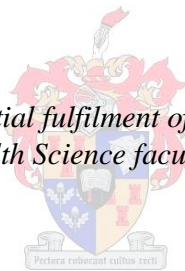


An investigation of pelvic floor muscle strength and vaginal resting pressure in nulliparous women of different ethnic groups

by
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*Thesis presented in partial fulfilment of the Master of Science in
Physiotherapy at the Health Science faculty, Stellenbosch University*



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March 2010

Dedicated to my mother, Rozelle Uys

25/04/1941 - 12/09/2008

DECLARATION

By submitting this dissertation electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the owner of the copyright thereof (unless to the extent explicitly otherwise stated) and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

March 2010

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PRESENTATIONS ARISING FROM THIS STUDY

PAPERS PRESENTED

Van der Walt 2009 An investigation of pelvic floor muscle strength in nulliparous women of different race groups. South African Society of Physiotherapy Congress, Cape Town, South Africa

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ABSTRACT

The pelvic floor muscles (PFM) contribute to urinary continence and overactive PFM seem to be associated with pelvic pain syndrome (PPS). The literature indicates that ethnic differences regarding symptoms of urinary incontinence may exist. Research is needed to establish relationships between PFM function and symptoms reported by women of different ethnic groups. **Objectives:** To compare the PFM strength and endurance in black, white and coloured women. To investigate relationships between PFM strength, vaginal resting pressures, risk factors and symptoms associated with PFM dysfunction and PPS. **Method:** A cross-sectional study assessed the PFM strength and vaginal resting pressures of 122 nulliparous black (n=44), white (n=44) and coloured (n=34) university students. A self-developed questionnaire determined inclusion, demographic variables, factors affecting/factors associated with PFM strength and symptoms related to PPS. Maximum voluntary contraction pressure (cmH₂O) and vaginal resting pressure (cmH₂O) were measured with the Peritron™ 9300 (Cardio Design, Australia) used with the Camtech^{AS} vaginal balloon sensor (Sandvika, Norway). Two sets of 3 maximum voluntary contractions of the PFM were recorded. **Results:** The mean age of the group was 22 ± 3.54 years and mean BMI of 23± 4.16 kg/m². Black women (25 cmH₂O ± 13.5) had significantly stronger PFM than white (p=0.02) or coloured (p<0.01) women, but no significant difference (p=0.78) in PFM strength existed between white (18.4 cmH₂O ± 9.8) and coloured (15.6 cmH₂O ± 8) women. In black women, PFM strength decreased significantly (p=0.02) between the sets, whereas no significant difference between sets was noted in the other ethnic groups. Increased PFM strength was associated with SUI (p=0.03) and amenorrhoea (p=0.01) and decreased PFM strength was associated with decreased frequency of bowel motion (p=0.01). In this sample, increased vaginal resting pressure was associated with menorrhagia (p=0.04). **Conclusion:** Black nulliparous women had stronger PFM than white and coloured women. There was no difference in PFM strength between white and coloured women. Endurance, as measured in this study, indicates that black women have decreased endurance of the PFM compared to white and coloured women. These findings inform the current research on ethnic differences in the prevalence of urinary incontinence. Preliminary data suggest that there was no relationship between vaginal resting pressures and symptoms of PPS and risk factors for PFM dysfunction, except for menorrhagia.

ABSTRAK

Die bekkenvloer spiere (BVS) dra by tot urinêre kontinensie en ooraktiewe BVS kan moontlik geassosieer wees met pelviëse pyn sindroom (PPS). Uit die literatuur blyk dit of daar etniese verskille bestaan in die simptome van urinere inkontinensie gerapporteer deur vroue. Navorsing is nodig om die verwantskap tussen BVS funksie en simptome wat deur pasiënte van verskillende etniese groepe gerapporteer word vas te stel. **Doel:** Om 'n vergelyking te tref tussen BVS sterkte in swart, wit en kleurling vroue. Om vas te stel of daar assosiasies bestaan tussen BVS sterkte, rustende vaginale druklesings en risiko faktore en simptome geassosieer met bekkenvloer disfunksie en PPS. **Metodologie:** 'n Dwarssnit studie het die BVS sterkte en rustende vaginale drukke van 122 nullipareuse swart (n=44), wit (n=44) en kleurling (n=34) universiteit studente geëvalueer. Insluiting, uitsluiting, demografiese veranderlikes, faktore wat kan affekteer/faktore geassosieer met BVS sterkte en simptome geassosieer met PPS is deur 'n self ontwikkelde vraelys geëvalueer. Maksimale willekeurige spiersametrekking drukke (cmH₂O) en rustende vaginale drukke (cmH₂O) was gemeet met 'n Peritron™9300 perineometer (Cardio Design, Australië) wat saam 'n vaginale ballon sensor (Camtech AS, Sandvika, Noorweë) gebruik is. Twee stelle van 3 maksimale willekeurige sametrekings van die BVS was gemeet. **Resultate:** Die groep se gemiddelde ouderdom was 22±3.54 jaar en die gemiddelde liggaamsgewig indeks was 23±4.16kg/m². Swart vroue (25 cmH₂O ±13.5) het beduidend sterker BVS gehad as wit (p=0.02) en kleurling (p<0.01) vroue, maar daar was geen beduidende verskil (p=0.78) in BVS sterkte tussen wit (18.4 cmH₂O ± 9.8) en kleurling (15.6 cmH₂O ± 8) vroue nie. Die BVS sterkte in swart vroue het beduidend (p=0.02) verminder tussen die stelle, maar geen beduidende verskille was waargeneem in die ander etniese groepe tussen stelle. Verhoogde BVS sterkte was geassosieer met druklek (p=0.03), amenorrhoea (p=0.01) en verminderde BVS sterkte was geassosieer met verminderde frekwensie van opelyf (p=0.01). Verhoogde rustende vaginale drukke was geassosieer met menoragie in hierdie steekproef. **Gevolgtrekking:** Swart nullipareuse vroue het sterker BVS gehad as wit en kleurling vroue, Daar was geen verskil in BVS sterkte tussen wit en kleurling vroue nie. Uithouvermoë soos in hierdie studie getoets toon dat swart vroue verminderde uithouvermoë het i.v.m. wit en kleurling vroue. Hierdie bevindings dra by tot die huidige navorsing oor etniese verskille in die prevalensie van urinêre inkontinensie. Daar was geen verwantskap tussen vaginale rustende drukke en simptome van PPS en risiko faktore vir die ontwikkeling van bekkenvloer disfunksie, behalwe vir menoragie.

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ABBREVIATIONS AND ACRONYMS

BMI	Body mass index
CPP	Chronic pelvic pain syndrome
DO	Detrusor over activity
DOI	Detrusor over activity incontinence
EMG	Electromyogram
GSI	Genuine stress incontinence
IAP	Intra-abdominal pressure
IBS	Irritable bowel syndrome
ICC	Intra class correlation
ICS	International Continence Society
LBP	Low back pain
MUI	Mixed urinary incontinence
MVC	Maximum voluntary contraction
OAB	Over active bladder syndrome
PFD	Pelvic floor dysfunction
PFM	Pelvic floor muscles
POP	Pelvic organ prolapse
PPS	Pelvic pain syndrome
SUI	Stress urinary incontinence
SD	Standard deviation
UDS	Urodynamic studies
UGH	Urogenital hiatus
UI	Urinary incontinence
UUI	Urge urinary incontinence
USI	Urodynamic stress incontinence

DEFINITIONS AND TERMINOLOGY

According to a report from the Standardisation Sub-committee of the International Continence Society (Abrams et al, 2002) the following comprise standardised terminology for Lower Urinary Tract function according to lower urinary tract symptoms, signs and urodynamic observations.

Increased day time frequency is the complaint of the patient who considers that he/she voids too often by day.

Nocturnal urine volume is defined as the total volume of urine passed between the time the individual goes to bed with the intention of sleeping and the time of waking with the intention of rising.

Pelvic organ prolapse is defined as the descent of one or more of: the anterior vaginal wall, the posterior vaginal wall, and the apex of the vagina (cervix/uterus) or vault after hysterectomy. Absence of prolapse is defined as stage 0 support; prolapse can be staged from stage I to stage IV.

Pelvic floor muscle function can be qualitatively defined as strong, weak or absent by the tone and the strength of a voluntary or reflex contraction or by a validated grading system (e.g. Oxford 1-5). A pelvic muscle contraction may be assessed by visual inspection, by palpation, electromyography or perineometry. Factors to be assessed include strength, duration, displacement, and repeatability.

Genito-Urinary pain syndromes and symptom syndromes suggestive of lower urinary tract dysfunction:

Painful bladder syndrome is the complaint of suprapubic pain related to bladder filling, accompanied by other symptoms such as increased daytime and night-time frequency, in absence of proven urinary infection or other obvious pathology.

Urethral pain syndrome is the occurrence of recurrent episodic urethral pain usually on voiding, with daytime frequency and nocturia, in the absence of proven infection or other obvious pathology.

Vulval pain syndrome is the occurrence of persistent or recurrent episodic vulval pain, which is either related to the micturition cycle or associated with symptoms suggestive of urinary tract or sexual dysfunction. There is no proven infection or other obvious pathology.

Vaginal pain syndrome is the occurrence of persistent or recurrent episodic vaginal pain which is associated with symptoms suggestive of urinary tract or sexual dysfunction. There is no proven infection or other obvious pathology.

Perineal pain syndrome is the occurrence of persistent or recurrent episodic perineal pain which is associated with symptoms suggestive of urinary tract or sexual dysfunction. There is no proven infection or other obvious pathology.

According to a report from the Pelvic Floor Clinical Assessment Group of the International Continence Society (Messelink et al, 2005) the following comprise standardised terminology for pelvic floor muscle function and dysfunction according to symptoms, signs and conditions:

Symptoms:

Obstructed defecation can be described as having the urge to defecate, but being unable to completely empty the rectum with or without straining.

Irritable bowel syndrome (IBS) is a functional bowel disorder in which abdominal pain or discomfort is associated with defecation or a change in bowel habit, and with features of disordered defecation. Rome III classification (Longstreth et al, 2006).

Dyspareunia is the symptom of painful sexual intercourse.

Signs:

Voluntary contraction of the pelvic floor muscles means that the patient is able to contract the pelvic floor muscles on demand. A contraction is felt as a tightening, lifting, and squeezing action under the examining finger. A voluntary contraction can be absent, weak, normal, or strong.

Voluntary relaxation of the pelvic floor muscles means that the patient is able to relax the pelvic floor muscles on demand, after a contraction has been performed. Relaxation is felt as a termination of the contraction. The pelvic floor muscles should return at least to their resting state. A voluntary relaxation can be absent, partial, or complete.

Conditions:

Normal pelvic floor muscles: A situation in which the pelvic floor muscles can voluntarily and involuntarily contract and relax. Voluntary contraction will be normal or strong and voluntary relaxation complete. Involuntary contraction and relaxation are both present.

Underactive pelvic floor muscles: A situation in which the pelvic floor muscles cannot voluntarily contract when this is appropriate. This condition is based on symptoms such as urinary incontinence, anal incontinence or pelvic organ prolapse, and on signs such as no voluntary or involuntary contraction of the pelvic floor muscles.

Racial classification: For the purposes of this study, the classification of race, indicated by the subjects themselves, determined their allocation to a race group.

- Black: Anybody who identified themselves as Black.
- White: Anybody who identified themselves as White.
- Coloured: Anybody who identified themselves as Coloured.

CHAPTER 1

INTRODUCTION AND STATEMENT OF THE PROBLEM

The pelvic floor forms a muscular diaphragm which supports the pelvic contents and helps prevent their prolapse through the bony pelvic outlet. The pelvic floor functions by contracting and relaxing. In its resting state, the pelvic floor gives support to the pelvic organs through the activity of the muscles at rest (active support) and the integrity of the fascia (passive support). With a conscious pelvic floor muscle contraction, the urethra and rectum are occluded which prevents leakage of urine and faeces and also resists downward pressures. However, when urine or faeces need to be expelled, the pelvic floor muscles have to relax to let the contents pass through (Messelink et al, 2005).

Pelvic floor dysfunction can occur if the pelvic floor muscles do not give support and do not occlude the urinary and faecal passages which will result in urinary and faecal incontinence. The pelvic floor may become tight and overactive resulting in dysfunctional voiding, constipation or sexual problems (Messelink et al, 2005). Some authors, also suggest that through neurogenic/fascial mediation, the overactive pelvic floor can affect pelvic organs and structures resulting in irritative and painful conditions in the lower urinary tract, uterus and vagina or rectum and anus (Weiss, 2001; Prendergast and Weiss, 2003; Wise and Anderson, 2006). This condition is described as pelvic pain syndrome or chronic pelvic pain. Pelvic pain syndrome is defined as persistent or recurrent episodic pelvic pain, associated with symptoms suggestive of lower urinary tract, sexual, bowel or gynaecological dysfunction, where there is no proven infection or other obvious pathology (Abrams et al, 2002).

Both pelvic pain syndrome and urinary incontinence are prevalent conditions. Pelvic pain syndrome is a substantial health problem and is the reason for 10-15% of all gynaecological referrals, 25-35% of laparoscopies and 10-15% of hysterectomies (Reiter, 1998). An estimated 250 million women worldwide suffer from urinary incontinence (Milsom, 2009). The mean estimated prevalence levels of urinary incontinence increase with age; with a prevalence of 20-30% in young adult women,

increasing in middle-aged women (30-40%), and peaking in elderly women (30-50%). It is a distressing condition with significant social implications (Hay-Smith et al, 2009). Milsom (2009) reports in his review of lower urinary tract symptoms, that the cost of illness for urinary incontinence and overactive bladder syndrome is a substantial economic and human burden and is likely to increase in the future, highlighting the need for effective forms of treatment.

Studies on pelvic floor dysfunction have been done, predominantly in white populations (Hunnskaar et al, 2003). However, the limited studies that have been conducted in other ethnic groups, indicate that white women are more at risk for developing stress urinary incontinence (Milsom, 2009), which is a leakage of urine with exertion such as with coughing, sneezing and jumping. Whereas, black women have a higher prevalence of overactive bladder syndrome (Milsom, 2009), which is a combination of urinary frequency, urinary urgency and increased night time voiding (nocturia).

Little is known of the aetiology of these ethnic differences in the prevalence of urinary incontinence. There may be inherent structural or physiological factors that could explain the ethnic differences in prevalence of urinary incontinence. These factors need to be investigated. The pelvic floor muscles form an integral part in the continence mechanism (Ashton-Miller et al, 2001; Messelink et al, 2005). Decreased pelvic floor muscle strength has been associated with stress urinary incontinence (Hahn et al, 1996; Mørkved et al, 2002; Amaro et al, 2005; Thompson et al, 2006). Therefore, investigating pelvic floor muscle (PFM) strength may contribute to the understanding of the reported differences in racial prevalence of different types of urinary incontinence.

Skinner and Crichton (1963) and Knobel (1975) have investigated pelvic floor muscle strength in South African black and Indian women. However, in these older studies, small samples were used and information on the methodology was scant. Therefore studies with sound methodological approaches and sufficient sample sizes are needed to investigate pelvic floor muscle strength in different ethnic groups.

The understanding of the relationship between pelvic floor muscle function and pelvic pain syndrome is still unclear. There is an indication that increased tone in the pelvic floor muscles could be associated with pelvic pain syndrome (Weis, 2001; Prendergast and Weiss, 2003; Anderson et al, 2005; Wise and Anderson, 2006). This understanding is further complicated by the fact that the pelvic floor muscle of a person can have overactive and underactive parts (Dietz, 2009). There is also a lack of consensus in the current literature concerning the terminology used to characterize pelvic floor muscle tonicity such as hypertonicity, overactivity, spasm, tension and spasticity (Morin and Bergeron, 2009). As a result the understanding and investigation of pelvic floor muscles in the pathophysiology of pelvic pain syndrome is compromised. More studies are needed to investigate the relationship of pelvic floor muscle function to the symptoms of chronic pelvic pain. This is supported by recommendations of the International Continence Society (ICS) indicating the need for further research on the relationship of pelvic floor muscle dysfunction and symptoms reported by patients. They also encourage researchers to investigate ways of measuring and quantifying pelvic floor muscle tone, force and volume (Messelink et al, 2005).

Measurement of squeeze pressure is the most commonly used method to measure pelvic floor muscle strength and endurance (Bø and Sherburn, 2005). However, this method also reflects vaginal resting pressure values. Griffin et al (1994), using a vaginal pressure probe, showed a significant increase in pelvic floor resting pressures after the completion of a pelvic floor muscle exercise program and related it to increased muscle tone.

Pelvic floor muscles contribute to the continence mechanism and are also associated with symptoms of chronic pelvic pain. The observed differences in the prevalence of types of urinary incontinence between different race groups, and the association between muscle activity and pelvic floor dysfunction lead us to the investigation of pelvic floor muscle strength and vaginal resting pressures. The main aim of this cross-sectional study was therefore to compare the PFM strength and endurance, in nulliparous women of different ethnic groups. The secondary aim was to establish if

relationships exist between PFM strength, vaginal resting pressures and risk factors and symptoms associated with pelvic floor dysfunction and pelvic pain syndrome.

Pelvic floor dysfunction is a prevalent and disabling condition with suboptimal treatment (DeLancey, 2005). This study might contribute to the understanding of the underlying factors that can lead to disease and therefore help to determine effective strategies for assessing women with pelvic floor dysfunction and planning more effective physiotherapeutic management strategies for these problems.

CHAPTER 2

REVIEW OF RELATED LITERATURE

This literature review provides the background to support the argument that racial differences in the prevalence of urinary incontinence (UI) exist and that further investigation is needed into the aetiology of these differences.

This chapter will be presented in two sections. In the first section, a brief description will be given of the anatomy of the pelvic floor, pelvic floor muscle (PFM) function and dysfunction and continence mechanism. Overactive bladder syndrome (OAB) and stress urinary incontinence (SUI) will be described in relation to the pelvic floor muscle function. A literature review of studies will be presented on the incidence and prevalence of urinary incontinence and the anatomy related to the continence mechanism, with the emphasis on differences according to race.

In the second section, literature related to chronic pelvic pain, symptoms related to chronic pelvic pain, pathology as a result of overactive pelvic floor muscles and signs of over activity of the pelvic floor muscles will be addressed.

The terminology used conforms to the definitions recommended by the International Continence Society, except where specifically noted (Abrams et al, 2002; Messelink et al, 2005).

2.1 REVIEW OF RELATED LITERATURE ON RACIAL DIFFERENCES IN PELVIC FLOOR DYSFUNCTION

2.1.1 Background Information

Urinary incontinence is defined as the complaint of any involuntary leakage of urine (Abrams et al, 2002). Urinary incontinence has a high prevalence among women. An estimated 250 million women worldwide suffer from UI and the prevalence is expected to increase to 275 million in the year 2013. The prevalence of urinary

incontinence in women ranges from 25-69%, with most studies reporting prevalence in the range of 25-45% (Milsom, 2009).

Increasingly it is recognized that most of our diagnostic and therapeutic recommendations are based on studies predominantly doing research on white populations. It is therefore important to study other ethnic groups, because of the uncertainty of whether projection of these guidelines onto other groups is clinically meaningful (Bump, 1993). There is a paucity of literature on urinary incontinence and pelvic organ prolapse in non-white populations world wide (Hunnskaar et al, 2003). The understanding of the epidemiology is critical in the search for risk and protective factors that lead to primary and secondary disease prevention (Hunnskaar et al, 2003).

Population-based studies carried out in several different countries, using standard methodology, are needed to improve the approach on UI and to implement health interventions specifically targeted to the social and political needs of each country (De Araujo et al, 2009).

2.1.2 Pelvic floor function

In the following sections an overview of pelvic floor function and dysfunction will be presented. This will explain the terminology and concepts that will be discussed in the review of the prevalence of racial differences in pelvic floor muscle dysfunction.

The pelvic floor forms a muscular diaphragm which supports the pelvic contents and helps prevent their prolapse through the bony pelvic outlet. It consists of the superficial muscle groups of both the urogenital and anal triangles and the deep group, which is termed the levator ani. Fascia invests these muscles and forms the connection between organs, muscles and the pelvic walls (DeLancey, 1994).

The function of the pelvic floor is characterized by contraction and relaxation. In its resting state, the pelvic floor gives support to the pelvic organs through activity of the muscles at rest (active support) and the integrity of the fascia (passive support) (Messelink et al, 2005). The pelvic floor muscles (PFM) are the only muscle group in the body capable of giving structural support for the pelvic organs (urethra, vagina

and rectum) (Wei and DeLancey, 2004). A conscious, voluntary PFM contraction causes a squeeze and inward lift of the PFM, with resultant urethral closure, stabilisation, and resistance to downward movement (Ashton-Miller et al, 2001). A pelvic floor contraction can also inhibit detrusor contraction (Messelink et al, 2005).

2.1.3 Pelvic floor dysfunction

Dysfunction of the pelvic floor muscles, fascia and ligaments can lead to urinary incontinence (Wei and DeLancey, 2004), faecal incontinence (Bump and Norton, 1998), pelvic floor organ prolapse (Wei and DeLancey, 2004) together with gynaecological and sexual problems (Abrams et al, 2002). These symptoms of pelvic floor dysfunction are related to underactive pelvic floor muscles (Messelink et al, 2005). However, symptoms such as voiding problems, obstructed defecation, or dyspareunia are normally related to overactive pelvic floor muscles (Messelink et al, 2005).

Identification of the type of pelvic floor muscle dysfunction related to the symptoms of pelvic floor dysfunction is complicated. For example overactive (Wise and Anderson, 2006) and underactive pelvic floor muscles (Mørkved et al, 2002; Amaro et al, 2005; Thompson et al, 2006) can be related to stress urinary incontinence. Both overactive (Travell and Simons, 1992) and underactive PFM (Messelink et al, 2005) are not able to generate force and can be weak. This is further complicated by the fact that parts of the PFM can be overactive, whereas other parts can be underactive (Dietz, 2009). For instance, after a unilateral avulsion of the puborectalis muscle, the intact contra lateral puborectalis may become spastic and very tender leading to chronic pelvic pain and dyspareunia, whereas the side of the avulsion is underactive (Dietz, 2009).

It is often the case that dysfunction of the pelvic floor muscles will lead to dysfunction of more than one organ system (Messelink et al, 2005). The symptoms associated with pelvic floor dysfunction (PFD) can be divided into: lower urinary tract symptoms, bowel symptoms, vaginal symptoms, sexual function and pain (Messelink et al, 2005).

2.1.3.1 Risk factors for the development of PFD

Many factors have been identified which can cause pelvic floor dysfunction. Little is known of how these risk factors relate to overactive pelvic floor muscles, underactive pelvic floor muscles or both. Risk factors include anatomical differences in localisation of the pelvic floor with a decrease in strength of pelvic floor muscles and fascia; constipation with frequent pressure with defecation; overstretch, radiation and surgery in the pelvic floor area; smoking and lung disease; medicine; urinary tract infection; hormonal fluctuation with the menstrual cycle; pregnancy, damage with vaginal delivery; gradual weakening with age and changes in connective tissue with menopause (Bump and Norton, 1998). An association between low back pain and PFD has also been indicated in some studies (Smith et al, 2006; Eliasson et al, 2008).

In addition to these factors mentioned above, McLennon et al (2002) showed that education levels, low income, increased weight, poor quality of life, high use of health services, psychiatric visits, diabetes, osteoporosis and arthritis were all significantly associated with pelvic floor dysfunction.

More evidence is needed on the effect of strenuous exercise on the pelvic floor and the association of PFD and occupations requiring heavy lifting (Hay-Smith et al, 2009). In a systematic review of literature relating to strenuous activity and PFD, Hay-Smith et al (2006) pointed out that strenuous exercise is likely to unmask the symptoms of stress urinary incontinence during provocation, although there is currently no evidence that strenuous exercise causes UI (Hay-Smith et al, 2009). However there is evidence suggesting that moderate exercise decreases the incidence of UI in middle-aged and older women (Hay-Smith et al, 2009).

Another possible risk factor for the development of PFD that has been suggested in the literature is the use of the western toilets versus the squatting position for defecating or urinating (Zacharin, 1977). The position assumed on a western toilet, to obtain satisfactory emptying of the bowel, has been associated with increased straining compared to the ease of defecation in the squatting posture (Sikirov, 2003).

Assuming a simulated squatting position has been proposed for treatment of obstructive defecation to facilitate more effective evacuation of stool (Markwell and Sapsford, 1995).

It is more probable that combinations of anatomical, physiological, genetic, lifestyle, and reproductive factors interact throughout a woman's life-span and contribute to PFD, rather than any single factor, DeLancey et al (2008) describe these factors in an integrated lifespan model. Pelvic floor development is influenced by factors such as an individual's genetic code, nutrition, and environment, just as their height is. An individual who develops excellent pelvic floor function may never have sufficient deterioration to develop PFD symptoms throughout her lifespan, despite inciting or lifestyle events. Conceptionally then, the role of genetics must be considered in the analysis of PFD causation.

2.1.4 Stress urinary incontinence

Stress urinary incontinence is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing. The sign of SUI is the observation of involuntary leakage from the urethra, synchronous with exertion/effort, or sneezing or coughing. Urodynamic stress incontinence (USI) is noted during filling cystometry, and is defined as the involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction (Abrams et al, 2002).

The urethra is 3-4 cm long and maintains sufficient pressure to prevent urine passage during times of increase in intra-abdominal pressure, caused by factors such as coughing or physical activities. The skeletal muscle in the female urethra is composed of small, type I fibres, located predominantly in the middle third region of the urethra. Urethral smooth muscle is deposited in longitudinal and circular layers. Both skeletal and smooth muscles contribute to resting tone (Ashton-Miller et al, 2001).

Normal levator ani muscles maintain a constant state of contraction, by the action of type I muscle fibres, thus providing an active floor that supports the weight of the

abdominopelvic contents against the forces of intra-abdominal pressure. This baseline activity of the levators keeps the urogenital hiatus (UGH) narrowed and draws the distal parts of the urethra, vagina, and rectum towards the pubic bones. The pelvic floor muscles, contract with sudden increases in abdominal pressure (Corton, 2005).

Pelvic floor muscles are major contributors to continence. Normal function of the urethral support system requires the contraction of the levator ani muscles, which support the urethra through the endopelvic fascia. During a cough, there is a simultaneous contraction of the levator ani muscle with the diaphragm and abdominal wall muscles to build abdominal pressure. This levator ani muscle contraction helps to tense the suburethral fascial layer and thereby enhance urethral compression. It also protects the connective tissue from undue stresses (Ashton Miller et al., 2001). Levator ani muscle contraction pulls the vagina forward towards the pubic symphysis, creating a backstop for the urinary tract. This stable backstop compresses the two walls of the urethra, thus preventing leakage of urine during cough or similar intra-abdominal increases (DeLancey, 1994; Ashton-Miller et al, 2001).

Stress urinary incontinence arises when bladder pressure exceeds urethral pressure, with sudden increases of intra-abdominal forces. This might occur because of a loss of the backstop support at the bladder neck. The loss of support could occur if there are breaks in the continuity of the endopelvic fascia, or if the levator ani muscle were to be damaged, the supportive layer under the urethra would likely be less stiff. Loss of bladder neck support is referred to as bladder neck hypermobility. The supportive layer would then provide less resistance to deformation during increases in abdominal pressure and thus closure of the urethral lumen would not ensue, resulting in SUI (Ashton-Miller et al, 2001; Norton and Brubaker, 2006).

Measuring of forces, generated by PFM contraction, may be of value in understanding the pathophysiology of SUI. In particular, understanding the dynamic role that the pelvic floor plays in preventing incontinence would be extremely productive in the development of new approaches requiring conservative intervention (Moore 2000).

2.1.5 Overactive bladder syndrome

The definition of urgency is the complaint of a sudden compelling desire to pass urine, which is difficult to defer and urge urinary incontinence (UUI) is defined as the complaint of involuntary leakage accompanied by, or immediately preceded by, urgency (Abrams et al, 2002). Overactive bladder syndrome is defined by the International Continence Society (ICS) as urgency, with or without urgency incontinence, usually with increased daytime frequency and nocturia (Abrams et al, 2002).

The diagnosis of urgency and UUI can be confirmed with urodynamic studies (UDS) and then the terminology of detrusor overactivity and detrusor overactivity incontinence is used. Detrusor overactivity (DOA) is an urodynamic observation characterized by involuntary detrusor contractions during the filling phase which may be spontaneous or provoked. Detrusor overactivity incontinence is incontinence due to an involuntary detrusor contraction (Abrams et al, 2002).

Approximately 13% of women in four European countries and Canada reported OAB symptoms in a population-based survey of urinary incontinence, which used the current ICS definition of OAB (Irwin et al, 2006).

OAB syndrome can have a neurogenic or idiopathic origin (Abrams et al, 2002). There is no consensus on the true cause of idiopathic OAB syndrome. There are two trains of thought about the role PFM play in OAB syndrome, one being an association with high-toned PFM and the other with weak PFM.

High-toned PFM:

Messelink (1999) postulated that OAB symptoms are caused by overuse of the pelvic floor muscles to inhibit bladder (detrusor) contractions. This can happen, for instance, in people who must postpone voiding for a long time due to their occupation, resulting in hypertonic PFM. In this situation, voiding changes from an involuntary regulated reflex action to a voluntarily initiated and most often unco-ordinated action of the bladder and PFM.

Theoretically, the development of an overactive pelvic floor may induce peripheral and central changes leading to a new system managing and controlling the lower urinary tract cycle (Messelink, 1999). According to Messelink (1999) this system could be more vulnerable to loss of co-ordination between the detrusor and PFM, and loss of inhibitory signals to the detrusor, therefore leading to detrusor overactivity. It can become a vicious circle, whereby irritative PFM give rise to an irritative bladder, causing irritative pelvic floor muscles etc. (Weiss, 2001).

The theory of increased PFM tone is supported by a few studies (Kaplan et al, 1980; Schmidt and Tanagho, 1981; Butrick et al, 2009). They found increased tone in the external urethral sphincter with urodynamic studies in women presenting with urinary urgency and frequency. Schmidt and Tanagho (1981) and Butrick et al (2009) found that discomfort of urge was proportional to the elevation in urethral sphincter pressure. Urge discomfort dramatically diminished with the initiation of micturition and therefore relaxation of the external urethral sphincter. Moreover Kaplan et al (1980) showed that the institution of diazepam therapy provided clinical relief of OAB symptoms, but also brought about sphincter synergy as demonstrated with post-treatment urodynamics.

Weak PFM:

A pelvic floor muscle contraction can inhibit a detrusor contraction (Burgio et al, 1985). Mahony et al (1977) described the perineo-detrusor inhibiting reflex, which is activated by an increase of tension in the PFM. This means that a contraction of the PFM can induce reflex inhibition of the bladder. Inhibition involves an automatic (unconscious) increase in tone for both the pelvic floor muscles and the urethral striated muscle (Hay-Smith et al, 2009). Therefore if the PFM are weak and have decreased tone, the bladder will not be inhibited, resulting in an overactive bladder.

