



2008

# Effectiveness of Pelvic Floor Exercises on Women with Urinary Incontinence :

Kayla Bucher  
*University of North Dakota*

Brittany Carter  
*University of North Dakota*

Ashley Waller  
*University of North Dakota*

Rachel Zinski  
*University of North Dakota*

Follow this and additional works at: <https://commons.und.edu/pt-grad>

 Part of the [Physical Therapy Commons](#)

---

## Recommended Citation

Bucher, Kayla; Carter, Brittany; Waller, Ashley; and Zinski, Rachel, "Effectiveness of Pelvic Floor Exercises on Women with Urinary Incontinence :." (2008). *Physical Therapy Scholarly Projects*. 79.  
<https://commons.und.edu/pt-grad/79>

This Scholarly Project is brought to you for free and open access by the Department of Physical Therapy at UND Scholarly Commons. It has been accepted for inclusion in Physical Therapy Scholarly Projects by an authorized administrator of UND Scholarly Commons. For more information, please contact [zeinebyousif@library.und.edu](mailto:zeinebyousif@library.und.edu).

Effectiveness of Pelvic Floor Exercises on Women with Urinary Incontinence.

by

Kayla Bucher, Brittany Carter, Ashley Waller, Rachel Zinski  
Doctor of Physical Therapy  
University of North Dakota, 2008

A Scholarly Project

Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine

University of North Dakota

in partial fulfillment of the requirements

for the degree of

Doctor of Physical Therapy

Grand Forks, North Dakota

May  
2008



This Scholarly Project, submitted by Kayla Bucher, Brittany Carter, Ashley Waller, and Rachel Zinski in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

Cindy Flom-Meland  
(Graduate School Advisor)

Thomas Moe  
(Chairperson, Physical Therapy)

PERMISSION

Title: Effectiveness of Pelvic Floor Exercises on Women with Urinary Incontinence

Department: Physical Therapy

Degree: Doctor of Physical Therapy

In presenting this Scholarly Project in partial fulfillment of the requirements for a graduate degree from the University of North Dakota, we agree that the Department of Physical Therapy shall make it freely available for inspection. We further agree that permission for extensive copying for scholarly purposes may be granted by the professor who supervised our work or, in her absence, by the Chairperson of the department. It is understood that any copying or publication or other use of this independent study or part thereof for financial gain shall not be allowed without our written permission. It is also understood that due recognition shall be given to us and the University of North Dakota in any scholarly use which may be made of any material in our Scholarly Project.

Signature(s) Bridget Carlin

Signature(s) Rachel Zimow

Signature(s) Ashley Waller

Signature(s) Kayla Bucher

Date 12/12/07

## TABLE OF CONTENTS

List of Tables.....	v
Acknowledgements .....	vi
Abstract .....	vii
Chapter I. Introduction.....	1
Chapter II. Literature Review.....	3
Chapter III. Methods.....	9
Chapter IV. Results	
Case One.....	14
Case Two.....	17
Case Three.....	20
Chapter V. Discussion/Conclusion.....	23
Appendices	
Appendix A.....	26
Appendix B .....	42
Appendix C.....	52
Appendix D.....	56
Appendix E.....	75
References.....	77

## LIST OF TABLES

Table	Page
1. Demographics.....	10
2. Initial and Follow-up Data for Case Study 1.....	17
3. Initial and Follow-up Data for Case Study 2.....	20
4. Initial and Follow-up Data for Case Study 3.....	23

## ACKNOWLEDGEMENTS

We would like to personally acknowledge and thank all faculty and staff at the Physical Therapy Department at the University of North Dakota for sharing their knowledge and supporting us professionally and personally over the past three years.

We would also like to give a special thanks to our advisor Dr. Cindy Flom-Meland for all her help and encouragement, and Lisa Martin, PT for devoting time and knowledge to our research project.

Finally, we would like to thank our families for all their love and support throughout this process.

## Abstract

### Effectiveness of Pelvic Floor Exercises in Women with Urinary Incontinence

Purpose: Urinary incontinence is common in women; especially those who have had one or more vaginal deliveries. The purpose of our case study was to measure the effectiveness of pelvic floor exercises and biofeedback in women with urinary incontinence (UI) in a rural midwest physical therapy clinic.

Methods: Patients participating in this study were referred to a physical therapy clinic by their physician for a urinary incontinence program. During the initial evaluations, baseline biofeedback readings were recorded and home exercise programs were given. Patients were then seen for follow-ups at approximately two weeks, four weeks, and three months thereafter. Final biofeedback testing and completion of the three inventories were performed at the three-month follow up.

Results: Due to a small sample size, we chose to display our results on an individual case basis. Case study 1 showed improvement subjectively, however, did not improve in objective measures. Case studies 2 and 3 showed improvement both in subjective and objective measures.

Discussion: Limitations of our study included a small sample size, rural community environment, lack of normative data for biofeedback, and time constraints. All three patients reported subjective improvement from the UI program, and the continuation of this study will help to determine the significance of this physical therapy intervention.



## Chapter I

### INTRODUCTION

Urinary incontinence (UI) affects 13 million Americans, 11 million of whom are women.<sup>1</sup> People with urinary leakage wait an average of seven to nine years to seek help because they are embarrassed or think it is a normal part of aging; while eighty percent of cases can be cured or improved.<sup>1</sup> Women's health is a growing area of the physical therapy practice, and physical therapy intervention is a conservative method for treating urinary incontinence.

#### PROBLEM STATEMENT

Surgery is a solution to this problem; however, a more conservative approach includes physical therapy. This approach, as an adjunct to surgery or on its own, can provide positive results in a less invasive, more convenient manner.

#### PURPOSE

The purpose of our study was to evaluate the outcomes of the UI physical therapy program at a rural, upper midwest physical therapy clinic. Based on past research conducted about pelvic floor exercises in patients with pelvic floor weakness, it has been shown to benefit patients with this condition.<sup>2,3,4</sup>

#### SIGNIFICANCE OF STUDY

This outcome study measured the effectiveness of a current UI program utilized at the rural midwest clinic, with the new addition of two quality of life questionnaires – the

Urinary Distress Inventory (UDI-6) and the Incontinence Impact Questionnaire (IIQ-7); and the Sandvik Incontinence Severity Index (ISI). These tools are discussed in detail in Chapter II. This study did not experiment with new exercises; instead, conservative exercises that were already being utilized in the clinic were used for the interventions. The patients experienced the same standard of care the clinic provides all of their patients with UI. Our research study was designed to evaluate the outcomes of conservative interventions for women with pelvic floor weakness and incontinence at this particular physical therapy clinic.

#### RESEARCH QUESTION

What is the effectiveness of pelvic floor exercises using results from biofeedback and scores from subjective outcome surveys measured pre- and post-physical therapy intervention?

#### HYPOTHESES

Null Hypothesis: Pelvic floor exercises do not have a significant effect on pelvic floor weakness and incontinence scores measured by the Urogenital Distress Inventory (UDI-6), Incontinence Impact Questionnaire (IIQ-7), Sandvik's Incontinence Severity Index, Urine Stream Interruption Test, and biofeedback.

Alternate Hypothesis: Pelvic floor exercises have a significant effect on pelvic floor weakness and incontinence scores measured by the Urogenital Distress Inventory (UDI-6), Incontinence Impact Questionnaire (IIQ-7), Sandvik's Incontinence Severity Index, Urine Stream Interruption Test, and biofeedback.

## Chapter II

### LITERATURE REVIEW

#### ANATOMY

The pelvic cavity is composed of an anteroinferior wall, two lateral walls, a posterolateral wall, a roof, and a floor. The floor consists of the coccygeus and levator ani muscles. The levator ani is one of the most important muscles of the pelvic floor, consisting of three parts: 1) puborectalis, 2) pubococcygeus, and 3) iliococcygeus.<sup>5</sup>

Urinary incontinence can be classified into four primary categories:<sup>6,7</sup>

1. *Stress incontinence* (SUI) occurs when the support for the bladder or urethra is weak or damaged, but the bladder itself is normal. With stress incontinence, there is involuntary loss of urine with activities that increase intraabdominal pressure such as coughing, sneezing, laughing, lifting, exercising, or any other type of physical exertion that increases pressure within the abdomen.
2. *Urge incontinence* (UUI), also known as overactive bladder, is the involuntary contraction of the detrusor muscle (smooth muscle of the bladder wall) with a strong desire to void (urgency) and loss of urine as soon as the urge is felt. Urge incontinence is often related to reduced bladder capacity or detrusor instability. It is often idiopathic but can be caused by medications, alcohol, bladder tumor, neurogenic bladder, or bladder outlet obstruction.

3. *Overflow incontinence* is the constant leaking of urine from a bladder that is full but unable to empty. The client with incontinence from overflow will often report a feeling that the bladder does not empty completely with an urge to void frequently, including at night.
4. *Functional incontinence* occurs in people who have normal urinary control, but who have difficulty reaching a toilet in time because of mobility or access deficits. In addition to the four categories named above, some people can present with more than one type of incontinence – most often stress and urge incontinence together – known as *mixed incontinence*.

Vaginal delivery is an important risk factor in the development of urinary incontinence. During childbirth, the fetal head is supported by the pelvic floor while the cervix is dilating to allow fetal delivery. The levator ani may become damaged due to stretching or tearing during childbirth. Abnormalities in the levator ani muscle are present on MRI after vaginal delivery.<sup>8</sup> As a result of continued muscle weakness, the position of the bladder and urethra may be altered which can potentially lead to stress urinary incontinence.

Women who have become pregnant are not the only population at risk for urinary incontinence; other contributing factors include gender, age, obesity, smoking, chronic constipation, and participating in high-impact sports, to name a few.

## EXERCISES

Physical therapists commonly treat pelvic floor dysfunction with conservative techniques including pelvic floor exercises (often referred to as Kegel exercises) and biofeedback therapy. Kegel exercises include both tonic and phasic contractions of the

levator ani muscles that draw the urethra, vagina, and rectum toward the pubic bone.<sup>9</sup> Physical therapy intervention also includes oblique abdominal strengthening. Research documents that conservative management is effective in treating many conditions associated with pelvic floor dysfunction.<sup>10</sup> Pelvic floor exercises help to strengthen the muscles that control the flow of urine and thus reduce the symptoms associated with urinary incontinence. Practice of pelvic muscle exercise by primiparas results in fewer urinary incontinence symptoms during late pregnancy and postpartum.<sup>11</sup>

Borello-France et al<sup>12</sup> concluded that exercise positions do not impact the outcome in regard to bladder diary, pad tests, urodynamic tests, IIQ, and pelvic floor muscle strength. They compared exercises done in supine only versus those done in both supine and upright positions (anti-gravity). This is contradictory to previous ideas that exercises performed in gravity-eliminated positions (supine) are less effective than those performed against gravity.

## BIOFEEDBACK

Biofeedback is a tool commonly employed by physical therapists with regard to a variety of conditions. In the case of pelvic floor dysfunction, biofeedback is used as an educational tool in order to teach patients to properly contract the muscles of the pelvic floor. Patients may choose from internal or external electrode placement, although the internal method is preferred as long as no contraindications exist. For external electrode placement, the therapist places the electrodes in a ten o'clock and four o'clock positions with reference to the anus. For internal placement, patients are instructed to insert it as they would a tampon, with the sensor tab facing upward. After application of the electrodes, patients are instructed to contract the pelvic floor muscles. As they are

contracting, muscle activity is simultaneously recorded in a computer software program and displayed upon a computer screen to allow the patient to see a visual representation of the muscle contraction. This, in theory, teaches the patient how to correctly perform pelvic muscle contractions without substitution from other muscle groups.

The biofeedback unit utilized at the clinic involved in this study is the Pathway MR-20. There is no normative data in available literature. However, the physical therapist involved in this study has found through her clinical practice a trend of resting tone of the pelvic floor musculature to be less than 3 mV when the patient is supine and less than 5 mV when the patient is sitting.

Capelini et al<sup>13</sup> conducted a study to evaluate the benefits of pelvic floor strengthening exercises associated with biofeedback for the treatment of stress urinary incontinence. The results concluded that treatment of incontinence with pelvic floor exercises using biofeedback caused significant changes in the parameters analyzed, with maintenance of good results three months after treatment. In addition, Glazer and Laine<sup>14</sup> critically reviewed 28 prospective, randomized studies with regard to pelvic floor muscle biofeedback in the treatment of urinary incontinence. The overall mean treatment improvement was 72.61%. In 21 of 35 paired comparisons, biofeedback demonstrated superior symptomatic outcomes versus control or alternate treatment groups.

#### QUALITY OF LIFE QUESTIONNAIRES: UDI-6 AND IIQ-7.

The Urinary Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ) are quality of life questionnaires that pertain to urinary incontinence. When used together, the UDI and the IIQ determine the effect that urinary incontinence has on women's lives more clearly than generic health-related quality of life scales.<sup>15</sup> The IIQ is

a “life-impact assessment instrument specific to urinary incontinence”<sup>16, pg.132</sup> and the UDI is “specific to symptoms associated with lower urinary tract dysfunction and genital prolapse.”<sup>16, pg.132</sup> For our study, the UDI-6 and the IIQ-7 were used, as they are quicker to administer and have been found to be valid in comparison to their longer counterparts (.93 and .97, respectively).<sup>16</sup> Both instruments are validated and useful in determining the efficacy of treatment of UI and are recommended by the Second International Consultation on Incontinence<sup>17</sup> (see Appendix C).

