAR test: Chi square = 18.405, df= 50, sig. = 1.000. There was < 15% of data missing in the acupuncture study. The missing data were identified as being missing completely at random (MCAR) from examining the descriptive statistics and tabulated patterns and confirmed by Little's MCAR test: Chi square = 52.909, df = 92, sig.= 1.000. The last observation carried forward (LOCF) method is one method used to impute missing values. One limitation of this method is that it may not be an accurate presentation of the data being measured because it assumes the case remained stable from the last measurement point to the end of the study. This may actually give an over or under estimation of the true value (Tabachnick & Fidell, 2007, p. 67-68). The expectation-maximization (EM) algorithm is also utilized for the imputation of missing values to limit the possibility of under-estimating the treatment effects. This method computes the likelihood of the missing value based on the normal distribution by running iterations of filling in missing values until convergence identifies the expected value which creates an EM variance-covariance matrix. The EM method is more conservative and often the preferred method for imputation (Tabachnick & Fidell, 2007, p. 68-69). Both methods of imputation gave similar results. Therefore, missing values were estimated using the EM algorithm and these imputed data were used in the final analyses. Deletion of cases, other than those who did not meet inclusion criteria for this secondary analysis or those who had participated in both studies, was not considered to avoid concerns for selection bias. The χ^2 statistic for independence or Fisher's exact test was used for comparison of categorical variables with one or more variables having greater than 2 levels such as the satisfaction with treatment variable in Aim #3. Cronbach's alpha was used to report the internal consistency of the multi-item measures, i.e. GDS, CES-D, Patient Satisfaction Questionnaire, and SF-36.

Prior to addressing the specific aims, a detailed exploratory analysis was performed to summarize and describe the data. This analysis was accomplished through an examination of descriptive statistics and graphic representations of the variables. There were several extreme outliers in both studies identified when boxplots and standardized z-scores were examined. The data were also negatively skewed. The instruments were checked for valid responses and the data were found to be true values. The analyses were conducted with and without the outliers and similar findings were obtained.

There were several subjects within each study that showed a worsening of the urinary incontinence from pre- to post-intervention. Since the difference in the scores resulted in a negative number for these cases, additional alteration of the scores through the addition of a constant to all values in both studies was necessary so further remedial measures could be attempted. Both square root and log base 10 transformations of the data were examined to see if the distributions could be brought to more normal distributions. The transformations did not improve the distributions and therefore no transformed data were used in the analyses.

Paired t-tests, for within group analysis, were used as part of the analysis. The three assumptions for the t-tests were examined. The assumptions for the t-test are: 1) independence (each subject contributes one score to each time point), 2) the distribution of the dependent variable is normal, and 3) homogeneity of variance (the variance for each time point is similar to protect against Type II errors). When violations were identified for the paired t-test, the analogous non-parametric test, i.e., Wilcoxon Signed Rank Test, was performed for within group analyses with medians being reported.

The groups were unequal in relation to age and duration of UI at baseline and it was felt using the percent change in means for each group rather than the mean difference would be a better indicator of the effectiveness of the interventions for the outcome being examined. To address Aim #1, the percent change in mean number of UI episodes/day was used as the dependent variable. This value was also used as the independent variable to address Aim #5. Calculation of the mean number of UI episodes/day was accomplished by using the total number of accidents recorded divided by the valid days in that visit diary. These variables were calculated for both baseline and post-intervention. The numbers were then included in the equation below to calculate the percent change in mean number of UI episodes from pre- to post-intervention.

$$\left[\frac{\text{(\# of UI episodes at baseline/day - \# of UI episodes post-intervention/day)}}{\text{\# of UI episodes at baseline/day}} \right] * 100 = \text{\% change}$$

For Aim #2, calculation of the percent change (mean) scores for the Physical (PH) and Mental Health (MH) components was performed using the following equation.

$$\left[\frac{\text{(PH or MH component score post-intervention – PH or MH component score at baseline)}}{\text{PHC or MH component score at baseline}} \right] * 100 = \text{\% change}$$

Q-Q plots were examined to check for normality. The plots for each time point were examined to check the independence of variables. Boxplots and histograms of the variables were examined to examine at the distribution for normality of the variables as well as to look for outliers within each treatment group. The outliers were checked to see if they are valid responses and how much they contributed to the shape of the distribution. Remedial measures were used since the data were skewed in an attempt to achieve a closer to normal distribution. Valid responses of outliers were recoded (e.g., adding a constant to the next lower or highest values in the distribution) and those values were then used in the analysis. The distributions were re-examined. For variables with data that were not normally distributed after score alteration, square root (sqrt) and $\log_{10}$ transformations were applied and both were examined to see which brought the distributions to a more normal distribution in order to meet the assumption of normality and enable further testing. Neither transformation improved the distributions.

Two different studies with different inclusion criteria were used in this analysis; therefore, the two samples were compared to see if there were significant differences before deciding on the appropriate analyses to use in the final analysis. To control for the possibility of the women in the acupuncture group who were initially in the control group and then crossed experience some improvement via placebo effect, the analyses were repeated with only the women initially randomized to the treatment group. The results of both analyses were reported for each aim.

3.2.1 Specific Aim #1: Comparative effectiveness of both interventions on UI

Prior to comparing the intervention groups, we first looked at each intervention group individually to determine if there was a significant change in UI following the intervention. The distribution of the data for the mean reduction in UI episodes per day violated the assumption of normality for both groups. Therefore, Wilcoxon Signed Rank Test was performed to examine the effectiveness of the intervention within each group. The percent change in the (mean) number of urinary accidents was used to compare the effectiveness of the two interventions for the treatment of UI.

The difference in percent reduction in UI between the PFMT and acupuncture groups was examined with and without controlling for the covariates. Preliminary data analysis revealed that two groups were significantly different in relation to age and years lived with UI. Analysis of covariance (ANCOVA) was conducted to compare the mean percent change in incontinent episodes from pre- to post-intervention in the two groups (i.e., PFMT and acupuncture). The independent variable was the type of intervention (PFMT or acupuncture), and the dependent variable was the percent (mean) change in UI. The ANCOVA was used to control for the difference in the groups (age and duration of incontinence) which were treated as covariates to reduce the error variance (Tabachnick & Fidell, 2007, p. 211-218).

To ensure a valid interpretation of the ANCOVA, the assumptions underlying the test were checked. The assumptions include: 1) the groups should be mutually exclusive, 2) there is homogeneity of group variances, 3) the DV should be normally distributed, 4) the covariate should be a continuous variable, 5) the covariate and DV must have a linear relationship, and 6) the direction and magnitude of the relationship between the covariate and DV should be similar in each group, i.e. homogeneity of regression across both groups (Tabachnick & Fidell, 2007, p. 201). The distributions of residuals were examined to test the assumptions of normality, linearity, and homoscedasticity between the predicted DV scores and errors of prediction. The assumption of normality was found to be violated and several remedial measures were attempted to bring the data to a near normal distribution. When scores were identified as outliers, they were replaced by values computed by score alteration, i.e., by adding a constant value to the next highest score in the distribution or subtracting a constant value to the next lowest score. Score alteration was necessary for 5 extreme outliers in the PFMT group and 2 extreme outliers in the acupuncture group. The analyses were run with and without the extreme cases to see the effect of these outliers. The results remained unchanged and therefore these cases were not deleted.

3.2.2 Specific Aim #2: Comparative effectiveness of both interventions on HRQoL

HRQoL was defined as those aspects of QoL that relate specifically to a person's health as measured by the SF-36v1 component scores. The percent change in the (mean) score was used to compare the effectiveness of the two interventions in improving HRQoL. In both samples, the Physical and Mental Health Component scores were skewed. Consequently, the Wilcoxon Signed-Rank Test was performed for the within group analyses with medians being reported for each group pre- and post-intervention.

When examining the graphs, plots and z-scores to identify outliers in both studies, there were three extreme values/outliers for the percent change in the means for the Physical Component for the PFMT study and two for the acupuncture study. For the Mental Health Component scores there were five extreme outliers identified for the PFMT study and three for the acupuncture study. To bring these values closer to a normal distribution, score alteration was used. This was accomplished by adding or subtracting a constant to the next lowest or highest values in the distribution. These values were then used to replace the values for the extreme values in the analysis. The distributions and z-scores were re-examined after the scores were altered. The distributions of the mean percent change in Physical and Mental Health Component scores were near normal after the outlier scores were altered.