The theory of weak PFM contributing to OAB syndrome is supported by Goldberg and Sand (2002) as well as Burgio et al (1998). Goldberg and Sand (2002) proposed that “funneling” of urine into a poorly supported proximal urethra may trigger a reflex detrusor contraction through efferent pathways. Loss of extrinsic pelvic floor muscle tone or diminished competency of the intrinsic urethral sphincter may predispose to

this process of reflex bladder overactivity (Goldberg and Sand, 2002). Burgio et al (1998), showed a statistically significant reduction in the number of incontinence episodes and subjective improvement in women with urge urinary incontinence, on an active PFM training program.

2.1.6 Measurement of pelvic floor muscle function and strength

Palpation, visual observation, electromyography, ultrasound, and magnetic resonance imaging (MRI) measure different aspects of PFM function. Vaginal palpation is standard when assessing the ability to contract the PFM. Ultrasound and MRI seem to be more objective measurements of the lifting aspect of the PFM, whereas dynamometers and pressure transducers measure PFM strength (Bø and Sherburn, 2005).

It cannot be assumed that a person would be able to do a correct pelvic floor muscle contraction after verbal instruction. Several studies (Benvenuti et al 1987; Bø et al 1988; Hesse et al, 1990; Bump et al, 1991) have demonstrated that more than 30% of SUI women, although thoroughly taught in PFM anatomy and function, are unable to perform a correct PFM contraction at their first attempt. Thompson et al (2006) found that even healthy subjects find it difficult to obtain an inward lift of the pelvic floor muscles after a short verbal instruction. Therefore, a correct PFM contraction has to be established with vaginal palpation or visual inspection of the perineum (Bø et al, 2007).

Measurement of squeeze pressure is the most commonly used method to measure PFM maximum strength and endurance. Vaginal pressure rise is not specific to PFM contractions. Therefore, when using vaginal squeeze pressure measurements, careful instructions need to be given to the patient, with visual observation of the perineum and/or vaginal palpation by the physical therapist to ensure valid measurements (Bø et al, 1990b). Contraction of other muscles such as the hip adductor and external rotator muscles and the gluteal muscles, also alters intravaginal pressure measurement (Bø et al, 1990b). Therefore when measuring vaginal squeeze pressure, patients must be instructed not to do a posterior pelvic tilt

or contract gluteal and hip adductor muscles (Bø et al, 2007). A rise in intra-abdominal pressure will also be reflected in a vaginal pressure measurement, consequently breath-holding is not allowed when measuring vaginal squeeze pressure (Bø et al, 2007).

2.1.7 Discussion of ethnic studies

An overview is presented of the epidemiology of urinary incontinence among black ethnic groups in the South African, American and African environment.

2.1.8 Ethnic studies on incontinence

In the literature, the racial distribution of prevalence of UI has been established through questionnaires, urodynamic studies (UDS) and evaluation of medical records.

Several American studies, using urodynamic evaluation for diagnosis of UI, agree that black women are more frequently diagnosed with detrusor instability (DI) and that white women are more frequently diagnosed with genuine stress incontinence (GSI) (Bump, 1993; Peacock et al, 1994; Graham and Mallet, 2001; Duong and Korn, 2001). However, Klingele et al (2002) reported that the distribution of UI was evenly divided among genuine stress incontinence (GSI), detrusor instability (DI) and mixed incontinence, but still agreed that patients with genuine stress incontinence are more likely to be white. Graham and Mallet (2001) found that race was the most significant predictor of genuine stress incontinence (white race) and detrusor instability (black race) despite the inclusion of such recognized risk factors as age, parity, obesity, diabetes, previous hysterectomy and tobacco use. Kraus et al (2007) evaluated women on a trail for SUI surgery with UDS and found no difference in the severity of UI in the different race groups, but could obviously not differentiate between women experiencing GSI or DI in their study.

Other American studies, using questionnaires or telephone interviews to collect data, report that UI is more prevalent in white women (Fenner et al, 2008; Sampsel et al,

2002; Grodstein et al, 2003; Sze et al, 2002; Burgio et al, 1991). Some of these studies differentiated between the prevalence of UI into SUI, UUI and mixed urinary incontinence (MUI). Sze et al (2002) found that the prevalence of SUI was higher in white women, whereas black women had more complaints about urinary frequency and nocturia. Similar results were reported by Fenner et al (2008), who also found a higher prevalence of SUI in white women and a higher prevalence of UUI in black women. Thom et al (2006) reported that after adjustment for confounders in their study, the risk of SUI remained significantly lower in black and Asian women compared to white women, and the risk for urge incontinence was the same in black and Asian women compared to white women. Contrary to this, Rhaza-Kahn et al (2006) found no statistically significant differences in respect of antenatal or postpartum values or types of incontinence in different race groups.

Gray Sears et al (2009) reviewed the ICD 9 diagnosis codes of 720 electronic medical records of women with pelvic floor disorders in an equal access health care system, finding that the prevalence of urge urinary incontinence (UUI) was higher in black women and that white women were two times more likely to have SUI than UUI. In a review of the data from the American National census and American National Hospital Discharge Survey for 2003, Shah et al (2008) reported that 10 in 10000 white women, 3 in 10000 black women and 6 in 10000 other races underwent surgery for SUI in the USA.

One study in Uganda, reported an overall prevalence of UI to be 42%, with 25.9% women leaking on their way to the toilet, 12.5% leaking with a cough and 20.1% leaking with exercise (Gashugi and Louw, 2005). In Ghana, Adanu et al (2006) found that 42% of women had a positive paper towel test, indicating UI. Of these women with UI, 48% had loss of urine while waiting to use the toilet and 43% had loss of urine on coughing. These two studies indicate that the prevalence of incontinence is quite high in the African context and that urge urinary incontinence is more frequently reported than SUI.

In a South African study in 1943, Heyns reported that he had only seen one case of SUI among black women. However, in subsequent studies in South Africa, higher

prevalence of SUI was reported. Skinner and Crichton (1963) report an equal distribution of minor SUI among black, Indian and white nulliparous groups. In an epidemiological study on urinary incontinence in the Western Cape (van der Walt and Rienhardt, 2002), 14.7% of women reported UI and an equal distribution of SUI between black, white and coloured groups was found. In this study (van der Walt and Rienhardt, 2002), it was also found that symptoms of urge and urge incontinence were more common in black women. This is the only study that has investigated pelvic floor dysfunction in coloured women.

If all of these studies are taken into consideration, there is consistent evidence to suggest that white women are at increased risk of SUI and that UUI is possibly more frequently reported in black women. This may suggest that there are differences in detrusor muscle function, or in the functionality of the sphincter mechanism. The differences in the function of the detrusor in women with detrusor overactivity suggest that there may be differences in bladder function or disease aetiology, depending on ethnic origin which deserve further study (Teo et al, 2004).

2.1.9 Ethnic studies on pelvic floor muscle strength and anatomy

Howard et al (2000) and Duong and Korn (2001) reported a higher urethral closure pressure among black women, however Graham and Mallet (2001) found no racial difference in the maximum urethral closure pressures of women with detrusor instability. The urethral length has also been found to be longer in black women (Skinner and Crichton, 1963; Knobel, 1975).

A few studies, using different methods of testing, have found that black women have stronger PFM muscle. Stress urinary incontinent black women, evaluated in a trial to receive surgery for SUI, had stronger PFM, with better endurance, than white women, measured with the Brink vaginal palpation score (Kraus et al, 2007). Researchers (Skinner and Crichton, 1963; Knobel, 1975; Howard et al, 2000) found that the vaginal pressure increase, developed during a maximal pelvic floor contraction, is higher in black women. However, in their study, Levitt et al (1979),

found no statistically significant difference in strength between races when a Kegel perineometer was used as the measurement tool.

Small sample sizes were used in these studies and PFM strength was evaluated with different measuring devices. Howard et al (2000) evaluated PFM strength in 18 black and 17 white women with an instrumented speculum. Knobel (1975) evaluated PFM strength in 10 black and 10 Indian parous women and Skinner and Crichton (1963) evaluated 20 black and 20 Indian continent women with the Kegel perineometer. The pressure measurements of these studies cannot be compared or combined in systematic reviews or meta-analyses, because different measuring devices were used and the position in which the measurement was taken and the procedure in which the measurement was performed, were not well defined (Bø, 2005 and Frawley et al, 2006).

Bø et al (1990b) found that vaginal pressure rise was obtained regardless of correct or incorrect PFM contraction, showing that vaginal pressure is not specific to PFM contraction. However, as the action of the PFM is elevation, a simultaneous inward movement of the vaginal probe is present only during correct PFM contraction. In these studies measuring vaginal pressure with a pelvic floor contraction (Skinner and Crichton, 1963; Knobel, 1975; Levitt et al, 1979), it was not stated or verified that the person participating in the study was in fact able to do a correct pelvic floor muscle contraction. It was also not stated whether other muscle groups, that might contribute to an increase in vaginal pressure, were eliminated (Bø et al 1990b). Therefore the results of these studies on vaginal pressure measurements may not be valid.

Studies on racial differences in pelvic morphology, using magnetic resonance imaging (MRI), reported significant differences between black and white races. Hoyte et al (2005) found an increased muscle bulk and closer puborectalis attachment in nulliparous African American women compared to nulliparous white American women. Hoyte et al (2005) also reported that in African American women the bladder neck was closer to the symphysis pubis and the angle of the urethra to the symphysis was smaller. According to this author these differences suggest a

levator ani complex in African American women that is more intimately associated with its connective tissue. Downing et al (2007) found that nulliparous black women had significantly thicker Levator ani muscles compared to white women. He advised that further research has to be done to see if muscle thickness correlates closely with muscle function, because this would be clinically useful.

Ethnic differences in the bony pelvis also exist. On comparative examination of the bony measurements of the pelvis, it was reported by Baragi et al (2002) that African American women had a 5.1% smaller pelvic floor area than white women and that they had a 10.4% smaller posterior area than white women.

2.2 REVIEW OF RELATED LITERATURE ON CHRONIC PELVIC PAIN

The International Continence Society (ICS) uses the term pelvic pain syndrome (PPS) to describe the occurrence of persistent or recurrent episodic pelvic pain associated with symptoms suggestive of lower urinary tract, sexual, bowel or gynaecological dysfunction, where there is no proven infection or other obvious pathology (Abrams et al, 2002). However, the term chronic pelvic pain (CPP) is used in the European Association of Urology guidelines (Fall et al, 2009) to describe non-malignant pain perceived in structures related to the pelvis of either men or women. According to Fall et al (2009) the term, pelvic floor muscle pain syndrome, is defined as the persistent or recurrent episodic pelvic floor pain with associated trigger points either related to the micturition cycle or associated with symptoms suggestive of urinary tract, bowel, or sexual dysfunction with no proven infection or other obvious pathology.

Chronic pelvic pain (CPP) is a widespread problem and is the reason for 10-15% of all gynaecological referrals, 25-35% of laparoscopies and 10-15% of hysterectomies (Reiter, 1998).

2.2.1 Overactive pelvic floor muscles

Overactive pelvic floor muscles are defined as a situation in which the pelvic floor muscles do not relax, or may even contract when relaxation is functionally needed, for example during micturition or defecation (Messelink et al, 2005).

The pelvic floor muscles are intimately connected to the vaginal wall, urethra and rectum through the endopelvic fascia, paravaginal fascia and arcus tendineus fascia pelvis (DeLancey, 1994). The PFM are therefore connected to pelvic organs through the fascial system. Because the pelvic floor muscles act as an entity, it is often the case that dysfunction of the PFM will lead to dysfunction of more than one organ system (Messelink et al, 2005). The opposite could also be true, that visceral structures could affect the PFM. Prendergast and Weiss (2003) proposed that recurrent yeast infections could cause pelvic floor muscle spasm through spinal cord

reflexes between the mucosa and muscle. Overactive pelvic floor musculature can therefore be associated with symptoms and pathologies related to these structures through the myofascial connections.

These symptoms can relate to the lower urinary tract, vagina and uterus, rectum, musculoskeletal and neural system (Weiss, 2001, Goldberg and Sand, 2002; Prendergast and Weiss, 2003; Anderson et al, 2005; Wise and Anderson, 2006; Steege and Zolnoun, 2009; Fall et al, 2009, Butrick et al, 2009; Morin and Bergeron, 2009). Symptoms related to the urethra and bladder are urgency, frequency of daytime and night-time urination, painful bladder syndrome (PBS), interstitial cystitis, SUI, urethritis, OAB and chronic prostatitis. However the symptoms related to the vagina and uterus are dyspareunia, vulvodynia, vulvar vestibulitis, vaginismus and dysmenorrhoea. Symptoms and pathologies that can be related to the rectum are obstructive defecation, anismus and irritable bowel syndrome. If symptoms are related to the musculoskeletal and neurological structures, pathologies such as coccygodynia, pelvic floor myalgia, perineal pain and pelvic nerve entrapment are mentioned.

Patients have been handled by different specialist medical practitioners i.e. orthopaedic surgeon, neurologist, gynaecologist, urologist or gastroenterologist, depending on the structure where the most symptoms arise. Consequently, it has been difficult to identify relationships between overactive pelvic floor muscles and symptoms and pathologies (Wise and Anderson, 2006). Generally studies identified risk factors in relation to symptoms of pelvic floor dysfunction such as urinary incontinence, pelvic organ prolapse and pelvic pain syndrome. However, they have not related these risk factors to pelvic floor muscle function to identify if symptoms of PFD are related to overactive pelvic floor muscles, underactive pelvic floor muscles or a combination. Furthermore, there is also a lack of consensus in the current literature concerning terminologies used to characterize pelvic floor muscle tonicity i.e. hypertonicity, overactivity, spasm, tension and spasticity (Morin and Bergeron, 2009). This compromises the understanding and investigation of pelvic floor muscles in the pathophysiology of pelvic pain syndrome.

Weiss's study (2001) was the first study in a major peer-review journal to draw attention to the efficacy of treating hypertonic pelvic floor muscles with manual therapy techniques in patients with interstitial cystitis and urgency-frequency syndrome. Since then, more studies have been published on PFM as a common denominator in all of these symptoms and pathologies and a fresh interest in evaluating PFM function or behaviour in relation to chronic pelvic pain has arisen (Lukban et al, 2001; Oyama et al, 2004; Anderson et al, 2005; Tu et al, 2006). Recently, the report of the ICS on pelvic floor clinical assessment (Messelink et al, 2005) recommended that in a patient interview, it is mandatory to ask about symptoms of the different tracts influenced by the pelvic floor muscles.

A few descriptive studies, without case controls, reported on the treatment of PFM in patients with symptoms of chronic pelvic pain. Oyama et al (2004), Anderson et al (2005) and Weiss (2001) assessed men or women with pelvic pain symptoms and evaluated tone of the PFM with vaginal or rectal palpation and reported increased tone and trigger points in the PFM (refer 2.2.2). The PFM were treated with manual therapy techniques and in all of these studies a significant reduction in pelvic pain symptoms was reported. The sample sizes in the studies by Anderson et al, (2005) and Weiss (2001) were adequate for analysis, but the sample size in the study of Oyama et al (2004) was small (n=21), which decreased the efficacy of the study.

2.2.2 Trigger points and PFM tone

Travell and Simons (1992) define trigger points as the presence of exquisite tenderness at a nodule in a palpable taut band of muscle. Trigger points are able to produce referred pain, either spontaneously or on digital compression. The proposed etiology of myofascial trigger points are that constant or repeated activity in a small number of muscle fibres, predominantly Type I fibres, will create muscle overload, causing a metabolic crisis ending in an ischemic environment (Simons et al, 1992; Waersted et al, 1993). Trigger points can therefore be the result of excessively long-held muscular tone.

Recent studies confirmed that a variety of chronic symptoms in the pelvic area, including the bladder, urethra, prostate and the lower bowel, can be caused, aggravated or maintained by the presence of active myofascial trigger points. These trigger points can be inside the pelvis in the pelvic floor muscles and obturator internus muscle, or in the external pelvic muscles such as the abdominals, adductors, iliopsoas, piriformis and gluteal muscles. (Weiss, 2001; Lukban et al, 2001; Oyama et al., 2004; Anderson et al, 2005; Tu et al, 2006).

A recurring feature in all of these studies is excessive tone in the pelvic floor muscles. There is some indication that vaginal resting pressure may be able to relate to pelvic floor muscle tone. Griffin et al (1994), using a vaginal pressure probe, showed a significant increase in pelvic floor resting pressures after the completion of a pelvic floor muscle exercise program and related it to increased muscle tone.

Whether the overactive pelvic floor is the primary cause of symptoms or an effect of pathology elsewhere, it is crucial that it be evaluated in order to understand the underlying pathology of PPS, so that more effective treatment options can be established.

2.3 Conclusion

From the literature review one can conclude that the distribution of symptoms of SUI and OAB in the black population may be different from that of the white population and therefore worth investigation. Significant differences in the adjusted risk of stress incontinence among white and black women suggest the presence of additional, as yet unrecognized, risk or protective factors for stress incontinence (Thom et al 2006), whereas black women seem to have an increased risk of developing OAB symptoms. The pelvic floor muscles play an important role in the continence mechanism (DeLancey, 1994) and decreased PFM strength has been associated with stress urinary incontinence (Hahn et al, 1996; Mørkved et al, 2002; Amaro et al, 2005; Thompson et al, 2006).

Therefore, the main objective of this study is to investigate PFM strength in different ethnic groups, in an endeavour to contribute to the understanding of the differences in the incidence of UI among different ethnic groups. Consequently light may be shed on the possible aetiology of urinary incontinence. This study forms part of a larger investigation into urinary incontinence among the black population, including the epidemiological study (van der Walt and Rienhardt, 2002) and a study on collagen quality (Laborda et al, 2005) comparing white and black races.

The relationship between PFM function and pelvic pain syndrome is still unclear. The International Continence Society (ICS) indicated that further research is needed on the relationship between PFM dysfunction and symptoms mentioned by patients, as well as further investigation into ways of measuring and quantifying pelvic floor muscle tone, force, and volume (Messelink et al, 2005). Therefore, the secondary objective of this study is to establish if relationships exist between PFM strength, vaginal resting pressures and risk factors and symptoms associated with PFM dysfunction and pelvic pain syndrome.

Evaluation of the scope of the type and magnitude of normal variation in pelvic floor function in a population is important to other investigators in order to differentiate normal from abnormal (Tunn et al, 2003). This can help to avoid the identification of a visible pattern as pathologic, when it is simply an uncommon variant. Although many investigators assume normal values are available on PFM function, such data rarely exist, therefore Dietz et al (2003) encouraged other investigators to reproduce and extend findings on normative pelvic floor values in nulliparous women. The current study seeks to initiate the process of establishing areas in which racial variation occurs and to gain some preliminary idea of the range of variation.

To achieve accurate measurement of PFM strength, possible confounders need to be taken into account. In the following section, the questionnaire assessing inclusion and exclusion criteria and demographics will be addressed as well as the methodology used for the measurement of vaginal squeeze pressure.

CHAPTER 3

RESEARCH DESIGN AND METHODOLOGY

This chapter describes the methodology used to answer the research question: Is there a difference in the pelvic floor strength of nulliparous women from different ethnic groups?

Included in this chapter are the research questions and the specific aims of the study. It is structured to give a description of the sampling process, instrumentation and the procedure used to collect data. This is followed by an outline of the ethical considerations taken into account during the execution of this project. The methods used for statistical analysis are also described.

3.1 Aims and Objectives

The objectives of this study are described as primary and secondary objectives respectively.

3.1.1 Primary objectives

The primary objectives of the study were:

- To determine the PFM strength of nulliparous women by measuring the vaginal pressure increase during a maximal voluntary contraction (MVC) of the PFM.
- To determine the PFM endurance of nulliparous women by measuring the pressure difference between two sets of three maximum voluntary contractions.
- To compare the PFM strength and endurance between nulliparous women in the black, white and coloured ethnic groups.

3.1.2 Secondary objectives

The secondary objective was to establish if relationships exist between PFM strength, vaginal resting pressures and risk factors and symptoms associated with PFM dysfunction and pelvic pain syndrome.

3.2 Research setting

This study was completed at the three institutions of higher learning situated in the Western Cape, South Africa.

The Research team consisted of a primary researcher and one assistant.

The primary researcher was responsible for the PFM lectures, recruitment of physiotherapy and nursing students, personal interviews and completion of questionnaires, testing procedure, data extraction and data capturing and storing. This researcher had eight years experience in the management of patients with incontinence, teaching of PFM exercises and conducting vaginal and anal examinations.

A research assistant was employed for the duration of the study. This researcher was responsible for the recruitment of students and signing of informed consent forms at the University of the Western Cape Student Health Clinic. The research assistant also helped with the weighing and height measurement of the participants.

3.3 Population

The population included physiotherapy and nursing students studying in the Western Cape or students attending the University of the Western Cape Student Health Clinic.

3.4 Sample

A sample of convenience was used.

3.4.1 Inclusion criteria

- The volunteers provided informed consent.
- Age 18-45 years
- Nulliparous
- The participant's classification of herself as part of the black, coloured or white ethnic group.

3.4.2 Exclusion criteria

- Gynaecologic surgery including pelvic floor surgery
- Current pregnancy
- Menstruating on the day of the test
- Inability to understand the instructions given in English
- Inability to contract the PFM, assessed by observing the movement of the perineum while contracting.
- Participant on an active pelvic floor strengthening program for longer than two weeks
- Low back pain sufferers with radiating pain or any participant who had a neurological condition that would affect the pelvic floor function and strength
- Radiotherapy to pelvis/pelvic organs
- Diabetes Mellitus
- Urinary tract infection on the day of the test
- Previous spinal surgery
- Vaginal infection on the day of the test
- Non RSA citizens

3.4.3 Recruitment of participants

A pilot study (Pilot A) was conducted to establish the recruitment strategy of the students (Addendum A).

The aims of the pilot study were to determine:

- How to recruit students to participate in the study.
- How many students would be willing to participate in the study?
- What would motivate students to participate in the study?
- What would discourage the student from participating?
- How they feel about the insertion of a vaginal sensor.

The amendments and considerations made to the recruitment strategy of the students are described in Addendum A.

Volunteers were recruited from the Physiotherapy Departments of the University of Stellenbosch, University of Cape Town and University of the Western Cape. Nursing students were recruited at the Nursing Department of the University of the Western Cape and University of Stellenbosch.

Lectures on PFM, arranged by lecturers responsible for women's health, were given at the physiotherapy and nursing schools of the different universities. A lecture of approximately two hours on pelvic floor anatomy, function and dysfunction and rehabilitation was given by the primary researcher in a class setting. The outline of the lecture is included in Addendum B. Following the lecture, the study was explained, the balloon catheter was shown to the students and volunteers were recruited. Students who were willing to participate, completed an informed consent form (Addendum C) and the screening part of the questionnaire (Addendum D). For those students included in the research, arrangements were made with the primary researcher and or lecturer to plan a meeting for the test procedure as arranged with each physiotherapy and nursing school.

After recruitment at all the physiotherapy and nursing departments had been done, the sample size was still not large enough. Students from other university disciplines, waiting to see the student health nurses at the University of the Western Cape Student Health Clinic, were then recruited. The research assistant helped with the recruitment of the participants, while the primary researcher was testing other participants. A diagram with the pelvic floor muscles in relation to the pelvic organs and a model pelvis with pelvic floor muscles were shown to the students. The function and dysfunction of the pelvic floor muscles were explained. A brief description of the study was then presented to the students and the vaginal balloon catheter was shown, after which they were asked if they would like to participate. Those who volunteered completed the informed consent form and screening questionnaire. If included, an appointment was made to do the testing, or they were tested immediately after recruitment. The testing was done at the University of the Western Cape Physiotherapy Clinic which was located in the same building as the student clinic.

3.4.4 Sample size calculation

During the planning of the study, no published data were available that compared groups in order to estimate a clinically significant value. Therefore a sample size was calculated based on data of a study conducted by Frawley et al (2004) using the Peritron perineometer with its standard vaginal probe, with reported standard deviation of 15 cmH₂O. A sample size of 75 participants was calculated with 90% power and p-value <0.05, to identify 15 cmH₂O.

Because a different vaginal sensor was used than in the study of Frawley et al (2004), the sample size was recalculated after 50 participants were included. The data was analysed by the statistician, Prof Martin Kidd, using ANOVA. It was then calculated that a sample size of 37 in each ethnic group would have 90% power to identify a mean difference of 8 cmH₂O between the three groups of participants.

3.5 Ethical considerations and study permission

During the execution of the project the following ethical considerations were made:

- The study involved an observation of the perineum to assess whether the participant was able to do a correct pelvic floor muscle contraction. It also involved the insertion of a vaginal probe to assess the increase in vaginal pressure with a pelvic floor muscle contraction. This in itself could be quite stressful to the participants. Assessment of the pelvic floor was therefore done with professionalism and skill as described in the Chartered Society of Physiotherapists Guidelines (2005). All efforts were made to secure the privacy of the participants. The confidentiality of the participants was respected at all times.
- Data were saved confidentially for possible use in an article in a scientific journal, with the anonymity of the study participants guaranteed.
- A summary of the results of the study would be given to each physiotherapy department, with students participating, to inform the students of the results.
- Sexual function or dysfunction was not assessed in this study. This was decided because questions on sexual function were too personal to include in this study of women who were not married and had no children.
- If a decrease in PFM strength was found or an inability to contract the PFM, a training program was offered.
- The participation in the study was entirely voluntary. Informed consent was obtained from each student participating in the study.
- The participants benefited from the study by learning to do a correct PFM contraction.
- Nursing and physiotherapy students benefited from the study by being informed on the latest techniques for assessment and rehabilitation of the pelvic floor and could therefore be more efficient in treating patients.
- All efforts were made to prevent infection.

- With the background of apartheid in South African history, special care was taken not to give racial offence with this ethnic study. Comments and presumptions made without ethnic intention might have been taken as racial prejudice. Therefore special care was taken with all communication to make sure that no racial offence was given.
- If the researcher identified problems as a result of the testing, the participant would be referred to an appropriately qualified person to manage the problem.
- The research was conducted according to the ethical guidelines and principles of the International Declaration of Helsinki (Helsinki Declaration, 2008) South African Guidelines for Good Clinical Practice (Guidelines, 2009) and the Medical Research Council (MRC) Ethical Guidelines for Research (MRC guidelines, 2009).
- Students at the University of Western Cape Student Health Clinic who participated were given a small gift which consisted of a chocolate and pack of tissues and sanitary towels which were sponsored by Kimberly Clark.
- Nursing and physiotherapy students who participated in the study received a copy of a book on urinary incontinence: "Women's waterworks" which was sponsored by Biostim medical.

Permission was obtained from the following people or institutions to conduct the study:

- The project was registered by the University of Stellenbosch Ethical Committee. The registration number of the study: N06/03/058 (Addendum E)
- Dr Thomson, Tygerberg Hospital Administrator, gave permission for the pilot study to be conducted at the Family Planning Clinic. (Addendum F)
- Written permission to recruit students from the University of the Western Cape was obtained from the Registrar of the University, Dr. I. Miller (Addendum G and H)
- A letter of permission was obtained from Prof. Amosun to recruit students at the University of Cape Town Physiotherapy Department. (Addendum I)

3.6 Intervention

The following is a flow chart, describing the test procedure:

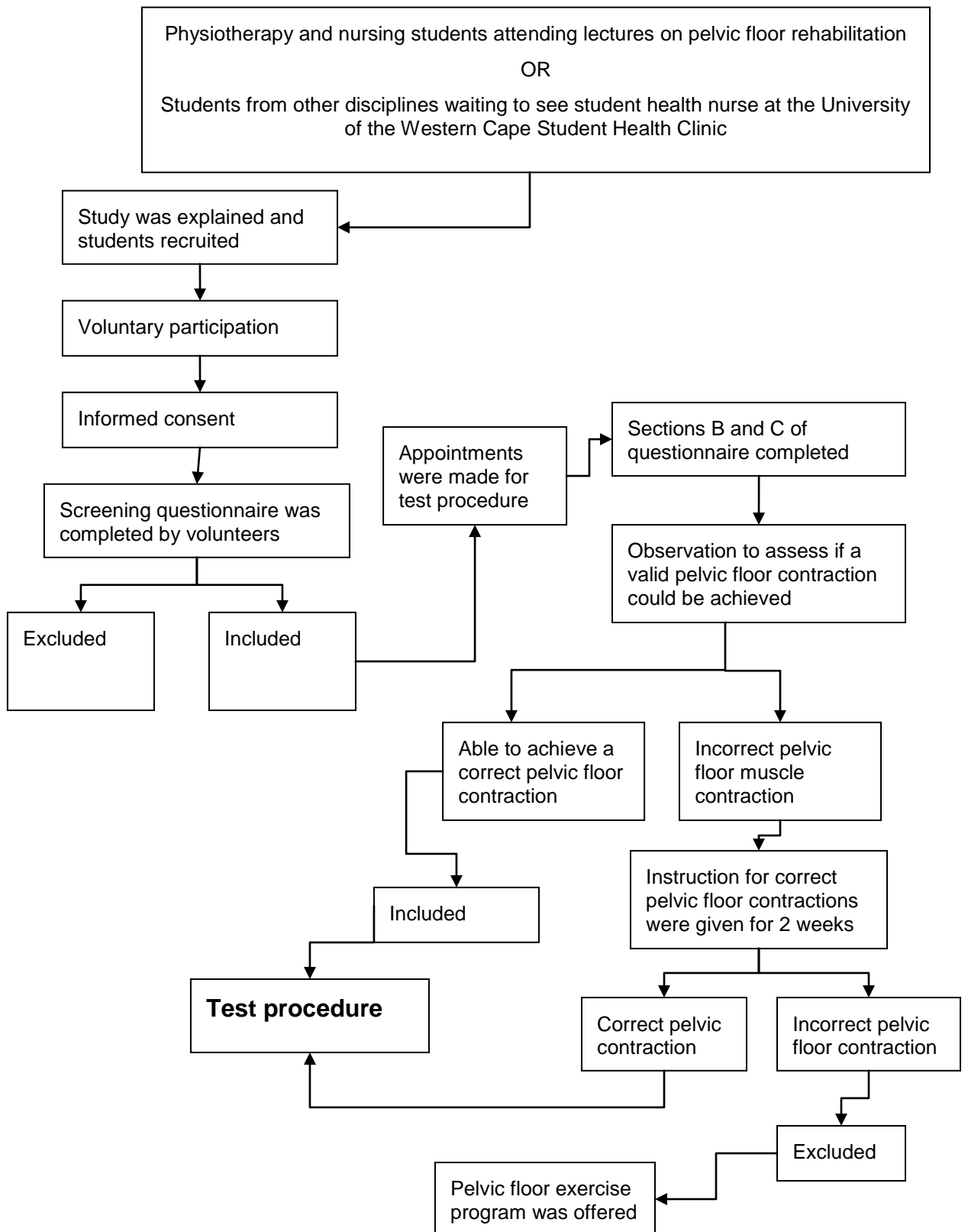


Figure 3-1: Flow chart describing the instrumentation

3.6.1.1 Personal interview

A personal interview by the primary researcher was conducted according to sections B and C of the self-developed questionnaire (Addendum D) on the day of recruitment or test procedure. The aim of the questionnaire was to obtain demographic data and variables that could influence strength and vaginal resting pressure.