#### SANDVIK INCONTINENCE SEVERITY INDEX (ISI)

The Sandvik ISI consists of two questions that establish the frequency and amount of urine lost in women with UI. The frequency of urine lost is determined by the patient as less than once a month, a few times a month, a few times a week, or every day and/or night. The amount of urine lost is rated as drops or more. UI is then categorized as slight, moderate, or severe by multiplying the above scores (see Appendix C).

The ISI has been validated against pad weighing tests in several studies.<sup>18,19</sup> Hanley et al<sup>18</sup> determined that the ISI is valid, reliable, and sensitive to measure urinary incontinence in women, and therefore is recommended for routine use. The ISI has received the highest recommendation from the 2<sup>nd</sup> and 3<sup>rd</sup> International Consultations on Incontinence.<sup>19</sup>

Murphy et al<sup>20</sup> concluded the Sandvik Incontinence Severity Index (ISI) is highly correlated to the IIQ-7 and the UDI-6 in regard to post-treatment scores and percent change from pre- to post-treatment. However, the pre-treatment IIQ-7 and UDI-6 scores were not correlated to ISI scores.

## URINE STREAM INTERRUPTION TEST (UST)

The Urine Stream Interruption Test (UST), also referred by the primary physical therapist as the Functional Faucet Test, is used to determine the pelvic floor strength of women with stress urinary incontinence or to determine the effectiveness of a pelvic floor strengthening program. The goal of the UST is to stop the flow of urine mid-stream. The following were used as criteria for scoring: 0=no deflection or change in stream; 1=slight deflection; 2= able to slow urine stream; and 3= able to completely stop the flow. Based on theory, women suffering from SUI should not be able to stop the flow of urine secondary to weak pelvic floor muscles.

The UST was examined by Sartore et al<sup>21</sup> and was determined to be an effective outcome measure of women who have undergone treatment after a vaginal delivery. Other benefits include its low cost, non-invasive nature, and ability to provide objective information about pelvic floor muscles. However, other studies have not shown such positive results. Onyeka et al<sup>22</sup> concluded that the UST is a poor determinant of pelvic floor muscle function because 87% of the women in the study with SUI were able to perform the UST. They concluded it is not reliable to determine the success of treatment.

Urinary Incontinence is a common problem in many women. Based on current literature, physical therapy intervention is a positive and reliable treatment for women with urinary incontinence. The purpose of our study was to evaluate the outcomes of the UI physical therapy program at a rural, upper midwest physical therapy clinic.



## Chapter III

### METHODOLOGY

#### PARTICIPANTS

The patients that participated in this study included women who were referred to an upper midwest physical therapy clinic by their physician for a urinary incontinence program. Prior to beginning the program, all patients were given an explanation of the study and signed consent forms (see Appendix B).

Eligibility for this study included women over the age of 18 with pelvic floor weakness, stress UI, mixed UI (stress and urge), and uterine prolapse. Exclusion criteria were: males; women with post-surgical correction for urinary incontinence; state or local prisoners; and women with cognitive disabilities. This study was approved by the Institutional Review Board at the clinic facility and at the University of North Dakota (see Appendix A).

Demographics included in this study represented three women who had completed the program prior to this publication. Unfortunately, due to time constraints, the researchers were only allowed a short period of time to collect data on patients. However, this particular study is long-term and is currently ongoing to more accurately determine the outcomes of the pelvic floor program.

**Table 1. Demographics**

---

Total number of participants	3
Age range	40-57
Average age	50
Length of symptoms range	3wks-3yrs
Average number of childbirths	3
Mixed UI	3
Uterine prolapse	2

---

#### INSTRUMENTATION

Biofeedback was performed at the clinic using their personal instrumentation. Upon the patients' first appointments, they were instructed to complete two quality of life questionnaires and a severity index – the Short Form of the Incontinence Impact Questionnaire (IIQ-7), the short form of the Urogenital Distress Inventory (UDI-6), and the Sandvik's Incontinence Severity Index (ISI). The ISI is scored by multiplying the women's self-reported frequency of UI by the self-reported amount of urine leakage, and the women's self-perceived UI severity. The short form of the Urogenital Distress Inventory (UDI-6) is divided into 5 subscales: discomfort/pain; urinary incontinence; overactive bladder; genital prolapse; and obstructive micturition (see Appendix C). The IIQ and the UDI-6 were both recommended by the Second International Consultation on Incontinence and found to be valid.<sup>17</sup>

Biofeedback was performed at the initial examinations and again at approximately a three-month follow-up appointment. The desired resting tone biofeedback readings

measured in microvolts in the pelvic floor and gluteal musculature is less than 3 mV in supine or less than 5 mV in sitting. The patients chose to use external or internal biofeedback electrodes, depending on their preference and/or any existing contraindications. Biofeedback has been found to be reliable and of clinical use in outcome analyses of interventions for urogenital symptoms in women.

However, overall studies show that reliability and validity can be controversial for biofeedback. The physical therapist in our study treated all three patients, ensuring reliability through biofeedback and external electrode placement. If the patient chose to have internal electrode placement, it was inserted by the patient privately. The clinician assured correct electrode placement on the patient prior to biofeedback readings.

#### PROCEDURE

All patient interventions were based on the clinic's current standard of care. The patients received a letter and brochure from the clinic regarding the details of the urinary incontinence program. This was done to increase the patients' awareness of the program and to assure they did not have any questions prior to the examination and intervention. All of the questionnaires, including the IIQ-7, UDI-6, and the Sandvik Severity Index were given at the time of each patient's first appointment (see Appendix C). These outcome tools were used along with subjective and objective data to collect pre-physical therapy intervention data on the patients. These data included a general medical history, brief obstetrical history (past pregnancies, miscarriages, vaginal deliveries, etc.), brief urogynecologic history (prior urinary tract infections and incontinence issues), prior surgical history, Functional Faucet Test estimate, and biofeedback testing of the pelvic floor (see Appendix E).

Prior to biofeedback testing, all patients were educated in the function of the pelvic floor and received a brief overview of the anatomy through a pictorial diagram (see appendix D). Standard positioning was utilized for all patients in the gravity-eliminated position (supine). Handouts were given to the patient to imagine the pelvic floor as a hammock for the bladder. The patient was instructed to maintain relaxed breathing and to avoid talking or lower extremity movement during testing. Specifics in regard to ratio of work/rest and positioning were individualized based on the Functional Faucet Test score or whether a prolapse was noted per the physician. Contraindications for biofeedback use with an internal electromyographic (EMG) sensor were read to the patient. If no contraindications were noted, the patient privately inserted the sensor. External electrodes were considered if the patient was not comfortable using the internal electrodes or if internal electrodes were contraindicated. Placements of the external electrodes were at a ten o'clock and four o'clock position with reference to the anus. For internal electrode placement, patients were instructed to insert it as they would a tampon, with the sensor tab facing upward. Two channels were used during the biofeedback testing – channel A (pelvic floor) and channel B (right lateral gluteal region). Throughout the biofeedback testing, patients were educated on the proper firing of the pelvic floor muscles, both isolated phasic and tonic contractions (type one and two fibers), without gluteal substitution. This testing was used for EMG baseline strength, for increasing the patient's sensory input for accuracy in performing kegel contractions, and for providing patient education for increased awareness of the pelvic floor.

After biofeedback testing, all three patients received their initial written and illustrative exercise program handout and proper demonstration of exercises (see

Appendix D). A walking program was also advised with emphasis on the patient performing transversus abdominus stabilization during ambulation. Patients were asked to fill out a walking log, with the goal of a minimum of three times per week for thirty minutes (see Appendix D). Patients with urge UI were educated in their pathology including: urge urinary suppression techniques; use of a bladder diary; education on normal bladder habits; and avoidance of bladder irritants (see Appendix D).

After the initial session, the patients were seen at approximately two weeks, four weeks, and three months thereafter. Final biofeedback testing and completion of the three inventories were performed at the three-month follow up.

#### DATA COLLECTION

Outcome data was collected via chart review by the student researchers and faculty advisor on-site at the physical therapy clinic. A form was developed to quickly and easily gather the data from each patient's initial and final examination physical therapy notes (see Appendix E).

#### DATA ANALYSIS

Simple descriptive statistics were used to analyze data for this study. Comparisons were made between scores from the initial and final testing results.

#### REPORTING OF RESULTS

Upon completion of this study, a summary of results were given to the University of North Dakota Department of Physical Therapy, the Harley E. French Library of Health Sciences, and to all of the researchers involved in the study. This study was completed as partial fulfillment of requirements for the University of North Dakota School of Medicine and Health Sciences Physical Therapy Program.

## Chapter IV

### RESULTS

The following results are displayed as an outcome study based on chart reviews of three separate patients. The results were not compared between patients, but were based on each patient's baseline to final biofeedback results, Sandvik Severity Scale, UDI-6, IIQ-7, and subjective reports of improvement.

#### CASE STUDY 1

The patient in case one was a 53 year-old female who was post-menopausal and presented with symptoms of mixed urinary incontinence, stress UI being the primary complaint and urge UI being the secondary complaint. Symptoms for this patient were brought on with coughing, sneezing, laughing, lifting, and exercise. Frequency of urination was seven times per day or greater. The onset of symptoms began about 1.5 years prior to her initial examination. The patient's general medical history was unremarkable, but obstetrical/urogynecological history revealed that she was a multipara who vaginally delivered two children, the largest weighing six pounds and one ounce. Neither delivery required an episiotomy or the use of forceps. Medications/supplements for this patient included occasional aspirin as needed, multivitamins, and additional vitamin E. She was a non-smoker who consumed caffeine (one cup of coffee per day) on a regular basis and alcohol on occasion. She also took in approximately 72 ounces of non-caffeinated fluid daily. Prior to the onset of her urinary incontinence, the patient was

participating in aerobic exercise four to seven times per week and also walking five miles two to three times per week. After the onset of urinary incontinence, her frequency of activity declined to zero to three times per week.

#### EXAMINATION AND INTERVENTION

Initial and final examination results are reported in Table 2. The patient was given standard protocol exercises as described in the methods section.

#### FINAL EXAMINATION

The patient reported feeling 50% better at this time, although the urge UI was still present. At final examination, the patient was walking one time per week for three and a half miles. She was also attempting aerobics two times per week and noted no UI during exercise. However, she planned her fluid intake around these activities. Biofeedback changes from initial to final showed that while her pelvic floor muscle contractions were slightly weaker, she was using less gluteal substitution. Her UDI-6 score did not change during the three months, but her IIQ-7 decreased from 28.57 to 19.05.

**Table 2. Initial and Follow-up Data for Case Study 1**

	<b>Initial</b>	<b>Final</b>
Height (inches)	60	60
Weight (pounds)	110	112.5
Body Mass Index	21.5	22
UST Score	2-	2+
ISI Score	8	8
UDI-6	50/100	50/100
IIQ-7	28.57/100	19.05/100
Voiding at night	Not available	Not available
Biofeedback electrode placement	Internal	Internal
Biofeedback: Pelvic Floor (Resting Tone)	4.5mV	5.01mV
Biofeedback: Pelvic Floor (Phasic)	13.4mV	11.4mV
Biofeedback: Pelvic Floor (Tonic)	13.1mV	11.4mV
Biofeedback: Gluteals (Resting Tone)	1.04mV	unknown
Biofeedback: Gluteals (Phasic)	2.33mV	.70mV
Biofeedback: Gluteals (Tonic)	3.70mV	.74mV
Tonic Holding Ability	Not available	Not available
Work-Rest (Phasic)	3.25mV	1.49mV
Work-Rest (Tonic)	6.95mV	4.12mV



## CASE STUDY 2

The patient in case two was a female of 57 years who was post-menopausal and presented with symptoms of mixed urinary incontinence, stress UI being the primary complaint and urge UI being the secondary complaint. Symptoms of stress UI began gradually over the past two years prior to the initial examination. Urgency was brought on approximately four weeks preceding the examination. General medical history for this patient revealed that she had undergone three breast biopsies, none of which were recent. She also related sacroiliac/low back pain. With regard to obstetrical/urogynecological history, she reported occasional dyspareunia (painful intercourse) and had a mild uterine prolapse. She was a multipara who gave birth four times to five children (one set of twins). She underwent a cesarean section for the twin birth. There were a total of two episiotomies and two forceps deliveries throughout all four births. The largest child weighed in at 9 pounds and 12 ounces. Her medications included Lexapro, Lipitor, Lorazepam, and Imipramine. She was a non-smoker who regularly consumed fluids that are known irritants to the bladder such as pop and green tea, in addition to occasional alcohol. Non-caffeinated fluid intake was approximated at 20 ounces per day. Activity level prior to symptoms of UI consisted of a walking program. At the time of the initial examination, the patient was participating in a *Curves*® program three times per week with low impact activities in addition to walking four to five times per week for one to two miles each session.

## EXAMINATION AND INTERVENTION

Initial and final examination results are reported in Table 3. The patient was given standard protocol exercises as described in the methods section.

## FINAL EXAMINATION

The patient reported feeling 60% better at this time, with absence of SUI. She participated in exercise five times per week for 45 minutes and a home exercise program was completed daily. Biofeedback changes from initial to final showed that her pelvic floor muscle contractions increased along with her gluteal substitution. Both her UDI-6 and IIQ-7 decreased over the three-month period going from 44.44 to 16.67, and 14.29 to 0, respectively.

