PELVIC FLOOR REHABILITATION IN WOMEN UNDERGOING PELVIC FLOOR RECONSTRUCTIVE SURGERY

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DEDICATION

This thesis is dedicated to my late father, Prof E.V. Brandt, who encouraged me to have Faith and to forever seek true Wisdom, Knowledge and Intelligence…

And to Prof H.S. Cronje, who taught me Knowledge and Wisdom in the field of Uro-Gynaecology…

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- The Uro-Gynaecology Clinic, Universitas Hospital, and its personnel for their help with administrative tasks.
- The special people in my life, for their support and motivation.

DECLARATION

I, Corlia Brandt, certify that the script hereby submitted by me for the Ph.D. (Physiotherapy) degree at the University of the Free State is my independent effort and had not previously been submitted for a degree at another university/faculty. I furthermore waive copyright of the script in favour of the University of the Free State.

C. Brandt

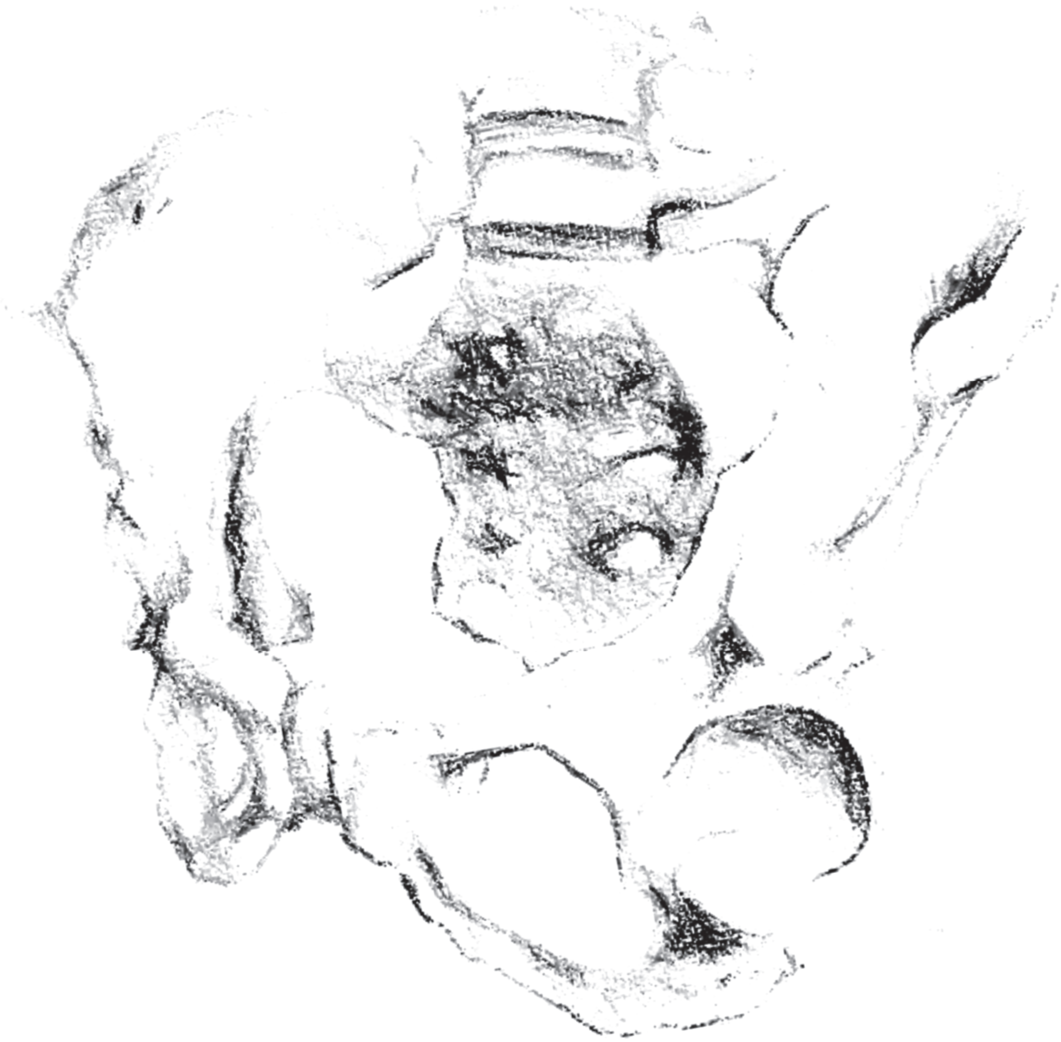
July 2016

I, Prof. H.S. Cronjé, approve submission of this thesis as fulfilment for the Ph.D. (Physiotherapy) degree at the University of the Free State. I further declare that this thesis has not been submitted as a whole or partially for examination before.

Prof. H.S. Cronjé (Promoter)

July 2016

"The scientific study of pelvic floor dysfunction is in its infancy. … major discoveries remain to be made. The high prevalence of prolapse, frequent recurrence after surgery, and the great impact of vaginal birth, all indicate the need for further research into the cause and prevention of this distressing condition" (DeLancey *et al.* 2007:301).



ABSTRACT

INTRODUCTION: Pelvic organ prolapse (POP) has a mean prevalence of 455 to 681 per 1000 women (aged 50 to 60 years). Approximately 11% may need surgery, of which 30% may need follow-up surgery. The effect that comprehensive muscle training can have on prevention and treatment of POP in conjunction with surgery, is still under-investigated and controversial.

AIMS: To describe the symptoms, signs, quality of life (QOL) and muscle function in women scheduled for pelvic floor reconstructive surgery; and to determine/compare the outcomes of a pelvic floor muscle training (PFMT) programme, and a core training programme in this population.

METHODOLOGY: Eighty one women scheduled for PF reconstructive surgery were randomly assigned to three groups in this randomised, controlled, double blind trial. Group 1 received a PFMT programme, group 2 a core stability programme, while group 3 was the control group. Participants received intervention for six months from pre- to post-operative. The P-QOL, SF-36, two-dimensional ultrasound, POP-Q staging, the PERFECT scale, EMG, Sahrmann scale and PBU was used to measure QOL, POP, PFM and abdominal muscle function respectively. Additional outcome measures included exercise compliance and the Visual Faces Scale for pain assessment. Descriptive statistics and 95% CI`s were used to determine statistical significance. Spearman, Pearson CC`s, and effect sizes were used to correlate muscle variables at baseline.

RESULTS: Women (mean age 59 years) with predominantly stage III POP (n=100) showed affected prolapse impact (66.7%), social (median 33.3%), emotional (median 44.4%0) and severity measures (median 25%) according to the P-QOL at baseline. Women were physically inactive (80-85%) and showed a tendency towards hypertension (47%), depression (12%), and hypothyroidism (18%). Only 15% had previously been introduced to PFM exercises, and 7% to core training. All outcomes for the PFM and abdominal muscle function were not within normal reported ranges pre-operatively. Statistical significant correlations were found between different components of PFM function, and between PFM and abdominal muscle function ($p<0.05$) at baseline. PFMT yielded the most significant changes regarding PFM function during the first three months (endurance, thickness of perineal body, length of levator hiatus), while only group 2 showed significant changes in abdominal muscle function (Sahrmann and PBU levels, 95% CIs [1;3] and [1;9]) in addition to the latter up to six months. Both intervention groups had some statistically significant muscle changes when compared to the control group. Only group 2 yielded a statistical significant improvement in the total P-QOL score (95% CI [1.5;28.4]).

DISCUSSION/CONCLUSION: It seems that both PFMT and core muscle training are important to address different, but specific biomechanics and muscle function for the prevention and treatment of POP. Co-morbidities, symptoms and signs, and the effect they may have on motor control and QOL, motivates for a comprehensive, lifestyle orientated, and biopsychosocial rehabilitation model for patients scheduled for pelvic floor reconstructive surgery.

NOMENCLATURE/ CONCEPT CLARIFICATION

Andragogy: "...the art or science of helping adults learn." Four assumptions underlie andragogy, namely the self-concept of the learner, the prior experiences of the learning, readiness to learn and orientation to learning (Knowles *et al*. 2005:68).

Biomechanics: "The application of mechanical laws to living structures, especially to the musculoskeletal system and locomotion; biomechanics addresses mechanical laws governing structure, function, and position of the human body" (McGraw Hill Concise Dictionary of Modern Medicine 2002:online).

Constructivism: "… is an approach to learning whereby learners actively make sense of their experiences based on their own values, beliefs, knowledge, skills, and prior learning" (Plack & Driscoll 2011:200).

Core: can be represented as a double walled (muscular) cylinder consisting of the lower back and abdomen and the upper back and chest. The inner wall consists of the deep local muscle system and the outer wall of the outer global muscle system (Comerford, Mottram & Gibbons 2005:3.11).

Cystocele: "Anterior vaginal wall prolapse. Observation of descent of the anterior vaginal wall. Most commonly this would be due to bladder prolapse (cystocele, either central, paravaginal, or a combination). Higher stage anterior vaginal wall prolapse will generally involve uterine or vaginal vault (if uterus is absent) descent. Occasionally, there might be anterior enterocele (hernia of peritoneum and possibly abdominal contents) formation after prior reconstructive surgery" (Haylen *et al*. 2010:8).

Global stabiliser: "The functional stability role is to generate torque and provide eccentric control of inner and outer range of joint motion. They need to be able to concentrically shorten into the full physiological inner range position, isometrically hold position, and eccentrically control or decelerate functional load against gravity. They should contribute significantly to rotation control in all functional movements" (Comerford & Mottram 2001:4).

Global mobiliser: "Muscles which primarily have a mobilizing role are required to have adequate length to allow full physiological and accessory (translational) range of joint movement without causing compensatory overstrain elsewhere in the movement system. Their functional stability role is to augment stability under high load or strain, leverage disadvantage, lifting, pushing, pulling or ballistic shock absorption. These muscles are particularly efficient in the sagittal plane, but even though they can generate high forces they do not contribute significantly to rotation control and they cannot provide segmental control of physiological and translational motion." Referring to the pelvic floor muscles, it would implicate fast, strong, and short contractions of the muscle (Comerford & Mottram 2001:4).

Local stabiliser: "The functional stability role is to maintain low force continuous activity in all positions of joint range and in all directions of joint motion. This activity increases local muscle stiffness at a segmental level to control excessive physiological and translational motion, especially in the neutral joint position where passive support from the ligaments and capsule is minimal. Their activity often increases in an anticipatory action prior to load or movement, thus providing joint protection and support" (Comerford & Mottram 2001:4).

Motor control stability: describes low threshold stability concepts and is defined as central nervous system modulation of efficient integration and low threshold recruitment of local and global muscles systems (Comerford *et al.* 2005:4.3).

Participant: Refers to the subject/patient participating in the study.

Pelvic diaphragm: consists of the levator ani and coccygeus muscles and the fascia covering the superior and inferior aspects of these muscles (Janda, Van der Helm & De Blok 2003:749; Moore & Dalley 1999:341).

Pelvic floor: the pelvic floor is formed by the pelvic diaphragm (Moore & Dalley 1999:341).

Pelvic organ prolapse: "The descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix), or the apex of the vagina (vaginal vault or cuff scar after hysterectomy). The presence of any such sign should be correlated with relevant POP symptoms" (Haylen *et al.* 2010:8).

Perineum: refers to an external surface area and a perineal compartment which lies inferior to the pelvic outlet, and is separated from the pelvic cavity by the pelvic diaphragm (Moore & Dalley 1999:389).

Rectocele: "Posterior vaginal wall prolapse. Observation of descent of the posterior vaginal wall. Most commonly, this would be due to rectal protrusion into the vagina (rectocele). Higher stage posterior vaginal wall prolapse after prior hysterectomy will generally involve some vaginal vault (cuff scar) descent and possible enterocele formation. Enterocele formation can also occur in the presence of an intact uterus" (Haylen *et al.* 2010:8).

Stages of pelvic organ prolapse (POP):

> **Stage 0** = No POP is demonstrated.
>
> **Stage I** = The criteria for stage 0 are not met, but the most distal portion of the prolapse is more than one centimetre above the hymen.
>
> **Stage II** = The most distal portion of the prolapse is 1cm or less proximal to or distal to the plane of the hymen.

Stage III = The most distal portion of the prolapse is more than one centimetre below the plane of the hymen but protrudes no further than 2cm less than the total vaginal length in centimetres.

Stage IV = Complete eversion of the total length of the lower genital tract is demonstrated. The distal portion of the prolapse protrudes to at least 2cm of the total vaginal length.

(Bump *et al.* 1996:13)

Uterine/cervical prolapse: “Observation of descent of the uterus or uterine cervix” (Haylen *et al.* 2010:8).

Vaginal vault (cuff scar) prolapse: “Observation of descent of the vaginal vault” (Haylen *et al.* 2010:8).

LIST OF ABBREVIATIONS

ADL: activities of daily living

AI: anal incontinence

CC: correlation coefficient

CI: confidence interval

CNS: central nervous system

EAS: external anal sphincter

EMG: electromyography

IAP: intra-abdominal pressure

ICC: intra class correlation

ICF: International Classification of Functioning, Disability and Health

IO: internal obliques

LH: levator hiatus

MVC: maximum voluntary contraction

PBU: Pressure Biofeedback Unit

PCSS: perineo-colpo-sacro-suspension

PERFECT: power, endurance, repetitions, fast contractions, every contraction timed

PFD: pelvic floor (muscle) dysfunction

PFM: pelvic floor muscle(s)

PFMT:pelvic floor muscle training

POP: pelvic organ prolapse

POP-Q: Pelvic Organ Prolapse Quantification System

PR: puborectalis

RUTI: recurrent urinary tract infections

SD: standard deviation

SIJ: sacro-iliac joint

SSF: sacrospinous fixation

TrA: transversus abdominus

UI: urinary incontinence

US: ultrasound

UsR: uterosacral resilience

UUI: urge urinary incontinence

VAS: Visual Analogue Scale

VFS: Visual Faces Scale

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CHAPTER 1
INTRODUCTION AND BACKGROUND

1.1 INTRODUCTION

Symptomatic pelvic organ prolapse (POP) has a mean prevalence of 455 to 681 per 1000 women between the ages of 50 and 60 years. The disability adjusted life years lost per one women due to symptomatic POP has recently been calculated at 14.5 and 10.3 years in women of 50 and 60 years of age (Svihrova, Svihra, Luptak, Swift, & Digesu 2014:24). In addition to this, it has been reported that 50% of parous women may lose support of their pelvic floor resulting in POP. These statistics, however, were already published in 1983 by Beck (as cited by Olsen, Smith, Bergstrom, Colling & Clark 1997:501). In 1997, Olsen *et al*. stated that recent statistics on true incidence were still unknown (1997:501). In 2011, Cronje reported that POP occurs in between 46 and 73% of women in South Africa (2011:online).

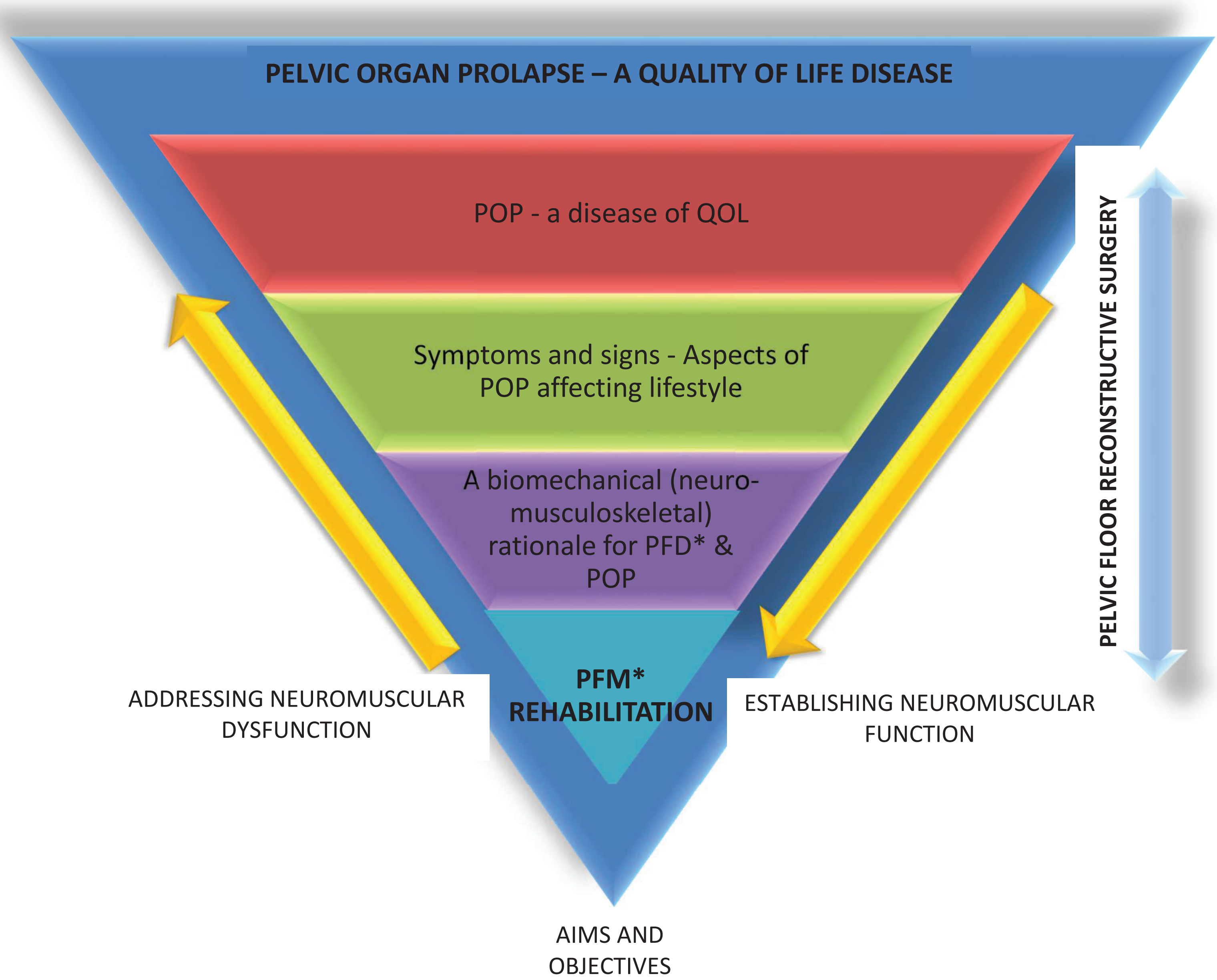
In the general population, it is estimated that 11% of women suffering from POP or urinary incontinence will need surgery, with 30% of these patients needing follow-up surgery within two years (Henn, Van Rensburg & Cronje 2009:229; Olsen *et al.* 1997:501). These results correlate with findings in other populations worldwide as Digesu *et al.* (2010:1013) reported that vaginal wall prolapse may recur in up to 30% of women following repair surgery.

The issue of surgical management, sufficient follow-up, and prevention of recurrence is complicated in a low resource/primary health care setting in a developing country. Eleje, Udegbunam, Ofojebe and Adichie (2015:798) reported that only 33.7% of patients who needed surgery in a low resource setting, received surgery, while the remaining 66.3% of patients scheduled for surgery, were already lost to follow-up prior to surgery. These authors (*ibid*.) reported a 13.6% recurrence rate, with an additional 29.9% of treated patients lost to follow-up.

Bo, Berghmans, Morkved and Van Kampen (2007:87-88) reported an even higher recurrence rate of 58% in women who had pelvic floor reconstructive surgery in a developed country with a resource supported health care system. It is speculated that one of the contributing factors to the success rate post-surgery may be the integrity of the innervation of the pelvic floor muscles (PFM) and the muscle strength, amongst other co-morbidities and complications such as older age, postmenopausal status, parity, and a high body mass index (BMI) (Jarvis, Hallam, Lujic, Abbott & Vancaillie 2005:300). Adverse changes in the levator ani muscle function also seem to be associated with early presentation and recurrence of prolapse after surgery (Bo *et al.* 2007:87-88). Despite the evidence on recurrence rates and the importance of the PFM in possible prevention of it, very little evidence is available on physiotherapy as an adjunct therapy to surgery, and the effect it may have on POP pre- and post-operatively.

Recommendations regarding the role of pelvic floor muscle training (PFMT) as an adjunct to pelvic floor reconstructive surgery have been based on clinical experience only. PFMT has been hypothesised to be of great importance since accurate rehabilitation of the PFM may provide additional support for the pelvic organs that cannot necessarily be improved with surgery. Studies investigating this matter are only beginning to emerge (Bo *et al.* 2007:243).

Within this emerging research environment, Chapter 1 introduces the background, rationale and conceptual framework for this research study (Figure 1).



*PFD = pelvic floor dysfunction
*PFM = pelvic floor muscles

Figure 1. Background, rationale, and conceptual framework of the research study.

1.2 PELVIC ORGAN PROLAPSE - A DISEASE OF QUALITY OF LIFE

POP is a common and debilitating condition seldom brought to the attention of doctors by patients. Patients are reluctant to talk about these problems and many have these symptoms for years, adapting their lifestyle and physical activities to the symptoms they experience (Vimplis & Hooper 2005:387; Mouritsen & Larsen 2003:122). However, increasing evidence exists that women with POP seek treatment primarily to improve their quality of life (QOL) (Srikrishna, Robinson, Cardozo & Gonzalez 2008:520). It has been reported that nearly 75% of women in the United States of America (USA) experience a profound effect on their QOL, which is associated with symptoms of POP (Rortveit, Brown, Thom, Van den Eeden, Creasman & Subak 2007:1396). Therefore, contemporary uro-gynaecology has been considered as a QOL disease.

QOL may be affected despite the stage or type of POP (Mouritsen & Larsen 2003:126). Associated symptoms including bladder, bowel, sexual and pain dysfunction, caused by the multifactorial pathophysiology of POP, are the main causes for decreased QOL (Digesu, Chaliha, Salvatore, Hutchings & Khullar 2005a:972; Mouritsen & Larsen 2003:126). In a survey, women with self-reported POP in the USA reported the following issues that influence their QOL (ranked from the most to the least affected):

- Compromises with respect to bladder and/or bowel control.
- Inability to enjoy sports and physical activities.
- Compromised enjoyment of intimacy with their spouse or partner.
- Inability to exercise for good cardiovascular health and weight management.
- Physical pain and discomfort.
- Compromises in the workplace (Muller 2010:74).

The women also reported dissatisfaction with conservative management options, surgery, their relationship with their doctors, and the lack of information and education provided by the health sector (Muller 2010:74, 76-78).

It was reported in a small pilot study that QOL outcomes, which are based on questions by a physician during an interview, may be an underestimation of the distress that the patient is feeling (Srikrishna *et al*. 2008:520). For example, although it might sometimes be necessary for the women to reduce the prolapse by pushing it up with their fingers in order to urinate or defecate, women may withhold this information due to embarrassment (Maher, Baessler, Glazener, Adams & Hagen 2007:2).

Goldberg, Kwon, Gandhi, Atkuru and Sand (2005:336) found that other symptoms, such as urge and urinary incontinence (UUI and UI), had a strong and negative effect on QOL in a young female population with previous multiple gestation and delivery (Goldberg *et al*. 2005:336). Barber, Visco, Wyman, Fantl and Bump (2002:281, 285-287) also reported that women with POP are more likely to be sexually inactive and to perceive POP as affecting their sexual relations when compared to women with UI. It seems that these experiences might be independent of diagnosis of, or therapy for, incontinence or prolapse. The study had several limitations which should make interpretation of the results cautious. The perception of sexual satisfaction depends on many complex interactions such as emotional well-being, intimacy with one`s partner, QOL, and physical health (Barber *et al*. 2002:281, 285-287).

The effect of POP on QOL has not been well understood (Srikrishna *et al.* 2008:520). Fritel, Varnoux, Zins, Breart and Ringa said in 2009 that no studies have investigated the deterioration of general health-related QOL as a function of POP symptoms in a general population (2009:609). They continued to explore this aspect and found that POP symptoms had a significant effect on general health-related QOL, as measured by the Nottingham Health Profile dimensions in 2009. Interestingly, at that stage of the study, they reported that no validated disease-specific questionnaire existed to measure QOL in women with POP, considering the fact that improvement of symptoms and QOL should be the main outcome of the treatment according to literature, especially for surgical intervention (Maher, Feiner, Baessler & Schmid 2013:25; Fritel *et al.* 2009:615).

Surgical correction may also affect sexual, bladder, and bowel function temporarily, and therefore QOL, though difficulties with these functions may already have been experienced pre-operatively due to the prolapse. Surgery for POP can also contribute to dyspareunia by narrowing the introitus or vagina – depending on the surgical techniques used. Not all surgery leads to this problem (Weber, Walters & Piedmonte 2000:1613). It should be kept in mind that connective tissue, during the healing process post-surgery, tends to contract and that PFM contraction could also be painful. This may contribute to the mentioned problem and could be addressed by physiotherapy post-operatively.

It is therefore clear that pelvic floor muscle dysfunction (PFD) may be socially embarrassing and may cause the patient to avoid certain social situations, for example to withdraw from participating in leisure, sport and physical activities. This may eventually lead to a lifelong avoidance of health and fitness activities, a lower activity level, and thus an increase in mortality and morbidity (Bo 2004:453). Although conservative treatment for POP sometimes includes advice on lifestyle and environmental changes, data to support this advice for POP is lacking (Miedel, Tegerstedt, Mahle-Schmidt, Nyren & Hammarstrom 2009:1089; Weber & Richter 2005:621).

Evidence regarding PFM function/dysfunction is important to aid in the success of corrective surgery and conservative management to improve the QOL for patients (Epstein, Graham & Heit 2007:165.e6). There is very little evidence available in order to counsel women about appropriate post-operative exercises, as well as about the long-term subjective and objective cure rates after prolapse surgery (Bo 2004:460; Culligan, Murphy, Blackwell, Hammons, Graham & Heit 2002:1473). The role of the neuro-musculoskeletal system in the development of the symptoms associated with POP seems a factor to be considered. This could indicate that treatment of the underlying neuro-musculoskeletal causes may affect the patient`s QOL by addressing the symptoms.

A more recent study concluded that improvement in QOL (together with improved continence and PFM strength) was maintained over a six (6) month follow-up period after the patients were exposed to an intensive exercise programme initially. The study reported on several limitations in the methodology and interpretation of the results, which motivated for further investigation (Borello-France, Downey, Zyczynski & Rause 2008:1551-1552).

Validated and reliable assessment of the pelvic floor morphology and function, as well as a responsive condition-specific and generic QOL measurement tool are needed to address the unsubstantiated and controversial issues regarding the impact on QOL in patients with POP (Dumoulin & Hay-Smith 2010:18; Maher, Baessler, Glazener, Adams & Hagen 2007:17).

1.3 A BIOMECHANICAL (NEURO-MUSCULOSKELETAL) RATIONALE FOR PELVIC FLOOR DYSFUNCTION AND PELVIC ORGAN PROLAPSE

Levator ani muscle defects play a major role in the pathophysiology of POP, but do not account for all POP. On magnetic resonance imaging (MRI), 30% of women with stage II to IV POP had no defect, indicating the complexity and multifactorial involvement of factors in POP. Multiple aspects of the neuro-musculoskeletal and other systemic systems can contribute to failure. Failure of the supporting muscles may lead to failure of other components, such as the connective tissue and smooth muscles (neural system), due to increased demands on these components (DeLancey *et al*. 2007:300).

The levator ani muscle group consists of several muscles that function in coordination to control supportive and functional mechanisms of the pelvic organs. The pelvic floor muscle group forms part of the inner and outer wall of the core where it acts synergistically with the respiratory diaphragm, psoas, transversus abdominus (TrA), segmental multifidus, the oblique abdominal, superficial multifidus and spinalis muscles, and the oblique fibres of the quadratus lumborum muscle (Comerford, Mottram & Gibbons 2005:3.11; Janda, Van der Helm & De Block 2003:749; Sapsford 2001:624). As part of the core, the PFM can be defined as having a local stabiliser, global stabiliser, and global mobiliser role, depending on the functional support required (Comerford *et al*. 2005:3.9).

Multiple studies have investigated the interaction between the PFM and the abdominal muscles and their role in motor control and specifically maintaining continence (Thompson, O`Sullivan, Briffa & Neumann 2006a:274-275; Bo, Sherburn & Allen 2003:582; Shafik, Doss & Asaad 2003:311-313; Sapsford, Hodges, Richardson, Cooper, Markwell & Jull 2001:38-39). However, there is still some controversy as to exactly what the output mechanism is, as well as the integration on central nervous system (CNS) level. There seems to be different opinions on whether the PFM precedes contraction of the TrA muscle, or if TrA muscle contraction precedes PFM contraction, also during reflex contractions (Verelst & Leivseth 2004a:146).

Most studies investigating the interaction between the TrA muscle and the PFM have concentrated on their functional role in maintaining continence/incontinence. Devreese *et al.* (2004:195) stated that continence depends on the speed, strength, timing, and coordination of the PFM. These factors cannot be generalised to a different population, such as with POP. Sapsford *et al.* (2001:31-42) found a close relationship (co-activation pattern) between the pubococcygeus muscle and specifically the TrA muscle in an asymptomatic population. Recruitment of the local abdominal stabilisers may potentially be used to enhance pubococcygeus muscle training. However, further research is required to investigate such possible effects in symptomatic populations (Bo, Morkved, Frawley & Sherburn 2009:371).

Contradicting the study of Sapsford *et al.* (2001), Bo, Sherburn and Allen (2003:587) concluded in their study that instruction to contract the PFM was significantly more effective in elevating the pelvic floor than contraction of the TrA muscle with or without PFM contraction. In their study, 30% of skilled physical therapists depressed the levator plate when contracting the TrA muscle (Bo *et al*. 2003:587). The question could be raised as to the extent that activation of the TrA muscle can contribute to the activation of the PFM and to the decrease of intra-abdominal pressure (IAP) during daily activities. Correct activation of the abdominal stabilisers could cause less strain on the pelvic fascia and ligaments than when using the Valsalva manoeuvre to provide trunk stability, decreasing the strain on the pelvic organs (Thompson *et al.* 2006a:274).

Thompson *et al.* (2006a) indicated that incontinent women, having weaker PFM function, were prone to substitute PFM contraction by increased activation of the global rather than the local abdominal stabilisers. This strategy may lead to increased stress on the ligaments and fascia and worsen symptoms of prolapse and incontinence by increasing IAP and causing PFM descent (Thompson *et al*. 2006a:268-269, 273-275). It has also been indicated that symptomatic POP may be enhanced by poor pelvic connective tissue resilience related to menopause, in the presence of weakened PFM (Jones, Healy, King, Saini, Shousha & Allen-Mersh 2003:470).

Summarising the above literature and relating the motor control system, the hypothesis is that coordinated interaction of the articular, myofascial, neural and connective tissue systems of the body, as well as other autonomic systems, is necessary for prevention of symptoms, disability, and dysfunction (Comerford *et al.* 2005:1.3-1.4). At neuro-musculoskeletal level, the connective tissue system links all systems to provide structure and support, energy storage, passive force transmission, proprioception, and feedback (Figure 2) (Sapsford 2001:621; Comerford *et al.* 2005:1.3). Disturbance of any of these systems in the pelvic region may lead to poorly coordinated PFM contraction and consequently urinary and/or faecal incontinence, prolapse of the anterior and posterior vaginal wall, the vaginal apex and uterus, or pain and sexual dysfunction (Bo 2004:454).

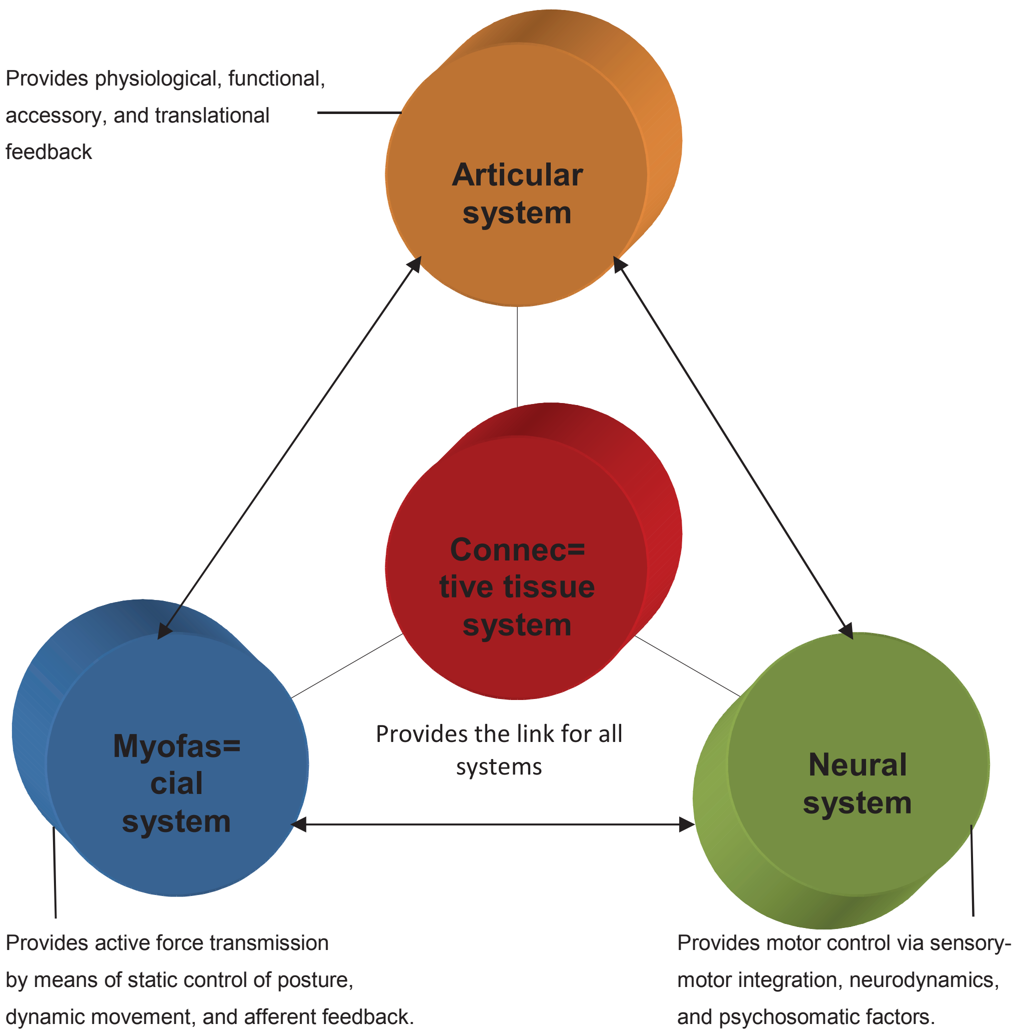


Figure 2. **The neuro-musculoskeletal control system** (Comerford *et al.* 2005:1-3).

1.4 PELVIC FLOOR MUSCLE TRAINING AND RECONSTRUCTIVE SURGERY

Despite insufficient evidence, PFMT is frequently recommended by physicians as a less invasive technique to conservatively treat moderate cases of POP (Hagen, Stark, Maher & Adams 2009:1; Bo *et al.* 2007:237). A Cochrane review stated that trials are needed to establish the effect of PFMT in conjunction with surgery for POP (Hagen *et al.* 2009:8). Surgical intervention is used to correct the more severe stages of POP, but does not necessarily restore the function of the PFM (Hagen *et al*. 2009:1; Sapsford 2001:620). Inflammation, pain, and swelling may lead to further inhibition of muscle function due to the impairment of proprioception (Figure 3) (Comerford *et al.* 2005:2.7).

Figure 3. Circle of muscle dysfunction and compensation (Comerford *et al.* 2005:2-7).

PFMT can be started immediately after surgery to aid in the formation of functional scar tissue and therefore an improved support mechanism (Hunter 1994:15). The question remains whether morphological changes of the levator ani muscle can affect surgical outcome.

Many questions remain unanswered, with specific reference to the role of PFMT in partnership with pelvic floor reconstructive surgery; the knowledge of specific patient attributes in women undergoing POP surgery; and the repair of deficient connective tissue and its effect on PFM action (Bo *et al.* 2007:243).

Jarvis *et al*. (2005:300-303) conducted one of the first studies to investigate the synergistic potential of physiotherapy and surgery for UI and POP in a sample of 60 women. Peri-operative physiotherapy significantly improved the physical outcomes and QOL ($P<0.0001$) in women undergoing the corrective surgery. The following should, however, be taken into account:

- The method of statistical analysis should be questioned for using means and no standard deviations in non-parametric testing (Jarvis *et al.* 2005:302).
- Twenty-six gynaecologists were involved performing the corrective surgery which could have influenced the reliability of the outcomes.
- No clear classification or categorisation was made regarding the stages or type of pathology of the sample. Determining treatment effect on specific pathology requires detailed description and categorisation of participants in order to make judgements on the treatment outcomes (Norton, Cody & Hosker 2007:10).
- The study emphasised the importance of the pubococcygeus muscle in the outcome of antero-posterior vaginal repair surgery and in the prevention of symptoms such as post-operative incontinence. Limited outcome measures were included to assess the changes in the PFM in response to the treatment, namely manometry and the modified Oxford scale (Jarvis *et al*. 2005:300-303).
- Patients received a home exercise programme and made two follow-up visits. The treatment and control groups returned after three (3) months for a final assessment. It is not clear whether a treatment diary was kept in order to assess the reliability of the patients performing their exercises (Jarvis *et al*. 2005:300-303). The literature proposes weekly visits and frequent re-assessments for optimal treatment outcomes. To satisfy the muscle training principle of overload, exercise should be performed over a period of at least

15 to 20 weeks (Norton *et al.* 2007:6; Bo 2006:266; Laycock & Jerwood 2001:635; Bo 1995:283).

- The inclusion of other techniques (different to the methodology of the study of Jarvis *et al.* (2005:300-303), such as electromyography (EMG), neuromuscular electrical stimulation (NES) and retraining of motor control, may also contribute to optimal rehabilitation (Norton *et al*. 2007:3, 7-9; Bo 2006:266; Hagen *et al*. 2009:8; Robert & Ross 2006:1113-1117; Laycock *et al*. 2001:23; Bo 1995:282-284, 288).

A more recent randomised controlled trial investigated the effect of a pre- and post-operative PFMT programme in women undergoing surgery for prolapse and hysterectomy. The primary outcome measures included the Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ). No significant differences were found between the groups. However, it could be argued that these outcome measures were not designed for a prolapse-specific population and that other instruments may give more valid results (Frawley, Phillips, Bo & Galea 2010:720-722).

Treatment parameters were also identified to be limited in the study by Frawley *et al.* (2010). The PFMT programme included only pelvic floor muscle exercises (based on previous literature) and did not explore the possibility of additional core training (see Figure 2 & 3). Recent literature, however, has emphasised that studies on PFMT should be on investigating different exercise protocols based on scientific guidelines for exercise and training. A sufficient number of treatment sessions and the intensity of the programme may have a substantial effect on the outcomes. However, the study did find PFM strength to be significant in favour of the training group, which could motivate the investigation of other dosages and protocols of training.

Another factor that needs to be considered is the fact that the study by Frawley *et al.* (2010:719-724) was limited to an Australian population. It also was not reported how many gynaecologists performed the surgery and no objective assessment of POP was undertaken (Frawley *et al.* 2010: 719-724). The conclusion of the study substantiates the present viewpoint (Weber & Richter 2005:621) that more high quality research is needed before evidence-based recommendations can be made.

It is important to understand that the aim of treatment and surgery is not only to correct the prolapse, but also to address the associated symptoms and dysfunction which may affect the patient`s QOL (Bo *et al.* 2007:105). This was illustrated in a recent randomised controlled trial by Efthekhar, Sohrabi, Haghollahi, Shariat and Miri (2014:7-14) which compared the effect of PFMT with surgery on sexual function in patients with a disorder of the pelvic floor (POP). In pelvic floor repair, improvement of QOL and subjective cure is the patient`s main goal and clinically the most relevant outcome measure (Doaee *et al*. 2014:154). Although PFMT can be beneficial for recovery, QOL and complaints after pelvic floor reconstructive surgery, it is not routinely offered to all patients (Pauls, Crisp, Novicki, Fellner & Kleeman 2013:271).

Improved outcomes for women undergoing reconstructive surgery would benefit the patient and health care providers, reduce costs, and most importantly, address the burden of maternal disease/illness (Jarvis *et al*. 2005:300). The challenge from a physiotherapeutic/neuro-musculoskeletal point of view is to find the most effective management and PFMT guidelines. However, it still seems to be a controversial subject, according to literature.

The pathophysiology of POP is complex (see 2.2) and some aspects are still not completely understood, resulting in the choice of surgery and/or physiotherapy techniques not always being the most accurate or effective. It therefore leads to what could be interpreted as ineffective treatment. Although Cochrane reviews have indicated that abdominal approaches may give better results with a lower recurrence rate, most surgery is still done using the vaginal approach (Maher *et al.* 2007:17). On the other hand, the question could be asked as to what extent the abdominal muscles and PFM are affected by each approach, and the effect that it may have on the long-term outcome and well-being of the patient.

1.5 THE CONTROVERSIES AND GAPS IN PELVIC FLOOR REHABILITATION RESEARCH

Literature indicates a definite need for high-level evidence on the outcomes of PFMT in general and in conjunction with corrective surgery (Hagen *et al*. 2009:2; Borello-France *et al.* 2008:1546,1552; Norton *et al.* 2007:1,3; Bo 2004:458; Bo 2006:263). Only three studies were found during the literature search on the outcomes of peri-operative physiotherapy for women undergoing uro-gynaecological surgery. The quality of those studies were questionable (see 1.4) and the conclusions should therefore be interpreted with caution.

The findings from those studies are substantiated by the most recent Cochrane review on the conservative management of POP (Hagen *et al.* 2009:2). Only three studies were found to be sufficient for inclusion. Two of the studies specified were applicable for discussion in this thesis (see 2.7). The Cochrane review also concluded that the studies had several methodological limitations, which made the evidence insufficient to draw any conclusions (Hagen *et al.* 2009:2).

Issues such as the effect of a rehabilitation programme on PFM function and POP support has not been investigated comprehensively (Norton *et al* 2007:1,3; Bo 2006:263). Furthermore, it is not known what the effect of corrective surgery is on PFM function (Bo *et al*. 2007:243), and how it could be affected by consequent physiotherapy. In order to answer such questions and generate clinically relevant evidence, PFMT should be scientifically prescribed and investigated according to the latest evidence on motor control. Limited evidence exists on conservative treatment protocols and there is a lack of standardisation in the prescription of such protocols when compared to the general and scientifically based principles of rehabilitation (Bo *et al*. 2009:372; Borello-France *et al*. 2008:1546; Bo 2006:266; Hagen *et al*. 2009:11; Laycock & Jerwood 2001:641; Ballanger *et al*. 2000:10).

Controversy exists regarding the role of the abdominal muscles in the training and activation of the PFM. Sapsford *et al.* (2001:31-42) reported a close interaction between the TrA muscle and the PFM, measured by means of EMG. This could indicate a co-activation pattern between these muscles to be utilised when training the PFM. It supports the findings of Janda *et al*. (2003:749-750) who reported on the coordinated function of the core muscles, as generating an increase in IAP to support the pelvic organs. The latter statement contradicts the findings of Bo *et al.* (2003:587), which demonstrated a depression of the levator plate on contraction of the TrA muscle which may contribute to the development of POP and uro-gynaecological disorders. According to Thompson *et al*. (2006a), descent of the levator plate is a phenomenon to be expected on contraction of the global stabilisers. Correct activation of the local stabiliser muscles would cause less strain on the pelvic connective tissue and generate a lower IAP than when using the Valsalva manoeuvre for stability. This mechanism would enhance the support of the pelvic organs (Thompson *et al.* 2006a:268-269, 273-275; Bo *et al.* 2003:587; Sapsford *et al.* 2001:31-42).

A Cochrane review by Dumoulin and Hay-Smith (2010) concluded that the relationship between, and the effect of rehabilitation of the PFM and the TrA muscle on uro-gynaecological disorders, still needs to be established (Dumoulin & Hay-Smith 2010:4).

Conclusively, randomised, controlled clinical trials are needed to investigate the outcomes of PFMT on PFM function and uro-gynaecological disorders, independent and as an adjunct to corrective surgery, as well as to determine the most effective rehabilitation protocol.

1.6 AIMS AND OBJECTIVES OF THE STUDY

The aim of the study was therefore to determine the outcomes of a PFMT protocol, a core training protocol (which included PFMT), and a control group who received no training, on the PFM and QOL in women undergoing corrective surgery for POP. The results were used to propose a rehabilitation model for PFD.

1.6.1 Objectives

1.6.1.1. To determine baseline data regarding the abdominal muscles and the PFM, as well as QOL **pre-operatively,** in women undergoing corrective surgery for POP.

1.6.1.2. To determine the outcomes, within groups, of a

i. PFMT programme,
ii. core training programme, and
iii. control intervention,

on the PFM, abdominal muscles and QOL **post-operatively** in women who have had corrective surgery for POP.

1.6.1.3. To **compare** the outcomes, between groups, of a

i. PFMT, and
ii. a core training protocol, versus no training (control group), on the PFM, abdominal muscles and QOL (pre-operatively and post-operatively) in women with POP.

1.6.1.4. To **compile a proposed model for rehabilitation** for patients with PFD in the public and private sector, pre- and post-operatively.

1.7 ADDRESSING THE RESEARCH PROBLEM

The anatomy of the pelvic viscera and the function of the PFM, as well as the connective tissue ‘link’ to the neuro-musculoskeletal motor control system, theoretically indicate the role of PFMT to improve pelvic organ support.

Clinically PFMT has been accepted as an important component of conservative treatment, since it is the only component with few reported adverse effects. It is hypothesised to limit surgical failure rates and to improve the QOL for patients with POP.

However, literature indicates a need for randomised controlled trials to determine the most effective exercise regime, as well as the outcomes of PFMT in partnership with uro-gynaecological surgery. Most recommendations have not been tested clinically and may still need modification (Bo *et al.* 2009:372; Epstein *et al.* 2007:165.e6; Bo 2006:266; Bo 2004:459; Laycock & Jerwood 2001:641).

1.8 OUTLINE OF THE THESIS

The first chapter sets POP in a context of decreased QOL as it forms the primary basis for women to seek treatment and it has led to a situation where contemporary uro-gynaecology can be considered as a QOL issue. It indicated how the symptoms and signs of POP, and the biomechanics of the pathology and surgery, fit into this context from a neuro-musculoskeletal point of view (Figure 1). Based on this foundational framework as presented in Figure 1, the continuous and interrelated discussion of concepts in Chapter 1 and 2 (and continuing throughout the thesis) can be depicted by Figure 4 below.

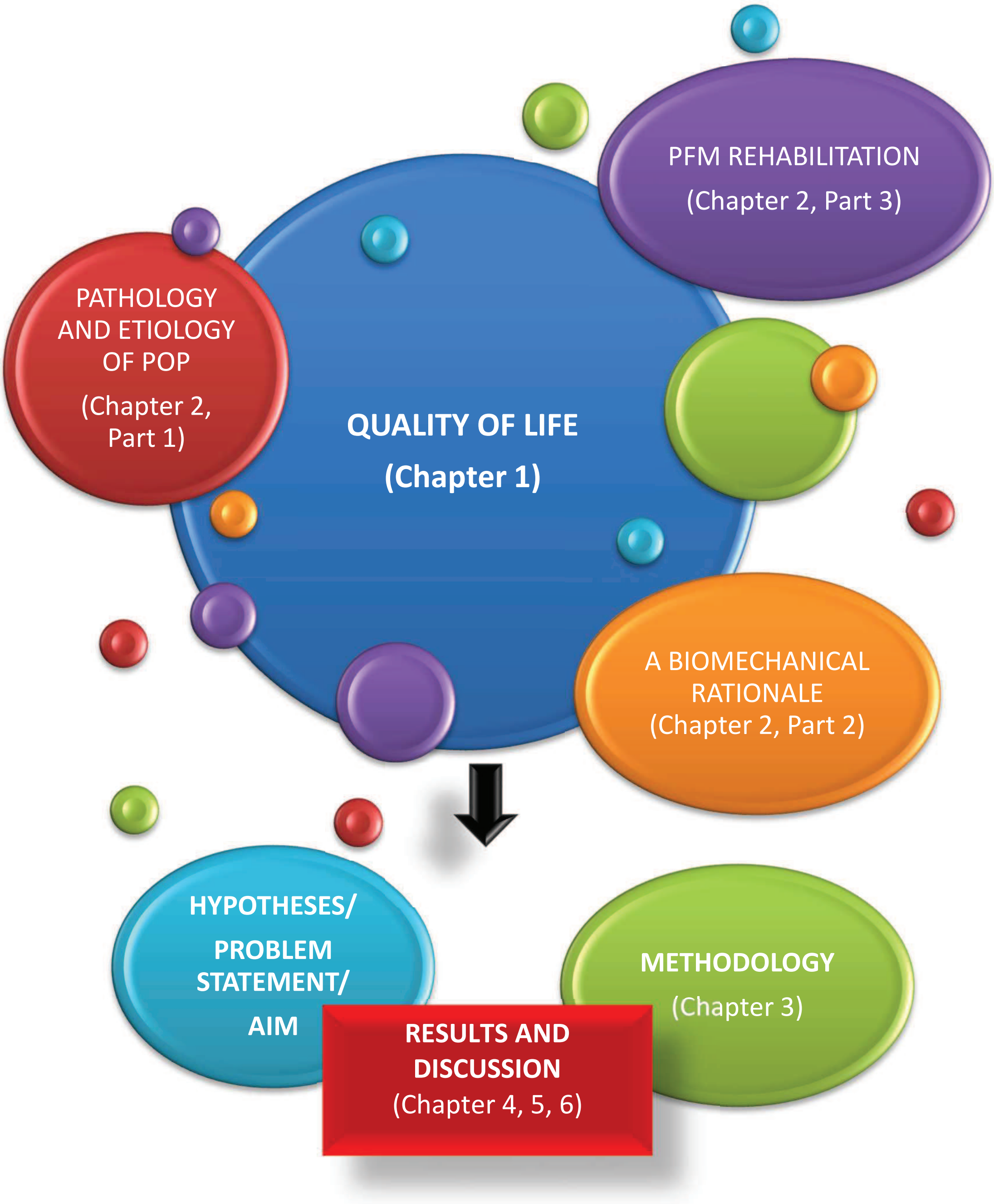


Figure 4. The interrelated discussion of concepts within the study context.

The next chapter (Chapter 2) offers an in-depth discussion of the literature on the above-mentioned concepts. Firstly, it explores the pathology, and secondly, it integrates biomechanical principles and concepts of motor control into the reconstructive surgical process and POP pathology. Hypotheses are formulated in text boxes and related to the objectives in 1.6.1 throughout the discussion.

The third part of Chapter 2 explores guidelines for the effective management of POP pre- and post-operatively. This is discussed in the context of exercise science, existing evidence, and the understanding and integration of the biomechanics of the PFM and pelvic floor reconstructive surgery. This part of the literature review formed the basis upon which the rehabilitation programmes for the intervention groups were compiled.

To answer the research objectives and test the identified hypotheses, a randomised controlled clinical trial was designed, comparing two different intervention programmes with each other and a control group. The methodology of the research is presented in Chapter 3, where the sampling methods, measuring instruments, data collection procedures, and ethical principles are discussed. The methodology was designed to specifically investigate the changes in the PFM and the abdominal muscles, as well as QOL, in a sample of participants who received pelvic floor reconstructive surgery.

The results to answer each objective are presented in Chapter 4. It is supported by graphs and tables depicting relevant information to gain insight into the interpretation of the results and hypotheses. The statistical analysis used for each calculation is defined, and the results are presented in the context of normal values where applicable and available.

The thesis concludes with Chapter 5, 6 and 7 where the objectives of the study and hypotheses derived from the literature are discussed in terms of the results of the study and compared to the existing evidence and literature. Some questions are answered, and new and more questions are raised as recommendations and limitations are identified. Concluding the study, the biomechanical and neuro-musculoskeletal findings are related back to the context of QOL, which was sketched in Chapters 1 and 2.

CHAPTER 2

PELVIC ORGAN PROLAPSE AND RECONSTRUCTIVE SURGERY - A PHYSIOTHERAPEUTIC POINT OF VIEW

2.1 INTRODUCTION

Little evidence exists on conservative treatment protocols regarding POP and the role of the PFM (Bo 2006:266; Hagen *et al.* 2009:11). Laycock and Jerwood (2001:641), among others, reported a lack of standardisation and scientific application in PFM exercise regimens, when compared to scientifically-based rehabilitation methodology (Braekken, Majida, Eng & Bo 2010:170e7; Quartly, Hallam, Kilbreath & Refshauge 2010:312). Ballanger *et al*. (2000:10) also raised concerns regarding the lack of evidence on:

- The effect of training on specific populations.
- The long-term effects of rehabilitation.
- How patients accept PFMT techniques.
- The effect of prevention techniques for the development of PFD.
- At risk populations.

In addition to limited evidence regarding pre- and peri-operative physiotherapy, the lack of scientific evidence regarding conservative treatment protocols complicates pre- and peri-operative exercise prescription. Additional biomechanical and pathological factors regarding the PFM and motor control system, due to the surgery, need to be taken into account when prescribing exercise post-operatively. It necessitates a clear understanding of the pathology of POP, the surgical procedures, the effect on the connective tissue and the muscles, the motor control system lying central to all of these aspects, the scientific planning of the rehabilitation programme and outcome measurement, as well as the possible interrelation of these aspects. Discussion of these aspects have been divided into three (3) parts, where the first part will address the pathology, followed by the second part addressing the biomechanical principles and motor control issues associated with POP and the surgical treatment. The third part will discuss the literature on rehabilitation guidelines and the principles underlying it. It also includes an overview of outcome measurement relevant to the PFM and POP.

Figure 5 is a depiction of the concepts to be discussed in this chapter (large circle) and how it relates to the rest of the study (small circles). The untitled circles are a representation of unidentified variables which still need to be discovered. Each of the following chapters will be introduced in a similar manner, indicating the sections to be discussed in the chapter at hand and its relevance to the rest of the thesis and study.

PART 1

PELVIC ORGAN PROLAPSE: symptoms and signs affecting lifestyle

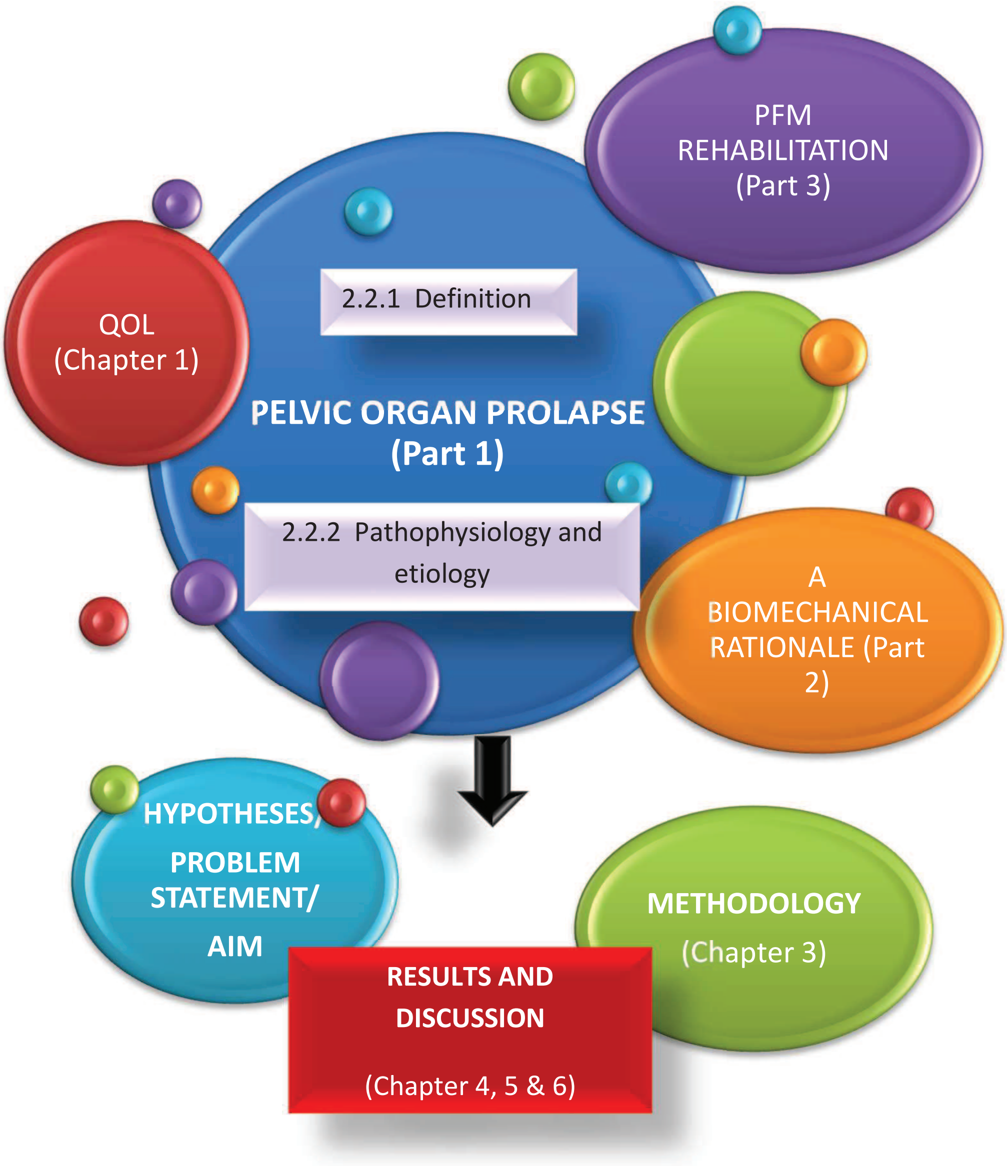


Figure 5. The interrelated discussion of concepts regarding POP within the study context.