3.6.1.2 Procedure of testing (Bø et al, 2007)

Pilot study B was performed to assess the test protocol before testing could commence (Addendum J).

The aims of pilot study B included:

- Determining the process of data capturing and storing
- Determining the time required to complete the test procedure
- The researcher to familiarize herself with the test procedure

The completion of questionnaires and explanation of the procedure were conducted by the primary researcher according to the amendments made after pilot study B (See Addendum J). Before the start of the test procedure, the weight and the height of the participants were measured and recorded on the questionnaire. A standardised test procedure described by Bø et al (2007) was used. Nobody else was present during the procedure.

Phase 1: Information given to all volunteers by primary investigator prior to testing

- The participant was informed about the test procedure
- A detailed description of the anatomy and function of the pelvic floor was explained to the participants in a group or individually, depending on where the recruitment of students had taken place.

- A description was given of the correct pelvic floor contraction. The contraction was explained as lifting and squeezing the muscles around the anus, as if stopping a wind and simultaneously lifting and squeezing the muscles around the front as if stopping urine (Kegel, 1948).
- A description was given of muscles which should not be recruited: gluteus maximus, hip adductor muscles and rectus abdominus.

Phase 2: Observation



Figure 3-2: Test position

- The participants undressed the bottom half of the body, after which they were placed in a crook lying position with 2 pillows under the head and covered with a sheet (Figure 3.2).
- The primary researcher then observed:
 - The perineum to monitor that a cephalic displacement of the perineum was achieved with a pelvic floor muscle contraction.
 - That the participant did not get a posterior pelvic tilt during PFM contraction to ensure that rectus abdominis was not recruited.
 - That the participant did not get gluteal or hip adductor activity with a PFM contraction.

Phase 3: Testing for a correct Pelvic floor contraction

In case of an incorrect PFM contraction, the participant was given instructions on pelvic floor muscle contractions and provided with a follow up appointment two weeks later.

The PFM contraction was defined as incorrect when:

- no cephalic displacement of the perineum was observed
- the participant strained or used other muscles instead of the PFM

The same procedure was used during the two week follow-up appointment. If the participant was still not able to obtain a correct contraction, she was excluded from the study and offered an appointment to attempt to facilitate PFM contractions.

Phase 4: Measurement

- The Peritron™9300 was switched on and the blue tooth connection with the computer was established, then the tester washed her hands and put examination gloves on.
- The balloon catheter was compressed by an estimated 10-20% to allow for air expansion at body temperature and then connected to the silicon tubing of the Peritron (Bø et al 1990a).
- The participant inserted the vaginal sensor with the marking at the level of the introitus of the vagina.
- The primary researcher checked that the vaginal sensor was inserted at the right level.
- The primary researcher gave support to the vaginal sensor to keep it in the same intravaginal position.
- The participant was instructed to contract the PFM as hard as possible, with no visible co-contraction of hip adductor, gluteal or rectus abdominus muscles (pelvic tilt) and then to relax without pressing the perineum downwards.

- While the participant performed the PFM contraction, the primary researcher assessed the following aspects:
 - that the catheter was drawn inwards as an indication of a correct PFM contraction,
 - that no accessory muscles were used while contracting
 - that no posterior pelvic tilting took place.
- A small in-drawing or “hollowing” was allowed using internal abdominals (transversus abdominis and internal oblique) with maximum contraction and no tilting of the pelvis.
- The participants were asked to do three consecutive maximal voluntary pelvic floor contractions, each held for as long as the patient could maintain it or up to 10 seconds with a rest period of 20 seconds between each contraction.
- Resting pressure and peak pressures of repeated contractions were registered on the Peritron™ 9300.
- Two sets of three contractions each were done with a resting phase of five minutes in between the sets.
- The contractions were registered on the Peritron™ 9300 and on the computer connected via Blue tooth to the Peritron™ 9300.
- After the session the vaginal sensor was withdrawn by the participant.
- The vaginal sensor was then discarded.
- The participant was given privacy to get dressed and was given disposable wet wipes to clean herself after the session.

Phase 5: Follow up

If the participant was found to have a reading below 10 cmH₂O, extra time was spent on guiding the participant through a strengthening program. The participant also received a handout with a pelvic floor strengthening program (Addendum K).

3.7 Study design

This is a cross-sectional study comparing three South African ethnic groups.

3.8 Outcomes

Three pilot studies were completed (See Addendum L-N). This included studies on the sensitivity of the demographic questionnaire, intra-tester reproducibility of the measurement and accuracy of measurement.

3.8.1 Pilot studies

Pilot study C:

Aim:

The Peritron™ 9300 perineometer (Cardio-Design, Australia) was purchased for the study with the vaginal sensor that is issued with the perineometer. After the students saw the Peritron™ sensor, their feedback was, that it was too big and the shape of the probe was not acceptable to the students for usage in this study (Figure 8.1). It was then decided to use the smaller vaginal probe from Camtech (Camtech AS, Sandvika, Norway) with the Peritron™ perineometer. The objective of this pilot study was to determine if the readings by the Peritron™ 9300 perineometer used in conjunction with the Camtech vaginal probe were accurate.

Outcome:

The readings on the Peritron™ perineometer used in conjunction with the Camtech AS vaginal probe were found to be accurate ($r = 0.99$; $p < 0.01$). (Figure 8.2)

Pilot study D (Addendum M):

Aim:

The aim of this study was to determine the intra-tester reproducibility of the investigator.

Outcome:

It was found that the measurements on the two consecutive days were comparable [ICC agreement = 0.997 (0.954; 1.00) and ICC consistency = 0.996 (0.938; 1.00) and SEM = 0.882].

Pilot study E:

During 23-28 May 2007, a pilot study was conducted at the Tygerberg Hospital Family Planning Clinic.

Aim:

The aims of this pilot study were to test the following aspects of the study:

The demographic questionnaire

- The time needed to complete the questionnaire
- To test if the participants understood the questions in the questionnaire
- To test demographic questionnaire
- To ask for feedback from participants to see if adjustments needed to be made to improve the clarity of the questionnaire

Amendments made to the questionnaire can be viewed in Addendum N.

3.8.2 Instrumentation

The following flow chart gives an overview of the instrumentation used in the study including the Peritron™ perineometer and the self-developed questionnaire

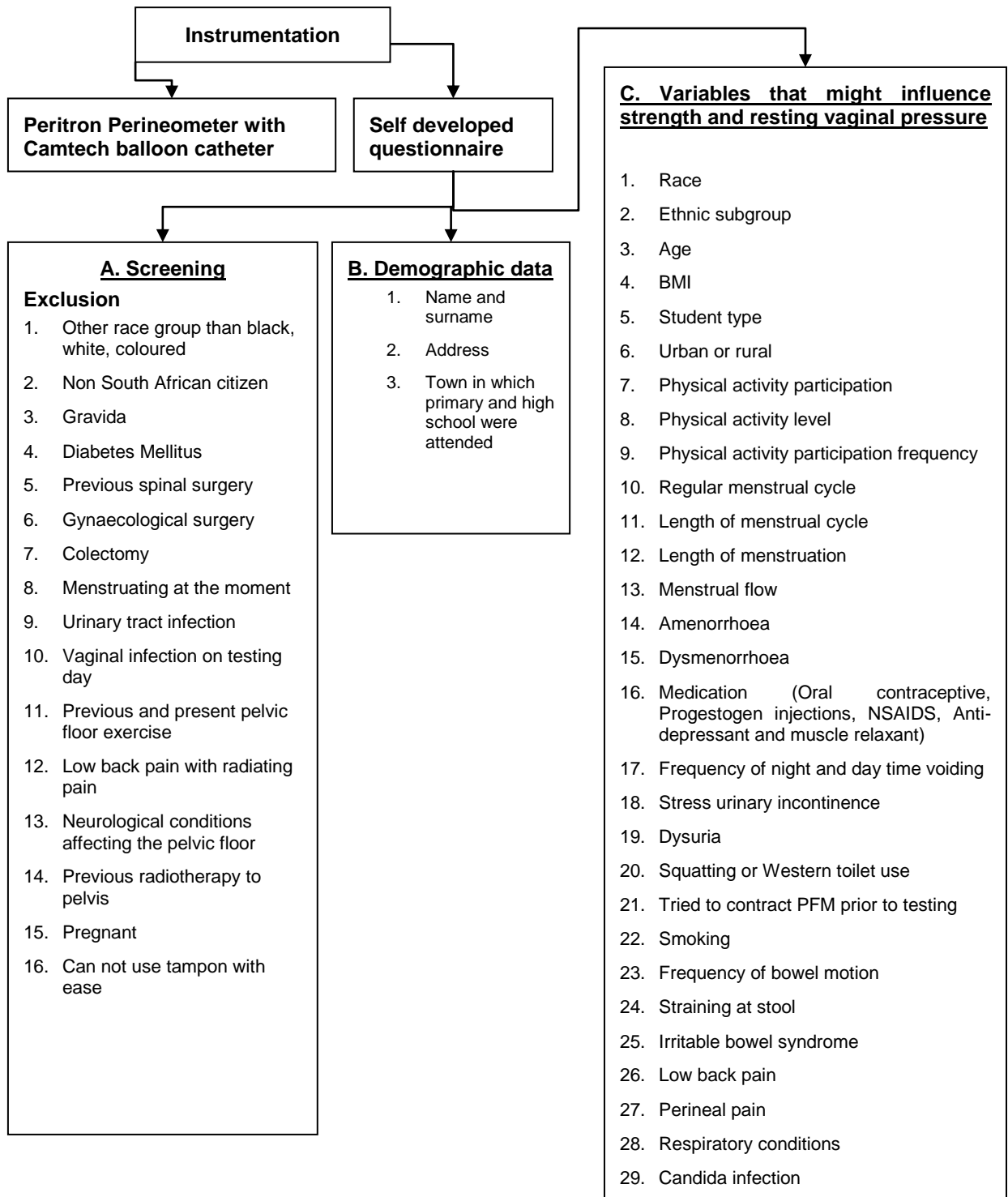


Figure 3-3: Flow chart describing the instrumentation

3.8.2.1 Questionnaires

Two questionnaires were compiled. The first questionnaire (Screening A) was completed by all volunteers. The second questionnaire was only completed by volunteers who were included in the study. The second questionnaire consisted of sections B and C. A description of the questions included in the questionnaires and the reason for inclusion will be discussed. An overview of the questions is given in Figure 3.3 and the questionnaire can be viewed in Addendum D.

Questionnaire one: Screening A

Screening A was designed to provide information on exclusion criteria. The questions included in the questionnaire were for determination of exclusion from the study which were stipulated earlier in 3.4.2 and appear in Figure 3.3.

Questionnaire two: Section B and C

Section B: The question was aimed to provide information on the rural or urban background of the participants.

Section C: This part of the questionnaire was designed to provide demographic information and variables that might influence or be associated with PFM strength. The questions were compiled according to the risk factors identified in the literature for the development of pelvic floor dysfunction as described in 2.1.3. Other questions, contained in the questionnaire, were designed to assess symptoms associated with pelvic pain syndrome. These symptoms were described in the literature review in section 2.2.1. Although symptoms of sexual dysfunction are also related to pelvic pain syndrome, it was not investigated.

The questions in section C provided information on age, BMI, ethnic subgroup, physical activity, menstrual cycle, previous attempt to contract PFM, squatting or western toilet use, medication, smoking history, bowel motion habits, frequency of day and night time voiding and dysuria.

The definitions and terminology that were used in the questionnaire are described in Addendum O.

3.8.2.2 The Peritron™ 9300 perineometer

In this section a description of the measuring device and the validity and reliability of the device will be given.

Peritron™ 9300 perineometer

An objective measurement of pelvic floor strength was recorded with the vaginal pressure measurement in cmH_2O in crook lying with the Peritron™ 9300 perineometer (Cardio Design, Australia) (Figure 3.4). The Peritron™ 9300 is connected to a vaginal balloon catheter manufactured by Camtech AS, Sandvika, Norway (Figure 3.4 and 3.5). The balloon sensor is 17mm wide and 67mm long and connected to a 175mm long catheter. This balloon catheter is connected to the Peritron™ unit via an 80cm plastic tube.

The balloon catheter is for single patient use and was discarded after each participant.

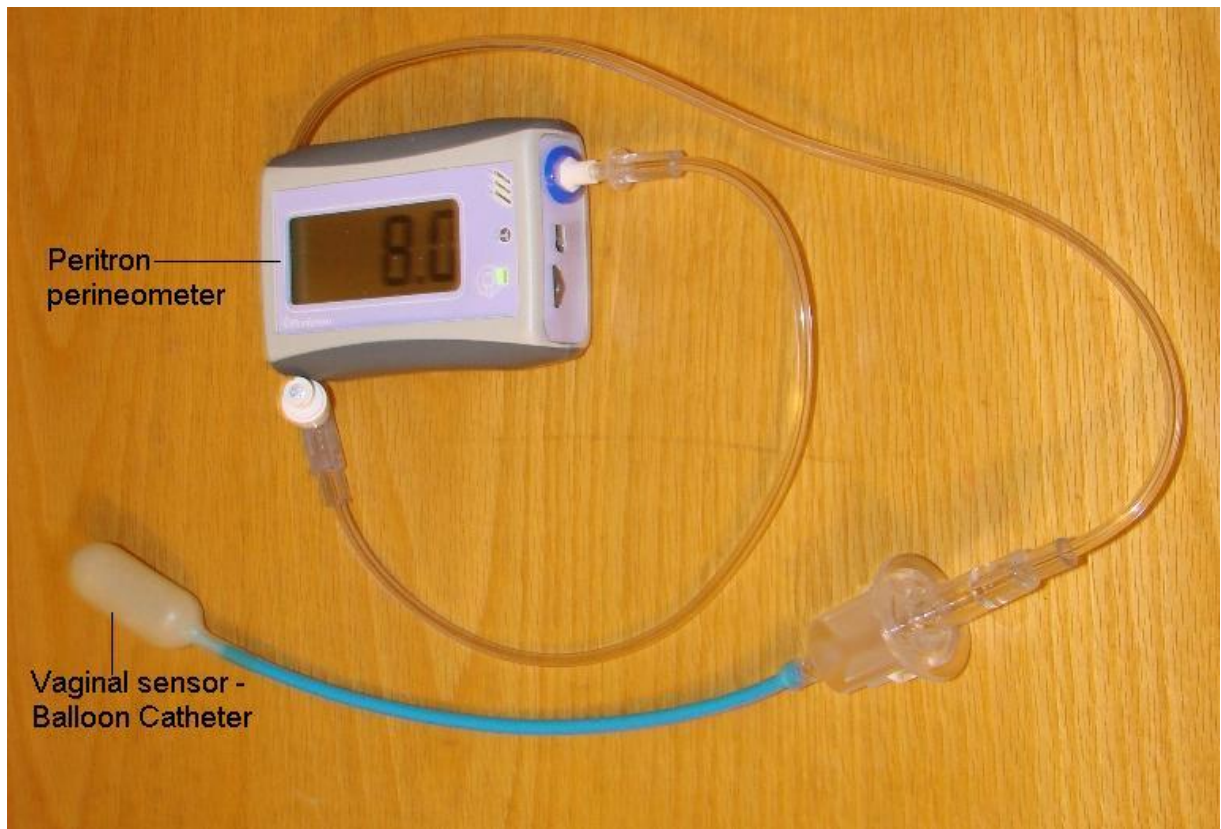


Figure 3-4: Peritron™ 9300 perineometer and vaginal balloon sensor

Validity and reliability

The Peritron™ 9300, used with its standard vaginal probe, has been tested for reproducibility and has been found to be reliable (Frawley et al 2006, Rhamani and Mohseni-Bandpei, 2009). Frawley et al (2006) tested intra-tester reliability of the Peritron™ 9300 perineometer within sessions (ICC=0.97) and between sessions (ICC=0.95), and concluded that there were high values of reliability of maximal voluntary contraction measured by the Peritron™ in crook lying position. Resting pressures had good reliability (ICC=0.74) between sessions in bent knee lying position (Frawley et al, 2006). In pilot study C, it was established that the Peritron™ 9300 gives accurate measurements used in conjunction with the Camtech balloon catheter (Addendum L).

The vaginal balloon catheter (Figure 3.4) was designed by Bjorn Gjersør (Camtech SA, Sandvika, Norway) and has been found to be reliable (Bø et al, 1990a). In a study by Bø (1992) the recommended depth of insertion has been established to be 3,5 cm from the introitis to the middle of the balloon.

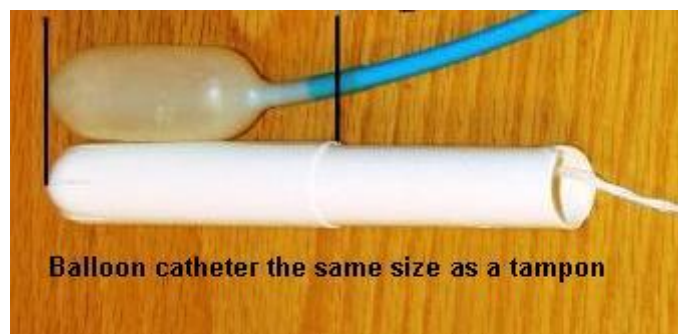


Figure 3-5: Size of balloon catheter compared to tampon

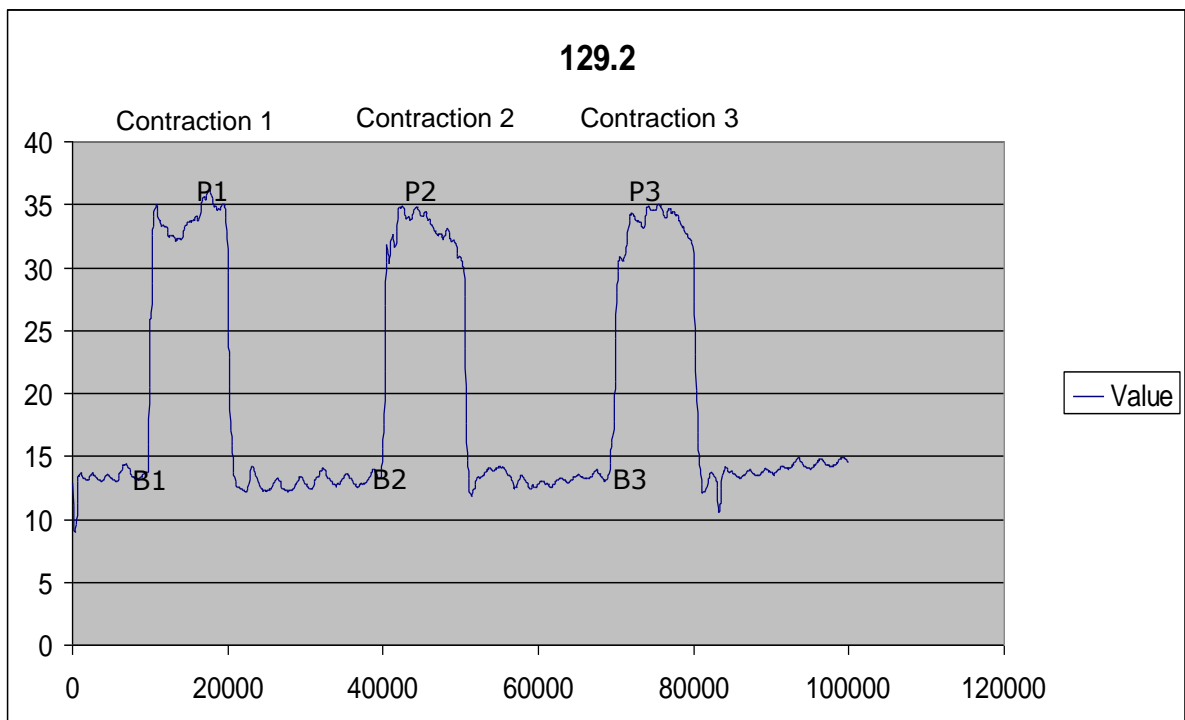
3.8.3 Data Processing

3.8.3.1 Process of data extraction

Data was saved as a comma-separated values (csv) file on the laptop computer. The csv-file was then resaved in an Excel format by the primary investigator. In Excel, a graph was compiled as can be seen in Figure 3.6. Using the graph, a measurement in cmH₂O was plotted on the baseline (B1/2/3) before each of the three

contractions commenced. On the graph, a measurement in cmH₂O was plotted at the peak (P1/2/3) of the three contractions. The baseline measurement was then subtracted from the peak measurement to obtain the measurement of the pressure increase with a MVC.

Following pilot studies B and E (Addendum J and E), an Excel spreadsheet was designed in conjunction with the statistician, Prof M. Kidd, to capture the data from the questionnaires and test measurements. The recordings from contractions one to three were saved in the data capturing Excel spreadsheet, where the mean of the three contractions was calculated for each participant.



P1 = Peak 1	B1 = Baseline 1	Contraction 1 = P1 – B1
P2 = Peak 2	B2 = Baseline 2	Contraction 2 = P2 – B2
P3 = Peak 3	B3 = Baseline 3	Contraction 3 = P3 – B3

Figure 3-6: Graph of one set of three MVC of the PFM

3.8.3.2 Process of data capturing and storing

The data storing and numbering was done by the primary researcher. Each student was given a number immediately after completion of her questionnaire and all the data was saved according to the number allocated to the student. Data sets were stored on a flash drive and on the researcher's computer. The data sets were stored in accordance with the dates of the last entries.

The primary researcher captured data at the end of each day of testing onto a specifically designed Excel spreadsheet.

3.8.4 Statistical analysis

Statistica software version 8 by Statsoft™ was used to analyse the data in conjunction with the statistician, Prof Martin Kidd. Data was analysed as follows:

- Cross tabulation and the Chi-square tests were used to compare categorical variables such as age, BMI, participation in physical activity, type of toilet used (western or squatting), smoking, regular low back pain, medication, respiratory conditions, menstrual status, menstrual cycle, length of menstrual cycle, length of menstruation, menstrual flow, dysmenorrhoea, previous attempt to contract the PFM, frequency of voiding (night and day), urinary continence status, dysuria, candida, vaginal infection, perineal pain, frequency of bowel motion, straining at stool and IBS.
- One-way ANOVA was used to compare mean values of continuous/ordinal variables between different groups. This included mean contraction and resting values. One-way ANOVA was also used to compare the following variables: urinary continence status, menstrual status, frequency of bowel motion, BMI, age, frequency of day and night time voiding, straining at stool, low back pain, respiratory conditions, ethnic subgroups, physical activity participation, physical activity intensity level, student type, previous attempt to contract the PFM, oral contraceptives, progestogen injections, regular menstrual cycle, length of menstrual cycle, length of menstruation,

menstrual flow, dysmenorrhoea, irritable bowel syndrome, dysuria, candida and perineal pain.

- Two-way ANOVA was used for testing the effects of two categorical variables combined on continuous/ordinal measurements. These variables were mean contraction values combined with BMI and frequency of night time voiding.
- Spearman correlation was used to test relationships between continuous/ordinal variables including the relationship between mean resting values and mean contraction values and the relationships of BMI, age, frequency of night and day time voiding to mean contraction values. The relationship between mean vaginal resting pressures and BMI, age, frequency of day and night time voiding were also tested.
- Repeated measures ANOVA were used to compare first and second contractions between different groups (ethnic groups).
- Descriptive statistics including percentages, bar graphs, means, 95% confidence intervals (95%CI) and standard deviations (SD) were used in the description of the sample.
- Results were accepted as significant at $p < 0.05$.

CHAPTER 4 RESULTS

4.1 Introduction

In this chapter the results of the study that were gathered from June to October 2007 will be presented under the following headings:

- Description of sample
- PFM strength and endurance
- Factors significantly associated with PFM strength
- Factors not significantly associated with PFM strength
- Vaginal resting pressures
- Factors associated with vaginal resting pressures
- Factors not significantly associated with vaginal resting pressures

4.2 Description of the sample

In this section a description of inclusion and exclusion and basic characteristics of the sample will be given.

4.2.1 Sample description

One hundred and twenty-two (91%) of the 135 women who initially volunteered for this project were included in this sample. Six students were excluded because they were on an active pelvic floor strengthening program or they have had children. Seven students did not arrive for the testing procedure.

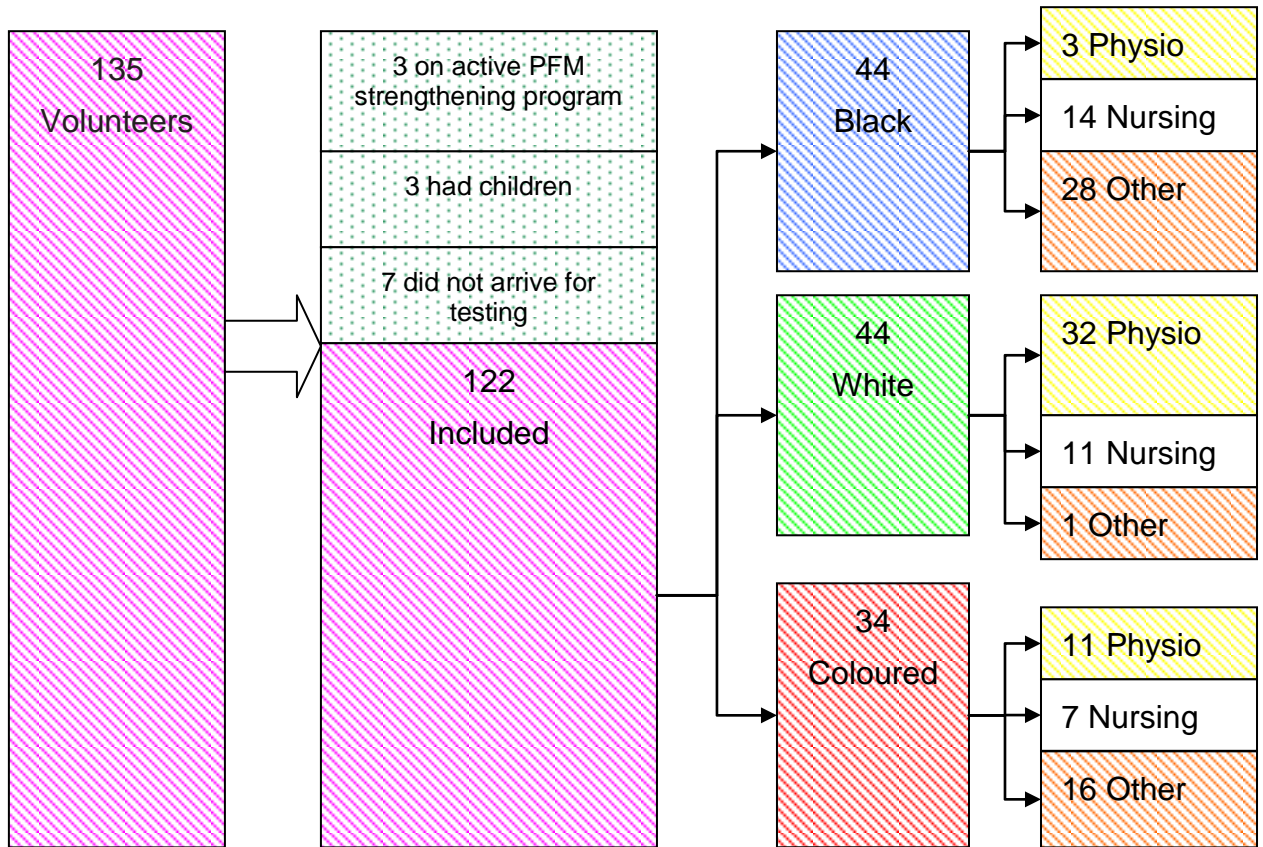


Figure 4-1: Consort diagram

Of the 122 students included in the sample, 36% were black, 28% were coloured and 36% were white (Figure 4.1).

Seven ethnic subgroups were identified in the group that classified themselves as black. The majority were Xhosa (70%), and the remaining 30% were from the Sotho (5), Venda (1), Tsonga (2), Tswana (3) and Zulu (1) ethnic subgroups.

There were statistically significant ($p < 0.01$) differences in the distribution of the type of students in the different race groups. Almost 75% of women in the white group were physiotherapy students. This was significantly more than in the black group (<1%) or the coloured group (32%). Sixty-three percent of the black group were students in other study fields than physiotherapy or nursing, which was significantly more than in the white group (<1%) and the coloured group (47%).

4.2.2 Basic characteristics of the sample

The participants' ages ranged between 18 and 45, with a mean of 22 (SD=3.54). Nine outliers were identified in the age range 27 to 45 years. Five of these outliers were white, three coloured and one black (Figure 4.2).

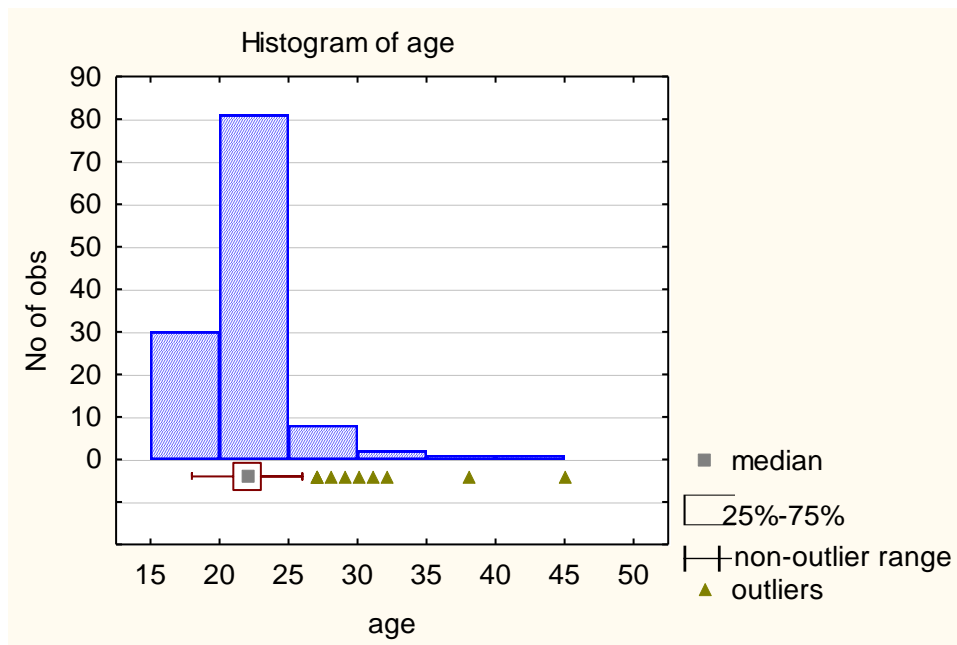


Figure 4-2: Age range of sample

There were significant ($p = 0.02$) age differences between the white and coloured groups, with the white group being older than the coloured group. No significant differences in age were found between the white and black groups, and the black and coloured groups. There was only a small variation in the mean ages of the groups, with the mean ages of the white group being 23 years, black group, 22 years and the coloured group, 21 years (Table 4.1).