The groups differed at baseline both in age and duration of UI. These variables were controlled when examining the relationship between the type of intervention (acupuncture or

PFMT) and HRQoL. In this analysis, the Physical and Mental Health Component scores were the dependent variables of interest and were analyzed simultaneously using multivariate analysis of covariance (MANCOVA). The univariate assumptions of the ANCOVA, as noted for Aim #1, apply to MANCOVA with the addition of one other assumption, i.e., the dependent variables should have a multivariate normal distribution with the same variance-covariance matrix in each group (Tabachnick & Fidell, 2007, p. 250-253). This means that the homogeneity of variance assumption should be met for each DV and the correlation between the two dependent variables must be the same in both groups. This was checked using Box’s M (Tabachnick & Fidell, 2007, p. 252). Levene’s Test for equality of errors variance for each dependent variable was also examined. Preliminary assumption testing was conducted to check for normality, linearity, univariate and multivariate outliers, homogeneity of variance-covariance matrices, and multicollinerarity. Examination of the data was done using log10 and square root transformations because the data distributions were near normal and the homogeneity of variance-covariance matrices was very close to being met. The analysis was performed using only the score altered data and not the transformed data as all of the methods tried yielded the same outcome. When consideration was given to the differences in the two groups, it was elected to go forward using Pillai’s criteria to evaluate multivariate significance. Pillai’s criteria is more robust than Wilk’s lambda when conditions are less than ideal as it pools the statistics from each dimension to test the significance of the effect (Tabachnik & Fidell, 2007, p. 269). After excluding crossover subjects from the acupuncture study, the percent changes in Physical and Mental Health Component scores for the two groups were compared controlling for age and duration of UI.

3.2.3 Specific Aim #3: Perceived satisfaction with post-intervention progress

To address Aim #3, contingency table analyses with chi-square type test statistics were used to describe and compare the perceived satisfaction of the participants in each study. Prior to the final analysis, the women in both acupuncture groups (initial treatment and crossover) were compared to see if they were significantly different in responses to satisfaction with progress. There was one item related to satisfaction on the patient satisfaction questionnaire. The responses were 3 = "completely satisfied", 2 = "somewhat satisfied," and 1 = "not at all satisfied". Based on their satisfaction scores, subjects were divided into two groups: completely or somewhat satisfied and not satisfied. Frequency counts and percentages for each level of satisfaction were reported for each study group along with the Mann Whitney U for comparison between the groups. Mann Whitney U was utilized because it is not dependent on equal cell sizes and there was at least one cell in the table that did not have 5 cases. Cohen's *d* was reported as a measure of the effect size. To interpret Cohen's *d* the following values were used: 0.2 = weak, 0.5 = medium, and 0.8 = large (Cohen, 1988). Because of the unequal sample sizes and the distribution of responses showed cell sizes to be small in some categories, the variable was collapsed into two categories and the Mann Whitney U was used to examine the relationship between the intervention and the satisfaction reported following the intervention between the groups.

3.2.4 Specific Aim #4: Examination of the treatment burden of each intervention

Prior to examining the treatment burden between the intervention groups, a t-test was conducted to determine if there was a significant difference between the initial acupuncture treatment and crossover women in the acupuncture study. Since the crossover group received 24 treatment visits (12 sham + 12 true treatments) and not 12 treatments, consideration was given to controlling for the differences in the final analysis if differences between the acupuncture groups were identified. There were 67 women in the acupuncture study and all completed the Patient Satisfaction Questionnaire. Fourteen (9.5%) of the 148 women from the PFMT group did not complete the Patient Satisfaction Questionnaire. The distributions of scores from the two studies were skewed and therefore, the Mann-Whitney U test was used to compare the two groups with respect to treatment burden. Absolute r will be used to indicate the association between treatment burden and intervention with .10 = small, .30 = medium, and .50 = large effect. The effect size r was calculated using the following equation $|r| = z/\sqrt{N}$ where N is the number from the samples and z is the standardized value of the test and used because the nonparametric test uses a near normal distribution.

3.2.5 Specific Aim #5: Examination of the association between the change in UI and the change in HRQoL following the PFMT and acupuncture interventions

Data from both studies were combined and the percent change in the mean number of UI episodes pre- to post-intervention and the percent change in the component scores from the SF-36 pre- to post-intervention were examined. Multivariate linear regression using a hierarchical approach was used. The assumptions of this statistical model are: 1) the sample must be representative of the population to which the inference will be made, 2) the model errors should be normally distributed.), 3) homoscedasticity, i.e., constant error variance.), 4) linear relationship, and 5) no multicollinearity, i.e., small standard errors for regression coefficients. Mahalanobis and Cook's D were used to identify outliers. No multivariate outliers were identified. When examining the assumptions of normality, linearity and homoscedasticity, residual scatter plots were also examined. Multicollinearity and singularity were checked by examining the correlation matrix. Multicollinearity diagnostics (i.e., tolerance, variance inflation factors, condition indices, and variance decomposition proportions) were examined to assess the extent of multicollinearity.

There were two dependent variables, the SF-36 Physical and Mental Health Component scores. The covariates for this analysis were chosen if: 1) the variable was significantly related to either the, IV or predictor variable (percent change in UI) or the DV's (Physical or Mental Health Component scores at a $p \leq .20$ during bivariate analysis, or 2) they were significantly related to the IV (% reduction in UI) or related to one or both DVs (SF-component scores) in previous studies. In addition, because there were significant differences in the characteristics of the women in the two studies, intervention (PFMT and acupuncture) was included as a covariate coded as 0 = PFMT and 1 = acupuncture. The associations between the covariates (Age and Duration of UI) and reduction in UI and two SF-36 component scores were examined using Pearson's correlation coefficient. Mann-Whitney U (medians) was used to examine the associations between the independent variables (depressive symptomatology, the intervention and level of education) and the reduction in UI and the two SF-36 component scores. Several variables were dichotomized resulting in little to no variability in responses (race, income able to meet basic needs, and marital status). They were not included in the analysis.

Multivariate linear regression analysis using a hierarchical approach was performed to assess the ability of a reduction in urinary incontinence to predict an improvement in HRQoL. Based on the bivariate analysis, the initial model included age, duration of UI, level of education, the intervention group, and depressive symptoms allowing the examination of their contribution to the variability in the SF-36component scores. The main predictor of interest in this analysis was the percent reduction in UI and it was entered into the model in the final step. Multiple R and R-squared were used to examine the strength of the association between the set of covariate variables to the dependent variables. The partial F-test (t-test) was used to examine the association of each individual covariate variable and the dependent variable. The effect size (Cohen's f^2) for these analysis was calculated as R-squared/(1-R-squared) where a small effect = .02, medium effect= .15 and a large effect = .35 from a behavioral perspective. R^2 can also be used as an effect size and will be reported. It is an indicator of how well the model explains the variability in the outcome similar to Cohen's f^2 which is the proportion of variability accounted for by the statistical model or a measure indicating how well future outcomes are likely to be predicted by the model (Cohen, 1988). (R-squared, adjusted R-squared, unstandardized B, standard error of the means, beta (standardized) and standard error of variance were reported).

3.3 IRB

Approval for exempt status from the IRB at the University of Pittsburgh was obtained prior to conducting any research-related activities. See Appendix A. This was a secondary analysis of data previously de-identified. There were no risks identified in conducting this secondary analysis.

4.0 RESULTS

This study addressed the following questions:

1) Among non-homebound women age 50 years and older, what is the comparative effectiveness of biofeedback-taught pelvic floor muscle training (PFMT) and acupuncture in reducing UI?
2) Among non-homebound women age 50 years and older, what is the comparative effectiveness of PFMT and acupuncture in improving general HRQoL?
3) Among non-homebound women age 50 years and older, is there a significant difference in the satisfaction with progress reported by women in the PFMT group compared with women in the acupuncture group?
4) Among non-homebound women age 50 years and older, is there a significant difference in treatment burden experienced by women in the PFMT study compared with women in the acupuncture study?
5) Among non-homebound women age 50 years and older, what is the association between change in UI and change in HRQoL?