2.2 PELVIC ORGAN PROLAPSE

2.2.1 Defining pelvic organ prolapse

POP can be defined as the downward displacement or descent of the pelvic organs from their normal anatomical position. It is often symptomatic and affects the QOL of the patient, but is seldom life threatening. It may also be the cause of bladder and/or bowel dysfunction (Bo *et al*. 2007:105). According to the International Uro-gynecological Association and International Continence Society`s terminology of PFD, it can involve the descent of one or more of the following: anterior vaginal wall, posterior vaginal wall, uterus, or apex of the vagina (Haylen *et al*. 2010:8).

Prolapse of the lower anterior vaginal wall can be defined as an urethrocele, involving only the urethra. A cystocele is the prolapse of the upper anterior vaginal wall involving the bladder. If there is associated prolapse of the urethra, it is called a cysto-urethrocele. Anterior vaginal wall prolapse is multifactorial and three different defects may occur. The midline defect, which has been described in the past as the distention-type cystocele, the paravaginal defect, and the transverse defect (separation of the pubocervical fascia from the insertion around the cervix or at the apex) are the three defects which have been described by Baggish and Karram (2011:639). A paravaginal defect may be due to detachment of the vagina with its muscular layer or pubocervical fascia from the arcus tendineus fasciae pelvis bilaterally. It may also be due to avulsion of the arcus and the fascia of the obturator internus muscle (Baggish & Karram 2011:427).

An uterovaginal/vault prolapse involves the prolapse of the uterus, cervix and upper vagina respectively. It may be due to failure of the uterosacral ligaments and associated with hysterectomy, but the true incidence and prevalence are unknown (Baggish & Karram 2011:501, 695).

Prolapse of the posterior vaginal wall is usually classified as an enterocele if it involves the upper part of the wall, which may contain the small bowel. An enterocele develops due to the separation of the pubocervical and rectovaginal fascia. A peritoneal sac, with its contents, protrude through the fascial defect and comes into direct contact with the vaginal epithelium (Baggish & Karram 2011:669).

Prolapse of the lower part of the posterior vaginal wall, involving the anterior wall of the rectum, is defined as a rectocele (Bo *et al*. 2007:105). A defect of only the rectovaginal fascia is usually the cause of a rectocele. Defects may be transverse, longitudinal, or oblique (Baggish & Karram 2011:669). What is not clearly mentioned is prolapse of the Pouch of Douglas (deepened pelvis) and descent of the rectum. These two aspects have received almost no attention in the literature.

2.2.2 Pathophysiology and etiology of pelvic organ prolapse

POP is a benign condition which can either be non-symptomatic, or symptomatic. The symptomatic aspect affects the patient`s well-being or QOL (Doaee *et al*. 2014:153). A patient may complain of an abnormality in sensation, pain, structure, or function of the pelvic organs relating to the position of the pelvic organs. Common complaints include vaginal bulging, pelvic pressure, bleeding, discharge or infection (due to ulceration), splinting/digitation to assist voiding or defecation, or a lower abdominal or back pain associated with the prolapse. Symptoms worsen with the effects of gravity, for example after exercise or standing for long periods of time. Symptoms may also be exacerbated with increased abdominal pressure, such as chronic coughing, and straining during defecation (Haylen *et al*. 2010:6).

The multifactorial pathophysiology of POP may be the cause of associated symptoms such as bladder, bowel, sexual, and even pain symptoms (Weber & Richter 2005:617). Symptoms may include **lower urinary tract symptoms** e.g. urgency, frequency, UI, difficulty voiding; **sexual symptoms** such as dyspareunia, decreased orgasmic capacity, decreased libido, embarrassment or fear of abnormal anatomy; and **anorectal dysfunction** e.g. pain with defecation, splinting or straining to have a bowel movement, or even anal incontinence. Other symptoms include rectal urge and anal soiling. Many studies regarding PFD have focussed on UI and the associated pathophysiology and symptoms, but very few have studied POP and specifically anorectal dysfunction (Dietz & Steensma 2006:225; Burrows, Meyn, Walters & Weber 2004:982). Linking anorectal dysfunction with POP (at a neuro-musculoskeletal level) would require the investigation of specifically the puborectalis (PR) muscle and external anal sphincter (EAS) in such a population. Dietz and Steensma (2006:229) indicated that defects of the PR muscle may be a risk factor for prolapse, rather than incontinence.

Weber and Richter (2005:616), as well as Bump and Norton (1998:723-725), have divided the risk factors for POP into different categories, namely: 1. **predisposing** (genetic, race and ethnicity, gender, variations of anatomy and collagen synthesis and structure); 2. **inciting** (pregnancy and delivery injuring nerves and muscle, surgery e.g. hysterectomy, myopathy, neuropathy) (Sze, Gordon, Sherard & Dolezal 2002:984-985); 3. **promoting** (obesity, smoking, pulmonary disease, constipation, recreational or occupational activities); and 4. **decompensating** (aging, menopause, neuropathy, myopathy, debilitating, medication).

The etiology of POP remains poorly understood, and individuals seem to vary in their predisposition to POP (Miedel, Tegerstedt, Maehle-Schmidt, Nyren & Hammarstrom 2009:1089). In their study, Miedel *et al*. (2009:1094-1096) indicated that body mass index (BMI), conditions associated with deficient connective tissue (varicose veins, hernia, haemorrhoids), family history, and heavy lifting at work can be associated independently with the presence of POP. Significant associations of symptomatic POP with bowel symptoms (e.g. bowel habits, bowel emptying, hard/lumpy stools, difficult evacuation, pain with defecation) were also made in this study. However, the cross-sectional study design they used limited the conclusion of their findings.

Rortveit, Brown, Thom, Van den Eeden, Creasman and Subak (2007:1400-1401) also found an association between bowel symptoms, such as constipation and irritable bowel syndrome, and symptomatic prolapse. The presence of POP also seemed to increase with age and the number of vaginal deliveries in their population. In addition to these findings, they also found POP to be less common among African-American women, but more common in women with poor health status and prior vaginal delivery.

Results regarding ethnicity and race seem to reveal that POP is more common in a Caucasian population, less common in an Asian population, and uncommon in a Black population (Digesu, Khullar, Cardozo, Robinson & Salvatore 2005b:176; Sze *et al*. 2002:981). These results are supported by findings from other studies which found a 40% higher risk of POP in Caucasian women when compared to Black women (Whitcombe *et al*. 2009:1271-1277). Relating to the neuro-musculoskeletal system, a reason for these differences in prevalence between races might be contributed to differences in collagen content and pelvic anatomy (Cronje 2011:490).

Other etiological factors associated with the neuro-musculoskeletal system include risk factors, such as increased age and menopause, which have been associated with a decrease in the diameter and weakening of the PFM (Zhu, Lang, Chen & Chen 2005:403). Vaginal delivery may also cause damage to the PFM and the nerve endings (amount of motor units to be innervated). Many etiological factors of POP relate the increase to IAP (e.g. obesity, smoking, pulmonary disease, constipation, recreational or occupational activities) (Weber & Richter 2005:616).

Aukee, Penttinen and Airaksinen (2003:256) found the mean EMG reading of the PFM to be inversely related to an increase in age and the number of vaginal deliveries. Reay Jones, Healy, King, Saini, Shousha and Allen-Mersh (2003:470) demonstrated a decrease in the resilience of the uterosacral ligament with increasing age and in women with a history of normal delivery. Despite the contribution of the process of normal delivery and factors such as differences in bony pelvic structure

(Handa, Pannu, Siddique, Gutman, Van Rooyen & Cundiff 2003:1288), the authors also hypothesised that decreased resilience of the uterosacral ligament may be caused by the pregnancy-related changes in connective tissue. Weakening of the uterosacral ligament may lead to POP due to its important role in supporting the pelvic organs (see 2.3).

During menopause, the thickness of the uterosacral ligament appears to decrease by 36%, associated with a decrease in receptor density and uterosacral resilience (UsR) (Reay Jones *et al*. 2003:470). Zhu *et al*. (2005:403) indicated a decreased diameter of the type I and II muscle fibres of the levator ani muscle with increased menopausal time and age. It would therefore seem that older women/menopausal women have an increased risk of developing POP.

Hypothesis 1 (relate to objective 1.6.1.1)

Factors such as increased age, menopause, BMI, vaginal delivery, or causing increased IAP (obesity, smoking, pulmonary disease, constipation, recreational or occupational activities) seem to be associated with POP.

Hypothesis 2 (relate to objective 1.6.1.1)

Decreased diameter and weakening of the PFM have again been associated with some of the above-mentioned factors, such as vaginal delivery, increased age and menopausal time. Together with the anatomical position and function of the PFM, the literature seems to indicate the importance of these muscles' function in the development of POP.

PART 2

A BIOMECHANICAL RATIONALE FOR PELVIC FLOOR DYSFUNCTION, PELVIC ORGAN PROLAPSE, AND RECONSTRUCTIVE SURGERY

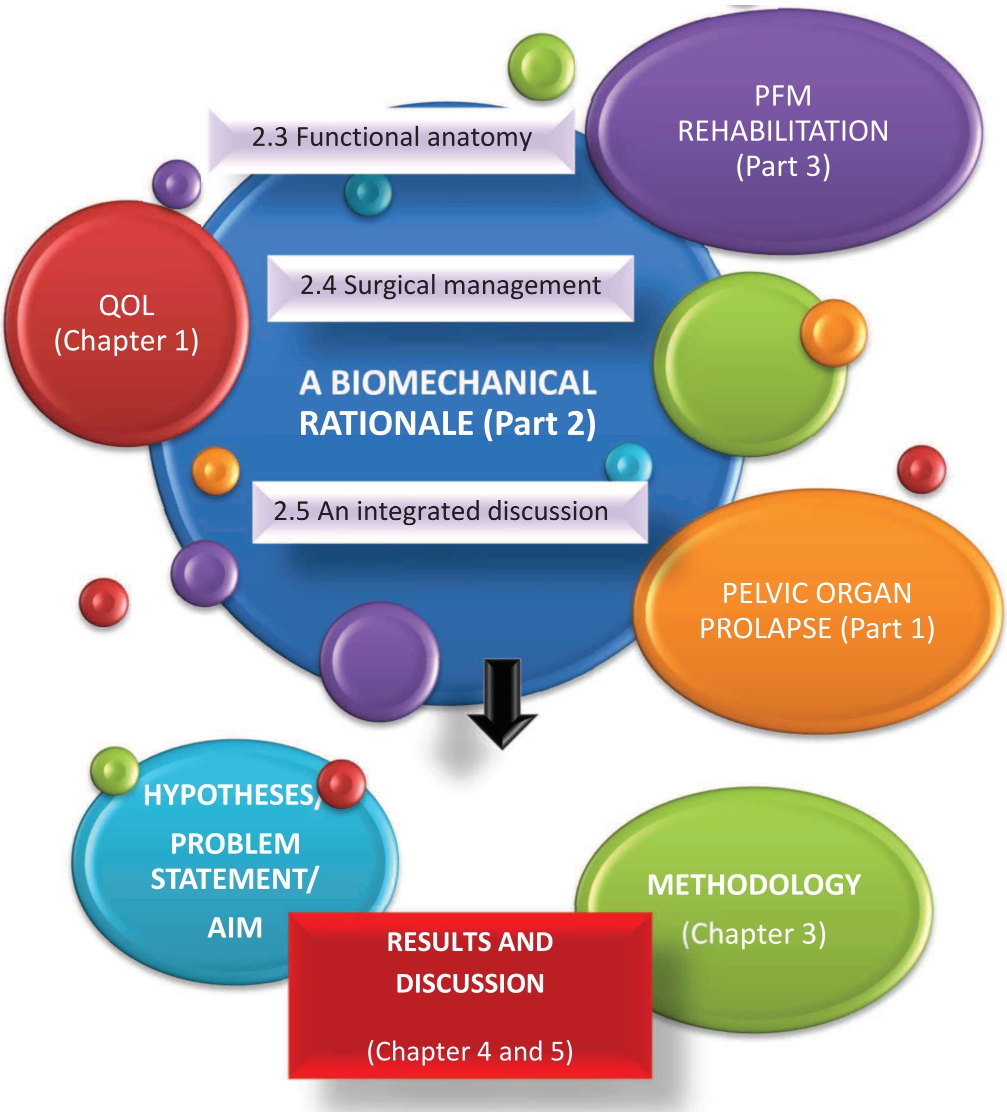


Figure 6. The interrelated discussion of biomechanical concepts within the study context.

The aim of the second part of Chapter 2 is to provide a detailed description of the specific anatomical connection between the fascia, ligaments, muscles, and viscera in order to explain the biomechanical concepts. The purpose is to indicate how surgery, at a seemingly remote level, may affect the function and integrity of the motor control system, and therefore the symptoms and signs of POP, and consequently rehabilitation.

2.3 INTRODUCTION TO THE FUNCTIONAL ANATOMY AND BIOMECHANICS OF THE PELVIC FLOOR MUSCLES AND PELVIC VISCERA

2.3.1 Functional anatomy of the pelvic floor muscles

The location of the PFM inside the pelvis makes it the only muscle group in the body able to structurally support the pelvic organs and the pelvic openings (Bo 2004:454). The PFM consists of a three layer muscular plate, which can also be described in terms of two diaphragms, namely the pelvic and urogenital diaphragm (Bo 2004:454) (Figure 7). From deep to superficial, the layers are described next. The pelvic diaphragm is composed of the levator ani and coccygeus muscles. It closes the pelvic outlet, apart from a gap between the anterior edges, which is filled with loose fascia. The urogenital diaphragm, and its superior fascia, close this gap. This membrane is a thin sheet of striated muscle composed of the deep transverse perineal muscles and the sphincter urethra muscle. It is surrounded by deep fascia which consists of an inferior and superior sheet. The inferior sheet is usually referred to as the perineal membrane. The deep perineal space is the space enclosed by the superior and inferior fasciae of the urogenital diaphragm. It contains part of the urethra, the sphincter urethra muscle, the deep transverse perineal muscle, and related vessels and nerves. The superficial perineal space, on the other hand, is found between the superficial perineal fascia and the perineal membrane. This superficial space contains the root of the clitoris and bulbs of the vestibule, related nerves and vessels, the greater vestibular glands, and the superficial perineal muscles (Moore 1992:295-301). The superficial space also contains the bulbospongiosus and ischiocavernosus muscles, which, similar to the deeper muscles from the pelvic floor, inserts into the perineal body posteriorly (Haderer, Pannu, Genadry & Hutchins 2002:248). Of these three (3) layers described above, the deep layer, namely the levator ani muscle group, is the largest and most important muscles in the pelvic floor. The reason might be due to its important function in supporting the pelvic viscera, resisting IAP, and the role it plays in forced expiration, coughing, vomiting, urinating, defecation, and stability during strong movement of the body (Moore 1992:254).

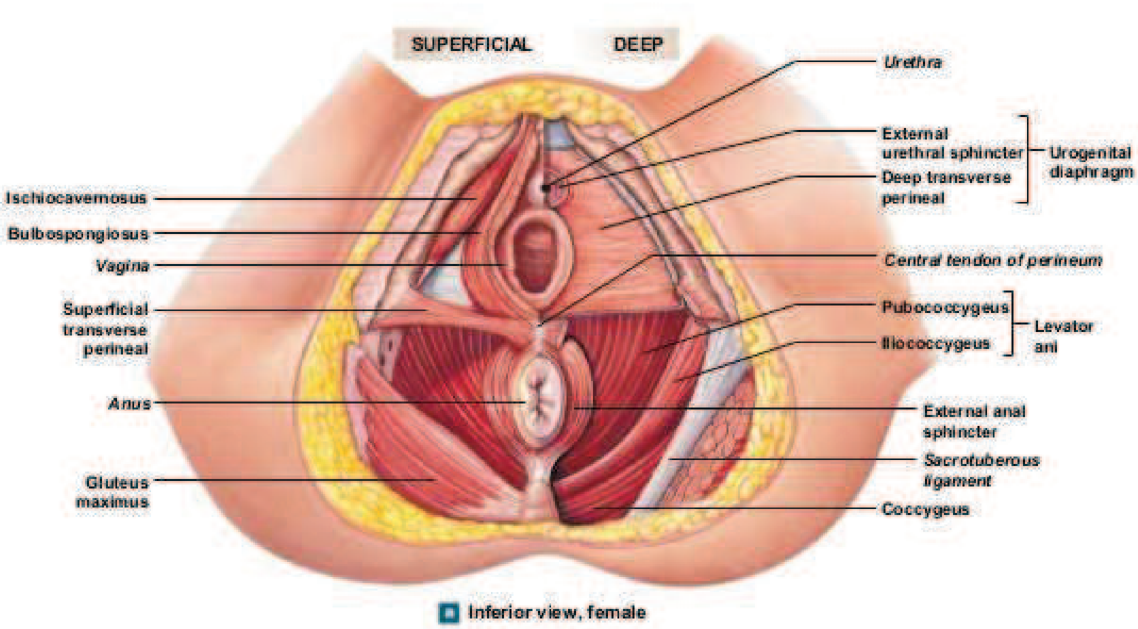


Figure 7. Three (3) layers of the pelvic floor muscles (http://image.slidesharecdn.com/ch10lecturepresentation-140913123821-phpapp02/95/dr-b-ch-10lecturepresentation-46-638.jpg?cb=1410612036).

The muscle consists of approximately 70% type I fibres and 30% type IIB fibres. It makes the muscle ideally suited to be tonically active as needed for pelvic organ support (by means of slow motor unit recruitment), but not always ideally developed for quick, strong movement needed, for example for maintaining continence (Zhu *et* *al*. 2005:401,403). The existence of both type I and II fibres make the PFM suitable to function as part of the inner and outer wall of the core.

The PFM consists of the pubococcygeus (pubovaginalis and PR) muscles, the iliococcygeus muscle, the ischiococcygeus muscle, and the pelvic part of the piriformis muscle (Norton *et al*. 2007:1). The PFM can be divided into a deep and superficial layer. The deep layer, amongst which the pubococcygeus muscle is classified, has attachments to the pelvic viscera, whereas the iliococcygeus muscle has no fibres that connect with the pelvic viscera (Haderer *et al*. 2002:245). The focus of this study is specifically the investigation of the deeper layer (the pubococcygeus and PR muscles) in the different stages of the research (Coffey, Wilder, Jamsak, Stolove & Quinn 2002:799).

Functions of the PFM include constricting the caudal part of the rectum and urethra, as well as forming a muscular diaphragm to support the pelvic viscera. The deep layer of the PFM attaches anteriorly to the pubic bone and posteriorly to the coccyx, and also has an attachment to the fascia of the obturator internus muscle. A few fibres of the pubococcygeus muscle insert on the urethra and become part of the intrinsic musculature of the bladder. Other fibres insert on the vagina and the rectum. The PR muscle, consisting of the most medial fibres of the pubococcygeus muscle, has some fibres that sling around the anal canal and the rectum to form the anorectal angle. The fibres of this muscle also contribute to the perineal body between the distal vagina and the anal canal. The PR muscle lines the edge of the genital hiatus, and during contraction, it constricts the genital hiatus, pulls the rectum anteriorly towards the pubic bone, and helps to maintain faecal continence together with the contraction of the EAS (Coffey *et al*. 2002:799; Haderer *et al*. 2002:245). As part of the pelvic diaphragm it also opposes the downward thrust of IAP to generate and control IAP together with the abdominal muscles. In this manner, the PFM contributes to spinal stiffness and to force closure of the sacro-iliac joint (SIJ) by increased tension as well as counter-nutation (Pool-Goudzwaard, Van Dijke, Van Gurp, Mulder, Snijders & Stoeckart 2004:564, 565, 568).

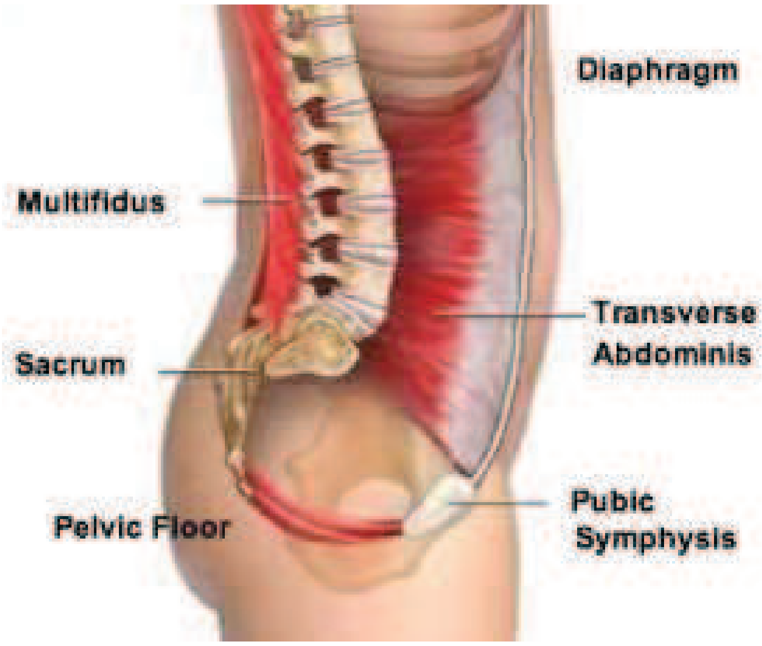


Figure 8. Anatomy of the core muscles (http://pilatescape.co.za/wp-content/uploads/2014/09/core-muscles-300x2281.jpg).

The latter is an example of how the PFM functions as part of the core (Figure 8) to optimise motor control. However, dysfunction in one component of this integrated mechanism, such as the TrA muscle function (either due to pain, weakness, or fatigue), may lead to compensation by another mechanism, such as increased tone of the PFM to maintain postural stability and pelvic organ support. Should this increased load prevail, it may lead to failure of the PFM. Eventually this may lead to hypomobility, imbalance, and/or pain of the SIJ, lumbar and pelvic area. Under normal circumstances an increase in IAP will be distributed equally to the sides of the abdominal and pelvic walls. This equal pressure distribution may be disturbed in the case of a weak or inactive levator ani muscle, causing the pelvic organs to descend and leading to problems such as incontinence or POP (Janda *et al.* 2003:749-750).

Hypothesis 3 (relate to objectives 1.6.1.1, 1.6.1.2 and 1.6.1.3)

According to the above explanation, it seems that dysfunction of the TrA muscle may lead to either increased tone of the PFM, or weakness due to failure in response to sustained overload and compensation.

2.3.2 Anatomy of the pelvic viscera and fascia

The importance of motor control and normal muscle function for pelvic organ support has been discussed in 2.3.1 above. To understand the complexity of the pathophysiology of POP, it is important to refer to certain anatomical factors of the pelvic organs and the inter-relationship of these factors in regard to the neuro-musculoskeletal support system.

The cavity of the pelvis minor, forming the "floor" of the abdomino-pelvic cavity (Pouch of Douglas), contains the pelvic viscera (Figure 9). The posterior wall is formed by the concave surface of the sacrum and coccyx, while the anterior wall is formed by the posterior surface of the symphysis pubis. In between is the 'floor', which can be seen as the genital hiatus (levator ani muscle), filled by the rectum, vagina, and urethra. The lateral walls consist of the bony pelvic side walls (mainly the ilium and ischium). Medially to the bony side walls are important blood vessels and nerves (Moore 1992:248).

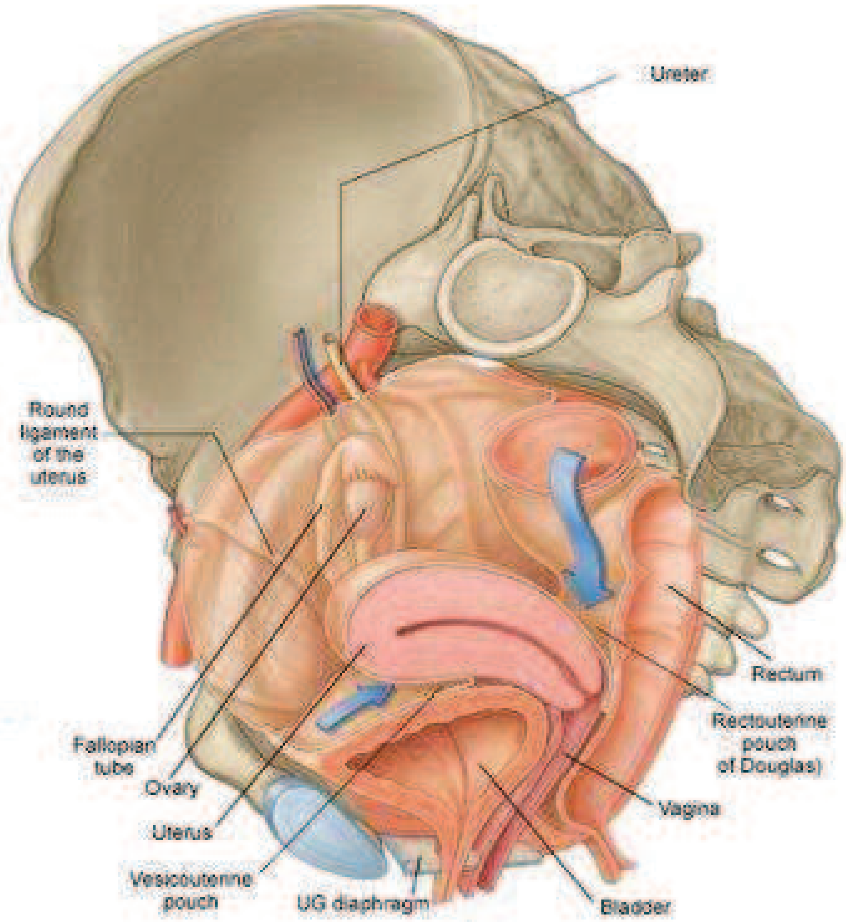


Figure 9. **Anatomy of the female pelvic cavity** (https://classconnection.s3.amazonaws.com/223/flashcards/1190223/jpg/female_pouches1331839347853.jpg).

Embedded amongst these walls are the bladder, vagina, and rectum. The empty bladder lies slightly posterior and inferior to the pubic bones in adults, separated by the retropubic space from the pubic bones. The infero-lateral surface is in contact with the fascia of the levator ani muscle. The fundus of the bladder fills the space between the symphysis pubis and the cervix (uterus). The distal part of the bladder, including the bladder neck, is surrounded by endopelvic fascia. There are no ligaments or muscles directly attached to the bladder. Also important to note is the vesico-uterine pouch. This is a reflection of peritoneum from the superior surface of the bladder onto the anterior wall of the uterus. Usually this pouch is empty, but when retroverted, as with prolapse of the uterus, this pouch may be filled with a loop of bowel (Baggish & Karram 2011:66; Moore 1992:268-276). An anterior enterocele may rarely develop here.

Posterior to the urinary bladder, lies the vagina which descends in an antero-inferior direction. It lies anterior to the rectum, where only loose connective tissue of the rectovaginal septum separates the posterior wall of the vagina from the rectum. More inferiorly the vagina is connected to the perineal body, and passes between the medial margins of the levator ani muscle, where it pierces the urogenital diaphragm by means of the pubococcygeus muscle. This muscle is attached to the sphincter urethra muscle and the vaginal wall (Moore 1992:282). The pubovaginalis muscle, urogenital diaphragm, and bulbospongiosus muscles can compress the vagina similar to sphincters. Contraction of the pubococcygeus muscles, which are in contact with the lateral walls of the vagina, draws the lateral walls of the vagina together to close the lumen. Superior to the pubococcygeus, the lateral walls of the vagina are attached to the endopelvic fascia, which extends into the broad ligaments of the uterus on both sides (Baggish & Karram 2011:42, 66; Moore 1992:282-283).

The cervix of the uterus projects into the proximal vagina, separating the anterior and posterior walls (as well as the lateral walls). This reflects as a right angled position of the uterus relative to the axis of the vagina, if the uterus is in its normal anteroverted position. With a filled bladder, the fundus of an anteroverted uterus is pushed posteriorly, resulting in a uterus that lies in line with the proximal vaginal axis. However, when the uterus is in retroversion, bladder filling has little effect on the position of the uterus due to the large space between the symphysis pubis and the uterine fundus. When the bladder is fully distended, it will push any uterus in retroversion. The uterus normally lies superior-anteriorly over the bladder when it is empty (Moore 1992:282-83).

The uterus is supported in its position by the uterosacral ligaments (from the cervix to the sacrum), the PFM, the surrounding viscera and the endopelvic fascia (Figure 10). Laterally to the cervix, the endopelvic fascia forms a condensation known as

Mackenrod`s ligament or the transverse cervical ligaments. Similarly, a condensation anteriorly, in the midline, is known as the pubocervical fascia. The peritoneum, which covers the uterus, reflects onto the bladder and the rectum, connecting these pelvic organs. The broad ligament, also a fold of peritoneum, extends from the uteral sides to the lateral pelvic walls and floor of the pelvis to hold the uterus in a normal position (Moore 1992:284-285).

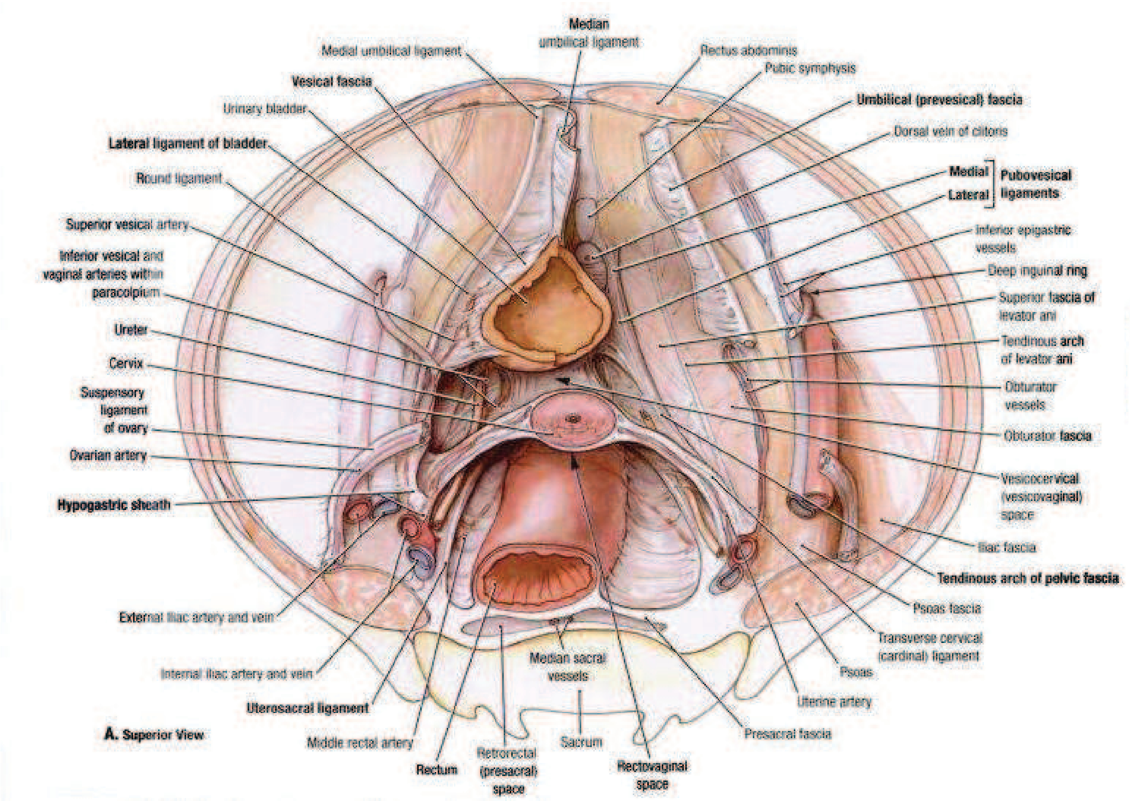


Figure 10. The fascia of the female pelvis ([https://anatomytopics.files.wordpress.com/2008/12/pouches-and-ligaments-of-female-pelvis-ct.jpg).](https://anatomytopics.files.wordpress.com/2008/12/pouches-and-ligaments-of-female-pelvis-ct.jpg)

As mentioned above, the anterior reflection of the peritoneum from the uterus, namely the vesico-uterine pouch, separates the anterior body of the uterus from the bladder. Posteriorly it is separated from the sigmoid colon and the rectum by a layer of peritoneum, the peritoneal cavity, and the recto-uterine pouch (of Douglas) respectively (Moore 1992:286).

The recto-uterine pouch also separates the rectum from the posterior part of the vagina at the fornix. Inferiorly to this, the separation is by means of the weaker rectovaginal septum (Moore 1992:291).

The rectum rests on musculoskeletal structures such as the anterior three sacral vertebrae, the coccyx, and the anococcygeal ligament. It is loosely attached to the sacrum by a fascial sheath that surrounds it. The PR muscle produces the 90 degree angle where the rectum turns postero-inferiorly to become the anal canal. The anal canal terminates posterior to the perineal body, and three to four centimetres antero-inferior to the tip of the coccyx. The most terminal part has a distensible anterior dilation, the rectal ampulla, to hold the faeces before defecation. The levator ani muscles, which meet at the anococcygeal ligament, are important for the support of the rectal ampulla. Laterally to the middle part of the rectum, a condensation of the endopelvic fascia exists, known as the rectal ligaments (Baggish & Karram 2011:18; Moore 1992:291).

Hypothesis 4 (relate to objectives 1.6.1.1 and 1.6.1.2)

The muscles, such as the levator ani, can therefore contribute to dynamic as well as static support of the pelvic organs. The dynamic support is provided by means of muscle activity, and the static support by means of the effect of the muscle activity on the connective tissue (such as ligaments and fascia) to which it is connected.

Connective tissue, such as the fascia covering the PFM, is continuous with the visceral fascia covering the pelvic organs. As mentioned before, the visceral fascia is thickened laterally to become the transverse cervical, the cardinal, and the uterosacral ligaments, suspending and supporting the pelvic organs (Bo 2004:457; Janda *et al*. 2003:749; Moore 1992:259). The visceral fascia binds the viscera to the parietal pelvic fascia, which lines the pelvic cavity (Bo *et al*. 2007:234; Moore 1992:259).

The parietal fascia of the abdominal and pelvic cavities is continuous (Figure 10). The fascial connection between the pelvis and abdomen is important to consider when investigating the role of the abdominal muscles and motor control in the pelvic support system. The parietal fascia extends onto the superior surface of the pelvic diaphragm, from where it passes to the pelvic viscera to become continuous with the visceral fascia. In addition, the parietal fascia covers the pelvic surfaces of the obturator internis muscle (obturator fascia), piriformis, coccygeus, sphincter urethra, and levator ani muscles. The obturator fascia also fuses with the psoas fascia and the levator ani muscles, where the latter attach to the tendinous arch (Bo *et al*. 2007:234; Moore 1992:259-261).

Both surfaces of the levator ani muscles are covered with fascia from the pelvic diaphragm. The superior lining, namely the superior fascia of the pelvic diaphragm, attaches to the pubis, the bladder neck, the vagina and the rectum. The fascia at the bladder neck forms the cordlike pubovesical ligaments, which also attaches to the vagina. The inferior lining, namely the inferior fascia of the pelvic diaphragm, is continuous with the obturator internis muscle and the EAS (Bo *et al*. 2007:234; Moore 1992:259-261).

Anatomically the pelvic viscera, ligaments, and PFM are all connected by means of connective tissue, which includes a continuous layer of fascia. This supports the tensegrity model of movement dysfunction, where disturbance of one small component by injury or dysfunction may lead to failure or compensation by another (Comerford *et al*. 2005:3-10).

Hypothesis 5 (relate to objectives 1.6.1.1 and 1.6.1.2)

Referring back to Figure 2 (see 1.3), namely the neuro-musculoskeletal control system, the discussion of the anatomy supports the hypothesis of the model where the connective tissue lies central to the whole system, connecting all the neuro-musculoskeletal components. Failure of the connective tissue at any level may contribute significantly to failure of the support mechanism of the pelvic organs.

2.4 A BIOMECHANICAL AND ANATOMICAL PERSPECTIVE OF SURGICAL MANAGEMENT OF PELVIC ORGAN PROLAPSE

Following on the above discussion on the interconnection between the fascia and the muscular and visceral structures in the pelvis, it seems appropriate to continue with a discussion on how these structures are affected during pelvic floor reconstructive surgery.

Indications for surgery include ineffective conservative treatment, symptomatic stage II prolapse where surgery may relieve symptoms, and stage III to IV prolapse (Cronje 2011:502). Other factors such as medical condition and age, the patient's choice of treatment, the surgeon's preference and capabilities, the patient's general health, the presence or absence of urethral hypermobility or pelvic floor neuropathy, the presence of other pelvic floor conditions, and a history of previous pelvic surgery are also taken into account (Maher *et al*. 2007:2).

The aims of surgery in POP remain an integral part of the decision-making process. These include the restoration of normal vaginal anatomy, and the restoration or maintenance of normal bladder, bowel, and sexual function, as these are the main aspects affecting QOL (Maher *et al*. 2007:3). However, the anatomical correction itself is likely to influence bladder, bowel, and sexual function in unpredictable ways, depending on the type of operation (Maher *et al*. 2007:15).

Pelvic floor reconstructive surgery can be done vaginally or abdominally. Vaginal approaches include anterior or posterior vaginal wall repair (with or without mesh), sacrospinous colpopexy, paravaginal repair, perineal body repair, and the STARR procedure. Abdominal approaches include sacral colpopexy, paravaginal repair, uterosacral ligament plication, and posterior vaginal wall repair. The abdominal approach can be through an open incision or laparoscopy (Maher *et al*. 2007:3). In our local unit, a rectal mobilisation with rectopexy is done at the time of sacrocolpopexy to eliminate an enterocele.

Abdominal incisions can further be divided into midline and transverse incisions. Transverse incisions can involve the splitting or cutting of the muscles. With the Maylard incision the fascia of the rectus abdominus muscle is cut transversely (including a portion of the external obliques aponeurosis), as well as in the midline between the two recti. The Pfannenstiel incision is similar to the Maylard incision, but is continued upwards, even to the level of the umbilicus. The rectus muscles, during this procedure, are separated vertically in the midline, and the pyramidalis muscles are also cut in the midline down to the level of the symphysis pubis. The Cherney incision is made one centimetre lower than the Maylard incision. The rectus sheath is opened transversely and the rectus muscles are divided transversely from their insertion onto the symphysis pubis. The incision may extend laterally through the aponeurosis of the external obliques muscle and the rectus may be freed upward. The Kustner incision differs from the above since the transverse incision is made through skin and subcutaneous tissue only. The fascia is then opened along the linea alba, the rectus muscles is separated vertically, and the pyramidalis muscle is cut (Baggish & Karram 2011:161-172). The Pfannenstiel incision is the most popular.

The midline incision is vertical, starts at the level of the umbilicus, and is carried as a straight line to the symphysis pubis. The rectus sheath is opened vertically, the left and right rectus muscles are separated caudad to the level of the pyramidalis muscles, and the pyramidalis muscles are cut in the midline down to the upper edge of the symphysis pubis (Baggish & Karram 2011:173).

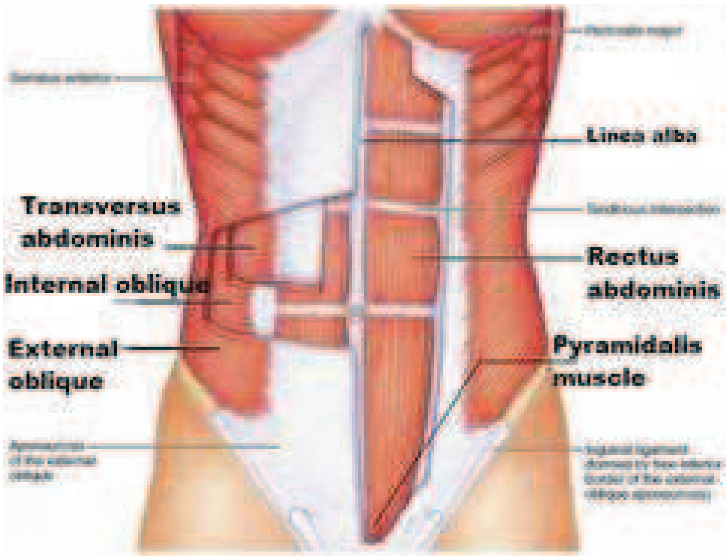


Figure 11. Anatomy relating to the midline incision (https://o.quizlet.com/OgchdJV7e6ukihvgDsZWGg_m.jpg).

It is important to consider these incisions' effect on connective tissue and the integrity of the muscles involved (global and local abdominal muscle stabiliser function) (Figure 11). Above the arcuate line, the anterior rectus sheath contains fascia from the internal obliques (IO) and external obliques muscles, while the posterior sheath contains fascia from the IO and TrA muscles. Below the arcuate line, the anterior rectus sheath contains fascia from the IO, external obliques, and TrA muscles. The posterior sheath below the arcuate line is very thin and contains only fascia from the TrA muscle (Baggish & Karram 2011:152). The surgery itself therefore leads to anatomical disruption and dysfunction of the motor control system (see 1.3 and 1.4, Figure 2 and Figure 3).

Laparoscopic surgery is less invasive and causes less disruption of the musculature. In laparoscopic procedures, a small incision is made intra-umbilically for the placement of the primary trocar. Secondary trocars are placed lateral to the rectus abdominus muscle or suprapubic (Baggish & Karram 2011:1294-1296). Although there is less disruption of the abdominal musculature, there is still pain and inflammation present post-surgically. The consequences of pain and inflammation in regard to motor control are shown in Figure 12.

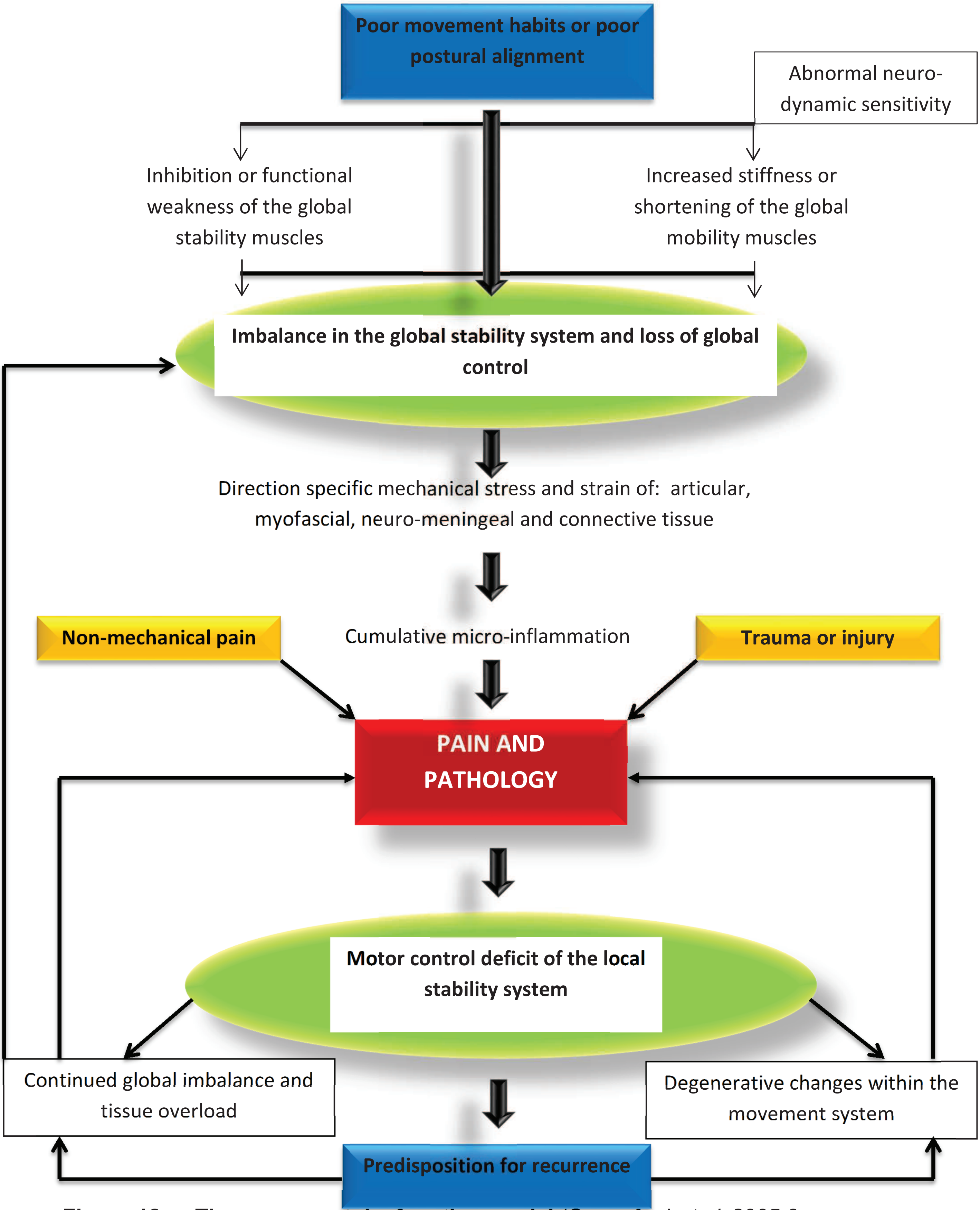


Figure 12. The movement dysfunction model (Comerford *et al.* 2005:3-10).

As the surgical procedure of pelvic floor reconstructive surgery progresses (abdominally, laparoscopic or vaginally), more tissue may be affected during the procedure, which can also affect the fine balance of motor control. Some of these aspects/procedures applicable to this study are briefly described below.

2.4.1 Abdominal approaches

2.4.1.1 Sacral colpopexy

This procedure has been advocated as an effective treatment for uterovaginal prolapse and vaginal vault prolapse. During this operation the vagina is suspended to the sacral promontory. Natural materials (such as fascia lata or rectus fascia) or synthetic materials can be used for grafts (Baggish & Karram 2011:505). Surgical procedures performed in this study made use of synthetic materials such as polypropylene mesh.

When the vaginal vault only is suspended to the sacrum by means of mesh, it supports the vaginal vault but leaves room distally for the development of anterior and/or posterior vaginal wall prolapse (cystocele, rectocele, enterocele). However, the more the anterior and posterior vaginal walls are covered by mesh, the lower the incidence of subsequent recurrent prolapse (Cronje 2013:45-48). With the mesh fixed only to the vault, the incidence of recurrent prolapse was 23%; when it covered the full vaginal length, the recurrence rate declined to 7%.

A laparotomy is performed by means of a midline or low transverse incision. If the uterus is still present, a hysterectomy should be performed. Dissection includes incision of the peritoneum over the anterior and posterior vaginal wall. The graft is fixed by means of sutures which are placed through the full thickness of the posterior and sometimes anterior vaginal wall. The graft is then fixed to the carefully dissected anterior sacral longitudinal ligament, over the sacral promontory (Baggish & Karram 2011:505-511).

2.4.1.2 Paravaginal repair

The aim of a paravaginal repair is to re-attach the anterior lateral vaginal sulcus with its fascia bilaterally. Dissection is therefore via the retropubic space up to the ischial spine to reach the arcus tendinous fasciae pelvis and the obturator internus muscle. Stitches are placed through the underlying muscular tissue and the full thickness of the vagina and the pubocervical fascia, into the arcus tendineus fasciae pelvis or the obturator internus fascia. The most distal suture should be placed into the pubourethral ligament (Baggish & Karram 2011:427).

2.4.1.3 Uterosacral ligament plication

This repair is done according to the assumption that the uterosacral ligaments break at certain points in cases of uterovaginal prolapse or post-hysterectomy vaginal vault prolapse. To repair this, a ridge is created by placing permanent sutures to plicate the ends of the uterosacral ligaments. Sutures are placed through the ridge of the uterosacral ligaments, the rectovaginal fascia, the vaginal vault, and the pubocervical fascia to suspend the prolapsed vagina to the uterosacral ligaments. This method also creates continuity between the pubocervical fascia and the rectovaginal fascia (Baggish & Karram 2011:501).

2.4.1.4 Posterior vaginal wall repair

A poorly-researched aspect of surgery for POP is rectal mobilisation with rectopexy. The rectum is elevated and fixed to the mesh (at the time of sacrocolpopexy) or directly to the sacrum. Since an enterocele develops between the vagina and the rectum, this procedure is meant to close this defect. Some surgeons also shorten the recto-sigmoid colon for this purpose, but there is no support in the literature for this procedure.

The description of the repair of the pelvic organ support indicates that other important mechanical support mechanisms, such as the fascia and connective tissue, which are all continuous between the pelvic walls and the musculature, are affected during surgery. The difference between abdominal and vaginal surgical approaches, from a motor control point of view, is that less of the stabiliser muscles will be affected during vaginal surgery when compared to an abdominal approach.

2.4.2 Vaginal approaches

No entering incision is necessary in the case of a vaginal procedure to reach the vaginal walls where the surgery is indicated.

2.4.2.1 Anterior vaginal wall repair

The midline repair (for a midline defect in the anterior vaginal wall) involves the plication of the layers of the vaginal musculature and pubocervical fascia in order to reduce or support the prolapsed bladder. The midline incision may extend from the apex of the vagina up to the level of the proximal urethra at the level of the inferior pubic ramus. One to two rows of stitches are placed in the musculature of the vaginal wall and the pubocervical fascia to restore the necessary support. The repair may be augmented by laterally anchoring a mesh or graft over the midline repair, or by anchoring it to the inside of the anterior vaginal wall (Baggish & Karram 2011:648-657).

2.4.2.2 Paravaginal repair

The paravaginal defect, defined as a defect of the anterior vaginal wall, is a bilateral detachment of the vagina from the lateral pelvic walls. With the vaginal approach, the dissection between the bladder and the vagina extends up to the inferior pubic rami until the retropubic space can be reached. A midline plication may be performed, but the vagina is also attached to the arcus tendinous fascia pelvis or the fascia of obturator internus muscle by means of sutures. This repair is therefore three-pointed: there is closure between the vaginal epithelium, the vaginal musculature and endopelvic fascia, but also at the lateral pelvic side wall (Baggish & Karram 2011:657).

If only strengthening of the paravaginal support is required, a two-point closure may be performed. This entails suture of the fascia to the upper part of the anterior vaginal wall. Surgeons may include the inside lining of the vaginal wall, but this may lead to a scarred, foreshortened anterior segment and a possibility of post-operative pain (Baggish & Karram 2011:657).

2.4.2.3 Posterior vaginal wall repair

Associated with varying degrees of anterior or vault prolapse are defects of the posterior vaginal wall, commonly due to an enterocele and/or rectocele.

The repair of an enterocele includes a midline incision through the vaginal epithelium over the enterocele and a dissection of the epithelium away from the peritoneal sac. Closure involves re-approximating the vagina with the fascia and sutures which incorporate the uterosacral ligaments (Baggish & Karram 2011:669).

Repair of a rectocele involves dissection of the posterior vaginal wall off the anterior rectal wall. Vaginal epithelium may be removed in the midline. Closure involves the re-approximation of the edges of the defects (connective tissue) by means of sutures. Should a relaxed perineum be identified, reconstruction of the perineal body may accompany the posterior vaginal wall repair (Baggish & Karram 2011:669).

2.4.2.4 Perineal body repair

The perineal body consists of the junction of the rectovaginal fascia to the anal sphincter, the anal sphincter itself, the superficial and deep transverse perineal muscles, and the bulbocavernosus muscles. The levator ani muscles insert lateral to and into the anterior anal sphincter, whereas the superficial perineal muscles contribute minimally to the perineum. The bulk of the perineal body consists of the anterior external anal sphincter. A perineorrhaphy involves the reconstruction of these components (Baggish & Karram 2011:669, 959).

Reconstructive surgery to the perineal body is usually indicated in patient cases of dyspareunia and the formation of excessive scar tissue after tearing (childbirth), excessively tight closure of an episiotomy, scar formation due to breakdown of an episiotomy, infection or inflammation, faulty perineal repair, trauma, ulcer formation, burn scar formation, chronic infection, and atrophy. The restoration of normal anatomy and physiologic function is the primary goal of perineal surgery (Baggish & Karram 2011:959).

Incisions are made across the posterior vaginal wall and the plane of dissection is the fascia between the anus and the vagina, and the fascia underlying the vestibule and perineum. After dissection the vaginal fascia is again sutured to the fascia underlying the perineal skin. In cases where muscle mass is plicated across the midline, it might create an unnatural hump. A large number of sutures may also cause an inflammatory response, diminish the blood supply to the epithelium, and result in scar tissue formation (Baggish & Karram 2011:959). The latter may therefore lead to pain and also inhibition of normal muscle function (Figure 12).

In the uro-gynaecological unit of Universitas Hospital in Bloemfontein, a new form of posterior repair has been developed and was used in this study. Through a midline incision in the posterior vaginal wall, the rectovaginal space is opened and the rectum (rectocele) exposed. Distal to the PR muscle, the pararectal spaces are opened for placing the sutures for the perineal body repair (see below). The rectocele is reduced and eliminated by a series of longitudinal sutures in and out of the rectal wall, without perforating it. When these sutures are tied, the rectocele is compressed in a zig-zag fashion from top to bottom (proximal to distal). Thereafter three stitches are placed on each side into the deep part of the external anal sphincter and tied in the midline anteriorly to the anal canal. This is the perineal body repair. By opening the pararectal spaces, perforation of the anal canal is prevented. This method appears to be superior to the traditional posterior repair (unpublished data).

2.4.2.5 Sacrospinous ligament suspension

This procedure is used to suspend the apex of the vagina. The technique firstly involves a downward traction on the apex of the vagina to determine the extent of the prolapse and the associated pelvic support defects. The vaginal apex is then reduced to the sacrospinous ligament intended to be used. If associated with an enterocele, the upper part of the posterior vaginal wall is incised, the enterocele sac mobilised off the vaginal apex, entered, and excised. The next step would be to enter the perirectal space and identify the coccygeus sacrospinous ligament. Two sutures are then passed through the ligament by using one of two techniques, namely a long-handled Deschamps ligature carrier and nerve hook, or the Miyazaki technique. The stitches are then brought to the apex of the vagina by bringing the apex to the surface of the ligament complex. After placement of the stitch in the ligament, it is sewn into the full thickness of the fibromuscular layer of the under surface of the vaginal apex. Traction of the free end of the suture then pulls the vagina into the muscle and ligament (Baggish & Karram 2011:695-703). A second technique could also be used to bring the stitches to the apex, especially in cases where the vaginal wall is thin or a greater vaginal length is required. This technique differs from the latter in that both ends of the sutures are passed through the vaginal epithelium (Baggish & Karram 2011:703).

Sacrospinous ligament suspension is very popular due to its simplicity and low morbidity. However, the disadvantages of the procedure are significant. Firstly, it pulls the vaginal vault posterior. Secondly, due to the sacrospinous ligament being approximately at the same height as the vaginal vault, the suspension effect of this procedure is only moderate. Lastly, this procedure also allows the opportunity for the development of anterior vaginal prolapse (cystocele) due to the lack of support in that area.

Hypothesis 6 (relate to objectives 1.6.1.1 and 1.6.1.2)

It is evident from the above descriptions that disruption of the fascia and musculature, contributing to normal motor control and support of the pelvic viscera, may lead to decreased function and coordination of the neuro-musculoskeletal system immediate post-surgery. Due to insufficient evidence, it is not clearly understood whether normal healing would be sufficient to return the tissue to its pre-operative state and motor control function. However, pre-operatively it is assumed that the patient has already decreased PFM function and motor control in most cases of POP. Should the tissue not return to its pre-operative state, the motor control and PFM function could be speculated to be worse post-operatively due to suboptimal healing, therefore contributing to a poor surgical outcome.

2.5 RELATING BIOMECHANICS AND MOTOR CONTROL TO PELVIC ORGAN PROLAPSE AND SURGERY – AN INTEGRATED DISCUSSION

The central concept complicating the interpretation and literature discussion of this study is the connection between the fascia and muscular structures (soft tissue) in the pelvic region, as described by Haderer *et al*. (2002:245):

"*The complicated fusion of fascial layers and muscle fibres may be explained by the development of these structures from the same embriological tissue. They should thus rather be regarded as extensions of a single entity.*"

Referring back to Figure 3 (see 1.4), the interpretation within this thesis will be approached in terms of the role of the connecting fascia providing myofascial force transmission, proprioceptive feedback for movement control, and thus the role it plays in pelvic organ support, movement and stability (Kumka & Bonar 2012:186).

