

A Comparison of Two Pelvic Floor Muscle Training Programs in Females with Stress Urinary Incontinence: A Pilot Study

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ABSTRACT

Background: Stress urinary incontinence (SUI) is a condition affecting millions of Americans. Few studies have assessed the benefits of different exercises involved in pelvic floor muscle training (PFMT).

Purpose: The purpose of this study was to compare the effects of a traditional PFMT program to an assisted pelvic floor muscle training (APFMT) program that included contraction of hip musculature.

Methods: Eleven subjects, ages 42-74, were obtained from a convenience sample of women diagnosed with SUI by an urogynecologist. The degree of incontinence was determined by the International Consultation on Incontinence Modular Questionnaire (ICIQ_UI Short Form), the Urogenital Distress Inventory (UDI-6 Short Form) and the Incontinence Severity Index (ISI). Changes in the electrical activity of the pelvic floor musculature were determined using the Prometheus Pathway NMR 400 quad channel EMG and a 4 day bladder diary was completed. Subjects were randomly divided into

two groups: traditional pelvic floor muscle training (PFMT) and assisted pelvic muscle training (APFMT) and received instructions from a physical therapist on these exercises. Surface EMG (sEMG) data was taken monthly and all baseline measurements were repeated at the end of 12 weeks. General linear model repeated measures tests were run to determine if there was a statistically significant, within-group difference in the long, moderate, or short hold measures taken at baseline, weeks 4, 8 and 12 and to determine if there was a statistically significant difference in these measures between the two groups. Paired sample T tests were run to determine if there was a statistically significant difference between baseline and study completion on the ICIQ_UI, UDI-6, or ISI. Gain scores were calculated as final minus initial ICIQ_UI, UDI-6, and ISI scores and independent samples T tests were run to determine if there was a statistically significant difference in gain scores between groups. **Results:** Six subjects completed the study, two in the PFMT group and four in the APFMT group. There was a statistically significant within-group improvement from pre- to post-test for long, moderate,

and short hold measures for both groups. There was no statistically significant between-group effect on these measures. Paired samples T tests revealed a statistically significant difference in the pre to post ICIQ_UI, UDI-6 and the ISI. Independent samples T tests revealed a statistically significant difference in the gain scores for the UDI-6 between groups. Subjects reported increases in quality of life. **Conclusions:** The results of this study are consistent with previous research that pelvic floor muscle training is beneficial in increasing function and decreasing subjective views on level of SUI. Further research with a larger sample size, a control group and utilization of more sensitive measures is needed in order to determine the most effective exercises.

INTRODUCTION

Urinary incontinence, is a condition affecting millions of Americans.¹ Stress urinary incontinence (SUI) is the most common type and is defined as the involuntary leakage of urine during activities that increase intra-abdominal pressure.² Cammu and Van-Nylen³ described SUI as the “loss of urine from the urethra synchronous with physical exertion and in the absence of a detrusor contraction”, while other definitions simply define it as “involuntary leakage from effort or exertion.”⁴ Studies have shown that the prevalence and incidence of SUI in women are 53% and 34% respectively,^{5,6} affecting 29.5 million Americans.⁷ It has also been estimated that the 10 year cost of untreated SUI is \$86,726 per person.⁸ This condition affects mostly women and can be due to weakened pelvic floor muscles and urethral sphincter hypermobility after childbirth, pelvic surgery, or idiopathic causes.² Providing patients with pelvic floor muscle training exercises for these muscles may provide them the opportunity to decrease their episodes of incontinence.^{9,10}

Various conservative therapies have been used to manage incontinence. These include lifestyle intervention and pelvic floor muscle training (PFMT) with and without the use of biofeedback, electrical stimulation

(ES), and vaginal cones.^{4-6,11-28} Many studies have shown significant improvements in increasing muscle strength and quality of life, and decreasing episodes of incontinence with the use of these PFMT methods when compared to untrained controls.^{3,13,14,16,19,26}