Table 4-1: Basic characteristics of sample data; age and BMI

Age and BMI								
Nr	Characteristics	Black		Coloured		White		p-value
		Mean	Std dev	Mean	Std dev	Mean	Std dev	
1	Age in years	22	2.82	21	1.94	23	4,73	$p=0,02$
2	BMI in kg/m^2	24,45	4,5	22,05	4,48	22,48	3,11	$p=0,02$

The Body Mass Index (BMI) of the sample ranged between 16 and 38 with a mean of 23 (SD=4.16). The Black group had a significantly higher mean BMI than the White and Coloured groups (Table 4.1).

Table 4-2: Summary of general characteristics of the sample

Nr	Characteristics	Subdivision	Total	Black		Coloured		White		p-value
				n	%	n	%	n	%	
			N							
1	Rural		3	3	7 %					
2	Physical activity	Participate in regular physical activity	74	22	50 %	15	43%	37	84%	<0,01
3	Type of toilet used: Western or squatting	Squatting	1	0	0 %	1	1%	0	0%	
4	Smoking		21	5	11%	11	31%	5	11%	0.04
5	Regular low back pain		42	10	23%	16	45%	16	37%	0.09
6	Medication	Oral contraceptive	32	8	18%	7	20%	17	39%	0.06
		Progestogen injection: Depo Provera® or Nur-Isterate®	21	14	32%	7	20%	0	0%	<0.01
		Anti depressants	6	2	4.5%	0	0%	4	10%	
		Muscle relaxants	1	1						
		Thyroid	2					2	4.5%	
7	Chronic respiratory conditions		9	2	4.5%	4	9%	3	7%	

Table 4.2 gives a summary of general characteristics of the sample gathered with the demographic and screening questionnaires. Significant differences in the groups were noted with the participation in physical activities, smoking habits and medication.

Sixty percent of the students (n=74) participated in physical activities. Significantly (p <0.01) more white students participated in physical activities than the other ethnic groups. Eighty-four percent of the white group exercised, compared to 50% of the black group and 43% of the coloured group. The most frequently reported physical activities were running, swimming and gym (Figure 4.3 A). The majority (60%) of the

students exercised twice a week or every second day (Figure 4.3 B). Fifty-four percent of the students exercised 40-80 min per session (Figure 4.3 C). There were slightly more participants who exercised with a low intensity (55%) than with a high intensity (Figure 4.3 D).

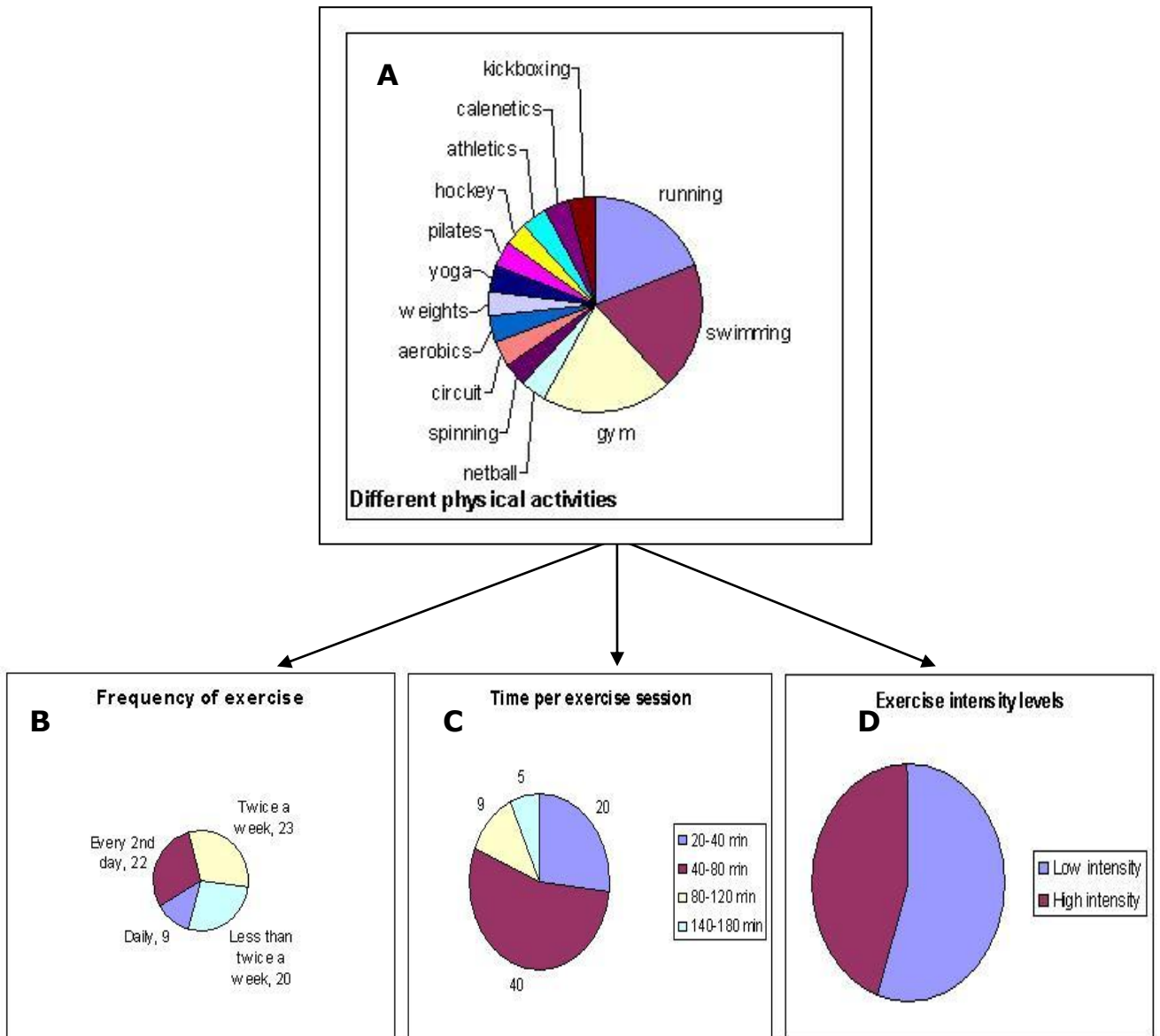


Figure 4-3: A: Physical activities; B: Frequency of exercise; C: Time per session; D: Intensity level.

Thirty-one percent of the coloured students smoked ($p=0.04$) compared to 11% in the black and white groups respectively (Table 4.2).

Significant ($p<0.01$) differences between the race groups were noted in the distribution of the usage of progestogen injections as contraception (Depo Provera® and Nur-isterate®), with the black group using it more frequently (32%), than the white (0%) and coloured (20%) groups. The most frequently used medications amongst the students were the oral contraceptives (26%) followed by the progestogen injections (17%) (Table 4.2).

Table 4-3: Characteristics of the sample associated to the menstrual cycle

Characteristic	Frequency	Total	Black		Coloured		White		p-value
		N	n	%	n	%	n	%	
Not menstruating / Amenorrhoea			7	16 %	5	14 %	1	2 %	0,04
Menstruating			37	84 %	30	86%	43	98 %	
Regular cycle		92	27	67%	26	78%	39	88%	0.05
Cycle	21 day	12	9	30%	2	7%	1	2.5%	0.01
	28 day	78	18	60%	24	86%	36	90%	
	35 day	8	3	10%	2	14%	3	7.5%	
Length of menstruation	<7 days	102	35	92%	27	85%	40	91%	0.58
	>7 days	12	3	8%	5	15%	4	9%	
Menstrual flow	Minimal	13	6	16%	3	9%	4	9%	
	Moderate	86	26	68%	26	79%	34	77%	0.83
	Heavy	16	6	16%	4	12%	6	13%	
Dysmenorrhoea		59	23	55%	18	52%	18	41%	0.38
Endometriosis		3							

Characteristics of the sample associated with the menstrual cycle are summarised in Table 4.3. Dysmenorrhoea was reported by nearly half (48%) of the students in the sample. Significantly ($p=0.04$) more students in the black group (7) had amenorrhoea than in the coloured (5) or white (1) groups. Eighty-eight percent of the white group had a regular cycle, this was significantly ($p=0.05$) more than the

coloured (78%) and black (67%) group. The 28 day cycle was the most frequently reported cycle amongst the white students (90%). Thirty percent of the black students had a 21 day cycle, which was significantly ($p=0.01$) more than the coloured (7%) or white (2.5%) students respectively.

Table 4-4: Characteristics of the sample associated with the pelvic area

Nr	Characteristic	Sub divisions	Frequency	Total	Black		Coloured		White		p-value
				N	n	%	n	%	n	%	
1	Previous attempt to contract PFM			69	13	30%	16	46%	40	91%	<0.01
2	Frequency of urination	Day	2X	3	3	75%	0	0%	0	0%	0.05
			3-5X	78	30	68%	23	68%	25	57%	
			6-8X	36	9	20%	10	29%	17	39%	
			10X	5	2	5%	1	3%	2	4%	
		Night	0X a night	57	10	22%	16	49%	31	70%	<0.01
			1X a night and more	65	34	77%	18	51%	13	30%	
3	Urinary incontinence	Stress incontinence		5	2	4%	2	6%	1	2%	0.71
4	Urinary tract complaints	Burning urination		17	4	10%	7	20%	6	14%	0.38
5	Perineal area complaints	Candida		11	6	14%	1	3%	4	10%	0.21
		Vaginal infection		1	1						
		Perineal pain		22	13	30%	7	20%	2	5%	< 0.01
6	Constipation	Bowel motion	Every 3d day	14	4	9%	8	29%	2	4.5%	
		Straining at stool		29	10	23%	12	34%	7	16%	0.16
7	Irritable bowel syndrome			14	5	11%	2	6%	7	16%	0.34

Table 4.4 gives a summary of the characteristics of the sample associated with the pelvic area. Significant differences between the groups were noted amongst the following characteristics: previous PFM contraction, frequency of night time urination, frequency of day time urination and perineal pain.

Sixty-nine students (56%) reported that they have tried to contract their pelvic floor muscles prior to the study, but were not on an active training pelvic floor training program. Significantly more ($p < 0.01$) white students reported that they had contracted their pelvic floor muscles before commencement of the study.

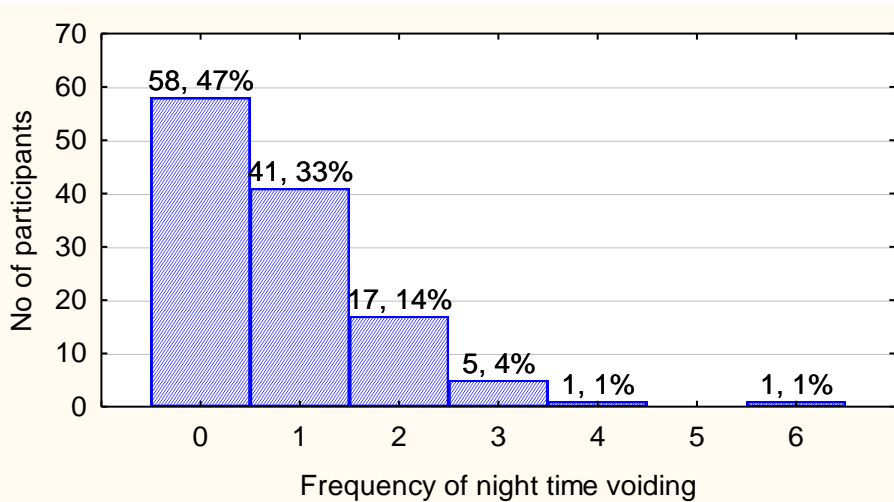


Figure 4-4: Frequency of night time voiding of participants.

Fifty-three percent ($n=65$) of the students voided once or more a night. (Figure 4.4) Significant ($p < 0.01$) differences were found in the reporting of frequency of night time voiding, with 77% percent of the black students voiding once or more a night compared to 51% in the coloured group and 30% in the white group. There were no significant differences in night time voiding when the coloured group was compared to the white ($p=0.1$) and black group ($p=0.1$). The black group had the highest average of urination in the night with (1.3 ± 1.2 times), followed by the coloured group with (0.8 ± 0.9 times) and the white group (0.34 ± 0.56 times). (Figure 4.5)

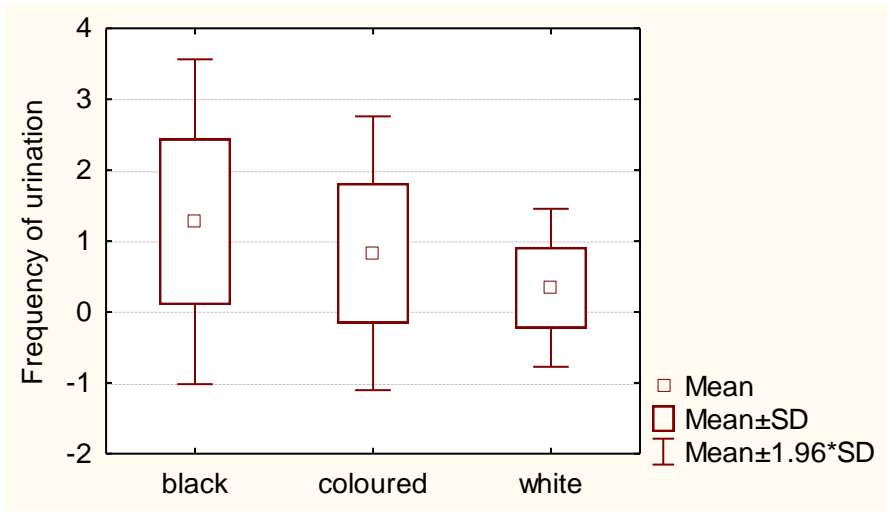


Figure 4-5: Ethnic distribution of night time voiding frequency

The mean day time frequency of urination of the total sample was 5.1 ± 1.8 times a day (Figure 4.6).

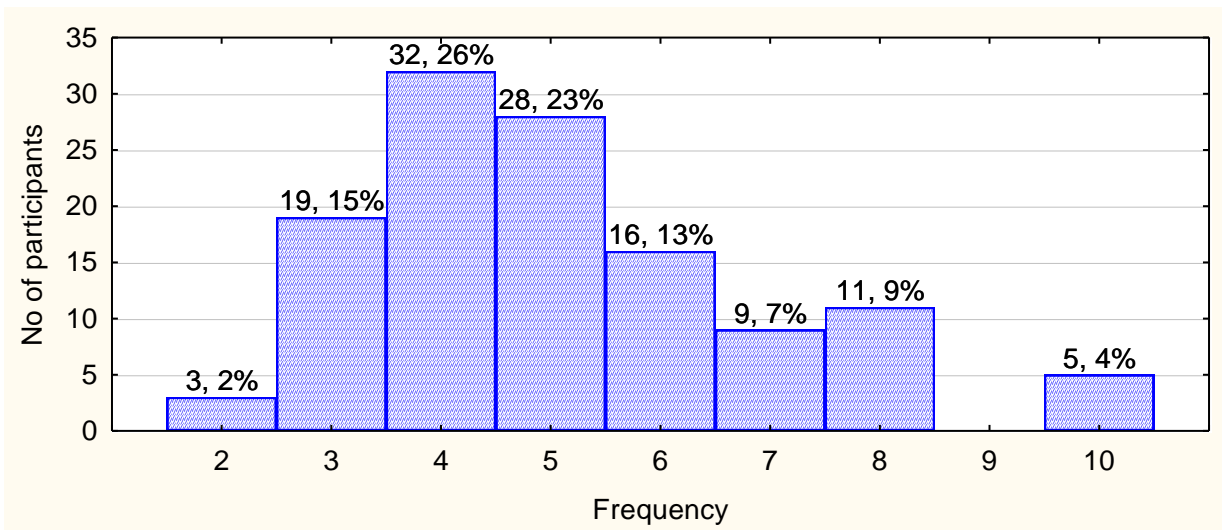


Figure 4-6: Frequency of day time voiding of participants

There were significant differences in the frequency of day time urination between the black and white groups ($p=0.02$) with the mean frequency of urination in the white group 5.5 ± 1.8 times a day and the black group 4.6 ± 1.9 times a day. There were no significant differences in mean frequency of urination of the coloured group (5.2 ± 1.6) compared to the white group ($p=1$) and black group ($p=0.1$) (Figure 4.6).

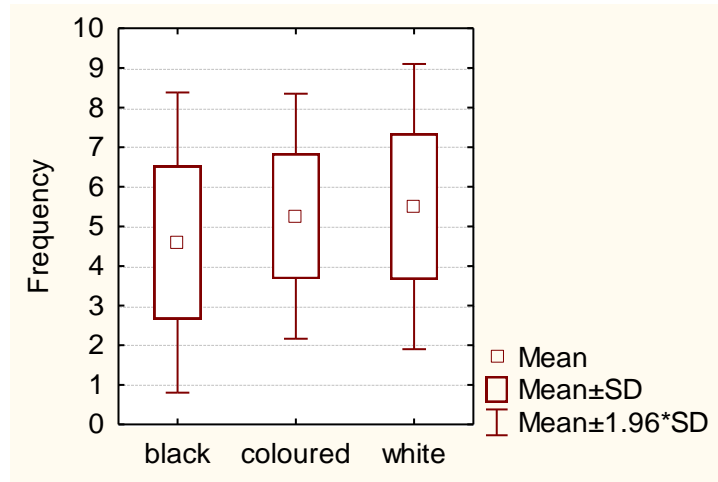


Figure 4-7: Ethnic distribution of day time voiding

Of the twenty-three students (19%) who reported perineal pain, 30% were of the black group, which was significantly more than in the coloured (20%) or white (5%) group (Table 4.4).

Fifteen students (12%) had a bowel motion every third day and 15% strained with a motion, both of which are symptoms of constipation. Irritable bowel syndrome was reported by 14 (11%) participants (Table 4.4).

Thirty-four percent of the participants (42) reported regular low back pain and nine students (7%) had chronic respiratory conditions (Table 4.4).

4.3 PFM strength and endurance

This section describes the results of PFM strength measurement in cmH₂O of the first and second set of contractions in relation to different ethnic groups. This will be reflected according to maximum voluntary contraction (MVC) and endurance.

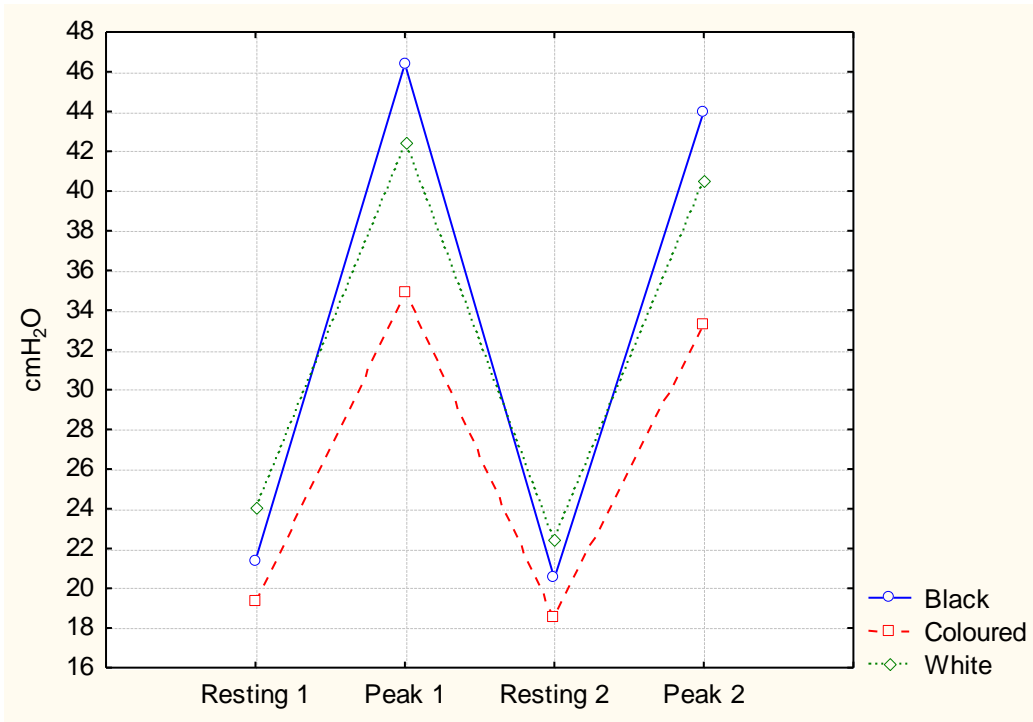


Figure 4-8: Mean vaginal resting and MVC values in cmH₂O of first and 2nd set

4.3.1 MVC in first and second set of contractions

Statistically significant differences in PFM strength were found between the different race groups when the means of the first and second set of contractions were compared (Table 4.5 and Figure 4.8).

Table 4-5: Mean MVC value of set 1 and 2 in cmH₂O and p-value of differences in sets

		Set 1		Set 2		
Group	N	Mean MVC value in cmH₂O	95% CI	Mean MVC value in cmH₂O	95% CI	p-value
Total	122	20	18-22	17.9	16.3 - 19.6	< 0.01
Black	44	25	20.9-29.1	23.6	20.7-26.4	0.017
Coloured	34	15.6	12.8-18.4	14.9	11.6-18.1	1.00
White	44	18.4	15.4-21.4	18	15.1-20.8	1.00

First set of contractions (Table 4.5):

In the first set, the black group had significantly higher MVC values than the white ($p=0.02$) and coloured ($p<0.01$) women. No significant difference between the white and coloured groups ($p=0.78$) were noted. The black group had the highest mean of the first set of contractions followed by the white group, and the coloured group had the weakest vaginal squeeze pressure (Table 4.5). A greater standard deviation (SD) was noted amongst the black group (13.5) compared to the white (9.8) and coloured (8) groups. PFM strength of black women was 26% stronger than white women and 37% stronger than coloured women.

Second set of contractions (Table 4.5):

Also, in the second set, it was found that the black group had significantly higher MVC values than the white ($p=0.02$) and coloured ($p<0.01$) groups. No statistically significant differences were noted between the white and coloured groups ($p=1$). In this second set, the black group also had the highest mean contraction value, followed by the white and coloured groups.

4.3.2 Endurance

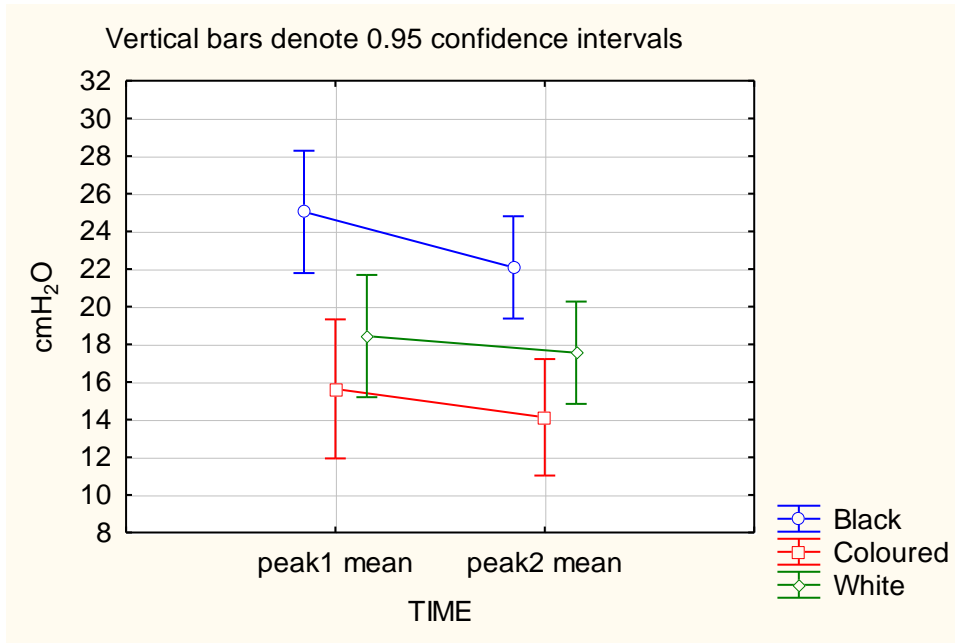


Figure 4-9: Difference in MVC pressure in cmH₂O between sets 1 and 2

The black group had a significant ($p=0.02$) decrease in MVC squeeze pressure from the first to the second set of contractions. The other two groups had a decrease in MVC squeeze pressure between the first and second set, however it was statistically insignificant ($p=1$) (Table 4.5 and Fig 4.8 and 4.9).

4.4 Factors related to pelvic floor muscle strength

Factors that were significantly associated with pelvic floor muscle strength will be described, as well as other possible factors that were not significantly associated with pelvic floor muscle strength.

4.4.1 Factors significantly associated with MVC values

This section describes the association or influence that stress urinary incontinence, body mass index, amenorrhea and frequency of bowel motions had with MVC values, as measured in cmH₂O, with the first set of contractions. MVC values related to frequency of night time voiding will also be described.

Table 4-6: Factors significantly associated with MVC values in cmH₂O

Nr	Tested factors significantly associated with MVC values	n	Mean MVC value in cmH ₂ O	SD	-95% CI	+95% CI	p-value
1.	Stress urinary incontinence (SUI)	5	30.9	15.4	11.7	50.1	0.03
	Urinary Continent	116	19.6	11.1	17.5	21.6	
2.	Amenorrhoea	13	28.6	15.5	18.7	38.5	0.01
	Menstruating	109	19	10.6	17.1	21.1	
3.	Bowel motion more than 3X a week	108	21	11.5	18.8	23.1	0.01
	Bowel motion 3X a week or less	14	12.9	9.2	7.6	18.2	

1. Urinary Continence (Table 4.6)

A statistically significant difference ($p = 0.03$) in MVC values was found between stress urinary incontinent and continent participants. The mean contraction value was higher in the stress urinary incontinent (SUI) group than the urinary continent group. CI varied greatly in the SUI group compared to the continent group (Table 4.6). Two of the SUI women were from the black group and had mean pressures of 55.7 and 29.9 cmH₂O, two coloured women had values of 24.9 and 13.6 cmH₂O and one white woman with a pressure of 30.3 cmH₂O. The sample size was too small in the SUI group to do a covariate analysis on race and SUI versus muscle strength.

2. Amenorrhoea:

There was a statistically significant difference ($p < 0.01$) in MVC pressure measurement in women with amenorrhoea and menstruating women. Women with amenorrhea had higher MVC pressure measurements (28.6 cmH₂O) than menstruating (19 cmH₂O) women (Table 4.6). The sample size ($n=13$), in the group with amenorrhoea was too small to do a covariate analysis of race versus muscle

strength. Table 4.7 gives a breakdown of the ethnic group, BMI, contraceptive medication and PFM strength of the women with amenorrhoea.

Table 4-7: Race, BMI, contraceptive medication and MVC of women with amenorrhoea.

Race	BMI in kg/m ²	Contraceptive medication	PFM strength in cmH ₂ O of first set
White	25.7	No medication	21.6
Coloured	20.3	Oral contraceptive	17.1
Coloured	18.3	Progestogen	13.2
Coloured	30.3	Progestogen	22.1
Coloured	18.7	No medication	21.2
Coloured	26.3	No medication	40.4
Black	19.1	Oral contraceptive	45
Black	31.8	Progestogen	46.4
Black	20.4	Progestogen	10.2
Black	36.6	No medication	12.3
Black	30.6	Progestogen	41.1
Black	25.1	Progestogen	53.5
Black	26.7	Progestogen	19.7

3. Frequency of bowel motion:

Students who had a bowel motion three times a week or less had significantly ($p=0.01$) lower MVC values (12.9 cmH₂O) compared to students who had more regular bowel motions (21 cmH₂O). (Table 4.6)

4. BMI:

A weak positive correlation (Spearman $r = 0,19$; $p=0.04$) between BMI and MVC values was observed. However, a covariate test of significance was done with BMI and race and it was found that the ethnic group is independently associated ($p < 0.01$) with pelvic floor muscle strength.

5. Night time urination:

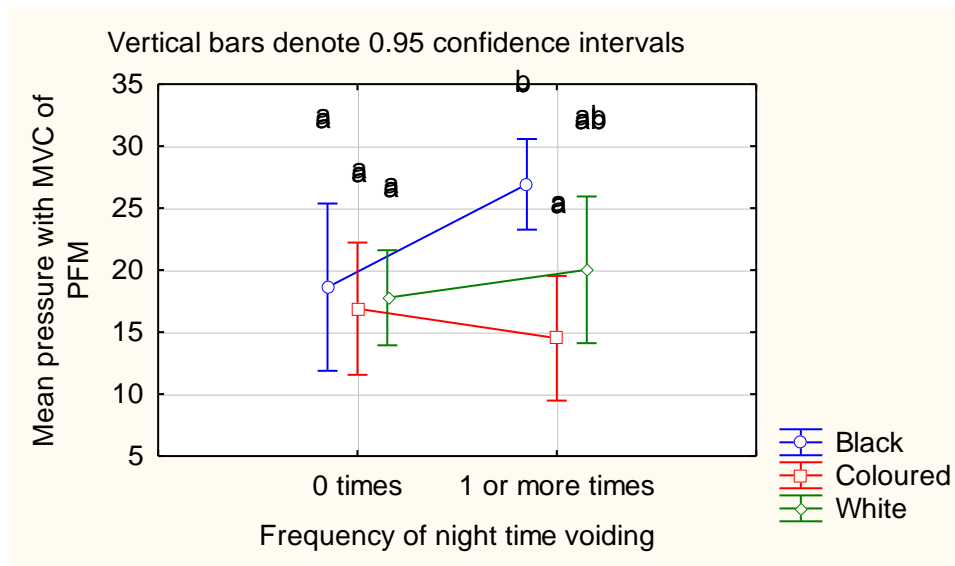


Figure 4-10: Ethnic group MVC values in cmH₂O versus frequency of night time voiding

There were no significant ($p=0.7$) differences in MVC values between the race groups for the students who did not void at night (Figure 4.10). However, in the black group, MVC values were significantly ($p=0.03$) higher in the students who voided during the night (mean=26.9 cmH₂O, SD=13.3) than those who did not urinate at night (mean=18.6 cmH₂O, SD=12.4) (Figure 4.10).

4.4.2 Factors not significantly associated with MVC values

No significant correlations could be found between age, frequency of daytime voiding and frequency of night time voiding and MVC values (Table 4.8).

Table 4-8: Factors not significantly correlated with MVC values

Factors tested for correlation with MVC values	Spearman p-value	Spearman Strength of correlation (r)
Age	p = 0.96	r = 0.00
Frequency of day time voiding	p=0.77	r = -0.03
Frequency of night time voiding	p=0.05	r = 0.18

Table 4.9 describes 17 factors that were found to have no significant association with MVC pressure measurement.