2.5.1 The biomechanical properties of soft tissue in the healing process

The soft tissue in the body demonstrates a dynamic ability to cope with tension forces, such as the ligaments, fascia, and muscle involved with pelvic organ support. During surgery the tensile strength of the supporting fascia and muscle is compromised due to incision (Hunter 1994:15). Disruption of the connection between the fascia and muscle may lead to loss of normal mechanical function of the levator ani muscle (Bo *et al*. 2007:28).

It has been suggested that the pelvis should be considered as a unit when referring to the support of the pelvic viscera. The PFM, the ligaments and the fascia form a supportive system for the pelvic viscera. This mechanism and interaction has also been referred to as the 'boat in the dry dock theory' (Figure 13). The ship represents the pelvic organs, the ropes the ligaments and fasciae, and the water the support of the PFM (Bo *et al*. 2007:1).

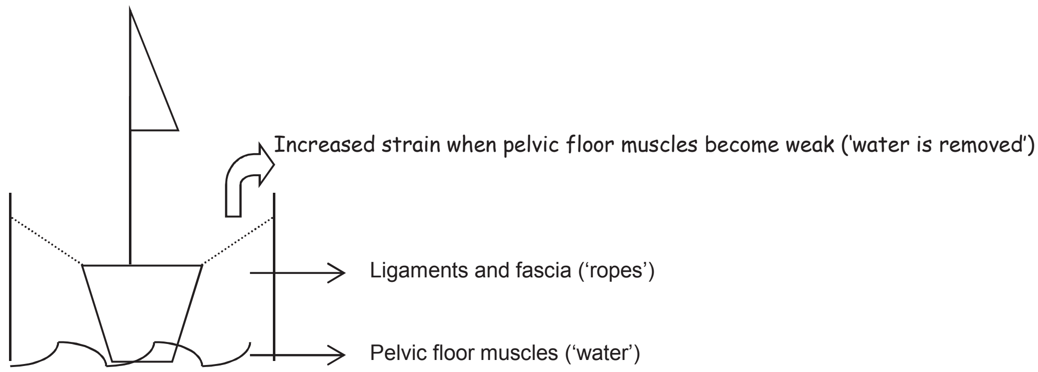


Figure 13. The 'boat in the dry dock' theory.

When the PFM functions normally, the supporting ligaments and fascia should be under normal tension. When either one of these supporting structures are damaged the tension will increase on the functioning or intact structure. Over time the connective tissue in the functioning or loaded structures will be stretched. POP (especially the more severe stages) is of such a nature that the viscera, due to its movement, causes a loading and unloading cycle on the supporting fascia, ligaments, and muscles. The connection among these structures was discussed in section 2.3. Due to the visco-elastic nature of the connective tissue, it may lose some of its ability to store energy due to the phenomenon of hysteresis (Hunter 1998:4). Should the tissue be overloaded eventually or damaged, the tissue may fail, with consequent POP or other associated symptoms such as incontinence (Bo *et al*. 2007:2, 26). The loading and failure of the tissue can be depicted by the stress strain curve (Figure 14) (Hunter 1998:4).

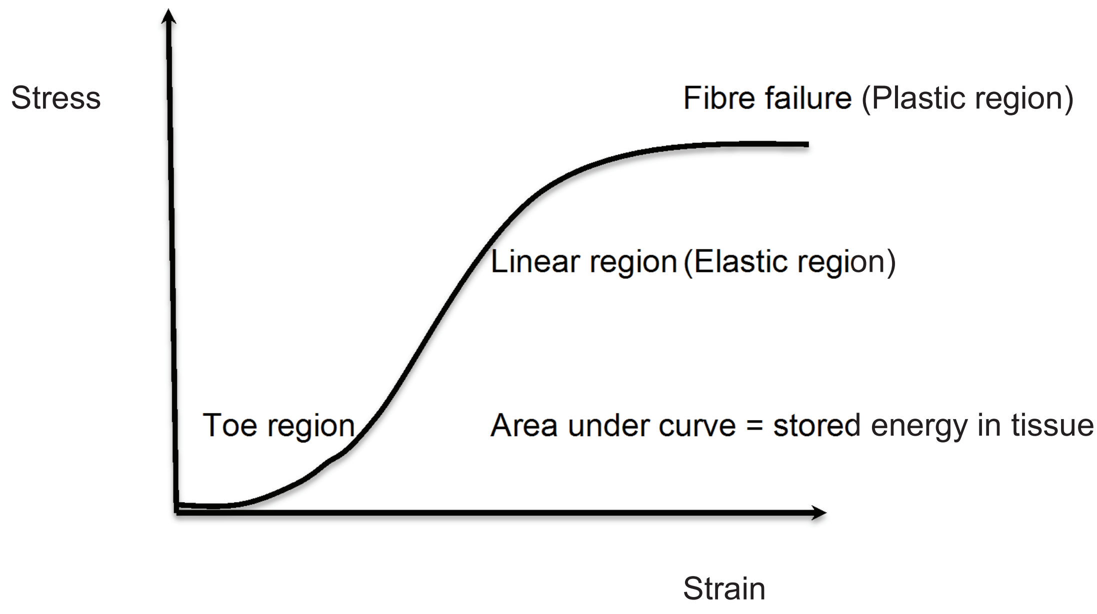


Figure 14. Stress strain curve (Hunter 1998:4).

Muscle injury and denervation (associated with childbirth) have been indicated as possible causes for the development of pelvic floor laxity (Reay Jones *et al*. 2003:466). Considering the effects of pain, swelling, and inflammation on the neuromuscular tissue (as explained in 2.4 above), similar consequences might be considered post-reconstructive surgery (Figure 12). Surgery interrupts fascia and may damage muscle which may affect the normal anatomy of the pelvis. It may also affect hormonal influences, or diminish the nervous and vascular supply of the region, which may affect normal PFM function (Haderer *et al*. 2002:236).

The delayed onset of symptoms after any PFM injury may relate to progressive PFM weakening, resulting from connective tissue degradation. The fascial sheet that overlies the PFM condenses to form ligaments within the looser areolar tissue. The resilience of the pelvic connective tissue can firstly be affected by the fact that repairing connective tissue after injury involves a change from strong type I to weaker type III collagen, and secondly, the decrease of the collagen content of cutaneous connective tissue after menopause (Reay Jones *et al*. 2003:466). The controversial role of the abdominal muscles and the effect they could have on the pelvic connective tissue should not be discarded and should also be considered. This will be dealt with in section 2.5.2.

Reay Jones *et al*. (2003:266-270) investigated specimens of uterosacral ligaments to determine pelvic connective tissue resilience in their study. They found a fourfold reduction in UsR in women with symptomatic uterovaginal prolapse between the ages of 40 and 80 years. POP cannot occur without the stretching of the attached connective tissue beyond its plastic limit, therefore stretching (and POP) should be associated with a loss of resilience. The study also indicated that variation in pelvic connective tissue resilience had little influence on pelvic visceral movement where pelvic muscles were preserved - indicating the possible importance of PFMT restoring the normal mechanical properties of the connective tissue (Reay Jones *et al*. 2003:266-270).

However, other factors such as circulating oestrogen levels may also influence pelvic connective tissue resilience. Hormone replacement therapy inhibits smooth muscle and collagen degradation in postmenopausal women, and might attenuate the menopause-associated reduction in pelvic connective tissue resilience. Oestrogen and progesterone receptors have been found within the uterosacral ligament. Reay Jones *et al*. (2003:470) found decreased receptor density and UsR with menopause, but there was no relationship between the oestrogen and progesterone density and UsR. However, UsR was halved in women with a history of vaginal delivery. The UsR was reduced by 36% with menopause, and the findings suggested that the smooth muscle and collagen were depleted equally within the uterosacral ligament after menopause. The decreased resilience was rather explained by qualitative changes in the collagen structure, than the depletion of the smooth muscle and collagen (Reay Jones *et al*. 2003:470).

To reach optimal quality collagen structure and tensile strength after injury, the tissue has to go through four (or three, without the inclusion of the *injury* phase) different phases of healing (Figure 15). Although the tissue has to go through all the phases for optimal healing, the time and length of each phase may differ depending on various factors (Hunter 1998:5). Intrinsic factors (e.g. age, gender, somatotype, personality, posture, previous treatment, genetic factors), extrinsic factors (e.g. type of force causing the injury, environmental factors, equipment), and task-related factors (e.g. adequate coaching and instruction, exercise intensity) should all be considered when assessing the progression of the healing process. The *inflammatory (lag) phase* usually has a duration of approximately four to six days, the *fibroblastic (regeneration) phase* a duration of two to three weeks, while the *remodelling phase* may continue for between six and twelve months (Hunter 1994:16-17).

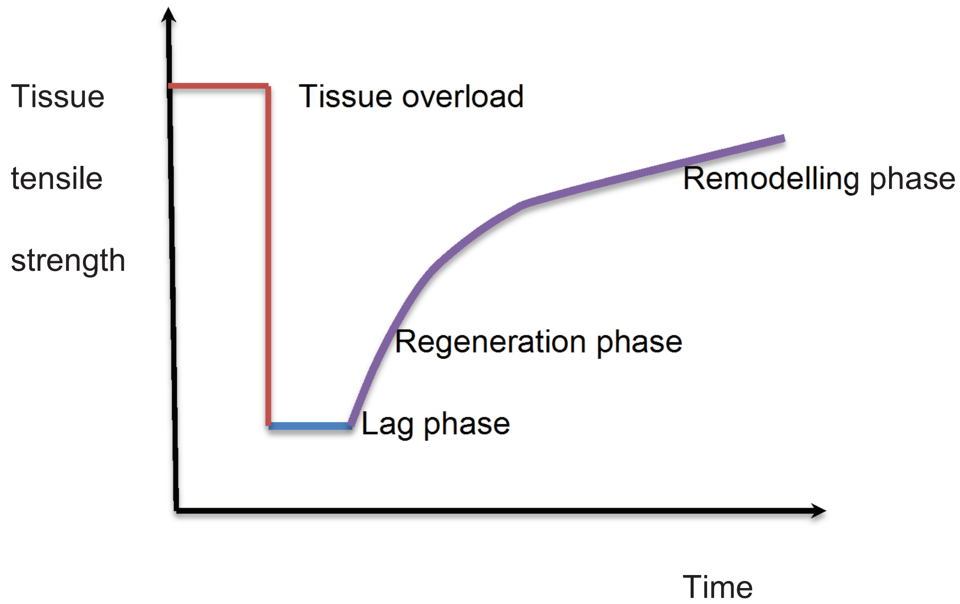


Figure 15. Hypothetical model of the phases of healing (Hunter 1998:5).

During the first phase, which is the *injury phase*, there is a sudden decrease in the tissue's ability to withstand tensile stress (Figure 15). This decrease depends on the area and degree of tissue damage, which may range from bruising to total obliteration of the tissue in the case of surgery. During this phase it is important to protect the affected tissue from any further damage. This should coincide with treatment decisions immediately post-operatively. The damaged tissue must be protected during treatment, but further damage to the body must also be prevented by increasing circulation and chest expansion to prevent post-operative complications (Hunter 1994:16).

Following the injury, the tissue enters a second phase of inflammation, namely the *inflammatory* (lag) phase, which may last between four and six days. During this phase the fragile wound is stabilised by a weak fibrin network, which may easily be disrupted should too much tension be applied to the area (Hunter 1998:5). The goal of treatment should therefore be to preserve the soft tissue`s ability to shorten, broaden, and move in relation to the surrounding tissues, without disrupting the phagocyte activity and formation of the new collagen and capillaries. Care with intravaginal devices, which may stretch and disrupt the tissue, should therefore be taken immediately post-operatively. Active physiological contractions should rather be started as soon as possible in a shortened position (Hunter 1998:5; Hunter 1994:16).

As soon as the wound has been stabilised by the fibrin bond, the tissue enters the next phase of *regeneration*. This phase is characterised by collagen synthesis and the period of greatest increase in tensile strength. However, the strength of the healing collagen is only 15% of the tensile strength of the surrounding tissue. Should the tissue not be carefully tensioned during this period, the formation of randomly orientated collagen fibres will only increase structure, but not the capacity of functional tensioning. Tensioning of the tissue during this phase will increase collagen synthesis, promote functional collagen alignment, and increase the collagen cross linkages to become more stable. Normal physiological movement of the tissue, directed at the site of dysfunction, is an example of how careful tension can be applied during treatment in this phase. However, too vigorous mobilisation and exercise should still be avoided (Hunter 1998:6; Hunter 1994:16).

During the next phase, the *remodelling* phase, the applied tension to the affected area during treatment may be increased to mobilise the intra- and extra-molecular cross linkages that improve the tissue’s tensile strength. Inadequate mobilisation of the soft tissue during this phase may lead to the tissue becoming stiff and less able to tolerate the demands of functional loading. Functional training implies that the body must be able to perform optimally in real world movement patterns. This implies progressive tensioning of the tissue during treatment to restore the mechanical properties to a level compatible with the potential imposed demands. The vigour of the exercise and mobilisation must be adapted according to the degree of recovery. The collagen only reaches full tensile strength at between six to twelve months. The latter motivates the continuing of training for strength, endurance, and coordination for a period of at least six months (Hunter 1998:5-6). Only when the tensile strength of the healing tissue is sufficient to withstand the normal stresses imposed on it, the patient is fit to resume her activities of daily living (ADL) (Hunter 1994:15).

The importance of the healing process, and the place of appropriate treatment during which high quality collagen structures and normal tensile strength are restored in damaged tissue, is evident from the above discussion. It has therefore been suggested that more than surgical repair of fascia and ligaments is required to provide long-term support of and prevention of the recurrence of POP (Bo *et al.* 2007:243). In the case of pelvic floor reconstructive surgery, it might be difficult to optimally reach all tissue affected during the surgery due to its anatomical location.

Hypothesis 7 (relate to objectives 1.6.1.2-1.6.1.4)

However, due to the connection between the fascia, viscera and muscle, restoration of the mechanical and supportive properties of the pelvic floor muscles and fascia, as well as the abdominal muscles, may lead to improved mechanical properties of the more distant fascial, ligamentous, and visceral structures.

2.5.2 The motor control system: aspects and interactions relevant to pelvic organ prolapse

2.5.2.1 Motor control and pelvic organ prolapse

The optimal outcome of the healing process following surgery should be restoration of the supportive role of the PFM in the prevention and treatment of POP. The basic mechanisms to support such restoration are (Bo *et al*. 2007:241):

- Contraction of the PFM to prevent descent during increases in IAP.
- Tone and structural support which prevents descent of the pelvic organs by closing the levator hiatus (LH) and reducing the tension on the ligamentous support. Damage or weakening of the pubovisceral/PR muscle will lead to an inability of the muscle to keep the hiatus closed.

Reducing the prolapse itself will also aid in the restoration of the PFM function. The prolapse distends the hiatus and stretches the tissue, which leads to the weakening of the PFM. Eliminating these tensile forces by means of conservative or surgical treatment will therefore lead to improved muscle strength due to the change in muscle length (Clark, Brindcat, Yousuf & DeLancey 2010:595e17).

Another mechanism affecting the PFM strength and length, though still controversial, is the role of the abdominal muscles in coordination with the PFM to help control the IAP. The abdomino-pelvic cavity is a flexible, pressurised cylinder. IAP is generated and controlled by the muscles surrounding the cylinder, namely the PFM, the diaphragm, the abdominal wall and the posterior spinal muscles. All of these muscles have the potential to influence the activity of the PFM and the PFM position (Thompson, O`Sullivan, Briffa & Neumann 2006b:148). The contraction of the PFM during increases in IAP relies closely on the interaction between the abdominal muscles, the diaphragm, and the multifidus muscle, in other words the motor control mechanism. The function, such as tone and structural support of the PFM, can be more specifically defined in terms of the tonic and phasic activity of the muscle, the endurance and strength of the muscle, the amount of muscle bulk, and the movement of the muscle to decrease the urogenital hiatus and increase the tension in the fascia and ligamentous structures.

The type II fibres are activated during an increase of IAP, but in this case to counteract the downward displacement of the muscle and associated structures such as the bladder neck (Shafik *et al*. 2003:309). In order to increase the functional capacity of the type II fibres, strength and power training, with resultant muscle hypertrophy (see 2.8.1.3) can provide additional structural (passive) support (Bo 1995:284).

The function of the PFM is closely related to the morphological characteristics of the muscle and how it can be affected by rehabilitation. The morphologic alteration of the levator ani muscle in POP is unclear. A study by Zhu *et al*. (2005:401-403) demonstrated by means of biopsies that the rate of occurrence of striated muscle in the levator ani muscle differs between patients suffering from stress urinary incontinence (SUI) and POP, when compared to a control group without PFD. They found a 26.7% occurrence of striated muscle in the SUI group, compared to an occurrence of 100% in the control group not suffering from any PFM dysfunction. No values were reported for the POP group. They reported a presence of 54.9 to 70.3% type I fibres in the control group and 29.7 to 45.1% type II fibres. It should however be noted that these results were only determined by investigating three control specimens, four specimens from patients with SUI and three specimens with POP. Other authors have made similar findings regarding the ratio of type I to type II muscle fibres in the PFM (Bo 1995:284).

Few studies have reported on both muscle thickness and strength of the PFM. The study by Morkved, Salvesen, Bo and Eik-Nes (2004:384-390) indicated a strong correlation between muscle thickness and muscle strength in a group of incontinent women. In general, an increased cross-sectional area of a muscle is strongly correlated with increased strength capabilities. However, in this study only the urogenital diaphragm part of the PFM was investigated, due to its function in continence. They found a significant difference in muscle thickness of 6.3mm in incontinent women, and a thickness of 8.2mm in continent women.

A more recent study investigated pubovisceral muscle thickness, endurance and strength and the association with the LH in women with POP, which is more applicable to this study. They found significant positive associations between pubovisceral muscle strength, thickness, and endurance. The LH was moderately negatively associated with strength and endurance (Braekken *et al*. 2013:1520). An interesting study by Quartly *et al*. (2010:313) pointed out that with increasing age, there is an increase in the proportion of type I fibres and thus the endurance capability, and a decrease in the proportion of type II fibres, meaning that the patient may struggle with quick, fast contraction of the PFM.

The type I fibres of the levator ani muscle are responsible for the maintenance of tone of the PFM to support the viscera (Shafik *et al*. 2003:309). It would seem that the muscles are more suitable for providing pelvic organ support by means of a stabilising function, due to the seemingly greater ratio of type I to type II fibres. The study by Shafik *et al*. (2003:311-313) indicated the presence of smooth muscle bundles in the levator ani muscle, which may be the reason for the resting electrical activity and tone. The EMG activity increased in response to an increased IAP and increased visceral weight, such as with obesity, intra-abdominal swelling (as may be a result of surgery), and pregnancy. This effect is probably mediated by the straining-levator reflex. However, a chronic increase in IAP or visceral weight (as might be the case in the presence of decreased connective tissue resilience), and therefore increase in EMG activity, may affect the muscle integrity or function adversely. It was not clear exactly how the EMG activity and muscle function correlate, so the author suggested that more studies of the EMG activity in PFM disorders needed to be performed to help prevent the harmful effects of PFM and abdominal dysfunction (Shafik *et al*. 2003:311-313).

Hypothesis 8 (relate to objectives 1.6.1.1-1.6.1.3)

It therefore appears that, according to available studies, increased muscle thickness, strength and endurance could possibly contribute to a decreased LH which will prevent descent of the pelvic organs. EMG activity of the PFM however seems to be more complicated to interpret, due to reactions to adverse effects, such as increased IAP, as well as positive effects, such as increased activation of motor units in response to muscle training and improved neuromuscular control.

The muscle activity of the PFM not only responds to changes in IAP, and should be further clarified. Hodges, Sapsford and Pengel (2007:368), as well as Neumann and Gill (2002:128), provided evidence that the coordinated functioning of the PFM, the TrA muscle and the diaphragm, contribute to both postural and respiratory functions. During tasks that challenge the spine in a sustained manner, such as repetitive limb movements, the tonic postural activity of the diaphragm and the TrA muscle were modulated phasically at the frequency of respiration and arm movements. PFM activity was coordinated in a similar manner (Hodges *et al*. 2007:368). PFM activity increased in advance to arm movements, and stayed tonically active, with bursts of increased activity in association with each arm movement, during repetitive arm movements (Hodges *et al.* 2007:365).

Activity of the abdominal muscles and the PFM was greatest during expiration, while the erector spinae muscle activity was greatest during inspiration. IAP also increased during inspiration. The PFM activity was not linked to the respiratory phase with the greatest IAP, but with the phase in which the abdominal muscle activity was increased. The PFM activity was thus initiated as part of the anticipatory postural adjustment associated with arm movement. The increase in PFM activity preceded that of the abdominal muscles, as well as the increase in IAP. The increased activity could therefore not be explained by a reflex response to stretching of the PFM secondary to an increase in IAP (Hodges *et al*. 2007:366, 368).

Feed forward activation has been indicated by EMG measurements for the PFM, the TrA muscle and the diaphragm, in response to an increase in IAP and rapid limb movement (Hodges *et al*. 2007:365-368; Neumann & Gill 2002:128-129). This suggests a neural pre-planning mechanism to activate the PFM prior to loading, and is an indication of the synergistic control of the muscles forming the abdomino-pelvic cavity. Pre-programmed postural adjustments are known to be controlled by multiple regions in the nervous system, including the motor cortex and pre-motor areas. The PFM receive corticospinal inputs, but it is unclear whether these are involved in the organisation of postural activity of the PFM. Nucleus retroambiguus, which contributes to control of IAP through inputs to the abdominal motor neurons, also innervates the motor neurons of the PFM (Brostrom, Jennum & Lose 2003:310). Multiple sources may thus contribute to the coordination of the postural activity of the muscles that surround the abdominal cavity. It might also provide an explanation for the controversial findings by different authors in the activation patterns and co-activation of the TrA and PFM, as discussed in 1.5.

Hypothesis 9 (relate to objectives 1.6.1.2 and 1.6.1.3)

The mechanisms of motor control, explained above, are in accordance with the accepted motor control mechanism, and may clinically implicate the importance of maintaining a "normal" IAP by coordinated muscle actions, and the inclusion of postural changes and normal functional movements of the limbs during the rehabilitation of PFM function. At the same time, the consequences of surgery should be considered, such as the effect of abnormal, compensatory postures and inhibition of the PFM and abdominal muscles (in the case of abdominal approaches) in the motor control mechanism.

2.5.2.2 Motor control, pelvic organ prolapse, and lumbo-pelvic pain

The same motor control mechanism, and the coordinated function of the same muscles as required for optimal PFM functioning, is also central to spinal stability and the etiology of low back pain (Deepak 2000:132). Although the etiology of low back pain is not known in most patients, a certain percentage of these patients may have sub-optimal neuromuscular control, especially under dynamic conditions (Pulkovski *et al*. 2012:756-757; Panjabi 2003:376; O`Sullivan, Twomey & Allison 1997:23). Smith, Russel and Hodges (2009:879) found in a longitudinal study (n=7499) that women with incontinence, gastro-intestinal problems such as constipation and other bowel problems, and breathing disorders (allergies and sinusitis) were more likely to develop low back pain. The presence of incontinence, gastro-intestinal problems, and breathing disorders was significantly related to the development of low back pain. Smoking, body weight, physical activity, mental health, stress, and pelvic surgery were however not significant predictors of the development of low back pain in their study (Smith *et al*. 2009:879). POP was not included as a variable in their study.

POP has traditionally been considered in the differential diagnosis of chronic pelvic pain and has been investigated by Heit, Culligan, Rosenquist and Scott (2002:23). Their descriptive study hypothesised that patients with the least and greatest amount of POP would have less pain (pelvic or lower back) than patients with a moderate amount of prolapse (due to the innervation being affected). The study, however, failed to indicate any significant association between POP and lower back/pelvic pain due to several limitations (Heit *et al*. 2002:27). Considering the motor control mechanism and its role in POP and lower back/pelvic pain, the researcher supports the conclusion of the study that POP itself may not be directly responsible or the cause of the pain associated with POP. The literature indicates that the neuro-musculoskeletal system's integrity and function must be taken into account when considering pelvic and lower back pain. This was illustrated by a study by Eliasson, Elfving, Nordgren and Mattson (2008:209) where they found lower back pain and PFM dysfunction to be risk factors for the development of UI.

Motor control of the lumbo-pelvic region must serve to move and control the spine with complex interactions between internal and external forces, and in a range of environments. The challenge is complicated by the fact that without the muscles, the spine and pelvis are structurally, inherently unstable (Hodges & Moseley 2003:362). The trunk muscles, which have been argued to play a major role in spinal and pelvic stability, are primarily the TrA muscle, the multifidus muscle, the PFM, and the diaphragm (Bystrom, Rasmussen-Barr & Grooten 2013:E350; Hodges & Gandevia 2000:972). The concept of different trunk muscles playing different roles in the provision of dynamic stability of the spine was proposed by Bergmark (1989:20). He hypothesised the presence of two muscle systems in the maintenance of spinal stability.

Firstly, the global muscle system consists of large, torque-producing muscles that act on the trunk and spine without being directly attached to it. These muscles include the rectus abdominus muscle, the external obliques abdominal muscle, and the thoracic part of the lumbar iliocostalis muscle. They provide general trunk stabilisation, but are not capable of having a direct segmental influence on the spine (Comerford & Mottram 2001b:16).

The local muscle system consists of muscles that directly attach to the lumbar vertebrae. These muscles are responsible for providing segmental stability while directly controlling the lumbar segments. The lumbar multifidus muscle, the TrA muscle, the posterior fibres of the IO muscle, the posterior psoas muscle, the diaphragm and the PFM form part of this local system (Sapsford 2004:4; Comerford & Mottram 2001b:16).

The dynamic local and global neuromuscular systems interact with intact passive structures such as ligaments and fascia. Transversely orientated muscles of the lumbopelvic region, such as the TrA muscle, the IO muscle, the piriformis muscle and the coccygeus muscle act to stiffen the lumbo-pelvic joint for weight-bearing. In particular, the TrA muscle stiffens the SIJ and increases IAP, thereby contributing to intervertebral stability (Hodges, Eriksson, Shirley & Gandevia 2005:1876).

The literature has suggested that the joint complex is one of the most important aspects responsible for optimal load transfer (stability) in the lumbo-pelvic region (Franke 2003:13-14). The four components responsible for stability are: form closure, force closure, neuromuscular control and factors associated with the awareness of emotions. The force closure depends on the transmission of forces from the force generated within the muscle, through the integrity of the ligamentous and fascial connections to the bony components. As indicated in the discussion on surgical approaches (see 2.4), it is clear that there could be a disturbance of this integrity, and thus IAP, post-surgery, due to the effects on the connective tissue system (see 1.4, Figure 3) (Stuge, Saetre & Braekken 2012:150; Whittaker 2004:45).

Increased activity of the PFM may be a compensation strategy for decreased pelvic stability, due to its contribution to force closure of the SIJ. Sustained contraction may lead to overload, and therefore altered timing and motor control of the muscles and also voiding dysfunction (Pool-Goudzwaard *et al*. 2004:570). Sustained contraction of the PFM may also pull the coccyx ventrally, leading to pain syndromes such as coccygodinia (Pool-Goudzwaard *et al*. 2004:570). The pain due to sustained contraction may lead to PFM descent, whereas contraction of the PFM also has the capacity to increase IAP. An increased IAP is related to increased spinal stiffness, but also to consequences such as POP (Pool-Goudzwaard *et al*. 2004:564-565).

IAP influences spinal stability via the production of an extensor moment, by exerting a force down on the pelvic floor and up on the diaphragm. Although the extensor moment does not necessarily increase stiffness, antagonist flexor and extensor moments increase trunk stability. The opposing extension moment from IAP and flexion moment from the abdominal muscle contraction may increase spinal stability and stiffness (Hodges, Cresswell, Daggfeldt & Thorstensson 2001:74). Hodges *et al*. (2005:1878) demonstrated that an increase in IAP increased the postero-anterior stiffness of the spine. The IAP may contribute to spinal stability and control of perturbations in multiple directions because of the fact that increased abdominal cavity stiffness may limit intervertebral translation and motion (Hodges, Cresswell & Thorstensson 2004:167; Hodges, Cresswell & Thorstensson 1999:74). The IAP may also prevent shortening of the abdominal muscles, thus maintaining the hoop-like geometry of these muscles around the abdominal cavity and their ability to generate tension. IAP is not elevated by the selective activation of the diaphragm in functional tasks. Abdominal and extensor muscles will be active as well. The stability and stiffness of the spine will be dependent on the net-effect of all the elements (Hodges *et al*. 2005:1879).

An increased IAP has been positively correlated with an increased intradiscal pressure. Harmful effects of an increased IAP also concern herniation of the borders of the abdominal muscles, the diaphragm, vaginal and rectal prolapse, and urinary incontinence. A study by Mens and colleagues (2006:627-634) indicated increased values of IAP (104-520N) in overweight patients during straining, vigorous work, and heavy exercise when compared to slim, healthy subjects. The load was also higher in people with pain, muscle fatigue, and distended abdomens (Mens, Van Dijke, Pool-Goudzwaard, Van der Hulst & Stam 2006:627-634). In an attempt to stabilise the spine, people are still sometimes taught the Valsalva manoeuver, which includes the co-contraction of mainly the global trunk stabilisers and mobilisers. However, this manoeuver has been shown to increase the intradiscal pressure and IAP, compared to co-contraction of the local stabilisers which barely increase the IAP, while controlling and stabilising intervertebral movement (Mens *et al*. 2006:628, 633).

Thompson, O`Sullivan, Briffa, Neumann and Court (2005:152) found more activity in the PFM than the other muscles surrounding the abdomino-pelvic cavity during a correct PFM contraction. This indicates the ability of a woman to isolate this contraction from the rest of the musculature during a voluntary contraction. At the same time, there was a significant increase in the activity of the IO muscles, more than in the activity of the more superficial abdominal muscles. The IAP increased with marginally when compared to the increase in IAP during the Valsalva manoeuver. These findings could suggest the beneficial effect of using the lower transverse abdominal wall and PFM to limit increases in IAP and thus intradiscal pressure pre- and post-operatively to limit the risk for POP and straining on the healing tissue post-operatively.

Sapsford *et al*. (2001:38) found an increase in PFM activity, measured by fine wire electrodes in seven subjects, with contraction of TrA, IO, external obliques, and rectus abdominus muscles. The opposite was also indicated, namely contraction of the PFM increased the activity of the abdominal muscles. The subjects found it difficult to perform a PFM contraction in a flexed position of the lumbar spine. A flexed lumbar spine position causes an increase in IAP, resisting the ‘lift’ of the PFM (Sapsford *et al*. 2001:38).

Flexion/extension positioning of the lumbar spine can be argued not to influence the activity of the TrA muscle significantly by altering the length-tension relationship. This argument is based on the fact that the fibres of the muscle are horizontally orientated (Sapsford *et al*. 2001:31). The findings of the latter study supported this hypothesis by indicating that the response of the abdominal muscles to contraction of the PFM was independent on the position of the lumbar spine. This highlights the viewpoint of functional loading, as suggested by the literature, to facilitate pre-activation and specificity (Jull *et al*. 2015:483-484).

The PFM can be defined as mainly local stabilisers having an anticipatory and non-direction specific activation (Comerford & Mottram 2001b:16-17). The CNS anticipates the spinal/pelvic loading and increases the activity of the local stabilisers. Again this may account for an increased EMG reading in some muscles as a compensatory response to poor spinal and pelvic stability. However, these muscles may lose their anticipatory response due to dysfunction, for example, directly after surgery, leading to dynamic instability. An individual`s ability to produce a voluntary, isolated muscle contraction of these muscles can be an indication of this ability to access the specific neurological pathways (Comerford & Mottram 2001b:16-17). Increased EMG activity of the PFM (e.g. increased resting tone) may therefore indirectly indicate poor pelvic or lumbar stability. This suggests the need for assessment of the abdominal and pelvic stabilisers when addressing the functional interpretation of the outcome measures regarding PFM.

Hypothesis 10 (relate to objectives 1.6.1.1-1.6.1.3)

Similar to the case of pelvic floor dysfunction and pain, the stabiliser muscles exhibit disturbed motor control patterns and changed physiological properties in individuals with low back pain (Hodges & Richardson 1996:2647). On the other hand, altered postural activity and morphological changes in these muscles are related to the development and the recurrence of low back pain (Cholewicki et al. 2005:2614). Pain may cause inhibition of the stabiliser muscles, and therefore is hypothesised to contribute to PFM dysfunction, such as POP and even incontinence (Comerford & Mottram 2001b:23).

2.5.2.3 Motor control, pelvic organ prolapse and continence

As previously mentioned, the role of the PFM is mainly to provide continence and pelvic organ support against gravity at rest, as well as with slow, rapid and unpredictable loading. These functions require the ability of the muscles to pre-activate prior to increases in IAP (Sapsford 2004:4). Functional tasks such as lifting, coughing, sneezing, nose blowing, laughing, and Valsalva recruit the PFM with the abdominal muscles to increase IAP, generate an expiratory force and maintain continence. If continence is to be maintained, the PFM complex must ensure urethral and anal closure, before the increase in IAP (Sapsford 2004:4).

The integral theory of continence states that POP and abnormal pelvic symptoms are mainly caused by connective tissue laxity in the vagina and its supporting ligaments. The three pelvic organs (bladder, vagina, and rectum) are suspended from the pelvic brim by three suspensory ligaments, namely the pubourethral ligament (PUL), the cardinal or uterosacral ligament, and the arcus tendineus fascia pelvis. The close link between these structures has been indicated in 2.3. Three directional muscle forces tension the organs to give them position, shape and strength. The forward forces act against the PUL, the backward force against the PUL and the perineal body, and the downward force against the uterosacral ligament. If any of these ligaments are lax or damaged due to surgery or injury, the muscle can neither open nor close the urethral or anal tubes (Petros & Woodman 2008:35, 37).

Urinary continence relies on the optimal function of two systems, namely the urethral support system and the sphincteric closure system. The structures which provide support for the urethra include a passive system (consisting of endopelvic fascia which is anchored to the arcus tendineus fasciae), an active system for this fascial hammock or sling (including the levator ani muscle), and the control system (including the pudendal nerve which innervates the levator ani muscle as well as the central control of reflex function between the detrusor muscle and the pelvic floor) (Ashton-Miller, Howard & DeLancey 2001:2) (see 1.3, Figure 2).

Various theories exist to explain UI/voiding dysfunction. The role that the PFM and the abdominal muscles can play, and the consequences of poor muscular and fascial functioning such as after surgery, may be depicted by the following explanation of (in)continence.

Hypothesis 11 (relate to objectives 1.6.1.1-1.6.1.3)

Relating to the neuro-musculoskeletal control mechanism (see 1.3, Figure 2), continence requires the interaction of anatomical systems, which include muscular, fibrous, and fascial systems. They provide the structure and support to keep the tissues in a normal functional relationship. Due to the close interaction between these systems, the failure of one may lead to the failure of one/all of the other components (Haderer et al. 2002:240).

Grewar and McLean (2008:375-376) described the integrated continence system that summarises the interaction of modifiable external factors, with the unmodifiable (relating to Physiotherapy) structural systems (Figure 16). Deficits in the modifiable external factors may strain the system and lead to the development of UI. These modifiable factors may include motor control (PFM dysfunction, postural and movement dysfunction, low back and pelvic pain, breathing disorders), musculoskeletal factors (decreased range of motion, muscle strength, and muscle endurance), and behavioural factors (chronically elevated intra-abdominal pressure, physical inactivity, abnormal fluid intake and voiding patterns, poor psychosocial health).

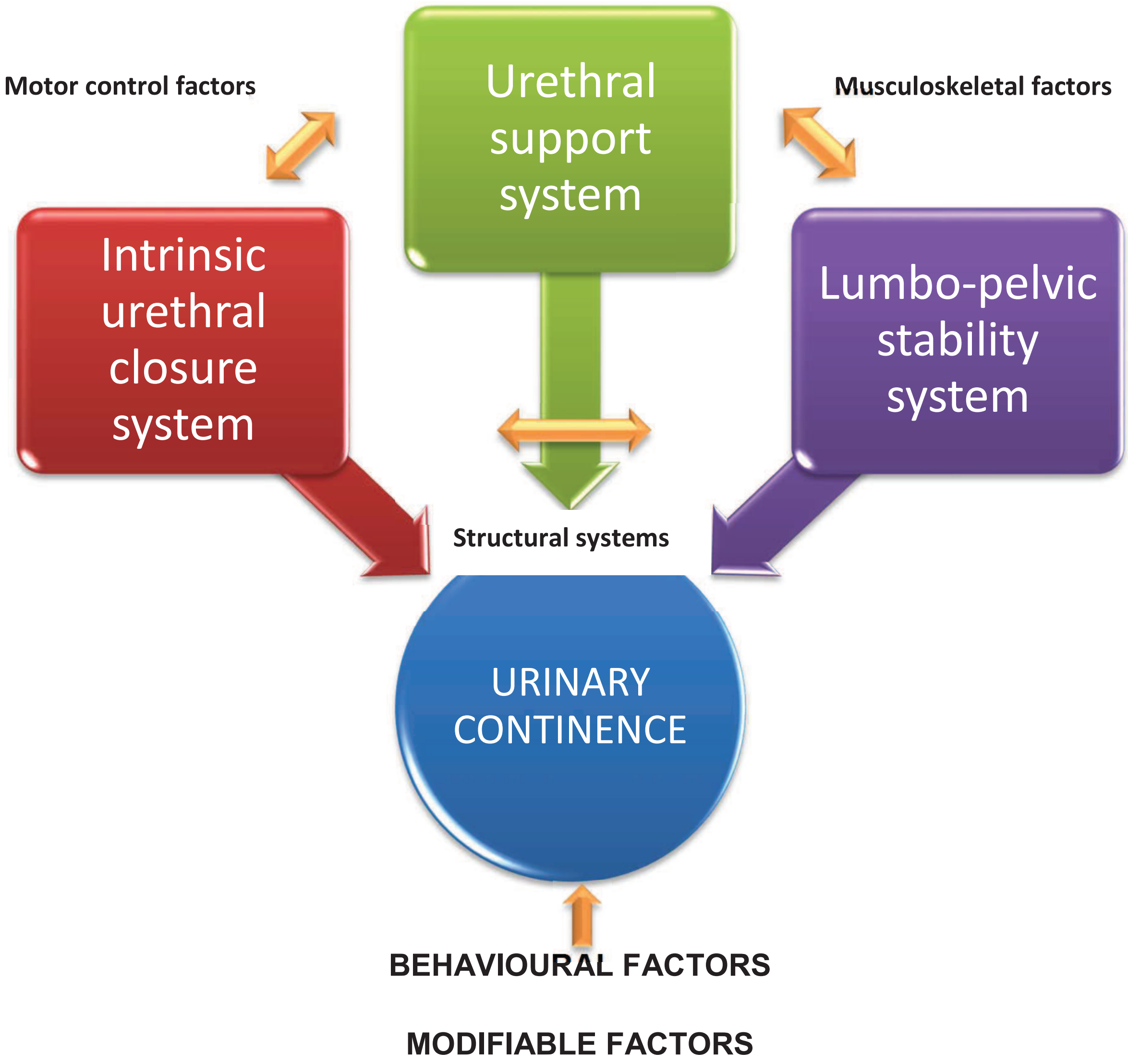


Figure 16. The integrated continence system (Grewar & McLean 2008:376).

The structural systems of the integrated continence system constitute the anatomical structure for urinary continence and are functionally interdependent (Figure 16). Neural control and fascial connections link these systems (Grewar & McLean 2008:375). Several changes in anatomy may contribute to UI, namely inferior descent of the urethrovesical junction, a fault in the fulcrum of the urethra (pubourethral ligaments), a disturbance in the function of the intrinsic sphincter, and decreased function of the extrinsic sphincter. It is thus clear that a disturbance in the function of the PFM or related fascial structures, either pre- or post-operatively, may contribute to UI (Haderer *et al*. 2002:240).

A drop in the level of the urethrovesical junction may disturb the distribution of the abdomino-pelvic pressure. This may be caused by weak PFM support or increased IAP due to poor motor control. At a proper level, the bladder and proximal urethra lie superior to the pelvic diaphragm and thus in the pelvic cavity. The abdomino-pelvic pressures exerted on the urethra and bladder in the pelvic cavity are equal under ideal circumstances, and thus the lumen remains closed. Normally intraurethral pressure is greater than intravesical pressure, and therefore continence is maintained. Should an increased IAP be present, urine may still enter the proximal urethra in 50% of women (Haderer *et al*. 2002:240). The biomechanics of the pathology should therefore always be considered when interpreting the symptoms and signs of the patient. Another example may be a cystocele, where patients may present continent with a urethra that lies as far as inferior to the introitus. This phenomenon may be explained by the urinary retention due to kinking of the urethrovesical junction causing a pseudo-continence scenario.

Another factor that may affect the normal position of the urethra behind the pubic bone is a weakness of the PUL. This ligament acts as a fulcrum between the bladder and the external urethral meatus. Decreased function of this fulcrum may cause poor response of the urethra to the action of the levator ani muscle that elongates and compresses it. The posterior PUL fuses strongly with the fascia of the levator ani muscle at the ATLA (Haderer *et al*. 2002:249).

Bladder outlet obstruction can therefore be associated with POP, but it also seems to be associated with detrusor over activity and/or overactive bladder (OAB). A few theories exist by which bladder outlet obstruction can induce detrusor over-activity or OAB. The first is due to a denervation of the autonomic nerve supply to the detrusor muscle. Ischemia and hypoxia of the bladder wall due to sustained distension and contraction may play a role in this denervation theory. The second theory entails changes in the spinal micturition reflex after outlet obstruction. There is a decrease in the cell-to-cell propagation of electrical activity, while the membrane potential displays greater instability causing depolarisation of the cell (De Boer *et al*. 2010:33-34).

Other pathophysiological mechanisms of OAB may include stretching of the bladder wall due to the POP. The stretch receptors are stimulated with this stretching causing a detrusor contraction. Relating closely to the incontinence mechanism, a cystocele can also put traction on the urethra which may lead to urine entering the urethra and causing a detrusor contraction (De Boer *et al*. 2010:34). It would therefore be expected that repair of the POP during surgery may have an immediate effect on the restoration of OAB symptoms (De Boer *et al*. 2010:35).

However, both the intrinsic and extrinsic sphincters of the urethra may be affected by surgical scar tissue infiltration in the vicinity, such as the anterior vaginal wall. The reason for this is the fact that especially the distal two thirds of the urethra are inseparable from the anterior vaginal wall (Haderer *et al*. 2002:240). Under normal circumstances the amount of scar tissue in the sphincters increases, while the amount of striated muscle fibres decreases with increasing age. This reduction in striated fibres, as seen in the extrinsic sphincter, may reduce the capability of the extrinsic sphincter to compress the urethra against the circular fibres. The striated sphincter allows for fast interruption of urination, increasing the efficiency of the intrinsic sphincter. These changes in the sphincters may affect the muscular and arteriovenous anastomoses' functioning, which is controlled by hormones. Oestrogen levels during menopause may thus also play a role in the function of the urethral sphincter and should be considered as differential diagnoses when seeking explanations for voiding dysfunction (Haderer *et al*. 2002:238).

Relating the above biomechanics of continence to surgical consequences, the following can be considered. The urogenital sphincter consists of the PR muscle, the urethral sphincter, the urethrovaginal sphincter, and the compressor urethra. Some of the fibres of the urethral sphincter attach to the vagina or the endopelvic fascia – both structures which are frequently affected during pelvic reconstructive surgery (see 2.4). The endopelvic fascia is an extension of the fascia transversalis, and is the fascia covering the superior fascia of the pelvic diaphragm, as well as the fascia which constitutes the fascia of obturator internus muscle. It reflects from the dorsal surface of the pubic bone, to the urethra and bladder surfaces (Haderer *et al.* 2002:245).

Demonstrating the close interaction between pelvic myofascial structures, the compressor urethra originates from the urogenital diaphragm and ischiopubic rami, and blends with the urethral and urethrovaginal sphincter. The constitution of the urogenital diaphragm is still one of the most disputed concepts; however, it is believed that it constitutes a superior and an inferior fascia. These fascial layers meet anterior to form the transverse perineal ligament, and join posterior even as far as the midpoint of the rectum. The inferior layer is represented by the perineal membrane, and the superior layer by the endopelvic fascia. The urethrovaginal sphincter, compressor urethra, deep transverse perineal muscles and/or modifications of these muscles lie between the layers.

The above indicates that indirectly the intrinsic urethral sphincter function may be affected by factors such as position of the pelvis, dysfunction of the PFM and/or the abdominal muscles pre- or post-operatively, due to the effect of these factors on the extrinsic urethral sphincter. Authors such as Haderer *et al*. (2002) recognise the insertion of a few fibres of the pubococcygeus muscle onto the posterolateral surface of the urethra, where it may even become part of the intrinsic musculature (Haderer *et al*. 2002:245).

Associations between sexual dysfunction and micturition can even be made when analysing the anatomy and neurological innervation of the relevant structures. The erectile tissue lies in the superficial perineal space. The touch capsule of the clitoris hangs inferiorly from the pubic arch by the suspensory ligament of the clitoris. The crurae of the clitoris are covered anteriorly and superiorly by the ischiocavernosus muscle, which again merges with the bulbocavernosus muscle inferiorly. Assumptions have been made that muscular sheaths of the erectile tissues contribute to the striated urogenital sphincter. This consideration is important from a neurological point of view. Voluntary spinal innervation from the muscular coats to the urogenital sphincter allows for voluntary control and interruption of micturition (Haderer *et al.* 2002:247-248). Another important association that can be referred to is the continuity of the anterior PUL with the suspensory ligament of the clitoris, which again is important for sexual functioning (Haderer *et al*. 2002:249).

The continuity of the pelvic system is further demonstrated by the fibres of the urethrovaginal sphincter which surround both the urethra and the vagina and insert in the perineal body. The perineal body is an important supportive mechanism, also frequently affected by pelvic floor reconstructive surgery. The displacement or absence of the perineal body could have major adverse effects on pelvic support. It seems that forces that are exerted by the abdominal cavity pass directly towards the perineal body. The PR muscle contributes to the perineal body between the distal vagina and the anal canal (Haderer *et al*. 2002:245). The PR muscle is recognised as the part of the levator ani muscle that forms the vaginal high-pressure zone (Shobeiri *et al.* 2012:205). The perineal body therefore joins the fibres of the superficial and deep transverse perineal muscles, the bulbocavernosus muscles (which again merge with the inferior fibres of the ischiocavernosus), the urethrovaginal sphincter and the anal sphincter (Haderer *et al.* 2002:245).

PFM dysfunction can occur in either the urethrovesical, uterovaginal, or anorectal systems and frequently in more than one system simultaneously. Similar muscle functions, including phasic and tonic PFM activity, are necessary for optimal functioning of all of these systems (Sapsford 2004:6). Regarding anal continence, the phasic and tonic PFM activity is necessary to achieve a sensory awareness of rectal filling. The sensory awareness of rectal filling triggers increasing external anal sphincter activation and anal closing pressure, which is greater than rectal pressure, when rectal content is present until a suitable time for evacuation (Sapsford 2004:6; Sapsford 2001:621). The internal anal sphincter relaxes with rectal filling, while voluntary activity in the EAS can increase the anal resting pressure, as well as during coughing when additional pressure is needed to counteract the effect of the increased IAP (Bo *et al*. 2007:307; Sapsford 2001:622-623; Sapsford *et al.* 2001:32, 38-41).

The co-ordinated function of the PFM and the abdominal muscles is necessary for anal release, rectal support, expulsive effort and continence. Isometric abdominal contraction has been shown to increase anal pressure and EMG activity (Sapsford 2001:622-623; Sapsford *et al*. 2001:32, 38-41). When sitting to evacuate, the PFM and the abdominal muscles must relax in order for the anorectal junction to descend one to two centimetres and for the anal sphincter to relax. Rectal contractions and/or increased IAP with an expulsive effort initiate rectal emptying. However, an isometric hold of the PFM (PR/pubococcygeus muscle) in the lowered position provides rectal support to counteract the increased IAP and the strain on the ligaments, while the anal outlet opens (Sapsford 2001:621). The role of the PFM and the PR muscle post-operatively during evacuation is therefore also evident to prevent excessive strain on healing connective tissue and to aid in hiatal closure. Incorrect activation of the TrA muscle and co-contraction of the PFM may open up the LH and push the PFM downwards (Bo *et al*. 2009:31).

A causal relationship has been posed by Clark *et al.* (2010:595.e22) that levator ani muscle (and associated structural) defects yield perineal descent and greater hiatus width. Avulsion of specifically the PR muscle has been indicated to have a marked effect on hiatal dimensions. These factors have been associated with increased risk of POP (Abbas-Shobeiri *et al*. 2012:205, 209; Majida, Braekken, Bo & Eng 2012:711). If pelvic neuro-musculoskeletal structures do not heal optimally post-surgery, it may increase the likelihood of recurrence of POP, unless strategies to address operative failure by augmenting the strength of the connective tissue supports to aid in hiatal closure are implemented. However, the latter may introduce additional risks, costs, morbidity, and thus decreased QOL (Clark *et al*. 2010:595:e21).

2.6 CONCLUSION

Part 1 and 2 of this chapter explored the biomechanical principles defining the role of the neuro-musculoskeletal system in POP, pre- and post-operatively, and its associated symptoms. It provided a rationale and justification for the discussion on rehabilitation of the motor control system (including the PFM) in the treatment of POP.

PART 3
PELVIC FLOOR MUSCLE REHABILITATION

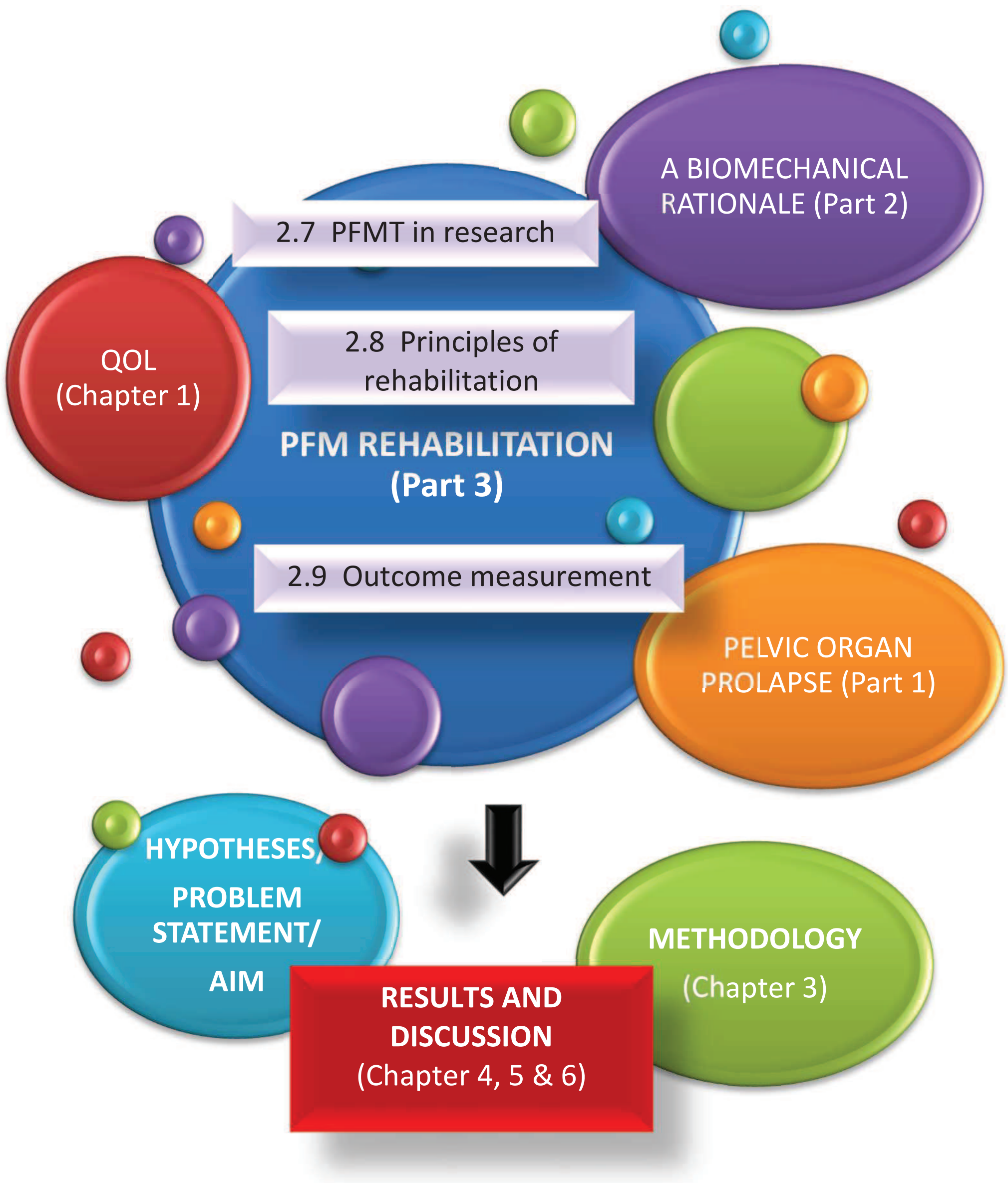


Figure 17. The interrelated discussion of concepts regarding rehabilitation within the study context.

The overview in Chapter 1 and Chapter 2, Part 1 and 2, regarding the role of the abdominal muscles and PFM pre- and post-operatively, indicates the need for discussion on retraining of these muscles for optimal functioning. An interesting finding in the literature is the difference in rehabilitation approaches when comparing guidelines in exercise physiology and neuro-musculoskeletal therapy, with guidelines for training of the PFM. Approaches for training of the PFM have not been based on scientific evidence and guidelines, neither on biomechanical and kinetic assessment findings, up to *recently* (Bo *et al*. 2009:372; Epstein *et al*. 2007:165.e6; Bo 2006:266; Bo 2004:459; Laycock & Jerwood 2001:64).

This section will discuss the scientific, evidence-based principles and guidelines for muscle training in an adult population. Reference will be made to exercise physiology, neuro-musculoskeletal therapy, and training of the PFM. It will also discuss outcome measurement relevant to assessing different aspects of a rehabilitation programme and muscle function in women undergoing pelvic floor reconstructive surgery/with POP (Figure 17).

2.7 PELVIC FLOOR MUSCLE TRAINING PROGRAMMES IN RESEARCH

Only three (3) randomised, controlled trials have investigated the effect of PFMT on POP. One of the trials scored low on methodological quality, one was a small pilot study, and the third a small trial which assessed symptoms only (Braekken *et al.* 2010:170e1; Hagen, Stark, Glazener, Sinclaire & Ramsay 2009a:45-51; Piya-Anant, Therasakvichya, Leelaphatanadit & Techatrisak 2003:509-515). The limitations of the studies on PFMT, in conjunction with reconstructive surgery, were referred to in 1.4. The effect that an extensive, scientifically-based rehabilitation programme can have on PFM function, POP and other associated factors, has not been established yet (Hagen *et al.* 2014:804; Hagen *et al.* 2009:2; Borello-France *et al.* 2008:1546, 1552; Norton *et al.* 2007:1, 3; Bo 2006:263; Bo 2004:458).

The limited number of studies investigating PFMT in patients with POP have based their programmes mainly on those found to be effective in urinary incontinent patients. This could be acceptable due to the fact that PFMT in these patients also focuses on strengthening (Bo 2006:265), however, as discussed earlier, POP is multifactorial and different aspects of muscle function may need to be addressed for treatment to be effective.

Hypothesis 12 (relate to objectives 1.6.1.2 and 1.6.1.3)
The question remains if the programmes for PFMT, as suggested up to now in literature, are optimal for patients with POP, and if more structured programmes based on sound rehabilitation principles and assessment findings would be more effective.

The control groups in the above-mentioned studies received home advice (lifestyle advice) and were taught how to contract their PFM before and during increases in IAP (“the Knack”). The intervention groups received PFMT with biofeedback, were advised to do eight (8) to 12 close to maximum strength PFM contractions per day, recorded their training adherence, received individual supervision by the therapist, and also received booklets describing their exercise programmes. When necessary, adjunctive therapies were given, for example to stimulate muscle contraction by means of NES (Braekken *et al.* 2010:170e2; Frawley, *et al.* 2010:720; Jarvis *et al.* 2005:301). Clarity was lacking regarding the guidelines and principles on which the exercises were prescribed, and whether they were based on specific assessment findings to address the appropriate component of muscle dysfunction.

2.8 PRINCIPLES OF REHABILITATION

2.8.1 Guidelines for muscle training and motor control

A protocol planning to investigate PFMT should be based on sound rehabilitation principles and outcome measurement. The following components, identified by exercise scientists, should be addressed when a rehabilitation programme is planned for a patient (Brukner & Khan 2007:175):

- Muscle conditioning.
- Muscle flexibility.
- Neuromuscular control.
- Functional exercises.
- Sport or functional skills (if applicable).
- Correction of abnormal biomechanics.
- Maintenance of cardiovascular fitness.
- Psychology.