**Table 3. Initial and Follow-up Data for Case Study 2**

	<b>Initial</b>	<b>Final</b>
Height (inches)	64.5	64.5
Weight (pounds)	165	163
Body Mass Index	27.9	27.5
UST Score	3	Not Available
ISI Score	4	2
UDI-6	44.44/100	16.67/100
IIQ-7	14.29/100	0/100
Voiding at night	3 times	3 times
Biofeedback electrode placement	External	External
Biofeedback: Pelvic Floor (Resting Tone)	1.38mV	2.34mV
Biofeedback: Pelvic Floor (Phasic)	6.45mV	12.3mV
Biofeedback: Pelvic Floor (Tonic)	8.94mV	14.2mV
Biofeedback: Gluteals (Resting Tone)	.84mV	Not Available
Biofeedback: Gluteals (Phasic)	1.04mV	3.50mV
Biofeedback: Gluteals (Tonic)	1.44mV	2.65 mV
Tonic Holding Ability	5 seconds	Not Available
Work-Rest (Phasic)	3.72mV	4.29mV
Work-Rest (Tonic)	6.86mV	11.0mV

### CASE STUDY 3

The patient in case three was a female, aged 40, who had a diagnosis of mixed urinary incontinence and uterine prolapse. Her primary complaint was urge UI, which had been present for the past three years. She also had a secondary complaint of stress UI with symptoms existent for three months preceding the initial evaluation. Frequency of urination was approximately ten times per day, with two to three urinations at night. General medical history revealed that this patient had undergone a laparoscopy and a scoping of her right knee about two years prior to the examination. With regard to obstetrical/urogynecological history, she was diagnosed with pelvic inflammatory disease, and also dyspareunia. This patient had eight pregnancies, three miscarriages, two abortions and three completed full term births. The largest child weighed eight pounds and ten ounces. One delivery required an episiotomy. She also reported a history of abuse. She was a non-smoker who consumed up to four caffeinated beverages on a regular basis and alcohol on occasion. Current exercise at the time included biking for 30 minutes every other day.

### EXAMINATION AND INTERVENTION

Initial and final examination results are reported in Table 4. The patient was given standard protocol exercises as described in the methods section.

### FINAL EXAMINATION

The patient reported feeling 50% better at this time. She was walking one to two miles, four times per week and her home exercise program was performed two to three times a week. She also lost 13.5 pounds over the three-month period. Biofeedback changes from initial to final show that her pelvic floor muscle contractions increased

along with her gluteal substitution. Both her UDI-6 and IIQ-7 decreased over the three-month period, changing from 50 to 44.44 and 28.57 to 9.52, respectively.

**Table 4. Initial and Follow-up Data for Case Study 3**

	<b>Initial</b>	<b>Final</b>
Height (inches)	64.25	64.25
Weight (pounds)	206	192.5
Body Mass Index	35.1	32.8
UST Score	2	2+-3
ISI Score	8	4
UDI-6	50/100	44.44/100
IIQ-7	28.57/100	9.52/100
Voiding at night	2-3 times	1-2 times
Biofeedback electrode placement	Internal	Internal
Biofeedback: Pelvic Floor (Resting Tone)	1.79mV	1.95mV
Biofeedback: Pelvic Floor (Phasic)	13.6mV	15.9mV
Biofeedback: Pelvic Floor (Tonic)	19.0mV	23.4mV
Biofeedback: Gluteals (Resting Tone)	.31mV	unknown
Biofeedback: Gluteals (Phasic)	.39mV	.81mV
Biofeedback: Gluteals (Tonic)	.51mV	.93mV
Tonic Holding Ability	7 seconds	9 seconds
Work-Rest	15.5	21.5

## Chapter V

### DISCUSSION/CONCLUSION

Patient one reported feeling 50% better at discharge. Her frequency of exercise increased to walking one time per week and also performing aerobics two times per week, without reports of urinary incontinence. Although biofeedback testing revealed that her pelvic floor muscles were weaker than at the initial evaluation, she was able to decrease substitution by the gluteal muscles. With regard to the IIQ-7, she did show improvement.

The second patient reported a 60% improvement at completion of the program, with complete elimination of stress urinary incontinence. Her pelvic floor muscle strength improved, but she also used more gluteal muscle substitution. The scores for the UDI-6 and IIQ-7 both decreased, which was a positive effect.

The third and final patient also stated that she felt 50% better at discharge. She increased her pelvic floor muscle strength, but she also increased the usage of her gluteals. In addition, there were decreases in symptoms reported on both the UDI-6 and IIQ-7.

With respect to reporting changes in scores for these three patients, there was some concern. The numbers that were assigned to each patient's score on the questionnaires had no inherent mathematical relationship. In other words, they were nothing more than a categorical label and had no arithmetic properties. Therefore, they were not interpretable for our purposes.<sup>23</sup> We were able to report increases or decreases

in performance, but we could not necessarily state the patients' levels of improvement unless it was their own subjective reports.

These three case reports demonstrate the effects that pelvic floor exercises can have on symptoms of urinary incontinence. Although there were not large changes with regard to the results of biofeedback readings, all three patients had subjective reports of feeling at least 50% better at discharge. A patient's perception of his/her own condition can be as valuable, or even more valuable, than objective measurements. If a patient shows significant changes in objective measures but does not necessarily "feel better," then the outcome of the treatment cannot truly be successful.

Several limitations were noted with this study, the first being a very small sample size. Our intention was to design an outcome study to investigate the effectiveness of pelvic floor exercises, but due to the limited number of participants, using a case study format was the only plausible alternative.

Another drawback to our study was the lack of normative data for biofeedback readings. The therapist that worked with the three patients has normative data that was provided to her when the biofeedback system was purchased. She uses these numbers to evaluate the effectiveness of her intervention program, but there are no normative guidelines in scientific literature with respect to biofeedback that we are aware of. Because of this, it is impossible to ascertain whether or not the results are significant.

The final limitation that we noted was the narrow time frame. New patients were only eligible to participate between the months of June and August of 2007. Information was recorded at the initial examination and approximately three months later. Long-term effects of the intervention program are unknown.



There are several options for improving the design of a future study similar to this one. Conducting the research in a more populated area would ensure a more optimal number of participants. If the researcher would want to determine the significance of the results, he/she would have to establish normative data with regard to biofeedback. Also, long-term effectiveness could be verified by follow-up examinations at perhaps six months or one year post-intervention.

Urinary incontinence is not a rare occurrence in women, especially in those who have become pregnant. Fortunately, physical therapy intervention utilizing exercise therapy can help improve symptoms in most of these cases, therefore eliminating the need for surgical intervention for many patients. Although the symptoms of urinary incontinence can often be decreased, many women do not seek help due to feelings of embarrassment about their condition. In more recent years, though, the physical therapy specialty field of women's health has continued to expand, resulting in more women becoming aware of treatment options for many women's issues.

## Appendix A

University of North Dakota Human Subjects Review Form

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University's policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the "IRB Checklist" for additional guidance.

Please provide the information requested below:

**Principal** Cindy Flom-Meland  
**Investigators:** \_\_\_\_\_  
Telephone: (701) 777-4130 E-mail Address: cfmeland@medicine.nodak.edu  
Complete Mailing Address: Stop 9037  
School/College: University of North Dakota School of Medicine and Health Sciences Department: Department of Physical Therapy

**Student Adviser (if applicable):** Cindy Flom-Meland, PT, PhD, NCS  
Telephone: (701) 777-4130 E-mail Address: cfmeland@medicine.nodak.edu  
Address or Box #: Stop 9037  
School/College: University of North Dakota School of Medicine and Health Sciences Department: Department of Physical Therapy

Project Title: Effectiveness of Pelvic Floor Exercises in Women with Urinary Incontinence

Proposed Project Dates: Beginning Date: May 2007 Completion Date: December 2009  
(Including data analysis)

Funding agencies supporting this research: \_\_\_\_\_

Did the contract with the funding entity go through UND Grants and Contracts Administration?  YES or  NO  
Attach a copy of the contact. Do not include the any budgetary information. The IRB will not be able to review the study without a copy of the contract with the funding agency.

Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

YES  or  NO

Will research subjects be recruited at another organization (e.g., hospitals, schools, YMCA) or will assistance with the data collection be obtained from another organization?

YES  or  NO

If yes, list all institutions: \_\_\_\_\_

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands their involvement in that study, and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on letterhead.

Does any external site where the research will be conducted have its own IRB?  YES  NO  N/A

If yes, does the external site plan to rely on UND's IRB for approval of this study?  YES  NO  N/A  
(If yes, contact the UND IRB at 701 777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

_____	Date submitted: April 2007	Status: <input type="checkbox"/> d <input checked="" type="checkbox"/> Pending
_____	Date _____	Status: <input type="checkbox"/> Approve <input type="checkbox"/> Pending

**Type of Project:** Check "Yes" or "No" for each of the following.

YES  or  NO New Project  YES or  NO Dissertation/Thesis/Independent Study

YES  or  NO Continuation/Renewal  YES or  NO Student Research Project

YES  or  NO Is this a Protocol Change for previously approved project? If yes, submit a signed copy of this form with the changes bolded or highlighted.

YES  or  NO Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.

YES  or  NO Does your project include Genetic Research?

YES  or  NO Does your project include Internet Research?

**Subject Classification:** This study will involve subjects who are in the following special populations: Check all that apply.

- Children (< 18 years)
- Prisoners
- Persons with impaired ability to understand their involvement and/or consequences of participation in this research
- Other \_\_\_\_\_
- UND Students
- Pregnant Women/Fetuses

Revised 10/15/06 2

Please use appropriate checklist when children, prisoners, pregnant women, or people who are unable to consent will be involved in the research.

This study will involve: Check all that apply.

- |   |  |
|---|--|
| <input type="checkbox"/> Deception (Attach Waiver or Alteration of Informed Consent Requirements) | <input type="checkbox"/> Stem Cells            |
| <input type="checkbox"/> Radiation  | <input type="checkbox"/> Discarded Tissue      |
| <input type="checkbox"/> New Drugs (IND) IND # _____ Attach Approval                              | <input type="checkbox"/> Fetal Tissue          |
| <input type="checkbox"/> Investigational Device Exemption (IDE) # _____ Attach Approval           | <input type="checkbox"/> Human Blood or Fluids |
| <input type="checkbox"/> Non-approved Use of Drug(s)  | <input type="checkbox"/> Other _____           |
| <input checked="" type="checkbox"/> None of the above will be involved in this study              |  |

### I. Project Overview

The purpose of our study is to measure the effectiveness of pelvic floor exercises and biofeedback on women with pelvic floor weakness and incontinence in a rural Physical Therapy clinic. Based on past research conducted about pelvic floor exercises in patients with pelvic floor weakness, it has been shown to benefit subjects with this condition. We want to reinforce that the exercises being performed at \_\_\_\_\_ are statistically beneficial for their patients. Conservative exercises are already being utilized in the clinic. This study does not experiment with new exercises. The patients will be experiencing the same standard of care that \_\_\_\_\_ provides all of their patients with pelvic floor weakness and prolapse.

### II. Protocol Description

Please provide a succinct description of the procedures to be used by addressing the instructions under each of the following categories.

#### 1. Subject Selection.

- a) Women with pelvic floor weakness, Stress UI, Mixed Urinary Incontinence (UI) (stress and urge) and prolapse, referred to \_\_\_\_\_ by a physician. The period that subjects will be recruited is from May 2007 until December 2009.
- b) Subjects will be referred to \_\_\_\_\_ for PT by a Physician. Subject acceptance will be determined by the Physical Therapist's discretion (Women with pelvic floor weakness, Stress Urinary Incontinence, Mixed Urinary Incontinence (stress and urge) and prolapse). Participation in this study is voluntary for the patients.
- c) Subjects excluded include: males, women post-surgical correction for UI, history of pelvic cancer, severe endometriosis, and use of an intrauterine device.
- d) About two hundred subjects will be recruited. The physical therapist we are working with states she acquires about one new patient with pelvic floor problems per week.
- e) Power analysis was not completed.

#### 2. Description of Methodology.

- a) We devised an informed consent form through the University of North Dakota and also (see attached).
- b) The examination will be performed at \_\_\_\_\_ by the Physical Therapist. Students from UND will be collecting data at the \_\_\_\_\_ facility through chart review and running statistical tests at the University.

Revised 10/15/06 3

- c) Cindy Flom-Meland, PT, PhD, NCS; Lisa Martin, MPT; Brittany Carter, SPT; Kayla Bucher, SPT; Rachel Hanson, SPT; Ashley Waller, SPT
- d) All subjects referred for PT at the \_\_\_\_\_ for UI will receive a general letter and brochure from the clinic regarding the program and the research study. Informed consent and outcome questionnaires (see attached) will be completed at the time of the subject's arrival on admit. Physical therapy intervention will be carried out by Lisa Martin, MPT as per standard of care at the clinic. Data collection via chart review will be conducted by Cindy Flom-Meland, PT and student research assistants (listed in 'f' below). Data collected from the charts will consist of the three outcome questionnaires and examination information (please see data collection form). Data will be collected upon admission and at discharge from PT services (at approximately 3 months post initial visit).
- e) Not applicable.
- f) Lisa Martin, MPT, has been a physical therapist for 15 years. She has received advanced training in the area of women's health specifically physical therapy for urinary incontinence. Cindy Flom-Meland has been a physical therapist for 16 years and has been involved in research for the past 8 years. Kayla Bucher, Brittany Carter, Rachel Hanson and Ashley Waller are all students of physical therapy and are participants in this scholarly project in partial fulfillment towards their DPT.
- g) There is no compensation for the subjects involved in this study.

*Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.*

### 3. Risk Identification.

- a) This type of exercise is considered low-risk, however, with any form of exercise; there can be some risk for injury. If injury should occur, you and your third party payer will be responsible for all charges. There might also be some mild discomfort regarding placement of internal muscle activity equipment if you choose to do so. This discomfort should be minimized with use of visual aides and education of procedure.
- b) Each subject will be given a code that will go on the consent and all PT forms. This code will remain constant throughout the study in order to assess efficacy of treatment from evaluation to three months of therapy.
- c) There is no research that involves greater than minimal risk.
- d) Does not apply.

### 4. Subject Protection.

- a) Each subject will be given a description of the procedure and its risks and benefits and be asked to sign a consent form. The subjects will be assured that the procedures of the study are the typical standard of practice for their condition and that the researchers are measuring treatment effectiveness with use of the outcome assessments.
- b) Each subject will be given a code that will go on the consent and all PT forms. This code will remain constant throughout the study in order to assess efficacy of treatment from evaluation to three months of therapy.
- c) The PT will provide the subjects with a copy of the consent form at their initial examination.
- d)
  - 1) Research data will be stored in a locked file in a locked office for three years. The research data will be

Revised 10/15/06 4

kept separate from the consent forms and subject personal data.

- 2) The principal investigators and collaborators will have access to the data. (Cindy Flom-Meland, Lisa Martin, Kayla Bucher, Brittany Carter, Rachel Hanson and Ashley Waller).
- 3) Three years after completion of the study data will be shredded.
- 4) Consent forms and personal data will be stored in a locked file in a locked office for three years. The consent forms and subject personal data will be kept separate from the research data.
- 5) Three years after completion of the study consent forms will be shredded.

- e) Since this study is investigating typical physical therapy interventions any adverse reactions will be handled in a usual way. Adverse reactions to these procedures are rare, but in the event one does occur, the subject will be referred back to see her physician. There might also be some mild discomfort regarding placement of internal muscle activity equipment, if the subject chooses internal placement. This discomfort should be minimized with the use of visual aides and education of procedure.
- f) This type of exercise is considered low-risk, however, with any form of exercises; there can be some risk of injury. If injury should occur, the subject and their third party payer will be responsible for all charges. As stated above subject will be referred back to her physician if there are any adverse reactions.

**III. Benefits of the Study**

Conservative exercises are already being utilized in the clinic. Our research study is designed to evaluate how effective the conservative treatment in women with pelvic floor weakness and incontinence. This study does not experiment with new exercises. The patients will be experiencing the same standard of care that provides all of their patients with pelvic floor weakness and prolapse.

**IV. Consent Form**

See attached

**Necessary attachments:**

- Signed Student Consent to Release of Educational Record Form (students only);
- Investigator Letter of Assurance of Compliance;
- Consent form, or Waiver or Alteration of Informed Consent Requirements (Form IC 702-B)
- Surveys, interview questions, etc. (if applicable);
- Printed web screens (if survey is over the Internet); and
- Advertisements.

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

**Signatures:**

Cindy Flom-Meland 4-30-07  
 (Principal Investigator) Date:

\_\_\_\_\_  
 (Student Adviser) Date:

**INVESTIGATOR LETTER OF ASSURANCE OF COMPLIANCE  
WITH ALL APPLICABLE FEDERAL REGULATIONS FOR THE  
PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS**

I Cindy Flam-Meland  
(Name of Investigator)

agree that, in conducting research under the approval of the University of North Dakota Institutional Review Board, I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. Specific regulations include the Federal Common Rule for Protection of the Rights of Human Subjects 45 CFR 46. I will also assure compliance to the ethical principles set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research document, The Belmont Report.

I understand the University's policies concerning research involving human subjects and agree to the following:

1. Should I wish to make changes in the approved protocol for this project, I will submit them for review PRIOR to initiating the changes. (A proposal may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subjects or others. However, the IRB must be notified in writing within 72 hours of any change, and IRB review is required at the next regularly scheduled meeting of the full IRB.)
2. If any problems involving human subjects occur, I will immediately notify the Chair of the IRB, or the IRB Coordinator.
3. I will cooperate with the UND IRB by submitting Research Project Review and Progress Reports in a timely manner.

I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.

Cindy Flam-Meland  
Investigator Signature

4-30-07  
Date



**HIPAA Compliance Application**

Research Development and Compliance, University of North Dakota

PO Box 7134, Twamley Hall, Room 105, Grand Forks, North Dakota 58202

FWA-00000376/IRB-00001040

Phone: (701) 777-4279/ Fax: (701) 777-6708 <http://www.und.nodak.edu/dept/orpd/regucomm/IRB/index.html>

<b>PROJECT TITLE</b> Effectiveness of Pelvic Floor Exercises in Women with Urinary Incontinence
<b>PRINCIPAL INVESTIGATOR</b> Flom-Meland, Cindy

Please complete this form if you intend to use/disclose protected health information (PHI) in your research. PHI is health information transmitted or maintained in any form or medium that: identifies or could be used to identify an individual; is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual

An investigator may access PHI using one or more of the following methods. Unless otherwise noted, you should complete this entire form as applicable.

**A. Please check the appropriate box(es) for your specific research.**

- 1.  **De-identified Information:** De-identified Information is health information that cannot be linked to an individual. Research which involves the use of "de-identified" PHI is exempt from HIPAA requirements. The HIPAA Privacy Rule regulations [45 CFR 164.514(b)] lists 18 specific identifiers that must be removed from the health information before the researcher obtains the information for it to be considered not identifiable. The list includes: Name/initials; Street address, city, county, precinct, zip code and equivalent geocodes; All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death); Elements of date, including year, for persons 90 or older; Telephone number; Fax number; Electronic mail address; Social Security Number; Medical record numbers; Health plan identification numbers; Account numbers Certificate/license numbers; Vehicle identifiers and serial numbers, including license plate numbers; Device identifiers and serial numbers; Web addresses (URLs); Internet IP addresses; Biometric identifiers, including finger and voice prints; Full face photographic images and any comparable images; Any other unique identifying number, characteristic or code.

If the research does not include access to any of the above identifiers, sign the certification at the bottom of the page. The HIPAA privacy regulations do not apply and you are not required to complete the rest of the application.

(Sign and Date this section only if the research involves De-Identified Information)

I certify the PHI received or reviewed by research personnel for the research referenced above does not include any of the identifiers listed above.

Principal Investigator Signature

Date

2.  **Limited Data Set:** A limited data set is a subset of information (PHI) that only contains the following identifiers linked to the subject: city, state, zip code, or elements of date such as date of birth, death or service. The other specific identifiers included in the list above may not be included in the health information that is being received by the research team. The use of a Limited Data Set requires a Data Use Agreement to be in place. The Data Use Agreement is a legal contract between the covered entity and the recipient.
3.  **Patient Authorization:** A patient authorization is a document, signed by the subject that gives the researcher permission to use/disclose PHI collected during the research study for defined purposes. An Authorization Form needs to be prepared in addition to the Informed Consent Document. The authorization information may also be addressed in the consent form. Please prepare the Authorization Form and submit it with your IRB application.
4.  **Waiver/Alteration:** A waiver/alteration is a request to forgo the authorization requirement based on the fact that the use and/or disclosure of PHI involves minimal risk to the subject's privacy and the research cannot be practically done without this waiver/alteration and access to/use of PHI. Refer to Section H to see if you may qualify for a waiver/alteration. Please designate if a waiver is being sought for initial recruitment purposes or for the entire research protocol.

Once a waiver of Authorization is granted, contact your source of PHI (i.e. Health Information Management) to ensure that you follow the accounting procedures established as required by the Privacy Rule. Per the Privacy Rule, the covered entity must receive documentation of the waiver/alteration before PHI can be used or disclosed for the research.

The categories listed below are additional opportunities allowed under the HIPAA Privacy Rule to view/record PHI without prior individual authorization.

5.  **Reviews Preparatory to Research:** Preparatory work is when PHI is reviewed for the purpose of designing a research study or identifying potential subjects. No information may be removed from the records.
6.  **Research on Decedent's Information:** Decedent research is when PHI is collected from deceased (prior to the study) patients/subject's records.

**B. Provide a description of the Protected Health Information (PHI) to be used or disclosed for your research:**

age, gender, onset of diagnosis, number of pregnancies (full term, miscarriage, and abortion), number of vaginal deliveries, height, weight pre-treatment, weight post-treatment, Body Mass Index pre-treatment, Body Mass Index post-treatment, bladder irritants, prior exercise/activity level, current exercise/activity level, obstacles to exercising, non-caffeinated fluid intake, primary complaint, secondary complaint, sacroiliac or low back pain issues, abuse history, psych/social/sexual history, exercise/walking log (Home Exercise Program), patient satisfaction survey responses, Sandvik Incontinence Severity Index Scores (ISI), Urogenital Distress Inventory Scores (UDI-6), Incontinence Impact Questionnaire Scores (IIQ), electrode placement (internal vs. external), biofeedback scores, Urine Stream Interruption Test Scores, general medical history, brief obstetrical/urogynecologic history, brief surgical history, and medications/supplements.

**C. Source and Data Collection**

1. Indicate your sources of health information:

<input type="checkbox"/> Data containing no health information*	<input checked="" type="checkbox"/> Hospital/medical records (in and out patient)
---	---

<input type="checkbox"/>	Physician/clinic records	<input type="checkbox"/>	Psychotherapy Notes
<input type="checkbox"/>	Lab, pathology and/or radiology results	<input type="checkbox"/>	Data previously collected for research purposes
<input type="checkbox"/>	Biological samples	<input type="checkbox"/>	Billing records
<input checked="" type="checkbox"/>	Interviews/Questionnaires	<input type="checkbox"/>	Other (describe below)

*\*If the research does not include PHI, the HIPAA Privacy Rule regulations do not apply to this research study and you do not need to finish this form. Please be sure to note on your initial review protocol application that the research does not include PHI.*

**2. Indicate how the research team will access and/or receive health information:**

- With limited identifiers: ZIP codes, geocodes, dates of birth, or other dates only.  
*The study qualifies as a Limited Data Set and requires a Data Use Agreement.*
- With a code that can be linked to the identity of the subject.\*  
*The research includes PHI because the research team will have health information with identifiers.*
- With unrestricted identifiers.\*

*\*Requires Consent and Authorization from the subject or a Waiver of Consent and Waiver of Authorization from the IRB.*

**3. Indicate how the research team will record health information:**

- Without any direct or indirect identifiers – as a de-identified data set
- With limited identifiers: ZIP codes, geocodes, dates of birth, or other dates only.
- With a code that can be linked to the identity of the subject.
- With unrestricted identifiers

**D. Summary:** *Briefly summarize the collection, use and sharing of PHI for this research study.*

All PHI in this study will be collected through private chart reviews and recorded on a data sheet kept at the University of North Dakota Physical Therapy Department. It will be reviewed and recorded by Cindy Flom-Meland, and Brittany Carter, Ashley Waller, Rachel Hanson, and Kayla Bucher- students of physical therapy at UND. The information collected and the individual results will only be shared between the researchers and Lisa Martin MPT who will be the physical therapist providing the interventions.

**E. Recruitment:** *Please mark all that apply:*

1. PI/collaborators will recruit his/her/their own patients.
2. PI will send an IRB approved letter to colleagues asking for referrals of eligible patients. The treating physician will make initial patient contact. If the patient is interested, the patient will contact the PI.
3. PI will send an IRB approved letter to colleagues asking the physician to send out IRB approved general "Dear Patient" letters describing the research study. *The PI may draft the letter with the treating physicians' signature, but may not have access to the patient names or addresses for mailing. If the PI wants the letters to be personalized (Dear Mr. Doe), the personal information would have to be entered by the treating physician.*
4. Advertisements/media. *All recruitment materials must have IRB approval.*
5. The PI requests an initial Waiver of Authorization for the purpose of identifying subjects for recruitment purposes including (with permission of the patient) the treating physician will invite the PI/research team to talk with the patient about enrollment. Be sure and complete section H.

6. Other, please specify:

**F. PHI Sharing:**

1. Indicate who may receive PHI during the course of the research study.

<input checked="" type="checkbox"/> Statistician	<input type="checkbox"/> Consultants
<input checked="" type="checkbox"/> Colleagues (s) / Collaborators	<input type="checkbox"/> Data, Tissue, Specimen Registry(s)
<input type="checkbox"/> Other Research Laboratory (s)	<input type="checkbox"/> Sponsor / Funding Agency
<input type="checkbox"/> Study Data Coordinating Center	<input checked="" type="checkbox"/> Publication (s)
<input type="checkbox"/> Other. <i>please specify:</i>	

2. Indicate how the data will be shared or disclosed.

- Without any identifiers.  With a linked code\*.  
 With identifiers\*.  As a Limited Data Set\*.

\* In this format, Authorization must specifically note who data will be shared or disclosed to.