Table 4-9: Factors not significantly associated with MVC values in cmH₂O

Factors tested for association with MVC values	Variable	n	Mean in cmH ₂ O	SD	CI	p-value
Straining at stool		28	18.3	13.50	13.1-23.5	0.37
Regular low back pain		41	20.7	13.65	16.4-25	0.64
Respiratory conditions		9	24.1	15.90	11.9-36.3	0.27
Ethnic subgroups	Xhosa	31	26.2	13.77	21.1-31.2	0.87
	Sotho	5	27.3	16.06	7.3-47.2	
Physical activity participation		73	20.7	11.72	18-23.4	0.43
Physical activity intensity level	high	33	19.8	12.43	15.4-24.2	0.55
	low	40	21.5	11.22	17.8-25	
Student type	Nursing	32	23	13.78	18.1-28	0.07
	Physio	46	17.1	9.60	14.3-20	
	Other	43	20.9	11.00	17.5-24.5	
Tried to contract PFM prior to testing		68	19.4	11.03	16.7-22	0.48
Oral contraceptive		32	19.9	13.34	15-24.7	0.92
Progestogen injection		21	23.2	11.84	17.9-28.6	0.16
Regular menstrual cycle		92	19.1	11.10	16.8-21.4	0.17
Length of menstrual cycle	21 days	12	21.4	10.51	14.7-28.1	0.77

	28 days	78	18.9	11.21	16.4-21.4	
	35 days	8	19.4	11.66	9.6-29.1	
Length of menstruation	Less than 7 day	102	19.4	10.94	17.3-21.6	0.65
	7 and more days	12	17.9	8.042	12.8-23	
Menstrual flow	Minimal	13	23.8	13.41	15.7-31.9	0.20
	Moderate	85	19	10.34	16.8-21.2	
	Heavy	16	16.9	9.34	11.9-21.8	
Dysmenorrhoea		58	19	9.82	16.4-21.6	0.41
Irritable bowel syndrome		14	16.3	7.939	11.7-20.8	0.19
Frequency of daytime urination	7X and less	107	19.9	11.25	17.7-22	0.66
Burning urination (Dysuria)		16	15.4	6.68	11.8-19	0.08
Candida		11	21.8	15.31	11.5-32	0.60
Pain around vagina and anus (Perineal pain)		21	19	11.37	13.8-24.2	0.66

4.5 Mean resting values and factors related to mean resting values of the pelvic floor muscles

In this section, the mean vaginal resting values of the first and second set of contractions will be described, as well as factors that have been found to have an association with PFM resting values and factors that were found to have no association to PFM resting values.

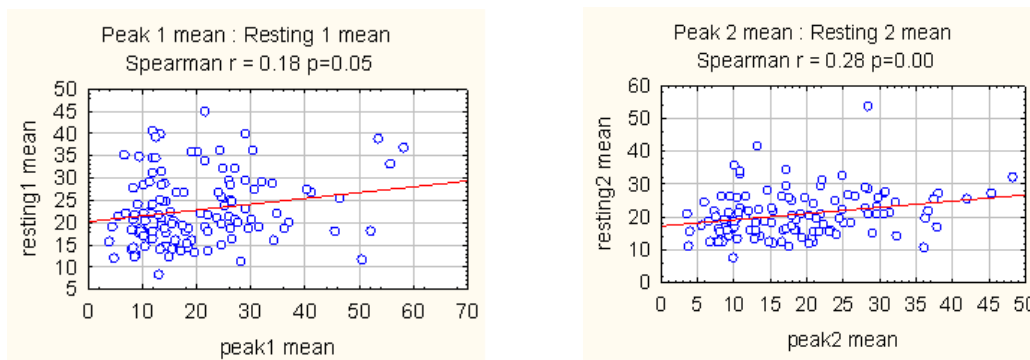
4.5.1 Mean resting values of the first and second set of contractions

Resting pressures of the white group were significantly higher during the first set ($p < 0.01$) than the coloured group. No significant differences in resting pressures were found between the black and coloured groups ($p = 0.54$) or the black and white groups ($p = 0.19$) during the first set of contractions. During the first set, the white group had the highest mean resting pressure followed by the black group and the coloured group had the lowest mean resting pressure (Figure 4.8 and Table 4.10).

Table 4-10: Mean vaginal resting pressure in cmH₂O of set 1 and 2

Ethnic group	N	First Set			Second set		
		resting1 Mean	SD resting 1	95%CI	resting2 Mean	SD resting 2	95%CI
Total	122	22.8	7.7	21.4 -24.1	20.7	6.8	19.5 -22
black	44	22.2	6.9	20.1 -24.3	20.5	5.7	18.8 -22.3
coloured	34	19.9	6.8	17.5 -22.2	18.7	6.1	16.6 – 20.8
white	44	25.7	8.2	23.2 -28.2	22.5	8.0	20.1 – 25.0

No significant differences in resting pressures were noted during the second set of contractions between the black, coloured and white groups. During the second set of contractions, the white group again had the highest mean resting pressure, followed by the black group and the coloured group with the lowest resting pressures. During the first and second set of contractions the resting pressure measurement had minimal influence on the strength of the first set of contractions (Spearman $r = 0.18$ $p=0.05$) and second set of contractions (Spearman $r = 0.28$ $p=0.00$) (Figure 4.11).

**Figure 4-11: Correlation of vaginal resting with MVC pressures of set 1 and 2**

4.5.2 Factors significantly associated with mean vaginal resting pressures

Twenty-four possible factors, as described in the research methods, were tested to see if there was a significant association in this sample. Heavy menstrual flow was the only factor that was identified as having a significant association with mean resting values (Figure 4.12).

4.5.2.1 Heavy menstrual flow (Menorrhagia)

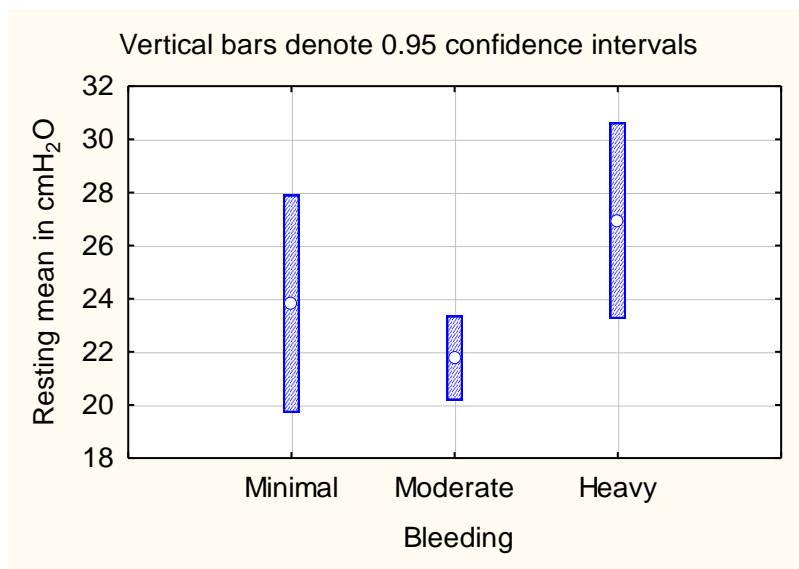


Figure 4-12: Menstrual flow and vaginal resting pressures in cmH₂O

Students, who have described their menstrual flow as heavy, had a statistically significantly ($p = 0.04$) higher resting measurement than students with moderate menstrual flow. No significant differences ($p=0.79$) could be found between moderate menstrual flow and minimal menstrual flow and vaginal resting pressures (Table 4.11).

Table 4-11: Menstrual flow and vaginal resting pressures in cmH₂O

Factor associated with resting values	Yes/No	n	Mean of resting values of first set of Contractions in cmH ₂ O	SD	CI in cmH ₂ O
Menstrual flow	Minimal	13	23.8	7.02	19.6-28
	Moderate	86	21.8	6.98	20.3-23.3
	Heavy	16	26.9	9.98	21.6-32.3

4.5.3 Factors not significantly associated with mean vaginal resting pressures

No correlations were found between BMI, age, day time urinary frequency, night time urinary frequency and the resting vaginal pressure of the first set of contractions (Table 4.12).

Table 4-12: Factors not significantly correlated with vaginal resting pressures

Factors tested for correlation with resting values	Spearman p-value	Spearman Strength of correlation (r)
BMI	p = 0.32	r = 0.09
Age	p = 0.65	r = 0.04
Frequency of urination per day	p=0.49	r = 0.06
Frequency of urination per night	p=0.17	r = 0.12

Twenty-two factors that were tested had no significant association with PFM resting values (Table 4.13).

Table 4-13: Factors with no significant association with vaginal resting pressures

Possible factor tested for relationship to mean resting value	Subgroup	n	Resting mean in cmH ₂ O	SD	95% CI	p-value
Low back pain		42	24.1	7.65	21.7-26.4	0.18
SUI		5	28.3	7.63	18.8-37.8	0.10
Respiratory conditions		9	26.6	7.75	20.6-32.5	0.12
Ethnic subgroups	Xhosa	31	22.1	6.91	19.6-24.6	0.88
	Sotho	5	22.6	9.59	10.7-34.5	
Physical activity participation		74	23.4	7.84	25.2	0.31
Physical activity intensity level	high	33	23.5	7.75	20.8-26.3	0.87
	low	41	23.2	8.01	20.7-25.7	
Student type	Nursing	32	24.6	8.18	21.6-27.5	0.16
	Physiotherapy	46	23	8.07	20.6-25.4	
	Other	43	21.3	6.74	19.2-23.3	
Tried to contract PFM prior to testing		69	23.2	7.76	21.3-25	0.54
Birth control pill		32	23.2	7.25	20.6-25.8	0.73
Progesterone injection for birth control		21	23.2	7.15	19.9-26.4	0.80
Absence of menstrual cycle/ Amenorrhoea		13	24.9	9.88	18.9-30.8	0.31
Regular menstrual cycle		92	22.2	7.57	20.6-23.8	0.21
Length of menstrual cycle	21 days	12	21.9	6.85	17.5-26.2	0.65
	28 days	78	22.7	7.90	20.9-24.5	
	35 days	8	20.2	5.55	15.5-24.8	
Length of menstruation	Less than 7 day	103	22.5	7.62	21-23.9	0.33
	7 and more days	12	24.7	7.53	19.9-29.5	
Painful menstruation/ Dysmenorrhoea		59	23.7	8.05	21.5-25.7	0.26
Irritable bowel syndrome		14	24.2	9.83	18.5-29.9	0.46
Bowel motion	Straining at stool	29	22.7	7.77	19.7-25.6	0.90
Frequency of bowel motion	Every 3d day or less	15	22.4	7.38	18.3-26.5	0.84
Burning urination		17	25.1	8.96	20.5-29.7	0.18
Frequency of daytime urination	7 times and less	106	22.9	7.83	21.4-24.4	0.72
Candida		11	19.6	6.61	15.1-24	0.14
Pain around vagina and anus		22	20.1	6.88	17.-23.1	0.07

In the current study, significant ethnic differences in PFM strength were found. Differences were also identified between ethnic groups. Factors that were significantly associated and not significantly associated with PFM strength and vaginal resting pressures were identified. The following chapter will discuss these results in more detail and compare them with findings in the literature.

CHAPTER 5 DISCUSSION

5.1 Introduction

In this cross sectional study, differences in both the strength and the endurance of pelvic floor muscles between nulliparous women of different ethnic groups were observed. The black women included in this sample presented with significantly stronger PFM than the white and coloured women. However, decreased endurance of the PFM in nulliparous black women compared to white and coloured nulliparous women was observed. Factors identified which were significantly associated with increased muscle strength included amenorrhoea and stress urinary incontinence. Decreased PFM strength was significantly associated with decreased frequency of bowel motion. No significant relationships were noted between vaginal resting pressures and symptoms and risk factors for pelvic pain syndrome and PFM dysfunction, except for menorrhagia. The results of the study will be discussed under two main headings i.e. discussion of results and discussion of methodology.

5.2 DISCUSSION OF RESULTS

In this section the results of pelvic floor muscle strength measurement will be discussed and these results will be put into context with other studies on pelvic floor muscle strength using the same measuring device. A discussion on the results of endurance measurement will be presented as well as a discussion of factors significantly associated and not significantly associated with pelvic floor muscle strength. This will be followed by a discussion on the results of the vaginal resting pressure measurement.

5.2.1 Pelvic floor muscle strength

Maximum voluntary contraction (MVC) refers to “a person’s effort to recruit as many muscle fibers as possible to develop force” (Knuttgen and Kreamer, 1987). In the current study, the MVC of PFM was assessed by vaginal squeeze pressure.

Squeeze pressure measurement is an indirect measurement of force (Bø and Sherburn, 2005). Muscle strength can be defined as the measurement of a person's maximum voluntary muscle contraction with movement at a constant speed (Mital and Kumar, 1998). In this study significantly stronger PFM were observed in black women when compared to white or coloured women (refer 4.3.1, Table 4.5 and Figure 4.8).

These results are in line with previous reports. Two other South African studies also compared strength between ethnic groups. Skinner and Crichton (1963) and Knobel (1975), measured PFM strength with a Kegel perineometer and found that black women have stronger PFM than Indian women. In 1963, Skinner and Crichton compared PFM strength of black and Indian nulliparous and parous female nurses and reported that black African women have 72% stronger PFM than Indian women, whereas in 1975, Knobel reported, that in a small sample of 10 black women and 10 Indian women, the PFM strength of the black women was 56% stronger than the Indian women. However, in the current study, PFM strength of black women was found to be 26% stronger than white women and 37% stronger than coloured women. It must be taken into account, that comparison to the studies of Skinner and Crichton (1963) and Knobel (1975) is hampered by the fact that different measuring devices and probes were used, different ethnic groups had been compared, the description of the methodology was poor and small samples sizes were used.

However, considering the results of the current study and of Skinner and Crichton (1963) and Knobel (1975), there is an indication that the PFM strength of black women could have decreased over the years. Moreover, there was also a change in the reported prevalence of SUI over the years. Heyns, reported that SUI rarely existed among black women in 1943 and the reported prevalence of SUI in black women is now much higher (van der Walt and Rienhardt, 2002). It is possible, therefore, that lifestyle changes of South African black women over the last 70 years have had an influence on their pelvic floor muscle strength. An investigation into lifestyle influences on PFM strength may well be necessary in the future.

The difference in PFM strength is also supported in other studies reporting on the cross-sectional area of muscles. According to Brown (2002), the maximal force potential of a muscle is proportional to the sum of the cross-sectional areas of all the fibres, therefore the thicker the muscle, the greater the force potential. This was confirmed by Bernstein (1997) and Mørkved et al (2004), who found a positive correlation between muscle thickness and PFM strength. With MRI studies, Duong and Korn (2001) found that the PFM in nulliparous black women are thicker than white women, therefore it is expected that black women would have stronger PFM than white women, which was confirmed in the current study.

Furthermore the interaction of the PFM and fascia in black women might also contribute to PFM strength. Laborda et al (2005) described the paravaginal tissue of black women as more elastic and less prone to injury than that of white women and according to Hoyte et al (2005), differences in pelvic morphology, among asymptomatic nulliparous women, imply that black women have a levator ani complex that is more intimately associated with its connective tissue. The main support of the anterior and posterior vagina is provided by the interaction between the levator ani muscles and the connective tissue that attaches the lateral walls of the vagina to the pelvic walls (Corton, 2005). This might well mean that black women are able to generate much more force with a PFM contraction in order to occlude the urethra with increased abdominal pressure, thus preventing SUI.

There are indications that black women could have PFM that are better equipped to withstand the effect of intra-abdominal forces on the urinary tract. One of theories that is proposed to explain the effectiveness of PFM training for SUI, is that it builds a muscle with larger muscle volume, increased tone, increased connective tissue stiffness, which is situated within the abdominal cavity (Bø, 2004a). Black women have been shown to have larger PFM volume (Hoyte et al, 2005 and Downing et al., 2007), connective tissue of a better quality (Laborda et al, 2005) and have now been found to have stronger PFM than white women, possibly explaining the findings in the literature of a decreased prevalence of SUI in black women.

5.2.1.1 Results of studies using the same vaginal balloon catheter

Bø and Sherburn (2005) found significant differences in measurements of PFM strength when different vaginal probes were used in the same person, and concluded that only results of PFM pressure measurement using the same vaginal probe could be compared. Therefore results from this study could only be compared to studies using the same vaginal balloon catheter. All of these studies were done in countries with white sample populations. The strength measurements of these studies will be described according to the sample populations used in the studies i.e. continent women, stress urinary incontinent women and women on an active PFM strengthening program for SUI.

Similar results were found if the PFM strength of the white students (18.4 cmH₂O) in this study were compared to strength measurements of continent physiotherapy students in Norwegian studies (Bø and Stien, 1994; Bø and Finkenhagen, 2001, Bø, 2004b; Bø et al, 2005). The mean contraction values reported in these studies, ranged from 19.3 to 21 cmH₂O.

Moreover, other studies evaluating vaginal squeeze pressure in continent women reported values between 14 and 18 cmH₂O, which compares favourably with values of coloured (15.6 cmH₂O) and white (18.4 cmH₂O) women in this study. These studies reported maximal contraction values of 28 healthy nurses and physiotherapists (14 cmH₂O) (Bø et al, 1990a), continent sport and physical education students (14.3 cmH₂O) (Bø 2004b) and parous women with or without pelvic girdle pain (18 cmH₂O) (Stuge et al, 2006). However, much higher values were reported by Mørkved et al (2004) than any of the other studies using the same vaginal probe, in continent 20 week pregnant women (39.5 cmH₂O) and incontinent 20 week pregnant women (32 cmH₂O).

Mean maximal contraction values for women with SUI or mixed incontinence have much lower reported values. (5-16.2 cmH₂O) The mean maximal contraction pressures in SUI women before the commencement of a trial, ranged from 11-14.8

cmH₂O in the four different groups receiving different modalities for the treatment of SUI (Bø et al, 1999). Mørkved et al (2002) reported a mean contraction value of 13.6 cmH₂O and 14.4 cmH₂O in two groups of women with SUI before the commencement of a trail. In a study reporting on the response of a six month PFM strengthening program for SUI patients, Bø and Finkenhagen (2003), reported baseline values on the commencement of the study of 5 - 7.2 cmH₂O in women who did not respond to PFM strengthening and 9.2 -11.7 cmH₂O in women who did respond to PFM strengthening. In another study reporting on the use of a balloon catheter with or without a firm reinforced tip, 14 women with SUI, participating in a PFM strengthening trail were used in the sample and values of 11.5 – 13.5 cmH₂O (Bø et al, 1990b) were reported with a PFM contraction. A mean value of 16.2 cmH₂O in a group of SUI physical and sport education students was reported (Bø, 2004b).

Contrary to the findings of other studies with a SUI sample population, Ree et al (2007) reported values of 23.7-25.8 cmH₂O in nulliparous women with mild SUI during strenuous physical activity. Measurements were taken before and after a 90 minute interval training program or 90 minute control period of rest in the sitting position. The values reported by Ree et al (2007) differed from the values reported in the other studies assessing SUI women, possibly because the women in this study by Ree et al (2007) only leaked with strenuous physical activities, while women in the other studies leaked urine in daily activities. However, the results were in the same range as the black women in the current study.

Coloured students had the lowest maximal pressure readings (15.6 cmH₂O) in this study and can be compared to the bottom range of values reported by healthy women and the upper range of values of women with SUI.

In studies with samples consisting of women who completed a PFM strengthening program for SUI, higher mean values were reported (19.2-26.6 cmH₂O). In one of these studies (Bø, 2003) women with urodynamically proven SUI, who were on a PFM strengthening program for six months and responded to the treatment, had mean maximal strength measurements of 24 cmH₂O and women who did not

respond to treatment, 12 cmH₂O. Bø and Finkenhagen (2003) reported maximal PFM contraction values of 24.1 cmH₂O in women with SUI and mixed incontinence on a PFM training program and Mørkved et al (2002) reported mean maximal pressure measurement of 26.6 cmH₂O after 6 months of PFM training. After a PFM training protocol for SUI, the mean contraction values were 19.2 cmH₂O in women who participated in the study. It seems, therefore, that women on an active training protocol may have stronger pelvic floor muscles, than the general population of white women. These values of women on a strengthening program compared well with the values of the black group.

In conclusion, if the studies by Ree et al (2007) and Mørkved et al (2004) are not taken into account, then the reported values of SUI women were in the range of 5-16.2 cmH₂O, the values of continent women ranged between 14-21 cmH₂O and the values of SUI women on an active PFM strengthening program ranged between 19.2-26.6 cmH₂O. If the lower values of these three groups were compared, there is an increment of 9 cmH₂O between SUI and continent women and a 5 cmH₂O increment between continent women and SUI women on a PFM strengthening program. If the upper values of these groups are compared, increments of 5 cmH₂O exist between SUI and continent and also between continent and SUI on an active strengthening program. Therefore it seems that a difference in PFM strength of 5 cmH₂O could be of clinical importance.

5.2.2 Endurance of PFM

Muscle fatigue is defined as “any exercise-induced reduction in the capacity to generate force or power output” (Vøllestad, 1997), whereas the definition of muscular endurance is:

1. The ability to repeatedly develop near maximal or maximal forces, determined by assessing the maximum number of repetitions that can be performed at a given percentage of 1RM (one-repetition maximum).
2. The ability to sustain near maximal or maximal forces, assessed by the time it takes to sustain fixed or static muscle actions. (Bø, 2001).

There is no reliable protocol for PFM endurance testing, using vaginal pressure measurement, described in the literature and there is also no consensus on the method used to measure endurance. Frawley et al (2006) did not find the endurance test protocol, consisting of one set of 20 fast contractions reliable. In the literature, two different protocols were described, one being time of sustained contraction and the other, two or three sets of three maximal contractions. These two protocols give conflicting results on endurance regarding parity and continence.

Conflicting results exist in the reporting of endurance in parous and nulliparous women. Hundley et al (2005), employing an endurance protocol of 2 sets of 3 maximum voluntary contractions, found that vaginal squeeze pressure decreased with the second set of contractions in parous women compared to nulliparous women. Contrary to this, Thompson et al (2006) did not find any difference in endurance between parous and nulliparous women when using a sustained hold protocol to test endurance.

There are also differences in the reporting of endurance in continent and incontinent women. Thompson et al (2006); Amaro et al (2005) and Madill and McClean (2009) report that continent women have greater PFM endurance than incontinent women, when measuring endurance with the length of the contraction held, whereas Hahn et al (1996) found little difference in endurance when testing endurance with three sets of 3 maximal contractions.

As explained in the methodology of the study (refer 3.6.1.2), the protocol utilized to assess endurance was two sets of three MVCs with a 5 minute rest period between sets. Black women in this study had a significant decrease in PFM strength between the first and second set of contractions, whereas no significant decreases were found between the first and second set of contractions in the white and coloured women (refer 4.3.2, Figure 4.9). This implies that the PFM in black women fatigues more easily than in the other race groups and has decreased endurance. Conversely it

could be stated that the PFM in the white and coloured groups is more fatigue resistant.

However, Mital and Kumar (1998) reporting on human muscle strength definitions and measurement, admit that differences in the results of endurance measurement exist between the length of hold protocol and repetitive contraction protocol. “In the holding protocol, the decline in static strengths is very rapid in the first two minutes of the exertion with a strength decline by as much as 75% during this period. When the repetitive protocol is utilized to assess endurance, the muscular strength also declines with the duration of exertions, but not quite as rapidly as in the case of continuous static muscular exertions” (Mital and Kumar, 1998).

The group of black women in this study had a mean decrease of 1.4 cmH₂O from the first to the second set of contractions, which is less than the value reported by Ree et al (2007). The same vaginal balloon catheter was used in the testing procedure; however different protocols were utilized for the assessment of endurance. The decrease in PFM strength in the study by Ree et al (2007) was 4.4 cmH₂O after a 90 minute interval training program in nulliparous women with mild SUI during strenuous physical activity (Ree et al, 2007). Comparison of the studies is also hampered by the fact that Ree et al (2007) used women with SUI, while this study had a sample of predominantly continent women.

During daily activities, the PFM needs constant tone to support pelvic organs and inhibit detrusor contractions through the perineo-detrusor inhibitory reflex (Mahony et al, 1977). This reflex works on the principle that a contraction of the PFM would decrease detrusor contraction and so inhibit urinary urge. Therefore, if the PFM fatigues, it could possibly result in a decreased inhibition of the detrusor, resulting in an increased excitation of the detrusor and overactive bladder (OAB) symptoms. Thus the fact that the PFM of black women fatigues more easily could be an indication of why there is an increased prevalence of overactive bladder symptoms.

In the results of other studies there were subtle indications that there could be a link between decreased endurance and symptoms of an overactive bladder. Thompson et al (2006) found that women with UUI had significantly decreased endurance compared to SUI women. Yoon et al (2003) tested the duration of a PFM contraction in two groups of women after 8 weeks of either bladder training or PFM training. The group who only did bladder training had an improvement in PFM endurance and their day and night frequency of urination decreased, although the urinary leakage was the same.

Therefore there is some evidence that a link between overactive bladder symptoms and endurance might exist, but this needs further investigation.

5.2.3 Factors associated with PFM strength

5.2.3.1 Voiding frequency

Night time voiding frequency

According to ICS guidelines, nocturnal polyuria is present when an increased proportion of the 24-hour output occurs at night (during the 8 hours a patient is asleep). An interesting finding in this study is that 77% of the black women voided once or more a night versus 51% of coloured and 33% of white women (Table 4.4).

Night time voiding frequency increases with age, therefore only studies reporting results from the same age group can be compared (Parsons et al, 2007). In a large community-based study (19165 participants) in five countries, with a predominantly white (95%) population, nocturia in women between 18 and 39 years was reported to be 34.5% for voiding once and more a night and 12.9% voiding twice a night or more. This compared favourably with the white group in this study (Irwin et al, 2006). However the results from Irwin et al (2006) highlight the high percentage of night time voiding in the black women in particular, but also in the coloured women.

Several studies support the finding of increased night time voiding in black women. Van der Walt and Rienhardt (2002) also found a higher frequency of night time

voiding amongst black women in the Western Cape, with 27.6% of them and 12.6% of white women and 6.2% of coloured women voiding two times a night (Addendum P). Although other studies (Sampselle et al, 2002; Sze et al, 2002) reported that black women have a higher night time voiding frequency, they did not offer any explanation. However, Kupelian et al (2009), reports that socio-economic status accounts for part of the racial/ethnic disparities in the prevalence of nocturia.

On the other hand, some studies did not find any difference of frequency in night time voiding. FitzGerald et al, (2006) compared data on night time voiding of black, white, Hispanic, Asian and mixed races. They did not find significant differences in the frequency of night time and day time voiding in this racial distribution, but found that black women had lower median voided volume, maximum voided volumes, voids per litre intake and voids per litre output. Furthermore, Lukacz et al (2009) found that race had no influence on frequency of day or night time voiding.

The normal range of nocturnal urine production differs with age and the normal range remains to be defined. Drake et al (2005) found that the white race was associated with nocturnal polyuria in women older than 55 years. However only 18% of the study population was non-white and it might be possible that with a more diverse racial population the white race would no longer be a risk factor. They also did not find any difference in frequency of night time urination between race groups.

Interestingly enough, the black women, who voided during the night, had significantly ($p=0.04$) stronger PFM than the black women who did not void at night (refer 4.4.1, Figure 4.10). There seems to be a link between endurance and OAB symptoms, which include nocturia as described above (Yoon et al, 2003; Thompson et al, 2006). The lack of PFM endurance in the black group might be a contributing factor to the increased night time voiding.

In conclusion, racial differences regarding night time voiding seem to exist, which deserves further investigation. Further studies are needed to establish normal values of night time voiding in the black population to be able to discern pathology.

Day time voiding frequency

There is no consensus regarding voiding patterns of normal, healthy women without any bladder complaints across various age groups (Drake et al, 2005).

Significant differences were found between black and white women with regard to daytime voiding frequency, but not between coloured and white groups, and coloured and black groups (Table 4.4, Figure 4.7). White students in this study voided 5.5 times a day on average compared to black students who voided 4.6 times a day, whereas the coloured group voided 5.2 times a day on average.

In this study the mean daytime voiding is 5.1 times a day. This compared well to a recent study by Lukacz (2009), who reported a mean daytime voiding of 5.3 times a day. However Parsons et al (2007) reported frequencies to be 6.7 times a day. In a community-based study amongst 560 non-institutionalized elderly women, Diokno et al (1986) described voiding frequency in continent elderly women. Voiding frequency per 24 hours was as follows: 5.5% voided 1-3 times, 34% voided 4-5 times, 47.3% voided 6-8 times, whereas 12.3% voided two or more times. In the current study, amongst the black students, a much lower daytime voiding frequency (4.6 times a day) was reported than the frequency described in the aforementioned studies. Further studies are needed to establish normative values for frequency of daytime voiding in different race groups, because this would help in the assessment of pathology.

5.2.3.2 BMI

In this study a weak positive correlation between BMI and PFM strength was observed (refer 4.4.1), however in a covariate analysis of BMI and race, race was still independently associated with PFM strength. The BMI and PFM strength of the

black group was significantly more than the other groups and could therefore explain the correlation between strength and BMI.

However, in the literature, increased BMI has been positively correlated with increased risk of pelvic floor dysfunction. Sampsel et al (2002), reports that each unit increase in BMI was associated with a 5% increase in the odds of having urinary leakage. Obesity is a well-established risk factor for UI (Hunskaar, 2008). A possible biological explanation for Hunskaar's finding is that increased abdominal wall weight increases intra-abdominal pressure and also intravesical pressure, in addition to inducing changes of urethral mobility. The pelvic floor may be stressed as a result of a chronic state of increased abdominal pressure which could induce PFM weakness. There seems to be a stronger association between increasing weight and stress incontinence, than for urge incontinence and overactive bladder syndrome (Hunskaar, 2008). MacLennan et al (2000) found a statistically significant increase in PFD in women who were classified obese and overweight. Obesity causes a reduction in fascial strength, an increase in stiffness and a reduction in energy required for tissue failure (Sayer and Smith, 1994).

5.2.3.3 Amenorrhoea

Amenorrhoea can be described as the absence of menstruation and is a normal physiological event during pregnancy, lactation, before normal menarche and after the menopause. Other possible causes of amenorrhoea could be stress, phantom pregnancy (pseudocyesis), under-nutrition, anorexia and simple weight loss, strenuous exercise, idiopathic hypothalamic disorders, gonadal disorders, chromosomal abnormalities and polycystic ovarian syndrome (van der Spuy, 2007).

In this study, students with amenorrhoea had significantly stronger pelvic floor muscles than students who menstruate (refer 4.4.1, Table 4.6, Table 4.7). In seven of the cases, the amenorrhoea could be due to the effects of Depo Provera® or Nur-Isterate® injections (Table 4.7). The Depo Provera® injection of medroxyprogesterone acetate (MPA) ensures contraceptive protection for three

months and is the most frequent injectable form of contraception used in South Africa (Steyn, 2007). These injections contain progestogen which is a description of synthetic hormones with a similar action to natural progesterone. Norethisterone enanthate is the progestogen used in Nur-Isterate® injections and suppresses ovulation for two months (Steyn, 2007).