4.1 DEMOGRAPHICS

Two hundred and fifteen women were included in this secondary analysis. Of the 215 women, 148 (69%) women were in the PFMT study and 67 (31%) women were in the acupuncture study. The baseline characteristics of the two groups are summarized in Table 9. The majority of women from the studies, 97.3% from the PFMT study and 95.5% from the acupuncture study, were Caucasian. When comparing the two intervention groups at baseline, the groups were significantly different in age and duration of UI. The women in the acupuncture group were significantly younger (Mean$\pm$SD=62.75$\pm$8.9 years) than the women in the PFMT group (74.42$\pm$7.9 years) ($p < .001$). Women in the acupuncture group reported a significantly longer duration of UI (10.18$\pm$9.5 years) than those in the PFMT group (8.20$\pm$9.7 years) ($p = .03$).

Table 9: Characteristics of sample

Characteristic		Pelvic floor muscle training (PFMT) study n = 148	Acupuncture study n = 67	Test statistic, p-value
Age (years)				
	Mean (SD*)	74.42 (7.9)	62.75 (8.9)	$t_{(213)}$ = 9.62, p < .001
	Median (IQR**)	74.5 (13)	62 (14)	U = 1680.00, p < .001
	Minimum-Maximum	60-91	50-86	
Race				
White	n(%)	144 (97.3)	64 (95.5)	p = .680***
Non-White	n(%)	4 (2.7)	3 (4.5)	
Level of education				
≤ High School	n(%)	74 (50)	24 (35.8)	$\chi 2$ = 3.738, p = .056
>High School	n(%)	74 (50)	43 (64.2)	
Marital status				
Currently married/living with significant other	n(%)	88 (59.5)	41 (61.2)	χ^2 = 0.96, p = .328
Single, widow, divorced, or separated	n(%)	60 (40.5)	26 (38.8)	
Household income meets basic needs				
Yes	n(%)	141 (95.2)	61 (91.0)	p = .234***
No	n(%)	7 (4.8)	6 (9.0)	
Depressive symptoms				
Yes	n(%)	19 (12.8)	5(9.1)	χ^2 = 0.86, p = .355
No	n(%)	129 (87.2)	62 (90.9)	
Duration of urinary incontinence (years)				
	Mean (SD)	8.20 (9.7)	10.18 (9.5)	$t_{(213)}$ = -1.40, p =.165
	Median (IQR)	5 (7.8)	8 (12)	U = 4054.50, p =. 032
	Minimum-Maximum	≤1-63	1-47	
Number of urinary accidents/day at baseline				
	Mean (SD)	2.16 (1.96)	2.22 (1.56)	$t_{(213)}$ = -0.21, p = .834
	Median (IQR)	1.71 (1.96)	1.86 (1.58)	U = 4609.00, p = .409
	Minimum-Maximum	0.29-10.00	0.20-7.14	

* Standard deviation
** Interquartile Range
***Fischer's exact test (two-sided)

4.2 AIM #1: COMPARING THE EFFECTIVENESS PFMT AND ACUPUNCTURE IN REDUCING UI EPISODES

For the PFMT group, following the PFMT intervention, the percent mean reduction for the PFMT group was 54.1% $\pm$ 48.45, a median of 66.7%, with the minimum percent change of -75% (worsening of UI) to a maximum improvement of 100%. The PFMT group showed a statistically significant reduction in the daily median number of UI episodes from pre-intervention (Mdn = 1.71) to post-interventions (Mdn = 0.57), $z = -8.311$, $p < .001$. Using the pre-intervention and post-intervention daily number of accidents (means with standard deviations) the effect size was calculated by subtracting the means (2.17 minus 1.04) and dividing by the standard deviation of the data (1.54) to yield Cohen's $d = .73$ (large effect).

Following the acupuncture intervention, the group including the crossover women had a mean percent reduction of 31.50 $\pm$ 44.82%, a median of 33.7%, and a minimum per change of -72.73% (worsening of UI) to a maximum improvement of 100%. The acupuncture group showed a statistically significant reduction in daily incontinent episodes following the acupuncture intervention (from a median of 1.86 accidents per day at baseline to 1.00 following acupuncture), $z = -4.497$, $p < .001$. Using the pre-intervention and post-intervention number of daily accidents (means with standard deviations) the effect size was calculated by subtracting the means (2.22 minus 1.46) and dividing by the standard deviation of the data (1.43) to yield Cohen's $d = .53$ (medium effect).

Prior to controlling for the covariates (age and duration of UI), there was a significant difference between the groups, F (1, 213) = 0.874, p = .001. When the covariates were controlled, the difference between the two intervention groups remained statistically significant F(1, 211) = 13.630, p < .001, partial eta-squared = .061. See Table 10

Table 10: Between group mean difference (% change) in urinary incontinence (UI) before and after adjusting for covariates

Unadjusted means of PFMT[a] and acupuncture groups (n = 215)		
Intervention group	Unadjusted % change in UI Mean (SE[b]) 95% CI[c]	p-value
PFMT[a] (n = 148)	54.01 (3.98) [50.03, 58.00]	.001
Acupuncture (n = 67)	31.50 (5.47) [24.33, 38.67]	
Adjusted means of PFMT[a] and acupuncture groups (n = 215)		
Intervention group	Adjusted % change in UI Mean (SE[b]) 95% CI[c]	p-value
PFMT[a] (n = 148)	56.59 (4.13) [48.45, 64.77]	< .001
Acupuncture (n = 67)	25.80 (6.58) [12.86, 39.10]	

[a] pelvic floor muscle training
[b] standard error
[c]confidence interval
Covariates appearing in the model are: age = 70.78 years and duration of UI = 8.545 years for the total sample (n = 215).

In the parent acupuncture study, there was a reduction in UI for the women 50 years of age and older, during the control phase. Consequently, we also examined the change in incontinence among only the women who were initially randomized to the acupuncture intervention (n = 39). There was a statistically significant reduction in incontinent episodes for the women initially randomized to the intervention group (without the crossover women) from pre-intervention (Mdn = 2.29) to post-intervention (Mdn = 1.00), z = -4.738, $p < .001$, *d* = 0.68 (large effect).

We also compared the percent reduction in mean daily UI episodes for women in the PFMT group to that of women in the acupuncture study who were randomly assigned to receive acupuncture as their initial treatment (excluding crossover women from the analysis). After adjusting for age and duration of UI, there was a significant difference in the mean percent reduction in UI in the two intervention groups, [F (1,183) = 4.320, p = .039, partial eta-squared = .023]. See Table 11 for unadjusted and adjusted percent change (means) in UI episodes following treatment.

Table 11: Between group mean difference (% change) in urinary incontinence (UI) before and after adjusting for covariates without the acupuncture crossover women

Unadjusted means of PFMT[a] and acupuncture groups (n = 187)		
Intervention group	Unadjusted % change in UI Mean (SE[b]) 95% CI[c]	p-value
PFMT[a] (n = 148)	54.01 (4.44) [50.03, 58.00]	.148
Acupuncture (n = 39)	41.90 (5.93) [36.03, 47.83]	
Adjusted means of PFMT[a] and acupuncture groups (n = 187)		
Intervention group	Adjusted % change in UI Mean (SE[b]) 95% CI[c]	p-value
PFMT[a] (n = 148)	55.68 (3.92) [47.95, 63.41]	.039
Acupuncture (n = 39)	35.56 (8.37) [19.06, 52.07]	

[a] Pelvic Floor Muscle Training
[b] Standard Error
[c] Confidence Interval
Covariates appearing in the model are: Age = 71.95 years and Duration of UI = 8.487 years for the total sample (n = 187).

4.3 AIM #2: COMPARING THE EFFECTIVENESS OF PFMT AND ACUPUNCTURE FOR IMPROVING HRQOL

In the PFMT intervention group, there was significant decrease in the Mental Health Component score from pre-intervention (Median (Mdn) =58.11) to post-intervention (Mdn = 56.32; z = -3.086, p = .002). The median percent change in Mental Health Component score was -3.08%. The effect size was, however, small (Cohen's d = .18). The Physical Health Component score for the PFMT group did not change significantly (p=.827) from pre-intervention (Mdn = 39.56) to post-intervention (Mdn = 39.74, median percent change -.046%). In the acupuncture group there was no significant change (p=.431) in the Physical Health Component scores (pre-intervention Mdn = 53.29 and post-intervention Mdn = 53.78, median percent change -0.92%) or Mental Health Component scores (p=.321) (pre-intervention Mdn = 56.35 and post-intervention (Mdn= 54.77, median percent change = 2.80%). See Table 12.