**G. Data Security:** Describe how the data will be secured. *Please mark all that apply.*

1. Electronic data:

- secure network  password access  coded, with a master list secured and kept separately  
 other (specify):

2. Hardcopy data:

- locked suite  locked office  locked file cabinet  
 data coded by PI or research team with a master list secured and kept separately.  
 data de-identified by PI or research team  
 other: (specify)

**H. Waiver/Alteration of Authorization** [Complete this section to request a waiver of authorization for the entire research protocol, for recruitment purposes, or to request an alteration of authorization process such as no signed documentation].

1. Describe the protected health information (PHI) for which use, access, or disclosure is necessary. Include a detailed list of the PHI and also a list of the sources.

2. Criteria for Waiver/Alteration of Authorization:

A. Explain how the use and disclosure of the information presents no more than minimal risk to the privacy of the individual.

B. Describe the plan to protect the identifiers from improper use and disclosure (i.e., where will the identifiers will be stored and who will have access).

- C. Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. If there is a health or research justification for retaining identifiers or if such retention is required by law, please provide this information as well.
  
- D. Explain why the research could not be practicably conducted without the alteration or waiver.
  
- E. Explain why the research could not be conducted without access to and use of the PHI.
  
- F. The Privacy Rule requires that when a waiver is granted that only the minimum necessary health information be used/disclosed. Therefore, provide justification that the PHI being requested is the minimum necessary information reasonably necessary to accomplish objectives of the proposed research.

**STOP Continue to Section I**

---

The University of North Dakota IRB determined that this waiver request satisfies all of the requirements of the HIPAA Privacy Rule in 45 CFR 164.512(i)(2)).

- The proposed research activity will present no more than minimal risk to the privacy of the human subjects.
- There is an adequate plan to protect the patient identifiers from improper use and disclosure.
- There is an adequate plan to destroy the patient identifiers at the earliest opportunity and/or by the end of the research study, or there is a health, research or legal justification for retaining the patient identifiers.
- There are adequate assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of this research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule.
- The research could not be practicably conducted without the Waiver for Patient Authorization to access and use the requested PHI.
- The approval process was conducted by normal review procedures.

\_\_\_\_\_  
Signature of IRB Chair or Member

\_\_\_\_\_  
Date

---

**I. HIPAA Privacy Rule Assurance**

The information listed in the application is accurate and all research staff (investigators, key research personnel) that are involved in the research will comply with the HIPAA regulations. Further, I assure that all research staff will have completed the UND IRB research training requirement prior to research participation.

I assure that the information obtained as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those identified on this form, except as required by law. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entities I will seek approval by the UND IRB.

Cindy Flom-Melamed  
Principal Investigator Signature

4-30-07  
Date

April 26, 2007

Dear IRB,

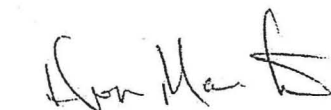
We, at Physical Therapy, will be working with the Department of Physical Therapy at the University of North Dakota in a women's health study. We will be collecting outcome data for our present urinary continence program, which provides us with valuable information. We will continue to provide the best possible care for our patients to reach the highest level of functional outcomes, which ultimately affect quality of life.

We look forward to working with Cindy Flom-Meland PT, PhD, NCS and students, at the Department of Physical Therapy at the University of North Dakota.

Sincerely,



Lisa Martin, MPT



Don Martin, PT  
PT Coordinator

**HIPAA<sup>1</sup> AUTHORIZATION TO USE AND DISCLOSE  
INDIVIDUAL HEALTH INFORMATION FOR RESEARCH PURPOSES**

---

**1. Purpose.** As a research participant, I authorize Cindy Flom-Meland, PT, PhD, NCS and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research project entitled Effectiveness of Pelvic Floor Exercises in Women with Urinary Incontinence.

**2. Individual Health Information to be Used or Disclosed.** My individual health information that may be used or disclosed to conduct this research includes: age, gender, onset of diagnosis, number of pregnancies (full term, miscarriage, and abortion), number of vaginal deliveries, height, weight pre-treatment, weight post-treatment, Body Mass Index pre-treatment, Body Mass Index post-treatment, bladder irritants, prior exercise/activity level, current exercise/activity level, obstacles to exercising, non-caffeinated fluid intake, primary complaint, secondary complaint, sacroiliac or low back pain issues, abuse history, psych/social/sexual history, exercise/walking log (Home Exercise Program), patient satisfaction survey responses, Sandvik Incontinence Severity Index Scores (ISI), Urogenital Distress Inventory Scores (UDI-6), Incontinence Impact Questionnaire Scores (IIQ), electrode placement (internal vs. external), biofeedback scores, Urine Stream Interruption Test Scores, general medical history, brief obstetrical/urogynecologic history, brief surgical history, and medications/supplements.

**3. Parties Who May Disclose My Individual Health Information.** The researcher and the researcher's staff may obtain my individual health information from  
MN.

**4. Parties Who May Receive or Use My Individual Health Information.** The individual health information disclosed by parties listed in item 3 and information disclosed by me during the course of the research may be received and used by Cindy Flom-Meland, PT, PhD, NCS, the researcher's staff, the UND Research Development and Compliance office, and the UND Institutional Review Board.

**5. Right to Refuse to Sign this Authorization.** I do not have to sign this Authorization. If I decide not to sign the Authorization, I may not be allowed to participate in this study or receive any research related treatment that is provided through the study. However, my decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

**6. Right to Revoke.** I can change my mind and withdraw this authorization at any time by sending a written notice to Cindy Flom-Meland, Physical Therapy Department Room 1510, University of North Dakota School of Medicine and Health Sciences, 501 N. Columbia Road Stop 9037, Grand Forks, ND 58202-9037 to inform the researcher of my decision. If I withdraw this authorization, the researcher may only use and disclose the protected health information already collected for this research study. No further health information about me will be collected by or disclosed to the researcher for this study.

---

<sup>1</sup> HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.



**7. Potential for Re-disclosure.** My individual health information disclosed under this authorization may be subject to re-disclosure outside the research study and no longer protected. For example, researchers in other studies could use my individual health information collected for this study without contacting me if they get approval from an Institutional Review Board (IRB) and agree to keep my information confidential.

7A. Also, there are other laws that may require my individual health information to be disclosed for public purposes. Examples include potential disclosures if required for mandated reporting of abuse or neglect, judicial proceedings, health oversight activities and public health measures.

I am the research participant or personal representative authorized to act on behalf of the participant.

I have read this information, and I will receive a copy of this authorization form after it is signed.

\_\_\_\_\_  
Signature of research participant or research participant's  
Personal representative

\_\_\_\_\_  
date

\_\_\_\_\_  
Printed name of research participant or research participant's  
Personal representative

\_\_\_\_\_  
description of personal representative's authority to act on behalf  
of the research participant

## Appendix B

## INFORMATION AND CONSENT FORM

### Effectiveness of Pelvic Floor Exercises in Women with Urinary Incontinence

You are asked to participate in a research study conducted by Lisa Martin MPT, Physical Therapist at MN, Cindy Flom-Meland PT, PhD, NSC, Assistant Professor of Physical Therapy at the University of North Dakota, and Kayla Bucher, Brittany Carter, Rachel Hanson, and Ashley Waller, students of Physical Therapy at the University of North Dakota (UND). This study is being conducted as a graduate school scholarly project. Please read the information below and ask questions about anything you do not understand, before deciding whether or not to participate.

The purpose of our study is to measure the effectiveness of pelvic floor exercises on women with urinary incontinence. Your participation in this study is entirely voluntary.

In order to participate in this study you must have diagnosed pelvic floor weakness, stress urinary incontinence, mixed (stress and urge) urinary incontinence, or uterine prolapse. You will be excluded from this study if you are male, have had surgical correction for UI, history of pelvic cancer, severe endometriosis, or use of an intrauterine device. This study does not experiment with new exercises. You will be experiencing the same standard care that Meritcare provides all its patients with urinary incontinence. You will be asked to fill out a survey, an initial measurement of muscle activity will be taken, and a home exercise program will be provided. You will be seen for follow-up appointments as instructed by your physical therapist, Lisa Martin, MPT.

Based on experience with pelvic floor exercises in patients with pelvic floor weakness, researchers believe it may be of benefit to subjects with this condition. Of course, because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case. However, the information this study obtains will help reinforce the effectiveness of conservative treatment for patients in the future.

This type of exercise is considered low-risk, however, with any form of exercise; there can be some risk for injury. If injury should occur, you and your third party payer will be responsible for all charges.

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Your record may be reviewed by Government agencies, the UND Research Development and Compliance office, and the UND Institutional Review Board. Your name will not be associated with any results of this study. There will be no audio/visual recordings of participants. All data will be destroyed three years after conclusion of the study. There will be no financial compensation to either you or the researchers associated with this study.

You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you do not want to answer.

*Initials of Participant:* \_\_\_\_\_

*IRB Number:*

*Date of IRB Approval:*

*Project Expiration Date:*

Page 1 of 2

If you have any questions or concerns about this research, please contact Cindy Flom-Meland at the University of North Dakota at \_\_\_\_\_ or Lisa Martin at \_\_\_\_\_. You can also reach any of the student researchers through the Department of Physical Therapy at the University of North Dakota at \_\_\_\_\_ between the hours of 8:00AM and 4:00PM.

If you have any questions about your rights as a research subject, you may contact the University of North Dakota Institutional Review Board (IRB) by telephone at \_\_\_\_\_. You will be given the opportunity to discuss any questions about your rights as a research subject with a member of the IRB. The IRB is an independent committee composed of members of the University community, as well as lay members of the community not connected with UND. The IRB has reviewed and approved this study.

---

I UNDERSTAND THE PROCEDURES DESCRIBED ABOVE. MY QUESTIONS HAVE BEEN ANSWERED TO MY SATISFACTION, AND I AGREE TO PARTICIPATE IN THIS STUDY. I HAVE BEEN GIVEN A COPY OF THIS FORM.

\_\_\_\_\_  
Printed Name of Subject

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

*Date of IRB Approval:*  
*IRB Number:*  
*Project Expiration Date:*

Page 2 of 2

## PARTICIPANT INFORMATION AND CONSENT FORM

**TITLE:** Effectiveness of Pelvic Floor Exercises in Women with Urinary Incontinence

**STUDY DOCTOR(S):** Lisa Martin MPT, Physical Therapist at \_\_\_\_\_, Cindy Flom-Meland PT, PhD, NSC, Assistant Professor of Physical Therapy at the University of North Dakota, and Kayla Bucher, Brittany Carter, Rachel Hanson, and Ashley Waller, students of Physical Therapy at the University of North Dakota

**PURPOSE OF THE STUDY:** The purpose of this study is to measure the effectiveness of pelvic floor exercises in women with urinary incontinence.

**DESCRIPTION OF PROCEDURES:** If you agree to participate in this study, you will be experiencing the same standard care that \_\_\_\_\_ provides all its patients with urinary incontinence. This research study does not experiment with new exercises. You will be asked to fill out two surveys, an initial measurement of muscle activity will be taken, and a home exercise program will be provided. You will need to be seen again in the clinic at 2 weeks, 4 weeks, and 3 months thereafter. Final muscle activity testing will be recorded at the 3 months visit. The survey is expected to take no longer than 20 minutes to complete. The only research procedure is the completion of the surveys. Approximately 200 subjects will be recruited for the study.

**RISKS AND DISCOMFORTS:** Participation in this study should cause you to experience little or no discomfort. This type of exercise is considered low-risk, however, with any form of exercise; there can be some risk for injury. There might also be some mild discomfort regarding placement of internal muscle activity equipment if you choose to do so. This discomfort should be minimized with use of visual aides and education of procedure. You will be asked for personal information to be included in the records for this research study. This information will be kept confidential, and you may refuse to answer any question that you do not wish to answer. There is no medical risk.

**ALTERNATIVE:** You understand that your participation in this study is completely voluntary. You may choose not to participate. Choosing not to participate will have no effect on your current or future medical care or any other benefits you are already eligible to receive. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind.

Version Date: 22 May, 2007

Participant Initials: \_\_\_\_\_

Date: \_\_\_\_\_

Page 1 of 3

**COMPENSATION:** You understand that there will be no compensation paid to you for your participation in this research study. If you believe that you have sustained an injury as a result of your participation in this research study, you understand that medical care will be available to you; however, you, or your health plan, will be responsible to pay for the medical services you receive.

**BENEFITS:** Based on experience with pelvic floor exercises in patients with pelvic floor weakness, researchers believe it may be of benefit to subjects with this condition. Of course, because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case. The research may not benefit you personally. However, the information this study obtains will help reinforce the effectiveness of conservative treatment for patients in the future.

**CONFIDENTIALITY:**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. You will be assigned a code number that will go on the consent form, physical therapy intake form, and surveys. This code will remain constant throughout the study and will be held confidential on paper; only the principal investigators will have access to the master list.

**CONTACT PERSON:** For more information concerning this research study and research-related risks and injuries, you can contact Cindy Flom-Meland at the University of North Dakota at \_\_\_\_\_ or Lisa Martin at \_\_\_\_\_. You can also reach any of the student researchers through the Department of Physical Therapy at the University of North Dakota at \_\_\_\_\_ between the hours of 8:00AM and 4:00PM.

If you want to ask questions about what it means to be in a research study or about your rights as a research participant, you can contact:

An institutional review board (IRB) is a group of people who review research studies to protect participants.