The precise impact of progesterone on the PFM is difficult to describe from the current literature. Specific tissue reaction to the administration of steroid hormones depends on the presence of intracellular receptor proteins. Progesterone receptors were found in levator ani muscles and fascia (Copas et al, 2001). The function of progesterone is normally described in conjunction with estrogen and it is therefore difficult to ascertain the specific effect of progesterone alone on PFM tissue. Some of the effects of progesterone on the pelvic floor area that were noted, were the preservation of collagen (Moalli et al, 2008), decreased tone of PFM (Dietz et al, 2003), decreased tone in the bladder and urethra and decreased urethral pressure (Miodrag et al, 1988). If these effects are taken into consideration, a decrease in PFM strength would be expected, rather than an increase in strength. Nichols et al (2008) found that a combination of oral contraceptives did not increase muscle strength gain beyond the stimulus of the training protocol of skeletal muscles in water polo and softball athletes. Wilson et al (1991) also did not find any difference between PFM strength measurements obtained during the menstrual cycle. However Skinner and Crichton (1963) reported that in nulliparous black women, mild SUI was aggravated by menstruation.

Two of the students who were amenorrhoeic had BMIs (18.7 and 18.33 kg/m²) lower than what is normally found in women with a normal reproductive function (19.1-25 kg/m²) which might be a contributing factor to their amenorrhoeic status.

The most plausible explanation for the differences in muscle strength could be that more than half of the amenorrhoeic students were black (7/13) and the black students had significantly stronger MVC pressure measurements than the white and

coloured students. Unfortunately the sample of amenorrhoeic students was too small to do a covariate analysis with race and muscle strength.

5.2.3.4 Urinary Continence

In this study, five students with reported stress urinary incontinence had significantly stronger PFM than urinary continent students (refer 4.4.1, Table 4.6). In contrast to the findings in the current study, several other studies reported that incontinent women had weaker PFM muscles than continent women (Mørkved et al, 2002; Hahn et al, 1996; Amaro et al, 2005; Thompson et al, 2006). Others have found no difference in PFM strength between continent and incontinent women (Morin et al, 2004; Madill and McClean, 2009).

However this result has to be evaluated with caution because of the small sample size of women with SUI. One of the black students with SUI had an extremely high (55 cmH₂O) pressure increase with a maximum voluntary contraction of the PFM. This could have “artificially” increased the mean contraction value of the incontinent students. Unfortunately, a covariate analysis of race and continence status could not be done because of the small sample size, and therefore it cannot be verified that the SUI is independently associated with muscle strength.

5.2.3.5 Bowel Motion

According to the Rome III classification, functional constipation presents as persistent difficult, infrequent, or seemingly incomplete defecation, which does not meet the irritable bowel criteria. Irritable bowel syndrome (IBS) is defined as a functional bowel disorder in which abdominal pain or discomfort is associated with defecation or a change in bowel habit, and with features of disordered defecation (Longstreth et al, 2006).

The diagnostic criteria for functional constipation according to the Rome III criteria (Longstreth et al, 2006):

Must include two or more of the following

- a. Straining during at least 25% of defecations
- b. Lumpy or hard stools in at least 25% of defecations
- c. Sensation of incomplete evacuation for at least 25% of defecations
- d. Sensation of anorectal obstruction/blockage for at least 25% of defecations
- e. Manual manoeuvres to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor)
- f. Fewer than three defecations per week

Twenty-three percent of the students in this study strained with bowel motions (refer 4.4.1, Table 4.6) which correlated well with results in a study by Kahn et al (2005), where he found that 24% of his study sample of women who attended a gynaecological clinic strained with bowel motion. Eleven percent of our study sample had bowel motions less than 2X/week compared to the finding of 15%.of Kahn et al (2005).

In the current study, women who had bowel motions less than twice a week had significantly ($p=0.01$) weaker PFM strength than others who has bowel motions more frequently. Chronic constipation has been associated with a weakening of PFM structures (Snooks et al, 1985).

In a systematic literature review, Holroyd-Ledue and Straus (2004), found evidence in three different studies, that constipation and other bowel problems are independently associated with increasing rates of urinary incontinence. Constipation is also associated with an increased risk of anal incontinence (Boreham et al 2005). Bowel motions less than twice a week had weak association with pelvic floor descent (Kahn et al, 2005), but straining with a bowel motion was strongly associated with anal incontinence.

5.2.4 Factors found not to be associated with PFM strength

Physical activity participation, student type, low back pain, respiratory conditions, ethnic subgroups, contraceptive pill, progestogen injections, regular menstrual cycle, length of menstrual cycle, menstrual flow, dysmenorrhoea and straining with a bowel motion had no significant association with PFM strength. No significant association of frequency of daytime voiding, dysuria, vaginal candida infection and PFM strength were found (refer 4.4.2, Table 4.8, Table 4.9).

Previous PFM contraction

Ninety-one percent of the white participants reported that they have previously tried to contract their PFM, compared to 46% of the coloured participants and 30% of black participants. This could be explained by the fact that most of the white participants were physiotherapy students, who received lectures on PFM before the test procedure. However, in this study, the reporting of having previously tried to contract the PFM did not have a significant influence on PFM strength measurement. This finding is supported by Dietz et al (2003) who also found that previous teaching of PFM had no influence on strength in nulliparous women. However he did find that the reported use of the levator muscle during intercourse was strongly associated with increased levator activity.

In the planning of the study, it was thought to add questions on intercourse to the demographic questionnaire. Due to the sensitive nature of this study in respect of race, HIV/AIDS in the South African context and the fact that the population was nulliparous and unmarried, the researcher did not think it was appropriate to add these questions in this study context.

Pelvic girdle pain

In this study, perineal pain and low back pain had no significant influence on PFM strength measurement. This was supported by Stuge et al (2006), who investigated differences between PFM strength in a group of parous women with pelvic girdle pain and a group who recovered from pelvic girdle pain and found no significant difference

in PFM strength between these groups as tested with vaginal squeeze pressure measurement.

5.2.5 Resting pressures

Muscle tone is the resting tension in a skeletal muscle. It occurs because there are always a few motor units contracting in a resting muscle. Muscle tone does not produce movements, but it keeps the muscles firm and ready to respond to stimulation (Sambrook et al, 2001). Griffin et al (1994) noted that as PFM strength increased, vaginal resting pressures increased and explained this by the increased resting tone of the PFM.

However, only one study (Levitt et al, 1979), considered reliability of resting pressure, but a different perineometer was utilized. Levitt et al (1979) did find a stronger correlation ($r=0.89$) between resting values and the difference between contraction and resting values, than in this study ($r=0.28$) (Figure 4.11). The results of the study by Levitt et al (1979) have to be used with caution, because details of methodology and analysis were scant, making comparison with the results of the present study difficult.

Very few of the studies that used the Camtech balloon catheter for vaginal pressure measurements reported resting values and the reported values ranged between 9.5 and 31.9 cmH₂O. Resting pressures in continent women were reported to be in the range of 9.5-29.1 cmH₂O. In a study by Bø et al (1990b), to validate the vaginal pressure measurement of the balloon catheter, resting values were reported to be 9.5-11 cmH₂O for women who had cranial lift with a PFM contraction and correct PFM contraction with a vaginal palpation. Other women, who could not perform a PFM contraction tested by vaginal palpation and cranial lift, had resting measurements of 12-18 cmH₂O. In a study reporting resting values in relation to testing positions, the mean resting value for supine was 29.1 cmH₂O (Bø and Finkenhagen, 2003), which is also much higher than the values reported in this study.

Two studies that reporting on resting values in women with SUI, reported a higher range of values in stress urinary incontinent women than in continent women (22-39 cmH₂O). Women with SUI, who could perform a correct PFM contraction, had mean resting values of 22-24 cmH₂O (95%CI 17-27 cmH₂O) (Bø et al, 1990a). This compares well with the mean resting value of the white group (24 cmH₂O) in this study. The mean resting values of the black group (21 cmH₂O) and coloured group (19 cmH₂O) compare well with the range of the 95% CI of this study by Bø et al (1990a) (refer 4.5.2, Table 4.10). Ree et al (2007) report mean resting values in a group of 12 nulliparous women, with mild SUI with strenuous activity, to be 31.9 cmH₂O at baseline. This is much higher than the resting values reported in the current study.

Griffin et al (1994), using a different vaginal probe, measured resting pressure in women on an active PFM strengthening program at baseline and then at intervals of 3 weeks. Griffin et al (1994) reported the changes in resting values and gave possible explanations for their findings. At 3 weeks the resting pressure increased, due to increased neural function, but a decrease in resting pressure was found at six weeks, which could be explained by improved relaxation. At weeks 12-15 resting pressure increased because of hypertrophy of the PFM. Griffin et al (1994) thought that these results suggested that an increase in resting pressure contributed to the occlusive function of the urethra and support of the pelvic organs, while the pelvic floor muscles are at rest. However, in the current study only a weak correlation was found between vaginal resting pressures and pelvic floor muscle strength.

This weak correlation to the study of Griffin et al (1994) could be explained by the difference in the size of the vaginal probe used to measure pressure. Although Griffin does not report the specific measurement of the vaginal probe, she did report that their probe touched the cervix. It would therefore appear that the Camtech balloon catheter is smaller than the one used by Griffin et al (1994) and measures pressures at a different site in the vagina from the vaginal probe used by Griffin et al. This might explain the differences in findings.

5.2.6 Symptoms in relation to resting mean values

There is a fair indication that a relationship may exist between overactive pelvic floor muscles and symptoms of pelvic pain, as discussed in the literature overview (refer to 2.2). Therefore, if the vaginal resting pressure is a true representation of PFM resting tone, it would be expected that some results indicating a relationship between vaginal resting pressure and symptoms of pelvic pain would be found. However, there were no significant results regarding a relationship between vaginal resting pressure and symptoms associated with chronic pelvic pain, except a significant ($p=0.04$) relationship with menorrhagia (refer 0, Table 4.12, Table 4.13).

The relationship of PFM trigger points in women of different race groups has been investigated. Tu et al (2006) evaluated 995 women with chronic pelvic pain from 1995-2000 and found that 22% of white women and 18% of black women had levator ani muscle tenderness with vaginal palpation. Piriformis tenderness was found in 12% of white women and 14% of black women. However, the prevalence of musculoskeletal pain did not differ among women with, and without, any of the three commonly encountered conditions (endometriosis, irritable bowel syndrome, intra-abdominal adhesions). Thus, overactive PFM are prevalent in women of different races. If vaginal resting tone is a valid reflection of muscle tone, it would be expected that some relationship between vaginal resting tone and symptoms of chronic pelvic pain would exist, which was not the case in this study and raises the question of whether vaginal resting pressure is a true reflection of PFM tone.

In this study no significant relationship between resting pressures and continence were found. This finding is supported by Hahn et al (1996), using a vaginal pressure probe to evaluate strength. However, Shishido et al (2008) found lower vaginal resting pressures in SUI women than in urinary continent women, using a novel, directionally sensitive, vaginal probe. The findings of Shishido et al (2008) confirm the suspicion that the balloon catheter might not be an appropriate tool to evaluate PFM tone.

According to Shishido et al (2008) the mean length of the vagina is 8.3 ± 0.77 cm and resting pressure is transmitted along the whole length of the vagina. The balloon

catheter measures the pressure in the vagina, 3.5 cm from the introitus (Bø et al, 1990a); this is the area in the vagina where the most pressure is generated with a pelvic floor muscle contraction, according to Shishidu (2008). The balloon catheter is therefore well situated to indicate maximal contraction pressures, but does not give an indication of the pressure generated along the whole vagina.

If the location of trigger points is considered, it may give an indication of why the balloon catheter may not reflect increased PFM tone. Jung et al (2007) proposed that the high pressure zone in the posterior part of the vagina is produced by the puborectalis muscle. If the position of myofascial trigger points are evaluated, a fair number of them are situated at the posterior part of the PFM (Prendergast and Weiss, 2003; Wise and Anderson, 2006), therefore increasing pressure more toward the posterior vagina, which would not be indicated by the balloon catheter.

An important question is therefore whether the balloon catheter is the optimal way to assess PFM resting tone. It may not give a good representation of resting tone, explaining the lack of correlation with pelvic pain symptoms thought to be associated with higher resting tone. Vaginal pressure is influenced by individual anthropometric differences and for this reason cannot be compared among groups (Madill and McClean, 2009). This is also supported by Messelink et al (2005) and Morin and Bergeron (2009) who commented on the lack of definitions for the tone of the PFM, the lack of objective measurement tools for pelvic floor tonicity and the lack of cut-off values for pathological conditions.

However, studies using EMG measurement, have found a relationship between pelvic pain and PFM tone. Glazer et al (1998) , using intravaginal EMG, showed that women with vestibulodynia have higher resting activity, lower strength and endurance as well as increased pelvic floor muscle instability. Weis (2001) reported a 65% decrease of the resting EMG recording of the PFM in women and men they treated for urgency-frequency syndrome.

As can be seen in the discussion of vaginal resting pressures, measurement of PFM tone is a complex issue and further research is needed to determine how the relative contributions of tonic PFM activity can be assessed more accurately.

5.3 DISCUSSION OF METHODOLOGY

The methodology of the study will be discussed along the following headings: population, sample size and power of the sample, the ability to generalize the findings, the outcome measures, reliability and validity of the study as well as the ethical considerations taken into account in the study.

5.3.1 Population

The subjects in the current study were nulliparous, university physiotherapy and nursing students and students from other study fields, studying in the Western Cape and between the ages of 18 and 45 years. A nulliparous population was chosen to exclude the negative effect pregnancy and childbirth has on PFM strength (Marshal et al, 2002; Chaliha, 2009) and a younger adult population was chosen to limit the effect of age on PFM strength (Aukee et al, 2003; Fox et al, 2006).

The main objective of the study was to investigate ethnic differences in PFM strength and racial classification therefore forms an integral part of the study. There is a danger of poor validity and predictive value when race is used in research, if social, cultural, behavioural and environmental confounders are not taken into account (Osborne and Feit, 1992; Risch et al, 2002; Manly, 2006). Therefore to understand the relationship between race/ethnicity background and health outcomes, specific variables have to be taken into account, which help to distinguish variables belonging to different ethnic groups and the variation between individuals within an ethnic group (Manly, 2006). Consequently, cultural experience, years of education/quality of education/literacy, socioeconomic status and racial socialization should be addressed to deconstruct race (Osborne and Feit, 1992; Risch et al, 2002; Manly, 2006). Universities have proved to be the ideal setting to find women who are nulliparous, matched in age and at a similar education level. Although selection of women from different ethnic groups, with regard to socioeconomic status and racial socialization, was difficult in the South African context, because differences in these factors still exist in the post-apartheid era.

Race was classified on a continental basis, because genetic differentiation is greatest when race is defined on a continental basis (Risch et al, 2002). Therefore, according to Risch et al (2002), race can be classified as African, Caucasian (European and Middle-East), Asian, Pacific Islander and Native American. The three main ethnic groups residing in the Western Cape were used in this study, i.e. white, coloured and black groups. The white ethnic group is from Caucasian origin, the black ethnic group is from African origin and the coloured group is a mixed ethnic group from African, Caucasian and Asian origins.

5.3.2 Sample

A sample of convenience was used, because of the difficulty in recruiting women for a study in which a measurement tool of such a personal nature would be used. Therefore, nursing and physiotherapy students were recruited, because they are predominantly nulliparous and during their studies they receive training on the treatment of PFM and would benefit from the exposure to PFM testing, while also improving their professional skills and knowledge.

The subgroup division was done by ethnic group according to the study subjects' self assignment. The students classified themselves into white, black and coloured ethnic groups because, according to Risch et al (2002), self-defined race, ethnicity or ancestry is genetically more informative than clusters based on random genetic markers, provided it defines an endogamous group that can be differentiated from other groups.

5.3.2.1 Similarities in ethnic groups

Different variables were investigated to assess the homogeneity of the different ethnic groups. No significant differences between the ethnic groups were found in the following aspects: the use of western toilets, reporting of regular low back pain, the use of oral contraceptives, those who do menstruate, length of menstruation (the 28 day and 35 day menstrual cycles), menstrual flow, reporting of dysmenorrhoea, dysuria, Candida infections, straining at stool and irritable bowel syndrome. All the

students, with the exception of one participant, were from an urban area (Tables 4.2, 4.3 and 4.4). However, sample sizes were too small ($n < 10$) to compare the different ethnic groups in the following aspects: the use of anti-depressants, SUI, chronic respiratory conditions and those diagnosed with endometriosis (Tables 4.2, 4.3 and 4.4).

5.3.2.2 Differences between ethnic groups

The sample reflected significant differences between the ethnic groups in the following aspects: age, BMI, student type, smoking history, physical activity participation, the use of progestogen injections as a contraceptive method, amenorrhoea, regular menstrual cycle, 21 day menstrual cycle, previous attempt at PFM contraction, day and night time urinary frequency, perineal pain and regular low back pain (Tables 4.1, 4.2, 4.3 and 4.4). Although significant differences existed between the ethnic groups, it was established through co-variate analysis, that these factors did not influence the effect that race had on the measurement of PFM strength. However, the sample of women with amenorrhoea was too small to do a co-variate analysis.

There were significant differences in the age ranges between the white and coloured women, which might be explained by the fact that most of the outliers in the age range were white (Figure 4.2). However, the mean ages of the different ethnic groups were comparable (Table 4.1).

Body mass index is a known risk factor in the development of UI (Hay-Smith et al, 2009). In this sample, the BMI in the black group was significantly higher than in the other race groups and is consistent with findings in several other studies (Graham and Mallet, 2001; Sampsel et al, 2002; Grodstein et al, 2003; Krause et al, 2007; Gray Sears et al, 2009). Differences in the BMI of black children were found to be 0.5-1 kg/m² more than in white children, consequently Rowe and Mohar (2004) proposed that separate BMI standards for obesity should be used in different racial groups.

There are a few possible explanations for the increased BMI in black women. According to Ortiz et al (1992), African American women when matched by age, BMI and menstrual status have greater appendicular skeletal muscle than their white counterparts, which may imply an increase in whole-body skeletal muscle. Aloia et al (2000) also found that African American women not only have a higher musculo-skeletal muscle mass, but also may have a slower decline of skeletal muscle mass as they age. Moreover, Cozier et al (2009) found that weight gain increased in black American women as levels of everyday and lifetime effects of racism increased. This reason for the increase in BMI in black women might account for some of the differences in BMI in South Africans with the background of apartheid, but needs further investigation.

Participation in physical activity could influence PFM strength positively or negatively, depending on the type of activity, the frequency of participation and the amount of impact involved in an activity (Hay-Smith et al, 2009). Eighty-four percent of the white women in the study did partake in physical activities, which was significantly more than the other groups (Table 4.2). However, the participation in physical activities or the impact of the activities did not have a significant influence on PFM strength.

Significantly more black women had a 21 day menstrual cycle than in the other ethnic groups (Table 4.3). As far as can be ascertained, no studies have investigated ethnic differences in menstrual cycle length and therefore this aspect needs further investigation.

Comparison of the prevalence of low back pain (LBP) with other studies is difficult, because of differences in the definitions and categorizing of low back pain. Thirty-four percent of the women in the study reported experiencing regular low back pain (Table 4.3). This is comparable to an Australian study (Walker et al, 2004) which found that 33% of adult women reported low back pain in the previous 24 hour period, and mothers in Lesotho had mild low back pain with a reported 35% prevalence (Woku, 2000).

5.3.3 Number and Power

It was realized that it might be difficult to recruit students for this study, because of the sensitive nature of the testing. Therefore, a pilot study was conducted to assess which factors needed to be considered when trying to recruit students for the study (Addendum A). The recruitment strategy was adjusted, according to the findings of this pilot study, to ensure that students would be willing to volunteer for the study.

The sample size was calculated by analysing the data after 50 women were tested. The data was analysed using ANOVA. It was then calculated that a sample size of 37 in each ethnic group would have 90% power to identify a difference between the three groups of participants.

In the final sample (N=122), the calculated alpha value for differences in PFM strength between the black and coloured group and between the black and white groups was highly significant. Furthermore, the difference between the coloured and white group was highly insignificant (refer 4.3.1).

As discussed previously (refer 5.2.1), it seemed as if a difference in PFM strength of 5 cmH₂O could be of clinical importance. In this study the significant difference in mean PFM strength between the black and white groups was 6.6 cmH₂O and the difference between the black and coloured groups was 9.4 cmH₂O (Table 4.5). These differences might not only be statistically significant, but could also be indicative of clinical significance.

5.3.4 Ability to generalize

A non-probability sampling method with an absence of randomization was used. This weakens the generalization of the sample and increases sampling error. The results of this study can therefore only be generalized to nulliparous black, white and coloured urban women, of 18-45 years with a tertiary education.

Another factor that might limit generalization of the sample, is that the subjects, willing to participate in this study, might have been less shy than others or might feel they have a problem with their PFM and want reassurance, or might actually be more inquisitive. It has been reported that subjects who are willing to participate as research subjects may differ from the general population (Domholdt, 2000).

Furthermore, most of the white women in the study were physiotherapists, who would be more likely to be in tune with their bodies and could present with stronger PFM than other white women. However, there were no significant differences reported in PFM strength between the different students groups in this study, but it might be worth investigating a more diverse white population in future studies to exclude possible strength differences because of occupation.

5.3.5 Outcome measures, reliability, responsiveness and validity

In observational research there is no randomization of groups that could ensure that the groups are equal, but there are statistical methods to determine if a variable is independently associated with an outcome. Therefore, all efforts have been made to exclude all known factors that would influence PFM strength and to include analysis of all other factors that might influence PFM strength or be associated with PFM strength, in order to verify if race is independently associated with strength (refer 3.8.2).

The instrumentation of the study consisted of a self-developed questionnaire and the Peritron™ 9300 perineometer. The use of the Peritron™ 9300 was motivated by the fact that it has been widely used in studies that recorded PFM strength with vaginal pressure measurement (Gilling et al, 2001; Thompson et al, 2006; Bø et al, 2005; Hundley et al, 2005) and is affordable. However the standard vaginal probe that was issued with the Peritron™ 9300 was not well accepted by the students, because of its size and shape (Figure 8.1). It was decided, therefore, to use the smaller vaginal balloon catheter from Camtech AS. The preference for the balloon catheter above the Peritron™ vaginal sensor was supported by Bø et al (2005). The

vaginal balloon catheter has also been widely used in studies recording PFM strength (Bø et al, 1990a, 1990b, 2005; Bø and Stien, 1994, Bø and Finkenhagen 2001, 2003; Mørkved et al 2002, 2004; Stuge et al, 2006).

Internal validity of the instrumentation was established through a few pilot studies. The PFM strength measurement and accuracy of measurement of the Peritron with the balloon catheter was established (Addendum L) as well as intra-rater reliability (Addendum M). The testing procedure was validated by the primary investigator with a pilot study to familiarize her with the equipment and test procedure (Addendum J). The questionnaire had been validated with a pilot study and expert review, but reliability of the instrument has however, not been established with testing and re-testing (Addendum N and reference 3.8.2).

Other factors that were identified, that could have influenced internal validity of PFM strength measurement, are the influence of other muscles or movements on vaginal pressure measurements. Muscle groups or movements that could increase vaginal pressure measurement are adductor muscles, posterior pelvic tilt, breath-holding, straining and gluteal contraction (Bø et al, 1990b). These factors, however, have been considered and controlled by the method used, in order to obtain valid PFM strength measurements (refer 3.6.1.2).

Self-classification of race could also be a possible threat to internal validity, if someone classified themselves as a member of another race group rather than the one they really belong to. However, self-classification is the most common method used for racial classification and is recommended above classification based on genetic markers (Risch et al, 2002).

Another factor that could contribute to a lack of validity and reliability was the decision to investigate the relationship between vaginal resting values and PFM strength. The decision to investigate vaginal resting pressures was made just before the implementation of the study. Because of a lack of time before the data collection

would start, no pilot studies were conducted to test the internal and external validity and reliability of vaginal resting pressure measurements with the balloon catheter as an assessment of PFM tone. This is a weakness of the study.

5.3.6 Ethics

A PFM training program (Addendum K) was offered to 19 women who had weak PFM (<10 cmH₂O), to three women who asked for a PFM training program and five women who reported SUI. It was difficult to decide what the range of values would be for someone with weak PFM, because there are no normative values available on PFM strength as measured with the balloon catheter. Based on clinical experience, the researcher decided that all the women who had measurements under 10 cmH₂O might have weak PFM and was offered PFM training.

All of the women achieved a correct PFM contraction after careful instruction and observation. This is contrary to several studies (Benvenuti et al. 1987; Bø et al. 1988; Hesse et al, 1990; Bump et al, 1991) that demonstrated that more than 30% of SUI women, although thoroughly taught in PFM anatomy and function, were unable to perform a correct PFM contraction at their first attempt. However, Stark et al (2000) showed that in women who could not contract their PFM on the first attempt could, with careful instruction, contract their PFM on the second attempt. Physiotherapy and nursing students participating in the study received lectures on PFM prior to the testing, and other students received careful instruction about the anatomy and function of the PFM before testing. This could possibly explain why everybody could get a correct PFM contraction.

None of the women reported any problems with vaginal infections or emotional problems after the testing.

The results of the current study indicate that ethnic differences in PFM strength exist and that it is difficult to interpret results relating to vaginal resting pressures. The implications of these findings will be discussed in the next chapter. The limitations of

the study will be addressed and recommendations for future studies will also be made.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

The main objectives of the study were to determine PFM strength and endurance, as measured by the vaginal squeeze pressure of nulliparous women during a maximal voluntary contraction of the PFM and to compare the PFM strength and endurance between black, white and coloured ethnic groups. The secondary objective was to establish if relationships exist between PFM strength, vaginal resting pressures and risk factors and symptoms associated with pelvic floor dysfunction and pelvic pain syndrome.

The results of the cross-sectional study indicate that black women had stronger pelvic floor muscles than white and coloured women. However no significant differences regarding PFM strength and endurance were noted between white and coloured women. Endurance measurements in this study indicate that black women had decreased endurance compared to white and coloured women. These findings inform the current research on racial differences in the prevalence of stress urinary incontinence, overactive bladder syndrome and pelvic floor anatomy. Differences in PFM strength might predispose women of different race groups to develop different kinds of urinary incontinence. The PFM strength measurements in this study compare well with other studies using the same vaginal balloon catheter.

In this study, women with amenorrhoea, stress urinary incontinence and increased BMI had stronger PFM. The small sample sizes in the women with stress urinary incontinence and amenorrhoea did not allow covariate analysis with race and these results need, therefore, to be handled with caution. Covariate analysis of race and BMI established that race was independently associated with PFM strength. Women who had decreased frequency of bowel motion (less than three times a week) had significantly weaker PFM than those with normal bowel frequency, which is consistent with findings in the literature.

Significantly more black women than white or coloured women voided more than once a night. Black women who voided at night had significantly stronger PFM than black women who did not void at night. Black women also voided significantly less often during the day than white women. Differences regarding daytime and night time voiding may exist, and deserve further investigation to establish normative values for the black population and to be able to discern pathology.

Preliminary data suggest that there were no significant relationships between vaginal resting pressures and risk factors, symptoms associated with pelvic floor dysfunction and pelvic pain syndrome, except for a significant relationship with menorrhagia. Due to small sample sizes, the variables investigated and the procedure used to determine tone, the results of this study must be interpreted with care. It does however raise potential questions regarding ethnic differences in voiding frequency and the effect of PFM function on voiding frequency patterns.

This study lays the groundwork for future studies to clarify the observed ethnic differences in voiding frequency and the establishment of more effective ways of assessing the relationship between pelvic floor muscle function and symptoms experienced by patients.

6.2 Limitations

It was not the primary objective of the study to evaluate resting vaginal pressures and therefore the study was not structured around the measuring of vaginal pressures. After analysing the results, it became clear that the vaginal balloon catheter might not be the most appropriate measurement tool for pelvic resting tone. It is recommended, therefore, that a validated tool for the measurement of vaginal resting tone be developed before further research on overactive pelvic floor muscles can be attempted. This tool must be able to take measurements along the whole vagina and must not register interference from other muscle groups or abdominal pressures. It also needs to be able to discern activity in different areas in the pelvic floor muscles. So far, such a device does not exist and would need to be developed, or a

combination of devices used to measure different aspects of pelvic floor muscle activity.

The study was designed to investigate PFM strength and the questions in the questionnaire were directed to assess PFM strength. Then questions related to PPS were added. Finally it was difficult to distinguish between risk factors and symptoms. What might be a risk factor for PFM strength could be a symptom of PPS. For example: constipation is a risk factor for PFM strength, but can also be a symptom of PPS. In future studies, it is recommended that PPS should be investigated in a separate study.

A few limitations regarding the self-developed questionnaire became obvious during the study. During the analysis of data, some of the questions in the questionnaire were found not to be reliable measurements of the variables that were being assessed. These questions were related to urinary incontinence, chronic respiratory conditions, low back pain, physical activities and tampon use.

- The question on low back pain was too broad and could be improved by adding options on a Likert scale (Domholdt, 2000) to indicate how regularly back pain was experienced and how severe.
- Stress urinary incontinence and chronic respiratory conditions were initially exclusion criteria, but during the course of the testing it was decided to include these volunteers and to analyse the data as a variable. This however created difficulties, since the questions were directed at assessing inclusion or exclusion and were not well defined to assess the impact it might have on variability or strength. It is recommended that in future studies the questions be refined to give more precise feedback on the variable being assessed. Urinary incontinence and urge urinary incontinence should also be assessed.
- The question on tampon use was included in the questionnaire to assess if the participant would be able to insert the vaginal balloon sensor easily. This did not result in reliable answers because a number of the students only used sanitary towels and did not use tampons. The question could be changed to: Do you think you will be able to insert the vaginal sensor with ease?

- It was difficult to make meaningful conclusions from the responses obtained from the questions on physical activity participation, because of the wide variety of responses to the question on what physical activities the students did partake in (Figure 4.3A). Analysis was complicated further with some of the students participating in a number of different activities.

6.3 Recommendations

On completion of this research the following recommendations for further research are:

- That the voiding frequency in black women be investigated to establish normative values.
- That a reliable measurement tool be found to measure pelvic floor muscle tone.
- That the effect of lifestyle changes on PFM strength be investigated. This might be accomplished by investigating the differences in PFM strength in rural versus urban black women.
- To investigate other aspects of PFM function in the different ethnic groups with a variety of measuring tools, such as ultrasound and EMG (Bø and Sherburn, 2005).
- To include more diversity into the sample group with regard to occupation, in order to limit the possible effect of occupation on PFM performance.
- That the study should be repeated in parous women matched by age and parity and mode of delivery.
- To establish a validated protocol to determine endurance and to investigate the interaction between PFM endurance and overactive bladder syndrome.

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ADDENDA

Addendum A: Pilot study A

A survey was done on 27 February 2007 amongst the third year physiotherapy students at the University of Stellenbosch.