Taking into account the morphology and functional anatomy of the PFM (namely that it consists of both type I and II muscle fibres and forms part of the core) (see 2.3.1), the muscle could be trained as a local and global stabiliser, and as a mobiliser. The components of muscle conditioning should include muscle activation and motor re-education, proprioception, muscle strengthening, improvement of muscle power, and training of muscle endurance, depending on the pathology and assessment findings (Brukner & Khan 2007:177). This should be incorporated into a biopsychosocial model of rehabilitation by means of appropriate communication and teaching skills (see 2.8.2), based on the ICF (see 2.9).

2.8.1.1 Core stability and motor control

Integrating the above components identified by Bruker and Khan (2007:175), and muscle characteristics into the core stability model defined by Comerford *et al.* (2005:4-2), necessitates a concept clarification before further discussion. The term “core stability” has undergone some changes over the years and has been re-defined from its generic status in the exercise and fitness industry, to terminology with scientific clarification. Core stability is now used to describe exercises that range from local stabilisation and activation, to strength training and proprioception exercises, integrating all of the components (Comerford *et al.* 2005:4-3). For the purpose of this study, this description of Comerford *et al.* will be adopted when referring to “core stability”.

The model of motor control developed by Comerford *et al.* (2005:1-2) has been based on evidence and literature by pioneers, such as Janda, Sahrmann, Richardson, Hodges, Jull, Hides and O`Sullivan, in the field of stability and movement dysfunction to clarify “core stability”. It is therefore an integration of a variety of original and ongoing ideas and principles by these researchers (Comerford *et al.* 2005:1-2).

Comerford *et al.* (2005:4-3) describe motor control stability as low threshold stability concepts which involve CNS modulation. This modulation comprises the integration and low threshold recruitment of the local and global muscle systems. The afferent spinal input influences the tonic motor output and slow motor units are predominantly recruited (Comerford *et al.* 2005:4-3). Vestibular, visual, and somatosensory information about the motion of the body are spatially and temporally integrated to produce normal movement. Normal motor control is integrated at all levels of the nervous system. Automatic and reflex movements are integrated at spinal cord level, balance and postural reactions at the level of the brain stem and basal ganglia, while complicated movements are mostly integrated at the motor/sensory cortices and the cerebellum. This process of control is depicted in Figure 18 and also indicates the importance of cognition in the learning of exercises (Petty & Moore 2008:162-163).

Two levels of control can be identified, namely direction-specific patterns of movement, which determines the activation, timing and sequencing of muscle function, and adaptation for specific tasks, based on the total afferent input from the body (Petty & Moore 2008:162).

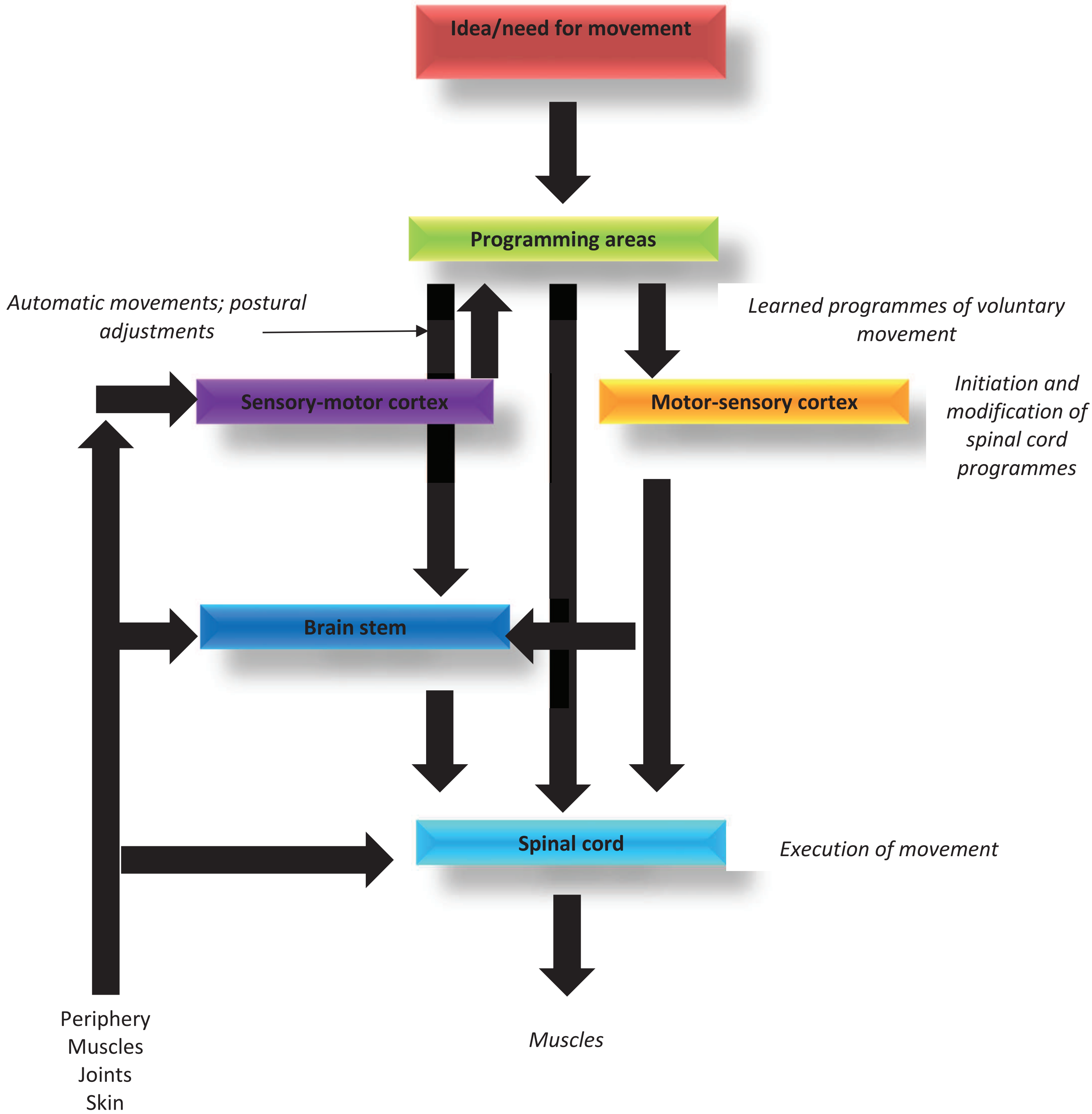


Figure 18. Schematic diagram of movement control (Petty & Moore 2008:163).

Contrary to stability training, core strength refers to high threshold or overload strength training of the global stabiliser muscle system which involves recruitment of both slow and fast motor units. The muscle adaptation that takes place is due to the principles of load and demand. The muscle hypertrophy is therefore a response to the overload training (Comerford *et al.* 2005:4-3).

Lastly, the authors suggest that symmetrical/traditional strength training be defined as training which involves high threshold or overload strength training of the global mobiliser system (Comerford *et al.* 2005:4-3). Table 1 is a summary by Comerford *et al.* (2005:4-4) on guidelines for training motor control stability and core strength, as well as traditional strength training.

Table 1. A summary of contemporary core stability (Comerford *et al.* 2005:4-4).

	SYMMETRICAL, TRADITIONAL STRENGTHENING	CORE STRENGTHENING	MOTOR CONTROL STABILITY (GLOBAL)	MOTOR CONTROL STABILITY (LOCAL)
ACTIVATION THRESHOLD	High	High	Low	Low
MUSCLE EMPHASIS	Global mobilisers	Global stabilisers +/- mobilisers	Global stabilisers	Local stabilisers
POSITION/ DIRECTION OF PRIMARY LOADING	Flexion-extension +/- side bend +/- abduction/adduction (no rotational control)	Neutral position +/- resistance +/- rotation movement	Neutral region and dissociate all three planes Rotation control, including flexion-extension control	Neutral region No direction
TYPE OF CONTRAC-TION	Isotonic: move limbs and trunk through range (concentric) Symmetrical and bilateral limb movement +/- isometric and isokinetic	Isometric: resist trunk motion Isotonic: move trunk through rotation (concentric)	Isometric: resist trunk motion (dissociation) Isotonic move through range (isometric hold in shortened range and eccentric lowering)	Isometric hold in different trunk postures, e.g. sit, stand, lying
GUIDELINES FOR TRAINING	Fatiguing high load exercise With/without speed Bilateral or symmetrical limb load No rotation challenge Limb or trunk lifting in the flexion-extension plane Allow global mobiliser dominance Encourage core rigidity	Fatiguing high load exercise With/without speed Unilateral or asymmetrical limb or trunk load High rotation challenge Resist rotation force at trunk Rotate trunk against resistance Discourage global mobiliser dominance	Non-fatiguing low load exercise Unilateral or asymmetrical limb or trunk load Trunk does not move out of neutral Dissociate rotation, flexion and extension Emphasise rotation control at trunk and girdles Shortened range hold for postural control Discourage core rigidity	Non-fatiguing low load exercise Trunk does not move out of neutral Allow slight global stabiliser co-activation Discourage global dominance Discourage core rigidity

Motor control is an integrated, simultaneous progressive process of local and global muscle function on all levels of the nervous system (Figure 18). Functional stability thus requires both the local and the global systems to integrate for efficiency. Low and high threshold function are required for functional stability and return to manual work or sport (Comerford *et al.* 2005:4-5). Figure 19 shows the suggested functional progression sequence after successful isolated activation of the stabiliser muscle.

PROGRESSION

1. Activation in neutral alignment with a variety of different postures or positions. Progression should be from a supported to an unsupported base.

2. Activation in a neutral alignment without co-contraction rigidity. This means that for the trunk the activation must be with normal relaxed breathing, and for the limbs the activation must be without resistance to passive rotation.

3. Activation in neutral alignment on an unstable base: in other words, a proprioceptive challenge is added.

4. Activation during directional control exercises. This includes dissociation or recruitment reversals.

5. Activation during normal physiological movements. The trunk and girdles must actively move away from the neutral joint position.

6. Activation during functional activities. This refers to normal movements of the unloaded limbs and trunk (= 'red dot' integration).

7. Activation during stressful or provocative movements and positions – taking into account the pathology and symptoms of the patient.

8. Activation during occupational, recreational, or sport specific skills.

Figure 19. Progression of stability training (Comerford & Mottram 2001a:7).

2.8.1.2 Muscle activation and motor re-education

Muscle activation and motor re-education (of the slow-motor units) require the teaching of very specific skills under low load. The local stabiliser function must first be facilitated as an unloaded contraction to recruit its mechanical action independently from the global system. After that it can be progressed by using low-functional-load or non-neutral positions to integrate the local and global stability systems. This may facilitate muscle recruitment by mechanically pre-loading the muscle through its fascial and connective tissue attachments (Comerford & Mottram 2001a:8,9). The following clinical guidelines have been published for the assessment and retraining of the local stabilisers (Comerford & Mottram 2001a:7) (compare Table 1):

- Palpate for the correct activation.
- Observe for correct contraction patterns and tonic recruitment with no fatigue or substitution under low load.
- No pain should be experienced.
- Breathing should be normal with consistent, sustained contractions with no co-contraction rigidity.
- A low force contraction should be sustained with normal breathing (10 seconds and repeat 10 times).
- The contraction should be performed in a variety of different functional patterns.

2.8.1.3 Muscle strength and power

As a patient moves through the functional progression of activation, the stimulus increases. Muscle strength (force) can be defined in terms of the amount of muscle fibres that are stimulated. The greater the stimulus, the greater the number of fibres recruited. Small motor neurones are usually recruited first, but as more force is required, larger motor neurones are also recruited. Optimal muscle strength/contraction is where there is a maximum overlap between the actin and the myosin filaments. The poor muscle strength in “toned” and “weak lengthened” muscles can therefore be explained by the fact that least tension of contraction is obtained in shortened and lengthened positions of the muscle fibres due to fewer cross-bridges between the actin and myosin (Petty & Moore 2008:159-161).

When the muscle strength/force is linked to speed of contraction, it is referred to as muscle power: a term sometimes wrongfully referred to as muscle strength or force of contraction. It is especially the type II fibres that are responsible for creating a greater force at a faster speed (Petty & Moore 2008:160-161).

In order to effectively strengthen skeletal muscles in adults (in other words, train it as a mobiliser, targeting the fast twitch type II fibres), the principles of overload and specificity should be followed (Brukner & Khan 2007:177; Bo 1995:283). It has been suggested that three (3) sets of slow-velocity close to maximum strength contractions, two (2) to four (4) days a week, is sufficient for strengthening to occur – taking into account that it should be continued for a period of three (3) to five (5) months (Bo 2006:265). Methods of progression could include increasing the frequency of the training, the number of repetitions, the intensity of the training, and/or changing the type and complexity of the activity (Brukner & Khan 2007:191-192; Bo 1995:284). Progression will depend upon the specific individual`s ability to perform correct muscle contractions while integrating the local and global stability system. Factors such as fatigue and substitution strategies should therefore be taken into account.

Central processing mechanisms (e.g. motivation), peripheral nervous impulse propagation, impulse transmission at motor endplates, and localised physiological properties of muscle cells may contribute to muscular fatigue (Verelst & Leivseth 2004a:145).

2.8.1.4 Muscle endurance

It has been suggested that the measuring of muscle endurance involves the measuring of the resultant muscular fatigue. An increase in EMG activity that accompanies muscular fatigue could therefore be an indication of isometric muscle endurance. Isometric contraction at 60% of the maximum voluntary contraction (MVC) will increase the pressure in the muscle and consequently decrease the blood flow. The ability to hold the contraction would therefore depend on the energy store in the muscle. This means that at less than 60% of the MVC, a muscle contraction should be able to be held for longer. At more than 60% of the MVC, a muscle would be able to contract for less time. Clinically muscle endurance may be measured by the length of time a patient can continue to perform a specific muscle activity, or by the ability to repeat a contraction (Petty & Moore 2008:162-163, 183). It is especially the type I fibres that demonstrate resistance to fatigue (Petty & Moore 2008:151).

2.8.1.5 The integrated approach to muscle training

Differentiating between different training regimes and components is important to target the correct type of muscle fibres to restore dysfunctional patterns. As previously demonstrated, the stabiliser muscles' recruitment and activation are affected by pathology and pain. In reaction to this, they increase their threshold and becomes less responsive to low load stimuli. They begin to respond to higher load activities, therefore acquiring a mobility function. At the same time, the mobiliser muscles attempt to compensate for the loss of stability by decreasing their threshold and becoming more responsive to low load stimuli. The increased activity of slow motor unit recruitment in the mobiliser muscles contributes to the observed dominance during a function which requires stability (Comerford *et al.* 2005:3-4). Correct training is therefore essential to reverse these abnormal patterns of muscle functioning.

Consequently, the discussion on motor control emphasises the complicated approach to muscle training, and that it is an integrated process of input and output mechanisms on a CNS level (Figure 18). These mechanisms can be explained by the more recent clarification of sensorimotor control. Sensorimotor control includes output that arises from elements of the nervous system that contribute to motor function; sensory input which contributes to the position and movement of the body;

features of the environment; and the interaction of the body with the environment. It also involves the central processing for interpretation of motor requirements, planning of appropriate responses, and interpretation of the success of the output (Jull, Moore, Falla, Lewis, McCarthy & Sterling 2015:53). The mechanisms for sensorimotor changes can therefore be broadly categorised into sensory, motor, or psychosocial mechanisms (Jull *et al.* 2015:62).

Any disruption of sensory input will compromise sensorimotor control. Sensory input can be affected by trauma to the sensory receptors or the tissues in which they are located. The responsiveness of the receptors may be affected by the injury, inflammation, or oedema. Afferent discharge from mechanoreceptors in the area of damaged tissue can also induce pain. Increased sympathetic drive is also important to consider, especially in cases of surgery where sympathetic activity can affect the muscle spindle receptors. At spinal level, reflex modulation of muscle activation can be modified by greater sensitivity of the muscle spindles, or in contrast to this, by the presence of muscle damage. Any change in afferent activity from receptors in the skin, ligaments, or tendons due to pain or injury, may therefore alter muscle activation or even affect the planning and organisation of motor behaviour at higher centres of the nervous system (Jull *et al.* 2015:62).

Changes at the level of the motor system may also occur at higher levels, such as the motor cortex, or at spinal level. Reflex inhibition has been indicated at spinal level as a consequence of injury to joint capsules or ligaments. It may lead to atrophy, decreased endurance, or changes in the muscle fibre type proportion. However, these changes can also be caused by general physical inactivity or reduced gravitational load. At a higher level, modified representations of specific muscles have been found in the motor cortex of patients suffering from lower back pain. This can be interpreted as a strategy to simplify protection of the specific area by the muscle. Change in motor behaviour can thus be seen as a purposeful modification of planning of behaviour to reach this goal of protection. The premotor, frontal, somatosensory areas and the limbic system modify the muscle coordination in order to reach this goal. It could also manifest as changes in movement variability, which initially increases as a new strategy for movement is searched for, and then decreases as the solution is found (Jull *et al.* 2015:63).

However, psychosocial aspects may amplify the above-mentioned motor adaptations and therefore lead to greater muscle activity or altered, protective movement strategies. Cognitive and emotional aspects may again change the excitability of the sensory pathways (as explained above) and also lead to altered sensorimotor control (Jull *et al.* 2015:65).

The key concept is therefore to understand how PFM dysfunction in each patient is related to sensorimotor changes and which of these changes require intervention. It is important that training programmes should be individualised. Correct training requires cognitive skills and understanding from the patient, and an effective exercise prescription from the therapist (Brukner & Khan 2007:174-175). The patient can therefore be seen as an adult learner in this process of motor learning, which in turn requires additional skills and understanding from the therapist in order to deliver the information effectively (see 2.8.2).

Motor learning takes place in three different stages. The first stage is the cognitive stage, which requires a high level of awareness from the patient. The second stage is the associative stage during which a particular movement pattern is refined. The final stage is the autonomous stage during which a low degree of attention is required for correct performance of the motor task (O`Sullivan 2000:9-10). It is the responsibility of the therapist to help the patient through these cognitive stages with appropriate facilitating and teaching skills.

One of the guiding principles for effective learning to take place is to consider the patient’s life stages and life events. The learning environment should reflect the physical, affective-social and intellectual dimensions needed to create an optimal learning climate (see 2.8.2). Following a biopsychosocial approach and taking into account the creation of an optimal learning environment, factors that need to be considered when compiling a rehabilitation programme should include the following:

- Individuality of the person – this includes psychological support, lifestyle interventions and customised rehabilitation programmes.
- Explanation of the time frame, goals, and rationale of the rehabilitation.
- Precise prescription of the exercises regarding the technique, progression, limitations, and modification of the programme.
- Availability of facilities/resources.
- Beginning immediately with training (Brukner & Khan 2007:174-175).

All information should be given to the patient prior to the objective evaluation. It has been suggested that at least one hour should be spent on a one-to-one basis with the patient to provide information on the anatomy and physiology of the lower urinary tract and PFM. Patient education is also important to assess whether the patient is suitable for treatment and to ensure successful treatment (Laycock *et al.* 2001:19).

2.8.2 Aspects of adult learning

Patient education includes not only instruction on exercises and therapy, but also education on illness and resources in order to optimise adherence to exercise programmes, facilitate behavioural changes, and to cultivate healthy lifestyles. The Joint Commission of the USA requires that patient education be based on sound educational principles and on the patient's needs and readiness to learn (Plack & Driscoll 2011:198). The patient can therefore be seen as an adult learner in the situational context of pre- and post-operative rehabilitation.

2.8.2.1 Defining adult learners

Defining adult learners remains a controversial subject (Buchler, Castle, Osman & Walters 2007:128). Definitions have been classified into different categories, namely:

- A biological category (Merriam & Brockett 2007:4-5).
- A legal category (Buchler *et al*. 2007:128).
- A psychological maturity category.

- A social category (Gravett 2005:7).

An 'internal factor' category has also been defined where factors such as motivation and the learner's ability to change are considered (Massyn 2009:5). It is clear that when teaching and working with adults, even during rehabilitation, a holistic approach should be followed in order to address this diverse group who has individual needs (Massyn 2009:6). The age (e.g. older generation, middle generation, or younger generation) (Illeris 2003:18-20), physical maturity, responsibility of the person, and his/her role in society should all be taken into account.

2.8.2.2 Adult development perspectives

In order to address the different needs and behaviour of individuals during learning, their development should be considered when creating a learning opportunity (Massyn 2009:6). Different perspectives on adult development exists, with the developmental, contextual, transition, and integrated perspective being of the most prominent perspectives (Massyn 2009:6-8; Merriam & Brockett 2007:144, 145; Merriam, Caffarella & Baumgartner 2007:299).

The developmental perspective acknowledges the influence of development on life tasks which again can influence their motivation (Massyn 2009:13). The developmental perspective, which can be emphasised when referring to *patient* education, is the biological approach. This approach considers the physical and biological changes in the adult due to his/her interaction with the environment. It includes factors such as life expectancy, health, and deterioration of the senses and nervous system (Massyn 2009:13; Merriam *et al*. 2007:299-305, 323). This means that health education can also have an effect on the adult`s *ability* to learn.

'Opposite' to the developmental perspective, the contextual perspective explains how the educator/therapist, with knowledge and information regarding the individual's life events, can better understand the influence of the events on the development and learning of the patient (Massyn 2009:15; Smith 2009:6-8). The influence that POP can have on the QOL of the participants in this study should therefore be taken into account when information and education is provided. Women with POP often seek treatment primarily to improve their QOL (see 1.6) (Srikrishna *et al*. 2008:520).

The life event itself (namely the disease or POP) can be a disorientation providing the opportunity for development and growth, according to the transition perspective (Merriam & Brockett 2007:145). The disorientation, followed by the reorientation, provides the growth opportunity and the change (Massyn 2009:15). Homes and Rahe (in Smith 2009:7) indicated that major personal injury or illness is the sixth most stressful life event that an individual can experience. This places a major responsibility on health practitioners who treat and teach patients how to take responsibility for their health.

Combining the different perspectives on adult development, a holistic view of adult development can be considered. This viewpoint is supported by the integrative perspective (Merriam *et al*. 2007:319, 322). This perspective supports the biopsychosocial approach of patient assessment and treatment which is currently used in the physiotherapeutic management of patients (Plack & Driscoll 2011:204).

In summary, adult development and adult learning cannot be separated (Massyn 2009:20). Adult learning must have development as an aim (Merriam & Brockett 2007:143; Merriam *et al*. 2007:146; Massyn 2009:19). This has the potential to give patient education by a therapist a whole new meaning, ever increasing the important role that health practitioners play in a patient's life and life experiences. Understanding and designing effective learning for adults is therefore imperative.

2.8.2.3 Adult learning theories

Speculation is rife on which learning theories play the most important role in adult learning. When one considers the major learning theories (namely, behaviourism, cognitivism, constructivism, and humanism), it would appear that the most important theories of adult learning have constructivism (see Nomenclature) and humanism as their foundation (Massyn 2009:21-22). They include the following:

- Andragogy (see Nomenclature).
- Self-directed learning.
- Transformational learning.
- Experiential learning.
- Reflective practice.
- Situated learning (Merriam *et al*. 2007:296).

The following assumptions underlie **andragogy**, namely (Massyn 2009:24; Merriam & Brockett 2007:136):

- The self-concept of the learner.
- The prior experiences of the learner.
- Readiness to learn.
- Orientation to learning.
- The learner's need to know.
- Their motivation to learn (Plack & Driscoll 2011:201-202; Fidishun 2000:2-4).

These assumptions indicate that the adult learner needs to take responsibility for his/her learning and that the learning process must be an active process involving the patient (Lieb 1991:2). The patient must take part in the decision-making process and must therefore be informed about the treatment, expected outcomes, risks and benefits of the management, sources of follow-up care, and training in self-help (Plack & Driscoll 2011:199). The goals of the treatment must be patient-centred. Involving the patient in decision-making will enhance their autonomy, self-efficacy, and even adherence to the training programme (Plack & Driscoll 2011:204-205).

Adults will demonstrate individual differences regarding background, motivation, needs, interests, and goals due to their different prior experiences (Massyn 2009:24-25). Prior experiences create certain perceptions regarding illness, and to influence the patient's behaviour, these should be fully understood by engaging in dialogue with the patient (Plack & Driscoll 2011:202).

Illness and health problems create situations that adults/patients need to cope with. It provides a learning opportunity in order to acquire skills and knowledge to cope with the situation. When they see the practical value of the knowledge (e.g. by applying it to a real-life situation when teaching), it also helps to motivate them (Massyn 2009:25-26; Lieb 1991:3). The most important motivators in adults are internal motivators that help build their self-esteem. The therapist/health practitioner must focus on issues such as job satisfaction, self-esteem, and QOL, which are classified as internal motivators (Massyn 2009:26; Fidishun 2000:15). The therapist must strive to improve the connectedness, self-efficacy, and autonomy of the patient to intrinsically motivate them (Plack & Driscoll 2011:201).

The therapist (teacher) must recognise the adult's independency in the learning process, though facilitation may be necessary to help them achieve self-directed learning. The concept of **self-directed learning** refers to the process where the adult takes control of his/her learning. They identify their learning needs, decide on their goals, recognise the resources, implement the learning method and strategy, and then evaluate/reflect on their progress (Massyn 2009:27-28; Merriam & Brockett 2007:138; Merriam *et al*. 2007:106).

Critical reflection, experience, and development are the key concepts of **transformational learning** (Smith 2009:1-6). Experience leads to critical reflection, which in turn leads to individual development (Merriam *et al*. 2007:144-149), thus indicating the interrelationship of transformational learning with reflection. Adults use **reflection** to visualise how to apply information, to obtain a holistic view of the learning content, and to compare their views with those of others by means of collaboration (Massyn 2009:35). This leads to adaptation in their thinking, behaviour, and skills in order to develop and grow in the situation (Merriam *et al*. 2007:144-149). This can be achieved by including reflective questions in their home programmes or during their follow-up visits (Plack & Driscoll 2011:217).

Educating and teaching patients usually takes place in an authentic situation, for example during their treatment. Non-authentic situations do exist where adults are taught, for example during preventative management in order to prevent illness and health problems. The **situated cognition approach** advocates that all learning should include authentic activities – even if it is through role-play (Massyn 2009:37; Merriam & Brockett 2007:155). It cannot be assumed that the learner will be able to apply the knowledge gained in a specific situational context, in another setting. The learner must understand the difference in settings and contexts. The educator must be sure that the learner understands this, or he/she must contextualise learning in a variety of real-life settings if the application of knowledge and skills in different settings is required (Massyn 2009:37-38). The advantage of using a variety of experiences and settings is that it expands the learner's resources and contributes to further learning (Gravett 2005:14). Exercises must therefore be prescribed, incorporating different functional activities and in different situations, to transfer learning.

The variety of experiences can be used, for example when considering prior knowledge, linking and reflecting on new knowledge, and when testing, evaluating, and adapting new knowledge (= **experiential learning**) (Gravett 2005:15-16).

In summary, there are various perspectives on adult learning, which ideally should be integrated to adopt a holistic approach to adult learning (Massyn 2009:42; Knowles in Eisen 2005:19). Some of the most important concepts to include in adult learning are self-directedness/responsibility for one's own decisions, motivation to learn, learner control, the importance of experiences, and reflection (Massyn 2009:41).

2.8.2.4 Designing learning for adult learners

Adult learning in a South African population is complicated by the fact that the above-mentioned concepts will have to be applied differently for a diverse population with different cultural, social, educational and economic backgrounds (Massyn 2009:49). This could for instance influence the learning strategy that the patient preferred, the motivation of the patient, and the health belief. The Four-lens Model (Kiely, Sandmann & Truluck 2004:18) provides a multi-dimensional perspective on adult education, which makes it ideal for application in such a situation. The guiding principles in designing learning for adults utilising the four lenses are summarised in Table 2. A section was added to each descriptor of Massyn's model to indicate the applicability to a context of patient teaching and learning during rehabilitation.

Table 2. Summarising learning design for adults (see 2.8.2.2 and 2.8.2.3)

Through an adult learner lens
1. Make provision for the characteristics of the adult learner, as described by andragogy.
2. Consider adults' life stages and life events.
3. Design with the overall goal of development in mind.
Application: exercise and rehabilitation programmes should be patient-specific - based on an accurate biopsychosocial assessment of the patient, including environmental and personal factors, aimed at improving the quality of life and self-esteem of the patient.
Through a context lens
4. The learning environment should reflect the physical, affective-social and intellectual dimensions needed to create an optimal learning climate.
5. The learning context (environment) should include the ideas related to situated cognition (submerging adults in real-world experiences and indicating the relevance of the learning to the real world).
Application: inclusion of functional exercises and activities of daily living, based on an accurate assessment of biopsychosocial factors.
Through a process lens
6. Design for active participation – as advocated in self-directed learning.
7. Make provision for the inclusion of prior experiences and reflection – as advocated by experiential and transformation learning respectively.
Application: active participation of the patient in the programme, taking self-responsibility for his/her programme by doing it at home, guiding the patient through the programme by reflecting and correcting them on exercises/management performed, motivating them by pointing out the progress that has been made, collaborating with other patients with similar problems in classes, for example, and teaching them lifelong skills for management/coping in different situations – a very important aspect in health issues such as POP and urinary/faecal incontinence.
Through a teacher lens
8. The learning environment should reflect a student-centred, self-directed learning environment.
9. Keep in mind that the roles of teachers are flexible and change continuously to accommodate the growth of the individual from dependent to self-directed.

(Massyn 2009:49-50)

Following on Table 2, Table 3 summarises and incorporates adult learning concepts in designing and developing a mutually agreeable plan of care for the physiotherapeutic management of patients. This plan of care was developed by Plack and Driscoll (2011:211) and then analysed by the researcher (by adding an additional row) to indicate the relevance to the adult learning theory, as discussed above (see 2.8.2.3).

Table 3. Plan of care that optimises patient adherence

Develop shared meaning through dialogue
• Identify your patient's explanatory model and health beliefs by means of a biopsychosocial evaluation. • Identify your own explanatory model and what you believe to be the best treatment. • Identify activity limitations and participation restrictions based on the patient's health status and physical abilities. • Negotiate a shared understanding of the disease state and the illness experience by engaging the patient and family members in the care plan.
Adult learning theory: self-directed learning and transformational learning
Develop a plan of care
• Link interventions to valued activities. • Identify your patient`s priorities. • Design a mutually agreeable plan of care.
Adult learning theory: self-directed learning, transformational learning, and situated cognition
Assess readiness
• Assess readiness to change, in other words, is the patient emotionally and physically able to participate in the teaching and learning situation. • Assess self-efficacy. • Identify potential barriers and supports to adherence, including comorbid conditions. • Identify patient and community resources. • Assess the literacy level of the patient, as well as of the reading material. • Assess learning preferences.
Adult learning theory: transformational and experiential learning
Provide intervention and education
• Provide background knowledge (e.g. rationale for intervention or home exercise programme, but avoiding excessive information). • Teach appropriate home exercises using appropriate learning strategies. • Provide instructions that consider appropriate literacy levels and learning preferences.
Adult learning theory: self-directed learning, transformational learning, situated cognition
Check for understanding
• Incorporate formative assessments throughout your session, as well as in written materials.

Adult learning theory: experiential learning
Check for adherence to maintain behaviour change
• Address issues which have arisen for the patient related to knowledge, motivation, and resources. • Continuously assess the situation regarding the understanding and adherence of the patient. • Advise regarding changes based on information from the re-assessment. • Assist in setting patient-centred realistic goals, in accomplishing them, and problem solving perceived barriers. • Arrange for follow-up to reinforce patient accountability and adherence, and to show care.
Adult learning theory: transformational and experiential learning
Reinforce adherence
• Problem solve any new barriers to adherence. • Identify additional community resources for support. • Modify the goals and plan of care to ensure continued compliance and to ensure that the patient's goals are being met. • Develop learning contracts, reflective journals, or weekly logs to reinforce accountability.
Adult learning theory: self-directed, transformational, situated cognition, and experiential learning

.(Plack & Driscoll 2011:221)

2.8.3 Patient motivation and adherence

2.8.3.1 Home-based exercise programmes

A home exercise programme is a concept that needs to be clarified when designing rehabilitation programmes, especially in a low income or rural setting. Home exercise programmes can be defined as activities performed in the patient's home environment and which is used to reinforce learning. The activities may be generic or in the form of advice, is mainly individualised, can be written or taught, and can be done with or without supervision (Novak 2011:1067).

In patients with POP, advice on lifestyle alterations, weight loss, and general exercises are recommended to be included in addition to specific PFM and abdominal exercises. Data is still lacking to support the inclusion of aspects of a healthy lifestyle, specifically for patients with POP. Due to these aspects being indicated as risk factors for POP, it seems logical to include them in such a programme. It could also include advice on how patients might need to cope with some of the associated symptoms, for example problems with defecation. Patients might need to alter their fluid intake, exercise regularly, and be taught the correct bowel habits. The same applies for problems such as OAB, where patients should be taught how to use a bladder diary. Monitoring improvement could also be seen as a form of motivation (Weber & Richter 2005:618-619).

Supervised home exercise programmes seem to be more effective than unsupervised programmes (Bo 2012:442). However, there is also strong evidence suggesting that home exercise programmes are more beneficial than no intervention at all. Home exercise programmes have been proven in some studies to have similar results as professional therapy interventions (Novak 2011:1082).

The key concepts regarding the effectiveness of a home exercise programme are patient motivation and adherence. When applying a home-based exercise programme it is important that the patients comply with their exercises and that they are motivated to improve their physical condition and reach optimal health. The rehabilitation process becomes the patient's own responsibility to a large extent; it is therefore important that the physiotherapist explains the importance of quality exercise and patient compliance prior to discharge (Jarvis *et al*. 2005:303). In the case of PFM training, it may include pre-operative consultation with the patient to teach the patient correct pelvic floor muscle activation. Pre-operative treatment offers patients a better understanding of the prescribed exercises and could thus assist in improving patient compliance in regards to home-based exercise programmes (Jarvis *et al*. 2005:303).

2.8.3.2 Compliance

The term '*compliance'* refers to the degree of constancy and accuracy with which a participant follows a prescribed regimen. Motivation is often overlooked as a facilitating factor enhancing compliance from the patient (Scales & Miller 2003:166-167). There is insufficient evidence with regards to patient compliance to home-exercise programmes compiled by physiotherapists (Bo 2012:442). Figure 20 provides some indication of factors that could influence compliance.

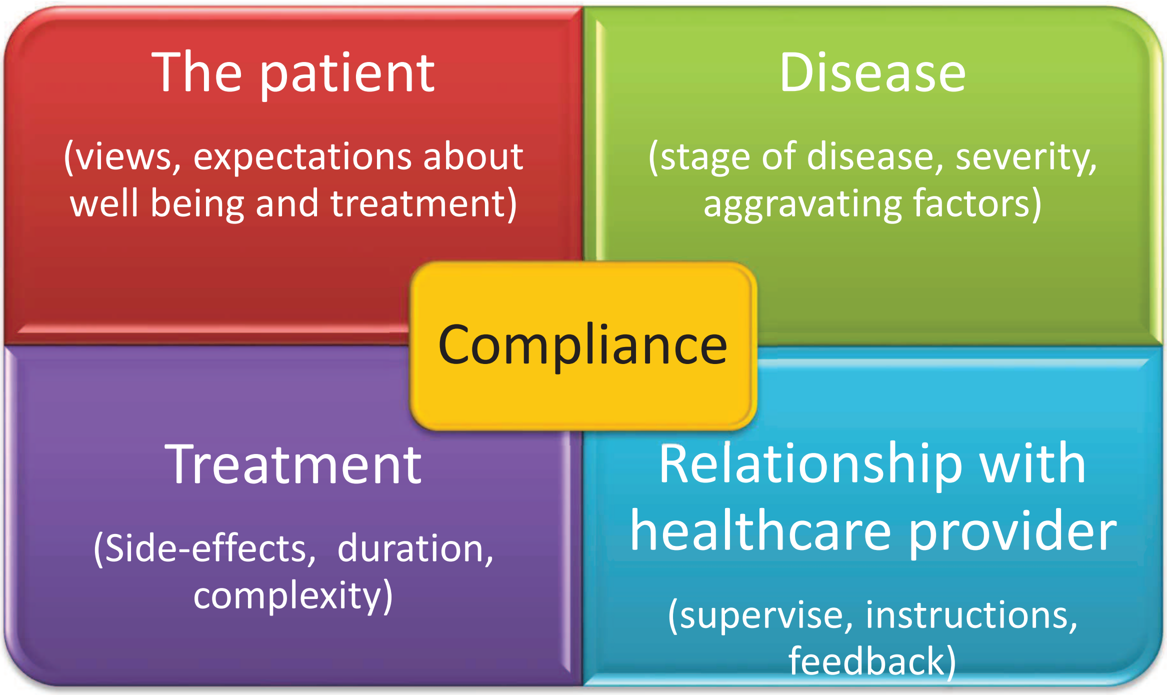


Figure 20. Interrelated factors affecting compliance.

A study by Escolar-Reina *et al.* (2010:5-6) found that all participants who received a home-based exercise programme reported a lack of clinical knowledge about their clinical condition, as well as their treatment. The patients' lack of knowledge on their condition and rehabilitation could have an impact on their compliance towards completing the exercise programme. The necessary information should therefore be conveyed in an accurate, understandable and convincing manner. The study found that the participants were more motivated to comply with the prescribed exercises after a care provider explained both the condition and the effect of treatment to them. Care providers also used specific reminders by giving written instructions, or giving exercises during specific daily activities. Participants were of the opinion that an exercise programme should be incorporated into their daily routine, since an exercise programme consumed a lot of time. The latter is also a reason why some patients may resort to a pharmaceutical or surgical intervention, rather than spending time on an exercise programme (Escolar-Reina *et al*. 2010:6).

This aspect was partially addressed by a separate study that was conducted in order to determine the effects of two different types of endurance exercises on exercise compliance. The randomised controlled trial was carried out with 61 healthy and moderately overweight young men over an intervention period of 12 weeks. The results showed that the group who was given a moderate exercise routine were untroubled by the workload and expressed a positive attitude towards exercise. The group given the high-dose exercise routine expressed far less positivity towards the task, experienced increased fatigue and perceived the exercises as time-consuming. It is thus clear that a physiotherapist should take the total workload and other activities of a patient into consideration when compiling a home-based exercise programme in order to increase compliance (Gram *et al*. 2014:42). It is however problematic to relate these findings among healthy young men to patients with POP.

Studies have also reported other risk factors associated with a lack of compliance. These factors include problems with personal behaviour and belief aspects, awareness, faith in the efficacy of care, a good self-esteem and supervision. Additional factors among patients may include variability in attitude towards their disease, the ability to understand instructions, and communication skills. Professional factors relating to the degree of compliance include communication skills, personal qualities, and the level of commitment of the healthcare professional (Criado & Tawese-Smith 2007:36).

The literature found that the most common barriers to patient compliance included finding time to exercise, uncertainty about performing the exercises correctly, complexity of the exercise programme, patients' knowledge of their condition, and lack of motivation. Emanating from these risk factors, factors that can improve compliance can thus be identified. A theoretical class on the anatomy of the lower abdomen and pelvic area could be given to explain the importance of the exercise programme. The patients can be given a calendar to mark off when they did the exercises or use a diary to keep track of the exercises they did, as well as to record their progress. The exercises can also be divided into two sessions per day to shorten the time spent exercising, or it can be linked to a daily task, such as exercising before bathing or showering (Kim, Kim & Oh 2011:137-138).

It is important that the medical team as a whole commit to relating well to the patient, and to ensure that he/she feels secure, confident and motivated to return to optimal health. The compliance a patient displays is a good reflection of their attitude and state of mind after surgery (Gram *et al.* 2013:40-42).

2.8.3.3 Patient motivation

Physiotherapists are in an ideal position to influence every individual they treat in terms of their exercise behaviour as promoters of health, preventers of disease and further complications, as well as rehabilitators of already diagnosed disorders. It is clear that physiotherapists are able to provide interventions which promote and positively influence compliance and physical activity (McGrane, Galvin, Cusack & Stokes 2015:10).

Studies have shown that roughly 65% of individuals do not comply with home exercises and 10% fail to complete their physiotherapy programme. Successful physiotherapy treatment plans entail both attendance at scheduled treatment sessions and compliance with unsupervised exercises. Compliance can be improved by motivation, which up to now has not been an intervention optimally utilised in physiotherapy (McGrane *et al.* 2015:11).

Self-motivation can be defined as a person's beliefs about their abilities and their goal-setting tendencies. Motivation emphasises one's effort and persistence to reach a goal once it has been set (André & Dishman 2012:232). There are intrinsic and extrinsic motivational principles. Extrinsically motivated behaviour includes activities which individuals do not engage in for pleasure, but rather in order to receive some form of beneficial outcome that is external from the activity itself (Vallerand 2004:428-429).

The Cognitive Evaluation Theory (CET) addresses the factors that influence intrinsically motivated behaviour. Motivation results from three innate physiological needs, namely the need for autonomy, competence and relatedness. If these needs are not satisfied, motivation and well-being are likely to be diminished (Lonsdale *et al*. 2012:2).

Means of motivation include communication, personal treatment and providing feedback and assessment of progression to the patients (Gram *et al*. 2013:42; Bo 2012:438). Another study indicates that a patient is more motivated to do their exercises when they are taught, rather than just given the information, and also when there is a personal goal to achieve. When the therapist is more involved and empathises with the patient about the progress, patients tend to be more self-efficient (Novak 2011:1081) (see 2.8.2).

Lonsdale *et al*. (2012:104) published a proposal for a single-blinded randomised controlled trial focussing on the self-determination theory, stating that support from health care practitioners can promote a patient's autonomous motivation and improve persistence during activities (i.e. adherence to a home-based exercise programme). The trial was to include patients with lower back pain. Physiotherapists involved with one group of patients would be trained on how to motivate patients through hand-outs, videos, role-play and discussions, while another group of physiotherapists would not receive any training on the subject. It was hypothesised that patients who were treated by physiotherapists who had received the training would be rated as more adherent during physiotherapeutic interventions (Lonsdale *et al*. 2012:2-3). An academic article on the outcomes of this study could not be traced.

2.8.3.4 Text messages as method of motivation

The possibilities to change behaviour by means of motivation have expanded due to the age of technology. However, reaching patients in a rural setting with limited technological resources may be challenging. Due to cellular telephones becoming the chosen means of communication, they can be regarded as good modalities to use as motivational interventions as it promotes self-regulation with regards to a home-based exercise programme (Dennison, Morrison, Conway & Yardley 2013:online).

A previous study indicated that the frequency at which exercises were done improved greatly when a reminder was sent to the patients via text message. Text messages are fast, affordable, convenient, and a less stigmatising method of communication in order to stay connected with the patients partaking in the study (Prestwich, Perugini & Hurling 2009:684).

2.8.3.5 Measurement tools for compliance

Recent studies have mentioned methods of assessing exercise compliance, including log books, training diaries and questionnaires. These particular assessments are however vulnerable to observer expectation bias (McGrane *et al.* 2015:10).

Exercise diaries and questionnaires have proven to be successful in measuring compliance, but incidents of recall bias may occur should the patients not complete them on a daily basis. Exercise diaries may improve patient compliance, but the ability to measure the compliance may be compromised. Questionnaires, on the other hand, can be completed after every exercise session and can be patient-specific (Basset 2012:1000e124).

Exercise adherence may vary considerably due to the variety of factors that may influence it. The literature has indicated adherence rates between 40% and 60% (Plack & Driscoll 2011:210). A study by Sluijs, Kok and Van der Zee (1993:779) found a less favourable result in exercise compliance where only 35% of patients fully complied with an exercise home programme. This result increased to 76% when they added the data for patients who were only "partly" compliant.

2.9 OUTCOME MEASUREMENT

Contributing to the challenges of treating and assessing PFD besides compliance and motivation is the fact that treatment of PFD is complex. This also complicates physical and subjective outcome measurement utilised in the assessment and treatment of PFD, as different PFDs may co-exist and interact. Treatment of one aspect may lead to the improvement, worsening or even predisposing of another factor. Therefore PFM function must be assessed in its totality, and not only one aspect of it (Claerhout, Moons, Ghesquiere, Verhuts, De Ridder & Deprest 2010:574). The assessment process is complicated even more by the fact that biopsychosocial factors should be taken into account when diagnosing and measuring treatment outcome in an 'adult learning' population.

The use of clinical evaluation tools for investigating the PFM is still limited. For research and clinical purposes, treatment and treatment outcome should be described in terms of the International Classification of Functioning, Disability, and Health (ICF) (Grape, Dedering & Jonasson 2009:395, 399). The complete description of treatment outcome should therefore entail description on more than one level of the ICF's level of body function.

When surgery is considered as a treatment option, methods such as EMG, ultrasound (US), or even MRI have been indicated to be indispensable in the outcome assessment (Devreese *et al.* 2004:196). Srikrishna *et al.* (2008:520) reported that in the treatment of PFD, an improvement of QOL and a subjective cure is the patient's goal, and clinically the most relevant outcome measure. Measurement of QOL would therefore describe the outcome on the participation level of the International Classification of Functioning, Disability, and Health (ICF) (Grape *et al.* 2009:399).

Examples describing each level of the ICF for a patient with POP are provided in the table below (Table 4).

Table 4. The hypothesised ICF for outcome measurement in patients with POP.

ICF LEVEL	DESCRIPTION	OUTCOME MEASUREMENT TOOLS
Body function	POP stage. PFM strength and endurance, movement, activation and coordination. TrA activation (local stability). Global stability of the abdominal muscles. Any associated bladder or bowel dysfunction.	POP-Q PERFECT scale, perineal US, EMG PBU, EMG Sahrmann P-QOL
Activity	Activities that cause a rise in IAP, e.g. handling heavy objects, running long distances, walking, coughing, sneezing, obstructive defecation, etc. Any activities that cause increased dysfunction of the bladder or bowel. Sexual functioning.	P-QOL, SF-36
Participation	Cannot participate in any activity that causes a rise in IAP. Social activities with family and friends. Intimate relationships.	P-QOL, SF-36

Hypothesis 13 (relate to objectives 1.6.1.1-1.6.1.4)

Based on theoretical biomechanical and exercise principles and guidelines, an effective exercise programme should lead to an improvement in disease specific symptoms and bother, and therefore in QOL.

2.9.1 Outcome measurement of quality of life

Injury and pathology may elicit a variety of emotional responses from the patient. It may include irrational thoughts and beliefs, attacks on self-image and self-esteem, feelings of helplessness, anger and depression, and uncertainty regarding the future outcome (Brukner & Khan 2012:247). Following protocols of previous studies investigating QOL in patients with POP, a general and disease-specific QOL instrument is recommended to determine the true impact of the intervention on the disease investigated (Pauls *et al.* 2013:271; Frawley *et al*. 2010:719; Jarvis *et al*. 2005:300).

In 2009, Fritel *et al*. (2009:615) stated that POP symptoms have a significant effect on general health-related QOL, as measured with the Nottingham Health Profile dimensions. Interestingly, at the time of the study, no validated disease-specific questionnaire existed to measure QOL in women with POP (Fritel *et al.* 2009:615). This statement was substantiated by Claerhout *et al*. (2010:573) who reported that QOL was becoming increasingly important in assessment during functional surgery and other PFDs. For 25 million Dutch- and Afrikaans-speaking patients, no validated language and disease-specific questionnaires existed. The Pelvic Floor Distress Inventory (PFDI) and the Pelvic Floor Impact Questionnaire (PFIQ) are the only prolapse-specific questionnaires, together with the Prolapse Quality of Life Questionnaire (P-QOL). The P-QOL combines a symptom inventory and a QOL assessment, and contains less questions than the PFDI and the PFIQ questionnaire (38 versus 139 questions in the latter). However, clinically a culturally relevant questionnaire should be developed, maintaining the meaning and intent of the original items; or else it might lead to erroneous research conclusions (Claerhout *et al*. 2010:573).

In 2010, a Dutch version of the P-QOL was translated and standardised. It was found to be valid, reliable and responsive (Claerhout *et al.* 2010:571-572). This is in concordance with the results from other studies that have standardised the original English version of the P-QOL into eight (8) languages (Claerhout *et al*. 2010:570; Manchana & Bunyavejchevin 2010:986; Svihrova, Digesu, Svihra, Hudeckova, Kliment & Swift 2010:55; De Oliveira, Tamanini & Cavalcanti 2009:1192; Lenz, Stammer, Brocker, Rak, Scherg & Sohn 2009:642; Cam, Sakalli, Ay, Aran, Cam & Karateke 2007:132-133; Digesu *et al*. 2003:185). Digesu *et al*. developed the original English version in 2005. The internal validity of this questionnaire has been established by measuring the Cronbach alpha coefficient in a study involving 155 symptomatic and 80 asymptomatic subjects. All items achieved a value of greater than 0.80, indicating good inter-rater variability. Severity according to the P-QOL correlated with objective vaginal examination findings ($p<0.1$, $rho>0.5$). Test-retest reliability, measured by Spearman`s correlation coefficient, ranged between 0.644 and 0.872 for the different domains. Symptomatic women scored an average of 64.78 on the questionnaire compared to asymptomatic women who scored an average of 5.89 (Digesu *et al*. 2005b:176-181). A detailed description of the questionnaire is outlined in 3.6.1.1.

The median scores for symptomatic and asymptomatic participants from other studies are presented in 5.2. Amongst them was a study on 233 symptomatic and 122 asymptomatic participants (in the United Kingdom), which revealed median domain scores ranging between 42 and 100 in symptomatic women, and between 0 and 25 in asymptomatic women ($p<0.001$) (Digesu *et al.* 2005a:974). Results therefore indicate that lower scores represent improved QOL, while higher scores represent poor QOL.

To substantiate and differentiate results from disease-specific QOL factors in a specific population and treatment group, from other factors that may affect QOL, a generic QOL questionnaire should be included in research protocols. A recent Cochrane review on PFM training for UI emphasised the use of condition-specific as well as generic QOL instruments for adequate assessment of QOL (Dumoulin & Hay-Smith 2008:18).

The Short Form-36 (SF-36) is a multi-purpose, generic health survey containing only 36 questions covering the domains of functional health and well-being, psychometrically-based physical and mental health, and a preference-based health utility index. It has been documented in over 4000 publications and the reliability, validity, and normative data has been established in several studies (Ware 2008:1). A scoring algorithm is used to convert the scores in a range of 0 to 100; higher scores indicate a higher level of function and health (Burholt & Nash 2011:589; Khader, Hourani & Al-Akour 2011:369) (see 3.6.1.2). For the USA, a mean value of 50 has been established for the general population and 10 as the standard deviation (SD). A score higher than 50 therefore indicates better function and health than the general population, and a score lower than 50 worse (Gandek 2002:2). The discussion on the interpretation and implementation of this scale will be continued in 3.6.1.2 and 4.3.1.

Contributing to the assessment of QOL is the specific assessment of pain. Considering the target population and characteristics of the sample of this study (see 3.4), a faces pain scale was deemed more appropriate to utilise as a measuring instrument, than for example the Visual Analogue Scale (VAS). Freeman, Smyth, Dallam and Jackson (2001:293) found a significant positive correlation between the VAS and the five point faces rating scale (r=0.89) in a population with lower educational levels. Li, Liu and Herr (2007:232) also found faces pain scales to be more reliable and valid compared to other pain scales in assessing post-operative pain in a Chinese population. Furthermore, good responsiveness and a large effect from pre-treatment to post-treatment have been found with faces pain scales in patients with chronic musculoskeletal pain. Significant statistical correlations have also been found with domains of the SF-36 (Dogan, Ay, Evcik, Kurtais & Öztuna 2012:127-128).

The SF-36 and P-QOL would therefore help to give an indication of a patient`s limitation on participation level, while the following sections describe measures which would indicate limitations in bodily function and activity levels, according to the ICF (Table 4).

2.9.2 Outcome measurement of pelvic floor muscle function

Different measuring instruments for assessment of PFM dysfunction have been used in research studies and tested for validity and reliability. Most instruments have limitations and it seems that a battery of measuring instruments, measuring the different aspects of muscle function and biopsychosocial factors, would be most appropriate for accurate assessment (Park & Lee 2013:530).

Manual palpation for muscle strength and tone has been reported by Bo (2001:884) to be unreliable with poor inter-rater reliability. This is a method that depends on the skill and clinical experience of the tester, but it is easy to utilise without the use of any equipment – an important consideration when diagnosing PFM dysfunction in a community-based population. Devreese *et al.* (2004:192-196) developed a palpation and inspection assessment scale to determine muscle tone, speed of contraction, endurance, coordination of the PFM and TrA muscle, and strength of contraction. The quantification of the scale, however, is problematic for research purposes and statistical analysis, since most measurements are qualitatively ranked. The scale was found to be reliable, but validity still had to be determined.

Conical devices of different weights may provide an objective, quantitative measurement by establishing the maximum cone weight that can be held in place. However, anatomical changes may also be responsible for not being able to hold a device with a certain weight (Bo 1995:283), which questions the validity and reliability of this method. Little evidence exists for using this device for objective measurement, and several adverse effects for using intravaginal cones have also been reported which might prompt researchers to using safer manual examination techniques (Bo 1995:283).

The PERFECT scale is a manual, reliable and valid intra-vaginal quantitative method for measuring PFM strength and endurance. This form of assessment correlates moderately to good with objective measures such as pressure perineometry, adding evidence to the validity of the PERFECT scheme for assessment purposes (Da Roza, Mascarenhas, Araujo, Trindade & Jorge 2013:208; Laycock & Jerwood 2001:633). However, concern has been raised as to the accuracy level of the scale to detect small differences in force production by the PFM (Morin, Dumoulin, Bourbonnais, Gravel & Lemieux 2004:340). Significant inter-examiner reliability, using Spearman's correlation, has been found for measurement of power ($r=0.947$; $p<0.0001$), endurance ($r=0.946$; $p<0.001$), repetitions ($r=0.730$; $p<0.005$), and number of fast contractions ($r=0.909$; $p<0.001$) in a reliability study on ten (10) participants (Laycock & Jerwood 2001:631-642). Fair inter-rater reliability (Cohen's kappa of 0.33) for the modified Oxford scale (which is part of the PERFECT scale) has also been found in a study by Ferreira *et al*. (2011:135).

Test-retest reliability of the PERFECT scale has been determined on 20 incontinent women. Significant correlations (Spearman`s rank correlation coefficients; $p<0.001$) were recorded between power ($r=0.929$) and endurance ($r=0.988$) values on two (2) different occasions. Internal validity was substantiated by significant positive correlations between power, lift, perineometric pressure, and digitally assessed endurance. The power in continent patients ("normal values") should be good (equals a four on the scale), and endurance should be at least seven seconds (Amaro, Moreira, Gameiro & Padovani 2005:353; Laycock & Jerwood 2001:631-642). Laycock and Jerwood (2001) found an average muscle strength of 3.6±1.1 in continent women and 3.1±1.2 in incontinent women ($p<0.00005$). The average endurance of the continent women were 7±2.9 seconds and of the incontinent group 6.3±3.3 seconds ($p=0.103$) (Laycock & Jerwood 2001:636). In another study, conducted on seven (7) healthy women, an average muscle strength of four was measured on the Oxford scale (Sapsford *et al.* 2001:35). A study by Fialkow, Gardella, Melville, Lentz and Fenner (2002:1446) found a muscle strength of less than 2 on the Oxford scale in 39% of women with a posterior vaginal wall defect and a strength of ≥2 in 63% of the participants with a Bp≤-1, according to the POP-Q staging.

The Pelvic Organ Prolapse Quantification system (POP-Q) is a specific standard of defining, measuring and describing POP recommended by The International Continence Society. It is a quantitative description of the position of the prolapsed pelvic organs used in all literature for standardised interpretation of results. A stage is assigned according to the most severe portion of the prolapsed organ. Supplementary physical examination techniques, such as described above and in the following paragraphs, are recommended in addition to these guidelines as essential to aid in the characterisation of the POP in an individual patient. These techniques include, but are not limited to, imaging procedures such as US, PFM inspection, palpation, EMG, and pressure recordings (Bump *et al*.1996:10-17).

Table 5. The POP-Q stages.

Stage	Definition
O	No prolapse is demonstrated.
I	The most distal portion of the prolapse is >1cm above the level of the hymen.
II	The most distal portion of the prolapse is ≤1cm proximal to or distal to the plane of the hymen.
III	The most distal portion of the prolapse is >1cm below the plane of the hymen but protrudes no further than 2cm less than the total vaginal length in centimetres.
IV	Complete eversion of the total length of the lower genital tract is demonstrated. The distal portion of the prolapse protrudes to at least *(TVL-2)cm.

*TVL = total vaginal length

Pressure measurements can also be used to assess PFM control and strength. These measurements, however, have limited/unproved reproducibility and potential for error (Chen, Song, Jiang, Hong & Ye 2011:931). One of the main concerns regarding the validity of vaginal squeeze pressure as an outcome measure is the fact that both straining and a correct contraction can give an equal increase in pressure (Morkved *et al*. 2004:388). Abdominal, anal sphincter, and detrusor contractions, as well as rectal peristalsis, can affect these pressure readings (Bump *et al*. 1996:16). An intravaginal balloon may sense any pressure changes within the vaginal or abdominal cavity and therefore not give a valid reflection of the pelvic floor contraction (Verelst & Leivseth 2004b:662). Another problem with measuring instruments (or any that has a standard probe diameter), such as the perineometer, is that it does not take into account differences in the anatomical diameter of different patients, and can therefore influence the length-tension relationship of muscle contraction by causing different proportions of muscle stretching/lengthening and therefore contractions in different patients (Verelst & Leivseth 2004b:663). Peschers, Vodusek, Fanger, Schaer, DeLancey and Schuessler (2001:274-275) concluded that pressure perineometry did not selectively depict PFM activity.