Historically, Dr. Arnold Kegel⁹ first reported that PFMT was effective in the treatment of SUI in 1948. Kegel developed this program to help postpartum women restore tone and function to relieve SUI. The patient used a perineometer to assist with visualizing the perineal muscle contraction and initially exercised 20 minutes 3 times a day. The exercises were spread out over 20-60 days and the time period would vary based on the muscular status. At the time of this paper, 64 patients were relieved of stress incontinence. Over the years, this program has changed to include quick and 10 second hold contractions and to avoid the use of the abdominal and gluteal muscles. These exercises are primarily recommended for those with stress incontinence.

In a 2003 study, Bø¹⁷ classified subjects with SUI from a previous PFMT study as responders or non-responders of treatment based on five variables covering urodynamic measurement, pad testing with standardized bladder volume, and self-reports. The results of the study showed a positive correlation between the responders and improvements in PFM maximal strength. Some studies have suggested that these results may be greater improved with the use of biofeedback.^{13,14} Aukee et al¹³ assessed women participating in a home exercise program including both long and short duration exercises for 20 minutes a day, 5 days per week. The study found that after 3 months of training, both the PFMT and the PFMT with surface EMG (sEMG) assisted biofeedback showed significant increases in pelvic floor muscle activity and decreases in urine leakage. However, greater changes were noted in the PFMT with biofeedback group.

Despite the changes that occurred when combining biofeedback with PFMT, few studies have demonstrated differences

between the various training methods of PFMT, ES, and vaginal cones. Castro et al¹⁹ conducted a study in which 118 subjects with SUI were randomized into PFMT, ES, vaginal cones, and no treatment groups and assessed after treatment 3 times per week for 6 months. The results of this study showed significant improvements in the pad test, SUI episodes, and quality of life for all treatment groups when compared to the control group. However, no significant differences were seen between the different interventions. Cammu and VanNylen³ studied 60 women with SUI and compared a once weekly, 30 minute private PFMT session for 12 weeks with a vaginal cones group who used the cones 2 times per day for 15 minutes for 12 weeks. This study found that, although equally significant results were reported between the PFMT group and vaginal cones group, those in the vaginal cones group were less compliant which suggested that this may not be the best treatment for women with SUI.

Although the majority of studies showed no difference between treatment methods, Bø et al¹⁶ assessed 107 females with SUI over 6 months and reported greater improvements with PFMT when compared to ES and vaginal cones and stated that PFMT exercises are effective and safe and should be offered as the first choice of treatment for SUI. Also, in 2001, Hay-Smith and colleagues²⁰ found in their review of the literature that not only was PFMT more effective than no treatment or placebo, but intensive PFMT appeared to be more effective than standard PFMT.

A more recent exercise program, Beyond Kegels, was developed by Hulme.²⁹ This protocol arose after many patients were not improving with Kegel exercises alone. The program has five components including lifestyle changes, physiological quieting and exercises. The Roll for Control exercises were designed to stimulate the pelvic floor muscles as well as muscles through the lower pelvis and those attaching to the femur. The exercises consist of four levels

as follows: relaxed awareness of the pelvic floor muscles; assisted pelvic muscle tightening in sitting; heel and toe clicks in sitting; and standing plie with small knee bends. These are often performed 5-10 repetitions, 2-3 times/day progressively adding the next exercise as they get easier.

Research utilizing this protocol is limited and most studies have not been published. Hulme and Nevin³⁰ compared the Beyond Kegels protocol with traditional Kegel exercises in 64 females with stress, urge, or mixed incontinence. They found that 61% in the Beyond Kegels group were continent after treatment vs. 48% in the Kegels group and in 3 weeks less time. In a study of 43 women with urge, stress or mixed incontinence who performed a 4 week home program of Beyond Kegels, daily leaking decreased from 81% to 0% after 4 weeks.³¹

Despite numerous studies published about the methods of decreasing SUI, few of them have assessed the benefits of specific exercises involved in PFMT. The purpose of this study was to measure the effects of a traditional PFMT program (PFMT), involving only PFM contractions, and to compare it to an assisted pelvic floor muscle training (APFMT) program, which includes contraction of the hip musculature in conjunction with the PFM contraction.