Table 12: Within group changes in health-related quality of life (HRQoL) from pre- to post-intervention

	SF-36 Component	Median component scores (pre-intervention)	Median component scores (post-intervention)	p-value[a]
PFMT[b] (n = 148)	Physical	39.56	39.73	.827
Acupuncture (n = 67)	Physical	53.29	53.48	.431
PFMT[b] (n = 148)	Mental Health	58.11	56.32	.002
Acupuncture (n = 67)	Mental Health	56.35	54.77	.321

[a] Wilcoxon Signed-Rank Test (within group)
[b] Pelvic Floor Muscle Training

The multivariate test for the effectiveness of the interventions for improving HRQoL was statistically significant $F(2, 212) = 3.319$, Pillai's trace = 0.030, $p = .038$, partial eta-squared = .030.

When comparing the Physical and Mental Health Component scores between the groups there was no significant difference between the Physical Health Component scores, $F(1, 213) = 0.843$, $p = .507$). However, there was a significant difference in the Mental Health Component Scores between the groups, $F(1,213) = 6.605$, $p = .011$. After controlling for age and duration of UI, there were no significant group differences in the mean percent change in either the SF-36 Physical Component scores, $F(1, 210) = 1.991$, $p = .160$, partial eta-square = .009, or the Mental Component scores, $F(1, 210) = 2.475$, $p = .117$, partial eta-squared = .012. The summary statistics for unadjusted mean and adjusted percent change in mean scores for the Physical Health and Mental Health Components are presented in Tables 13 and 14.

Table 13: Unadjusted group % change (means) for both the Physical and Mental Health Component scores from pre- to post-intervention (n = 215)

Intervention	SF-36 Component	Unadjusted % mean change in component scores Mean (SE[b]) [95% CI[c]]	p-value
PFMT[a] (n = 148)	Physical Health	2.09 (1.87) [-1.00, 3.174]	p = .507
Acupuncture (n = 67)	Physical Health	0.035 (1.97) [-3.905, 3.975]	
PFMT[a] (n = 148)	Mental Health	-2.40 (1.29) [-3.551, -1.113]	p = .011
Acupuncture (n = 67)	Mental Health	3.43 (1.81) [-2.007, 4.849]	

[a] Pelvic Floor Muscle Training
[b] Standard Error of the Means
[c] Confidence Interval
Covariates appearing in the model are: Age = 70.8 years (mean), Duration of UI = 8.5 years (mean) for the total sample (n = 215).

Table 14: Adjusted group % change (means) for both the Physical and Mental Health Component scores (n = 215)

Intervention	SF-36 Component	Adjusted % change in component scores Mean (SE[b]) 95%CI[c]	p-value
PFMT[a] (n = 148)	Physical Health	3.08 (1.83) [-0.537, 6.690]	p = .160
Acupuncture (n = 67)	Physical Health	-2.15 (2.92) [-7.908, 3.607]	
PFMT[a] (n = 148)	Mental Health	-1.93 (1.36) [-4.599, 0.743]	p = .117
Acupuncture (n = 67)	Mental Health	2.38 (2.16) [-1.876, 6.634]	

[a] Pelvic Floor Muscle Training
[b] Standard Error of the Means
[c] Confidence Interval
Covariates appearing in the model are: Age = 70.8 years (mean) and Duration of UI = 8.5 years (mean) for the total sample (n = 215).

The analysis was repeated on the subset of women from the acupuncture study who received acupuncture initially (n=39; crossover women were excluded from the analysis). Within treatment group changes in the Physical and Mental Health Component scores were examined. After omitting the crossover subjects in the acupuncture group, there was still no significant change in the Physical Health Component scores from pre-intervention (Mdn = 53.03) to post-intervention (Mdn = 53.28, z = -0.419, p=.675; median percent improvement = 0.47%) or Mental Health Component scores from pre-intervention (Mdn = 56.35) to post-intervention (Mdn= 54.77, z = -0.335, p =.738; median percent improvement = 2.80%).

The multivariate test showed there to be a significant change in the overall HRQoL score F (2, 212) = 3.319, Pillai's trace = 0.030, p = .038, partial eta-squared = .03 (small to medium effect (Cohen, 1988). There was no significant group difference in Physical Health Component scores, F (1, 183) = 3.124, p = .079, partial eta-squared = .017 (small effect), or Mental Health Component scores, F (1, 183) = .960, p = .329, partial eta-squared = .005 (small effect). The summary and test statistics for unadjusted and adjusted changes in Physical Health and Mental Health Components scores after excluding crossover women from the acupuncture study are presented in Table 15 and 16.

Table 15: Unadjusted % change (means) for the Physical and Mental Health Component scores after removing crossover acupuncture women (n = 187)

Intervention	SF-36 Component	Unadjusted % mean change in component scores Mean (SE[b]) 95% CI[c]	p-value
PFMT[a] (n = 148)	Physical Health	2.09 (1.87) [-1.000, 3.174]	p = .465
Acupuncture (n = 39)	Physical Health	-0.81 (1.35) [-2.156. 0.543]	
PFMT[a] (n = 148)	Mental Health	2.403 (1.29) [-3.516, -1.113]	p = .186
Acupuncture (n = 39)	Mental Health	1.299 (1.81) [-4.951, 3.651]	

[a] Pelvic Floor Muscle Training
[b] Standard Error
[c] Confidence Interval

Table 16: Adjusted group % change (means) for both the Physical and Mental Health component scores after removing crossover acupuncture women (n = 187)

Intervention	SF-36 Component	Adjusted % change in means Mean (SE[b]) 95% CI[c]	p-value
PFMT[a] (n = 148)	Physical Health	3.172 (1.86) [-.0.489, 6.833]	p = .079
Acupuncture (n = 39)	Physical Health	-4.92 (3.60) [-12.735, 2.887]	
PFMT[a] (n = 148)	Mental Health	-2.30 (1.33) [-4.916, 0.317]	p = .329
Acupuncture (n = 39)	Mental Health	.907 (2.82) [-4.675, 6.490]	

[a] Pelvic Floor Muscle Training
[b] Standard Error
[c] Confidence Interval
Covariates appearing in the model are: Age = 71.95 years (mean) and Duration of UI = 8.487 years (mean) for the total model (n = 187).

4.4 AIM #3: COMPARING SATISFACTION WITH PROGRESS BETWEEN INTERVENTION GROUPS

Of the total 215 women studied (148 and 67 from the PFMT and acupuncture studies, respectively), 14 (6.51%) from the PFMT study did not complete the Patient Satisfaction Questionnaire. There were no significant differences identified between the women who did and did not complete the questionnaire. All of the women in the acupuncture study completed the questionnaire. There was no statistically significant difference in satisfaction reported between the initial treatment and the crossover women in the acupuncture study, Fisher's Exact Test p =

.364. Therefore, it was not necessary to repeat the analysis without subjects who crossed over to active treatment.

When comparing the intervention groups, there was a statistically significant difference between the PFMT and acupuncture groups, Mann Whitney U = 3835.50, z = - 3.193, p = .001. See Table 17. There is a 2-3 times increased likelihood of being dissatisfied with treatment for women in the acupuncture intervention group vs. the PFMT intervention group [OR 2.89, 95% CI (2.084, 3.903)].

Table 17: Comparison of satisfaction with progress (reduction in urinary incontinence) between groups

	PFMT[a] (n = 134)	Acupuncture (n = 67)
Completely satisfied	57 (42.5%)	19 (28.4 %)
Somewhat satisfied	74 (55.2%)	34 (50.7%)
Not satisfied	3 (2.2%)	14 (20.9%)

[a] Pelvic Floor Muscle Training

Data were combined from the two groups to examine the relationship between satisfaction with progress and percent reduction in UI post-intervention overall and between intervention groups. For this analysis, the satisfaction categories were collapsed into completely/somewhat satisfied and not at all satisfied. This was also examined separately within the two intervention groups. Overall, there was a statistically significant difference in percent reduction in UI in women who reported being completely or somewhat satisfied with their progress (Mdn 63.3%) compared to women who were not satisfied with their progress (Mdn 12.5%, p < .001). Cohen's d = .48 (medium effect) (Cohen, 1988). Within the PFMT group the difference between those who were completely/somewhat satisfied with their progress vs. those who not satisfied was statistically significant ($p = .011$). The difference within the acupuncture group was not statistically significant ($p = .104$). See Table 18.