Aim:

The aims of the pilot study were to determine:

- How to recruit students to participate in the study.
- How many students would be willing to participate in the study?
- What would motivate students to participate in the study?
- What would discourage the student from participating?
- How they feel about the insertion of a vaginal sensor.

Procedure:

The procedure of the pilot study was as follows:

The primary researcher gave a ten minute talk to all the women in the third year physiotherapy class, on the nature of the study, the reason why the study was being conducted, the reason why students would be used in this study, how the student would benefit if participating in the study, how the study would be conducted and emphasizing pelvic floor rehabilitation as a subspecialty in physiotherapy. The vaginal probe was shown to the students and the depth of insertion into the vagina and the basic contents of the demographic questionnaire were explained. The students then had to complete a short anonymous questionnaire. The questionnaire that students completed follows:

M-study survey:

The answer you give here is not binding. This is just a survey to help me plan my study more effectively. Thank you for your time.

Die antwoord wat jy hier verskaf is nie bindend nie. Dit is slegs 'n opname om my te help om my studie te beplan. Baie dankie vir jou tyd.

- Sal jy bereid wees om deel te neem aan die studie? Ja/Nee

Would you be prepared to participate in this study? Yes/No

- Redes:

Reasons:

.....

.....

.....

.....

- Moontlike voorstelle?

Any suggestions?

.....

.....

.....

.....

Outcome:

All the women in the class (33) completed questionnaires. Twenty-two students (67%) said they were willing to participate. Ten students (30%) said that they were not willing to participate and one student (3%) was indecisive.

The reasons for participating were as follows:

The majority (>50%) of the students felt that they would be exposed to a new field of physiotherapy that the students at undergraduate level would not normally be exposed to..

Other themes identified amongst reasons to participate were:

- Exposure to research

- To help promote physiotherapy as a profession
- To clarify the concept of pelvic floor muscle function and knowledge and to experience pelvic floor muscle testing.

Reasons for not participating:

The most common themes identified for not participating in the study were:

1. Shyness and self-consciousness
2. Uncomfortable with the test procedure
3. Lack of time for participating
4. Participation would be considered if payment were offered

The following are some of the comments students offered in response to the questionnaire:

“The thought of having a probe inserted vaginally is daunting.”

“Is a vaginal examination really necessary?”

“Thank you for the opportunity to learn more about women’s health.”

“Could you offer payment for participation, it would motivate students.”

“The test equipment looks “scary”.”

“Privacy during the test procedure would be greatly appreciated.”

“I am concerned because I do not wear tampons – would I still be able to insert the probe?”

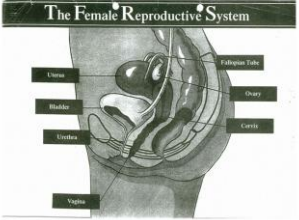

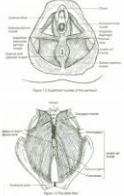

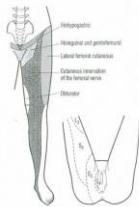
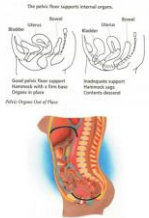
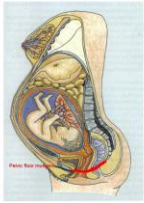
“Lectures and testing times and venue must be scheduled to suit all students, especially the students that do not live on campus.”

“I would like to attend lectures and learn more about pelvic floor rehabilitation, but the test procedure is too personal and daunting.”

The following amendments to the study were made after the survey on recruitment strategy was completed:

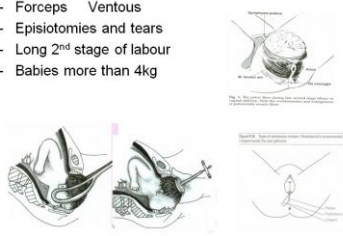
- It was decided to present lectures on PFM dysfunction before the recruitment of students.
- To ensure that all students had the opportunity to attend the lectures, the lecture was given to a whole class of students and then students were recruited to participate in the study.
- An effort was made to ensure that the study was not too time consuming for the students. Therefore the lectures were given during the time allocated for women's health lectures at all the universities. The testing procedure was done during lunch time or off periods.
- The testing procedure was done on campus to make sure that students would be able to attend it easily.
- An internal vaginal examination was not done; instead an observation of the perineum was done to verify a correct pelvic floor contraction.
- An extra question was added to the questionnaire on the use of tampons to establish if the student would be able to insert the probe easily.
- The students inserted the probe themselves in privacy. The researcher then checked to see if the probe was inserted to the right depth.
- During the recruitment of students, it was stressed that all efforts would be made to ensure their privacy during the testing procedure and ensure anonymity.

Addendum B: Outline of the lectures presented


<p style="text-align: center;">Pelvic floor rehabilitation</p> <p style="text-align: center;">Understanding the pelvic floor</p>	<p style="text-align: center;">Questions to answer</p> <ul style="list-style-type: none"> How often do you visit the toilet to urinate per day? • times per day How often do you have a bowel motion? • per day/per week Do you leak urine when you cough, sneeze, laugh or jump? • Yes or No? Do you have to run to the toilet when you get the urge to urinate? • Yes or No? Do you leak urine on your way to the toilet? • Yes or No?
<p style="text-align: center;">Fluid intake</p> <ul style="list-style-type: none"> How many cups of coffee do you drink per day? • How many cups of tea do you drink per day? • How many cups of Rooibos tea do you drink per day? • How many glasses of water per day? • Cool drink per day? • Alcoholic beverages per day? • Other? • <p style="text-align: right;">• Cups/Glasses per day</p> <p style="text-align: right;">• Total</p>	<p style="text-align: center;">Anatomy</p> <p style="text-align: center;">The Female Reproductive System</p> 
<p style="text-align: center;">Anatomy</p> 	<p style="text-align: center;">The pelvic floor</p> <ul style="list-style-type: none"> Superficial muscle group consists of the urogenital and anal triangles Deep muscle group (Levator ani) consists of pubococcygeus, iliococcygeus and puborectalis termed the Levator ani. Connected to the Endopelvic fascia 
<p style="text-align: center;">The Pelvic floor</p> <ul style="list-style-type: none"> 30% fast twitch fibers (white) 70% slow twitch fibers (red) 	<p style="text-align: center;">Myotomes and Dermatomes Pudendal Nerve (S2-S4)</p> <ul style="list-style-type: none"> Myotomes <ul style="list-style-type: none"> -Pelvic floor -Glut maximus -Plantar flexors -Intrinsic foot muscles Dermatomes <ul style="list-style-type: none"> Perineum Glans penis and clitoris Behind upper leg Outside of upper leg 
<p style="text-align: center;">Function of pelvic floor</p> <ul style="list-style-type: none"> Supportive sling Stabilizer (slow twitch) Fast contractor under increased abdominal pressure (fast twitch) Allow release of the pelvic sling or passage of faeces from the rectum Co-ordinate to cortex controlled activities (when and where to void) Guarding reflex. (cough, lift etc) Contraction inhibits bladder Sexual sensation 	<p style="text-align: center;">Pelvic floor weakness due to: Pregnancy</p> 

Pelvic floor weakness due to: Vaginal deliveries

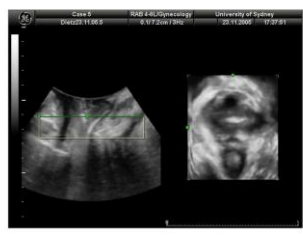
- Forceps Ventous
- Episiotomies and tears
- Long 2nd stage of labour
- Babies more than 4kg




Normal anatomy of Levator ani



Avulsion of Levator ani

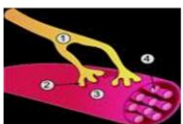


Spot the difference



Two types of injuries with excessive muscle and fascial tension during childbirth (Kegel 1948)

- Type 1: actual laceration and separation of the muscles and fascia
- Type 2: separation of individual muscle cells from the motor nerves by which they are innervated.



In tact pelvic floor

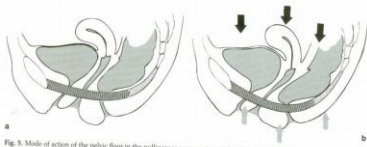


Fig. 5. Mode of action of the pelvic floor in the nulliparous women at rest (a) and during intra-abdominal pressure rise (b). During coughing (black arrows), the intact pelvic floor acts as passive abdominal (grey arrows), causing posterior compression of the urogenital junction.

Pelvic floor insufficiency

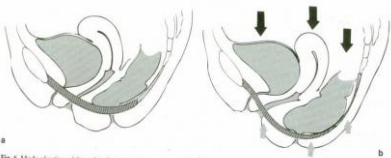



Fig. 6. Mode of action of the pelvic floor in parous women with pelvic floor insufficiency at rest (a) and during intra-abdominal pressure rise (b). During coughing (black arrows), the overstretched pelvic floor is not able to counterbalance (grey arrows) the intra-abdominal pressure rise. Therefore, it is forced downward, causing hypermobility of the urogenital junction.


Pelvic floor weakness due to:

- Constipation




Pelvic floor weakness due to:





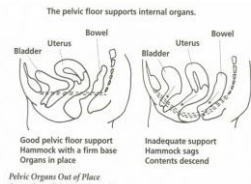
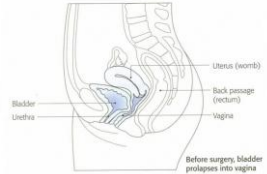


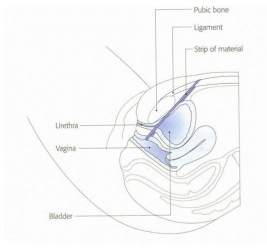
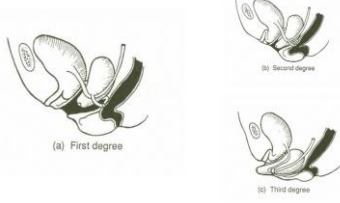
- Age

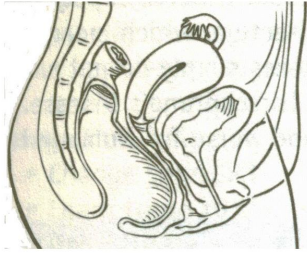


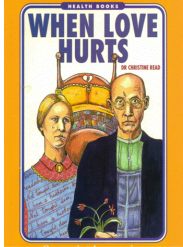
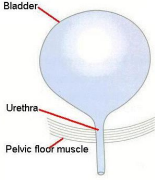
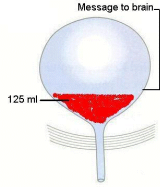
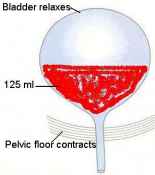
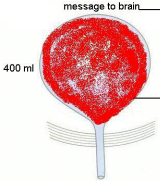


Pelvic floor weakness due to:

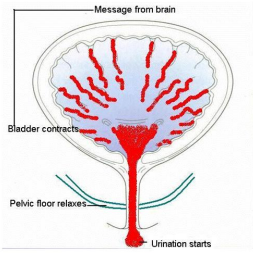
- Chronic respiratory conditions ie. Asthma and Bronchitis



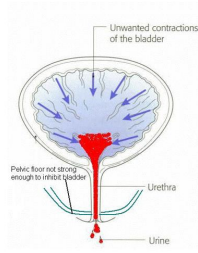
<p>Pelvic floor weakness due to:</p> <ul style="list-style-type: none"> • Heavy smoking and coughing 	<p>Pelvic floor weakness due to:</p> <ul style="list-style-type: none"> • Regular straining with lifting heavy objects 
<p>Obesity</p> 	<p>Nulliparous women can have weak pelvic floor due to:</p> <ul style="list-style-type: none"> • Constipation • Heavy lifting • Respiratory conditions • To test for soft tissue laxity 
<p>Effects of weak pelvic floor musculature:</p> <ul style="list-style-type: none"> • Pelvic organ prolapse  <p><i>Pelvic Organs Out of Place</i></p>	<p>Anterior wall prolapse (cystocele)</p>  <p><i>Before surgery, bladder prolapses into vagina</i></p>
<p>Cystocele</p>  <p><i>Cystocele</i></p>	<p>Urethrocele</p>  <p><i>Urethrocele</i></p>
<p>Sling procedure</p> 	<p>Uterine prolapse (Enterocoele)</p>  <p>(a) First degree (b) Second degree (c) Third degree</p>

<p>Posterior wall prolapse (rectocele)</p> 	<p>Rectocele</p> 
<p>Effects of weak pelvic floor musculature</p> <ul style="list-style-type: none"> • Urinary and Faecal incontinence 	<p>Effects of weak pelvic floor musculature</p> <ul style="list-style-type: none"> • Decreased sexual function 
<p>Normal bladder function</p> 	<p>Bladder filling – first stretch</p> 
<p>Response on first stretch</p> 	<p>Full Bladder</p> 

Emptying bladder



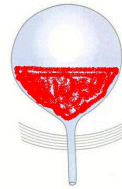
Overactive bladder



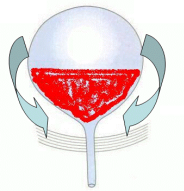
Overactive bladder



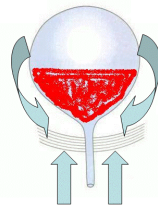
Normal bladder with increased abdominal pressure



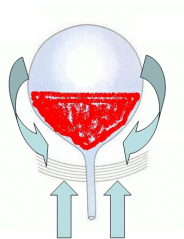
Increased abdominal pressure – helps to close urethra



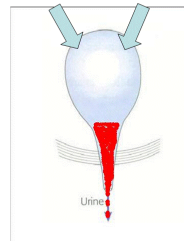
Increased abdominal pressure = Pelvic floor contracts



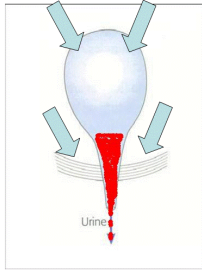
Pelvic floor contracts = No leakage



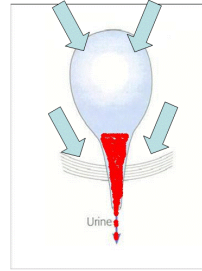
Increased abdominal pressure – Pressure onto bladder



Increased abdominal pressure – Straining on pelvic floor



Straining on pelvic floor = Leakage of urine = stress incontinence



Normal values

- How often do you visit the toilet to urinate per day?
- How often do you have a bowel motion?
- Do you leak urine when you cough, sneeze, laugh or jump?
- Do you have to run to the toilet when you get the urge to urinate?
- Do you leak urine on your way to the toilet?
- Normal 5-7 times per day
- More = frequency
- 3X per day- 3X per week (constipation)/straining at stool
- Yes – Stress incontinence
- Yes – Urgency
- Yes – Urge incontinence
- Urgency and Urge incontinence = overactive bladder

Suggested fluid intake with overactive bladder

- How many cups of coffee do you drink per day?
- How many cups of tea do you drink per day?
- How many cups of Rooibos tea do you drink per day?
- How many glasses of water per day?
- Cool drink per day?
- Alcoholic beverages per day?
- Other?
- Cups/Glasses per day
- 0 caffeinated drinks, rather decaffeinated coffee
- 0 caffeinated, rather decaffeinated tea
- Rooibos OK
- OK – up to 2litres of fluid
- No caffeinated i.e. Coke, Fanta, Diet Coke rather non sour Juices
- Alcohol a bladder irritant
- Should be between 1.5 and 2 liters of FLUID in Total

Kegel 1956

- EARLY SIGNS OF DEGENERATIVE PROCESSES OF THE PELVIC FLOOR CAN BE REVERSED THROUGH ACTIVE EXERCISES



Addendum C: Informed consent**PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM****TITLE OF THE RESEARCH PROJECT:**

An investigation of pelvic floor muscle strength in nulliparous women of different race groups.

REFERENCE NUMBER: N06/03/058

PRINCIPAL INVESTIGATOR: Mrs I van der Walt

ADDRESS:

34 Fifth avenue

Boston Estate

Bellville

7530

CONTACT NUMBER: H+W: (021) 948 0259

Cell: 0722165578

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

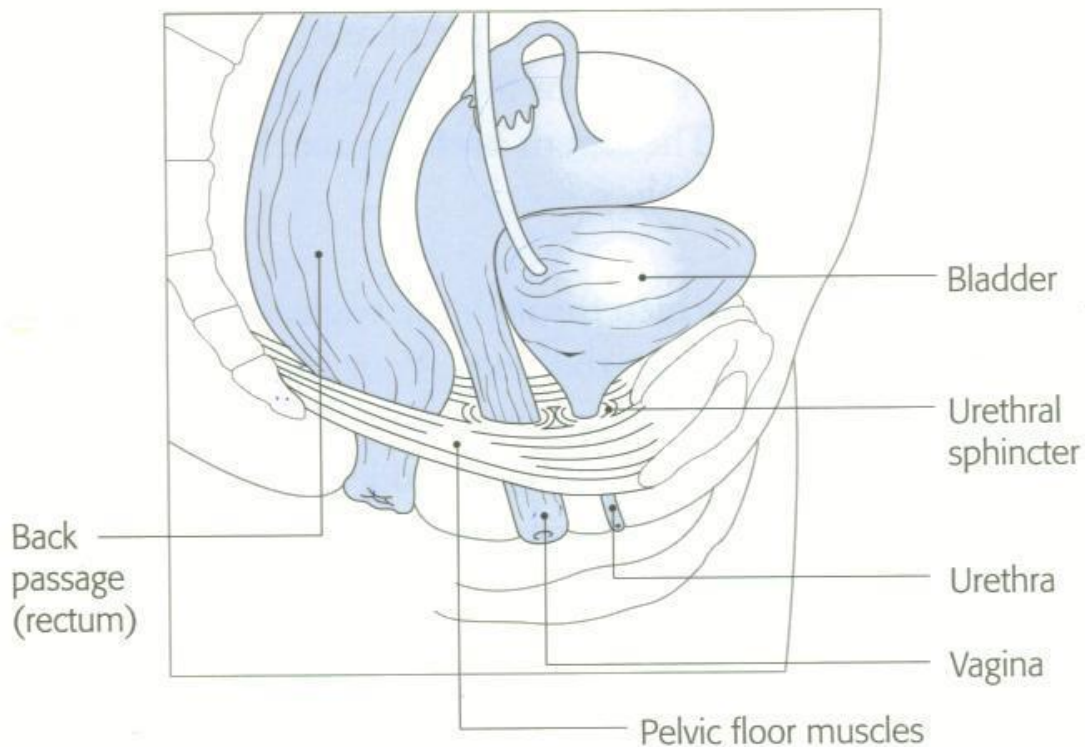
This study has been approved by the Committee for Human Research at Stellenbosch University and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

Your Pelvic Floor

The pelvic floor is a large sling, or hammock, of muscles stretching across the floor of the pelvis. It attaches to the pubic bone at the front, and extends backwards to attach to the base of the spine, the coccyx. It forms your 'undercarriage'.

The opening to the bladder, birth canal (vagina) and bowels all pass through the pelvic floor.



What Does the Pelvic Floor Do?

- It supports the pelvic and abdominal organs, especially when standing or on exertion.
- It supports the bladder to prevent leaking. It works harder when the pressure on it increases e.g. with coughing or lifting.
- It helps with the control of the bowels, both to 'hold on' and to hold wind.
- It is very important for healthy sexual function, and can increase sexual awareness for both partners during intercourse.

Prolapse

A prolapse is when the pelvic floor has stretched so that it no longer provides adequate support for the pelvic and abdominal organs, and they move downwards into an abnormal position.

Incontinence**Stress Incontinence**

When the pelvic floor muscles are weak or less responsive than normal any increase in abdominal pressure may cause a small amount of urine to leak. This can be due to coughing, sneezing laughing, lifting and jumping.

Urgency and Urge Incontinence

Normally, the bladder should relax and stretch to allow it to fill with urine, and only squeeze when it gets to the toilet to allow it to empty. When the bladder squeezes at the wrong time it can give the overwhelming sensation of needing to pass urine, and needing to do it NOW! Sometimes, the bladder squeezes so hard that it actually pushes some urine out, often en route to the toilet.

Most of the studies conducted worldwide on the incidence of incontinence had been among the white population and little is known about other populations and Ethnic

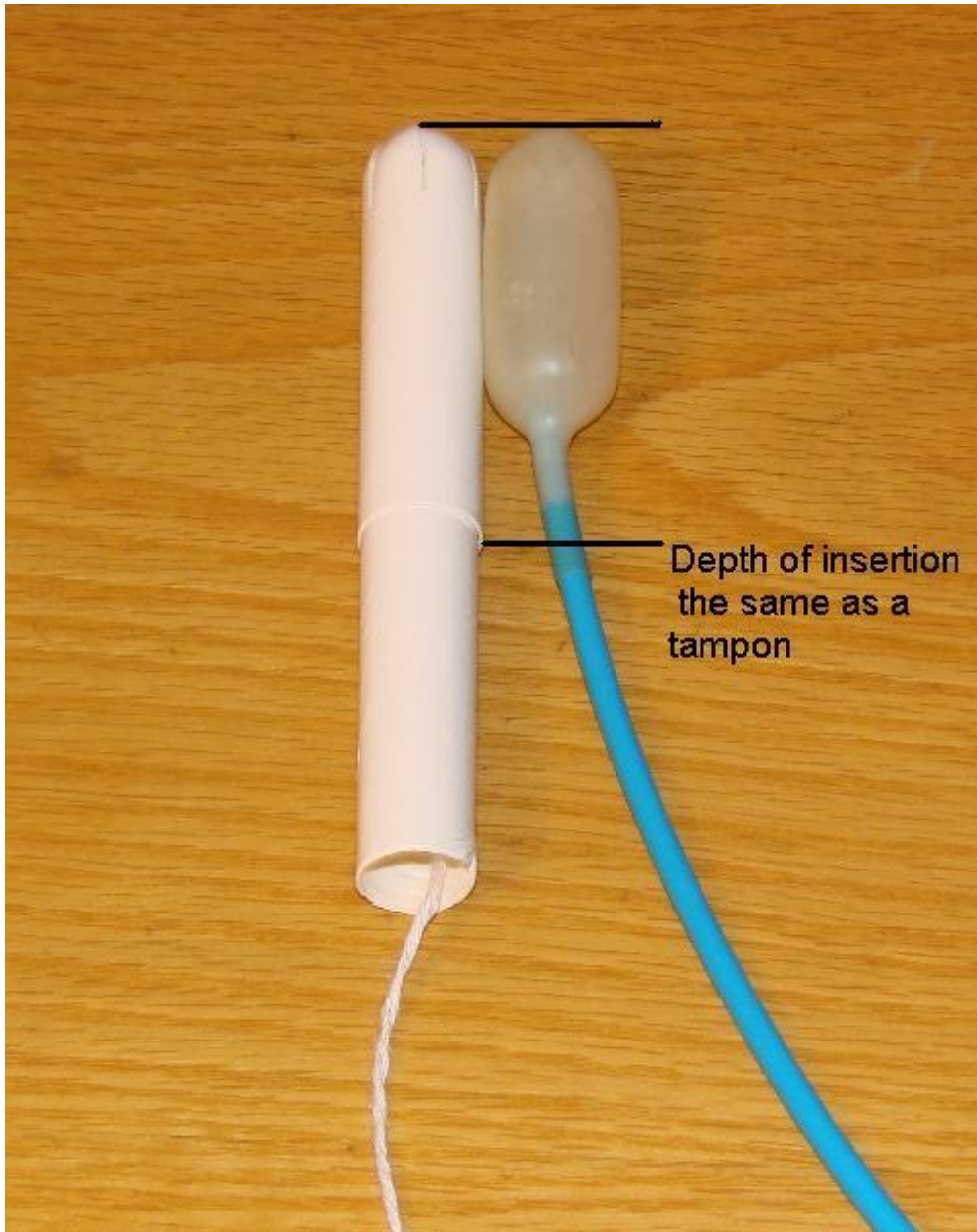
groups and therefore all the treatment strategies and explanations for the continence mechanism have been based on white populations.

The aim of this study is to see if there are differences in pelvic floor strength that might explain differences in incidence of incontinence noted in the literature. This would be able to contribute to the understanding of the continence mechanism and therefore enable us to give more effective treatment for incontinence specifically in the Black and Coloured community.

The study will be conducted at the University of Stellenbosch, University of the Western Cape and the University of Cape Town physiotherapy departments and also the University of the Western Cape Nursing department.

The aim would be to recruit 108 physiotherapy and nursing students who have not yet had children. There needs to be an equal amount of White, Black and Coloured students.

The device that would be used to measure pelvic floor strength is called the Peritron. It consists of a pressure filled balloon that is connected to the machine. The probe is about the length of a "Lillets" tampon and a little bit thicker.



The soft pressure filled balloon is inserted into the vagina. The depth of insertion of the balloon is the same depth a “Tampax” tampon would be inserted. When the pelvic floor muscles contracts it gives an increase of pressure on the balloon which is then measured by the machine. This pressure score would then be recorded on the computer.

The balloon catheters is single patient use, therefore each participant would get their own balloon catheter that would be disposed off after assessment. There is therefore no risk of infection.

The Peritron perineometer



Practical aspects of program:

- A time will be arranged with you to do the investigation.
- You will need to fill in a demographic questionnaire.
- An explanation of pelvic floor anatomy will be given.
- An explanation of the correct pelvic floor muscle contraction will be given.
- Every effort will be made to warrant privacy when examined.
- Only me (Ina van der Walt) and the research assistant (Karen Joubert) will be present with the test procedure.
- You will be asked to undress the bottom half of your body and to lie on a plinth and the bottom half of your body will be covered with a sheet.
- You will be asked to do a pelvic floor muscle contraction while the examiner watches the perineum to make sure that a correct pelvic floor contraction is present and that no accessory muscles are used.

- You will then yourself insert the balloon catheter of the Peritron will into the vagina.
- The researcher will then check if the balloon catheter is inserted the correct depth.
- You will be asked to do another pelvic floor muscle contraction in order for the researcher to see that there is an indrawing motion of the balloon catheter. This will also ensure the researcher that a correct pelvic floor muscle contraction is taking place.
- In very few cases the pelvic floor muscles might be too weak for the examiner to see a perineal lift with observation or an indrawing motion of the catheter with a pelvic floor contraction. Only then a valid pelvic floor muscle contraction will need to be verified with vaginal palpation. In such a case one finger will be inserted into the vagina (3cm deep) to feel if the participant is getting a valid contraction.
- With the balloon catheter in situ, you will be asked do 2 sets of 3 consecutive pelvic floor muscle contractions which will be recorded on the Peritron.
- You will take the probe out and you will get dressed.
- The whole procedure would take about 20 minutes to complete.

Why have you been invited to participate?

- Participants need to have the same socio economic and educational background.
- Because you haven't had children there wouldn't be any damage to your pelvic floor muscles.

What will your responsibilities be?

- You would need to comply with the instructions.
- You need to be able to get a valid pelvic floor muscle contraction.

Will you benefit from taking part in this research?

You will have the opportunity to learn the correct way to contract your pelvic floor muscles. You will also receive a brochure on pelvic floor muscle training program. You will therefore be able to get practical experience in pelvic floor testing. This will enable you to teach your patients the correct pelvic floor muscle contraction. You will be able to test objectively if your patients do the correct action. Normally this procedure is only taught in post-graduate courses; therefore you would be exposed to post-graduate study material. You will receive information on prevention and treatment programs for women with urinary incontinence.

By participating in this subject you will be contributing to increasing knowledge and comprehension on this subject.

Without you it would not be possible to get information to accomplish the study.

Are there in risks involved in your taking part in this research?

There are no risks involved in the participation of the study.

The balloon catheter is for single patient use. Each participant will get her own balloon catheter for the test procedure. The balloon catheter **will not be reused** and will be disposed of after the test procedure. Therefore there is no risk of infection.

Who will have access to your medical records?

The information collected will be treated as confidential and protected. Each participant will be allocated a number. All the data will be linked to the number and the identity of the participant will not be revealed. If the data collected is used in a publication or thesis, the identity of the participant will remain anonymous.

Only the researcher will have access to the information.

What will happen in the unlikely event of some form of injury occurring as a direct result of your taking part in this research study?

There is no chance of injury because of the test procedure.

If you should feel that you have any problems after the procedure, you would be referred to an appropriate qualified person to manage the problem.

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to take part in the study. There will be no costs involved for you, if you do take part.

Is there anything else that you should know or do?

- You can contact Mrs Ina van der Walt at tel: (021) 9480259, cell 0722165578 if you have any further queries or encounter any problems.
- You can contact the Committee for Human Research at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I agree to take part in a research study entitled: An investigation of pelvic floor muscle strength in nulliparous women of different race groups.

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) On (*date*)
2005.

.....

Signature of participant Signature of witness

Declaration by investigator

I (*name*) declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did not use a translator.

Signed at (*place*) on (*date*)

.....

Signature of investigator Signature of witness

Name:.....Email:.....

Contact telephone number:.....

Addendum D: Questionnaire

SECTION A: SCREENING

1. <u>Ethnic group:</u> Do you regard yourself as:	Black	Coloured	White
2. Are you a RSA citizen?	YES		NO
3. Have you had children?	YES		NO
4. Do you have diabetes mellitus:	YES		NO
5. Have you had any of the following operations? Back/Spinal surgery Colectomy Major gynaecological surgery e.g. hysterectomy	YES		NO
6. Are you menstruating at the moment?	YES		NO
7. Do you have a urinary tract infection?	YES		NO
8. Do you have a vaginal discharge/infection?	YES		NO
9. Do you do pelvic floor exercises more than twice a week or have participated in a pelvic floor muscle training program?	YES		NO
10. Do you suffer from low back pain with radiating	YES		NO

<p>pain, into your legs or buttock?</p>		
<p>11. Do you leak urine every time you cough, sneeze or jump?</p>	<p>YES</p>	<p>NO</p>
<p>12. Do you suffer from any of the following chronic respiratory conditions?</p> <p>Asthma</p> <p>Chronic Obstructive Lung Disease</p> <p>Chronic Bronchitis</p>	<p>YES</p>	<p>NO</p>
<p>13. Do you suffer from any neurological conditions e.g. multiple sclerosis?</p>	<p>YES</p>	<p>NO</p>
<p>14. Have you had any previous radiotherapy to the pelvis for cancer?</p>	<p>YES</p>	<p>NO</p>
<p>15. Are you pregnant?</p>	<p>YES</p>	<p>NO</p>
<p>16. Are you able to use a tampon with ease?</p>	<p>YES</p>	<p>NO</p>

Section B: Demographic Data

Name and Surname.....

Address.....

.....

In which town/s did you live while in Primary and High school?

Nursing student YES / NO **Physiotherapy student** YES / NO

Section C: Variables that might influence strength or has an association with vaginal resting tone:

1. Age (years).....

Height (cm)

Weight (kg)

BMI (Body mass index).....