Authors such as Grape *et al.* (2009:399) and Resende *et al.* (2011:292) describe EMG measurement as a reliable method with a good predictive validity for evaluating PFM activity, when compared to perineometers and subjective palpation. The advantage of this method, when compared to a perineometer (which measures the intra-vaginal pressure with contraction of the PFM), is that it also measures the resting tone of the PFM (Lang, Brown & Crombie 2007:126). A previous statement made by other authors regarding the lack of proportionality between EMG activity and PFM strength/force can be contested since EMG measurement is mainly for measuring the electrical activity of the muscle being assessed (Verelst & Leivseth 2004b:662).

The surface EMG is patient-friendly, non-invasive and can be used for biofeedback. It measures the action potential of the surface muscles and is expressed in amplitude changes. The activation of the motor units is measured by recording the electrical activity of the muscle on a cathode-ray oscilloscope (Grape *et al.* 2009:395; Aukee *et al*. 2003:254). A limitation is that EMG measurements do not distinguish between PFM contractions and contractions of surrounding muscles ("cross-talk"). Movement of the muscles under the electrodes may affect the accurate assessment of the activity as well. To overcome this problem, measurements are usually taken with isometric muscle contractions in a sustained posture (Verelst & Leivseth 2004b:662). Repeatability and reliability has been demonstrated (Aukee *et al*. 2003:254).

Thompson *et al*. (2006b:151) found an ICC (standard error of means) of 0.98 for EMG measurement of the PFM. An intra-class correlation (ICC) of 0.83-0.96 was calculated in a study that showed good to high reliability of surface EMG on the PFM of healthy women (Grape *et al.* 2009:396-399). A study by Auchincloss and McLean (2012:1007) indicated similar reliability measures for both fine wire and the Periform electrode (ICC of 0.72 to 0.98 and CV`s of 8.5 to 14.2%). EMG measurement with the Periform™ electrode has also been found to have good to high inter-trial reliability for MVCs (an ICC of 0.87 to 0.96 and CV of 9.6 to16.4%) (Auchincloss & McLean 2009:90).

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An average activity of 22.2цV and peak activity of 31.6цV with the surface EMG were measured in healthy women by Grape *et al.* (2009:396-399). Sapsford *et al.* (2001:34-36), in their study on healthy women, measured a surface EMG reading of the pubococcygeus muscle equal to 100цV on maximal contraction. Another case indicated an EMG value of between 10 and 20цV in a woman with genuine stress incontinence. After EMG biofeedback, the reading increased to between 30 and 40цV (Knight & Laycock 1994:146). Mean values of 17.0цV and 19.5цV have been documented among incontinent and continent participants respectively (Aukee *et al*. 2003:253). It is therefore clear that reported normal values have a wide range. Auchincloss and McLean (2012:1005) have reported a mean amplitude of 59.4µV (SD 42.2) in a small sample of healthy nulliparous women (mean age 31.1 years). These values are quite high when compared to previously mentioned values in women without PFM dysfunction. It is clear that factors such as age, parity, menopause, BMI, and others would influence what is to be interpreted as 'normal'.

Endurance for the PFM, as measured with the EMG, has been found to have a median of 5.5 seconds at 60% MVC for continent women younger than 40 years, and nine seconds for women 40 years or older (Quartly *et al.* 2010:313). They reported a median difference of -4 seconds (95% CI of -24 to 2 seconds) between the groups. However, the endurance suggested by Laycock and Jerwood (2001:631-642) to be present in asymptomatic participants, was found to be approximately seven (7) seconds.

In some instances, however, it might not be possible to use internal assessment techniques as described above to determine PFM function. Examples would be immediate post-operatively, after acute trauma, or in the case of perineal or pelvic pain syndromes. Techniques such as MRI or perineal US would then be indicated, if available. MRI can be used to determine correct PFM contraction. It provides high-resolution images and is therefore excellent for use in research, but it is expensive and not readily available to use as a clinical tool and for feedback purposes (Thompson & O`Sullivan 2003:84).

Contrary to MRI, US (abdominal and perineal) is a more available and cost-effective method of assessing PFM function. There is evidence that the most accurate indicators of PFM function are digital palpation and perineal US. It has been suggested that the use of standardised US measurement, together with a thorough history, physical and biomechanical assessment, could be an important tool to determine PFM motor control. US has been used to measure changes in the thickness of the PFM during contraction, and movement of the bladder neck (Whittaker 2004:46). The measurement of the size of the genital hiatus and LH could also be an indication of the muscle tone of the PFM (Fialkow *et al.* 2002:1444). This could be of value in patients with uro-gynaecological pathology and lumbo-pelvic dysfunction who require further investigation and treatment of the PFM (Whittaker 2004:46-48; Thompson & O`Sullivan 2003:84). Other advantages of this technique is that it is non-invasive, gives immediate visual feedback to the patient and clinician, is easy to apply, and can be used in populations where digital examination may not be possible (Thompson & O`Sullivan 2003:85). The method has been standardised (perineal US) and shown to be reliable and reproducible (Dietz 2004:82).

A study comparing transabdominal US and perineal US assessment of PFM activity found good repeatability for both techniques (ICC of 0.91 for transperineal US). It also found a significant correlation between manual muscle testing and transperineal US measurement. The authors concluded that transperineal US was a more reliable method than transabdominal US measurement (Thompson *et al.* 2005:288-289).

Intra- and inter-observer variability for perineal US assessment of bladder neck mobility has been published by Dietz. He found ICCs of 0.77 and 0.79 in two separate test-retest studies. Other studies calculated ICCs of between 0.75 and 0.98 for a test-retest series (%CV 0.219) and inter-observer variability (%CV 0.21) (Dietz 2004:82).

Movement of the bladder neck accompanied by a cranioventral shift of the pelvic organs can be taken as an indication of PFM contraction. The movement of the internal urethral meatus is taken as an indication of such a contraction. Intra-observer variability has been calculated as 3.3% in an unrelated series (Dietz, Wilson & Clarke 2001:166-167).

Most studies have assessed the movement of either the bladder neck, or the levator ani muscle/levator plate as an indication of PFM contraction. A study by Bo *et al.* (2003:586) found a mean translation of 12.4mm of the PFM in a population of mainly asymptomatic female physical therapists. A displacement of 16mm was found in a patient with correct PFM contraction. These measurements were taken by means of transabdominal US. Quantification of levator ani muscle contraction by measuring the cranio-ventral displacement of the bladder neck (with perineal US) has indicated values of 4.5mm of cranial displacement and 16.2mm of ventral displacement in an unknown population (Dietz 2004:86). An average displacement of 15mm of the PFM could therefore be considered as normal in a cranio-ventral direction (DeLancey & Hurd 1998:364, 367).

Increasing POP is also associated with increasing urogenital hiatus size associated with the cephalad displacement of the PFM during dysfunction. In women with normal support and without previous surgery, an area of 5.4cm² has been calculated, which is associated with a sagittal diameter of 1-3cm, a transverse diameter of 1-2cm, and a perineal body thickness of 2-3cm (DeLancey & Hurd 1998:364, 367).

Dietz, Shek and Clarke (2005:580) investigated 52 nulligravid, female, Caucasian volunteers with two- and three-dimensional US. They found an average diameter of the pubovisceral (PR) muscle in the axial plane to be 0.4-1.1cm (mean 0.73cm), and the LH at rest in the sagittal direction to average from 3.26-5.84cm (mean 4.5cm). The mean muscle diameter in the coronal plane was 1.33cm (SD 0.55) and the diameter between the perineal skin and the muscle (perineal body) was a mean of 2.42cm (SD 0.44). This was also the measurements taken in our study, and the latter values could be a norm for comparison for the findings of this study on women with POP. The assessment of this muscle should form an integral part in the evaluation of these patients, according to Dietz and Steensma (2006:225).

The value of US imaging in rehabilitation and motor control is that it provides dynamic study of the deeper, and many times difficult to palpate, muscle groups together with their patterning of muscle activation (Whittaker 2004:44). US can be used as biofeedback and gives valuable, visual information on the movement of the PFM. It should be used as an adjunct to other methods of assessment and treatment, since it only evaluates a certain aspect of PFM function (Thompson & O`Sullivan 2003:85).

2.9.3 Outcome measurement of the abdominal muscles

Disagreement exists amongst professionals regarding the most effective assessment strategies for core stability (Brumitt, Matheson & Meira 2013:504). The literature states fine-wire EMG to be the gold standard for measuring the deep abdominal muscles. High cost, pain, discomfort and risk of infection, however, limit the use of this assessment tool (Costa, Costa, Cancado, Oliveira & Ferreira 2006:48). Non-invasive strategies such as US and palpation can also be used to assess abdominal muscle activation (Rezasoltani 2003:35), but the results on reproducibility of these tests that have been published are not acceptable (Lima, Oliveira, Filho, Raposo, Costa & Laurentino 2012:390). However, a study by Ferreira *et al*. (2011:466) did find moderate to excellent association between the US assessment of the TrA and IO muscles with fine wire EMG (for TrA muscle $r=0.74$, $p < 0.000$ and for IO muscles $r=0.85$, $p < 0.000$). Contrary to other measurement tools, surface EMGs seem to be a more useful and comfortable technique that has been proven to have reasonable validity (cross-correlation of 0.69) and reproducibility (ICC of 0.9) (Lima *et al.* 2012:390).

Increasing the complexity of assessment of the abdominal muscles is the fact that different types of muscle function needs to be assessed (2.5.2.3). If the definition of core stability/motor control is accepted as including local stabiliser function, global stabiliser function, and mobiliser function, the assessment should include the measurement of different abdominal muscles under different loads (Comerford *et al.* 2005:3-1 – 3-6). Tests such as the abdominal drawing-in test in supine (with a PBU) are suggested to be used for measurement of the TrA muscle (Brumitt *et al.* 2013:504-506; Costa *et al*. 2006:49). Combining it with the Sahrmann test (Table 6), it can also give an indication of motor control. Comerford, Mottram and Gibbons (2005:xxvii-xxix) described the latter test further by differentiating between activation of the local stabilisers with the PBU (TrA muscle), rotational control of the global stabilisers (Sahrmann level 1), rotational strengthening (Sahrmann level 2 & 3), and abdominal strengthening of the global mobilisers (Sahrmann level 4 & 5). Tests such as the back extensor, the lateral musculature, and the flexion endurance tests have also been suggested to test the global stabilisers. However, depending on the patient's symptoms, age and pathology, the latter would not be appropriate to use for all patients when compared to the Sahrmann test (Brumitt *et al*. 2013:504-508).

Table 6. Levels of lumbo-pelvic stability – the Sahrmann test.

LEVEL	DEFINTION
1	In crook lying an abdominal hollowing manoeuvre pre-set the abdominal muscles and the participant slowly raises one leg to a position of 100° of hip flexion with 90° knee flexion. The other leg is slowly raised to a similar position. This is the start position for the following four levels.
2	From the start position, the participant slowly lowers one leg and, with the heel down on the plinth, slides the leg out to straighten the knee, then slides it back up into the start position.
3	From the start position, the participant slowly lowers one leg and, with the heel maintained approximately 12cm off the plinth, fully extends the leg and then moves it back to the start position.
4	From the start position, the participant lowers both legs together and, with the heels down on the plinth, slides the legs out to straighten the knees and then slides them back and raises them to the start position.
5	From the start position, the participant simultaneously extends both legs keeping the heels approximately 12cm off the plinth and then flexes the legs back to the start position.

(Mills, Taunton & Mills 2005:62-63)

The aim in research is to use the most applicable measurement tools with good clinimetric properties, namely validity and reliability. Repeatability of the Pressure Biofeedback Unit (PBU) has been established in the study by Jull, Richardson, Toppenberg, Comerford and Bui (1993), finding an average variation over six (6) trials of 9.3 AVU (calculated from the ANOVAs), which was considered acceptable for their study. In this original version of the test model they concluded that low load leg weight may be able to depict and identify loss of active trunk stabilisation; though further development was warranted (Jull *et al*. 1993:191-193). In other words, the cut-off value would be when the participant fails to perform *level 1* stability successfully (see 3.6.4.3).

More recent studies investigating the reliability and validity of the PBU have indicated good results for validity and reliability, when compared to previous literature finding low levels of test-retest reliability in the prone position (Storheim, Bo, Pederstad & Jahnsen 2002:245). Intra- and inter-reliability have more recently been established at 0.74 and 0.76 respectively (Brumitt *et al*. 2012:393). These studies were done on patients with low back pain.

Recent studies investigating the validity of the PBU have emphasised that research is lacking is regards to this topic. Park and Lee (2013:528) investigated the pressure changes in a supine testing position by monitoring the change in thickness of the TrA, the IO, and external oblique muscles with US. They found that a pressure change of 2mmHg most accurately represented a significant increase in TrA activation ratio, while the IO and external obliques muscles showed a significant decrease in muscle thickness, when compared to pressure changes of 6mmHg. However, pressure changes of 8mmHg and 10mmHg, as originally suggested, seemed to lead to an incorrect drawing-in manoeuver. The possibility of an inability to perform the right contraction at the higher pressure changes should be considered (Mills *et al.* 2005:60-66; Jull *et al*. 1993:187-193).

Lima *et al*. (2012:391-394) investigated the validity of the PBU by correlating it to surface EMG measurement. The testing was done in the prone position, although baseline data for the EMG were gathered in the supine position. They found a low sensitivity and specificity for the test (60% each). The interpretation of the results should take into account what the test apparatus are designed for. The EMG measures the amount of muscle activation (not force or movement), while the PBU is only able to detect movement of the abdominal wall with activation (Lima *et al.* 2013:394). It should also be mentioned that a mean maximum voluntary isometric contraction equalled 127.1µV (SD of 95.5) in these patients with low back pain. Significant EMG activity was defined as at least 10% of the maximum voluntary isometric contraction (Lima *et al*. 2012:391). There is a lack of normative data regarding EMG measurement, due to several intrinsic factors that can cause significant individual variation (Jull *et al*. 2015:168-175).

Baseline data is therefore important to detect individual differences when using instruments measuring muscle function and to establish improvement after intervention (Brumitt *et al*. 2013:505). Mills *et al.* (2005) found that a treatment group of female athletes showed a statistical significant improvement in their level of lumbo-pelvic stability after a ten (10) week training programme (Sahrmann level 1.3±1.3 – 2.8±1.5). A non-parametric Friedman analysis of variance by ranks chi square (2) equalled 22.45 ($p<0.01$) (Mills *et al.* 2005:62-64). No literature has described the parameters as described in this section, after an exercise intervention in women with POP, indicating the significance of the current research.

2.10 SUMMARY

Table 7 concludes this chapter with a summary of identified hypotheses from the literature, and how they relate to the aim and objectives of this study (see 1.6).

Table 7. Summary of hypotheses and related objectives.

Hypotheses	Objective*
Hypothesis 1 *Factors such as increased age, menopause, BMI, vaginal delivery, or causing an increased IAP (obesity, smoking, pulmonary disease, constipation, recreational or occupational activities), seem to be associated with POP.*	***1.6.1.1***
Hypothesis 2 *Decreased diameter and weakening of the PFM have again been associated with some of the above-mentioned factors, such as vaginal delivery, increased age and menopausal time. Together with the anatomical position and function of the PFM, the literature seems to indicate the importance of these muscles' function in the development of POP.*	***1.6.1.1***
Hypothesis 3 *According to the above explanation, it seems that dysfunction of the TrA muscle may lead to either increased tone of the PFM, or weakness due to failure in response to sustained overload and compensation.*	***1.6.1.1-1.6.1.3***
Hypothesis 4 *The muscles, such as the levator ani, can therefore contribute to dynamic as well as static support of the pelvic organs. The dynamic support is provided by means of muscle activity, and the static support by means of the effect of the muscle activity on the connective tissue (such as ligaments and fascia) to which it is connected.*	***1.6.1.1 & 1.6.1.2***

Hypothesis 5 *Referring back to Figure 2 (Chapter 1.2), namely the neuro-musculoskeletal control system, the discussion of the anatomy supports the hypothesis of the model where the connective tissue lies central to the whole system, connecting all the neuro-musculoskeletal components. Failure of the connective tissue at any level may contribute significantly to failure of the support mechanism of the pelvic organs.*	***1.6.1.1 & 1.6.1.2***
Hypothesis 6 *It is evident from the above descriptions that disruption of the fascia and musculature contributing to normal motor control and support of the pelvic viscera may lead to decreased function and coordination of the neuro-musculoskeletal system immediate post-surgery. Due to insufficient evidence, it is not clearly understood whether normal healing would be sufficient to return the tissue to its pre-operative state and motor control function. However, pre-operatively it is assumed that the patient has already decreased PFM function and motor control in most cases of POP. Should the tissue not return to its pre-operative state, the motor control and PFM function could be speculated to be worse post-operatively due to suboptimal healing, therefore contributing to a poor surgical outcome.*	***1.6.1.1 & 1.6.1.2***
Hypothesis 7 *However, due to the connection between the fascia, viscera and muscle, restoration of the mechanical and supportive properties of the pelvic floor muscles and fascia, as well as the abdominal muscles, may lead to improved mechanical properties of the more distant fascial, ligamentous, and visceral structures.*	***1.6.1.2-1.6.1.4***
Hypothesis 8	***1.6.1.1-1.6.1.3***

It therefore seems that, according to available studies, increased muscle thickness, strength and endurance could possibly contribute to a decreased levator hiatus which will prevent descent of the pelvic organs. EMG activity of the PFM however seems to be more complicated to interpret, due to reactions to adverse effects, such as increased IAP, as well as positive effects, such as increased activation of motor units in response to muscle training and improved neuromuscular control.	
Hypothesis 9 *The above-mentioned mechanisms of motor control are in accordance with the accepted motor control mechanism, and may clinically implicate the importance of maintaining a "normal" IAP by coordinated muscle actions, and the inclusion of postural changes and normal functional movements of the limbs during the rehabilitation of PFM function.*	***1.6.1.2 & 1.6.1.3***
Hypothesis 10 *Similar to the case of pelvic floor dysfunction and pain, the stabiliser muscles exhibit disturbed motor control patterns and changed physiological properties in individuals with low back pain (Hodges & Richardson 1996:2647). On the other hand, altered postural activity and morphological changes in these muscles are related to the development and the recurrence of low back pain (Cholewicki et al. 2005:2614). Pain may cause inhibition of the stabiliser muscles, and therefore is hypothesised to contribute to PFM dysfunction, such as POP and even incontinence (Grewar et al. 2008:376).*	***1.6.1.1-1.6.1.3***
Hypothesis 11 *Relating to the neuro-musculoskeletal control mechanism (Figure 2, Chapter 1.2), continence requires the interaction of anatomical*	***1.6.1.1-1.6.1.3***

systems, which include muscular, fibrous, and fascial systems. They provide the structure and support to keep the tissues in a normal functional relationship. Due to the close interaction between these systems, the failure of one may lead to the failure of one/all of the other components (Haderer et al. 2002:240).	
Hypothesis 12 *The question remains if the programmes for PFMT, as suggested up to now in literature, are optimal for patients with POP, and if more structured programmes based on sound rehabilitation principles and assessment findings could be more effective.*	***1.6.1.2 & 1.6.1.3***
Hypothesis 13 *Based on theoretical biomechanical and exercise principles and guidelines, an effective exercise programme should lead to improvement of disease specific symptoms and bother, and therefore QOL.*	***1.6.1.1-1.6.1.4***
***OBJECTIVES**	
Objective 1.6.1.1 *To determine baseline data regarding the abdominal muscles and the PFM, as well as QOL pre-operatively in women undergoing corrective surgery for POP.*	
Objective 1.6.1.2 *To determine the outcomes, within groups, of a* *i. PFMT programme,* *ii. core training programme, and* *iii. a control intervention,*	

on the PFM, abdominal muscles and QOL post-operatively in women who have had corrective surgery for POP.
Objective 1.6.1.3 *To compare the outcomes, between groups, of a* *i. PFMT, and* *ii. a core training protocol, versus no training (control group), on the PFM, abdominal muscles and QOL (pre-operatively and post-operatively) in women with POP.*
Objective 1.6.1.4 *To compile a proposed model for rehabilitation for patients with PFD in the public and private sector, pre- and post-operatively.*

2.11 CONCLUSION

The aim of Chapter 2 was firstly to discuss the literature on the pathology, symptoms and signs underlying POP as a disease of QOL. Secondly, the biomechanical and physiological aspects of surgical and conservative treatment approaches for POP (Part 2) were addressed. Lastly, Part 3 concluded the chapter with a discussion on the rehabilitation for patients with POP, if based on scientific guidelines and principles.

For the purpose of this study an exercise programme (Addendum 1, 2, 3 and 4) was compiled, based on previous research and current viewpoints, to be tested in a randomised, blind, controlled clinical trial comparing three groups by means of the stated outcome measures (see 2.9). The methodological approach to test the different hypotheses and objectives will be discussed in the following chapters.

CHAPTER 3

METHODOLOGY

3.1 INTRODUCTION

Chapter 3 introduces the research process that was followed to investigate the research aim and objectives for this study (see 1.6). The discussion focuses on methodological procedures, such as planning of the study, the study design, sampling, sources and data collection procedures, as well as measurement issues and methods of data analysis (Figure 21).

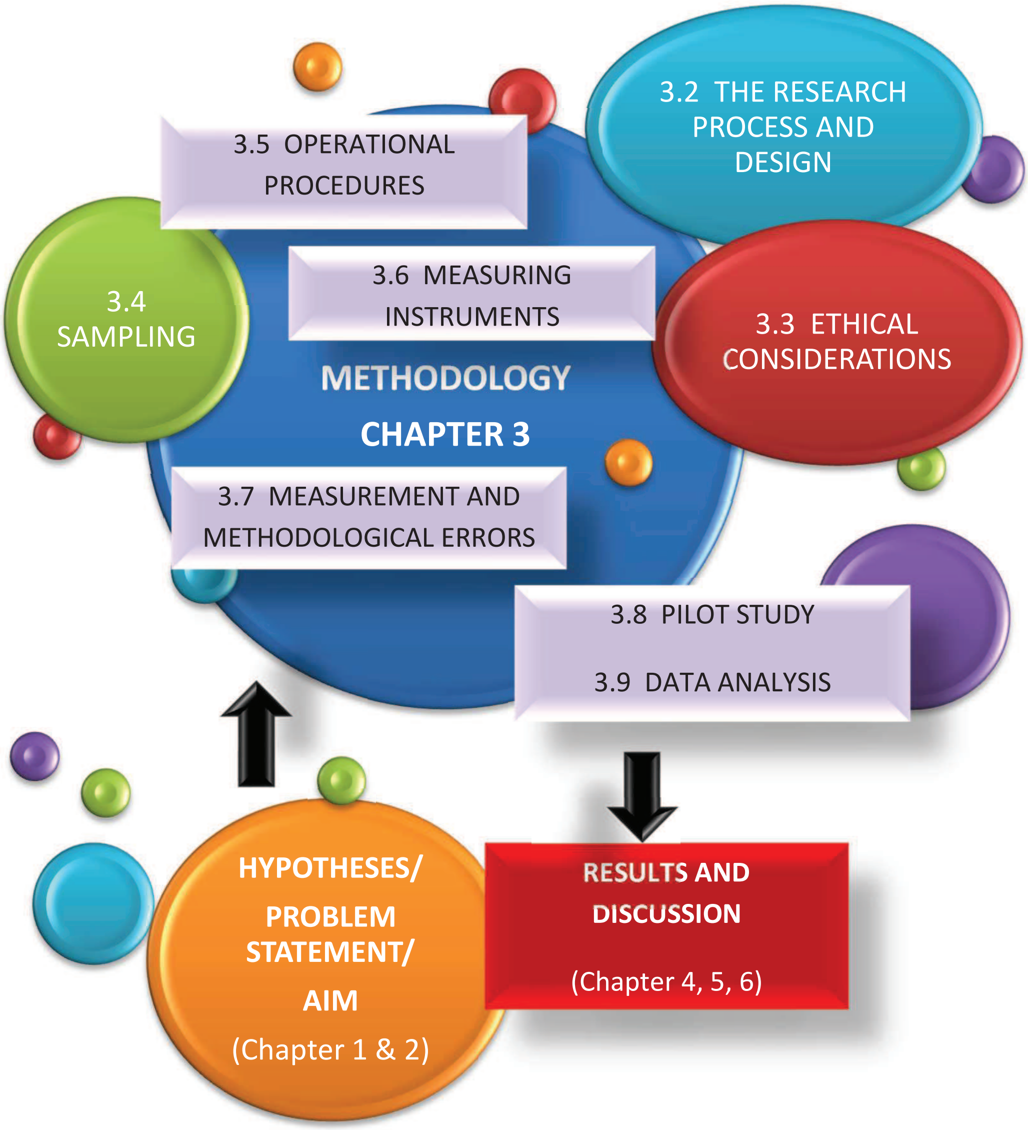


Figure 21. The interrelated discussion of methodological concepts within the study context.

3.2 THE RESEARCH PROCESS AND DESIGN

Research has to be a methodical and organised process in order for the information obtained to be relevant and of any use in initiating advances or even change. There are many different forms of research but ultimately research is designed to improve knowledge on a topic and to enhance reasoning and development in the field of interest (Oxford 2015: online; Maree 2013:51-52). Broadly, research can be divided into quantitative and qualitative research. The quantitative research process is characterised by three basic concepts, namely that it is systematic and objective, and uses numerical data from a selected subgroup in order to generalise the findings to similar populations (Maree 2013:145). When compared to the qualitative research process, quantitative research focuses more on establishing cause and effect than trying to understand and explore social and cultural contexts underlying behavioural patterns (Maree 2013:51). Table 8 below summarises the main differences between quantitative and qualitative research designs.

Table 8. Comparison of qualitative and quantitative research.

Qualitative	Quantitative
Smaller number of respondents	A large number of respondents
Not randomly selected	Randomly selected
More subjective	Measurements must be objective and statistically relevant
Refers to meanings, concepts, definitions, characteristics, metaphors, symbols and descriptions	Refers to counts and measures
Interpretation of what people do and say	Pre-determined options
Observation of perceived dynamic reality	Observation of perceived static reality
Answers research questions such as “what” or “why”	Answers research questions such as “how many” and “strength of association”
Develops a theory	Tests a theory
Interpretation of results	Measurable results
Researcher is part of the process	Researcher is separate
Context dependent	Context free
Study conducted in a ‘natural’ environment	Study conducted in a controlled environment
Seeks to discover patterns or causal links between variables	Establishes cause and effect relationships

(Maree 2013:145-153,47-68; Petty, Thomson & Stew 2012:267-271; Johnson & Christensen 2008:34)

For the purpose of this study, the researcher chose a quantitative study design, based on the theoretical framework and aim of the research, the role of the researcher during the process, and the researcher-respondent relationship. Based on a predetermined research question, hypotheses and research questions were generated from the existing literature to be tested in the study. The aim was to generate objective, measurable, statistical data in order to make recommendations for women with POP, pre-operatively, as well as the effect that an intervention programme could have on them post-operatively. The ideal situation was to control the environment and include the largest possible number of respondents to limit confounding factors and increase the validity of the findings. The quantitative research process made it possible to introduce factors such as blinding of the researcher and assessors, thereby increasing the objectivity of the findings.

However, ontology and epistemology were not ignored, especially when addressing concerns such as the relationship of the research to practice, and when analysing and formulating information on what should be considered as knowledge for practitioners (Maree 2013:30, 52). This paradigm was not the main aim of this study, therefore it is just briefly mentioned here. This consideration involves the exploration of the available knowledge on the neuromuscular rehabilitation for patients with POP. It also involves the extension of this knowledge in order to provide more effective exercise programmes to limit recurrence rates after surgery, or to prevent the development of POP (Gulbrandsen & Kyvik 2010:343-353).

This quantitative, outcome-driven approach therefore also defined the chosen research process as an applied approach. However, the chosen outcome measures, such as movement, thickness, strength and endurance of the muscles, and even QOL measurements, can also contribute to the extension of the existing knowledge and theoretical conceptualisation about the topic (Leedy & Ormrod 2010:44-45). Figure 22 depicts the quantitative research process for which the protocol was designed.

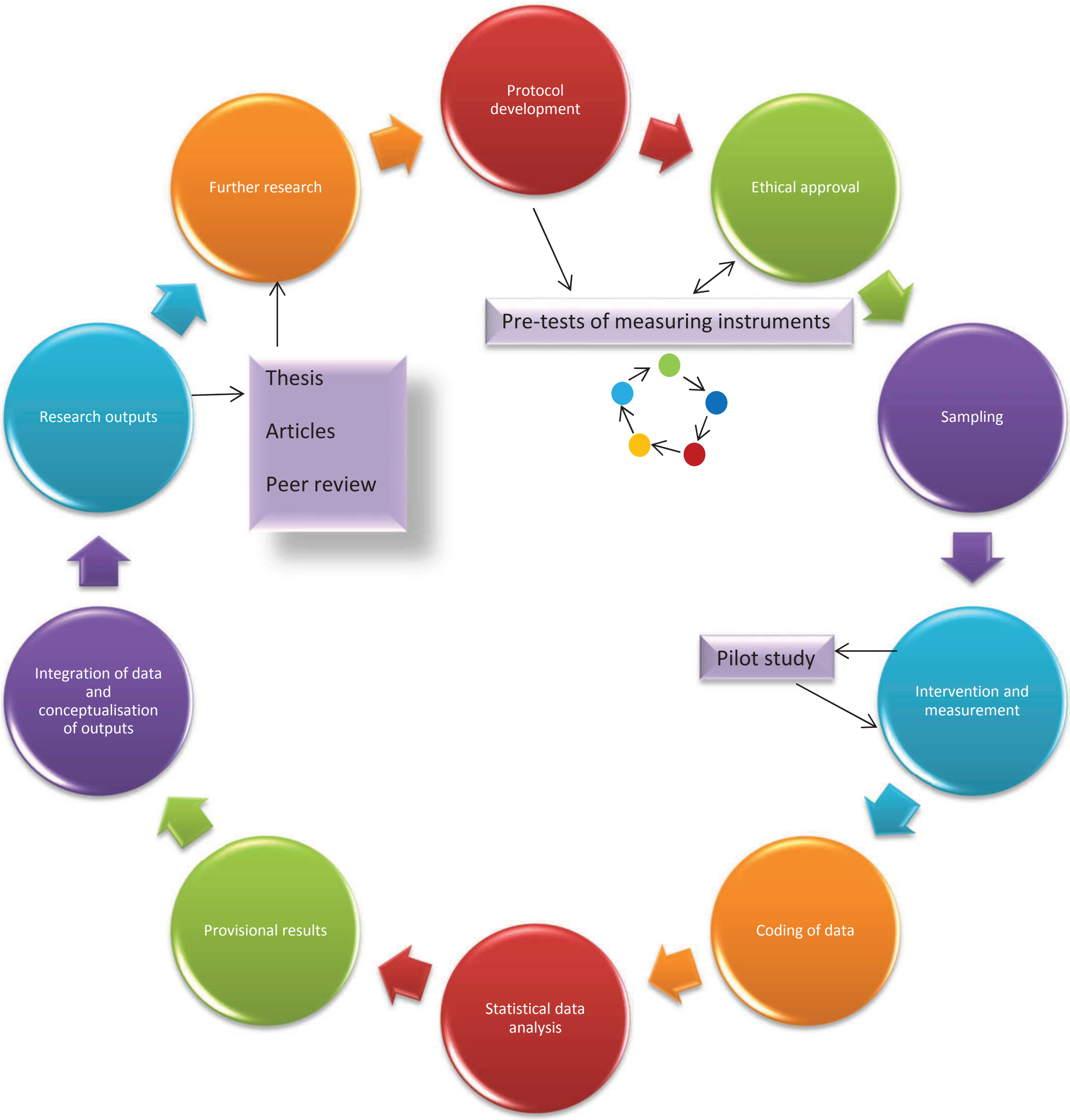


Figure 22. The quantitative research process.

The protocol was compiled for a classic prospective experimental design, as described by some authors (De Vos, Strydom, Fouché & Delport 2005:113-119), to determine the effect of the independent variables (namely the exercise programmes). A randomised, double blind, pretest-posttest control group design was utilised. This involved random assignment methods. This is an empirical study design utilising primary data to generate numerical data, ensuring a high level of evidence to be gathered on the rehabilitation of the PFM (Elwood 2002:22-23, 229; Mouton 2001:144-147; 155; Woolf 2000:4) (Figure 23).

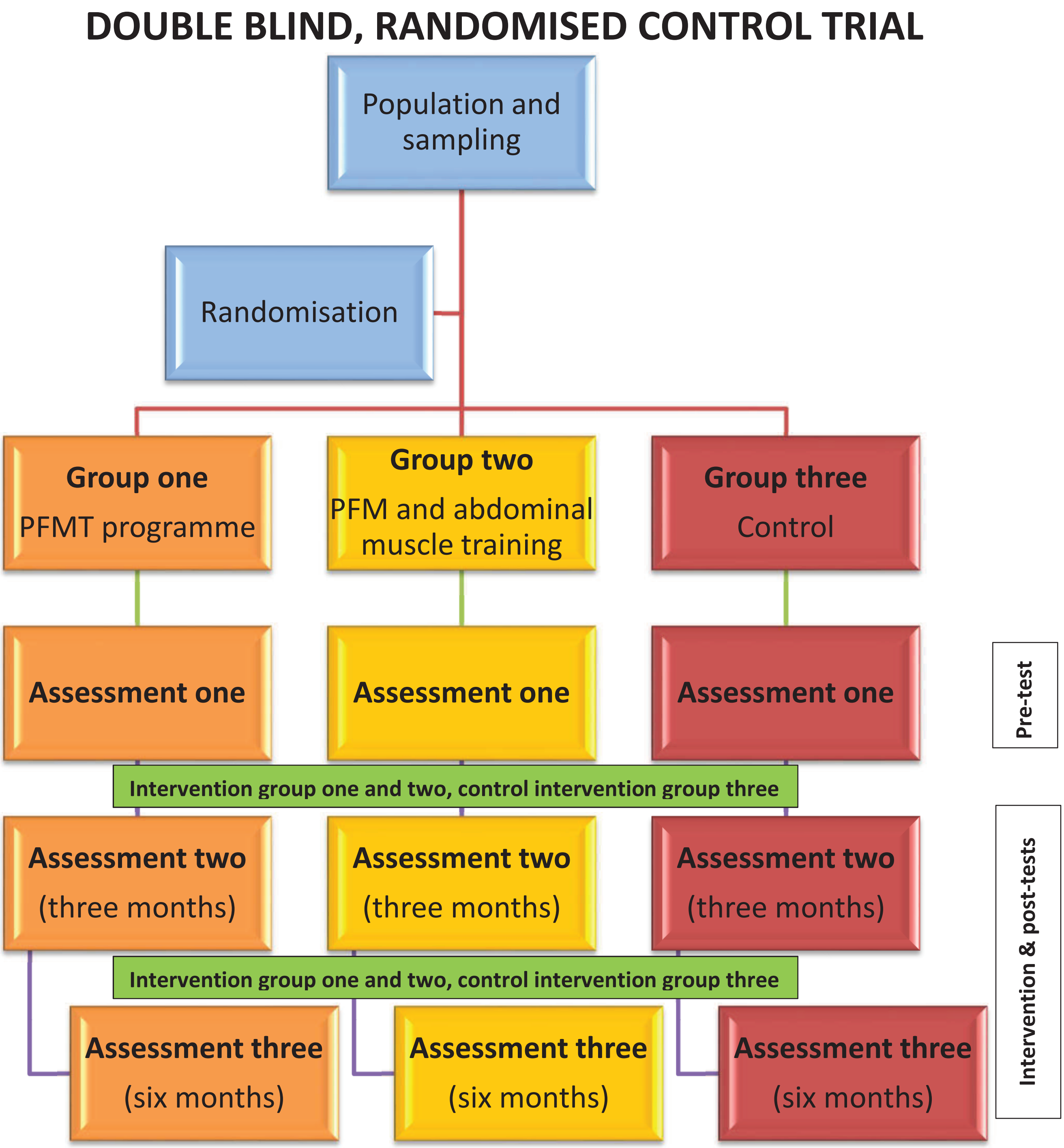


Figure 23. Schematic diagram of the study design.

The study design posed the opportunity to include all levels of measurement, for example nominal (demographic information), ordinal (PERFECT scale and Visual Faces Scale (VFS)), equal interval (muscle function), and ratio scale (demographic data and muscle function) measurement (De Vos *et al*. 2005:165-166). Different methods of data collection (De Vos 2005:166-191), namely subjective and objective methods, were utilised. Questionnaires (demographic and QOL questionnaires), indexes and scales (the QOL questionnaires and VFS), as well as more objective measures (such as EMG, PBU and US) were used.

All the groups were pre-tested, whereafter the independent variables (namely the exercise programmes) were given only to the experimental groups. After the intervention time, all the groups underwent the post-test to determine the outcome (Leedy & Ormrod 2010:231; De Vos *et al*. 2005:141). Figure 23 demonstrates how the classic experimental design was applied to investigate the research problem in this study.

Compared to pre-experimental designs, two problematic aspects were addressed by the inclusion of a control group, namely: it could determine whether a change took place after the intervention, and confounding variables could be limited when interpreting as to why the change occurred (Leedy & Ormrod 2010:231). Although the classic experimental design limited confounding factors, it did not eliminate them. An example of a confounding variable that is not necessarily underpinned by a classic experimental design is researcher and participant bias. This aspect was dealt with by introducing blinding into the research design (Maree 2013:151). These aspects, as well as other methods to improve validity and reliability, are discussed in the following sections.

3.3 ETHICAL CONSIDERATIONS

Scientific methods aim to generate data of the highest quality, but can give rise to certain ethical issues when they are in conflict with the values of the community (De Vos *et al*. 2005:68). Ethical considerations spread wider than only the design of the research study. When working with human subjects, the research must endeavour to protect the rights and dignity, and the physical and psychological welfare of the participants (Hicks 1999:63). This gives rise to ethics being defined as a set of moral principles, suggested by an individual or group, which is widely accepted, and which offers rules and behavioural expectations about the most correct conduct towards the experimental subjects and respondents, employers, sponsors, other researchers, assistants, and students (De Vos *et al.* 2005:57).

To ensure that the design of this study underpinned all ethical codes and guidelines, it was reviewed and approved by the Ethics Committee of the Faculty of Health Sciences of the University of the Free State (UFS) (ECUFS nr 25/2012, Addendum 5). The trial was also registered with the National Health Research Council (NHRC) of South Africa. Approval was also obtained from the following authorities or persons of authority: the Head of Universitas Hospital, where the study was conducted; the Head of the Department of Obstetrics and Gynaecology (UFS); the Head of the Uro-Gynaecology clinic at Universitas Hospital; as well as the private practitioners who were willing to partake in the study (Addendum 6).

The Ethics Committee ensured that the following aspects, as classified by De Vos *et al*. (2005:58), were adhered to: that no harm would be done to the subjects, that informed consent would be obtained, that subjects would not be deceived, that their privacy would not be violated, that researcher(s) would be competent, that the findings of the study would be published in a manner which portrays ethical conduct, and that the subjects would be debriefed regarding the outcomes of the study.

In this study, the subjects were protected from any physical or emotional harm by explaining the nature and potential impact of the study. This information gave them the opportunity to withdraw from the study at any time, should they wish. Participants were cleared as medically suitable/unsuitable for participation by the findings of the Uro-Gynaecologist during their first assessment at the clinic/practice. Aspects such as untrained muscles, which might become painful when exercised vigorously, were explained to them. However, this is a normal physiological response to exercise resulting in hypertrophy. Participants were made aware of such symptoms and had to understand the resultant effects (Laycock *et al*. 2001:26). In the case of any adverse events, or medical complications, it was documented comprehensively, reported to the Ethics Committee, and immediately managed by or referred to a medical practitioner, if indicated (Hagen *et al*. 2006:4). All events/complications were documented on the participant's treatment record (Addendum 7). Participants understood that they were to continue with their standard medical treatment, in addition to the research intervention, and would not be withheld from any standard procedures of care (Addendum 8), (De Vos *et al*. 2005:58).

This information was given verbally to each participant, as well as in written format (Addendum 8). It also included information regarding the goal of the investigation, the procedures to be followed, the possible advantages and disadvantages/dangers they might be exposed to, and the credibility of the researcher. The information on the procedures were compiled in such a manner that participants knew exactly what the intervention entailed, but without knowing which were the experimental and control groups. The researcher approached the patients privately for participation after their standard medical examination by the specialist surgeon. Written consent was obtained from the participants after they had been informed about the nature of the study. The researcher ensured that the participants understood all aspects, including that participation was voluntary, and therefore they could decline participation, without prejudicing their further medical care (De Vos *et al*. 2005:59; Laycock *et al.* 2001:19).

All information was handled confidentially and was anonymous to other co-workers, such as the Biostatistician. Each participant was assigned a participant number, instead of using any information that could identify the participant. This was an important factor in this particular study, due to the sensitive nature of the investigations and questionnaires. The participant was thus always assessed and treated in a private room; it was also highly recommended that a chaperone, relative or friend of the participant's choice be present during the examination/treatment sessions to limit discomfort for the participant (Laycock *et al*. 2001:20).

The sensitive nature of the investigations required highly skilled and competent researchers, more than would normally be indicated if the study was of a less sensitive nature (De Vos *et al*. 2005:63). The researcher has international experience, of more than a decade, in the field of Physiotherapy for PFD. She was assisted by a Gynaecologist, who is a super-specialist in Uro-Gynaecology, and has international experience in his field. The fieldworkers were all Physiotherapists with postgraduate training in PFD.

All practitioners were informed in writing regarding the extent of the study and the commitment that was expected from them (Addendum 9). Their skill and competence also required from them to make no value judgements on any cultural aspects of communities (De Vos *et al*. 2005:64). The language of the participant`s choice (limited to English or Afrikaans) had to be used during the treatment/rehabilitation sessions. Participants had the opportunity to complete questionnaires and receive information in their language of choice – limited to English and Afrikaans - which was based on the culture of the population that was studied. The choice of language by each participant was not only an ethical issue, but was also necessary for optimal adult learning to take place (see 2.8.2).

The research project itself could be seen as a learning experience for both the researchers and the participants. To conclude the concept of adult learning in this study and to comply with ethical principles, debriefing sessions were ideal to complete the learning experience during each participant`s final session. The most beneficial treatment programme was given as a training programme to all participants and also implemented in the community clinic where the study was conducted. The overall goal of research ultimately is to serve the community (De Vos *et al*. 2005:66-67).

Accountability to the participants and society was addressed by dissemination of the results to the relevant parties, and submitting the results for publication in a scientific journal (Addendum 10), and as a thesis for peer review. This entailed an accurate, objective, clear, and unambiguous description of the research, without affecting confidentiality, as to be discussed further in this chapter (De Vos et al. 2005:66).

3.4 STUDY POPULATION AND SAMPLING

The sample can be defined as the elements of the population which are considered for inclusion in the study, or the subset of measurements drawn from the population for inclusion. In other words, the sample is the means of understanding the population from which it was drawn (De Vos *et al*. 2005:194).

The main reason for sampling is feasibility. Time, money, and effort can be concentrated to produce better quality research when sampling is done, compared to including a large population. Better instruments, more in-depth information, and better trained fieldworkers and assessors can be used to execute the research. On the other hand, the researcher might need to deal with a small population size, as was the case with our study, especially when the phenomenon occurs on a limited scale in the institution. In such a case it would be preferable to involve the whole population in the study due to already compromised statistical findings and generalisability based on a small sample (De Vos *et al*. 2005:194,195).

3.4.1 Population

The target population for this study was women scheduled for/undergoing pelvic floor reconstructive surgery. The sample frame consisted of women who attend private practicing and public sector Gynaecologists in the Free State province. It mainly included patients who attend the Uro-gynaecology Clinic at the Universitas Private and Provincial Hospital, Bloemfontein, as it is the tertiary referral hospital for the district. This also ensured that the patients from both the public and private sector were medically screened and surgery was performed by the same surgeon, who is super-specialised in Uro-Gynaecology, throughout the study.

Ontological and epistemological considerations necessitated the researcher to consider differentiation within the population. Factors such as differences in anatomy, muscle morphology and culture had to be taken into account with the selection of the specific population, in order to limit internal variability and validity (see 3.4.2). Different populations necessitate different approaches to assessment and rehabilitation in order to comply with the principles of overload and specificity (see 2.4). This approach was implemented in this study by means of individual assessment and patient-specific exercise prescriptions.

An interesting study by Hoyte, Thomas, Foster, Shott, Jakab and Weidner (2005) compared the pelvic morphology between asymptomatic African-American women and white nulliparous women. They found significant differences in the levator ani muscle volume, the levator-symphysis gap, bladder neck position, urethral angle, and the pubic arch angle. Such differences may lead to differences in the development of PFD (Hoyte *et al*. 2005:2035-2040). This is supported by another study on racial differences in POP that reported the prevalence of symptomatic prolapse to be five (5) times higher for white and Latina women when compared with African-American women (Whitcomb *et al*. 2009:1276). Populations and samples should therefore be carefully selected and the interventions and assessment specifically and individually tailored to yield clinical valid results.

3.4.2 Sample selection

Due to the relatively small population (see 3.4), the whole population who fulfilled the eligibility criteria, was targeted for inclusion. Table 9 summarises the eligibility criteria that participants had to adhere to. Medical information applicable to the eligibility criteria was obtained by the surgeon during the participant`s medical interview and examination.

Participants were voluntary recruited and randomly assigned, by means of simple random allocation, to one of three treatment groups by means of a computerised list (Figure 23). This meant that all possible allocation of participants to a group of a fixed size n would have the same probability (De Vos *et al.* 2005:196-197). The randomisation list was compiled based on the matching of participants regarding the following criteria to optimise equivalence at baseline among the three groups:

- Age – participants were classified as 65 years or younger, or older than 65 years of age.
- A history of previous corrective surgery.
- Physiotherapy or other treatment involving motor control or core stability exercises during the previous six (6) months.
- The initial strength of the PFM. Participants were classified as those having a muscle strength of 2 or less, and those that had a muscle strength of greater than 2, according to the Oxford scale (PERFECT) (Laycock & Jerwood 2001:633).

The process of allocation was done by an independent researcher to limit bias.

Table 9. Eligibility criteria.

INCLUSION CRITERIA	EXCLUSION CRITERIA
Women over eighteen (18) years of age (Norton *et al.* 2007:4). Women scheduled for corrective surgery for POP (including Perineo-colpo-sacro-suspension (sacrocolpopexy), anterior and posterior Prolift or Avaulta, total Prolift or Avaulta, anterior and posterior repair, sacrospinous colpofixation). Participants able to execute a home exercise programme based on their educational level and literacy. Literate patients understanding English and/or Afrikaans. Caucasian, Asian, and Coloured women.	Women suffering from neuro-musculoskeletal disorders (Jarvis *et al.* 2005:301), or psycho-sexual problems (Norton *et al.* 2007:6; Laycock *et al.* 2001:22, 31), according to their medical history. . Pregnant women. African women. Women older than 75 years. Women with stage IV POP (exclusion for phase I). Women who have had more than two previous operations for correction of POP. Women not able to attend frequent follow-up assessments over a period of six (6) months. (Also see Addendum 2 for precautions and contraindications when administering biofeedback/vaginal examination, NES, and PFM training.)

At the time of the study standard treatment did not expose patients to a routine rehabilitation programme pre-operatively or post-operatively. Patients were examined at the clinic/practice pre-operatively and returned for follow-up visits at three months and six months post-operatively. Only if specifically indicated, patients would then be referred for Physiotherapy. The advantage of this study would be that all eligible participants would immediately benefit from and be exposed to Physiotherapy intervention, in addition to their routine treatment.

3.4.3 Sample size

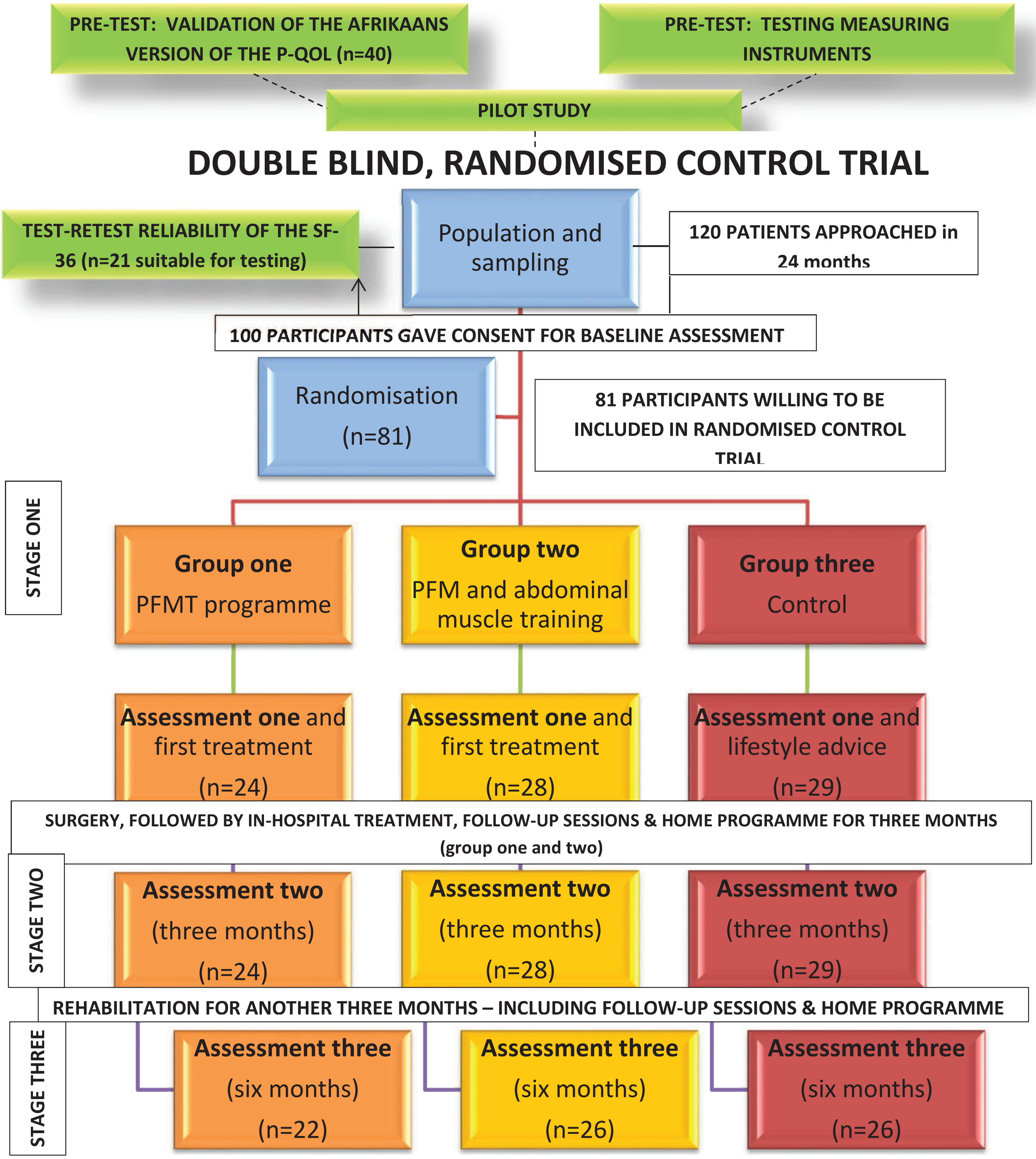
The population size was estimated at 2.5 patients per week who were scheduled for immediate reconstructive surgery. Recruiting of patients took place over a period of two (2) years; taking into account periods during which operations were not performed, the population size could be calculated by multiplying 2.5 by 46 weeks, which equalled 115 participants.

According to Stoker (1985), as cited in De Vos *et al*. (2005:195-196), a sample size of approximately 45% would be indicated (equalling 52 participants). However, due to the small population, it would be preferable to include the whole population as mentioned in 3.4.1 above (Leedy & Ormrod 2010:213). Although a small population/sample may pose some advantages (see 3.4.1), it also limits the researcher in drawing accurate and representative conclusions and making accurate predictions (De Vos *et al*. 2005:195).

The reason for the small population in this study was feasibility regarding time, cost and quality of assessment. Compared to other pathologies, POP is a condition that occurs on a smaller scale and is sometimes overlooked during assessment. Although pelvic floor reconstructive surgery is performed throughout South Africa, Bloemfontein is the only city which has an established Uro-Gynaecology Department and Pelvic Floor Unit in the Free State province. The result of this is that patients are referred from neighbouring cities and towns (and even provinces) to be operated on at these public and private units (De Vos *et al.* 2005:194-195).

All eligible participants were therefore approached during the time of the study to make the sample as large as possible and to make provision for possible dropouts due to complications/unforeseen circumstances, and voluntary withdrawals. Authors appear to differ regarding the minimum number of respondents required in order to perform statistical procedures (De Vos *et al.* 2005:195). This number seems to vary between 30 and 100 respondents. Heterogeneity of the population, the degree of accuracy, the type of sample, the available resources, and the number of variables should in actual fact be the determining factors (De Vos *et al.* 2005:195).

Figure 24 summarises the sampling and methodological procedures that are to be discussed in the following sections (3.5 to 3.9).



ASSESSMENT ONE (BASELINE): Demographic data form, P-QOL, SF-36, VFS, POP-Q, US, PERFECT scale, EMG OF PFM, endurance of PFM, SAHRMANN scale, PBU, EMG of IO/TrA

ASSESSMENT TWO: P-QOL, SF-36, VFS, US, PERFECT SCALE, EMG of PFM, endurance of PFM, SAHRMANN scale, PBU, EMG of IO/TrA, Likert scale for adherence

ASSESSMENT THREE: : P-QOL, SF-36, VFS, US, PERFECT SCALE, EMG of PFM, endurance of PFM, SAHRMANN scale, PBU, EMG of IO/TrA, Likert scale for

Figure 24. Schematic diagram of the research methodology.

3.5 OPERATIONAL PROCEDURES

Utilising the best available resources and based on the explanations above, all eligible study participants were referred to the researcher by the Uro-Gynaecologist after their medical examination at the clinic/practice. This was followed by an information session, which was presented by the researcher (at the clinic/practice), and by means of an information document (Addendum 8), if the patient was willing to partake. Participation was voluntary and informed consent (Addendum 8) was obtained from eligible patients. After consent was given and the participant was thus included in the study, the three (3) stages of the study (as described below) commenced.

The intervention and assessment were divided into three (3) stages (Figure 24):

- Stage one = pre-operative stage
- Stage two = post-operative stage
- Stage three = rehabilitation stage

Table 10 explains how these stages are related to the themes and objectives identified in Chapters 1 and 2.

Table 10. Relating themes, objectives, and methodology.

THEMES	OBJECTIVES	STAGE OF METHODOLOGY
POP – A disease of QOL	1.6.1.1	Stage 1
Symptoms and signs – aspects affecting lifestyle	1.6.1.1	Stage 1
A biomechanical rationale	1.6.1.1 – 1.6.1.3	Stage 1 - 3
PFM exercise and rehabilitation	1.6.1.2 – 1.6.1.4	Stage 2 & 3

3.5.1 Stage one

The participants were assessed and diagnosed by the specialist Uro-gynaecological surgeon, after which they were randomly allocated (by an independent researcher) to one of the three groups by means of a randomisation list. The participant, the researcher, and the specialist surgeon were not informed to which group they belonged. The fieldworkers were blind regarding assessment findings throughout the study. The PFM, trunk stability, QOL, and POP of all the groups were measured (Assessment one) (also see 3.6).

The specialist surgeon measured the direction, displacement, and diameter of the PR muscle, and the thickness of the perineal body by means of transperineal ultrasound, as well as the stage of the POP as determined by the POP-Q. The researcher assessed the PFM function by means of palpation (the PERFECT scheme) and EMG. Trunk stability was also assessed with a PBU placed under the lumbar lordosis of the participant and surface EMG measuring the activity of the IO muscles. All measurements were done in the presence of two (2) assessors, to ensure accuracy and correct documentation of the data. The researcher used a structured interview to gather medical data, while the participant completed a generic and condition-specific QOL questionnaire (Addendum 11 and 12). This was done during the first consultation at the clinic/practice, in a treatment room (see 3.6), immediately prior to surgery. All data was recorded on a structured data form (Addendum 13) by the researcher. The calculation of the QOL questionnaires' scores was done electronically during data analysis (see 4.3.1). The first assessment was followed immediately by an intervention session pre-operatively, as described in the following paragraphs.

All the groups received their exercise programme and advice from a trained field worker with experience in the field of PFMT and rehabilitation. Training of two fieldworkers was done by the researcher, and the field workers had to strictly adhere to the exercise prescription, as indicated by the researcher (Addenda 1 to 4).