Table 18: Comparison of satisfaction with progress with median % reduction overall and within intervention groups

	Median % reduction in UI					
	Overall (n = 201)		PFMT[a] (n = 134)		Acupuncture (n = 67)	
	Median (IQR[b])	test statistic, p-value	Median (IQR[b])	test-statistic, p-value	Median (IQR[b])	test statistic, p-value
Completely satisfied/somewhat satisfied	63.30 (62.48)	U = 727, p < .001	74.87 (54.62)	U = 39.00, p = .011	35.76 (57.20)	U = 265.50, p = .104
Not satisfied	12.54 (89.31)		-47.69 (*)		15.95 (66.69)	

[a] pelvic Floor Muscle Training
[b] Interquartile Range
*There was not sufficient data to calculate the necessary 75th percentile for this particular subgroup.

4.5 AIM #4: COMPARING THE TREATMENT BURDEN REPORTED BY THE WOMEN POST-INTERVENTION

Two hundred and one women (134 from the PFMT study and 67 from the acupuncture study) had data on their perceptions of treatment burden. The independent t-test performed prior to the final analysis revealed no significant difference between the perceived treatment burden reported by women in the crossover acupuncture group [n=28 (41.7%); Mean = 18.55)] and the initial acupuncture treatment group [n = 39 (58.2%); Mean = 17.24, $t(65) = 0.214$, $p = .831$]. Therefore, it was not necessary to repeat the analyses without the subjects who crossed over to active treatment. Based on the Mann Whitney U test, no significant differences were found for treatment burden reported by women in the PFMT group (Median = 20, IQR = 25, n = 134) and the acupuncture group (Median = 13.89, IQR = 19.44, n = 67), $U = 4480.500$, $z = -0.023$, $p = .982$, $|r| = .002$ (small effect).

4.6 AIM #5: EXAMINING THE ASSOCIATION BETWEEN THE CHANGE IN UI AND THE CHANGE IN HRQOL FOLLOWING THE PFMT AND ACUPUNCTURE INTERVENTIONS

The two groups were combined for this analysis. After examining the bivariate relationships between potential covariates and the independent variable (percent reduction in UI) and the dependent variables (percent change in Physical Health and Mental Health Component scores), age, duration of UI, level of education, depressive symptomatology, and intervention were added as covariates. See Table 21 for the bivariate associations between the covariates and the predictor variable of interest, change in mean daily frequency of UI and change in HRQoL as measured by the SF-36 Physical and Mental Health component summaries from pre-to post-intervention.

Table 19: Bivariate relationships between potential covariates and the percent change in UI and Physical and Mental Health Component Scores

Variables	Percent change in mean daily urinary incontinence (UI) episodes Test statistic, p-value	Percent change in Physical Health Component scores Test statistic, p-value	Percent change in Mental Health Component scores Test statistic, p-value
Age	r = 0.007, p = .916	r = -0.050, p = .468	r = -0.144, p = .035
Duration of UI	r = -0.093, p = .174	r = 0.079, p = .252	r = 0.072, p = .297
Depressive symptomatology	U = 2063.50, p = .425	U = 2232.00, p =.835	U = 1747.00, p = .058
Intervention	U = 3301.00, p < .001	U = 4792.00, p = .694	U = 3862.50, p = .010
Level of Education	U = 5478.00, p = .574	U = 5360.00, p = .412	U = 4897.50, p = .066

There was a significant change in the overall HRQoL score when examining the multivariate test F(102, 316) = 1.537, Pillai's trace = 1.653, p = .006, partial eta-squared = 0.826.

When examining the individual components of HRQOL based on the SF-36 Physical and Mental Health Component Summaries, the covariates, i.e., age, duration of UI, depressive symptomatology, intervention, level of education, accounted for only 2.0% of the variance in the percent change in the Physical Health scores, $F(5, 209) = 0.860$, $p = 0.509$. After entry of the main predictor variable (change in UI) into the final model, the total variance explained by the overall model was 2.3%, $F(6, 208) = 0.833$, $p = .546$, Cohen's $f^2 = .024$ (small effect). The percent reduction in UI explained an additional 0.3% of the variance in Physical Health, R squared change = .003, F change (1, 208) = 0.702, $p = .404$. For the Mental Health component, the covariates accounted for 7.1% of the variance in the Mental Health scores [$F(6, 208) = 2.638$, $p = .017$]. With the addition of percent change in UI into the final model there was no additional variance explained (0.0%) in Mental Health scores, R-squared change = .000, F change (1, 209) = 0.024, $p = .876$, Cohen's $d = .076$ (small effect). Depressive symptoms was the only statistically significant covariate in the model for Mental Health, $t(215) = -2.205$, $p = 0.044$, $B = -6.789$, $SE = 3.353$, beta = -.137. See Tables 20 and 21 for the multivariate summary statistics.

Table 20: Summary of multivariate analysis examining the association between percent reduction in UI and the SF-36 component scores (n = 215)

Physical Health Component Score

	Model 1 CVs[a] only			Model 2 CVs[a] + % reduction in UI		
	B (SE[b])	beta (standardized)	p-value	B (SE[b])	beta (standardized)	p-value
Age	-0.229 (0.174)	-0.108	.191	-0.209 (0.176)	-0.098	.237
Duration of UI	0.214 (0.168)	0.088	.203	0.224 (0.168)	0.092	.185
Level of Education	2.025 (2.905)	0.048	.487	2.044 (2.907)	0.049	.483
Depressive Symptoms	0.862 (4.603)	0.013	.852	0.828 (4.607)	0.012	.857
Intervention	-0.105 (0.071)	-0.123	.141	-0.090 (0.073)	-0.105	.221
% reduction in UI				0.026 (0.031)	0.059	.403
R^2		0.020			0.023	
R^2 Adjusted		-0.003			-0.005	
S[c]		20.952			20.967	

[a] Covariates
[b] Standard Error of the Means
[c] Standard Error of the Estimate

Table 21: Summary of multivariate analysis examining the association between percent reduction in UI and the SF-36 component scores (n = 215)

Mental Health Component Score

	Model 1 CVs[a] only			Model 2 CVs[a] + UI		
	B (SE[b])	beta (standardized)	p-value	B (SE[b])	beta (standardized)	p-value
Age	-0.128 (0.127)	-0.081	.313	-0.131 (0.128)	-0.083	.309
Duration of UI	0.104 (0.122)	0.057	.394	0.103 (0.123)	0.057	.403
Level of Education	-3.683 (2.111)	-0.118	.083	-3.686 (2.116)	-0.118	.083
Depressive Symptoms	-6.794 (3.345)	-0.137	.044	-6.789 (3.353)	-0.137	.044
Intervention	0.100 (0.051)	0.158	.053	0.098 (0.053)	0.155	.066
% reduction in UI				-0.003 (0.022)	-0.011	.876
R^2		0.071			0.071	
R^2 Adjusted		0.048			0.044	
S[c]		15.227			15.263	

[a] Covariates
[b] Standard Error of the Means
[c] Standard Error of the Estimate

The same regression analysis was performed without the crossover women from the acupuncture study. Again, there was a statistically significant change in overall HRQoL scores when examining the multivariate test, F (94, 268) = 1.492, Pillai's trace = 1.619, p = .012, partial eta-squared = .810 but there was no significant change in the individual component scores. When the relationship was examined for the Physical and Mental Health Component scores, the covariates (age, duration of UI, depressive symptomatology, intervention, and level of education) accounted for 4.9% of the variance in the Physical Health Component score and 3.1% of the variance in the Mental Health Component score. After entry of the main predictor variable, change in UI, into the final model for the Physical Health Component, the total variance explained by this model was 5.1%, F(6, 180) = 1.617, p = .145, Cohen's *d* = .054 (small effect). For the Mental Health component, after entry of the main predictor variable, change in UI, into the final model, the total variance explained by this model was 3.4%, F(6, 180) = .1.048, p =.396, Cohen's *d* = .035 (small effect). The percent change in UI explained an additional 0.2% of the variance in Physical Health [R squared change = .002, F change (1, 180) = 0.461, p = .498] and an additional 0.3% of the variance in Mental Health [R squared change = .003, F change (1, 180) = 0.513, p = .475]. In the final model for both Physical Health and Mental Health Component scores, there were no statistically significant predictors identified among the variables examined. See Table 22 and Table 23 for a summary of the multivariate summary statistics.