2. If Black, to which ethnic group do you identify yourself with?	Xhosa	Zulu	Tswana	Sotho	Swazi	Other – specify:
3. Do you participate in any <u>physical activity</u>?				YES	NO	

3.1. What type of activity?	Gym classes	Spinning	Aerobics	Calenetics	
Pilates	Weight training	Circuit training	Aqua aerobics	Yoga	Hockey
Athletics	Netball	Kickboxing	Basketball	Running	Swimming
Other.....					
3.2 Frequency of	Daily	Every 2 nd day	2 x week	Less than 2 x week	
3.3 Average time spent per session:		MINUTES.....			
3.4 Intensity of exercise:			HIGH	LOW	
4. Describe your menstruation cycle:					
4.1. Is your menstruation absent? (Amenorrhoea)			YES	NO	
4.2. Do you have a <u>regular</u> menstruation cycle?			YES	NO	
4.3. Cycle	21 days	28 days	35 days		
4.4. How long do you menstruate?			Less than 7 day	7 and more days	
4.5. How much bleeding with menstruation?		Minimal	Moderate	Heavy	
4.6. Do you have painful menstruation?(Dysmenorrhoea)			YES	NO	
4.7. Have you been diagnosed with endometriosis?			YES	NO	

5. Have you ever tried to contract you pelvic muscles before?				YES	NO
6. Toilet use:			Western toilet	Squatting	
7. Do you use any of the following medication?					
Birth control pill	Depo Provera or Nur-Isterate injections	Anti - depressants	Thyroid	Non steroidal anti inflammatory drugs(NSAIDS)	Muscle relaxants
8. 1.Do you smoke?			YES	NO	
8.2. If yes, how many per day?			per day	
9.1. How often do you have a bowel motion?		3X a day	1-2X a day	Every second day	Every third day
9.2. Do you always need to strain when having a bowel motion?			YES	NO	
9.3. Do you have irritable bowel syndrome or a spastic colon?			YES	NO	
10. How many times a day do you urinate on average?			times	
11. How many times a night do you have to get up to urinate?			times	
12. Does it ever burn when you urinate?			YES	NO	
13. Do you get regular vaginal yeast infection (Candida)?			YES	NO	

14.1. Do you ever get pain around the vagina or anus?		YES	NO
14.2. How severe is the pain?	A little	Moderate	Severe
15. Do you get regular low back pain?		YES	NO

Addendum E: Project registration



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• u • kennis • erfgoed • your knowledge partner

28 September 2006

Mrs I van der Walt
 Discipline of Physiotherapy
 Dept of Interdisciplinary Health Sciences

Dear Mrs van der Walt

RESEARCH PROJECT: "AN INVESTIGATION OF PELVIC FLOOR STRENGTH IN WHITE AND BLACK NULLIPAROUS WOMEN "
PROJECT NUMBER : N06/03/058

At a meeting of the Committee for Human Research that was held on 5 April 2006 the above project was approved on condition that further information that was required, be submitted.

This information was supplied and the project was finally approved on 8 September 2006 **for a period of one year from this date**. This project is therefore now registered and you can proceed with the work. Please quote the above-mentioned project number in all further correspondence.

Please note that a progress report (obtainable on the website of our Division) should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary).

Patients participating in a research project in Tygerberg Hospital will not be treated free of charge as the Provincial Government of the Western Cape does not support research financially.

Due to heavy workload the nursing corps of the Tygerberg Hospital cannot offer comprehensive nursing care in research projects. It may therefore be expected of a research worker to arrange for private nursing care.

The following two issues are conveyed to you as proposals to consider:

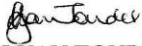
1. What happens if a white person or black person classifies himself or herself as either black or white? The central question of this study is on race differences.
2. Though one accepts that the participants will have a reasonable proficiency of English, it is presumptuous to assume that the Xhosa language does not have some of the aspects contained in the questionnaire. It is unclear if you are an expert of the Xhosa language.

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Fakulteit Gesondheidswetenskappe • Faculty of Health Sciences

Verbind tot Optimale Gesondheid • Committed to Optimal Health
 Afdeling Navorsingsontwikkeling en -steun • Research Development and Support Division
 Posbus/PO Box 19063 • Tygerberg 7505 • Suid-Afrika/South Africa
 Tel: +27 21 938 9677 • Faks/Fax: +27 21 931 3352
 E-pos/E-mail: rdsdinfo@sun.ac.za

Yours faithfully



CJ VAN TONDER
RESEARCH DEVELOPMENT AND SUPPORT (TYGERBERG)
Tel: +27 21 938 9207 / E-mail: cjvt@sun.ac.za

CJVT/pm

Addendum F: Permission granted for pilot study B

34 5th avenue
Boston Estate
Bellville
7530
4 May 2007

Dr. Thompson
Administration building
Tygerberg Hospital

Dear Dr. Thompson

RE: Request for permission to recruit participants for a pilot study at the family planning clinic.

I have approached Dr. Petrus Steyn and the Sister in Charge at the family planning clinic for permission to recruit patients at the family planning clinic for participation in a study evaluating pelvic floor strength. In principle they have given permission for the launching of the study. However they indicated that they also need clearance from you, hence the reason for this letter.

The study has been approved by the University of Stellenbosch ethics committee and will be completed in partial fulfillment of a MSc Physiotherapy at Stellenbosch University. The ethical clearance number is: N06/03/058

The purpose of this application is to get permission for the recruitment of participants at the family planning clinic for the pilot study and not to recruit participants for the main study.

Aims of the pilot study:

- To test demographic questionnaire
- For the researcher to familiarise herself with the test procedure
- To test for intra-tester reliability.
- To get feedback from participants to make the necessary changes to the questionnaire or test procedure.

Dr R R Thomson
(021) 938 5752
Sen Clin Exec

9/5/07

Maximum number of participants to be recruited at the family planning clinic:

10 participants

The participants in the pilot study will be subjected to the same procedure as outlined in the protocol.

Participation in the study is entirely voluntary

COMMENTS

- NOT for profit etc. Patient confidentiality fully protected. has gone via format ethics committee (is for her MSc. Physiotherapy). Has been approved by her Faculty Dept + mentor + ethics comm.
- will make use of own gloves, consumables etc.
- no extra visits or use of hospital resources / staff.
- She will fill in questionnaire herself.
- This is only pilot study. Rest will be done elsewhere.

approved ethics assessment will be replaced

Addendum G: Permission granted UWC physiotherapy

Private Bag X17, Bellville, 7535
South Africa
Tel: +27 (0) 21 959 2102/2111
Fax: +27 (0) 21 959 3126
Website: www.uwc.ac.za

OFFICE OF THE REGISTRAR

23 March 2007

Ina van der Walt
34 Fifth Avenue
Boston Estate
Bellville
7530

Dear Ms van der Walt

PERMISSION TO RECRUIT UNDERGRADUATE PHYSIOTHERAPY STUDENTS AT UWC

Thank you for complying with our requirements for obtaining permission to do research at the University of the Western Cape.

I am satisfied that you have obtained the necessary ethics clearance from the University of Stellenbosch and it therefore gives me great pleasure to grant you permission to proceed with your research.

Sincerely



Dr Ingrid Miller
REGISTRAR



UNIVERSITY of the
WESTERN CAPE

A place of quality, a place to grow, from hope to action through knowledge

Addendum H: Permission granted by UWC

OFFICE OF THE REGISTRAR

Private Bag X17, Bellville 7535
South Africa
Telegraph: UNIBELL
Telephone: +27 21 959-2102/2111
Fax: +27 21 959-3126
Website: www.uwc.ac.za

10 May 2007

Ina van der Walt
34 Fifth Avenue
Boston Estate
Bellville
7530

Dear Ms van der Walt

PERMISSION TO RECRUIT UNDERGRADUATE NURSING STUDENTS AT UWC

Thank you for complying with our requirements for obtaining permission to do research at the University of the Western Cape.

It gives me pleasure to grant you permission to proceed with your research and to recruit undergraduate nursing students at UWC.

With best wishes



**DR I MILLER
REGISTRAR**



**UNIVERSITY of the
WESTERN CAPE**

A place of quality, a place to grow, from hope to action through knowledge

Addendum I: Permission granted by UCT

Dear Ina,

Good afternoon.

My apologies in getting back to you late. I just returned from Eastern Cape this afternoon.

I had discussed your request with Soraya positively, and have requested her to get back to you. I am sure she will get back to you soonest.

Regards

Dele Amosun

>>> "Ina van der Walt" <inavdwalt@gmail.com> 3/8/2007 11:06 pm >>>

Dear Prof Amosun

I would like to make an appointment to come and see you to explain the outline of my MSc project and the involvement of the UCT physiotherapy students? From past experience, I have found it more suitable if I explain the study in person due to the sensitive nature of the project.

I have presented my project to Soraya Maart and she seemed to be positive about the launching of the project, but indicated that I need to get your approval for the implementation of the project at UCT.

My research protocol has been approved by the Stellenbosch University ethics committee and furthermore has been received positively at the other Universities that I have contacted. In a pilot study amongst 3rd year physiotherapy students at the University of Stellenbosch, 60% of the class indicated that they would like to take part in the study. After meeting with UWC physiotherapy department explaining my project, the department had given permission to launch the project amongst their students. In addition, UWC nursing has also given preliminary permission for the launching of the project.

I would appreciate an indication for a suitable time/date to arrange a meeting with you as soon as possible.

Kind regards Ina vd Walt

Addendum J: Pilot study B

Two aspects of the test procedure needed to be evaluated before testing could commence including; the sequence of events when performing the test procedure in order to streamline the test procedure and data capturing and storage.

Aim:

The aims of this pilot study included:

- The process of data capturing and storing of data.
- The time required to finish the test procedure
- For the researcher to familiarise herself with the test procedure:
- To determine the sequence of events when performing the test procedure
- To familiarize with the use of the equipment
- To streamline the test procedure
- Positioning of the participant during the test
- To determine how many sets and repetitions to perform
- To assess if an assistant was necessary and in what capacity
- To determine how a contraction needs to be performed to exclude muscle function that would give an invalid reading
- To determine how to check for the depth of the sensor
- To determine how to check for correct breathing patterns

Procedure:

The same eight women, who completed the questionnaire in pilot study E, volunteered to undergo the pelvic floor muscle testing procedure as a pilot study on the test procedure.

Outcome:

The following observations and modifications were made to the test procedure:

- A demonstration was given to each participant individually or in a group on what the sequence of contractions look like on the computer screen before they inserted the probe vaginally to do the test. This helped the student to understand what was expected of her.
- It was noted that KY gel used on the probe made it slip out of the vagina while performing the test. The probe was easily inserted without the use of KY gel.
- An assistant was helpful in recruiting the participants, helping with the completion of questionnaires and weighing the participants. The participants did not like having anyone else present during the test procedure and therefore an assistant could not be used during the test procedure.
- Participants did two sets of three MVC of the PFM. Each contraction was maintained for as long as possible, up to a maximum of 10 seconds. The reason for assessing two sets of contractions was to test endurance of the PFM and to see if baseline measures changed after one set of contractions.
- While conducting the pilot study, an indication that women who had urogenital tract, bowel and menstrual related complaints seemed to have higher baseline pressures, was noted. Recent studies (Prendergast and Weiss 2003, Slocumb 1984, Weiss 2001, Markwell 2001, Oyama et al 2004) started indicating that conditions such as menstrual pain, irritable bowel syndrome, burning urination and urinary frequency, and perineal pain could be associated with high toned pelvic floor muscles. Therefore

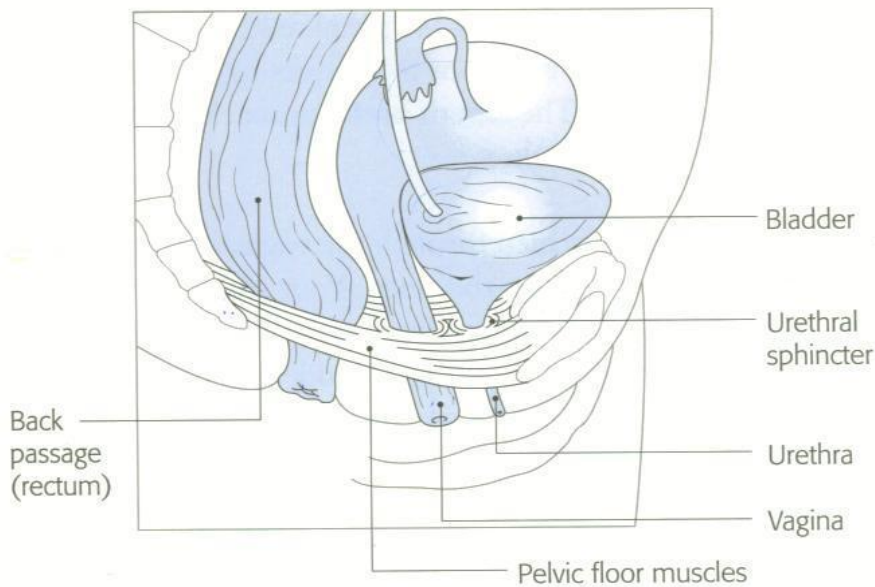
recordings of the baseline pressures were also made and questions on pelvic pain syndrome were added.

- It took 20 minutes for the test procedure with two sets of contractions.
- If the data was not saved in a specific folder after each measurement, it was replaced by the next participant's data and could not be retrieved again. Therefore a number had to be assigned to each participant and the data needed to be saved immediately in the participant's number-related folder.
- Three sets of data would be saved i.e.: peak, resting and contraction average.

Addendum K: Pelvic floor exercise handout

Your pelvic floor

The pelvic floor is a large sling, or hammock, of muscles stretching across the floor of the pelvis. It attaches to the pubic bone at the front, and extends backwards to attach to the base of the spine, the coccyx. It forms your 'undercarriage'.



The opening to the bladder, birth canal (vagina) and bowels all pass through the pelvic floor. Over time, the muscle stretches and weakens as a result of pregnancy, childbirth, lifting and the general effect of gravity! This daily pressure on the pelvic floor is responsible for problems such as prolapse and incontinence.

Prolapse

A prolapse is when the pelvic floor has stretched so that it no longer provides adequate support for the pelvic and abdominal organs, and they move downwards into an abnormal position. This may result in an uncomfortable feeling of pressure or 'something down below', but sometimes it may only feel like backache or heaviness at the tops of thighs at the end of the day.

Incontinence

Stress incontinence

When the pelvic floor muscles are weak or less responsive than normal any increase in abdominal pressure may cause a small amount of urine to leak. This can be due to coughing, sneezing laughing, lifting and jumping. It cannot be cured by limiting the number of drinks or going to the toilet more often, as the muscle remains weak.

Urgency and Urge incontinence

Normally, the bladder should relax and stretch to allow it to fill with urine, and only squeeze when it gets to the toilet to allow it to empty. When the bladder squeezes at the wrong time it can give the overwhelming sensation of needing to pass urine, and needing to do it NOW! Sometimes, the bladder squeezes so hard that it actually pushes some urine out, often en route to the toilet.

The natural reaction is to restrict drinks and increase the number of visits to the toilet; this actually makes the problem worse as it reduces the amount of fluid that the bladder can hold and also makes the urine more concentrated which makes the bladder more irritable.

What Does the Pelvic Floor Do?

- It supports the pelvic and abdominal organs, especially when standing or on exertion.
- It supports the bladder to prevent leaking. It works harder when the pressure on it increases e.g. with coughing or lifting.
- It helps with the control of the bowels, both to 'hold on' and to hold wind.
- It is very important for healthy sexual function, and can increase sexual awareness for both partners during intercourse.

What went wrong?

The pelvic floor muscles are affected by hormonal changes and may be damaged as a result of childbirth; this may not become apparent until the menopause. Other damaging factors include pelvic surgery, persistent straining due to constipation, a

chronic cough, repetitive lifting of heavy objects, high impact exercise and being overweight.

Pelvic floor muscles respond in a similar manner to all other muscles: if they are damaged they need to be exercised to improve their function and strength. Unfortunately, because we can't see them we often forget *how* to use them properly and this exacerbates the problem.

How to fix the problem

It is essential to maintain strength in the muscles of the pelvic floor to prevent problems occurring, or to increase the strength once they have.

Often, all that is needed is a specific exercise programme that focuses the effort on the pelvic floor muscles and encourages them to work properly again. In some circumstances, bad life habits, e.g. lifting technique, may also need to be addressed. If the bladder is 'misbehaving' it will need training to calm it down.

Exercise program

Tighten the muscle around the back passage, vagina and front passage and lift up inside - as if trying to stop passing wind and urine at the same time. The feeling should be of lifting up and inwards. It is very difficult not to use other muscles as well; try not to clench the buttocks, squeeze the knees together or pull the abdominal muscles in. It is, of course, essential that you are able to BREATHE throughout all this; try not to hold the breath but to tighten the muscles *at the end* of a breath out.

If you're doing it correctly no one should be able to see any movement just by looking at you!

Everybody differs in how the length of time for which they can squeeze, and in how many squeezes they can do before the muscle gets too tired to be effective. To determine where you should start, tighten the pelvic floor and time how long you can hold it before it starts to let go.

Release the contraction and have a 5 second rest.

Repeat the tighten-hold-release exercise as many times as you can (maximum 10 times).

Your starting block is:

 seconds repetitions

Practice your starting block times a day.

As your muscle gets stronger and fitter, your starting block will change. Progress slowly until you can do 10 repetitions and hold each squeeze for 10 seconds.

It is also important to be able to work these muscles very quickly, so that they can jump in and protect you when you cough or sneeze. Try to tighten the muscles and let go immediately; no hold.

Practice fast contractions times a day.

Bladder Training

The bladder can learn bad habits, often over a period of years. This means that the bladder starts to dictate when it should be emptied rather than allowing you to decide when it's convenient for you.

To regain control of your bladder it is necessary to 'train' it:

- Do not empty the bladder 'just in case'. If you need to go more often than every 2 hours try to wait a little longer, even a few minutes will help. This will help to stretch the bladder a little and encourage it to hold better volumes.
- When the urge to go to the toilet comes over you try to keep calm. Sit down, if possible, and try to hold a pelvic floor contraction (not as hard as you can, but hard enough to prevent leaking) for about 20 seconds, or as long as you are able. The desperate urge should pass. This either allows you to defer going for another minute or 2, or to get to the toilet without

leaking on the way. Sometimes the urge passes completely and it may be a half hour before you get it again

- Do not restrict your fluid intake; the less fluid, the stronger the urine, the more irritable the bladder becomes. Try to drink *at least* one litre a day. Water is by far the best!
- Some bladders are sensitive to caffeine. Caffeine is found in coffee, tea, cola and, horror of horrors – chocolate!!! Reducing your intake may prevent you going to the toilet so often. Bladders are also sensitive to alcohol.
- If you wake at night to empty your bladder, don't drink within two hours of going to bed.

Persevere – bladder training usually takes at least 6 weeks before it has a noticeable effect.

Some useful tips

- Avoid constipation. Excessive straining force to empty the bowels stretches and weakens the pelvic floor. Check your diet (sufficient fluid and fibre are both necessary), or consult your physiotherapist or doctor.
- Avoid heavy lifting or standing for long periods of time as these can stretch and weaken the muscles. If you do need to lift, tighten the pelvic floor before starting and try to maintain the contraction for the duration of the lift.
- Avoid high impact or strenuous activity – your pelvic floor supports your internal organs during activity; if it is weak and unable to provide adequate support these organs may start to descend. Change to low impact exercise like cycling, swimming or walking until the pelvic floor is stronger.

- Avoid straight leg sit-ups and double leg lifts as this increase the downward pressure on the pelvic floor.
- Avoid being overweight. Achieving and maintaining your correct weight reduces the strain placed on the pelvic floor, and can improve your symptoms considerably.
- Ensure that you empty the bladder fully each time you pass urine. This will help to prevent infection. It may help if you lean forwards slightly, and remember not to 'hover' but to sit on the seat properly.
- Tighten the pelvic floor each time you cough and sneeze to give extra protection.

Addendum L: Pilot study C

Aim:

The Peritron™ 9300 perineometer (Cardio-Design, Australia) was purchased for the study with the standard vaginal sensor that is issued with the perineometer. After the students saw the Peritron™ probe, their feedback was; that it was too big and the shape of the probe was not acceptable to the students for usage in this study (See Figure 8.1). It was then decided to use the smaller vaginal probe from Camtech (Camtech AS, Sandvika, Norway) with the Peritron™ perineometer. The objective of this pilot study was to determine if the readings by the Peritron™ 9300 perineometer used in conjunction with the Camtech vaginal probe were accurate.

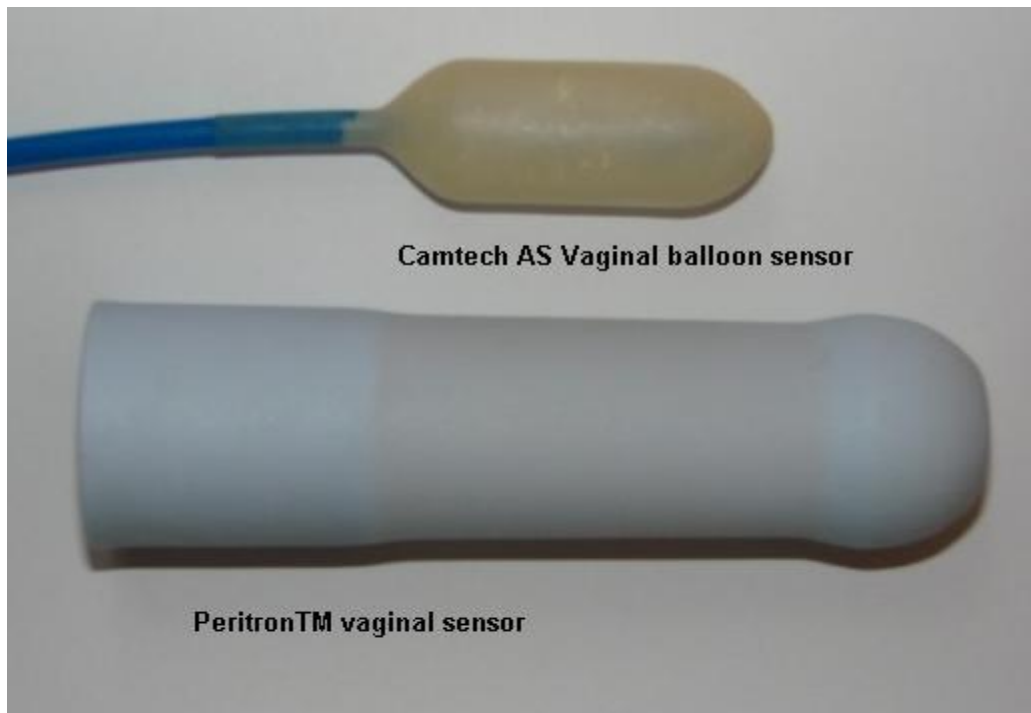


Figure 0-1: Peritron™ vaginal probe and vaginal balloon catheter

Procedure:

In March 2007 this pilot study was conducted to assess the accuracy of the Peritron perineometer with the Camtech vaginal probe. The Camtech vaginal probe was mounted on a 100cm ruler and connected to the Peritron perineometer. The middle of the probe was at the 0 cm marking. The ruler with the probe was then immersed to 5 cm under the surface of the water. The reading on the perineometer was then compared to see if it corresponded to 5 cmH₂O. The probe was then immersed by 5

cm increments up to 80cm, comparing the reading on the perineometer each time to see if it corresponded with the difference in water pressure.

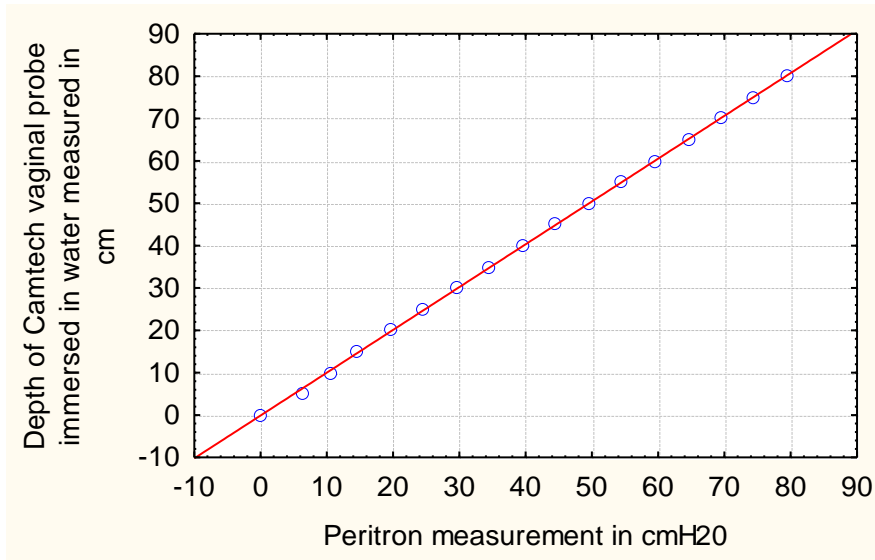


Figure 0-2: Depth of vaginal probe versus Peritron™ 9300 measurement

Outcome:

The readings on the Peritron™ perineometer used in conjunction with the Camtech AS vaginal probe were found to be accurate ($r = 0.99$; $p < 0.01$) (Fig 8.1).

Addendum M: Pilot study D**Aim:**

During the first week of May 2007 this pilot study was performed. The aim of this study was to determine the intra-tester reproducibility of the investigator.

Procedure:

Four continent parous women with a mean age of 30 (range 28-36) were tested by the same researcher on two consecutive days. The median value of three MVC of the PFM was determined for each woman (range 6.3-35 cmH₂O).

Outcome:

The measurements for each women on the two consecutive days were comparable (ICC agreement = 0.997 (0.954; 1.00) and ICC consistency = 0.996 (0.938; 1.00) and SEM = 0.882).

Addendum N: Pilot study E

During 23-28 May 2007, a pilot study was conducted at the Tygerberg Hospital Family Planning Clinic.

Aim:

The aims of this pilot study were to test the following aspects of the study:

- The demographic questionnaire
- The time needed to complete the questionnaire
- To test if the participants understood the questions in the questionnaire
- To test demographic questionnaire
- To ask for feedback from participants to see if adjustments needed to be made to improve the clarity of the questionnaire

Procedure:

Permission was granted from the Tygerberg Hospital administration to conduct the study (Addendum F). Eight women, who were recruited at the family planning clinic, gave informed consent and participated in the pilot study. This sample consisted of four coloured women, three black Xhosa-speaking women and one white woman. Six were nulliparous and two were parous. The mean age of the sample was 22 years (range 21-26 years) and had a mean BMI of 21 kg/m² (range 18-25 kg/m²). They completed a questionnaire to assess inclusion and exclusion criteria and the demographic questionnaire. Following this they were interviewed to see if they understood the questions and if they had any suggestions on clarification of some of the questions. Then they participated in the test procedure.

The demographic questionnaire was also discussed with an uro-gynaecologist for an expert opinion on gynaecological terminology and classification.

Outcome:

The following observations and modifications were made to the screening and demographic questionnaire:

Screening part of questionnaire:

- The participants did not know what neurological conditions meant and an example of a neurological condition was added to the question i.e. multiple sclerosis.
- The question about radiology to the pelvis was also too vague and participants thought that radiology meant X-rays. Therefore it was specified that it must be radiotherapy for cancer treatment.

Demographic questionnaire

- Questions on stress incontinence, bowel motion and respiratory conditions that were in the screening part of the questionnaire were treated as variables that could influence strength and not as exclusion criteria.
- Questions relating to the same subjects were grouped together under headings.
- A question was added to discover in which town the student attended high school to establish whether the student was from a rural or urban background.
- Only medications that would have a specific effect on pelvic floor muscle function have been included in the questionnaire.
- Questions on symptoms that could be associated with high-toned pelvic floor muscles were added to the questionnaire i.e. menstrual pain, irritable bowel syndrome, dysuria and urinary frequency, and perineal pain (Weiss, 2001; Goldberg and Sand, 2002; Prendergast and Weiss, 2003; Wise and Anderson, 2006; Anderson et al, 2005; Steege and Zolnoun, 2009; Fall et al, 2009; Butrick et al, 2009 and Morin and Bergeron, 2009). This was to assess if there could be an association between these conditions and the baseline vaginal pressure measurements.
- It took 10 minutes to complete the questionnaire.

Addendum O: Terminology used in questionnaire

The following are the definitions and terminology that were used in the questionnaire:

- The length in cm and the weight in kg were measured on the day of testing and used in the calculation of BMI.
- To define physical activity, participants had to respond to questions on: if they did participate in physical activity or not, the type of activity, the frequency of participation (daily, every 2nd day, 2X a week, less than 2X a week), the average time spent per session (minutes) and the intensity of participation (high or low).
- Menstrual cycle was defined by: if menstruation was present or absent, if they had a regular cycle or not, how long their menstrual cycle is (21, 28, 32 day cycle), how long they menstruate (<7 days or >7 days), menstrual flow (minimal, moderate, and heavy), the presence of dysmenorrhoea and diagnosis of endometriosis.
- Participants could indicate if they used one of the following medications which might have an influence on PFM function: contraceptive pill, progestogen injections including Depo Provera® and Nur-Isterate®, anti-depressants, thyroid medication, non-steroidal anti-inflammatory drugs (NSAIDS) and muscle relaxants.
- Participant's who smoked, had to give an indication of how many cigarettes they smoked a day.
- Bowel habits were defined by indicating how often they had a bowel motion (3X a day, 1-2X a day every second day, every third day), if they needed to strain every time they had a bowel motion and if they suffered from IBS.
- To obtain an indication of voiding frequency, participants had to indicate how many times a day they urinated on average and how many times a night they had to get up to urinate.
- Dysuria was qualified by indicating if they had burning urination, and perineal pain was defined by indicating if they experience pain around the vagina or anus and how intensely they experienced the pain.
- Participants needed to indicate if they experienced regular low back pain.

Addendum P: Epidemiology of urinary incontinence in the Western Cape

Following is a summary of the results of the unpublished study by van der Walt and Rienhardt.

Aim: This cross sectional study was conducted in 2001-2002 to determine the prevalence of urinary incontinence in women of different ethnic groups.

Method: An interview-lead modified version of the Leicester urinary symptom questionnaire was completed by black, white and coloured women at several primary health care clinics. **Results:** A total of 1200 women were interviewed (n=400 white, n=400 black and n=400 coloured). The following table gives the percentages of the women with different kinds of urinary symptoms and indication of bother.

Urinary symptoms	White %	Black %	Coloured %
Urinary incontinence	13.2	17.2	13.7
Stress urinary incontinence	17.4	19	19.5
Urge urinary incontinence	19.8	28.7	29
Day time urinary frequency – 9X/day and more	15.5	12	12
Night time urinary frequency – 2X a night	12.6	27.6	6.2
Night time urinary frequency – 2X a night and more	39.8	57	26.4
Urgency	15.3	23.4	25
Does urinary incontinence bother you a lot?	10.6	13.9	12.6
Would you like help with the incontinence?	15	24.8	20.3
Spoken to someone about your incontinence?	19.5	17	23
Would be mostly dissatisfied/terrible to spend the rest of life with this condition.	15	33.6	25.6