METHODS

Subjects: Eleven subjects, ages 42-74, were obtained from a convenience sample of women diagnosed with SUI who were recruited by word of mouth and direct referral from an urogynecologist in a Midwestern practice. Diagnosis of incontinence was determined by the referring physician using a combination of the following: urodynamic studies, a 24-72 hour bladder/fluid habit record, incontinence questionnaire, patient history, and examination of the pelvic floor. This quasi-experimental study was approved by the Institutional Review Board (IRB) at the University of Dayton (UD) and all subjects received the intervention.

Subjects were enrolled to participate by providing voluntary informed consent and

meeting the following inclusion criteria: female; age 18-70 years; a diagnosis of urodynamic SUI; ability to fill out questionnaires; and willingness to participate. Subjects were excluded for the following: if they experienced fecal incontinence, pudendal nerve damage, neurological conditions (multiple sclerosis, spinal cord injury, spina bifida, stroke, and Parkinson's), neurogenic bladder, lichen sclerosus, urge incontinence or insulin-dependent diabetes mellitus; used medications to treat lower urinary tract disabilities; were less than 6 weeks postpartum; had a grade 3 or greater vaginal prolapse (graded by the referring physician); or had gynecological surgery within the last 3 months.

Procedures:

After informed consent was obtained, each participant received an examination by a physical therapist who specialized in women's health. The degree of incontinence was determined by several tools. The International Consultation on Incontinence Modular Questionnaire, ICIQ_UI Short Form (ICIQ_UI), an efficient and comprehensive 4-item scale, was used to assess the prevalence, frequency, and perceived cause of urinary incontinence, and its impact on everyday life. Items were scored on a scale from 0-21 with greater values indicating increased severity of incontinence.³² According to Avery et al³², this tool has been shown to have high levels of reliability and validity, including content, construct, and convergent.

The Urogenital Distress Inventory (UDI-6 Short Form) was used to address the frequency and extent of urinary incontinence.³³ It consists of 19 questions divided into three subscales: irritative, obstructive/discomfort and stress symptoms. Each response was coded 1-4 (No=0, Not at all=1, somewhat=2, moderately=3, quite a bit=4). A mean range was calculated over all questions in a subscale and converted to a value ranging between 0-100. Subscales were summed, giving a total score between 0-300 with higher scores indicating more bothersome symptoms. This tool is a valid and reliable