Table 22: Summary of subgroup multivariate analysis examining the relationship between percent reduction in UI and in the SF-36 after excluding crossover subjects in the acupuncture study (n = 187)

Physical Health Component Score

	Model 1 CVs[a] only			Model 2 CVs[a] + % reduction in UI		
	B (SE[b])	beta (standardized)	p-value	B (SE[b])	beta (standardized)	p-value
Age	-0.332 (0.195)	-0.145	.090	-0.316 (0.197)	-0.138	.104
Duration of UI	0.277 (0.185)	0.111	.135	0.284 (0.185)	0.114	.126
Level of Education	9.235 (5.165)	0.133	.135	8.590 (5.260)	0.124	.104
Depressive Symptoms	-1.544 (4.955)	-0.038	.756	-1.725 (4.970)	-0.042	.729
Intervention	-10.254 (6.781)	-0.191	.132	-9.911 (6.810)	-0.184	.147
% reduction in UI				0.024 (0.036)	0.051	.498
R^2		0.049			0.051	
R^2 Adjusted		0.022			0.020	
S[c]		21.673			21.705	

[a] Covariates
[b] Standard Error of the Means
[c] Standard Error of the Estimate

Table 23: Summary of subgroup multivariate analysis examining the relationship between percent reduction in UI and the SF-36 after excluding crossover subjects in the acupuncture study (n = 187)

Mental Health Component Score

	Model 1CVs[a] only			Model 2 CVs[a] + UI		
	B (SE[b])	beta (standardized)	p-value	B (SE[b])	beta (standardized)	p-value
Age	-0.052 (.139)	-0.032	.710	-0.40 (0.141)	-0.024	.778
Duration of UI	0.086 (.132)	0.049	.514	0.092 (0.132)	0.052	.489
Level of Education	-3.973 (3.692)	-0.081	.283	-4.459 (3.759)	-0.091	.237
Depressive Symptoms	5.039 (3.542)	0.174	.157	4.902 (3.552)	0.169	.169
Intervention	8.573 (4.847)	0.225	.079	8.831 (4.867)	0.232	.071
% reduction in UI				0.018 (0.025)	0.054	.475
R-sq		0.031			0.034	
R-sq Adjusted		0.004			0.002	
S[c]		15.490			15.511	

[a] Covariates
[b] Standard Error of the Means
[c] Standard Error of the Estimate

5.0 DISCUSSION

5.1 SUMMARY

Urinary incontinence remains a costly, chronic health condition for at least 20 million people living in the U.S. (Landsford et al., 2008) and for many more people world-wide (Minassian et al., 2003). Pharmacotherapy and surgical interventions, depending on the type of UI experienced, have been widely used (Kincade et al., 2005). Both types of interventions come with undesirable side effects (Burgio et al., 2008; Herbison et al., 2003) or potential complications (American Urological Associations (AUA), 2009). PFMT has been recommended as a first-line intervention for treating UI but adherence to the exercise regimen long-term has remained problematic (Dougherty et al., 1993; Kafri et al., 2008; McDowell et al., 1999). Providing alternative treatment interventions is of utmost importance as there is no one treatment that works for everyone. Acupuncture has recently been considered by Western researchers as a possible treatment option for UI (Bergstrom et al., 2000; Emmons & Otto, 2005; Engberg et al., 2009). There have been limited studies examining the effectiveness of acupuncture for the treatment of UI. There have been no studies comparing the effectiveness of PFMT and acupuncture for the treatment of UI or the effect of these interventions on improving QoL.

In the present study, other than age and duration of UI, the groups were relatively homogeneous. Interestingly, however, the duration of urinary incontinence was reportedly longer in the acupuncture study, which included women 50-86 years of age with a mean age of 62.75 ($\pm$8.9) years as compared with the PFMT study, which included women 60-91 years of age with a mean age of 74.42 ($\pm$7.9) years. The reason for this is unclear.

For the women in the PFMT group in the present study, there was a 54% reduction (mean) in UI following the intervention. This is similar to what has been found in the other studies examining the mean reduction in UI following PFMT. Burgio et al. (2008) reported a 60% reduction in the mean number of UI episodes, while Burgio and colleagues (2000) reported a 63% reduction in the mean number of UI episodes, and Burns et al. (1993) reported a reduction of 61% in the mean number of UI episodes. Our results were somewhat lower than what has been reported in a study done by Castro (2008) showing a 75% mean reduction in UI and Sari and Khorshid (2009) who reported an 82% mean reduction in UI. Most subjects in the parent study had mixed stress and urge UI while those in the Castro study all had urodynamically confirmed detrusor over activity. Differences in the severity at baseline and the prescribed intervention may have contributed to the difference in results from the present study and the Sari and Khorshid (2009) study. The baseline severity of UI (mean accidents/day (standard deviation) in the Sari and Khorshid (2009) study was 1.55 (1.70) vs. 2.167 (1.77) in the parent PFMT study. Also, the prescribed intervention was not the same as that used in the parent PFMT study. The intervention in the Sari and Khorshid study consisted of three sets of 30 contractions/day compared with three sets of 10 to 15 exercises/day in the parent PFMT study. The percent (mean) reduction in UI in the PFMT group in the present study was higher than in the Perrin et al. (2005) study where the mean reduction was 39.16%. The women in the Perrin study (2005) study (n=5) were on a wait list for surgery for their UI. The baseline UI severity (mean accidents/day (standard deviation)) for these women was 3.37 (3.63) accidents/day vs. 2.167 (1.77) for the women in the parent PFMT study.

In the acupuncture study, the mean percent reduction in UI was 31.50% when all the women from the acupuncture study (initial treatment and crossover) were included and mean reduction was 41.50% when the sample included only the women randomized initially to the acupuncture intervention. While the percent reduction in UI episodes for the acupuncture women when the crossover women were included was lower (31.5%) than what was reported in the Bergstrom et al. (2000) study (43%), the 41.5% reduction for the women initially randomized to the intervention group was similar. One must be somewhat cautious about comparing the findings in the two studies, however, since the method of measuring incontinence was not the same. In the parent acupuncture study, subjects recorded incontinence episodes in an electronic bladder diary while Bergstrom et al. used a 48-hour pad test. The 31.5% and 41.5% reduction in UI for the acupuncture groups, with and without the crossover women, respectively, was lower than what had been reported in two previous acupuncture studies. The Emmons and Otto (2005) acupuncture study reported a 59% reduction in UI episodes and the Engberg et al. (2009) study reported a 63% reduction in UI episodes. The difference between the current study and the two prior studies might be related to size and characteristics of the samples, type of UI, or the treatment protocol. For example, the Emmons and Otto study focused on women who were experiencing urge urinary incontinence with overactive bladder while most women in the current study had mixed stress and urge UI. Emmons and Otto also used different acupuncture points than were used in the parent acupuncture study. The Engberg study was a pilot study with a very small sample size, n = 9 with only 4 women receiving the acupuncture intervention. The mean age (54.8 years) was younger than that of women in the current study (62.8 years). Future studies should examine characteristics associated with responsiveness to acupuncture.

When comparing the two intervention groups relative to their effectiveness for treating UI, PFMT was more effective in reducing UI. When adjusting for the difference in characteristics between the groups (age and duration of UI), there was a significant difference in response to PFMT (56.6% reduction in UI) and acupuncture (25.8% reduction) post-intervention ($p < .001$). Because the control (sham acupuncture) treatment group (crossover women) in the parent study also showed a reduction in UI during the control phase of the parent study, we repeated the analysis omitting these women. After controlling for age and duration of UI, there was still a significant difference ($p = .039$) in the mean percent reduction in UI in the intervention groups (55.7% in the PFMT group vs. 35.6% in the acupuncture group). There is limited research examining the efficacy of acupuncture in the treatment of UI and there are no previous studies comparing the effectiveness of these two interventions for the treatment of UI. The mechanism whereby acupuncture works for UI is unclear. It has been postulated acupuncture works through the neurological system, which is quite different than the biomechanical mechanism of the PFMT intervention.