**CONFIDENTIALITY:** You understand that any information obtained about you, as a result of your participation in this research study will be handled in a confidential manner. You understand also that your research records, just like hospital records, may be subpoenaed by court order or may be inspected by state or federal regulatory authorities. Also, you understand

Version Date: 22 May, 2007

Participant Initials: \_\_\_\_\_

Date: \_\_\_\_\_

Page 2 of 3

your confidential records will be available to the others identified above as involved in this study and their research staff (i.e. the University of North Dakota associates involved in this research study and \_\_\_\_\_ associates involved in this research study). In any publications that result from this research, neither your name nor any information from which you might be identified will be published without your authorization.

**PARTICIPANT'S STATEMENT OF CONSENT AND AUTHORIZATION**

**You should not sign this Consent unless all of the following statements are true:**

I have read this form, and I have been able to ask questions about this study. The study doctor and study staff has talked to me about this study. They have answered all of my questions. I voluntarily agree to be in this study. I authorize the use and release of my medical records and health information related to this study as described above.

By signing this form I have not given up any of my legal rights as a research participant. I understand that I will receive a signed copy of this consent and authorization form for my records.

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

**CONSENT STATEMENT**

I attest that I or my representative discussed this study with the above-named participant. This participant had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in this study.

\_\_\_\_\_  
Printed Name of Person Explaining Consent

\_\_\_\_\_  
Signature of Person Explaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Study Doctor

\_\_\_\_\_  
Date

Version Date: 22 May, 2007

Participant Initials: \_\_\_\_\_

Date: \_\_\_\_\_

Page 3 of 3

**HEALTH SYSTEM**

**AUTHORIZATION FOR USE AND DISCLOSURE OF INFORMATION  
FOR RESEARCH PURPOSES**

PATIENT NAME:

DOB:

I authorize the use and disclosure of my individually identifiable health information as described below. I understand that this authorization is voluntary. I understand that if the person or organization I authorize to receive the information is not a health plan or health care provider, the released information may no longer be protected by federal privacy regulations and could be re-disclosed.

Persons or organizations authorized to provide the information:

All entities

Persons or organizations authorized to receive the information:

- Any entity or associate involved in this particular research study.
- Any University of North Dakota Medical School entity or associated involved in this particular research study.
- Government agencies that oversee clinical research testing (NIH, NCI, DHHS)

Specific description of information to be used and disclosed, including dates:

Oral and written communication of and about:

- All of my care and treatment at MeritCare
- My care and treatment from \_\_\_\_\_ [date] to \_\_\_\_\_ [date]
- Other (specify): Any care or treatment involving physical therapy treatment for urinary incontinence.



Purposes of the use and disclosure:

√ Research (specify study): **Effectiveness of Pelvic Floor Exercises for Urinary Incontinence**

I understand that my health care and the payment for my health care will not be affected if I do not sign this form, except that research-related treatment may not be provided if I do not sign this form.

I understand that this authorization will not expire, but will continue indefinitely, unless I specify another date or event for expiration.  
(Specify date or event) \_\_\_\_\_

I understand that I may revoke this authorization at any time by notifying \_\_\_\_\_'s Privacy Officer in writing. I understand that if I revoke this authorization, my revocation will not have any effect on actions \_\_\_\_\_ took before it received my revocation, and that \_\_\_\_\_ may continue to use, for research purposes, the information it obtained before my revocation.

\_\_\_\_\_  
Signature of Patient or Patient's Representative

\_\_\_\_\_  
Date/Time

If signed by patient's representative, please state authority of representative to act for patient:  
\_\_\_\_\_

1. Human Subjects: Characteristics

Institutionalization			State of Health		
Group	Ages*	Type of Institution (circle one)	Special Group (if yes, explain)	Mental Health Relevant to Research (if Yes, explain)	Physical Health Relevant to Research (if yes, Explain)
Control Group		Inpatient Outpatient			
Experimental		Inpatient <u>Outpatient</u>			Assessing outcomes of UI PT intervention
Other Group (specify)		Inpatient Outpatient			

\*If study group includes minors (ages 17 and under), please attach the primary investigator's assessment on the issue of whether minor assent is appropriate and for which age category of minors that may be involved in the study. The IRB will determine if minor assent is appropriate. If the IRB determines that assent is appropriate for some or all of the minors involved in the study, verbal assent is sufficient. Generally, minor assent is not required in the following circumstances:

1. If the capability of some or all of the minors involved in the study is so limited that they cannot reasonably be consulted;
2. If the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research; and,
3. If the research meets the same conditions as those for waiver of alteration of informed consent in research involving adults as specified in the IRB manual, pages 30-31.

The primary investigator's assessment of the minor assent issue should address the above factors, if relevant to the study or for any particular age group of minors involved in the study. See IRB Manual, page 36 for more information on minor assent.

2. Possible Risks Involved (When high or medium risks are present), please explain.

Risks		High Risk	Medium Risk	Some Risk	No Risk or not Relevant
Physical	a. Loss of like, organs, tissue				
	b. Impairment due to use of drugs or to surgical procedures, or due to withholding of drugs or surgical procedures.				

	c. Injury due to exposure to infections or parasitic organisms, to radiation, immunologic sensitization, nutritional imbalance or mutagenic agents.				
	d. Other (specify)			X - *	See below
Psychological	a. Loss of or threat to self-esteem.				
	b. Development or exacerbation of anxiety or guilt feelings.				
	c. Breakdown of or initiation of doubts regarding values of significance to the society or to the individual.				
	d. Generation of conflict in or threat to interpersonal adjustment.				
	e. Other (Specify)				
Social and Economic	a. Public humiliation and/or economic loss resulting from release of information in which a subject can be identified (specified).				
	Legal sanctions from maintenance of files in which subject can be identified and which might expose him to legal or other action.				
	Other (e.g., family and marital, specify)				

**Estimated duration of study:**

The student researchers will be involved for up to 6 months. The two physical therapists (Lisa Martin and Cindy Flom-Meland) plan to continue the research for 2 years.

**Additional Comments:**

\*with any form of exercise there can be some risk of injury; there may also be some mild discomfort regarding placement of internal muscle activity equipment.

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

## Appendix C

## UDI-6

### Directions:

The following symptoms have been described by women who experience accidental urine loss and/or prolapsed. Please indicate which symptoms you are now experiencing, and how bothersome they are for you. Be sure to answer all items.

\*\*\* Please circle your response \*\*\*

### Urogenital Distress Inventory-Short Form UDI-6

#### Do you experience, and if so, how much are you bothered by:

1. Frequent urination?

Not at all                      Slightly                      Moderately                      Greatly

2. Urine leakage related to the feeling of urgency?

Not at all                      Slightly                      Moderately                      Greatly

3. Urine leakage related to physical activity, coughing, or sneezing?

Not at all                      Slightly                      Moderately                      Greatly

4. Small amounts of urine leakage (drops)?

Not at all                      Slightly                      Moderately                      Greatly

5. Difficulty emptying your bladder?

Not at all                      Slightly                      Moderately                      Greatly

6. Pain or discomfort in the lower abdominal or genital area?

Not at all                      Slightly                      Moderately                      Greatly

## IIQ-7

### Directions:

Some women find that accidental urine loss and/or prolapsed may affect their abilities, relationships, and feelings. The questions below refer to areas in your life which may have been influenced or changed by your problem. For each question, check the response that best describes how much of your activities, relationships, and feelings are being affected by urine leakage and/or prolapse.

\*\*\* Please circle your response \*\*\*

### Incontinence Impact Questionnaire- Short form IIQ-7

#### Has urine leakage and/or prolapsed affected your:

1. Ability to do household chores (cooking, housecleaning, laundry)?  
Not at all                      Slightly                      Moderately                      Greatly
2. Physical reaction such as walking, swimming, or other exercise?  
Not at all                      Slightly                      Moderately                      Greatly
3. Entertainment activities (movies, concerts, etc)?  
Not at all                      Slightly                      Moderately                      Greatly
4. Ability to travel by car or bus more than 30 minutes from home?  
Not at all                      Slightly                      Moderately                      Greatly
5. Participation in social activities outside your home?  
Not at all                      Slightly                      Moderately                      Greatly
6. Emotional health (nervousness, depression, etc)?  
Not at all                      Slightly                      Moderately                      Greatly
7. Feeling frustrated?  
Not at all                      Slightly                      Moderately                      Greatly

## Sandvik Severity Index

The severity index, developed by Sandvik et al, is an easy and reliable way to assess the severity of the incontinence problem (Sandvik et al., 1993; Hanley, Capewell, & Hagen, 2001).

How often do you experience urine leakage?

- 0 = never
- 1 = less than once a month
- 2 = one or several times a month
- 3 = one or several times a week
- 4 = every day and/or night

How much urine do you lose each time?

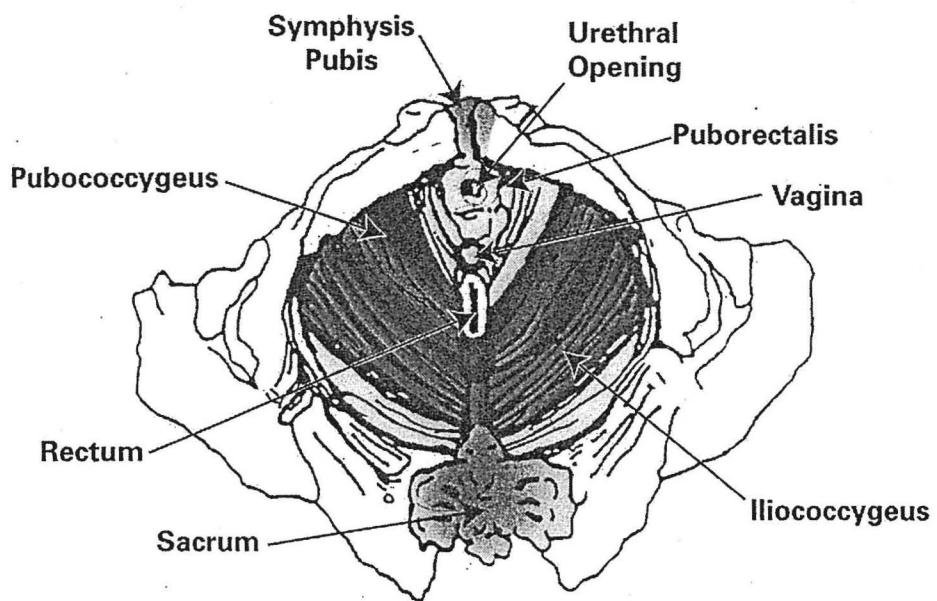
- 1 = drops or little
- 2 = more

The severity is described by the total score, which is the score for the first question multiplied by the score for the second question

- 0 = no incontinence
- 1-2 = slight
- 3-4 = moderate
- 6-8 = severe incontinence

Appendix D





## Endopelvic Musculature

## PELVIC FLOOR EXERCISE PROGRAM

**Purpose:** To strengthen the pelvic floor

How to perform: The muscles you want to strengthen are the muscles that stop the flow of urine. Avoid holding your breath, and relax other muscles.

**1. Short contractions: "Flicks"**

Hold \_\_\_\_\_ seconds, relax \_\_\_\_\_ seconds

Begin with \_\_\_\_\_ reps/time

Goal: repeat \_\_\_\_\_ times/ day

Decide on a specific time of day in which you will perform these, or an activity that is done daily such that performing these becomes habit.

**2. Endurance contractions: "elevators"**

Hold \_\_\_\_\_ seconds, relax \_\_\_\_\_ seconds

repeat \_\_\_\_\_ reps/time

Goal: \_\_\_\_\_ sec hold

**Exercise position**

**Faucet Test:**

Monitor your progress 1x/wk by attempting to stop the flow of your urine. If your pelvic floor muscles are strong you should be able to perform this with ease.

**Suggestions:**

- Eat a high fiber diet to avoid constipation and pressure on the bladder
- Get good water intake daily
- Avoid caffeine and nicotine
- Continue to consume min. 8 glasses of water/ day

**Success of this program depends on your compliance with the exercises!**

If questions, please call

Name \_\_\_\_\_ Date \_\_\_\_\_

## BEYOND KEGELS SELF CARE — HOME PROGRAM

- Caffeine Eliminated \_\_\_\_\_ cups/day
- Non Caffeinated Fluid/Day — 6-8 glasses
- Purposeless Activity/Day — 20 minutes/day
- Physiological Quieting
  - Audiotape 20 minutes/day
  - Hourly diaphragmatic breathing/hand warming

### Fabulous Four Exercises      Minutes      xDay

1. Relaxed Awareness of the Pelvic Muscles  
Focus on your breathing.  
Release head to toes into the support.  
Focus on pelvic muscles.  
Lift up/tighten gently, then release 3-4 times.



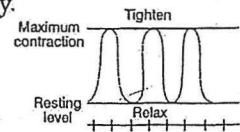
- 2A. Assisted Pelvic Muscle Tightening — Adductors  
Roll your knees in on soft ball  
as you lift up and in with pelvic muscles.  
Hold for 10 counts, release for 10 counts.



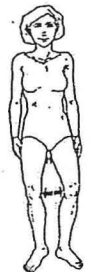
- 2B. Assisted Pelvic Muscle Tightening — Obturators  
Roll your legs out against elastic band,  
as you lift up and in with pelvic muscles.  
Hold for 10 counts, release for 10 counts.



3. Quick Contractions of the Pelvic Muscles  
Lift pelvic muscles up and in quickly and release quickly.  
Think "tighten, release, tighten, release".  
Repeat 6-10 times at the beginning and end of  
each session.