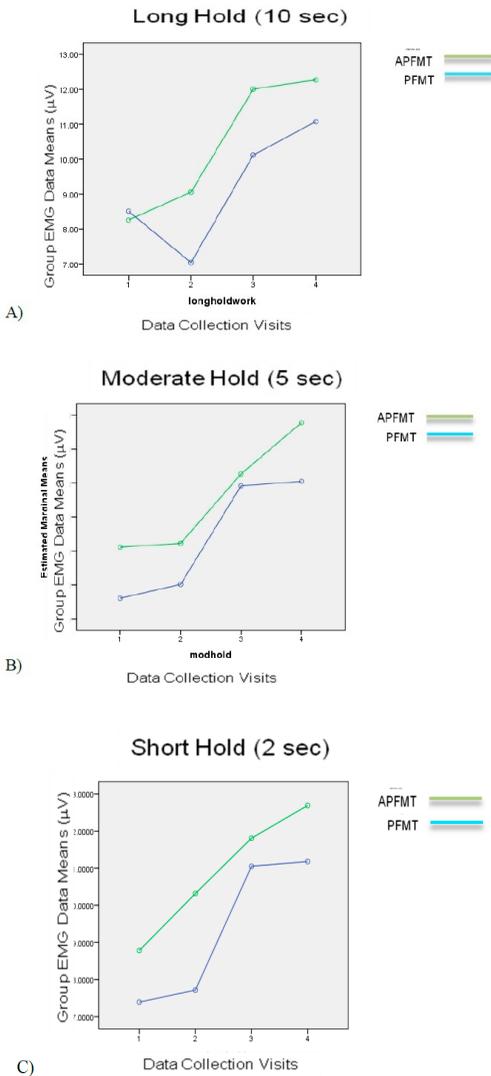
measure.³⁴

The Incontinence Severity Index (ISI), a 2-question survey, was used to determine frequency and amount of leakage. Scores range from 1-12 and are determined by multiplying the results from question 1 and question 2. Higher scores indicated increased severity of incontinence. This instrument has been shown to be a valid and reliable measure of urinary incontinence.³⁵ Outcome surveys were collected at baseline and following the completion of intervention at week 12.

In addition to the surveys, a 4 day bladder/fluid diary was completed within the 4 days following the initial evaluation and the final data collection at 12 weeks. The diary documented information regarding the number of pads used, frequency of episodes, amount of leakage, amount of fluid intake, and amount of bladder irritants consumed. Previous studies showed voiding diaries are a reproducible outcome measure in women with SUI and provide invaluable information about urinary frequency that should be included as a routine assessment.³⁶⁻³⁹ Locher et al³⁶ determined that 7-days of the bladder diary were required to obtain reliable results. However, Nygaard and Holcomb³⁷ found that completing at least 3 days produced comparable results as to completing 7 days while also reducing the patient's burden. Results showed a strong correlation between the first 3 days of the diary and the last 4 days ($r=0.887$), suggesting that a 3-day diary is an appropriate outcome measure for clinical trials evaluating treatments for stress incontinence. A duration of 4-days was used in this study allowing 1 day for patient error as was the preference of the examining physical therapist. All 4 days were included in the study analysis.

Changes in the electrical activity of the pelvic floor musculature, determined using the Prometheus Pathway NMR 400, quad channel EMG with the Synergy 3-D NMR 200 software program (The Prometheus Group, Dover, New Hampshire), were measured and recorded monthly through 12

Fig 1: EMG maximum work values at 0, 4, 8, and 12 weeks for group 1 (PFMT) and group 2 (APFMT) for A) long holds (10 sec), B) moderate holds (5 sec), and C) short holds (2 sec).



weeks. The evaluating physical therapist used a total of three electrodes (two recording electrodes on the pelvic floor and one ground electrode). First, all subjects were shown an anatomy picture of the perineum and the location of the electrodes. Subjects were then positioned in right side-lying to prep the area using an alcohol pad. The two recording electrodes were placed externally

on the perineum at three and nine o'clock around the anus. The ground electrode was placed on the left greater trochanter. Subjects were positioned supine with a round bolster (24"x 6") placed under their knees and a small pillow under their head. The physical therapist provided the patients with the following instructions during testing of pelvic floor activity:

1. You will rest quietly for 2 minutes to get a resting baseline of your pelvic floor muscles. Try not to move your arms, legs or cough.
2. You will contract your pelvic floor muscles. First it will be 10 times for 10 seconds, then 10 times for 5 seconds, then 10 times for 2 seconds.
3. You will hear the machine say "work", then "rest."
4. You will need to contract as quickly as you can, hold the muscle steady, and then relax as quickly as you can and release fully.
5. Relaxing is as important as contracting.
6. Do not bear down, hold your breath or lift your hips off the table.

Intervention:

Subjects were randomly divided into two groups: six in the traditional pelvic floor muscle training (PFMT) and five in the assisted pelvic floor muscle training (APFMT). Both groups were instructed to perform the exercises twice a day, once in the morning and once in the evening, every day of the week.