Whether these results are meaningful or clinically significant is difficult to say. There has been limited research examining how much improvement is needed to make a reduction in UI meaningful for individuals, i.e., what is considered clinically significant. Many experts have used the 50% reduction in UI episodes as the threshold for the determination of a clinically significant outcome when examining interventions such as PFMT for the treatment of UI (Yalcin, Peng, Viktrup, & Bump, 2009). The experts' opinions of 50% being clinically meaningful were supported by Yalcin et al.'s findings. Using data from four pharmaceutical

RCTs, Yalcin and colleagues examined the reduction in UI episodes that were clinically important for women as measured by the minimally clinical difference previously established for the validated Incontinence Quality of Life questionnaire. They reported that a reduction of approximately 50% was clinically meaningful. The 54% reduction for the group of women in the PFMT intervention group met the 50% reduction threshold for being clinically significant according to Yalcin et al. The percent reduction in the means for the acupuncture women, 31.5% and 41.5% (with and without the crossover women respectively), did not meet the clinically significant threshold.

Another study by Burgio, Goode, Richter, Locher, and Roth (2006) suggested using a 70% median reduction in UI episodes as a measure to determine a successful outcome for conservative UI therapies. Burgio et al. compared the proportion of women who reported being completely satisfied with their progress (measured on an ordinal scale with three response options; not at all satisfied, somewhat satisfied or completely satisfied) at various percent reductions in UI based on bladder diary data. Using the 70% threshold for a clinically meaningful reduction proposed by Burgio et al., neither the mean (31.50%) or median (33.7%) percent reduction UI in the acupuncture group nor the PFMT group (mean = 54.1% and median = 66.7% reduction) were clinically meaningful.

No studies were found that compared patient satisfaction with progress between the PFMT and acupuncture interventions. In the present study, we compared the reported satisfaction with their progress following treatment in two intervention groups. There was a significant difference between the two interventions groups relative to the satisfaction with their progress following treatment. More women in the PFMT (97.7%) group reported being completely or somewhat satisfied with their progress than in the acupuncture group (79.1% of women). One possible explanation for this may be that the acupuncture subjects were blinded to their assignment and this might have been affected by their perceptions while the PFMT subjects were not blinded and received feedback throughout the intervention related to their progress. We also examined the relationship between women reporting being satisfied with their progress and the median percent reduction in incontinent episodes. Across both intervention groups, women who were somewhat or completely satisfied with their progress had a median 63% reduction in UI. Our findings are similar to those reported by Burgio et al. (2006) when they examined the relationship between patient satisfaction and reduction of UI. Burgio et al. (2006) noted that there was a marked increase in the proportion of subjects who reported being completely satisfied when the median percent reduction in UI reached 70%. They also suggested that there are other aspects of UI such as decreased urgency, decreased in volume of leakage, and sense of better control over the UI, that need to be considered when asking patients to rate their satisfaction with progress following an intervention. Future studies should examine these characteristics in relation to patient satisfaction with treatments for UI.

No studies were found that compared the treatment burden related to acupuncture and PFMT interventions. Adherence to prescribed PFM exercise regimens has been reported to be difficult over the long term (Dougherty et al., 1993; Kafri et al., 2008; McDowell et al., 1999), but there have been no studies that measured treatment burden specifically. The present study compared the treatment burden reported by the women in each intervention group. There was no significant difference in the treatment burden perceived by the women in the two intervention studies. On a scale of 0-100 with the higher scores indicating extreme burden, both groups reported relatively low treatment burden related to their intervention. For the PFMT group, the median score for treatment burden was 20, while for the acupuncture women, it was 13.9. There were aspects of both treatment regimens that one could consider burdensome. For example, the women in the acupuncture study had to go to the acupuncture clinic for treatment twice a week for six weeks or 12 weeks depending on whether they were initially randomized to the control or delayed treatment (crossover) group. For the PFMT women, having to do the PFM exercises three times a day could be viewed as potentially burdensome. As reported, it does not appear these aspects of the treatment regimens were perceived or viewed as highly burdensome by the participants in either intervention group. The aspects of each intervention that were used to measure burden were intervention specific and were, thus, understandably very different in the two studies. In addition, however, the number of items and response options were different in the two studies. Consequently, caution must be taken when comparing treatment burden between the intervention groups.

We also compared the two interventions regarding their impact on HRQoL. First, the Physical and Mental Health Component scores at baseline were compared with females of the same age in the general population. This was accomplished using the 1988 National Norms for the Physical Health Component and Mental Health Component Scores for the SF-36 (http://www.sf-36.org/research/sf98norms.pdf) used in the two parent studies. The scores range from 0-100 with higher scores indicating better physical and/or mental health. The PFMT intervention women (mean age 74 years) had a baseline mean Physical Component score that was slightly lower than the population norm score for women of the same age, 39.36 (10.03) vs. 44.70 (10.66), respectively. The mean Physical Component score for the acupuncture women (including crossover women with mean age 63 years) was slightly higher than the population norm score for women in the same age group, 51.66 (8.82) vs. 47.44 (10.75).

When comparing the Mental Health Component scores for the PFMT women and the population norm score for females, the PFMT women had slightly higher mean Mental Health Component score than females in the general population, 56.39 (7.76) vs. 53.17 (9.29). The acupuncture women had a mean Mental Health Component score that was almost identical to females in the general population, 51.31 (11.44) vs. 51.71 (10.25).

Prior to comparing the percent change in Physical and Mental Health Component scores between the groups relative to the intervention, a within group analysis of the change in scores was completed. There was no significant change in the Physical Health Component Scores (PCS) for the PFMT group or Acupuncture group (with and without the crossover women) pre- to post-intervention. The Mental Component Scores (MCS) did not show a significant change from pre-intervention to post-intervention for the acupuncture groups. The PFMT women showed a significant decrease, however, the effect was very small and unlikely to be clinically meaningful. These findings are consistent with results of Tibaek et al. (2004) where there was no significant change in HRQoL scores from pre- to post-PFMT. SF-36 subscale scores of the SF-36 (all p's > .05). The Bo et al. (2000) study also examined changes in general HRQoL following a PFMT, intervention in women with stress UI and reported that there was no significant change (p =.16). Both of these studies also examined UI-specific quality of life. Tibaek and colleagues administered the IIQ before and after PFMT for women who had a stroke but were independent in ambulation and toileting. Consistent with their findings of no significant changes in general HRQoL, there were also no significant changes in UI-specific QoL. Bo and colleagues measured UI-specific QoL using the Bristol Female Lower Urinary Tract Symptoms questionnaire. A significantly greater proportion of women in the PFMT reported improvement in two of the five UI-specific QoL domains measured by the questionnaire compared to the control group. In a prospective observational trial, Balmforth et al. (2006) reported a statistically significant improvement in all but two of the subscales (general health perception and personal relationships) of the King's Health Questionnaire (KHQ), which is another instrument measuring general QoL. This was not an RCT and between group comparisons could not be made. The focus of this study was on bladder neck mobility following a 14-week intensive PFMT program, which included behavioral modifications such as fluid management and diet/bowel management along with an intensive PFMT regimen. Another study was conducted by Vaughn et al. (2011), which was an uncontrolled pilot study of men and women with Parkinson's Disease recruited from a movement disorders clinic. Examining UI-specific QoL was a secondary aim of this study. The instrument used was the International Consultation on Incontinence Questionnaire for overactive bladder (ICIQ-OAB). This pilot study reported a significant reduction in UI and improvement in HRQoL scores following PFMT in older adults with Parkinson's Disease. Most of the studies that examined the impact of PFMT on quality of life examined UI-specific QOL. In contrast to studies using the MOS SF-36 or another general HRQoL instrument, six out of seven studies reported a significant improvement in UI-specific QoL (Castro et al., 2008; Goode et al., 2006; Kafri et al., 2007; Kashanian et al., 2011; Perrin et al., (2005); Sari & Khorshid, (2009)). These findings support the importance of including a disease-specific QoL measure when assessing the impact of treatments for UI on QoL. Since only two studies examined both general HRQoL and UI-specific QoL, measures of both should be included in future studies examining the impact of PFMT for UI.