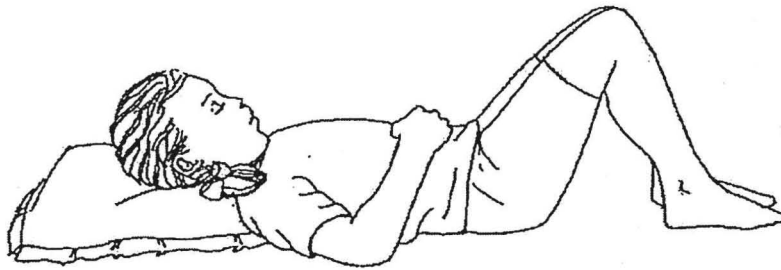
4. Standing Plié  
Stand with feet pointing outward hip width apart.  
Bend knees as you exhale, tightening pelvic muscles.  
Then slowly straighten knees as you inhale. Relax.  
Bend knees to a count of 5, straighten to a count of 5.  
Release/relax the pelvic muscles to a count of 5.



\_\_\_\_\_  
Signature

## Personal Exercise Program

---



© PhysioTools Ltd

### Diaphragmatic Breathing.

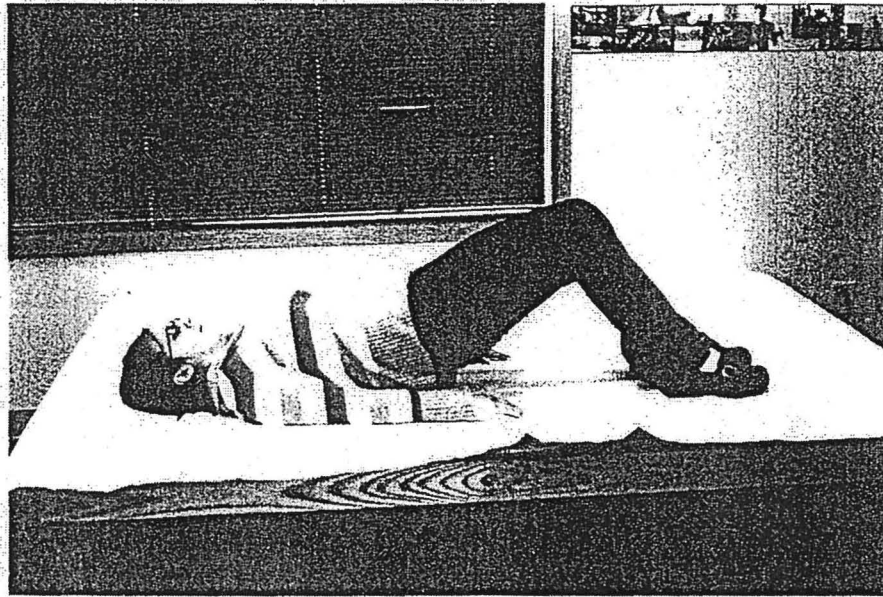
Lie on back with knees bent and both hands on the upper part of stomach. Breathe in slowly through the nose and breathe out slowly through the mouth.

During breathing in the hands on the stomach rise and when breathing out the hands go down.

---

Built on Tools® RG

## Bridge

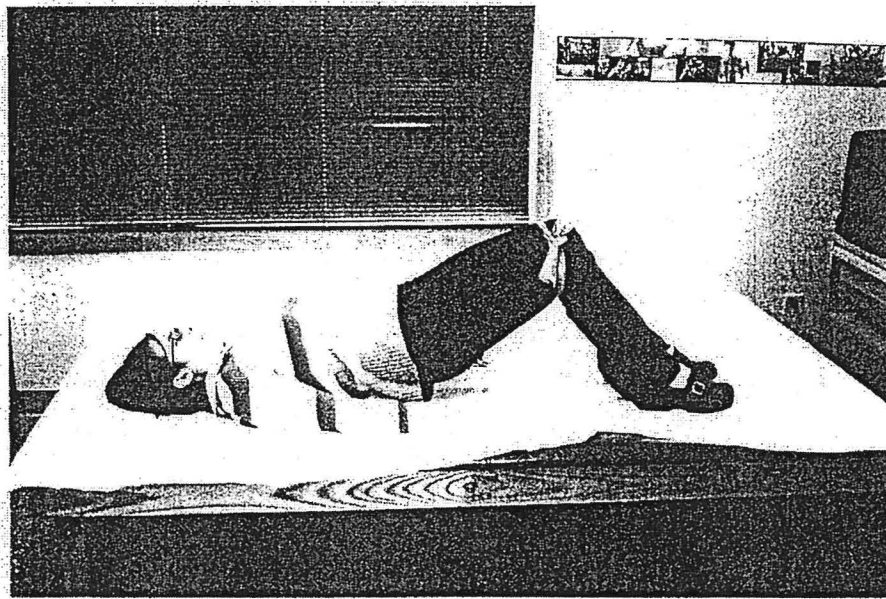


Bridging – lifting the hips “unloads” the pelvic floor.  
Tighten pelvic floor muscles with “Belly to spine”.

Hold \_\_\_\_ sec. Relax \_\_\_\_ sec.

\_\_\_\_ Reps. \_\_\_\_ Sets

### Bridge with T- band



Tighten the pelvic floor muscles with "Belly to spine". Then with the t- band tied above the knees pull band apart as you maintain the bridge and "Kegel" contraction.

Hold \_\_\_\_ sec. Relax \_\_\_\_ sec.

Repeat \_\_\_\_ Reps. \_\_\_\_ sets

### Bridge Over Ball

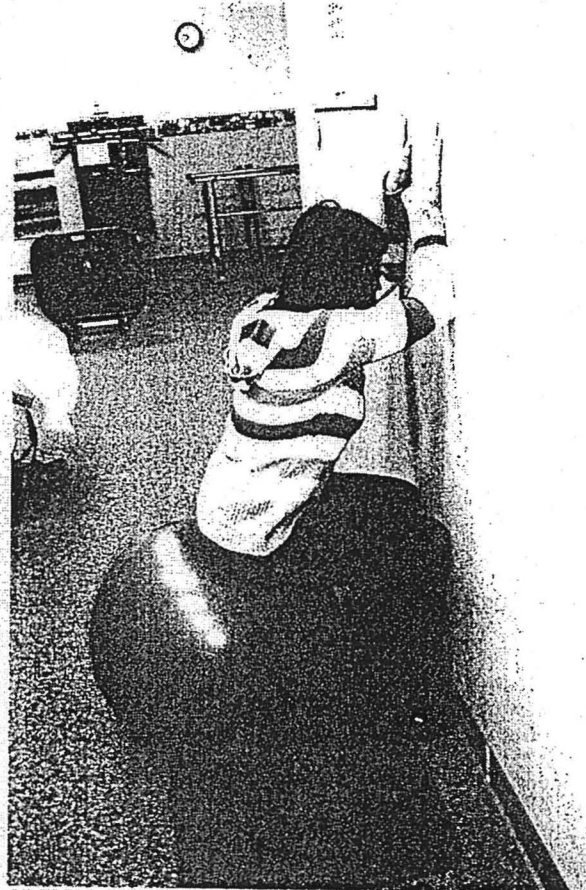


Tighten pelvic floor, "Belly to spine" as you lift up into a bridge position.

Hold \_\_\_\_ sec. Relax \_\_\_\_ sec.

Repeat \_\_\_\_ reps. \_\_\_\_ sets

### Sitting on Ball Exercise



Tighten pelvic floor as you press arms and knees gently into the wall. Per your physical therapist, you may attempt to tighten the pelvic floor as you roll the ball forward/ backward; side to side; or in a diagonal direction.

Hold \_\_\_\_ sec. Relax \_\_\_\_ sec.

Repeat \_\_\_\_ reps. \_\_\_\_ sets



## T-band and Ball Exercise



Sitting on a ball, pull legs apart and roll outward against the t-band as you tighten the pelvic floor. Pull your shoulder blades downward and back.

Hold \_\_\_\_ sec. Relax \_\_\_\_ sec.

Repeat \_\_\_\_ reps. \_\_\_\_ sets

### Ball in Diagonal Direction Exercise

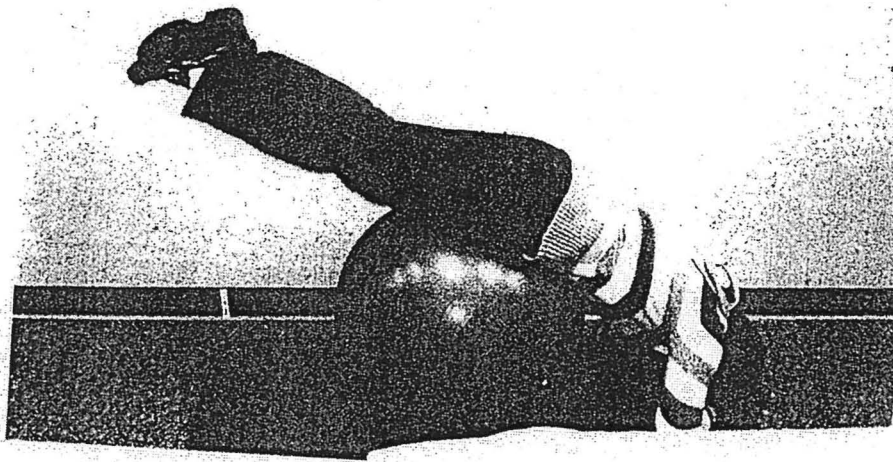


Diagonal muscle fibers of the pelvic floor can be contracted when the ball is pulled from the right sitting bone towards the left knee, vice versa.  
Tighten pelvic floor muscles.

Hold \_\_\_\_ sec. Relax \_\_\_\_ sec.

Repeat \_\_\_\_ reps. \_\_\_\_ sets

Gold Fish position

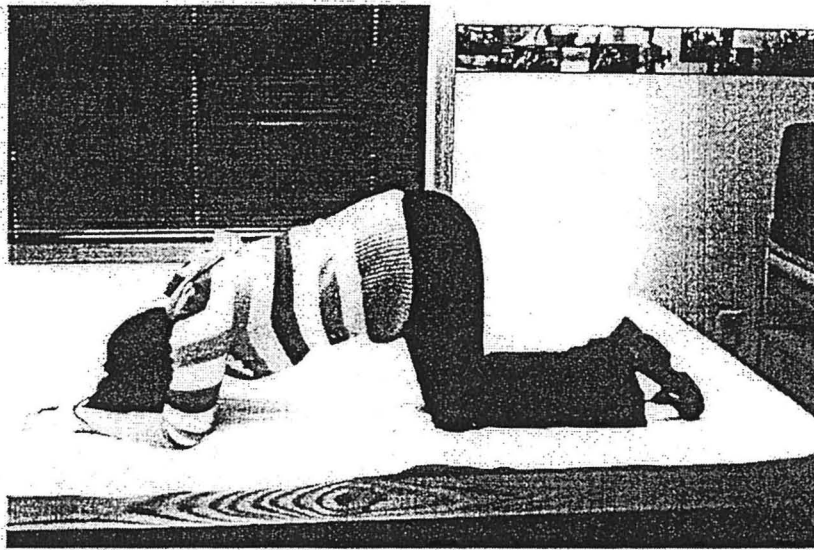


In face down position over the ball, press legs/ heels together as you tighten pelvic floor muscles.

Hold \_\_\_\_ sec. Relax \_\_\_\_ sec.

Repeat \_\_\_\_ reps. \_\_\_\_ sets

### Low Puppy Position



The pelvic floor is "unloaded" in a low puppy position.  
Perform pelvic floor tightening as follows:

Hold \_\_\_\_\_ sec. Relax \_\_\_\_\_ sec.

\_\_\_\_\_ Reps. \_\_\_\_\_ minutes



Walking Exercise Program\*

A.) Under 30 Years of Age:

<i>Week</i>	<i>Distance (miles)</i>	<i>Time Goal (minutes)</i>	<i>Freq/Wk</i>	<i>Points/Wk</i>
1	2.0	34:00	3	12.2
2	2.0	32:00	4	18.0
3	2.0	30:00	5	25.0
4	2.5	38:00	5	31.8
5	2.5	37:00	5	33.2
6	2.5	36:00	5	34.6
7	3.0	45:00	5	40.0
8	3.0	44:00	5	41.3
9	3.0	43:00	5	42.9
10	3.0	42:00	4	35.4

By the 10th week, an adequate level of aerobic condition has been reached & can be maintained with a 4 X per week schedule. This level of exercise equals 35 aerobic points per week, consistent with the good category of aerobic fitness.

B.) Thirty to 49 Years of Age:

<i>Week</i>	<i>Distance (miles)</i>	<i>Time Goal (min)</i>	<i>Freq/Wk</i>	<i>Points/Wk</i>
1	2.0	36:00	3	11.0
2	2.0	34:00	3	12.2
3	2.0	32:00	4	18.0
4	2.0	30:00	4	20.0
5	2.5	39:00	4	24.5
6	2.5	38:00	5	31.8
7	2.5	37:00	5	33.2
8	3.0	46:00	5	38.7
9	3.0	45:00	5	40.0
10	3.0	44:00	4	33.1

By the 10th week, an adequate level of aerobic conditioning has been reached & can be maintained with a 4 X per week schedule. This level of exercise equals 33 aerobic points per week, consistent with the good category of aerobic fitness.