Group one performed traditional Kegel exercises. They were instructed to lie in the supine position with knees bent when performing the exercises. First, they maintained long contractions (10 sec x 10 reps with 5-10 sec rest between holds) and then short contractions (1-2 sec x 10 reps with 1-2 sec rest between holds) of the pelvic floor and transversus abdominis musculature in order to utilize their coupling action to maximize the pelvic floor contraction. At the conclusion of the study, this group

Table 1: Descriptive statistics for the PFMT and APFMT groups for long, moderate, and short holds at weeks 0, 4, 8, and 12.

Week	Hold Length	PFMT		APFMT	
		Mean	SD	Mean	SD
0	Long (10 sec)	8.5100	5.9255	8.2550	2.1019
4	Long (10 sec)	7.0400	.2263	9.0550	2.3504
8	Long (10 sec)	10.1200	3.7901	12.0075	3.6091
12	Long (10 sec)	11.0750	3.2881	12.2700	2.6530
0	Mod (5 sec)	7.6100	2.5456	9.1150	1.8477
4	Mod (5 sec)	8.0150	1.8738	9.2250	2.8721
8	Mod (5 sec)	10.9200	3.0830	11.2700	3.1150
12	Mod (5 sec)	11.0500	2.7577	12.7825	2.9271
0	Short (2 sec)	7.3900	2.9133	8.7800	1.3008
4	Short (2 sec)	7.7150	1.4071	10.3175	2.2546
8	Short (2 sec)	11.0500	1.3435	11.8100	2.5524
12	Short (2 sec)	11.1800	2.7153	12.6900	2.4807

received instruction on APFMT in order to provide additional tools to help them overcome SUI.

Group two was trained to contract the pelvic floor musculature while performing resistive exercises that included the use of an elastic band and ball squeezes adapted from those referenced by Hulme.²⁹ This group also performed their exercises in the supine position with knees bent. Subjects were instructed to perform a moderate contraction of the pelvic floor/transversus abdominis followed by the addition of squeezing a ball between the knees (5 sec x 10 reps). It was reinforced that they should be squeezing the ball and the pelvic floor at the same time. Once these were completed, an elastic band was placed around the subject's knees to provide resistance to hip musculature and the subject performed a moderate pelvic floor/transversus abdominis contraction with hip abduction (5 sec x 10 reps). It was reinforced that they should be pushing out against the band while squeezing the pelvic floor muscles at the same time. Diagrams and written instructions, developed by the practicing PT, were provided to both groups for the home exercise program.

During exercises, subjects were further encouraged to not hold their breath or squeeze their buttocks, to think about gradually drawing in their muscles from the outside and to focus on the quality of the contraction. Subjects also received the following information on good bladder habits on day one: avoid irritants to the bladder such as caffeine; don't go to the bathroom "just in case," do not practice squeezing your pelvic floor muscles while urinating; before you cough, sneeze or lift anything, get the "knack," which means squeezing your pelvic floor muscles before you lift anything, cough or sneeze; and don't drink too many fluids (if you drink more than eight glasses of liquid per day, you may be drinking too much for your bladder to handle).

Subjects were seen by the physical therapist at weeks 4, 8 and 12 during which sEMG measurements were taken. They were asked if they had questions about good bladder habits or their home program. Their exercise program was reviewed to ensure that the position and hold times were correct. All subjects were asked if they performed their exercises twice a day.