When reviewing the literature for the acupuncture intervention and studies that examined quality of life, Emmons and Otto (2005) used the Incontinence Impact Questionnaire (IIQ), an incontinence-specific instrument and reported 52% improvement in QoL (mean) scores. The

Bergstrom et al. (2000) study used the Incontinence-Quality of Life instrument (I-QoL), another incontinence-specific QoL instrument, and reported a 34% improvement in QoL mean scores at 3 months for the women in their study. Because these two studies did not measure general HRQoL, their findings cannot be compared to those of the current study. The SF-36 used in the present study is a measure of general HRQoL and may not be as sensitive to changes in UI as the incontinent specific instruments. Only one study was identified that used the SF-36 to measure HRQoL before and after acupuncture for UI and the sample size was very small (Engberg et al., 2009). The median percent change in HRQoL scores for both the Physical and Mental Component scores were higher in the Engberg et al. study (Mdn 4.7% change for the PCS and Mdn 7.8% change in the MCS) than what was reported in the present study (Mdn % change of -0.46% in the PCS and Mdn -2.43% change in the MCS). As noted, the sample size for the pilot study was very small (n = 4) making a valid comparison questionable.

The impact of the two interventions on HRQoL was compared. The unadjusted means for the percent change in the Physical Component score (PCS) were not significantly different between the groups ($p = .507$). There was a significant difference in the unadjusted percent change in the Mental Component scores (MCS) of the two groups ($p = .011$). After controlling for the differences between the groups (age and duration of UI), however, it was no longer significant. Repeating the analysis after excluding the acupuncture women in the crossover group also produced no significant group differences in unadjusted or adjusted percent change in the PCS or MCS. The results of this secondary analysis would suggest that these two interventions do not have an impact on general HRQoL. We could not identify any other studies that compared the two interventions relative to impact on HRQoL. Future studies should also measure urinary incontinence-specific quality of life, which may be more responsive to the interventions for UI.

The two samples were combined to examine the relationship between the percent reduction in UI and HRQoL controlling for the effects of variables related to either the percent reduction in UI or the HRQoL bivariately. In the multivariate analysis, there was a significant relationship between a decrease in UI and change in HRQoL scores. When examining the relationship for each of the component scores multivariately, depression was the only covariate significantly related to the Mental Health Component scores ($p = .044$) and there was a trend toward significance ($p = .066$) for the intervention group. The covariates, i.e. age, duration of UI, level of education, depressive symptomatology and the interventions, did not explain a significant proportion of the variability in the component scores. When the percent reduction in UI was entered into the model, there was no significant change in the contribution to the variability. Therefore, it does not appear that a reduction in UI alone was a major predictor for improved HRQoL scores for women 50 years of age and older in this analysis. Given that the SF-36 is a general measure of HRQoL, it may not be as sensitive to changes in UI. Future studies should also include a UI-specific QoL measure.

5.2 LIMITATIONS

This study was a secondary data analysis of data collected in two independent studies that were not conducted during the same timeframe. Consequently, there are a number of limitations that need to be considered when interpreting the results. First, this study used data from two previous studies to compare the effectiveness of these two interventions. The two samples differed in relation to a number of characteristics (age and duration of UI) which were controlled for in the analysis but it is also likely that that they differed in relation to other characteristics i.e., co-morbidities, functional limitations, etc., that that may have influenced the response to these interventions. Second, because this was a secondary data analysis, potentially important outcome variables were not available in both data sets for comparison, e.g., data on UI-specific QoL. One of the limitations is that the parent PFMT study was originally designed to examine the efficacy of a relapse prevention intervention in maintaining post-PFMT continence in homebound elders (men and women). When that study was designed, the IIQ was modified to eliminate items that were irrelevant for homebound individuals (e.g. shopping for groceries, going to church, traveling, etc.). Approximately two and one half years into the study, the eligibility criteria were revised to include non-homebound men and women. The modified IIQ (MIIQ) continued to be used for all subjects in the study regardless of their homebound status. Since it is unlikely that the MIIQ used in the PFMT study and the IIQ used in the acupuncture study produced comparable data on the impact of UI on UI-specific QoL in non-homebound women, this potentially important outcome was not examined in this study. Another potentially important outcome that could not be examined was reductions in stress and urge accidents. While data on the numbers of urge and stress accidents were available for the acupuncture study, they were not available for the PFMT study. Another limitation is that the outcomes that were available in both studies were not always measured in the same way. For example, the number of items and their response options used to measure treatment burden differed in the two studies. In addition, different measures of depressive symptoms were used, i.e. the GDS and CES-D. While a bladder diary was utilized to measure changes in UI in both studies, there were two different types of bladder diaries used, i.e., paper/pencil diary for the PFMT study and the electronic PDA diary in the acupuncture study. Diaries may have an effect on the reporting, especially when the participant can see past data. The women in the acupuncture study could not review their entries unlike the women in the PFMT study. The assessment and measurement instruments were pre-determined and were chosen to answer different research questions and may not have been the best tools to address the research questions for this analysis. Finally, the samples in the parent studies were convenience samples which limit the generalizability of the results to women outside of the study sample for each intervention group. The acupuncture study sample was small further limiting the generalizability of the results.

5.3 CONCLUSION

Given that this was a secondary data analysis of data collected in two independent studies with a number of limitations, one must be cautious in drawing firm conclusions based on the findings. The findings, however, provide preliminary evidence to suggest that the PFMT intervention is the superior intervention when compared with acupuncture for the treatment of UI in women in this age group. Although there was improvement in the acupuncture intervention group, it did not rise to the level of being clinically meaningful. The PFMT intervention did reach the threshold for being clinically significant and should continue to be recommended as first line treatment for UI. The women in the PFMT were 2-3 times as likely to report being satisfied with their progress which is also related to the women in the PFMT group experiencing a greater reduction in UI.

The women in both intervention groups did not perceive the intervention phase as being burdensome. Neither intervention seemed to influence changes in HRQoL after controlling for age and duration of UI. When controlling for age, duration of UI, level of education, depressive symptoms and the interventions, the only variable that was significantly related the change in HRQoL scores, specifically, the mental health component score, was depressive symptomatology.

5.4 RESEARCH AND CLINICAL IMPLICATIONS

The results of this study may help guide future research and possibly clinical practice. Future research should compare these interventions in randomized clinical trials with larger, more heterogeneous samples of women examining their impact on urge and stress accidents and incontinence specific QoL as well as overall general HRQoL. Such studies should include a measure of satisfaction with the interventions and perceptions of their burden. Characteristics previously shown to influence the response to both interventions should be measured to determine if any predict which intervention is most effective for specific women. While overall acupuncture was less effective than PFMT in this study, within group comparisons revealed that responses to the interventions were variable with some women experiencing an increase in UI and some women reporting a marked improvement including elimination of all accidents. A larger sample and more comprehensive measurement of potential predictor variables might allow future studies to determine which women are more likely to benefit from each of these interventions.

Because of the limitations of this study, one being the interventions were not a part of the same RCT, one must be cautious when making clinical recommendations related to these two interventions. However, based on the findings, clinicians should continue to recommend PFMT as the first line treatment for UI for community-dwelling women 50 years of age and older. There is not enough evidence at this time to support the use of acupuncture to treat UI for women 50 years of age and older.

APPENDIX

APPENDIX A. IRB APPROVAL

PI Notification: IRB determination

irb@pitt.edu [irb@pitt.edu]

Sent: Friday, May 04, 2012 11:01 AM

To: Bolinger, Rosemary

University of Pittsburgh

Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
http://www.irb.pitt.edu

Memorandum

To: Rosemary Bolinger

From: Christopher Ryan PhD, Vice Chair

Date: 5/4/2012

IRB#: PRO12040644

Subject: Comparing the Effectiveness of Pelvic Floor Muscle Training (PFMT) and Acupuncture for the treatment of Urinary Incontinence (UI) for non-homebound women 50 years of age and older: A Secondary Analysis

The above-referenced project has been reviewed by the Institutional Review Board. Based on the information provided, this project meets all the necessary criteria for an exemption, and is hereby designated as "exempt" under section
45 CFR 46.101(b)(4)

Please note the following information:

- If any modifications are made to this project, use the **"Send Comments to IRB Staff"** process from the project workspace to request a review to ensure it continues to meet the exempt category.
- Upon completion of your project, be sure to finalize the project by submitting a **"Study Completed"** report from the project workspace.

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

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