According to the assessment findings, exercises were progressed or adapted individually and specifically for all patients by the researcher. In order to ensure that the researcher stayed blind to group allocation, and the fieldworkers stayed blind to assessment findings, all participants were deemed by the researcher as if they were required to receive all the exercises. It was then the responsibility of the field worker to teach the participant only the required exercises, according to their group allocation, during the first and follow-up visits. They had to be aware of substitution strategies and ensure correct muscle activation during the exercises (Addendum 1).

Incorrect PFM contractions were prevented by teaching the participants the correct contractions by means of vaginal palpation and by observation of inward movement of the perineum and a "squeeze" around the urethra, vagina and anus (Bo 2006:266; Bo 1995:284). Perineal movements were observed directly or assessed indirectly by movement of an externally visible device positioned in the vagina, for example the intra-vaginal probe (Bump *et al*. 1996:15). Substitution by means of the gluteal muscles, hip adductor muscles, and abdominal muscles had to be prevented. This included actions such as holding one's breath and forced inspirations. Straining was also not allowed (Bo 2004:455; Bump *et al.* 1996:15). Measurement by means of perineal ultrasound and EMG also helped to indicate/teach correct PFM contraction (Dietz *et al.* 2002:168). The exercise programmes and progressions for all the groups are explained in detail in Addenda 1 to 4.

All the treatment/exercise sessions (with exception of the in-hospital visits) were conducted at the Department of Physiotherapy (Universitas Hospital), FemSpes Clinic (Bloemfontein), or at Netcare (Bloemfontein), commencing on the day of the first assessment. Records were kept of each session, as well as the prescribed exercises by the fieldworker on a specific data form (Addendum 7). The sessions lasted approximately three-quarters of an hour and were used to train the participant on the EMG and PBU and to aid muscle contraction of the PFM with NES, as/if indicated by the exercise prescription and/or group allocation. At each follow-up session, muscle performance was reassessed by the researcher. According to these findings and the participant's performance, the exercises would then be progressed (Addenda 1 to 4) by the researcher and fieldworker, and the participant would receive a written (individually tailored) exercise programme to continue with daily at home until the date of surgery. A training diary (Addendum 4) had to be completed daily to improve adherence to the training programme (Laycock *et al.* 2001:24-27; Ballanger *et al*. 2000:7).

Group one received PFM exercises in addition to the standard treatment procedure (Addendum 1 and 3). This included activation and facilitation of PFM function using exercises, EMG biofeedback, and NES as indicated (Hagen *et al*. 2009:2-3; Sapsford, Richardson, Maher & Hodges 2008:1746; Bo *et al*. 2007:113-131, 171-184, 241-247; Kelly *et al*. 2007:190; Norton *et al*. 2007:4, 6; Bo 2006:263, 266; Robert & Ross 2006:1113-1117; Jarvis *et al*. 2005:300-303; Bo 2004:461; Sapsford 2004:8-10; Laycock & Jerwood 2001:635, 639, 641; Laycock *et al*. 2001:23-40; Sapsford 2001:623-625, 635; Ballanger *et al.* 2000:7-9; Bo 1995:282-284, 288). If NES was indicated, the treatment parameters for all participants were according to the international guidelines, as stipulated in Addendum 1.

Group two received the same intervention as group one, as well as activation, facilitation and rehabilitation of the local and global abdominal and pelvic stabilisers (motor control) (Addenda 1 and 3). A PBU and EMG were used to aid in the activation/facilitation of the TrA muscle, if indicated. These exercises were prescribed according to the principles of Mills *et al.* (2005:60-66), Sapsford (2004:8-10), Comerford and Mottram (2001a:3-14), O`Sullivan (2000:9-12), Richardson and Jull (1995:2-10), and other authors (MacKenzie, Grimshaw, Jones, Thoirs & Petkov 2014:457).

Group three received no additional treatment other than the standard lifestyle advice and post-operative education. Participants in all three groups received the same advice on lifestyle (Addenda 1 and 3). This was in the form of an information sheet with the applicable advice, tailored to their individual needs.

The end of the first stage was marked by the surgical intervention. The same Uro-Gynaecologist who assessed the patient, also did the surgery on all patients. After surgical intervention, the patients were admitted to a ward where they received the standard medical post-operative treatment regime (Addendum 1 and 3), entering stage two of the research study.

The precise methodology for the lifestyle advice, exercise instructions, exercise prescription and progression pre- and post-operatively, and NES are depicted in Addenda 1 to 4 in the form of guidelines for the fieldworkers and exercise programmes for the participants.

3.5.2 Stage two

Stage two consisted of appropriate, standard post-operative treatment (all three groups) (Addenda 1 and 3) in the hospital until discharge (two (2) to five (5) days, depending on the type of surgery). Group one and two received individualised and specific exercise programmes to continue with at home. These programmes were demonstrated pre-operatively (see 3.2), revised post-operatively, and provided in written format to the participants. Follow-up visits to the fieldworker were arranged at a convenient time for each participant. Participants in group three were again taken through the aspects of their lifestyle advice.

During the first six weeks post-operatively, rehabilitation included only active exercises, taking into consideration pain limits and precautionary measures (Hunter 1994:15). Thereafter the participants were allowed to progress with their exercises as indicated on their programmes until the three month follow-up assessment. Follow-up treatment sessions followed the same guidelines as originally stipulated and anticipated for stage one (see 3.2). All participants (group one, two, and three) were also sent a weekly reminder, in their language of choice, on their cellular telephone to encourage exercise and lifestyle adherence.

Assessment two occurred at the end of this stage; it included a full medical assessment and repeat measurements of QOL, the PFM, and trunk stability by the same blinded researcher and specialist surgeon during their follow-up visit to the clinic/practice.

3.5.3 Stage three

The final stage entailed rehabilitation of the participants (group one and two) as described in stage one for a period of three (3) to six (6) months. During this period it was especially important to emphasise participant adherence. Follow-up visits for training with the fieldworker on the EMG, PBU, and NES as indicated, was encouraged at the clinic/practice. The weekly reminders were continued until the end of this stage. These visits were arranged at a convenient time for the participant, so as to comply with ethical aspects. Group three was expected to comply with their lifestyle advice. At the end of this stage (six (6) months post-operative), assessment three was done by the blinded assessors; it included assessments of POP, the PFM, trunk stability, and QOL.

Results of the assessments during the three stages were recorded by the researcher on each participant's data form (Addendum 13). Throughout the study the researcher noted the number of participants who had declined to participate, who were lost to follow-up, who withdrew, who had to stop treatment, or who dropped out. The reasons were noted by the researcher on each participant's treatment and assessment record (Addendum 7).

3.6 MEASURING INSTRUMENTS: TECHNIQUE, VARIABILITY AND VALIDITY

In the previous chapter, the measuring instruments that were used in this study were introduced. To ensure an integrated and logical presentation of the research, and to link it to the literature discussion in Chapter 2, the description of the measuring instruments and the interpretation thereof are combined with the results derived from them in the following chapters.

Different options of assessment tools/measuring instruments applicable to this study were discussed in 2.9. The researcher explained the rationale for the choice of the measuring instruments that were used in this study, as well as the validity, reliability and values found for different populations with those instruments. This section will focus on the technique of application, while the comparative values will be referred to again in the results and discussion sections of this document.

The instruments are described in the sequence that they were used during the study. The same sequence was followed with all the participants and was applied in this manner throughout the study. The same researchers (see 3.5) also performed the same tests on all participants to limit inter-rater variability.

3.6.1 Measurement of quality of life

3.6.1.1 The Prolapse Quality of Life Questionnaire

Condition-specific QOL was measured by means of the P-QOL questionnaire (Addendum 11). The questionnaire consists of 20 questions which represent nine (9) domains, namely: general health perceptions (question 1), prolapse impact (question 2), role limitations (question 3 and 4), physical limitations (question 5 to 8), social limitations (question 5 to 8), personal relationships (question 9 to 11), emotional problems (question 12 to 14), sleep and energy disturbance (question 15 and 16), and severity measures (question 17 to 20) (Claerhout *et al*. 2010:570; Manchana & Bunyavejchevin 2010:986; Svihrova *et al.* 2010:55; De Oliveira *et al*. 2009:1192; Lenz *et al.* 2009:642; Cam *et al*. 2007:132-133; Digesu *et al.* 2003:185).

The responses are scored on a four-point Likert scale and a total score, ranging from 0 to 100, can be calculated for each domain (see Addendum 14 for the statistical formulas). The higher the score, the greater the impairment of QOL. The questionnaire also includes 18 questions on the severity of urinary, sexual, and defecation symptoms. However, these scores are not included when calculating the total score (Claerhout *et al.* 2010:570; Manchana & Bunyavejchevin 2010:986; Svihrova *et al*. 2010:55; De Oliveira *et al*. 2009:1192; Lenz *et al*. 2009:642; Cam *et al*. 2007:132-133; Digesu *et al*. 2003:185).

The researcher was available to clear any ambiguity or to answer questions while the participants were completing the questionnaires. However, these problems were limited to a minimum by the prior standardisation of the Afrikaans version of the P-QOL in a South African population, as described below.

3.6.1.1.1 Validation of the Afrikaans version of the Prolapse Quality of Life Questionnaire in a South African population – a pre-test study

This observational, descriptive study was approved by the Ethics Committee of the Faculty of Health Sciences of the University of the Free State (ECUFS nr 81/2011, Addendum 5), Bloemfontein, South Africa. Written consent and permission was obtained from the participants and institutions where the study was conducted.

Translation of the P-QOL

The original English P-QOL questionnaire was translated to Afrikaans by an independent medical translator. The translated Afrikaans version (Addendum 11) was reviewed and translated back to English by three independent Uro-gynaecologists. The Uro-gynaecologists agreed that the original content was retained and that no ambiguity was present. No changes were made to the translated version.

Pilot study

The translation was followed by a pilot study (n=5) to confirm the readability and participants' comprehension of the questions. These participants were asked to complete the questionnaire and were then interviewed by the researchers. No problems were identified and no changes were made to the translated Afrikaans version of the P-QOL. The same methodological procedures were followed in the main study.

Sampling

A convenience sample was used, consisting of 40 women meeting the inclusion criteria. The eligibility criteria was aligned with the validated versions of the P-QOL, and applied to the demographics of a South African population.

Procedures

The eligible participants had to complete an informed consent document, a P-QOL questionnaire, and a demographic data form after the study procedures were explained to them by the researchers. The same Uro-gynaecologist determined the POP-Q score for all participants, according to clinical and ultrasonography findings. The completed questionnaires and forms were checked by the researchers to ensure that all the information was gathered.

Following consultation, each participant was given a second blank P-QOL questionnaire in an addressed envelope, to complete and mail back after two (2) weeks in order to determine the stability of the questionnaire by a test-retest analysis. The date on which the questionnaire had to be completed was indicated by a note on the envelope. Reminders were sent to all participants to complete the second questionnaire.

The results of this pre-test is presented in the form of a draft manuscript in Addendum 15.

The test-retest reliability of the Afrikaans version of the SF-36 was tested in a similar manner as part of the main study. The same procedures were followed for translation of the questionnaire and the gathering of the data as described for the P-QOL pre-test. The sampling method, however, differed, and it is described in the next section.

3.6.1.2 The Short Form-36 (SF-36) Health Survey

As mentioned in 2.9, the SF-36 Health Survey (Addendum 12) is a well-established, reliable, and valid generic measure that has been documented in nearly 4000 publications (Ware 2008:1). The SF-36 measures physical and mental health by means of eight (8) domains, as depicted in Table 11.

Table 11. Domains of the SF-36.

PHYSICAL HEALTH	Questions
Physical functioning	3a-j
Role physical	4a-d
Bodily pain	7 & 8
General health	1, 11a-d
MENTAL HEALTH	
Vitality	9a,e,g,i
Social functioning	6 & 10
Role emotional	5a-c
Mental health	9b,c,d,f,h

A scoring algorithm (see 4.3.3) is used to convert the scores in a range of 0 to 100. Lower scores are usually an indication of a low level of functioning and health (Burholt & Nash 2011:589; Khader *et al.* 2011:369). The calculation of scores are described in detail in 4.3.3.

3.6.1.2.1 Determining the test-retest reliability of the Afrikaans version of the SF-36

The patients who were not willing/eligible to participate in the clinical trial were approached to determine the test-retest reliability of the Afrikaans version of the SF-36. It required that the patients had to be willing to complete the medical information sheet and the questionnaire during their consultation at the clinic. A second questionnaire was issued to them two weeks after the initial assessment in order to avoid recall bias. If patients were from elsewhere, they were issued with an addressed envelope with the follow-up questionnaire. They were then reminded by means of a SMS to complete the second questionnaire the day before they had to return it (also see 3.6.1.1.1).

3.6.1.3 Measurement of pain

The effect of pain on QOL and the central nervous system is well-known and has been extensively described in the literature (Jull *et al*. 2015:8-16). The effect of pain in the development and treatment of PFD was also discussed in 2.5.2.2.

The VFS is a pain rating scale especially applicable when assessing QOL, due to the faces in the scale which more directly represent the feelings of the participants. It is a reliable and valid method of assessment (with a median validity and test-retest reliability coefficients of 0.82 and 0.70 respectively) which has been used previously in a study investigating pain in patients with POP (Heit *et al*. 2002:23).

The VFS (Addendum 16) consists of five (5) faces with a numerical score and explanation (Table 12), assessing the amount of pain that the participant experiences. The participants were asked to rate their pelvic and low back pain according to this scale.

Table 12. The Visual Faces Scale: numerical score and explanation.

Numerical score	Explanation
0	no pain
1	mild pain
2	moderate pain
3	severe pain
4	very severe pain
5	worst pain

Due to individual pain thresholds that vary, it may be difficult to detect differences if individual scores are averaged. A single-factor repeated measures analysis was therefore suggested as the most accurate way of detecting associations (Heit *et al.* 2002:27).

3.6.2 The Pelvic Organ Prolapse Quantification Scale (POP-Q)

The POP-Q scale is recommended by the International Continence Society as the standard method of describing the stage of POP in all research studies, and was also used in this study (Bump *et al*. 1996:10-17). It defines the location of six (6) points (two (2) on the anterior vaginal wall, two (2) in the superior vagina, and two (2) on the posterior vaginal wall), with reference to the plane of the hymen. The anatomical position of the points is then measured as the amount of centimetres proximal (negative number) or centimetres distal to the hymen (positive number).

The points on the anterior vaginal wall include point Aa and point Ba. Point Aa is normally 3cm proximal to the external urethral meatus in the midline of the anterior vaginal wall. Point Ba was measured from the vaginal cuff or anterior fornix to point Aa and was the most distal position of any part of the anterior vaginal wall. In the absence of POP, point Ba is usually -3cm (Bump *et al*. 1996:11).

Points C and D are located in the superior vagina. Point C was the most distal edge of the cervix or the leading edge of the vaginal cuff. The location of the fornix was defined as point D (Bump *et al*. 1996:11).

On the posterior vaginal wall, points Bp and Ap were identified. Point Bp was the most distal point of any part of the upper posterior vaginal wall from the vaginal cuff or posterior vaginal fornix to point Ap. Point Bp is usually -3cm in the absence of POP. The last point, point Ap, was located in the posterior vaginal wall's midline 3cm above the hymen (Bump *et al.* 1996:12).

In addition, the total vaginal length was measured as the greatest depth of the vagina when reduced to its normal position. The genital hiatus equalled the distance from the middle of the external urethral meatus to the posterior midline hymen, while the perineal body thickness was measured from the posterior margin of the genital hiatus to the mid-anal opening (Bump *et al.* 1996:12).

These measurements were done with the patient in supine on a hard plinth, with the hip and knees in maximum comfortable flexion. The patient was not asked to empty the bladder or rectum, prior to this investigation. The distance of displacement was measured by the Uro-gynaecologist in centimetres (1996:10-17) and documented on a grid diagram in the patient's medical records (Figure 25). According to the most severe portion of the POP, a stage (Table 13) was then be allocated to the POP (Bump *et al*. 1996:11) (Figure 25). This investigation was followed by two-/ three-dimensional sonar investigations, which also helped to confirm the stage of the POP. The literature has indicated that there is not a good correlation between US and clinical assessment for central or lateral defects of the endopelvic fascia (Dietz, Pang, Korda & Benness 2005:190). To overcome the potential for errors in diagnosing the stage of POP, both methods were therefore included.

Anterior wall **Aa**	Anterior wall **Ba**	Cervix or cuff **C**
Genital hiatus **gh***	Perineal body **pb***	Total vaginal length **tvl***
Posterior wall **Ap**	Posterior wall **Bp**	Posterior fornix **D**

*gh = genital hiatus; pb = perineal body; tvl = total vaginal length

Figure 25. Three-by-three grid for recording quantitative description of pelvic organ support (Bump *et al*. 1996:11)**.**

Table 13. The POP-Q stages (Bump *et al*. 1996:11)**.**

Stage	Definition
O	No prolapse is demonstrated.
I	The most distal portion of the prolapse is >1cm above the level of the hymen.
II	The most distal portion of the prolapse is ≤1cm proximal to or distal to the plane of the hymen.
III	The most distal portion of the prolapse is >1cm below the plane of the hymen but protrudes no further than 2cm less than the total vaginal length in centimetres.
IV	Complete eversion of the total length of the lower genital tract is demonstrated. The distal portion of the prolapse protrudes to at least *(TVL-2)cm.

*TVL = total vaginal length

3.6.3 Measurement of the pelvic floor muscles

3.6.3.1 Two-dimensional ultrasound

Two-dimensional perineal US (Dietz 2004:80-94) was performed by the Uro-gynaecologist to measure the direction, displacement and diameter of the PR muscle when contracting, as well as the thickness of the perineal body and the LH (Thompson *et al.* 2005:285-292; Dietz *et al*. 2001:166-169).

A Phillips^{TM} HDIIXE was used for the US measurements. Prior to the assessment the participant was asked to void and empty the bowel to improve diagnostic accuracy. The participant was assessed in a dorsal lithotomy position. A transducer, covered with an exposable glove for hygienic reasons, was placed firmly on the vulva in the mid-sagittal plane at the perineum (Thompson *et al.* 2005:286). The labia were parted to improve image quality. The position of the transducer head was strictly maintained for all the measurements in the specific plane of investigation. The resting position of the PR muscle was marked electronically on the screen. The participant was asked to perform a PFM contraction and Valsalva manoeuver (depending on the measurement to be taken). The images were frozen on the screen respectively, and the displacement was measured by means of on-screen callipers (Bo *et al.* 2003:584). The participants were not allowed to view the ultrasound image as this could have had a biofeedback effect (Thompson *et al.* 2006a:269). Movement of the PR muscle with PFM contraction, as well as uterovaginal prolapse (on Valsalva), was measured as described by Dietz (Dietz 2004:80-92; Bo *et al*. 2007:81-85). The most successful attempt (with a maximum of three (3) of the participant was measured and recorded on the data form by the researcher (Addendum 13).

In the mid-sagittal plane, pelvic organ descent was measured on Valsalva to confirm the clinical findings. This was done by observing the position and displacement of the most dependent part of the bladder, the most inferior parts of the cervix, and rectal ampulla relative to the inferior margin of the symphysis pubis (Dietz *et al*. 2005:581). Classification of the stage of POP was then done according to the POP-Q scale, as explained in 3.6.2.

The LH was measured as the minimal hiatal dimensions in the mid-sagittal plane during rest, Valsalva, and contraction. The LH was defined as the minimal distance between the hyperechogenic posterior aspect of the symphysis pubis, and the hyperechogenic anterior border of the pubovisceral (PR) muscle just posterior to the anorectal muscularis (Majida *et al.* 2012:709; Chen *et al.* 2011:932; Dietz *et al.* 2005:581) (Figure 26). The difference in the dimensions from rest to contraction, and from rest to Valsalva, was calculated as the displacement of the PR muscle during these manoeuvers.

Figure 26. Measurement of the LH by means of two-dimensional ultrasound.

In the coronal plane, the perineal body was measured as the diameter between the perineal skin and the pubovisceral muscle. This was done in a plane perpendicular to the perineal surface, just anterior to the anorectal junction (Dietz *et al.* 2005:581).

Lastly, levator thickness was measured in the axial plane on the left and the right side of the pubovisceral muscle loop. This was done at a four (4) o'clock and eight (8) o'clock position respectively (Figure 27). During this assessment, it was also observed if avulsion of the PR muscle was present. Avulsion injury of the PR muscle can be defined as a detachment of the pubovisceral muscle from the pelvic side wall. Assessors may mistake localised atrophy of the muscle easily for an avulsion injury, due to the fact that it results in similar appearances. To assess avulsion, the left and the right side were compared, and were only rated as present if a dysfunction was observed during rest, contraction, and Valsalva (Dietz & Steensma 2006:226-227).

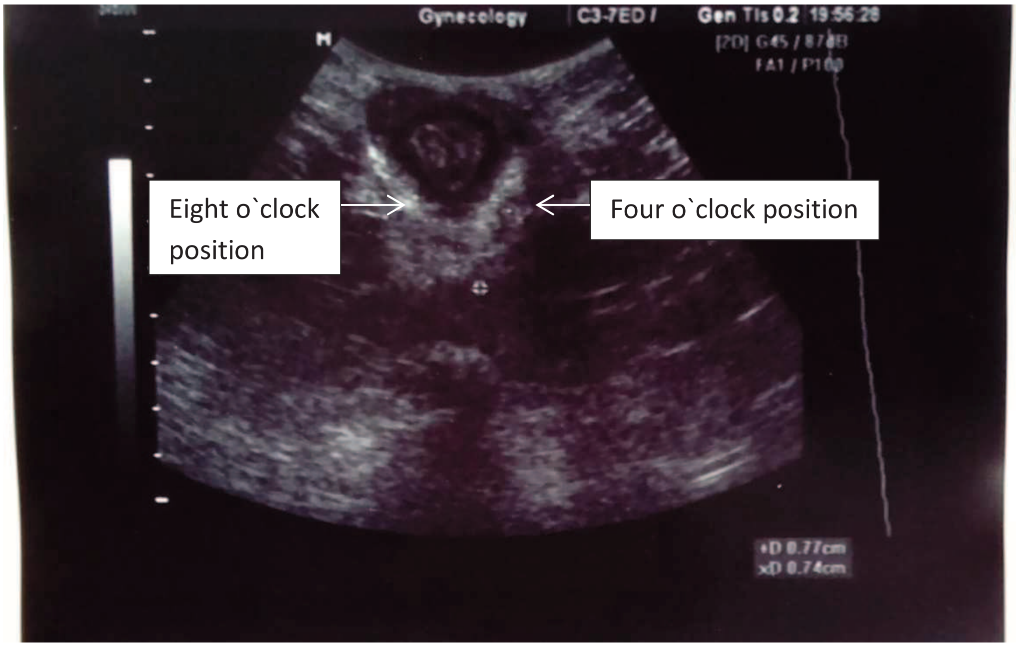


Figure 27. Measurement of the puborectalis muscle thickness by means of two-dimensional ultrasound.

After the US assessment, the participant concluded her consultation with the Uro-gynaecologist, after which she was accompanied to the next consultation room for further assessment of the PFM and abdominal muscles by the researcher (Physiotherapist).

3.6.3.2 The PERFECT scale

PFM strength was measured by means of intra-vaginal palpation using the PERFECT scheme, a reliable and valid assessment tool for measuring the PFM (Devreese *et al.* 2004:193-194).

The participant was positioned in supine with her head on two pillows. The hips were in flexion-abduction and the knees also in flexion. The index finger was placed 4-6cm inside the vagina (the two and a half distal phalanges) and positioned at four

(4) o`clock and eight (8) o`clock to monitor the muscle activity. A moderate pressure was applied over the muscle bulk to initiate a proper muscle contraction (Devreese *et al.* 2004:192; Laycock & Jerwood 2001:633).

The power (strength) of the deep part of the pelvic floor (PR and levator ani muscles) was measured by a modified Oxford scale. Table 14 defines the grades for the classification of the muscle strength, according to Laycock & Jerwood (2001) and Devreese *et al.* (2004). The registered grade can be augmented as just more or just less than the given grade with a **+** or a **–** symbol (Devreese *et al*. 2004:192; Laycock & Jerwood 2001:633).

Endurance was measured by timing the MVC up to 10 seconds, without substitution strategies, or until the muscle started to fatigue (usually when the muscle strength is reduced by 35% or more). The number of repetitions (up to 10) of the participant's specific MVC was also recorded. Four (4) seconds of rest was allowed between every contraction. If the participant could perform 10 repetitions of 10 seconds each, the rest interval was decreased.

Lastly, after a one minute rest interval, the number (up to 10) of one-second MVC's was determined. The participant had to contract and relax as quickly and strongly as possible, but in their own time until the muscle fatigued (Laycock & Jerwood 2001:634).

Table 14. Grading of pelvic floor muscle strength according to the modified Oxford scale.

GRADING	DEFINITION	MUSCLE RESPONSE
0	No discernible muscle contraction.	**Nil**
1	A flicker or pulsation is felt under the examiner`s finger.	**Flicker**
2	An increase in tension is detected, without any discernible lift / Inward displacement of the distal part of the finger without total extension.	**Weak**
3	Muscle tension is further enhanced and characterised by lifting of the muscle belly and also elevation of the posterior vaginal wall. A grade 3 and stronger can be observed as an in-drawing of the perineum and anus / Inward displacement of the distal part of the finger with total extension.	**Moderate**
4	Increased tension and a good contraction are present which are capable of elevating the posterior vaginal wall against resistance (digital pressure applied to the posterior vaginal wall) / Inward displacement of the distal part of the finger with total extension. While in extension the finger provides resistance to the caudal part of the vagina which can be resisted by the patient without contact with the cranial part of the vagina.	**Good**
5	Strong resistance can be applied to the elevation of the posterior vaginal wall; the examining finger is squeezed and drawn into the vagina / Inward displacement of the distal part of the finger with total extension. While in extension the finger provides resistance to the caudal part of the vagina which can be resisted by the patient. The pelvic floor muscles tighten around the finger.	**Strong**

(Devreese *et al.* 2004:192; Laycock & Jerwood 2001:633)

3.6.3.3 Surface electromyography of the pelvic floor muscles

A rest interval of three (3) minutes followed the assessment of the muscle endurance and strength with the PERFECT scale to limit the possibility of muscle fatigue. The activation of the motor units was then determined by recording the electrical activity of the muscle on a cathode-ray oscilloscope (Grape *et al*. 2009:395). A Neurotrac Myoplus^{TM} 2 was used to measure the EMG of the PFM and the abdominal muscles. For more precise measurement, a wide filter was used (19-375Hz).

Surface electrodes, by means of a Periform^{TM} intra-vaginal probe, were used. This method has also been described by several authors, such as Thompson, O`Sullivan and associates (2005:150), as well as Auchincloss and McLean (2012), to measure the activity of the PFM. The Periform™ probe is a pear-shaped device which tapers at the introitus (Figure 28). It has a length of 8 cm and is 3.4 cm wide in the medial lateral diameter at its peak width (Auchincloss & McLean 2012:1004). The probe was inserted with the opposing electrodes in contact with the lateral vaginal walls, with the participant in a dorsal lithotomy position (Thompson *et al.* 2006b:150-151). Participants were allowed the choice of inserting the electrode themselves, in which case the position would be checked by the researcher before measurement. The reference electrode was placed on the ulna, distal to the olecranon. The EMG probe was manually supported during the test procedure to prevent it from moving or losing contact with the PFM (Thompson *et al*. 2006a:270).

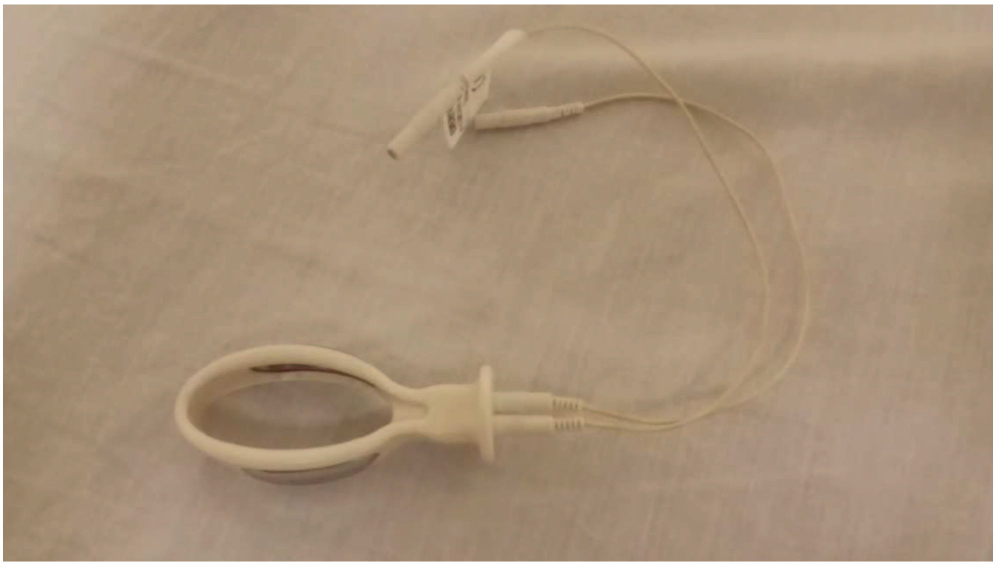
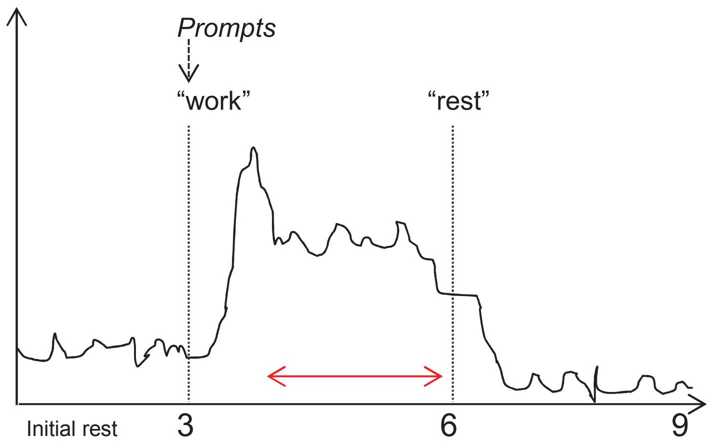


Figure 28. The Periform™ vaginal probe.

Differences of only 10mm in the positioning of electrodes may have a different effect during EMG (Laycock *et al*. 2001:35). Using a single unit containing two (2) electrodes (the Periform™ for intra-vaginal measurement) limits this problem, as well as the fact that the positioning can be monitored by ensuring that the electrode is inserted the same depth and horizontally in a supine position of the participant. This can be achieved by observation of the position of certain landmarks on the unit relative to anatomical landmarks on the participant. However, a recent study by Halski, Ptaszkowski, Bupska and Dymarek (2013:3-5) did not find a significant difference when different locations of the intra-vaginal probe were correlated with the functional activity of the muscle in standing. This was also confirmed by Auchincloss and McLean (2012) in an EMG study, comparing the EMG amplitudes as measured with fine wire electrodes, the Periform electrode and the Femiscan electrode. They did not find that change in sensory feedback, muscle position or length by the electrodes had any significant effect on the facilitation and activation of the PFM (Auchincloss & McLean 2012:1007). Previous literature however still reported that non-selective electrodes may have the risk of measuring activity from adjacent/synergistic muscles (Bo *et al.* 2007:56-63; Verelst & Leivseth 2004b:662). Careful monitoring of synergistic/compensatory muscle action thus accompanied EMG measurement.

The testing procedure consisted of asking the participant to "*draw in and lift the PFM"* for three (3) seconds. The test was repeated three (3) times with a ten second resting interval in between, and the average was recorded on the data form as determined by the software (Thompson *et al.* 2006b:151). The average value in microvolts, to a precision of 0.1μV, was recorded of the three (3) segments, excluding the first (1^{st}) second of each segment (Figure 29). The EMG readings were taken over a short period of time to limit/exclude normal variability of muscle behaviour or a non-specific muscle response (Bo *et al*. 2007:61).

Microvolts



Time in seconds

Figure 29. Determining statistics of the average EMG.

Sixty percent of the MVC was then calculated and set as a target value on the computer. Endurance was recorded as the time the participant was able to hold the contraction above 60% of her MVC up to a maximum period of one (1) minute. This recommendation is in accordance with the guidelines of the American College of Sports Medicine's physical activity and health guidelines (Quartly *et al*. 2010:313).

With completion of the test, the vaginal probe was removed and the reference electrode kept in place for the EMG measurement of the abdominal muscles.

3.6.4 Measurement of the abdominal muscles

3.6.4.1 Surface electromyography

Surface EMG measurement of the IO and underlying TrA muscles was done prior to pressure biofeedback measurement (see 3.6.4.2). The participant remained in the same position as for the PFM measurement, namely supine with the knees flexed to 90º. The skin surface was cleaned to allow for low impedance between the skin and the electrode and shaved, if indicated. The placement of the surface electrodes on the skin for the measurement of the TrA muscle was done according to the method described by Thompson *et al.* (2005:149). Two electrodes were placed respectively 2cm medial to the anterior superior iliac spine to record activity from the lower transverse fibres of the IO muscles. The suggestion is that placement of these electrodes may pick up activity of the TrA muscle which lies directly underneath it. Bipolar, disposable electrodes were placed in these positions. The patient was asked to activate their TrA muscle in a supine lying position by slowly drawing in the lower abdominal wall without any substitution strategies (see Addenda 1 and 3). In the case of measurement of the TrA and IO muscles, hip and trunk muscle action is expected to be of low intensity in the described test position. Cross-talk has been found to be insignificant during these measurements (Sapsford *et al.* 2008:1742).

Recordings were made for ten seconds with ten second rest intervals, and repeated three times. The average activity for the MVC was recorded by the EMG machine (Tahan, Massoud Arab, Vaseghi & Khademi 2013:109; Lima *et al.* 2012:391; Sapsford *et al.* 2008:1742; Sapsford, Richardson & Stanton 2006:220).

The patient was allowed a minute rest interval before measuring the same muscle contraction with the PBU.

3.6.4.2 The Pressure Biofeedback Unit

A Stabiliser Pressure Biofeedback Unit (PBU) (Chattanooga™, 92101D) was used to measure the activation of the TrA/IO muscle indirectly (Figure 30). The participant was positioned in a supine position with 90º of knee flexion on a hard surface, and the PBU placed under the lumbar lordosis. The PBU was inflated to 40mmHg. The participant was instructed to slowly draw in the lower abdominal wall without moving the spine, ribs, or pelvis. The participant was observed for any substitution strategies, such as holding the breath (Addenda 1 and 3). The participant was first given a trial run in order to calibrate the pressure cell and determine the pre-trial baseline pressure of 40mmHg (Park & Lee 2013:528; Jull *et al.* 1993:188-191).

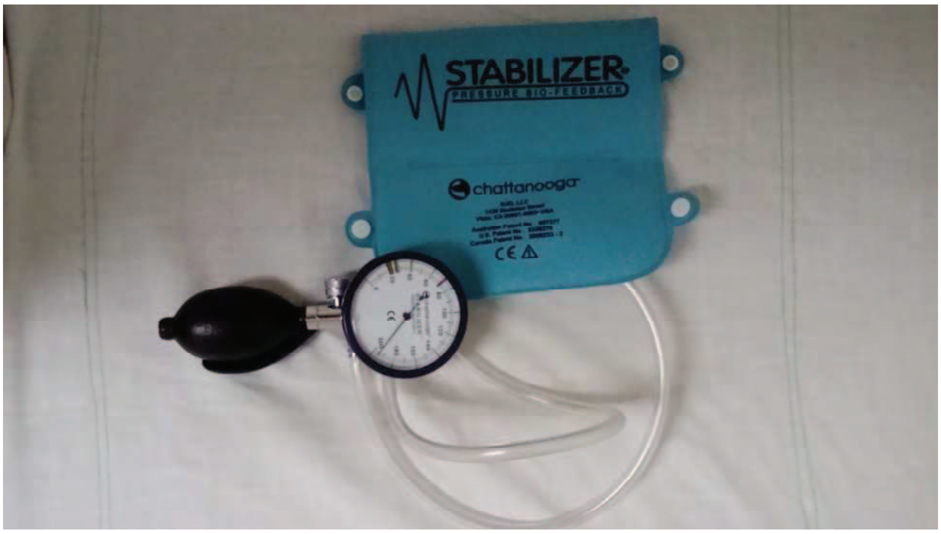


Figure 30. The Pressure Biofeedback Unit.

The amount of change in mmHg was then observed with the second trial. The correct action, as originally described with the development of the test by Jull *et al.* (1993:188-191) and also in more recent literature, was taken as a pressure increase of 10mmHg. If the participant was able to reach this level, the contraction was timed for the period that it could be held at 10mmHg, up to a maximum of ten seconds. Participants who were able to maintain this contraction had to continue to repeat this measurement, with ten seconds resting interval in between every ten second hold, up to a maximum of ten repetitions. The amount of repetitions to be held for ten seconds were recorded on the data form (Park & Lee 2013:529; Lima *et al.* 2012:253; Comerford *et al.* 2005:xxvii; Comerford & Mottram 2001a:7; Jull *et al*. 1993:188-191).

3.6.4.3 The Sahrmann Scale

Testing of rotational control (Sahrmann level 1), rotational strengthening (Sahrmann level 2 and 3), and sagittal strengthening of the abdominal muscles (Sahrmann level 4 and 5) (Table 15) was done in a similar testing position as explained for the PBU in the previous paragraph (see 5.4.2). All participants were instructed in the abdominal hollowing manoeuver prior to this testing procedure, and instructed to maintain this contraction during the testing procedure. The functional stability of the trunk was monitored by the PBU during limb load (Comerford *et al.* 2005:xxvi-xxix; Mills *et al.* 61-63).

The patient had to maintain 50mmHg during the limb load with each level. The starting position for each level was in supine, with the hip flexed to 100º, and the knees to 90º. During limb loading, any pressure decrease towards 40mmHg indicated a gross anterior tilt and a loss of stability into spinal extension. A pressure increase towards 60mmHg indicated a gross posterior tilt and a loss of stability into spinal flexion due to substitution with the rectus abdominus muscle. As soon as any deviation on the PBU or substitution strategy was observed (Addenda 1 and 3), the movement had to stop and the participant had to return to the starting position. A change greater than 10mmHg indicated poor control of the pelvis and the patient was scored at the last level successfully completed. The highest level attained in three trials was used for statistical analysis (Comerford *et al.* 2005:xxvi-xxix; Mills *et al.* 2005:61-63), (Table 15).

Table 15. Levels of lumbo-pelvic stability.

LEVEL	DEFINTION
1	In crook lying an abdominal hollowing manoeuvre preset the abdominal muscles and the participant slowly raises one leg to a position of 100° of hip flexion with 90° knee flexion. The other leg is slowly raised to a similar position. This is the start position for the following four levels.
2	From the start position, the participant slowly lowers one leg and, with the heel down on the plinth, slides the leg out to straighten the knee, then slides it back up into the start position.
3	From the start position, the participant slowly lowers one leg and, with the heel maintained approximately 12cm off the plinth, fully extends the leg and then moves it back to the start position.
4	From the start position, the participant lowers both legs together and, with the heels down on the plinth, slides the legs out to straighten the knees and then slides them back and raises them to the start position.
5	From the start position, the participant simultaneously extends both legs keeping the heels approximately 12cm off the plinth and then flexes the legs back to the start position.

(Mills *et al.* 2005:62-63)

This test concluded the physical assessment of the participant. Following the physical testing, the subjective outcome measures were to be completed by the participant in a private consultation room in their language of choice.

3.6.5 Measurement of exercise adherence `

Concluding the subjective measurements, the participants had to give a weekly indication of how regularly they exercised to increase the internal validity of the findings. Participants' compliance and adherence to the exercises was monitored by means of a training diary (Bo 1995:287), and regular measurement and refresher sessions with the physiotherapist and researcher (Dumoulin & Hay-Smith 2010:19; Borello-France *et al.* 2008:1552).

A Likert scale was used to measure compliance/adherence every week, together with a self-developed training diary (Addendum 4). The Likert scale (Table 16) has been used previously; and a study has been published by Sluijs *et al*. (1993) on determining exercise compliance.

Table 16. Scale for measurement of exercise compliance.

Question: Did you manage to exercise regularly last week?	
1	Not at all
2	A little
3	Rather regularly
4	Very regularly

(Sluijs *et al*. 1993:773)

A score of 1 or 2 on the rating scale was considered as non-compliant, whereas a score of 3 or 4 was considered as compliant (Sluijs *et al.* 1993:773).

The rating of compliance by the participant was monitored by the researcher by checking the training diary (Addendum 4). In the case of any discrepancies, adjustments were made by the researcher to the compliance score. This was done if it could be established by the researcher (by means of reflection or interviewing the participant) that the compliance score was not a true reflection of the patient's adherence. Reasons for non-compliance were documented in the training diary for reporting purposes and to make recommendations to improve exercise adherence.

3.7 METHODOLOGICAL AND MEASUREMENT ERRORS

The measurement of exercise compliance and other procedures to enhance the validity and reliability of the findings have been meticulously described in the methodology. Methods such as blinding of assessors, randomised allocation of participants, limitation of inter-rater bias, the use of standardised measuring instruments and procedures, and calculation of the validity and reliability of the translated questionnaires are some of the main factors that could contribute to the internal validity of the findings. Face, content, construct and criterion validity, as well as internal reliability of the standardised questionnaires, including the reliability and validity of all measuring instruments, have been well described by several authors (see 2.9).

Several additional measures were introduced to control variables other than the treatment to ensure that the treatment alone was the causal factor that produced the change in the muscle function and QOL (internal validity) (Maree 2013:151). Factors that could threaten internal validity, such as historical factors, had to be considered between the different measurements. Post-surgical complications or the development of other unforeseen illnesses had to be considered, as well as how it could affect tissue healing. Patients were withdrawn from the study if anything occurred that could have an effect on recovery, muscle function, and their general health. Factors, such as a change in medication pre-operatively and post-operatively, also had to be monitored and taken into account when interpreting the results of the study. Such changes were documented on the participant’s treatment record (Addendum 7).

The latter paragraph closely relates to the effects of maturation and mortality. The longer the duration of the study, the greater the chance were that changes could take place within the participants. The time of the study was therefore limited to six (6) months, which allowed for enough time for muscle adaptation to occur, but would be acceptable to limit the effect of maturation and mortality. The exercise period had to be sufficient to allow for hypertrophy and neural adaptation to occur. The recommended period for a rehabilitation intervention is 15 to 20 weeks, as described in 2.8.1.3, and adhered to in this study. With each medical assessment, any co-morbidities were closely checked for and the presence/absence thereof documented.

The dropout of participants due to unreliability and the period of the study were considered as limiting factors in the study, although a study by Jarvis *et al.* (2005:302) yielded significant group differences (n=60) regarding QOL (P=0.004) and PFM squeeze pressure (p=0.022) despite the loss of participants to follow-up and missed appointments. Participant dropout was limited by careful selection of participants, follow-up visits by group one and two, the reminders that were sent to the participants, and the fact that the follow-up assessments of the participants corresponded with their post-operative follow-up visits to the clinic/practice.

Other than the concern for the participant's well-being with each follow-up visit, care was also taken with each measurement, to detect any changes in the functioning of the measuring instrument (instrumentation). Normalisation of the baseline with measuring apparatus was done to ensure accurate measurements, for example with the PBU and the EMG. This procedure even limited changes in the instrument. However, all participants were exposed to pretesting and measurement with the same apparatus throughout the study. It could be reasoned that pretesting or the testing effect could influence all three groups in a similar manner due to similar exposure to all measurements, and not lead to differences between groups when calculating the effect. It could however threaten the external validity of the findings when considering if the results are a 'true' finding due to the intervention. If the effect of pretesting was to be eliminated, a Solomon's four group design would have to be introduced. The population size did however not allow for the inclusion of six (6) different pretesting groups (Maree 2013:152).

Contradicting the negative interpretation of the effect of pretesting, it can also be seen as a contributing factor to ecological validity, and thus external validity. In real life situations, patients are exposed to apparatus such as the PBU and the EMG for measurement purposes, but it is also used as a method of biofeedback when treating patients. The possible facilitation that a patient/participant receives with the measurement (even palpation) can contribute to more effective treatment outcomes.

A negative interpretation could be that participants may react differently during the research study (Hawthorne effect) due to the fact that they are monitored by assessors, keep a training diary, and compliance is measured. Participants may fake responses or become anxious. However, it may also truly increase their adherence, which can then be seen as a desirable ecological effect. To help control ecological validity in other ways, care was taken to assess participants at the (same) time of day and in the (same) familiar consultation room during their normal follow-up visits to the clinic. It was argued that the familiar surroundings would limit the Hawthorne effect by them not being exposed to a 'laboratory' situation (Maree 2013:152). Investigating participants in a clinical setting, where they are exposed to a multidisciplinary treatment approach, improves the external validity of the results (Elwood 2002:57-66).

It is clear that a variety of measures were taken to identify and increase validity by considering 'what' is being measured. A factor that is essential, following on the establishment of validity, is the reliability of the measurement; in other words, how well the variables are being measured (De Vos *et al.* 2005:163). The use of standardised measurement procedures with established and peer-reviewed reliability coefficients were used (see 2.9) and described in this chapter. It was important to define and differentiate between the different aspects of muscle function and QOL that needed to be measured. A suitable measuring instrument had to be used for all aspects, such as the EMG for measurement of the PFM activity and endurance, the PERFECT scale for the measurement of PFM strength and endurance, the PBU and the EMG for the activation of the TrA muscle, and the Sahrmann scale for the measurement of rotational and sagittal strength (global stability). Multiple indicators were therefore also used to measure a specific variable of the muscle function. According to several authors, detecting abnormalities of the pubovisceral muscle remains difficult clinically (Dietz, Hyland & Hay-Smith 2006:426; Dietz *et al.* 2005:190; Verelst & Leivseth 2004b:662). This reliability factor was also incorporated in the QOL measurement, where a condition-specific and a generic QOL questionnaire were included (De Vos *et al.* 2005:163).

The population also needed to be conceptualised taking into account the above concept clarification of muscle function and measurement. Studies need to characterise participants in detail in order to make judgements on the effect of the treatment alone (as far as possible) on a specific diagnostic category, namely POP (Norton *et al.* 2007:10). Confounding factors such as the effect of medication (for example, anticholinergics and tricyclic antidepressants), other diseases (for example, inflammatory bowel disease or irritable bowel syndrome, Diabetes Mellitus, Ehlers-Danlos Syndrome, Marfan's Syndrome, neuro-musculoskeletal disorders), age, race, stage of POP pre-operatively, previous surgery, previous PFMT, complications/problems experienced during the period of the trial, the surgeon who did the operation, and the level of activity/function of the patient pre-operatively should be taken into account when analysing the data. Randomisation of the participants to the three (3) groups and specific matching and eligibility criteria aimed to limit this problem. Matching participants according to their initial PFM strength, for example, helped to control for subtle differences between groups such as the amount of facilitation needed during each treatment session, as well as the rate of progression of exercises that could affect the outcome. Other factors were assessed during the medical screening and documented on the data form to be taken into account when interpreting the findings of the study (Epstein *et al.* 2007:165.e1; Norton *et al.* 2007:6; Amaro *et al.* 2005:356; Jarvis *et al.* 2005:301; Elwood 2002:57-66).

Although standardised measuring instruments and procedures were used during the study and several measures adopted to limit errors, there were still factors that could threaten methodological accuracy, such as the difference in population from other published reliability studies and the determining of the validity of the Afrikaans versions of the questionnaires. This indicated the need for pre-testing of measuring instruments and a pilot study to determine any unforeseen reliability or validity issues or errors (De Vos *et al.* 2005:163).

3.8 PILOT STUDY

A pilot study can be defined as the process to test the research design for a prospective study. It is a small scale trial run of all aspects to be used in the main study. Different from the pilot study, a pre-test can be used to test a certain aspect of the study, such as the questionnaires or the measuring instruments (De Vos *et al.* 2005:206). Both methods were used in this study to increase reliability and validity.

In 2009 and 2011, the first pre-test was conducted to test the measuring instruments and procedures used in this study. These studies were approved by the Ethics Committee of the Faculty of Health Sciences, UFS (ECUFS nr 71/2010). The aim of the study was to measure the electrical activity, muscle strength and endurance, and the movement and thickness of the PR muscle, as described for this study. The study sample consisted of women with uro-gynaecological dysfunction, but they were not necessarily due for surgery (Brandt *et al.* 2009:38).

A limitation that was identified during this pre-test was that the EMG machine used (namely a Chattanooga Advance™) could measure a minimum reading of 10цV, but none below that. This problem was overcome in the current and follow-up studies by using the Neurotrac ETS™ with an accuracy of 0.1 цV and a true zero value, ensuring accurate and precise readings.

A second pre-test was conducted to determine the validity of the Afrikaans version of the P-QOL in a South African population. The methodology of this pre-test was described under the P-QOL (see 3.6.1.2.1) and the results are presented in 4.3.3 (also see Addendum15) (Brandt *et al.* 2011:24-33).

The methodology of the current research study was tested by a pilot study on six (6) eligible participants, following the protocol for stage one and two described in the previous sections of this chapter. The data forms, questionnaires, and patient diaries were checked for errors and understanding of instructions. The rehabilitation programme and home programmes were also tested for feasibility, effectiveness and patient understanding.

During the protocol phase it was anticipated that participants (group one and two) would be seen for a follow-up treatment session before the date of surgery. However, the time between the first assessment and date of surgery did not allow for these sessions to take place during stage one of the study. The baseline assessments were therefore done just prior to the date of surgery for all the groups, and it was not feasible to allow for additional treatment sessions prior to surgery. The short time did not allow for neural or muscle adaptations to occur until surgery, ensuring validity of the baseline assessments prior to surgery.

The attendance of regular follow-up appointments was also overestimated. Many participants were from elsewhere, and belonged to a lower socio-economic class; these factors made it difficult for them to travel to Bloemfontein for the regular appointments between the follow-up assessments. This emphasised the importance of the fact that the exercise programme had to be of such a nature that the participant would be able to progress through it for a longer period without input from the fieldworker physiotherapist. The positive aspect of this was that it increased the external validity of the findings to the real life situation and would positively contribute to the response rate of the study.

However, the questionnaires and exercise programme were found to be sufficient and no changes were made. The participants from the pilot study were therefore able to go ahead and complete the full rehabilitation programme, and participate in the main study. Their results were included in the final data analysis.

Analysis of the statistics in regards to the diversity of culture within the target population revealed that inclusion of only Caucasian women (as originally planned) would limit the size of the sample to a great extent. It was therefore decided to include Coloured as well as Asian women who had similar somatotypes and pelvic anatomy when compared to Caucasian women. The sample size would have a major effect on the significance of the statistical findings.

3.9 DATA ANALYSIS

Data analysis was done by the researcher, in collaboration with the Department of Biostatistics at the University of the Free State, using the SAS software package and Excel (Version 2010).

Initial assessment data was summarised by means of descriptive statistics per group. Descriptive statistics, namely frequencies and percentages for categorical data, and means and standard deviations or percentiles for continuous data, were calculated. The change from initial to assessment two and three was calculated per group and groups were compared by means of 95% confidence intervals (CI's).

The test-retest reliability of the Afrikaans version of the P-QOL (Addendum 15) and the SF-36 Health Survey was calculated from the data of two-week follow-up completion of the questionnaires. The second completion of the SF-36 Health

Survey and P-QOL questionnaires was compared with the initial assessment completion. The SF-36 Health Survey scores and P-QOL scores were compared by means of the Kappa-value and percentage agreement respectively.

3.10 SUMMARY

This chapter discussed the quantitative, double blind, randomised, controlled clinical trial design that was used to compare two different intervention groups and one control group with one another. Measuring instruments were chosen to determine and distinguish between the effects that a scientifically based motor control programme, a simple pelvic floor exercise programme, and a control (standard intervention) programme could have on pelvic floor and abdominal muscle function, as well as QOL in women scheduled for pelvic floor reconstructive surgery.

Measuring instruments such as US, EMG, PBU, the Sahrmann and PERFECT scale, as well as subjective outcome measures such as the P-QOL and the SF-36, compliance and the Visual Faces Scale pain assessment, were described in detail. Factors that could influence validity and reliability were emphasised, as well as measures and methodology that could limit such errors.

The objective of the chosen methodology was to produce reliable and valid results in order to generalise the findings to a clinical situation.

The next chapter presents the statistical analysis and comparisons, and the extent of to which the results can be interpreted in regards to statistical validity and reliability.

CHAPTER 4

RESULTS

4.1 INTRODUCTION

The main purpose of this chapter is to present the results as the basis for the discussion to follow in the next chapter. For the purpose of continuity the applicable results are presented under the headings of the identified themes, hypotheses and objectives as identified in Chapters 1 and 2 (see Figure 1 and Figure 31). The same structure will be used in Chapter 5 for discussion purposes.

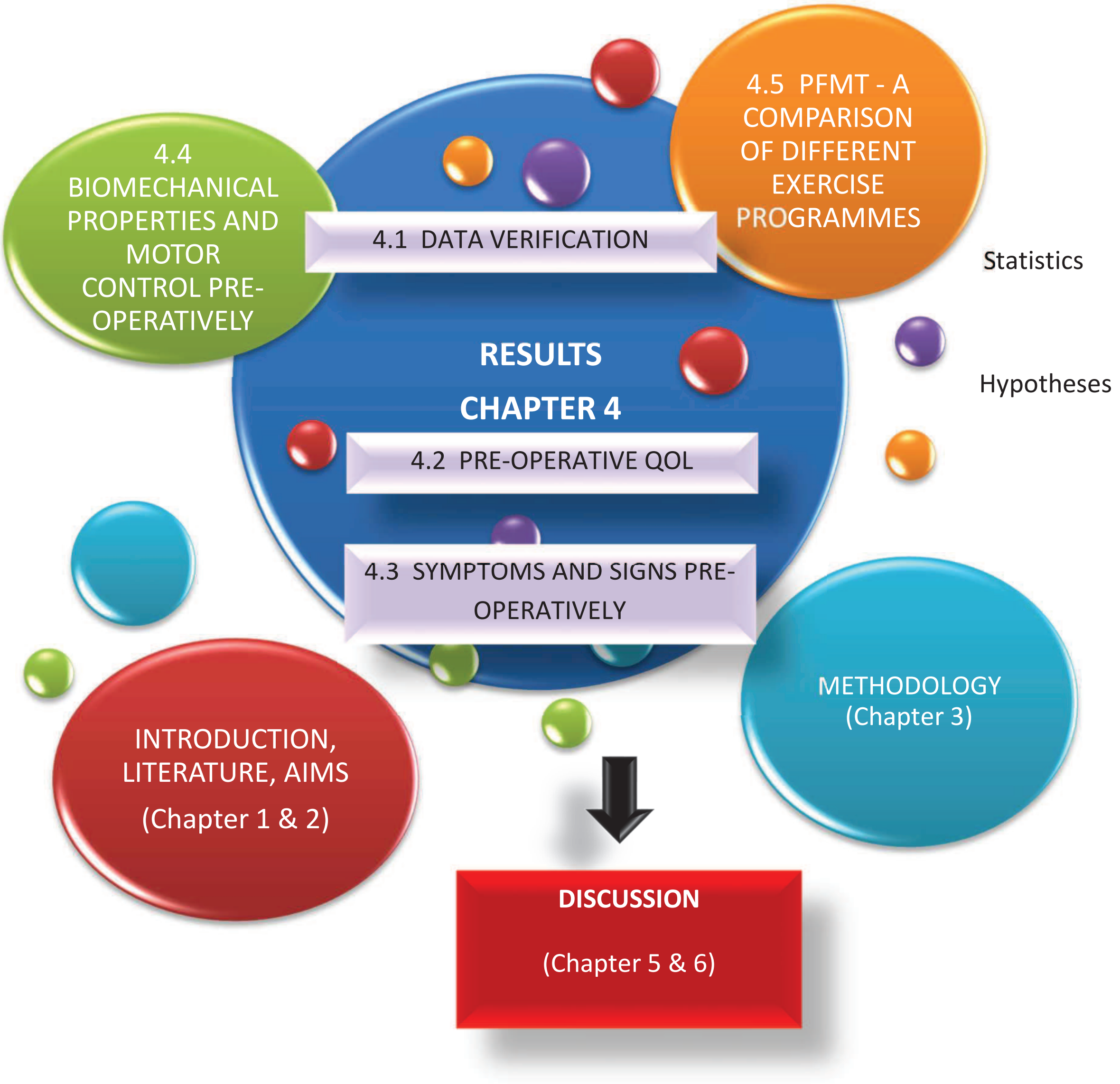


Figure 31. The interrelated discussion of findings within the study context.

Table 17 is a summary of the variables that were tested within each objective, and the integration into the hypotheses. It is also a depiction of how the analysis of variables is presented in this chapter.

Under each section (theme), the specific statistical formulas used for calculation are noted, as well as the analysis and presentation of the results of each specific variable. Results are interpreted and compared to normal values, where applicable, to help with clinical interpretation.