Table 2: Paired samples T tests comparing initial and final values for ICIQ_UI, UDI-6, ISI and Incontinence Episodes

	Paired Differences							
	Mean	SD	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
				Upper	Lower			
ICIQ_UI (Initial – Final)	7.167	5.529	2.257	1.365	12.969	3.175	5	.025*
UDI-6 (Initial –Final)	5.000	4.000	1.633	.802	9.198	3.062	5	.028*
ISI (Initial –Final)	2.833	2.483	1.014	.227	5.439	2.795	5	.038*
Incontinence Episodes (Initial - Final)	2.667	1.528	.882	-1.128	6.461	3.024	2	.094

*Statistically significant difference ($p \leq 0.05$)

Statistical Design:

sEMG Data: All statistical analyses were completed in SPSS (v 16.0) and alpha was set at 0.05. General linear model repeated measures (GLM RM) tests were run to determine if there was a statistically significant, within-group difference in the long hold (10 sec, μV), moderate hold (5 sec, μV) or short hold (2 sec, μV) measures taken at baseline, and again at the end of week 4, week 8 and week 12 of the study, and to determine if there was a statistically significant difference in these measures between the two intervention groups.

Survey Data: Paired sample T tests were run to determine if there was a statistically significant difference between baseline and study completion of the ICIQ_UI, UDI-6, or ISI. Gain scores were calculated as final minus initial ICIQ_UI, UDI-6, and ISI scores and independent samples T tests were run to determine if there was a statistically significant difference in gain scores between intervention groups.

RESULTS

A total of six subjects completed the study (two in the PFMT group and four in the APFMT group). Four subjects dropped out of the study, two due to problems with transportation to data collection appointments, one due to a hysterectomy, and one due to personal reasons. One subject’s data was removed from analysis due to the fact that

she performed the Valsalva maneuver during initial data collection. All subjects reported performing the exercises at least once per day but not always twice.

Descriptive statistics for the sEMG data are in Table 1. Subjects in both the PFMT and APFMT groups showed statistically significant improvements for long ($p = 0.029$), moderate ($p = 0.01$), and short ($p = 0.002$) hold measures from pre-test to post-test. Subjects in both groups improved similarly, as there was not a statistically significant difference in the pre- to post-test changes for subjects in the PFMT group compared to the APFMT group for the long hold, moderate hold or short hold. (Figure 1).

Paired samples T tests revealed a statistically significant difference in the pre to post ICIQ_UI ($p = 0.025$), UDI-6 ($p = 0.028$) and the ISI ($p = 0.038$) scores (Table 2). Independent samples T tests revealed a statistically significant difference in the gain scores between the PFMT and APFMT groups for the UDI-6 ($p = 0.043$) but not for the ICIQ_UI or the ISI (Table 3).

Statistical analysis of the bladder diaries was unavailable due to low compliance with returning final journals and inconsistency between reported values of intake, voidance, and leakage.

DISCUSSION

This study examined two different PFMT programs used to manage SUI in female

Table 3: Independent samples T tests comparing the change in ICIQ_UI, UDI-6, and ISI between Traditional and Assisted Pelvic Floor Muscle training groups.

T-test for Equality of Means							
	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						Lower	Upper
ICIQ_UI-gain	-1.056	4	0.35	-5	4.734	-18.142	8.142
UDI-6-gain	2.93	4	.043*	10.25	3.498	0.539	19.961
ISI-gain	-1.844	4	0.139	-5.25	2.848	-13.156	2.656

*Statistically significant difference ($p \leq 0.05$)

subjects. The overall results for both the traditional PFMT and APFMT groups showed significant improvements within-subjects for long, moderate and short contractions as well as on the ICIQ_UI, UDI-6 and ISI over the 3 month period. In addition, statistical significance was also seen in the gain score for the UDI-6 between groups, but not for the ICIQ_UI or ISI. Furthermore, results from sEMG recordings showed greater increases in electrical activity of the pelvic floor in the APFMT group. However, the data fail to reveal any significant changes between intervention groups.

Subjectively, all participants reported an increase in quality of life and were very grateful for the interventions. At initial follow-up visits, many reported that they felt the long holds would fatigue and fade off prior to the end of the 10 second hold. They noted that by month 3, the quality of their contractions had improved. Subjects showed good compliance, verbally reporting performing the exercises at least 1x/day 5-7 days per week.