C.) Fifty Years of Age & Older:

<i>Week</i>	<i>Distance (miles)</i>	<i>Time Goal (min)</i>	<i>Freq/Wk</i>	<i>Points/Wk</i>
1	1.0	20:00	4	4.0
2	1.5	30:00	4	8.0
3	2.0	40:00	4	12.0
4	2.0	38:00	4	13.3
5	2.0	36:00	4	14.7
6	2.0	34:00	4	16.2
7	2.5	42:00	4	21.7
8	2.5	40:00	4	23.5
9	2.5	38:00	4	25.5
10	3.0	47:00	4	30.0
11	3.0	46:00	4	31.0
12	3.0	45:00	4	32.0

By the 12th week, an adequate level of aerobic conditioning has been reached & can be maintained with 4 exercise periods each week. This level of exercise equals 32 aerobic points per week, consistent with the good category of aerobic fitness.

\*The Aerobic Program for Total Well-Being, Kenneth H. Cooper, MD, MPH, Bantam Books, Toronto, 1982.



## URINARY INCONTINENCE PROGRAM

### BLADDER TRAINING

- Increase voiding interval
- No scheduled night void
- Urge suppression
  - stop and sit – relax and breath – distract your thoughts (puff and tuck) – tighten pelvic floor as you exhale out of your mouth

avoid bladder irritants: caffeine, nicotine, soda, alcohol

continue to increase voiding interval

### NORMAL BLADDER FUNCTION

#### Norms

Number of voids per day	7
Number of glasses of 8 oz. Fluid to drink/day	6-8 (of which half of this should be water)
Voiding interval	2-5 hours between trips to the bathroom
Number of voiding episodes at night (nocturia)	0-2 times



## **History/Diary Constipation/Diarrhea/ Fecal Soiling**

### **Goals**

1. Improve functional strength of levator ani and sphincter musculature.
2. Increase frequency of normal bowel movements.
3. Increase functional activities without fecal soiling.
4. Eliminate diarrhea, constipation, fecal soiling.
5. Decrease paradoxical puborectalis contractions.

**< one bowel movement/day  
fecal staining of underwear  
medication or enemas used  
for bowel movement**

### **Plans**

1. 6-8 glasses of fluid daily
2. Eliminate caffeine & alcohol
3. Cooked or raw fruits/vegetables
  - one at breakfast.
  - two at lunch, two at dinner
  - prunes and apricots are good
4. Bran and yogurt at breakfast
  - 1-2 teaspoons wheat bran/day
  - 4-6 oz yogurt
5. Magnesium 250-500 mg  
Vitamin C 250-2000 mg (not recommended if renal failure or interstitial cystitis)
6. Fabulous Four Exercises
  - 2-3 x/day for 5-7 minutes
  - emphasize equal rest and contract time
  - emphasize obturator and adductor assist exercises
7. Nonpurposeful Moderate Aerobic Exercise
  - 20-30 min daily
  - in a.m. if possible
8. Physiological Quieting
  - 20 min. daily at bedtime
  - hourly diaphragmatic breathing
9. Myofascial Release
  - pelvic diaphragm release
  - sacral mobility
  - visceral motility
10. Self massage
  - clockwise circular massage from lower right abdomen up, across and down lower left abdomen
  - daily before arising
  - follow with drinking 2 cups of warm water
11. After a bowel movement roll knees in & out 2-3x to facilitate complete evacuation.

**straining to have bowel  
movement**

**feeling of  
incomplete bowel movement**

## Continenence Program Weekly Bladder Record

Name: \_\_\_\_\_

Week of: \_\_\_\_\_

### Instructions:

Insert the following symbols into the appropriate time spaces. . .

T = toilet urinary    F = 8oz. fluid  
 B = bowel movement    \* = caffeinated  
 L = small leak    P = Pad  
 A = large leak

### *Monday, Date*

6-8 am \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-2 \_\_\_\_\_  
 12-2 pm \_\_\_\_\_  
 2-4 \_\_\_\_\_  
 4-6 \_\_\_\_\_  
 6-8 \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-12 \_\_\_\_\_  
 Overnight \_\_\_\_\_  
 \*Pads used \_\_\_\_\_  
 comments \_\_\_\_\_

### *Tuesday, Date*

6-8 am \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-2 \_\_\_\_\_  
 12-2 pm \_\_\_\_\_  
 2-4 \_\_\_\_\_  
 4-6 \_\_\_\_\_  
 6-8 \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-12 \_\_\_\_\_  
 Overnight \_\_\_\_\_  
 \*Pads used \_\_\_\_\_  
 comments \_\_\_\_\_

### *Wednesday, Date*

6-8 am \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-2 \_\_\_\_\_  
 12-2 pm \_\_\_\_\_  
 2-4 \_\_\_\_\_  
 4-6 \_\_\_\_\_  
 6-8 \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-12 \_\_\_\_\_  
 Overnight \_\_\_\_\_  
 \*Pads used \_\_\_\_\_  
 comments \_\_\_\_\_

### *Thursday, Date*

6-8 am \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-2 \_\_\_\_\_  
 12-2 pm \_\_\_\_\_  
 2-4 \_\_\_\_\_  
 4-6 \_\_\_\_\_  
 6-8 \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-12 \_\_\_\_\_  
 Overnight \_\_\_\_\_  
 \*Pads used \_\_\_\_\_  
 comments \_\_\_\_\_

### *Friday, Date*

6-8 am \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-2 \_\_\_\_\_  
 12-2 pm \_\_\_\_\_  
 2-4 \_\_\_\_\_  
 4-6 \_\_\_\_\_  
 6-8 \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-12 \_\_\_\_\_  
 Overnight \_\_\_\_\_  
 \*Pads used \_\_\_\_\_  
 comments \_\_\_\_\_

### *Saturday, Date*

6-8 am \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-2 \_\_\_\_\_  
 12-2 pm \_\_\_\_\_  
 2-4 \_\_\_\_\_  
 4-6 \_\_\_\_\_  
 6-8 \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-12 \_\_\_\_\_  
 Overnight \_\_\_\_\_  
 \*Pads used \_\_\_\_\_  
 comments \_\_\_\_\_

### *Sunday, Date*

6-8 am \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-2 \_\_\_\_\_  
 12-2 pm \_\_\_\_\_  
 2-4 \_\_\_\_\_  
 4-6 \_\_\_\_\_  
 6-8 \_\_\_\_\_  
 8-10 \_\_\_\_\_  
 10-12 \_\_\_\_\_  
 Overnight \_\_\_\_\_  
 \*Pads used \_\_\_\_\_  
 comments \_\_\_\_\_

## Appendix E

**Data Collection**

Gender: Female                      Age: \_\_\_\_\_ ID #: \_\_\_\_\_

Diagnosis: \_\_\_\_\_

Onset: \_\_\_\_\_

Primary complaint: \_\_\_\_\_

Secondary complaint: \_\_\_\_\_

General medical history: \_\_\_\_\_

Obstetrical/urogynecologic history: \_\_\_\_\_

Surgical history: \_\_\_\_\_

Sacroiliac or low back pain issues: Yes      No

Abuse history: Yes      No

Psych/social/sexual history: \_\_\_\_\_

Medications/Supplements: \_\_\_\_\_

Bladder

Irritants: \_\_\_\_\_

Number of pregnancies: \_\_\_\_\_

    full term: \_\_\_\_\_ miscarriage: \_\_\_\_\_ abortion: \_\_\_\_\_

Number of vaginal deliveries: \_\_\_\_\_

Non-caffeinated fluid intake: \_\_\_\_\_

Height: \_\_\_\_\_

Weight pre-treatment: \_\_\_\_\_ Weight post-treatment: \_\_\_\_\_

Body Mass Index pre-treatment: \_\_\_\_\_ Body Mass Index post-treatment: \_\_\_\_\_

Prior Exercise/Activity level: \_\_\_\_\_

Current Exercise/Activity level: \_\_\_\_\_

Obstacles to exercising: \_\_\_\_\_

Sandvik Incontinence Severity Index Score (ISI)

Initial: \_\_\_\_\_ Final: \_\_\_\_\_

Urogenital Distress Inventory Score (UDI-6) Initial: \_\_\_\_\_ Final: \_\_\_\_\_

Incontinence Impact Questionnaire Score (IIQ) Initial: \_\_\_\_\_ Final: \_\_\_\_\_

Urine Stream Interruption Test Score initial: \_\_\_\_\_ Final: \_\_\_\_\_

Electrode placement: Internal      External

Biofeedback initial: \_\_\_\_\_ Biofeedback post: \_\_\_\_\_

Exercise/walking log (Home Exercise Program): \_\_\_\_\_

## References

1. Discovering the Non-Surgical Approach to Urinary Incontinence [brochure]. MeritCare Bemidji, MN October 2001.
2. Kotarinos RK. Pelvic floor physical therapy in urogynecologic disorders. *Curr Womens Health Rep.* 2003 Aug;3(4):334-9.
3. Hagen S, Stark D, Maher C, Adams E. Conservative management of pelvic organ prolapsed in women. *Cochrane Database Syst Rev.* 2006 Oct 18;(4):CD003882.
4. Jarvis SK, Hallam TK, Lujic S, Abbott JA, Vancaillie TG. Peri-operative physiotherapy improves outcomes for women undergoing incontinence and or prolapsed surgery: results of a randomized control trial. *Aust N Z Obstet Gynaecol.* 2005 Aug;45(4):300-3.
5. Moore KL, Dalley AF. *Clinically Oriented Anatomy.* Baltimore, MD: Lippincott Williams & Wilkins; 2006:368-375.
6. Goodman CC, Fuller KS, Boissonnault WG. *Pathology: Implications for the Physical Therapist.* Philadelphia, PA: Saunders; 2003:722-726.
7. Goodman CC, Snyder TE. *Differential Diagnosis for Physical Therapists: Screening for Referral.* St Louis, MO: Saunders; 2007:448-451.
8. DeLancey JO, Kearney R, Chou Q, Speights S, Binno S. The appearance of levator ani muscle abnormalities in magnetic resonance images after vaginal delivery. *Obstet Gynecol* 2003;101:46-53.
9. Borello-France DF, Handa VL, Brown MB, Goode P, Kreder K, Scheufele LL, Weber A. Pelvic-Floor Muscle Function in Women With Pelvic Organ Prolapse. *Phys Ther* 2007; 87(4) 399-407.
10. Kotarinos RK. Pelvic floor physical therapy in urogynecologic disorders. *Curr Womens Health Rep.* 2003 Aug; 3(4):334-9.
11. Sampselle CM, Miller JM, Mims BL, DeLancey JOL, Ashton-Miller JA, Antonakos CL. Effect of pelvic muscle exercise on transient incontinence during pregnancy and after birth. *Obstet Gynecol* 1998; 91:406-12.
12. Borello-France DF, Zyczynski HM, Downey PA, Rause CR, Wister JA. Effect of Pelvic-Floor Muscle Exercise Position on Continence and Quality-of-Life Outcomes in Women with Stress Urinary Incontinence. *Phys Ther* 2006; 86(7): 974-986.

13. Capelini MV, Riccetto CL, Dambros M, et al. Pelvic floor exercises with biofeedback for stress urinary incontinence. *Int Braz J Urol*; 2006; Jul-Aug; 32(4): 462-8.
14. Glazer HI, Laine CD. Pelvic floor muscle biofeedback in the treatment of urinary incontinence: a literature review. *Appl Psychophysiol Biofeedback*; 2006; Sep;31(3): 187-201.
15. Schumaker SA, Wyman JF, Uebersax JS, McClish D, Fantl JA, the Continence Program in Women Research Group. Health-related quality of life measures for women with urinary incontinence: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. *Quality of Life Research* 1994;3:291-306.
16. Uebersax J, Wyman J, Shumaker S, McClish D, Fantl J, the Continence Program for Women Research Group. Short Forms to Assess Life Quality and Symptom Distress for Urinary Incontinence in Women: The Incontinence Impact Questionnaire and the Urogenital Distress Inventory. *Neurourology and Urodynamics* 1995;14:131-135.
17. Cam C, Sakalli M, Ay P, Cam M, Karateke A. Validation of the short forms of the incontinence impact questionnaire (IIQ-7) and the urogenital distress inventory (UDI-6) in a Turkish population. *Neurourol Urodyn*. 2007;26(1):129-33.
18. Hanley J, Capewell A, Hagen S. Validity study of the severity index, a simple measure of urinary incontinence in women. *BMJ*. 2001; 322: 1096-1097.
19. Sandvik H, Espuna M, Hunskaar S. Validity of the incontinence severity index: comparison with pad-weighing tests. *Int Urogynecol J* 2006;17:520-524.
20. Murphy M, Culligan PJ, Arce CM, Graham CA, Blackwell L, Heit MH. Construct validity of the incontinence severity index. *Neurourol Urodyn*. 2006;25(5):418-23.
21. Sartore A, Pregazzi R, Bortoli P, et al. The urine stream interruption test and pelvic muscle function in the puerperium. *Int J Gynaecol Obstet*; 2002; Sep; 78(3): 235-9.
22. Onyeka BA, Ogah J. Cystometric urine stream interruption test in women with urodynamic stress incontinence. *J Obstet Gynaecol*; 2006; Oct;26(7): 667-8.
23. Portney LG, Watkins MP. *Foundations of Clinical Research: Applications to Practice*. Upper Saddle River, NJ: Prentice Hall, Inc.; 2000:101-109.