The chapter begins with a presentation of the QOL of participants pre-operatively (n=100), which includes a summary of the results of the reliability testing of the QOL questionnaires from the pre-test (n=40). This is followed by the results on symptoms, signs, and co-morbidities, biomechanical analysis of the pelvic floor and abdominal muscles pre-operatively (n=100), and the effect of different exercise programmes on all of these variables in 81 of the 100 participants who were eligible and willing to be included in the intervention post-operatively. To relate the results to the context of QOL again, the chapter ends with the presentation of the results of QOL after three (3) and six (6) months of rehabilitation respectively.

Table 17. Summary of hypotheses, related objectives and variables for analysis.

OBJECTIVE	HYPOTHESES	ANALYSIS OF VARIABLES
Objective 1.6.1.1 *To determine baseline data regarding the abdominal muscles and the PFM, as well as QOL pre-operatively in women undergoing corrective surgery for POP.*	*Hypotheses 1,2,3,4,5,6,8,10,* *11,13*	*QOL* *Age, menopause, BMI, childbirth, smoking, other diseases, recreation and occupation, bowel symptoms, stage of POP* *Pain* *PFM function* *Abdominal muscle function*
Objective 1.6.1.2 *To determine the outcomes, within groups, of a* *i. PFMT programme,* *ii. core training programme, and* *iii. a control intervention* *on the abdominal muscles, PFM and QOL post-operatively in women who have had corrective surgery for POP.*	*Hypotheses* *3-13*	*PFM function* *Abdominal muscle function* *Adherence* *QOL* *Pain*

OBJECTIVE	HYPOTHESES	ANALYSIS OF VARIABLES
Objective 1.6.1.3 *To compare the outcomes, between groups, of a* *i. PFMT, and* *ii. a core training protocol, versus no training (control group), on the abdominal muscles, PFM and QOL (pre-operatively and post-operatively) in women with POP.*	*Hypotheses* *3, 7-13*	*PFM function* *Abdominal muscle function* *Adherence* *QOL* *Pain*
Objective 1.6.1.4 *To compile a proposed model for rehabilitation for patients with PFM dysfunction in the public and private sector, pre- and post-operatively.*	*Hypothesis 13*	*Comparison of training programmes and their outcomes* *Available literature*

4.2 DATA VERIFICATION

Prior to analysis, all data was checked for errors in coding by investigating reasons for missing data. Missing information was gathered, where applicable, and zero values were inserted where missing values were being analysed.

Coding was done twice by the researcher and typing errors were eliminated by reading in the data twice. Spot checks were also done by the Biostatistician.

Firstly, logical checks were done to confirm that all participants fulfilled the eligibility criteria by checking the demographic data for inclusion. Categorical variables were checked for plausible values, while the ranges of the continuous data were checked for out of range minimum and maximum values. This was firstly done by a basic Excel analysis of the data - also to detect patterns and relationships to be explored further by formal statistical methods (De Vos *et al.*. 2005:222). The Excel analysis was followed by a formal statistical analysis by a Biostatistician using SAS software to compare findings.

In addition to the above, the translated versions of the general and specific QOL questionnaires were tested for reliability by comparing two (2) assessments that were two (2) weeks apart. This assessment was done in a population specific to this study to ensure external validity of this testing procedure and results. The findings determined the inclusion and exclusion of certain questions to ensure that the reported results were reliable for our population.

4.3 QUALITY OF LIFE – RESULTS FROM PRE-OPERATIVE TESTING

Findings on QOL have been defined as one of the main outcome measures for POP in the literature (see 1.2, 2.2 and 2.9.1). The results begin with a presentation of findings on QOL pre-operatively, in order to situate the sample within the context of QOL for the purpose of further interpretation.

4.3.1 Statistical method

A total of 120 women scheduled for pelvic floor reconstructive surgery were approached for participation in the study, of whom 100 were willing to complete the pre-operative QOL and demographic questionnaires. Disease-specific as well as general QOL were measured by means of the P-QOL questionnaire and the SF-36 Health Survey respectively. Instructions for scoring and coding of the P-QOL were obtained from the original author via personal communication (G.A. Digesu, personal communication, 2011). Addendum 14 gives the full description of these instructions for the P-QOL questionnaire.

Instructions for the coding and scoring of the SF-36 were obtained from the SF-36 Health Survey Manual and Interpretation Guide (Ware 1993:6.1-6.22).

A univariate analysis and descriptive statistics were used to describe the distribution of the data from the QOL questionnaires in order to decide on parametric/non-parametric methods of analysis. A definition and interpretation of these methods and statistics can be found under 4.4.1.

This section also includes a presentation of the results of the validation of the Afrikaans versions of the P-QOL and the test-retest reliability of the SF-36. The reason for inclusion in this section is that these findings are important to verify the validity of the results from the translated Afrikaans versions of these questionnaires. Ninety five percent (95%, n=100) of the sample was Afrikaans-speaking in the current study.

A total of 21 (twenty-one) SF-36 Health Survey questionnaires fulfilled the eligibility criteria to use for reliability testing (see 3.5.1.2.1). The test-retest reliability of the SF-36 was determined by calculation of the percentage agreement between domains and questions, as well as the kappa statistic and 95% CIs.

The kappa statistic (κ) was used as a measure of agreement between questions. A maximum value of 1.00 indicated perfect agreement, while a value of zero indicated no agreement better than chance. Table 18 describes the interpretation of different kappa values (κ). In practice, a kappa value (κ) below 0.5 usually is an indication of poor agreement (Altman 1991:404).

Table 18. Guidelines for interpretation of the kappa value (Altman 1991:404).

Value of κ	Strength of agreement
<0.20	Poor
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Good
0.81-1.00	Very good

The statistical methods, results and data analysis of 40 P-QOL questionnaires, used to determine validity and reliability in the pre-test, are presented in a draft manuscript included as Addendum 15.

4.3.2 Data analysis – Validity and reliability of the Afrikaans version of the P-QOL pre-test

Summarising the results from the pre-test, the translated Afrikaans version of the P-QOL appears to have good content, construct and criterion validity, as well as good stability, strength of agreement, and internal consistency. This study was done on women with POP in order to make the results clinically relevant to our investigation. Addendum 15 can be consulted for detailed results and analysis.

For the purpose of interpretation of the results of the P-QOL in this chapter, a few aspects regarding reliability can be highlighted which were found in the reliability study. Questions with the lowest reliability percentage were regarding physical limitations (question 23), the sleep/energy domain (questions 33 & 34), and severity measures (question 38). The kappa values of these questions were below 0.5, which also reflected poor agreement, according to Altman (1991:404). One question in the personal relationship domain (question 27) and the emotional domain (question 30) also had a kappa value below 0.5, although their percentage agreements did not reflect poor reliability as clearly. Table 19 summarise the domains and values of concern when interpreting the results from the Afrikaans version of the P-QOL.

Table 19. Questions with low reliability in the Afrikaans version of the P-QOL (n=40).

Domain	Question number	Percentage reliability (%)	Kappa value
Physical limitations	23	53.8	<0.5
Sleep/energy	33 34	53.8 53.8	<0.5
Severity measures	38	57.7	<0.5
Personal relationships	27	69.2	<0.5
Emotions	30	62.5	<0.5

Although one of the three (3) questions in the personal relationship domain had a poor kappa value, the remaining two questions (question 28 and 29) of this domain had the highest reliability percentages (81.8% and 84.6% respectively) as well as kappa values (kappa > 0.6) in the questionnaire. Questions 22 and 35 from the role limitations and severity measures domains also showed good reliability (73.1% and 76.9% respectively; kappa = 0.6 and >0.5 respectively).

It would therefore seem from these results that interpretation of the sleep/energy domain, in particular, should raise some concern regarding reliability.

4.3.3 Data analysis – Reliability of the Afrikaans version of the SF-36 Health Survey

Translation of a standardised general health questionnaire, such as the SF-36, poses certain challenges. Changes and adaptations to the questionnaire to fit a certain population were limited due to adherence to the standard of content and scoring, as described in the SF-36 Health Survey Manual and Interpretation Guide (Ware 1993:6.1-6.22). The aim of this methodology is to produce scores with similar validity and reliability as reported by other studies. It also enables the comparison of results across studies using the same standard of content and scoring (Ware 1993:6.1). On the other hand, it might compromise interpretation (namely generalisability and external validity) when used in certain populations, leading to less valid and reliable results.

In this study we followed the suggestion by Ware (1993:6.1) and limited adaptations of the questionnaire to our population, which might be reflected in the reliability results. We contained the standard of content in Afrikaans and standard of scoring, as suggested by Ware (1993:6.1-6.22).

A higher score on the SF-36 indicates a better QOL. The raw scores of each domain are first transformed into a percentage. Table 20 describes the scoring of the domains and the transformation of the scores (Ware 1993:6.18).

Table 20. Calculation and transformation of the domain scores of the SF-36 (Ware 1993:6.18).

DOMAIN	SUM FINAL ITEM VALUES (after recoding)	POSSIBLE RAW SCORE RANGE
PHYSICAL FUNCTIONING	3a+3b+3c+3d+3e+3f+3g+3h+3i+3j	20
ROLE PHYSICAL	4a+4b+4c+4d	4
BODILY PAIN	7+8	10
GENERAL HEALTH	1+11a+11b+11c+11d	20
VITALITY	9a+9e+9g+9i	20
SOCIAL FUNCTIONING	6+10	8
ROLE EMOTIONAL	5a+5b+5c	3
MENTAL HEALTH	9b+9c+9d+9f+9h	25
Formula for transformation of raw scale scores: **Transformed scale = (Actual raw score - lowest *possible* raw score) / (*Possible* raw score range) x 100**		

Measures of agreement between two evaluations in 21 Afrikaans-speaking participants yielded a variety of findings in the reliability of the different questions (Table 21). It was mostly question 2 to 5 that yielded a tendency to moderate reliability with a difference within the set limit of 30% between questions and/or an acceptable kappa value (κ>0.5). These questions entailed the physical, role physical, and role emotional domains (Table 20).

Table 21. Measure of agreement between questions of the SF-36 (n=21).

QUESTION	PERCENTAGE DISAGREEMENT	KAPPA VALUE	95% CI
1	57.1%	0.24	[0.0009;0.47]
2	43%	0.55	[0.3;0.8]
3a	48%	0.38	[0.08;0.68]
3b	28.6%	0.58	[0.3;0.86]
3c	28.6%	0.55	[0.32;0.79]
3d	28.6%	0.5	[0.19;0.8]
3e	23.8%	0.27	[-0.13;0.67]
3f	33.3%	0.39	[0.04;0.74]
3g	19%	0.73	[0.48;0.97]
3h	19%	0.7	[0.42;0.98]
3i	19%	0.46	[0.03;0.89]
3j	14.3%	0.52	[0.13;0.91]
4a	19%	0.59	[0.24;0.95]
4b	19%	0.61	[0.27;0.95]
4c	28.6%	0.42	[0.04;0.81]
4d	19%	0.62	[0.29;0.94]
5a	19%	0.48	[0.06;0.9]
5b	19%	0.57	[0.21;0.94]
5c	19%	0.42	[-0.0;0.83]
6	55%	-	-
7	55%	0.33	[-0.0;0.65]
8	40%	0.48	[0.18;0.79]
9a	55%	0.42	[0.15;0.69]
9b	45%	-	-
9c	50%	0.23	[-0.11;0.57]
9d	65%	0.10	[-0.2;0.4]
9e	55%	-	-

QUESTION	PERCENTAGE DISAGREEMENT	KAPPA VALUE	95% CI
9f	65%	-	-
9g	55%	0.24	[-0.09-0.58]
9h	55%	0.35	[0.05-0.65]
9i	55%	0.39	[0.08-0.69]
10	45%	-	-
11a	45%	-	-
11b	55%	0.42	[0.12-0.72]
11c	40%	0.52	[0.22-0.83]
11d	30%	-	-

If we allowed for a reasonably wide variation of 30% difference between the two (2) measurements (which was 10% more than the anticipated acceptable allowance of 20%), the reliability calculation for each domain yielded a completely different finding from the individual questions in regards to agreement percentages (Table 22). All domains scored above 80% agreement in this context. However, this lack of consistency was not acceptable for inclusion of the SF-36 for analysis in our study.

We could speculate that the physical, role physical and role emotional domains would have some sort of reliability based upon the individual questions included in these domains, as well as according to the analysis of each domain. Contrary to this, specifically the mental health, vitality, and general health domains would have to be interpreted with caution due to poor reliability of the individual questions included in these domains (Tables 21 and 22). Recent advances have recommended norm-based scoring which equates all scores of the SF-36. This would not be possible if only reliable questions were to be included in the scoring in our study. Together with a lack of normative data for a South African population, all arguments led to the SF-36 being omitted from further analysis (Gandek 2002:2) (see 4.3.5).

Table 22. Measure of agreement between the domains of the SF-36 in terms of percentage agreement and 95% CIs for the difference between measurement one and two.

DOMAIN	PERCENTAGE AGREEMENT	95% CI
PHYSICAL FUNCTIONING	90.46%	[-6.7;3.3]
ROLE PHYSICAL	90.46%	[0;0]
BODILY PAIN	80%	[0;19.2]
GENERAL HEALTH	100%	[-8;4]
VITALITY	80%	[-4.2;25]
SOCIAL FUNCTIONING	90%	[-10;0]
ROLE EMOTIONAL	85.71%	[0;0]
MENTAL HEALTH	85%	[-1.3;13.9]

4.3.4 Data analysis – Prolapse Quality of Life (pre-operatively)

Similar to the suggested analysis for the SF-36, the interpretation of the P-QOL questionnaire was based on interpretation of the individual domains. Authors tend to report each domain calculated as percentage impairment, rather than the total score (Claerhout *et al.* 2010:572; Manchana & Bunyavejchevin 2010:98;, Svihrova *et al.* 2010:55; De Oliveira *et al.* 2009:1194; Cam *et al.* 2007:134; Digesu *et al.* 2003:187). Symptomatic impairment can be based on impairment in one domain, or impairment in all of the domains. The importance is to differentiate between the different domains affected due to the important role it plays in surgical decision-making (G.A. Digesu, personal communication, 2011).

In our study, median values were calculated for each domain, due to the non-parametric distribution of data. These values are depicted in Table 23, together with a summary of the evidence-based values found by previous authors for symptomatic women. Table 60 in section 5.1 offers a detailed summary of the findings of the previous studies.

Table 23. Table of median domain scores of the P-QOL questionnaire pre-operatively.

DOMAIN	MEDIAN VALUE (%) & IQ RANGE n=100	EVIDENCE-BASED SYMPTOMATIC VALUES (Median % scores)
Prolapse impact	66.67 (33.33-100.0)	57-100
Role limitations	33.3 (0-75.0)	67
Physical limitations	33.3 (0-75.0)	50-67
Social limitations	33.3 (0-66.67)	16-56
Personal relationships	0 (0-66.67)	50-67
Emotions	44.4 (11.1-72.2)	44-67
Sleep/energy	33.3 (16.67-50.0)	33-67
Severity measures	25 (12.5-41.67)	11-42

The general health perception of most of the participants (n=100) ranged from good (34%) to fair (47%) on the Likert scale of the P-QOL. These findings did not indicate impaired QOL when compared to the evidence on symptomatic scores. The median value of 25% calculated for the general health item was also on the border of symptomatic classification, according to the literature (namely 25-70%). Contrary to this, the prolapse impact score of 71% of the participants (n=100) ranged from 67% to 100%, which indicated impairment in this domain. Reliability measures were acceptable for both of these domains with a kappa value of >0.5.

Other domains which were found to be impaired were social limitations, emotional aspects, sleep/energy, and severity measures. However, it should be noted that the results regarding the sleep/energy domain must be interpreted with caution due to questionable reliability of this domain (see 4.3.2). It seems that the domains that included physical activity as a limitation, namely the domains of role and physical limitations, were less impaired by the prolapse. Personal relationships were least affected with a median value of 0% (Table 23).

4.3.5 Data analysis – SF-36 Health Survey (pre-operatively)

Data analysis of the SF-36 was omitted from the results due to the finding related to poor reliability (see 4.3.3). It will therefore not be included in further presentation of the results in this chapter.

4.4 SYMPTOMS, SIGNS AND CO-MORBIDITIES IN THE PRE-OPERATIVE STAGE

4.4.1 Statistical method

Relating closely to the QOL are the symptoms, signs, and co-morbidities patients experience due to POP. A univariate analysis was done to describe these variables in a sample of 100 participants pre-operatively, scheduled for pelvic floor reconstructive surgery (De Vos *et al.* 2005:222). This sample was gathered over a period of two (2) years and included participants from the private (n=24) and public primary health care sector (n=76).

The aim of the analysis was to explore the distribution of the data in the whole sample, in order to challenge the first hypotheses (see Figure 1), and to explain and compare the characteristics of the experimental and control groups at baseline.

Descriptive statistics were used to describe the data. The statistics included the calculation of the mean, SD(s), and the minimum and maximum values in the case of a symmetric distribution of the variable. Where data was skewed positively or negatively, the median 25th percentile and 75th percentile were also included for interpretation.

The distribution of the data was interpreted as skewed where the value of the skewness was larger or smaller than 1 or -1 respectively. The distribution was confirmed by checking if the mean and median were lying close together, as well as if the *mean-2*SD* was larger than zero. If the latter two (2) estimates were not true, the question was raised as to the parametric distribution of the data. Box-plots were then drawn to observe and interpret the skewness of the data (Maree 2013:189,190; De Vos *et al.* 2005:236, 237).

Observations in the pre-operative stage were firstly made on the whole sample and it was therefore treated as a dependent group for analysis. Bi-variate analyses included calculation of correlations by means of the Pearson correlation coefficient (CC) (r) for parametric continuous data and by means of the Spearman CC (r_s) for non-parametric continuous and ordinal data. A correlation coefficient of $-1<r<0$ indicated a negative correlation, while $0<r<1$ indicated a positive correlation, where $r=0$ indicated no correlation (Leedy & Ormrod 2010:279). For categorical data, cross-tabulations were done to indicate a descriptive degree of association (De Vos *et al.* 2005:239). Statistical significance for correlation coefficients was calculated by means of the critical values of r at various levels of probability. The critical value for a 5% significance level, two-tailed test, and rejection of the null hypothesis was taken as the minimum level of probability. Any p-value greater than 0.05 was therefore interpreted as statistically insignificant (Hicks 1999:194-198). Practical significance was indicated by means of effect size, based on the r-value (Table 24).

Table 24. Interpretation of effect size (Maree 2013:211).

d or r	Meaning
0.2	Small effect
0.5	Medium effect
0.8	Large effect

4.4.2 Data analysis – Symptoms, signs, and aspects affecting lifestyle

Results for the first objective (see Table 17) were mainly based on the data survey during stage one (pre-operatively). Other independent variables, such as lifestyle, co-morbidities, medication and previous surgery, were noted and described in order to prevent erroneous interpretation of the results and false rejection or support of the hypotheses (Type I or Type II errors). The effects that some of the mentioned independent variables could have on the dependent variables identified in the hypotheses were discussed in 2.5 (Maree 2013:204).

For explanation purposes and continuity, the reader is occasionally referred back to extracts from Chapter 2 (Table 7) in the form of the hypotheses that were derived from the literature under each theme.

Hypothesis 1 (Objective 1.6.1.1)

"Factors such as increased age, menopause, BMI, vaginal delivery, or causing an increased IAP (obesity, smoking, pulmonary disease, constipation, recreational or occupational activities), seem to be associated with POP."

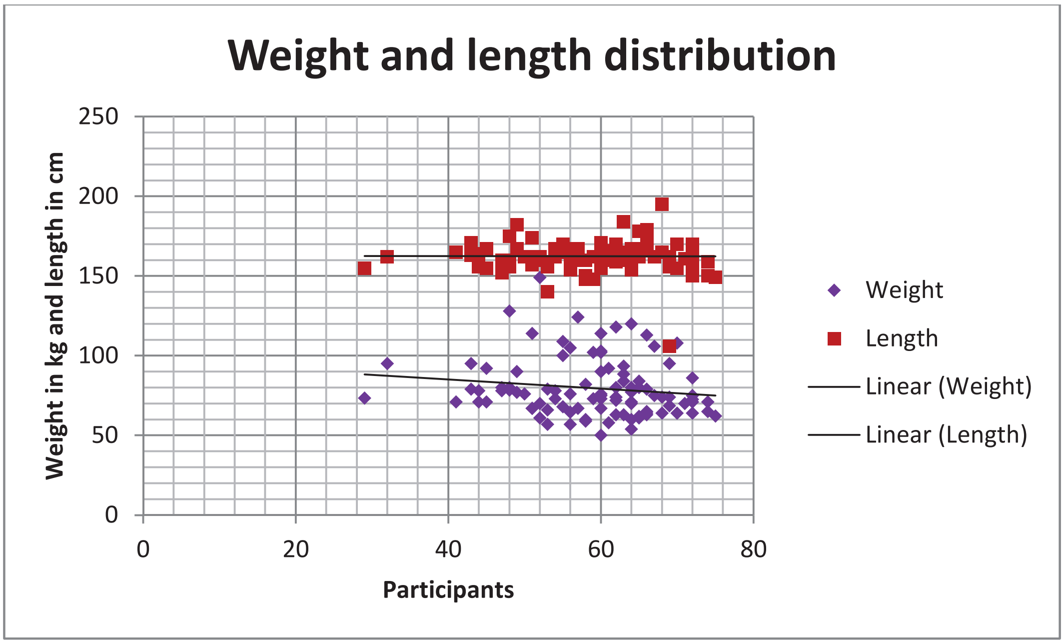
Table 25. Results for demographic variables (continuous).

VARIABLE	N	Skewness	Mean	SD (s)	Min	Max	Median	25th percentile	75th percentile
Age (years)	98	-0.706	59	9.131	29	75	60	n/a	n/a
Weight (kg)	97	1.245	79.4	18.563	50	149	75	66	86
Length (cm)	100	-1.417	162.27	9.846	106	195	162	159	167
Pregnancies	99	0.829	3.303	1.581	0	8	3	2	4
Deliveries	99	1.063	2.97	1.417	0	8	3	2	3

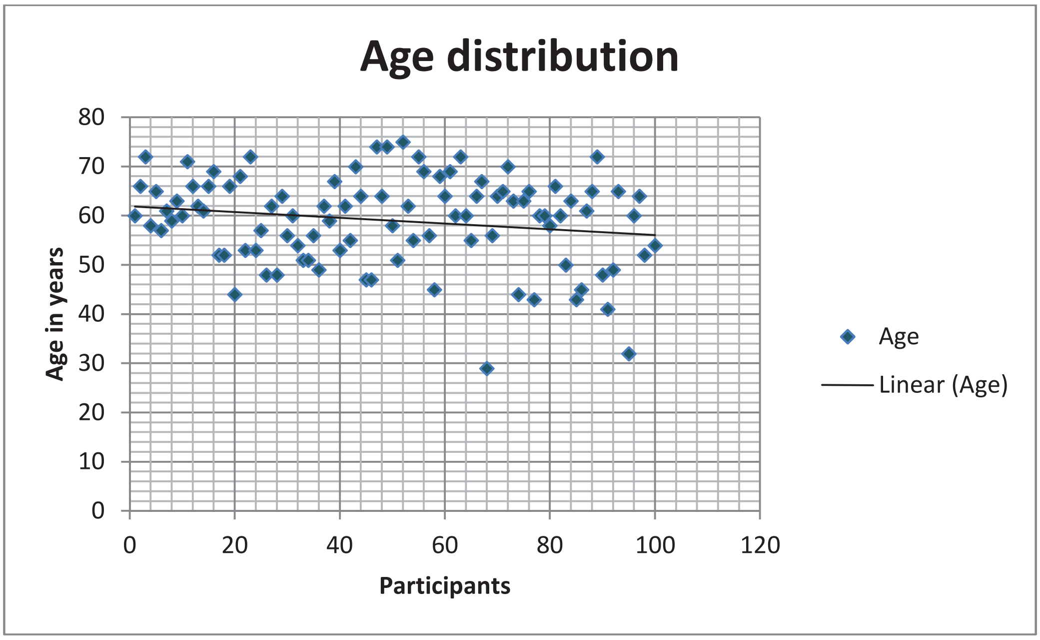
Min = minimum, Max = maximum, CI = confidence interval, SD = standard deviation

Red script indicates skewed distributions.

Referring firstly to some of the statistical values obtained in Table 25 above, the data for the length, body mass and amount of deliveries were classified and interpreted as skewed, due to the values being greater and lesser than one. Data for age was normally distributed (skewness = -0.706) (Graphs 1 and 2).



Graph 1. Distribution of weight and length pre-operatively (n=100).



Graph 2. Distribution of age pre-operatively (n=100).

The surveyed women had an average age of 59 years (n=98) with a median BMI of 28.67 kg/m^2 (interquartile (IQ) range of 26.08-32.99; n=97), which is below the upper limit of 35 kg/m^2. Most participants were Afrikaans-speaking (95%, n=100) and did some kind of manual labour (60%, n=100), which included mostly housework, and not formal employment (Table 26).

Table 26. Results for demographic variables (categorical).

VARIABLE	n	Frequency	Percentage (%)
LANGUAGE	100		
Afrikaans		95	95
English		5	5
WORK	100		
Manual labour		60	60
Office work		20	20
Pensioner		20	20
PARTICIPATION IN SPORT	100		
Yes		15	15
No		85	85
TYPE OF EXERCISE ACTIVITIES	100		
Jogging		1	1
Swimming		2	2
Tennis		0	0
Walking		18	18
Weight training		1	1
Pilates/yoga		1	1
Line dance		1	1
Fishing		2	2
LEVEL OF PARTICIPATION	100		
Social		24	24
Provincial		0	0
National		0	0
CO-MORBIDITIES	100		
Heart disease		14	14
Vascular disease		17	17
Pulmonary disease		3	3
Cancer		1	1
Allergies		21	21
Previous surgery		56	56
Inflammatory disease		19	19
Diabetes Mellitus		3	3
Hypothyroidism		3	3
Depression		1	1

VARIABLE	n	Frequency	Percentage (%)
Psoriasis		1	1
MEDICATION	100		
Hypertension/angina		47	47
Hormone replacement therapy		17	17
Anti-inflammatory medication		8	8
Antidepressants		12	12
Hypothyroidism		18	18
Vitamins and minerals		9	9
Gastric ulcer		3	3
Overactive bladder		2	2
Cholesterol		18	18
Pain		7	7
Diabetes Mellitus		9	9
Asthma		7	7
Constipation		1	1
Insomnia		3	3
Anti-coagulant		5	5
Antihistamines		2	2
Malaria		1	1
SMOKING	100		
Yes		20	20
No		80	80
HISTORY OF PELVIC FLOOR MUSCLE EXERCISE	100		
Yes		15	15
No		85	85
HISTORY OF CORE/STABILITY EXERCISE	100		
Yes		7	7
No		93	93
MENOPAUSAL STATE	100		
Pre-menopause		15	15
Peri-menopause		31	31
Post-menopause		54	54

VARIABLE	n	Frequency	Percentage (%)
HISTORY OF PELVIC/ABDOMINAL SURGERY	100		
Yes		45	45
No		55	55
Type of surgery:			
Anterior repair		25	25
Posterior repair		5	5
Partial colonostomy		1	1
Hysterectomy		18	18
Appendectomy		9	9
Laparoscopy		2	2
Laparotomy		3	3
Gall bladder		1	1
Hernia repair		2	2
TOT sling		1	1

Highlighted results indicate important findings referred to in the text.

Participants' (n=100) lifestyles were further characterised by low levels of sport participation (15%) and a lack of exercise. Only 21% (n=100) did some kind of cardiovascular exercise, which was mostly stated as walking (18%). Fifteen percent of the women (n=100) have been introduced to PFM exercises, while only 7% were familiar with exercises to strengthen the core (Table 26).

This lack of exercise could also be reflected by the fact that many of the participants (n=100) had heart and/or vascular disease (14% and 17% respectively). Forty seven percent was taking medication for hypertension and 18% for cholesterol. Hypothyroidism was also an area of concern (18% medicated), which could affect the metabolism and contribute to the development of cardiovascular disease, poor anthropometric results and poor general health (LeGrys *et al.* 2013:2309). The description of the general health of the participants could be further explained by also including emotional status, such as noting that 12% was using antidepressants (Table 26).

A cross-tabulation of exercise participation and heart disease indicated that 31% of participants, who were physically inactive (n=95), had heart disease compared to the 13% of participants who were physically active (n=15) (Table 27).

Table 27. Cross-tabulation of exercise participation with heart disease.

EXERCISE PARTICIPATION	HEART DISEASE	
	Yes	No
Yes (n=15)	13%	87%
No (n=85)	31%	68%

A cross-tabulation between exercise participation and the use of antidepressants indicated that none of the participants who exercised (n=15) used antidepressants, compared to the 14% of participants who did not exercise (n=85) but used antidepressants (Table 28).

Table 28. Cross-tabulation of exercise participation with antidepressants.

EXERCISE PARTICIPATION	ANTIDEPRESSANTS	
	Yes	No
Yes (n=15)	0%	100%
No (n=85)	14%	86%

Cross tabulating the amount of participants with depression/on antidepressant medication with the amount of participants with cardiovascular disease/on medication for cardiovascular disease indicated that almost 70% of the participants with depression/on antidepressant medication had cardiovascular disease, or were treated for cardiovascular disease (Table 29). To test for confounding factors that could also be a cause of cardiovascular disease, it was established that none of the participants with depression and cardiovascular disease did any form of exercise.

The participants with both of these diseases also had an increased mean BMI of 33.23kg/m^2.

Table 29. Cross-tabulation of participants with depression and cardiovascular disease.

DEPRESSION	CARDIOVASCULAR DISEASE	
	Yes	No
Yes (n=13)	69.23%	30.77%
No (n=87)	56.32%	43.67%

The reasons for a poor emotional and psychological state may also require a comprehensive discussion of many different variables affecting the participants' health. A cross-tabulation of the use of antidepressants with the history of previous surgery may indicate such possibilities (Table 30). More than half of the participants, namely 56% (n=100), had previous surgery, while 19% (n=100) complained of inflammatory disease. Contradicting the last result, only 8% (n=100) was using anti-inflammatory medication. Of the participants who had previous surgery, almost half (45%, n=56) of the sample had abdominal or pelvic-related surgery. The abdominal and pelvic surgeries mainly included anterior repairs (25%, n=100) and hysterectomies (18%, n=100) (see Table 26).

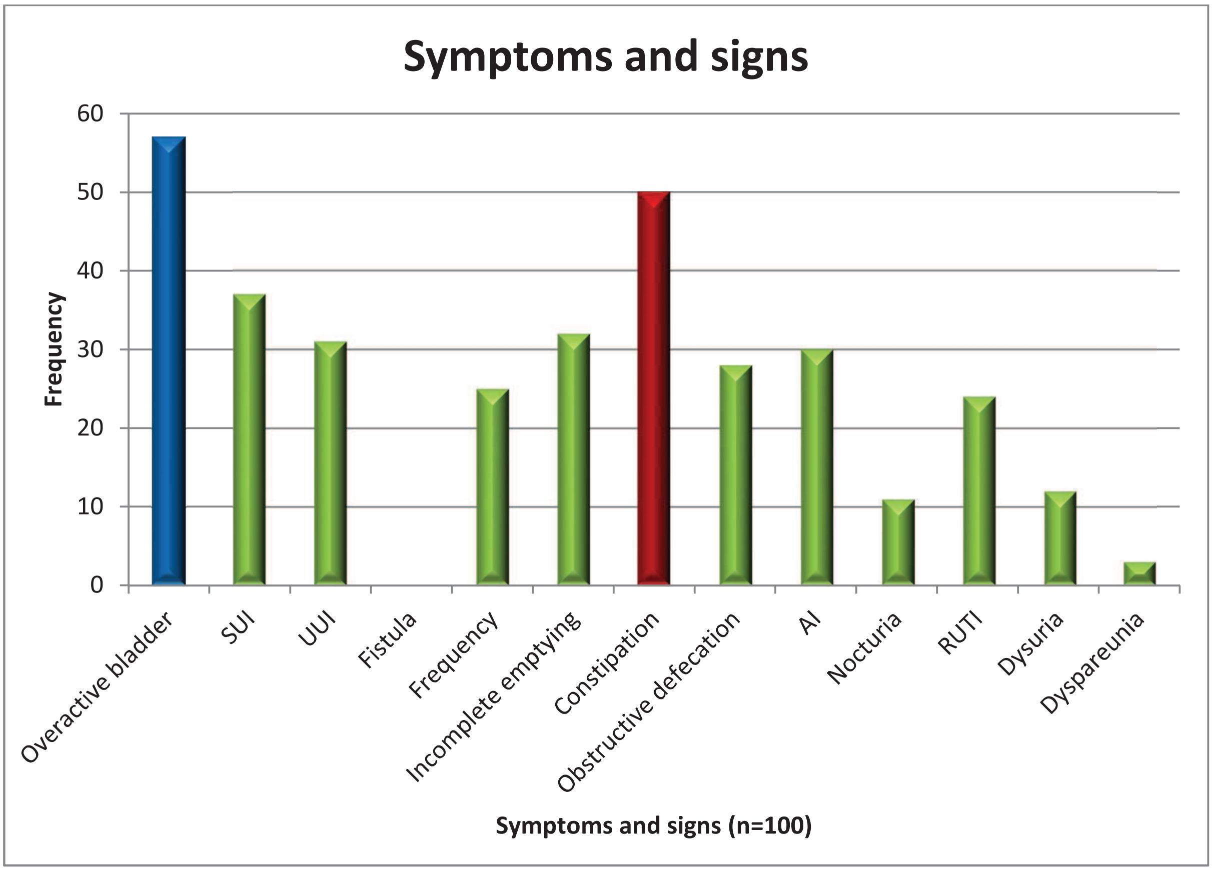
Table 30. Cross-tabulation of the use of antidepressants with a history of surgery.

ANTIDEPRESSANTS	PREVIOUS SURGERY	
	Yes	No
Yes (n=12)	100%	0%
No (n=88)	52.2%	47.7%

The participants' gynaecological history also indicated that a relatively small percentage of them were using hormone replacement therapy (17%, n=100), considering the percentage of them who were in menopause (31%, n=100), or post-menopausal (54%, n=100). Among the participants (n=100), a mean of 3.3 pregnancies and a median of three (3) deliveries were indicated in regards to their obstetrical history. Ninety participants in this sample had experienced normal childbirth (median = 3), with a total of 260 deliveries among them. Comparing this to the amount of women who had Caesarean sections, namely 19 (with a total of 31 deliveries among them and a median of 1), there appears to be a tendency towards normal delivery in this sample (see Table 25 and 26).

To summarise the demographic data, the participants were advanced in age (mainly post-menopausal), but with a BMI that was within the normal, upper range. A substantial percentage of the women had multiple normal deliveries and a history of abdominal and/or pelvic surgery.

The participants further presented with familiar symptoms and signs associated with POP and PFM dysfunction (Graph 3). Most participants complained of an OAB (57%, n=100), followed by complaints of constipation (50%, n=100), but also other prominent symptoms, namely SUI (37%, n=100), UUI (31%, n=100), incomplete emptying (32%, n=100), and anal incontinence (30%, n=100). The other symptoms and signs with a lesser frequency of occurrence are depicted in Graph 3. These symptoms and signs reflect the findings by the surgeon, while the subjective report of symptoms and signs were reflected by the P-QOL results under the QOL assessment in 4.3.



AI = anal incontinence

RUTI = recurrent urinary tract infections

Graph 3. Symptoms and signs.

It was interesting to note that although most participants complained of an OAB and constipation, these were the least frequent conditions that medication was taken for. Only two participants (n=100) reported taking medication for an OAB, while only one participant (n=100) reported that she took medication for constipation (see Table 26).

It was clear from the results that bladder and bowel symptoms were the prominent symptoms affecting the participants pre-operatively, and not symptoms such as pain – which many times may be mistaken for the bulging feeling women with POP may experience. Assessment of pain by the VFS revealed that the participants experienced a median value of zero pelvic pain (IQ range of 2) and a mean value of 1.49 lower back pain (SD = 1.654) (Table 31).

Hypothesis 10 (Objective 1.6.1.1-1.6.1.3)

"Similar to the case of PFD and pain, the stabiliser muscles exhibit disturbed motor control patterns and changed physiological properties in individuals with low back pain (Hodges & Richardson 1996:2647). On the other hand, altered postural activity and morphological changes in these muscles are related to the development and the recurrence of low back pain (Cholewicki et al. 2005:2614). Pain may cause inhibition of the stabiliser muscles, and therefore is hypothesised to contribute to PFM dysfunction, such as POP and even incontinence (Grewar et al. 2008:376)."

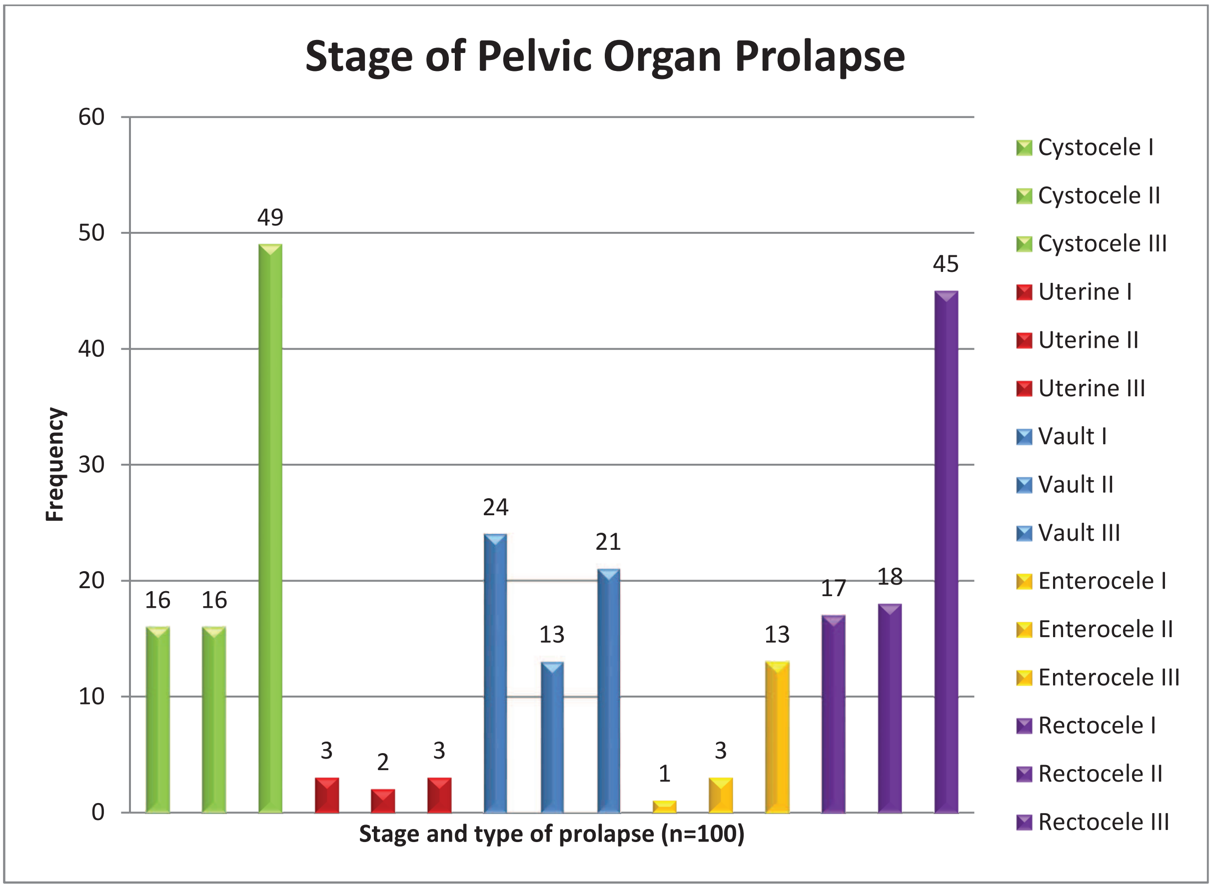
Table 31. Results for pain assessment.

VARIABLE	n	Skewness	Mean	SD (s)	Min	Max	Median	25th percentile	75th percentile
PAIN ASSESSMENT									
Pelvic pain	100	1.316	0.99	1.403	0	5	0	0	2
LBP	100	0.667	1.49	1.654	0	5	1	-	-

Min = minimum, Max = maximum, CI = confidence interval, SD = standard deviation

Red script indicates skewed distributions.

Coinciding with the most common bladder and bowel symptoms reported by the participants (namely OAB and constipation) were the results regarding the type and stage of POP. Symptoms commonly associated with cystocele and rectocele are OAB, constipation, and incomplete emptying (De Boer *et al.* 2010:33-36). Forty nine percent of the participants were diagnosed with a stage III cystocele (n=100) and 45% with a stage III rectocele (n=100) (Graph 4).



Graph 4. **Stage and type of Pelvic Organ Prolapse.**

In total, 86% (n=100) of the participants had stage III POP. Further analysis to identify confounding factors indicated that 94.73% of the sample who had hypothyroidism (n=19), had stage III POP, while only 80.24% of those without hypothyroidism (n=81) had stage III POP (Table 32).

Table 32. **Cross-tabulation of the presence of hypothyroidism and stage of Pelvic Organ Prolapse.**

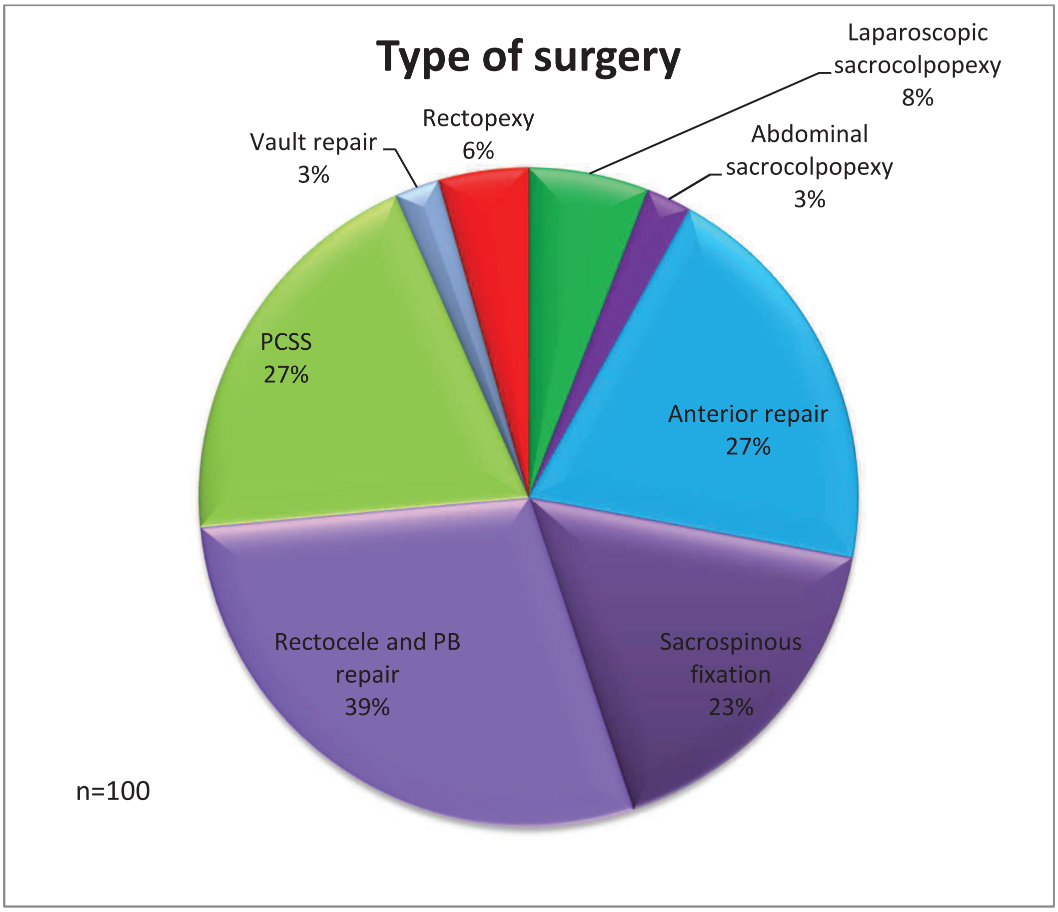
HYPOTHYROIDISM	STAGE OF POP	
	Stage III	< Stage III
Yes (n=19)	94.73%	5.26%
No (n=81)	80.24%	19.75%

An analysis similar to the latter one was done to investigate how many participants with hypertension had a severe stage of POP. However, participants with or without hypertension appeared to have a similar prevalence of stage III POP (Table 33).

Table 33. Cross-tabulation of the presence of hypertension and stage of Pelvic Organ Prolapse.

HYPERTENSION	STAGE OF POP	
	Stage III	< Stage III
Yes (n=58)	86.21%	13.79%
No (n=42)	85.71%	14.23%

The stage of POP is significant to note due to the fact that this is considered one of the criteria on which decisions are made whether to perform surgery, together with the physiological and morphological characteristics of the muscles and connective tissue. It was therefore expected that most participants were scheduled for an anterior repair (27%, n=100), a sacrospinous fixation (23%, n=100), a rectocele and perineal body repair (39%, n=100), or a perineo-colpo-sacro-suspension (27%, n=100) (Graph 5).



Graph 5. Type of scheduled surgical repair.

4.5 BIOMECHANICAL PROPERTIES AND MOTOR CONTROL OF THE PELVIC FLOOR AND ABDOMINAL MUSCLES PRE-OPERATIVELY

4.5.1 Statistical method

A similar method of statistical analysis was used as described in 4.4.1 to analyse results obtained for the PFM and the abdominal muscles pre-operatively.

4.5.2 Data analysis – Assessment of the pelvic floor muscles

The majority of participants were scheduled for pelvic floor reconstructive surgery involving a vaginal approach, or a combination of a vaginal and an abdominal approach (see 2.4 and Graph 5). Findings on pre-operative muscle testing of the PFM (and abdominal muscles) are therefore important in patients with POP, especially if scheduled for surgery which, together with other demographic variables and co-morbidities, may have an effect on the integrity and function of these muscles (see 2.5).

Hypothesis 2 (Objective 1.6.1.1)

"Decreased diameter and weakening of the PFM have again been associated with some of the above-mentioned factors, such as vaginal delivery, increased age and menopausal time. Together with the anatomical position and function of the PFM, the literature seems to indicate the importance of these muscles' function in the development of POP."

The data gathered for PFM function was mainly parametric, apart from the values obtained for the amount of repetitions (as measured with the PERFECT scale) and electromyographic values (skewness >1, Table 34).

Table 34. Results for pelvic floor muscle function.

VARIABLE	n	Skewness	Mean	SD (s)	Min	Max	Median	25th percentile	75th percentile
SONAR									
LH at rest (mm)	98	0.475	56.379	9.953	36	82.3	54.3	-	-
LH during Valsalva (mm)	96	0.269	60.709	12.455	34.7	92.7	60	-	-
LH during contraction (mm)	97	0.852	53.186	10.239	33	85.5	51.4	-	-
Thickness of perineal body (mm)	95	0.535	5.102	1.413	3	8.4	5	-	-
Thickness of left PR (mm)	97	0.669	6.773	1.876	3.2	11.9	6.4	-	-
Thickness of right PR (mm)	97	0.392	6.092	1.383	2.9	9.2	5.8	-	-
Amount of movement (mm)	97	0.195	4.281	6.844	-17.1	28	3.9	-	-
PERFECT scale									
Power	100	0.136	1.89	1.136	0	5	2	-	-
Endurance (sec)	100	0.569	4.04	3.324	0	10	3.5	-	-
Repetitions	100	1.326	2.8	2.416	0	10	3	1	4.5
Fast contractions	100	0.152	4.69	3.446	0	10	4	-	-
EMG OF PFM									
EMG at max contraction (µV)	97	1.781	22.32	17.4	2	88.8	17.9	11	25.6
Endurance with EMG (sec)	97	2.104	11.97	15.26	0	60	7	2	15

Min = minimum, Max = maximum, CI = confidence interval, SD = standard deviation

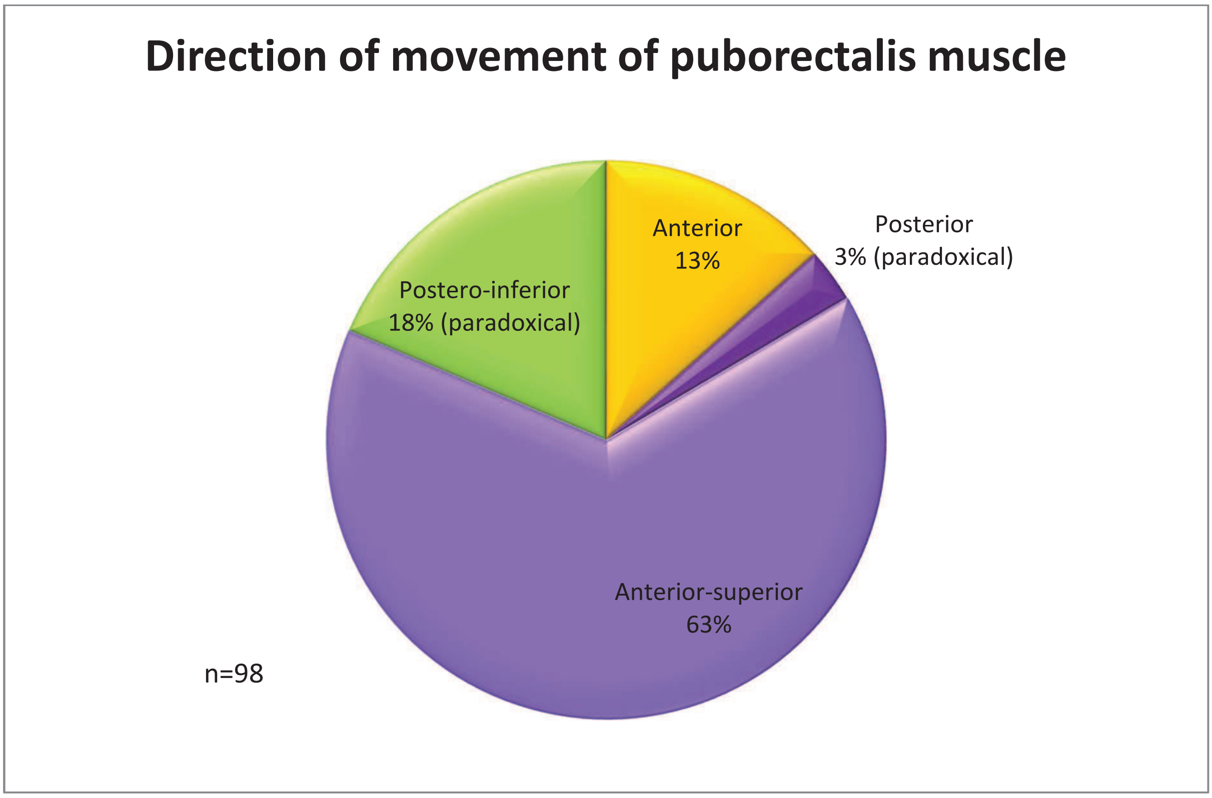
Red script indicates skewed distributions.

Highlighted results indicate important findings referred to in text.

Starting the report of the results at the top of Table 34, an increased LH has been significantly associated with POP in the literature. A mean LH of approximately 56mm (n=100) was found in this study. This value is more when compared to reported values found in women without POP (see Table 35). Many times a decreased LH is associated with an increased EMG, such as in women with increased tone of their PFM (Braekken *et al.* 2013:1520). A correlation between the LH at rest and PFM EMG however revealed no correlation in this study ($r=0.036$, $p>0.05$). It could also be postulated that increased muscle strength could lead to a decreased LH at rest, although correlation between these two (2) variables did not indicate any significant association ($r_s=0.188$, $p>0.05$) (see Table 38).

The mean length of the hiatus seemed to change less from rest to contraction (2.625mm) when compared to the length change from rest to Valsalva (4.33mm). The mean value obtained for the amount of movement was 4.28mm, which was calculated by subtracting the LH length during contraction from the LH length during rest. The value may therefore seem inaccurate if it is compared to the difference between the means of the LH length at rest and during contraction (2.62mm). It could be speculated that the paradoxical movement that took place in some participants during contraction (coded as a negative value due to the opposite direction of movement) would influence the value of the mean negatively. Paradoxical movement increased the hiatal length during contraction, but the length coded during rest and contraction remained a positive value (Table 34). The explanation is thus that the amount of movement was calculated as vectors, therefore the difference in findings.

Four different directions of movement were observed in the sample, with anterior-superior movement occurring in 63% (n=100) of the participants – similar to the reported normal movement pattern. Any movement in a posterior direction was taken as a negative value when calculating the amount of movement (Graph 6).



Graph 6. Observed directions of movement of the puborectalis muscle.

Comparing these findings with values obtained from the literature (see 2.9.2), it seems that the average movement of 4.28mm is less than half of the expected 10mm for normal PFM function.

The question as to the reason for the decreased movement was therefore raised. Decreased activation of the muscles did not seem to be a major problem. A median EMG value of 17.9μV (IQ range = 14.6) was found, which is low, but also not reflecting inactivity (Table 35).

Table 35. Normal values for pelvic floor muscle assessments.

VARIABLE	n	Mean	Median	Normal values (means)*
SONAR				
LH at rest (mm)	97	55.811	54.3	10-30 45
LH during Valsalva (mm)	96	60.709	60	-
LH during contraction (mm)	97	53.186	51.4	-
Thickness of perineal body (mm)	95	5.102	5	20-30 24.2
Thickness of left PR (mm)	97	6.773	6.4	10
Thickness of right PR (mm)	97	6.092	5.8	10
Amount of movement (mm)	97	4.281	3.9	15
PERFECT scale				
Power	100	1.89	2	3 to 4
Endurance (sec)	100	4.04	3.5	7
Repetitions	100	2.8	3	-
Fast contractions	100	4.69	4	-
EMG OF PFM				
EMG at max contraction (µV)	97	22.32	17.9	Inconsistent/not applicable Values >20µV have been reported
Endurance with EMG (sec)	97	11.97	7	>7

*See 2.9.2 for discussion on normal values and references

Poor muscle strength (mean of 1.89, SD=1.136) could also be considered as a reason why not much movement took place. Stronger muscles are usually associated with improved muscle function and hypertrophy, which indicated analysis of the strength of the PFM and thickness of the PR muscle and the perineal body respectively.

A Spearman CC of r_s=0.427 was found when PFM strength was correlated with the amount of movement. This indicated a significant association ($p<0.001$) between these two variables (see Table 38). Contrary to this association, no significant correlations were found when PFM strength was correlated with the thickness of the perineal body (r_s=0.03, $p>0.5$) or with the thickness of the left (r_s=0.0003, $p>0.5$) PR muscle. The same accounted for the correlation of the PFM strength with the right PR muscle (r_s=0.078, $p>0.2$) (see Table 38).

The values obtained for the left PR muscle (mean of 6.773mm, SD = 1.876), the right PR muscle (mean of 6.092, SD = 1.383) and the perineal body (mean of 5.102, SD = 1.413), however, were less than the expected 10-15mm found in normal subjects (see 2.9.2). Only 13% (n=100) of the participants had an EAS defect on the right side, which was observed by the sonar, which could explain decreased thickness in those instances.

The reduced strength of the muscle was also partially reflected in the amount of maximum voluntary fast contractions (mean 4.69, SD = 3.446), which were below 50% of the expected 10 MVC. Although endurance can also be closely related to the interpretation of this finding, endurance is better reflected by the time of the contraction and the amount of repetitions thereof.

The above assumption was substantiated by a correlation of PFM strength with endurance, as measured by the PERFECT scale. Analysis indicated a significant positive correlation between these two variables (r_s=0.677, p<0.001) (see Table 38).

Analysing the whole sample, endurance was found to be unsatisfactory with a mean endurance of 4.04sec (SD = 3.324), as measured by the PERFECT scale. This was also reflected by an inability to repeat this contraction more than a mean of 2.8 times (SD = 2.416). The EMG measurements however indicated a median endurance of seven seconds (IQ range = 13), which is similar to the value found in asymptomatic women (see Table 35).

It would therefore appear that all the findings were below the expected values found in asymptomatic patients without any PFM dysfunction, apart from endurance as measured by the EMG. These findings also relate back to the categorical data (see Table 26) gathered in which very few participants (15%, n=100) reported that they had ever done any PFM exercises, and where even fewer (7%, n=100) had been exposed to any type of core exercises, of which the PFM is an integral part (see 2.3.1 and 2.5).

4.5.3 Data analysis – Assessment of the abdominal muscles

The deep abdominal muscles are the other integral part of the core musculature. The hypothesis deducted from the literature (see 2.5.2.1) was that the local stabilisers, such as the TrA muscle, could lead to increased IAP if not functioning effectively. It was postulated that the global abdominal stabilisers and mobilisers would then compensate for stability, and further lead to increased IAP and pathology.

Hypothesis 3 (Objective 1.6.1.1-1.6.1.3)

"According to the above explanation, it seems that dysfunction of the TrA muscle may lead to either increased tone of the PFM, or weakness due to failure in response to sustained overload and compensation."

The data obtained for the abdominal muscles was skewed to the right for all three (3) outcome measures (Table 36).

Table 36. Results for abdominal muscle function.