Results of the present study do remain consistent with the findings from previous authors. This study is similar to the study by Aukee et al¹³. Both lasted 3 months, included home exercises programming with long and short hold contractions and found significant improvements within subjects performing PFMT. Cammu and VanNynlen³ also showed significant improvements in patients who practiced PFMT for only 3 months, although the subjects performed

exercises while in physical therapy. Bø et al¹⁶ and Castro et al¹⁹ also found significant improvements in decreasing episodes of incontinence and increasing quality of life in subjects but their protocols involved a longer period of 6 months. They further supported the findings of the current study by revealing that PFMT is not only beneficial in increasing strength and decreasing subjective views on level of incontinence, but also allows for increased patient compliance with the exercise program. The current study demonstrated that improvements can be made in less time, which may improve compliance.

Limited research was found that examined the effects of APFMT, even though these exercises are commonly used with patients with SUI. The results of this study support those found by Hulme and Nevin³⁰ in that those patients who performed the APFMT program showed greater increases in electrical activity of the pelvic floor with EMG measurements. The current study, though, did not use the entire Beyond Kegels program and did not find statistically significant differences between the two groups. In the current study, the APFMT exercises were varied from the originally published exercises as these are typically initiated in a seated position.²⁹ To be consistent, both groups were examined and treated in the supine as changing positions often alters how the person feels when doing the contraction. Our subjects had weak pelvic floor muscles and beginning the exercises

in supine eliminated the effect of gravity. If these subjects would have continued to be treated, they would have progressed to performing exercises in a seated position once they did well in supine.

It is difficult to conclude the clinical significance of these changes as there has yet to be a minimal clinically important difference (MCID) set for PFMT. It should also be noted that statistical insignificance for strength between groups may be due to small sample size. However, the current study supports the notion that PFMT decreases symptoms of SUI but may not provide a complete cure, as obtained through subjective self-reports to the physical therapist indicating improvements in quality of life. Those participating in the APFMT group reported feeling like they made greater improvements compared to those PFMT group.

The intent of this study was to determine a specific exercise regimen for practicing clinicians to utilize during patient care in an attempt to help decrease symptoms of SUI in women. Therefore, from the present study, it can be proposed that implementing a program focused on increasing the strength and endurance of the pelvic floor musculature (either through traditional or resisted exercises) that includes education regarding prevention of symptoms, will enhance the overall quality of life in these individuals.

Limitations in this study include the lack of administration of questionnaires at each session in order to detect more immediate changes. Standardization of the bladder diaries would have been helpful to maintain consistency and determine uniformity in the reported amount of urine lost during each episode between subjects throughout training sessions. This could be accomplished by utilizing plastic attachments for the toilet seat to measure bladder excretion. Also, it might have been helpful to have both groups perform exercises with the same hold time to ensure consistency.

We chose a 5 second hold time for the APFMT group, vs. a 10 and 2 second hold in order to keep the number of exercises

in their home program consistent with the PFMT group. Due to the fact that we only had one practicing woman's health physical therapist involved in the study, there was an inability to blind the researcher collecting the data. Since we had the same individual collecting data as teaching the exercises, this may have lead to an experimenter bias towards giving better instruction and more encouragement to those in the different groups. In addition, there were no objective measures collected during the initial examination to determine true pelvic floor muscle weakness. This examination was included in the original proposal but IRB approval could not be obtained without removing the internal examination. A significant limitation was the loss of 5 subjects over the 12 week period. None of the subjects removed themselves from the study because they did not want to exercise. A stipend or incentive to participate may have allowed more to be involved.

CONCLUSION

Stress urinary incontinence severely affects the lives of many women leaving them with a decreased quality of life. Pelvic floor muscle exercises, traditional or resisted, have been shown to reduce the symptoms of SUI bringing life and control back to these individuals. Further research with a larger sample size and control group is needed in order to determine the most effective intervention for increasing function and decreasing subjective level of incontinence.

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