VARIABLE	n	Skewness	Mean	SD (s)	Min	Max	Median	25th percentile	75th percentile
Sahrmann scale	100	1.917	0.7	1.02	0	5	0	0	1
EMG of IO/TrA	100	1.619	13.808	8.396	2.6	50.4	10.95	7.9	17.8
PBU of TrA	100	1.584	2.1	3.56	0	10	0	0	2

Min = minimum, Max = maximum, CI = confidence interval, SD = standard deviation

Red script indicates skewed distributions.

Highlighted results indicate important findings referred to in text.

The median value for the Sahrmann scale measurements were very poor, namely 0 (IQ range = 1). Similar results were indicated by the median values of the EMG and PBU, namely 10.95μV (IQ range = 9.9), and a median amount of zero repetitions (IQ range = 2) with the PBU, respectively. According to these results, it would appear that both the local and global stabilisers were functioning below the normal values attained for asymptomatic patients (see 2.9.3 and Table 37).

Table 37. Normal values compared to values obtained in the study for abdominal muscle assessment.

	Cut-off (normal) values*	Medians from current study
Sahrmann scale	Level 1	Level 0 (= no trunk stabilisation)
PBU	10 repetitions	0 repetitions (= no activation of TrA)
Electromyography	n/a *(values of 127.1 µV have been found in patients with LBP)*	10.95µV

*See 2.8.2 for discussion on normal values

Correlating local (PBU) and global abdominal muscle function (Sahrmann) yielded a significant positive correlation of r_s=0.516 ($p<0.001$). However, it must be emphasised that the median Sahrmann scale value was zero. Global muscle function is only tested effectively from a level two on this scale (see 3.6.4.3).

Further correlations between the PFM and the abdominal muscles did not indicate any significant association between the EMG of the TrA and PFM ($r=0.096$, $p>0.05$). No correlation was also found between PFM strength and values of the PBU (r_s=0.125, $p>0.5$). However, significant positive correlations were found between PFM strength and Sahrmann values (r_s=0.199, $p<0.05$), as well as between PFM endurance and the PBU values (r_s=0.280, $p<0.005$) (Table 38).

Table 38. Correlations between variables pre-operatively.

VARIABLES CORRELATED		CORRELATION COEFFICIENT (r or r_s)	Df	p (two-tailed)	EFFECT SIZE BASED ON r
PFM strength	PFM endurance	r_s=0.677	n/a	<0.001*	Large
PFM strength	PFM EMG activity	r_s =0.63	n/a	<0.001*	Medium
PFM endurance	PFM EMG activity	r_s=0.439	n/a	<0.001*	Medium
PFM strength	Perineal body	r_s=0.03	n/a	>0.5	Small
PFM strength	PR thickness left PR thickness right	r_s=0.0003 r_s=0.078	n/a	>0.5 >0.2	Small Small
Amount of movement PR	PFM strength	r_s =0.427	n/a	<0.001*	Medium
Amount of movement PR	PFM EMG activity	r=0.437	93	<0.001*	Medium
Levator hiatus	PFM strength	r_s =0.188	n/a	>0.05	Small
Levator hiatus	TrA activation with PBU	r_s=-0.02	n/a	>0.5	Small
Levator hiatus	Sahrmann level	r_s=0.079	n/a	>0.5	Small
Levator hiatus	PFM EMG activity	r=0.036	93	>0.05	Small
Levator hiatus	PR thickness left PR thickness right	r=-0.018 r=0.048	96	>0.05	Small

VARIABLES CORRELATED		CORRELATION COEFFICIENT (r or r_S)	Df	p (two-tailed)	EFFECT SIZE BASED ON r
Levator hiatus	PFM endurance with EMG	r=-0.047	93	>0.05	Small
PFM strength	Sahrmann level	r_s=0.199	n/a	<0.05*	Small
PFM strength	TrA activation with PBU	r_s=0.125	n/a	>0.5	Small
PFM strength	EMG activity of TrA/IO	r_s=0.052	n/a	>0.5	Small
PFM EMG activity	TrA/IO EMG activity	r=0.096	95	>0.05	Small
PFM EMG activity	Sahrmann level	r_s=0.198	n/a	>0.05	Small
PFM EMG activity	TrA activation with PBU	r_s=0.186	n/a	>0.05	Small
TrA activation with PBU	Sahrmann level	r_s=0.516	n/a	<0.001*	Medium
PFM endurance	TrA activation with PBU	r_s=0.280	n/a	<0.005*	Small
Perineal body thickness	PR thickness left PR thickness right	r=0.443 r=0.357	94	<0.001* <0.001*	Medium

*Statistically significant (p<0.05)

The following section continues with the data analysis on demographic variables and muscle function, as discussed in 4.3 to 4.5, but in the context of the randomised clinical trial and related to the intervention and control groups.

4.6 PELVIC FLOOR MUSCLE TRAINING – A COMPARISON OF DIFFERENT EXERCISE PROGRAMMES

4.6.1 Statistical method

Eighty one (81) of the participants analysed at baseline were willing to continue with the study. These participants were matched and randomly assigned to three different intervention groups, as described in 3.4.2. Group one, who received only PFM exercises, consisted of 24 participants. Group two, whose programme was based on the principles of motor control, consisted of 28 participants, while group three, the control group, included 29 participants. There was no statistical difference between the sizes of the groups.

The group sizes were similar to previous studies which proposed a power of 80% (namely 22 participants per group) to detect a 20% difference in symptoms, which was considered a clinically reasonable change in symptoms (Frawley *et al.* 2010:720). Jarvis *et al.* (2005:301) proposed a clinically significant difference of 30%, which would require approximately 30 participants per group.

The three different intervention groups were firstly described by a univariate analysis to determine the distribution of the baseline characteristics within each group. This analysis was done in a similar manner as described in 4.4.1 above.

As the study progressed through the different stages, patients were lost to follow-up, mostly due to a lack of transport or financial reasons. One participant in group one was lost to follow-up at six (6) months due to the diagnosis of breast cancer. Figure 32 shows the sample size at each stage of the study (see 3.5).

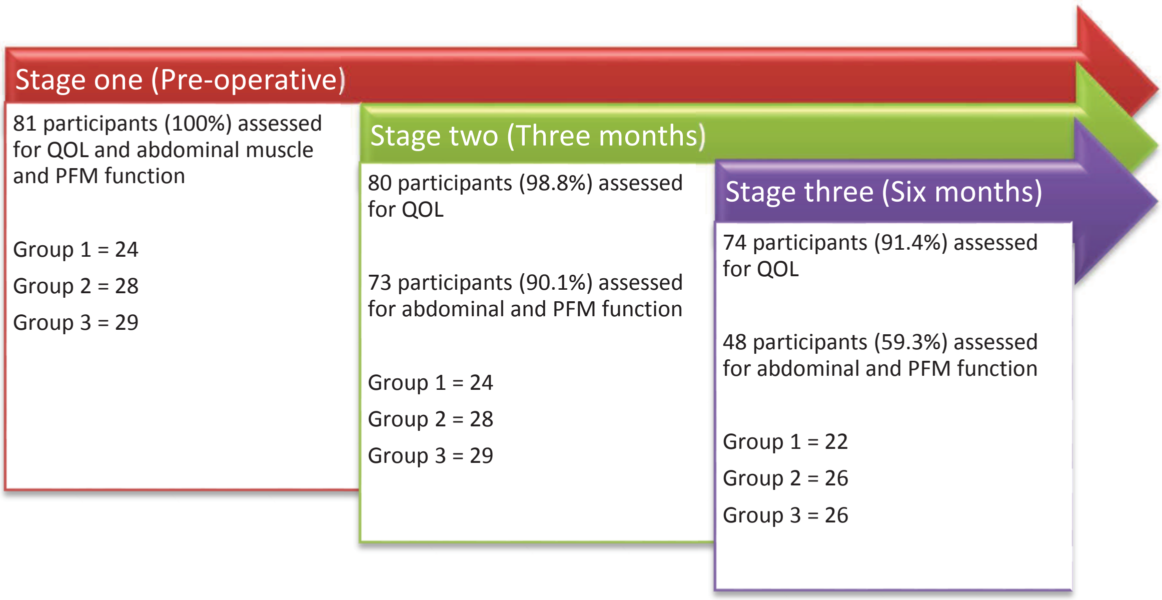


Figure 32. Number of participants during the course of the study.

The characteristics of the participants lost to follow-up were closely monitored to detect any group differences (Figure 32) during the progression of the study, which could affect the choice of statistical methods for analysis. Changes within each group (therefore dependent groups) from pre-operative assessment to three (3) and six (6) months post-operative were done by calculating the 95% CIs for the differences in the means and medians. This correlates with a p-value of less than 0.05. CIs and hypothesis tests give the same answer with respect to statistical significance. However, the advantage of (and current recommendation for) using CIs is that they can give an indication of practical significance when compared to hypothesis testing.

Due to the matching of the groups, the within-subject differences were reduced to a one sample problem for comparison of the groups (Figure 33). The 95% CI for the mean/median differences were used to calculate statistical (and therefore practical) significance. A p-value of less than 0.05 and a 95% CI excluding the value of zero were again taken as an indication of statistical significance.

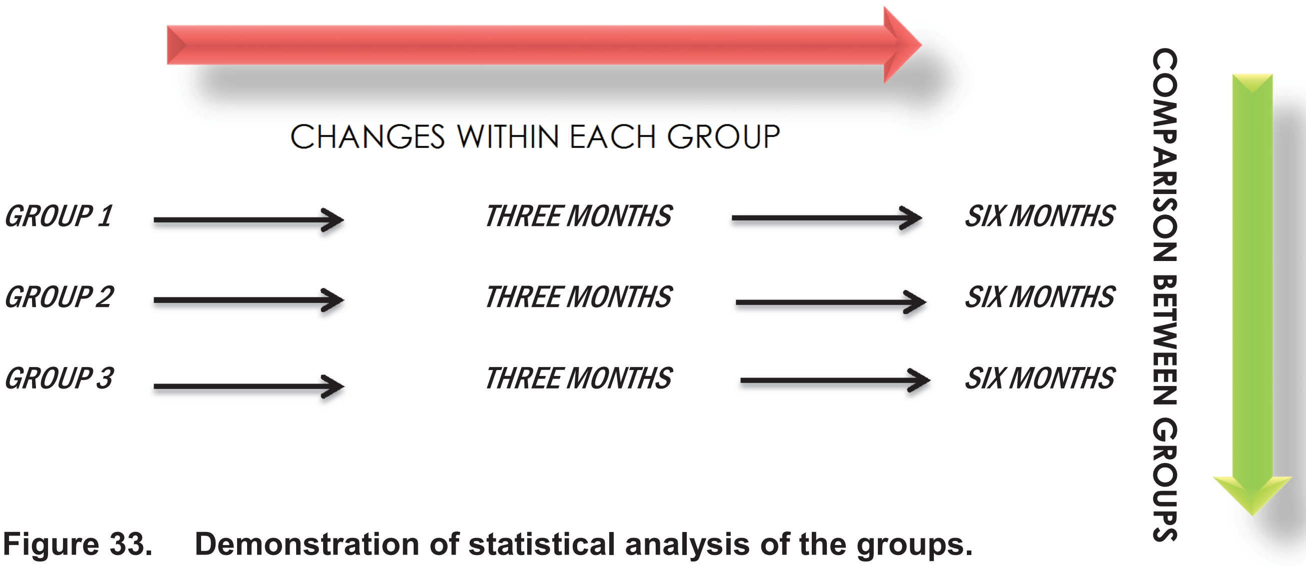


Figure 33. Demonstration of statistical analysis of the groups.

4.6.2 Data analysis – Comparison of groups at baseline

Valid interpretation and comparison of changes in outcome measures depend upon the similarity of groups at baseline. Certain variables were accounted for by matching the groups (see 3.4.2), however, all variables could not be dealt with in this manner due to the relatively small size of the groups. Groups were compared at baseline regarding all variables, dependent as well as independent, to detect any significant differences that could affect interpretation of the results.

Ninety five percent CIs did not show any significant differences between groups regarding the domains of the P-QOL at baseline, apart from the general health domain (Table 39). Analysis of specific individual questions revealed that group three had significantly more participants (24.24%, n=29) with *'very good health'* compared to group two (3.57%, n=28) (95% CI [-38.8%;-2.1%]). Due to the first domain consisting of only this one (1) question, this would have to be considered when interpreting the domain of general health. Another significant difference was regarding bowel symptoms. Significantly more participants in group two (95% CI [-35.6%;-0.8%]) complained of having to digitalise defecation '*a lot'* when compared to group one.

Table 39. Ninety five percent CIs for the median differences in P-QOL domains at baseline.

	GROUP 1 (n=24) AND 2 (n=28)	GROUP 1 (n=24) AND 3 (n=29)	GROUP 2 (n=28) AND 3 (n=29)
DOMAIN	**95% CI**	**95% CI**	**95% CI**
General health perceptions	[-4.2;32.5]	[-28.0;15.1]	[-38.8;-2.1]*
Prolapse impact	[-33.3;0]	[-33.3;0]	[0;0]
Role limitations	[-16.7;33.3]	[-16.7;33.3]	[-16.7;33.3]
Physical limitations	[-16.7;16.7]	[-16.7;16.7]	[-16.7;16.7]
Social limitations	[-33.3;0]	[-16.7;0]	[-16.7;33.3]
Personal relationships	[-33.3;0]	[0;0]	[0;33.3]
Emotions	[-33.3;11.1]	[-33.3;11.1]	[-22.2;22.2]
Sleep/energy	[-16.7;16.7]	[-16.7;16.7]	[-16.7;16.7]
Severity measures	[-8.3;16.7]	[-8.3;16.7]	[-8.3;16.7]

*Statistically significant difference

Physical examination findings did not reveal any significant differences at baseline between groups regarding urinary, bowel or sexual symptoms, or the stage of POP.

Medical history and demographic information supported the findings of the physical examination and P-QOL regarding similarity in symptoms between the groups at baseline. The only significant differences detected by these questionnaires were between group two and three regarding the use of hormone replacement therapy (95% CI [-45.9%;-7.7%]) and antidepressants (95% CI [-38.8%;-2.1%]). Due to the fact that hormone replacement therapy can also be transcribed for hypertension, an analysis was repeated with this combination of results, but it did not yield any change. Approximately 24% (n=29) of group three used both medication for hypertension and hormone replacement therapy, compared to a very limited percentage of 3% (n=24) and 6% (n=28) for group one and two respectively.

Table 40 summarises the 95% CIs for the median differences between groups for the demographic variables and medical history.

Table 40. Ninety-five percent CIs for the median differences for demographic data and medical history at baseline.

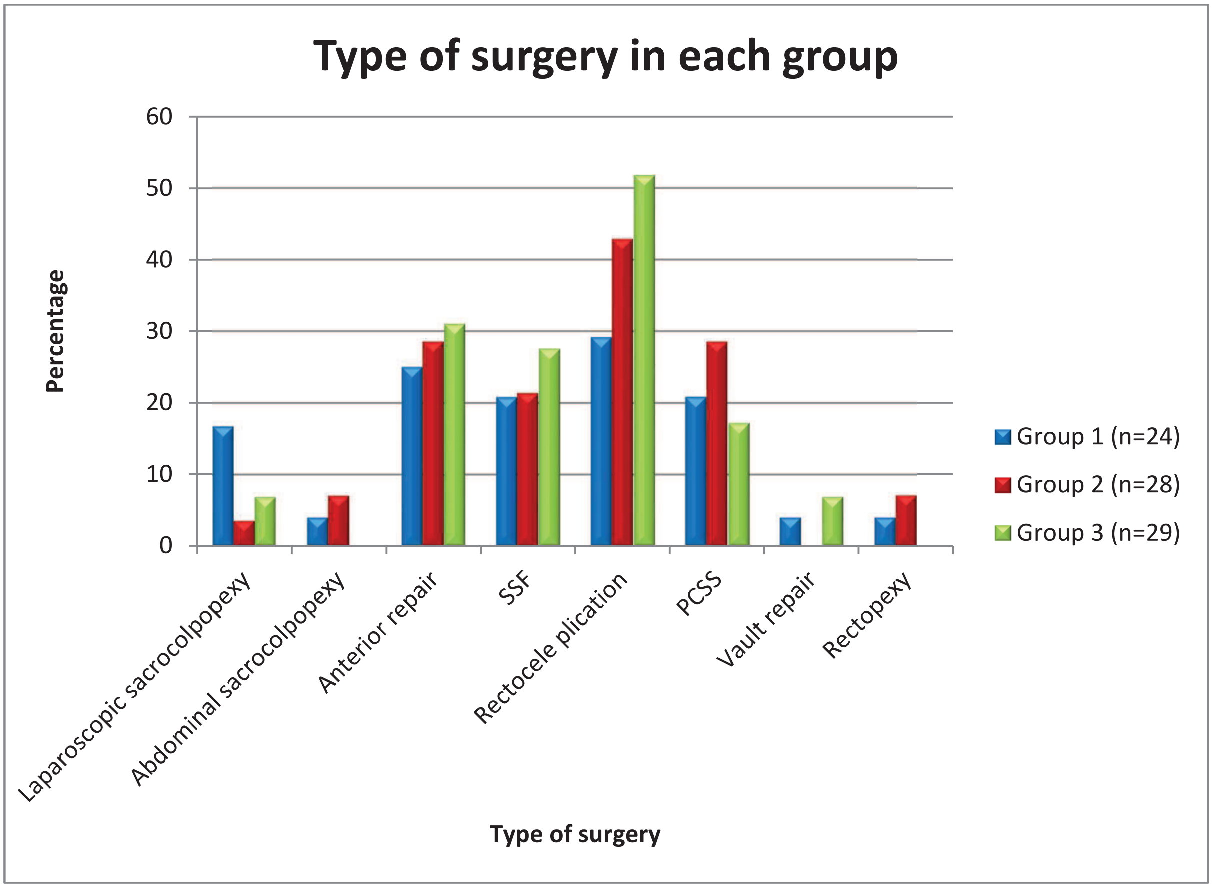
	GROUP 1 (n=24) AND 2 (n=28)	GROUP 1 (n=24) AND 3 (n=29)	GROUP 2 (n=28) AND 3 (n=29)
VARIABLE	**95% CI**	**95% CI**	**95% CI**
Age (years)	[-4;6]	[-4;5]	[-6;3]
BMI (kg/m^2)	[-1.2;4.7]	[-3.9;3.4]	[-4.8;1.2]
Language	[-16.5%;19.9%]	[-25.8%;4.8%]	[-27.2%;2.9%]
Type of work	[-29.7%;19.3%]	[-21.5%;28.1%]	[-15.1%;32.1%]
Sport participation	[-27.5%;15.5%]	[-5.1%;34.2%]	[-1.4%;37.1%]
Illness:			
Heart disease	[-28.3%;10.6%]	[-27.2%;11.1%]	[-19.4%;20.8%]
Vascular disease	[-32.2%;7.7%]	[-27.2%;11.1%]	[-16.4%;24.7%]
Pulmonary disease	[-14.0%;16.9%]	[-13.4%;17.0%]	[-13.9%;14.5%]
Cancer	[-8.4%;20.2%]	[-8.0%;20.2%]	[-11.7%;12.1%]
Allergies	[-25.4%;17.5%]	[-24.3%;18.0%]	[-20.2%;21.8%]
Previous surgery	[-28.7%;22.1%]	[-30.0%;20.4%]	[-25.8%;22.8%]
Inflammatory conditions	[-20.8%;18.6%]	[-35.0%;7.5%]	[-33.4%;8.2%]
Medication:			
Hypertension/angina	[-32.8%;17.8%]	[-34.2%;16.0%]	[-25.9%;22.8%]
Hormone replacement	[-7.4%;27.7%]	[-38.5%;4.5%]	[-45.9%;-7.7%]**
Anti-inflammatory	[-15.4%;19.5%]	[-19.1%;16.8%]	[-20.1%;13.7%]
Depression	[-10.6%;22.5%]	[-34.8%;5.4%]	[-38.8%;-2.1%]**
Hypothyroidism	[-29.6%;16.0%]	[-13.3%;28.4%]	[-6.6%;35.0%]
Vitamin and minerals	[-19.9%;16.5%]	[-19.1%;16.8%]	[-17.1%;18.2%]
Gastric ulcer	[-22.6%;7.6%]	[-17.2%;10.6%]	[-11.0%;19.5%]
OAB	[-8.4%;20.2%]	[-13.4%;17.0%]	[-17.2%;8.9%]
Cholesterol	[-32.6%;9.7%]	[-27.7%;13.3%]	[-17.3%;25.6%]
Pain	[-12.2%;24.6%]	[-11.5%;24.6%]	[-15.7%;16.5%]
DM	[-27.7%;8.1%]	[-18.2%;14.1%]	[-10.0%;25.3%]
Asthma	[-15.4%;19.5%]	[-19.1%;16.8%]	[-20.1%;13.7%]
Constipation	[-12.1%;13.8%]	[-17.2%;10.6%]	[-17.2%;8.9%]

Insomnia	[-14.0%;16.9%]	[-8.0%;20.2%]	[-8.5%;17.7%]
Anti-coagulants	[-23.4%;11.0%]	[-13.4%;17.0%]	[-8.1%;24.0%]
Antihistamine	[-12.1%;13.8%]	[-22.0%;7.8%]	[-22.0%;6.2%]
Smoking	[-11.4%;33.7%]	[-6.6%;37.0%]	[-15.4%;23.6%]
Amount of pregnancies	[-1;1]	[-1;1]	[-1;1]
Amount of deliveries	[-1;0]	[-1;0]	[-1;0]
Type of delivery:			
Normal	[-1;0]	[-1;0]	[-1;1]
Caesarean section	[0;0]	[0;0]	[0;0]
Previous PFM exercise	[-39.7%;1.8%]	[-19.1%;16.8%]	[-2.6%;37.9%]
Previous core stability exercise	[-14.0%;16.9%]	[-26.7%;8.5%]	[-27.2%;6.2%]
Menopausal state	[-17.5%;23.4%]	[-12.6%;26.7%]	[-14.3%;22.4%]
Previous abdominal/pelvic surgery:	[-42.8%;7.2%]	[-21.4%;27.6%]	[-3.0%;44.5%]
Anterior repair	[-21.5%;47.3%]	[-32.2%;42.2%]	[-42.0%;26.2%]
Posterior repair	[-26.6%;32.2%]	[-30.6%;34.5%]	[-29.2%;27.4%]
Partial colonostomy	[-19.4%;29.9%]	[-40.4%;21.0%]	[-40.4%;11.0%]
TAH*	[-19.4%;49.9%]	[-6.8%;64.9%]	[-18.9%;45.3%]
Appendectomy	[-17.7%;48.1%]	[-13.8%;55.6%]	[-24.0%;34.4%]
Laparoscopy	[-19.4%;29.9%]	[-27.8%;29.9%]	[-27.8%;19.4%]
Laparotomy	[-36.0%;18.7%]	[-27.8%;29.9%]	[-16.7%;36.0%]
Gall bladder	[-28.3%;24.1%]	[-27.8%;29.9%]	[-22.0%;28.3%]

*TAH = total abdominal hysterectomy

**Statistically significant differences

Participants were matched regarding initial muscle strength, age, previous surgery and exposure to previous motor control training in an effort to limit differences at baseline that could affect the motor control system. Other factors that could also influence muscle function such as lower back and pelvic pain, type of surgery (Graph 7), and neurological examination findings did not reveal any significant differences between the groups at baseline.



SSF = sacrospinous fixation; PCSS = perineo-colpo-sacro-suspension

Graph 7. Type of reconstructive surgery in each group.

Analysis of the variables upon which matching was based revealed that factors such as previous surgery and age could have affected baseline data, if the groups were not matched and randomised. Significant correlations were found between age and PFM strength and activity at baseline (Table 41). It was interesting to note that increased age were strongly and positively associated with an increased PFM strength (r_s=0.958, p<0.001) and thickness (r=0.157, p<0.01), while there was a significant negative association between age and EMG of the PFM (r=-0.245, p<0.02). The latter however had a small effect size.

Table 41. Correlation between age and muscle strength, endurance, and electromyography of the pelvic floor muscles at baseline.

VARIABLES CORRELATED		CORRELATION COEFFICIENT (r or r_S)	Df	p (two-tailed)	EFFECT SIZE BASED ON r
Age	**PFM endurance**	r=-0.019	96	>0.05	Small
Age	**PFM EMG activity**	r =-0.245	95	<0.02*	Small
Age	**PFM strength**	r_s=0.958	n/a	<0.001*	Large
Age	**PFM thickness**	r=0.157	94	<0.01*	Small
Age	**LH with contraction**	r=0.0654	94	>0.05	Small
Age	**LH at rest**	r=0.0016	94	>0.05	Small
Age	**LH with Valsalva**	r=-0.075	92	>0.05	Small

*Statistically significant differences

Cross tabulation and comparison between participants who had previous surgery and those who did not have previous surgery also yielded significant differences between these two groups regarding strength, endurance and EMG of the PFM, as well as of the EMG of the abdominal muscles (Table 42 and 43). Participants with a history of previous surgery had better PFM strength, endurance and activity (EMG), while the opposite was observed for abdominal muscle function.

Table 42. Cross tabulation and comparison of pelvic floor muscle function between participants with previous surgery and without previous surgery.

SURGERY	n	STRENGTH Mean (SD)	ENDURANCE (sec) Mean (SD)	EMG (μV) Mean (SD)
YES	45	1.96 (1.12)	4.11 (3.207)	22.97 (18.372)
NO	55	1.83 (1.15)	3.98 (3.445)	21.8 (16.732)
95% CI		[1.069;2.721]*	[3.22;4.87]*	[14.925;29.818]*

*Statistically significant differences

Table 43. Cross tabulation and comparison of abdominal muscle function between participants with previous surgery and without previous surgery.

SURGERY	n	SAHRMANN Mean (SD)	PBU (mmHg) Mean (SD)	EMG (μV) Mean (SD)
YES	45	0.6 (0.809)	1.57 (9.54)	13.58 (2.88)
NO	55	0.78 (1.166)	2.52 (7.38)	14.05 (4.004)
95% CI		[-0.454;1.834]	[-3.985;8.08]	[10.829;16.801]*

*Statistically significant differences

Statistics regarding possible associations between previous exposure to exercise and PFMT, with muscle strength at baseline, were not calculated due to the limited number of participants who had exposed to previous exercise (see 4.4.2).

Table 44 summarises the 95% CIs for the measurements of group one, two and three regarding muscle function at baseline. The only statistical significant differences of concern was the amount of movement of the PR muscle between group two and three (95% CI [-6.1;-0.5]) and the direction of movement. The median amount of movement for group two was 1.65mm, while it was 5.1mm for group three.

This relates closely to the findings of the direction of movement of the PR muscle. As explained in 4.5, the amount of movement is calculated as a vector. It would thus be expected that a significant difference in the direction of movement would yield a significant difference in the amount of movement. The PR muscle moved in an anterior-superior direction in 86.21% (n=29) of participants in group three, while this occurred in only 39.29% (n=28, 95% CI [-64.7%;-22.1%]) of participants in group two, and in 62.5% (n=24, 95% CI [-45.2%;-0.3%]) of participants in group one. The function of the PR muscle found in group two could also relate to the findings in the P-QOL regarding their difficulty with defecation.

Table 44. Ninety five percent CIs for the median differences in pelvic floor muscles and abdominal muscle function at baseline.

VARIABLE	GROUP 1 (n=24) AND 2 (n=28) 95% CI	GROUP 1 (n=24) AND 3 (n=29) 95% CI	GROUP 2 (n=28) AND 3 (n=29) 95% CI
SONAR			
LH at rest (mm)	[-2.1;8.2]	[-3.7;7.5]	[-6;3]
LH during Valsalva (mm)	[-4.1;9.4]	[-2.6;10.2]	[-6.4;7.5]
LH during contraction (mm)	[-3.7;6.1]	[-3.3;6.6]	[-4.3;5.0]
Thickness of perineal body (mm)	[-1.0;0.7]	[-1.1;0.6]	[-0.8;0.7]
Thickness of left PR (mm)	[-1.3;1.0]	[-1.2;0.8]	[-1.1;0.9]
Thickness of right PR (mm)	[-1.2;0.5]	[-1.4;0.2]	[-0.9;0.6]
Amount of movement (mm)	[-0.8;6.2]	[-3.6;2.9]	[-6.1;-0.5]*
PERFECT scale			
Power	[0;1]	[-1;1]	[-1;0]
Endurance (sec)	[-1;3]	[-1;2]	[-2;1]
Repetitions	[0;3]	[-1;2]	[-2;0]
Fast contractions	[-1;3]	[-2;2]	[-3;1]
EMG OF PFM			
EMG at max contraction (µV)	[-0.3;13.5]	[-2.4;9.0]	[-8.6;2.4]
Endurance with EMG (sec)	[-2;6]	[-6;3]	[-8;0]
ABDOMINAL MUSCLES			
Sahrmann scale	[0;0]	[0;0]	[0;0]
EMG of IO/TrA	[-4.3;3.2]	[-6.0;0.9]	[-5.3;1.6]
PBU of TrA	[0;1]	[-1;0]	[-1;0]

*Statistically significant difference

A cross tabulation of the direction of movement (anterior versus posterior) in the three (3) groups regarding anterior and posterior movement are depicted in Table 45.

Table 45. Cross tabulation of the direction of movement of the puborectalis muscle in the different groups at baseline.

DIRECTION OF MOVEMENT	GROUP 1 n=24	GROUP 2 n=28	GROUP 3 n=29
Anterior	75%	60.7%	93.1%
Posterior	25%	35.7%	6.9%

Table 46 and 47 summarise the median values for PFM function and abdominal muscle function respectively. The last column summarises the median values obtained from the whole group at baseline (see Tables 34 to 36) to give an indication of the deviation of the values per group when compared to similar findings in a larger sample. However, no CIs were calculated to determine significant differences of the groups when compared to the baseline values of the whole sample. It is interesting to note that it was only the amount of movement, as discussed above, which appeared to differ between the groups and the baseline value of the whole sample.

Table 46. Median values per group and of the whole sample (n=100) at baseline for pelvic floor muscle function.

	GROUP 1		GROUP 2		GROUP 3		WHOLE GROUP (n=100)
VARIABLE	**n**	**Median (IQ range)**	**n**	**Median (IQ range)**	**n**	**Median (IQ range)**	**Median**
SONAR							
LH at rest (mm)	24	54.9 (64.35-49.7)	28	52.25 (56.85-36.1)	29	54.3 (60.2-50.1)	54.3
LH during Valsalva (mm)	24	62.7 (66.75-52.8)	28	58.45 (69.0-47.5)	29	54.1 (64.6-48.6)	60
LH during contraction (mm)	24	50.1 (59.25-46.75)	28	50.65 (54.6-43.2)	29	48.6 (55.0-44.2)	51.4
Thickness of perineal body (mm)	24	4.9 (6.25-3.95)	28	5.05 (6.3-4.1)	28	5.15 (6.5-4.0)	5
Thickness of left PR (mm)	24	6.36 (7.8-5.35)	28	6.5 (8.4-5.3)	29	6.8 (8.0-5.5)	6.4
Thickness of right PR (mm)	24	5.8 (7.15-4.55)	28	6.25 (7.25-4.95)	29	6.2 (7.2-5.6)	5.8
Amount of movement (mm)	24	6.2 (8.0-0.1)	28	1.65 [6.95-(-0.97)]	29	5.1 (8.5-2.3)	3.9
PERFECT scale							
Power	24	2.0 (2.5-1.5)	28	2.0 (2.0-1.0)	29	2.0 (3.0-1.0)	2
Endurance (sec)	24	3.0 (7.0-1.5)	28	3.0 (5.5-0)	29	3.0 (5.0-2.0)	3.5
Repetitions	24	3.0 (4.0-2.0)	28	2.0 (3.0-0)	29	3.0 (3.0-2.0)	3
Fast contractions	24	5.0 (8.0-2.5)	28	4.0 (8.0-0)	29	4.0 (8.0-3.0)	4
EMG OF PFM							
EMG at max contraction (µV)	23	21.0 (37.3-14.0)	27	14.7 (22.5-8.1)	28	17.3 (25.25-12.0)	17.9
Endurance with EMG (sec)	23	7.0 (11.0-2.0)	27	3.0 (14.0-0)	28	7.0(15.0-3.5)	7

Highlighted results indicate important findings referred to in text.

Table 47. Median values per group and of the whole sample (n=100) at baseline for abdominal muscle function.

	GROUP 1		GROUP 2		GROUP 3		WHOLE GROUP (n=100)
VARIABLE	n	Median (IQ range)	n	Median (IQ range)	n	Median (IQ range)	Median
Sahrmann scale	24	0 (1.0-0)	28	0 (1.0-0)	29	0 (2.0-0)	0
EMG of IO/TrA	24	9.8 (15.95-6.55)	28	12.1 (16.9-6.7)	29	12.7 (18.2-9.3)	10.95
PBU of TrA	24	0 (6.5-0)	28	0 (1.5-0)	29	0 (3.0-0)	0

The next section describes the effect of the intervention programmes and surgery on the muscle function and whether it changed the muscle characteristics, as described above, from baseline up to six months post-operatively.

Hypothesis 12 (Objective 1.6.1.2 & 1.6.1.3)

"The question remains if the programmes for PFMT as suggested up to now in the literature are optimal for patients with POP, and if more structured programmes based on sound rehabilitation principles and assessment findings could be more effective."

4.6.3 Data analysis – Assessment of the pelvic floor muscles at three and six months post-operative

One of the main objectives of this study was to determine the changes/no changes in muscle function in response to two (2) different intervention programmes. This was done by three (3) different methods. Firstly it was done by determining the median values and IQ ranges at baseline, three (3) and six (6) months post-operative. Secondly, changes were determined by means of calculating the differences between each assessment, namely subtracting the values of assessment one from assessment three, assessment one from assessment two, and subtracting assessment two from assessment three within each group. An increased value in the follow-up assessment would therefore be indicated by a positive value. Thirdly, groups were then compared regarding the amount of change in each variable. The final observation was to determine the changes in the symptoms and signs and QOL as outlined in 4.6.6 as a response to these intervention programmes and surgery.

The median values and IQ ranges for PFM measurements, upon which analysis of these changes were based, are presented in Table 48.

Table 48. Median values and IQ ranges for pelvic floor muscle function per group at baseline, three months and six months.

VARIABLE	BASELINE n	BASELINE Median (IQ range)	THREE MONTHS n	THREE MONTHS Median (IQ range)	SIX MONTHS n	SIX MONTHS Median (IQ range)
GROUP 1						
SONAR						
LH at rest (mm)	24	54.9 (64.35-49.7)	21	55.0 (60.9-49.1)	14	55.2 (64.5-54.4)
LH during Valsalva (mm)	24	62.7 (66.75-52.8)	21	58.6 (65.0-49.2)	14	61.35 (70.1-55.0)
LH during contraction (mm)	24	50.1 (59.25-46.75)	21	47.4 (56.9-43.9)	14	46.9 (55.0-43.3)
Thickness of perineal body (mm)	24	4.9 (6.25-3.95)	21	6.4 (7.1-5.0)	14	6.1 (7.2-5.2)
Thickness of left PR (mm)	24	6.36 (7.8-5.35)	21	6.2 (7.3-5.6)	13	7.6 (8.3-6.1)
Thickness of right PR (mm)	24	5.8 (7.15-4.55)	21	6.8 (7.9-5.9)	13	6.0 (6.7-5.5)
Amount of movement (mm)	24	6.2 (8.0-0.1)	21	4.9 (6.2-1.6)	14	8.0 (11.7-4.6)
PERFECT scale						
Power	24	2.0 (2.5-1.5)	21	2.0 (3.0-2.0)	14	3.0 (3.0-2.0)
Endurance (sec)	24	3.0 (7.0-1.5)	21	7.0 (10.0-5.0)	14	6.0 (10.0-5.0)
Repetitions	24	3.0 (4.0-2.0)	21	3.0 (6.0-3.0)	14	4.5 (8.0-4.0)
Fast contractions	24	5.0 (8.0-2.5)	21	8.0 (10.0-5.0)	14	8.0 (10.0-8.0)
EMG OF PFM						
EMG at max contraction (µV)	23	21.0 (37.3-14.0)	21	18.1 (35.0-10.3)	13	21.6 (36.7-18.7)
Endurance with EMG (sec)	23	7.0 (11.0-2.0)	21	4.0 (20.0-0)	13	4.0 (12.0-4.0)

VARIABLE	BASELINE n	BASELINE Median (IQ range)	THREE MONTHS n	THREE MONTHS Median (IQ range)	SIX MONTHS n	SIX MONTHS Median (IQ range)
GROUP 2						
SONAR						
LH at rest (mm)	28	52.25 (56.85-36.1)	24	57.45 (64.4-50.7)	22	55.75 (59.0-49.5)
LH during Valsalva (mm)	28	58.45 (69.0-47.5)	23	61.0 (71.8-52.2)	22	61.0 (69.0-54.3)
LH during contraction (mm)	28	50.65 (54.6-43.2)	24	53.05 (57.95-48.55)	22	51.6 (56.0-43.3)
Thickness of perineal body (mm)	28	5.05 (6.3-4.1)	24	5.85 (7.0-4.85)	22	6.3 (6.7-5.6)
Thickness of left PR (mm)	28	6.5 (8.4-5.3)	23	7.0 (8.9-6.1)	22	6.9 (8.4-6.0)
Thickness of right PR (mm)	28	6.25 (7.25-4.95)	23	7.2 (8.22-6.0)	22	6.95 (7.5-5.7)
Amount of movement (mm)	28	1.65 [6.95-(-0.97)]	24	3.75 (10.25-0.5)	22	2.55 [6.7-(-0.3)]
PERFECT scale						
Power	28	2.0 (2.0-1.0)	25	2.0 (3.0-1.0)	22	2.0 (3.0-1.0)
Endurance (sec)	28	3.0 (5.5-0)	25	5.0 (10.0-2.0)	22	5.0 (10.0-1.0)
Repetitions	28	2.0 (3.0-0)	25	5.0 (8.0-2.0)	22	4.0 (8.0-1.0)
Fast contractions	28	4.0 (8.0-0)	25	8.0 (10.0-6.0)	22	10.0 (10.0-8.0)
EMG OF PFM						
EMG at max contraction (µV)	27	14.7 (22.5-8.1)	24	14.15 (26.05-7.1)	22	20.4 (29.5-9.9)
Endurance with EMG (sec)	27	3.0 (14.0-0)	24	9.0 (14.0-2.0)	22	5.0 (25.0-2.0)

VARIABLE	BASELINE n	BASELINE Median (IQ range)	THREE MONTHS n	THREE MONTHS Median (IQ range)	SIX MONTHS n	SIX MONTHS Median (IQ range)
GROUP 3						
SONAR						
LH at rest (mm)	29	54.3 (60.2-50.1)	24	56.25 (63.1-51.4)	12	56.75 (64.35-52.8)
LH during Valsalva (mm)	29	54.1 (64.6-48.6)	24	61.9 (65.65-56.3)	12	59.65 (71.95-57.85)
LH during contraction (mm)	29	48.6 (55.0-44.2)	24	53.5 (56.4-43.85)	12	54.8 (56.35-47.05)
Thickness of perineal body (mm)	28	5.15 (6.5-4.0)	24	5.8 (6.75-4.75)	12	6.25 (6.65-5.85)
Thickness of left PR (mm)	29	6.8 (8.0-5.5)	24	6.95 (7.85-6.2)	12	7.6 (9.35-5.35)
Thickness of right PR (mm)	29	6.2 (7.2-5.6)	24	6.9 (8.0-6.0)	12	7.7 (8.7-6.35)
Amount of movement (mm)	29	5.1 (8.5-2.3)	24	6.9 (9.25-2.55)	12	1.4 [10.5-(-1.6)]
PERFECT scale						
Power	29	2.0 (3.0-1.0)	26	2.0 (3.0-1.0)	12	2.0 (2.0-1.0)
Endurance (sec)	29	3.0 (5.0-2.0)	26	5.0 (10.0-2.0)	12	3.5 (8.0-2.5)
Repetitions	29	3.0 (3.0-2.0)	26	3.0 (4.0-2.0)	12	3.5 (4.5-2.5)
Fast contractions	29	4.0 (8.0-3.0)	26	6.0 (9.0-3.0)	12	4.5 (8.0-3.5)
EMG OF PFM						
EMG at max contraction (µV)	28	17.3 (25.25-12.0)	26	20.05 (29.6-11.3)	12	22.75 (25.75-12.7)
Endurance with EMG (sec)	28	7.0(15.0-3.5)	26	9.5 (30.0-6.0)	12	16.0 (45.0-3.5)

Statistical significant changes in the PR muscle and deeper PFM were mostly found in group one from baseline to three (3) months. This included improvement in the length of the LH during Valsalva (median change of -3.5mm, 95% CI [-10.3;-1.8]), thickness of the perineal body (median change of 1.5mm, 95% CI [0.5;4.1]), and endurance as measured with the PERFECT scale (median change of 2sec, 95% CI [1;5]). Group two also showed a significant improvement in the thickness of the perineal body from baseline to six (6) months post-operative (median change of 1.5mm, 95% CI [0.1;2.6]). Group three yielded no significant changes within the group (Table 49; see Graphs 8 to 17).

Most changes therefore seemed to have occurred within the first three (3) months post-operatively.

Table 49. Ninety five percent CIs for the changes in the pelvic floor muscle function from baseline to three months and six months within each group.

VARIABLE	CHANGES FROM BASELINE TO THREE MONTHS Median (IQ range) 95% CI	CHANGES FROM BASELINE TO SIX MONTHS Median (IQ range) 95% CI	CHANGES FROM THREE MONTHS TO SIX MONTHS Median (IQ range) 95% CI
GROUP 1			
SONAR			
LH at rest (mm)	-4.1 (-8.4 – 1.9) [-8.4 ; 1.9]	0.2 (-10.6 – 6.9) [-13.2 ; 10.3]	4.1 (-4.5 – 7.3) [-6.3 ; 8.6]
LH during Valsalva (mm)	-3.5 [-10.3 – (-1.8)] [-10.3 ; -1.8]*	-4.1 (-8.5 – 9.1) [-8.5 ; 9.7]	3.4 (-2.4 – 9.2) [-5 ; 10.9]
LH during contraction (mm)	-0.9 (-6.8 – 4.1) [-6.8 ; 4.1]	0.5 (-8.5 – 5.3) [-13.1 ; 6.7]	-2.1 (-4.0 – 5.4) [-4.4 ; 9]
Thickness of perineal body (mm)	1.5 (0.5 – 1.2) [0.5 ; 2.2]*	1.2 (0.8 – 2.5) [-0.1 ; 2.6]	0.5 (-0.5 – 1.4) [-1.8 ; 1.5]
Thickness of left PR (mm)	-1.1 (-2.02 – 0.7) [-2.0 ; 0.7]	1.3 (0.1 – 2.08) [-0.4 ; 2.3]	0.7 (-0.4 – 1.75) [-0.5 ; 1.9]
Thickness of right PR (mm)	0.5 (-0.71 – 2.8) [-0.7 ; 2.8]	0.5 (-0.3 – 1.2) [-0.4 ; 1.2]	-0.4 (-1.35 – 0.7) [-1.7 ; 1.2]
Amount of movement (mm)	-1.12 (-6.4 – 4.0) [-6.4 ; 4]	-0.8 (-4.0 – 3.7) [-5.3 ; 3.8]	-0.1 (-2.2 – 5.7) [-4.7 ; 6.4]
PERFECT scale			
Power	0 (0 – 1.0) [0 ; 1]	1.0 (0 – 1.0) [0 ; 1]	0 (0 – 1.0) [0 ; 1]

VARIABLE	CHANGES FROM BASELINE TO THREE MONTHS Median (IQ range) 95% CI	CHANGES FROM BASELINE TO SIX MONTHS Median (IQ range) 95% CI	CHANGES FROM THREE MONTHS TO SIX MONTHS Median (IQ range) 95% CI
Endurance (sec)	2.0 (1.0 – 5.0) [1 ; 5]*	3.0 (1.0 – 5.0) [0 ; 6]	0 (-1.0 – 0) [-1 ; 2]
Repetitions	1.0 (-2.0 – 2.0) [-2 ; 2]	0.5 (0 – 5.0) [-1 ; 6]	1.0 (-1.0 – 2.0) [-2 ; 4]
Fast contractions	2.0 (-1.0 – 3.0) [-1 ; 3]	2.5 (0 – 8.0) [0 ; 10]	1.0 (0 – 2.0) [-1 ; 3]
EMG OF PFM			
EMG at max contraction (µV)	-1.95 (-7.0 – 4.5) [-6.8 ; 2.8]	3.0 (-1.2 – 8.6) [-3.9 ; 14.4]	2.3 (-3.4 – 8.85) [-3.6 ; 9.4]
Endurance with EMG (sec)	-1.5 (-5.5 – 8.0) [-4 ; 7]	0 (-4.0 – 2.0) [-6 ; 2]	2.5 (0.5 – 8.5) [0 ; 9]

GROUP 2

SONAR			
LH at rest (mm)	4.4 (-2.6 – 9.9) [-1.6 ; 9.1]	2.0 (-5.0 – 9.1) [-5 ; 9.1]	-2.6 (-8.4 – 3.2) [-8.4 ; 3.2]
LH during Valsalva (mm)	4.1 (-3.0 – 8.0) [-2.8 ; 7.9]	5.6 (-4.3 – 11.6) [-4.3 ; 11.6]	-1.5 (-3.0 – 7.6) [-3 ; 7.6]
LH during contraction (mm)	1.35 (-4.65 – 7.35) [-4 ; 6.7]	0.8 (-8.5 – 10.8) [-8.5 ; 10.8]	0.35 (-6.6 – 4.8) [-6.6 ; 4.8]
Thickness of perineal body (mm)	1.25 (-0.2 – 2.15) [-0.1 ; 2.1]	1.5 (0.1 – 2.6) [0.1 ; 2.6]*	0.55 (-0.9 – 1.2) [-0.9 ; 1.2]
Thickness of left PR (mm)	0 (-1.0 – 1.66) [-0.8; 1.6]	0.35 (-1.0 – 2.1) [-1 ; 2.1]	-0.2 (-1.0 – 1.4) [-1 ; 1.4]
Thickness of right PR (mm)	0.6 (0 – 1.8) [0 ; 1.6]	0.9 (-1.1 – 2.1) [-1.1 ; 2.1]	-0.9 (-2.12 – 0.9) [-2.1 ; 0.1]

VARIABLE	CHANGES FROM BASELINE TO THREE MONTHS Median (IQ range) 95% CI	CHANGES FROM BASELINE TO SIX MONTHS Median (IQ range) 95% CI	CHANGES FROM THREE MONTHS TO SIX MONTHS Median (IQ range) 95% CI
Amount of movement (mm)	0.35 (-2.98 – 8.7) [-2.9 ; 7.5]	0.03 (-1.7 – 7.2) [-1.7 ; 7.2]	-1.7 (-5.7 – 3.5) [-5.7 ; 3.5]
PERFECT scale			
Power	0 (0 – 1.0) [0;1]	0.5 (0 – 1.0) [0;1]	0 (0 – 0) [0;0]
Endurance (sec)	2.0 (0 – 4.0) [0;3]	1.5 (0 – 5.0) [0;5]	0 (-1.0 – 1.0) [-1;1]
Repetitions	3.0 (1.0 – 5.0) [1;5]*	3.0 (0 – 5.0) [0;5]	0 (-2.0 – 1.0) [-2;1]
Fast contractions	2.0 (0 – 6.0) [0;6]	4.0 (0 – 8.0) [0;8]	0 (-1.0 – 2.0) [-1;2]
EMG OF PFM			
EMG at max contraction (μV)	1.4 (-1.9 – 6.8) [-1.8;3.6]	5.2 (1.9 – 12.4) [1.9;12.4]	3.75 (-0.6 – 14.8) [-0.6;14.8]
Endurance with EMG (sec)	2.0 (0 – 7.0) [0;7]	1.0 (0 – 5.0) [0;5]	-1.0 (-5.0 – 0) [-5;0]

GROUP 3

SONAR			
LH at rest (mm)	3.35 (-1.75 – 8.5) [-1;7.2]	-0.3 (-3.9 – 1.85) [-4.5;2.4]	-4.7 (-6.7 – 1.8) [-6.9;5.5]
LH during Valsalva (mm)	2.35 (-3.95 – 8.3) [-3.9;8.1]	-0.55 (-4.6 – 8.6) [-5;9.2]	0 (-7.8 – 6.1) [-8.1;9.6]
LH during contraction (mm)	0.3 (-3.85 – 4.65) [-3.8;4.3]	0.9 (-1.1 – 4.8) [-1.5;7]	-0.8 (-1.7 – 2.3) [-4.9;5.8]

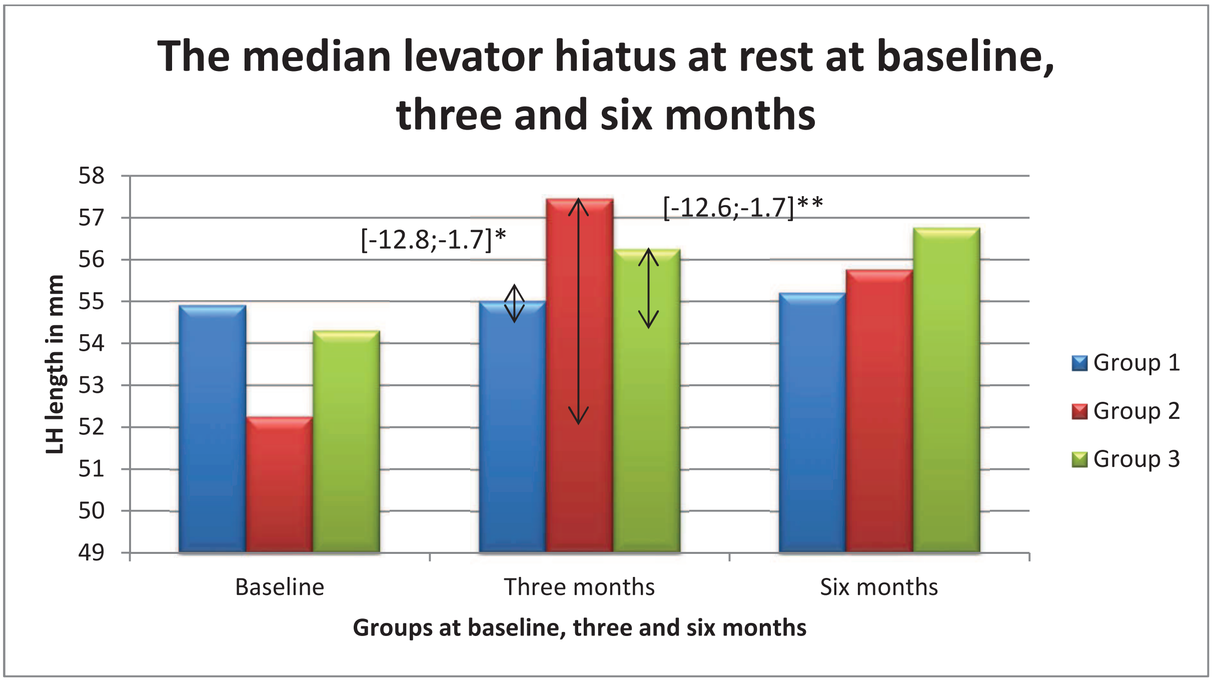
VARIABLE	CHANGES FROM BASELINE TO THREE MONTHS Median (IQ range) 95% CI	CHANGES FROM BASELINE TO SIX MONTHS Median (IQ range) 95% CI	CHANGES FROM THREE MONTHS TO SIX MONTHS Median (IQ range) 95% CI
Thickness of perineal body (mm)	0.1 (-0.5 – 1.9) [-0.5;1.5]	1.4 (0.3 – 2.6) [-0.5;2.9]	1.9 (0 – 3.1) [-0.7;3.1]
Thickness of left PR (mm)	0.35 (-1.25 – 1.25) [-1.2;1.2]	0.3 (-1.2 – 2.75) [-1.2;2.9]	0 (-0.7 – 2.4) [-1.7;3.6]
Thickness of right PR (mm)	0.6 (-0.5 – 1.65) [-0.4;1.5]	1.4 (0 – 2.9) [0;3.6]	0.3 (-0.3 – 1.0) [-0.4;1.8]
Amount of movement (mm)	1.65 (-2.55 – 3.75) [-2.4;3.3]	-1.5 (-4.6 – 1.25) [-4.8;1.7]	-4.3 (-7.7 – 0) [-9;3.5]
PERFECT scale			
Power	0 (-1.0 – 1.0) [-1;1]	0 (-0.5 – 0) [-1;0]	0 (0 – 1.0) [-1;1]
Endurance (sec)	1.0 (-1.0 – 5.0) [-1;4]	1.0 (0 – 3.5) [0;4]	0 (-2.0 – 1.0) [-4;2]
Repetitions	0.5 (-1.0 – 2.0) [-1;1]	0.5 (-0.5 – 1.5) [-1;2]	0 (0 – 2.0) [-1;2]
Fast contractions	0 (-2.0 – 3.0) [-2;2]	0.5 (-2.0 – 3.0) [-4;3]	-2.0 (-4.0 – 3.0) [-4;5]
EMG OF PFM			
EMG at max contraction (µV)	2.7 (-2.5 – 6.8) [-0.2;6]	3.7 (-2.4 – 6.8) [-5.2;12.5]	1.9 (0 – 5.7) [-1.3;9.3]
Endurance with EMG (sec)	1.0 (-4.0 – 14.0) [-4;6]	0 (-4.0 – 30.0) [-15;56]	0 (-1.0 – 16.0) [-7;60]

*Statistically significant difference

Hypothesis 8 (Objective 1.6.1.1-1.6.1.3)

"It therefore appears that, according to available studies, increased muscle thickness, strength and endurance could possibly contribute to a decreased LH which will prevent descent of the pelvic organs. EMG activity of the PFM however seems to be more complicated to interpret, due to reactions to adverse effects, such as increased IAP, as well as positive effects, such as increased activation of motor units in response to muscle training and improved neuromuscular control."

Firstly, when looking at the results for change in the LH as measured by ultrasonography, it was group two and three that demonstrated an increase in the median resting length at three months (median change of 4.4mm and 3.35mm respectively). This trend towards an increased length was again observed in group three at six (6) months, although the median change was -4.7mm from three to six months. The median for group two decreased again at six (6) months' measurement (median change of -2.6mm from three to six months). The LH at rest remained more or less constant for group one (namely 55mm) throughout the period of the study (Graph 8).

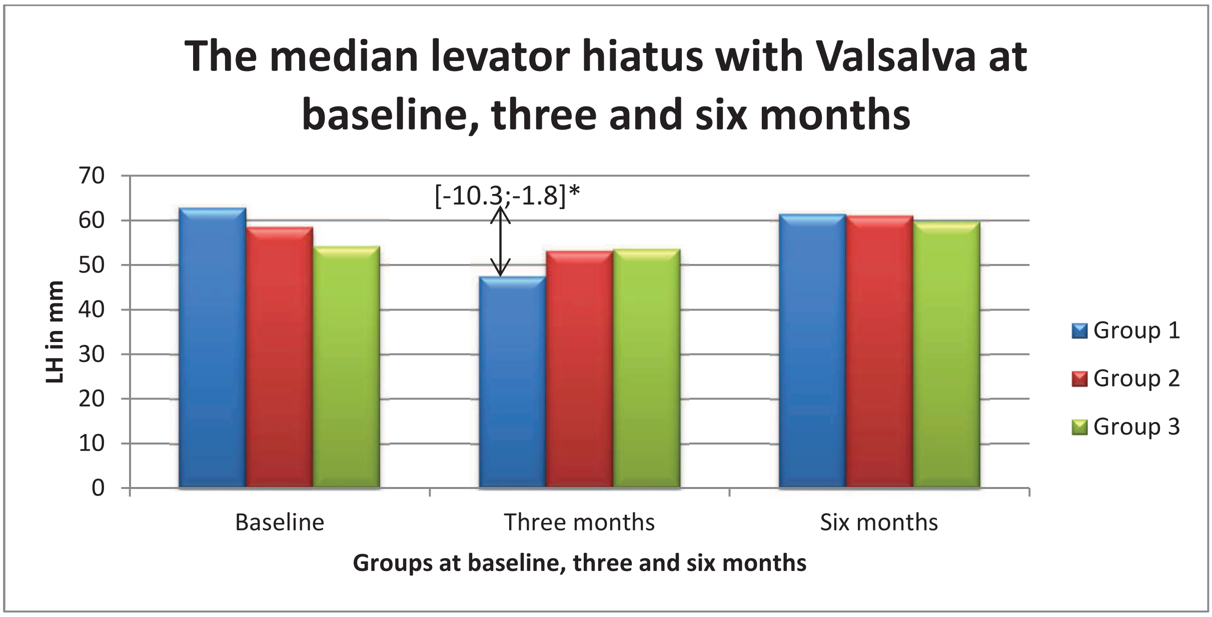


*95% CI indicating statistically significant difference between changes in group 1 and 2 from baseline to three months

**95% CI indicating statistically significant difference between changes in group 1 and 3 from baseline to three months

Graph 8. The median levator hiatus at rest at baseline, three and six months post-operative.

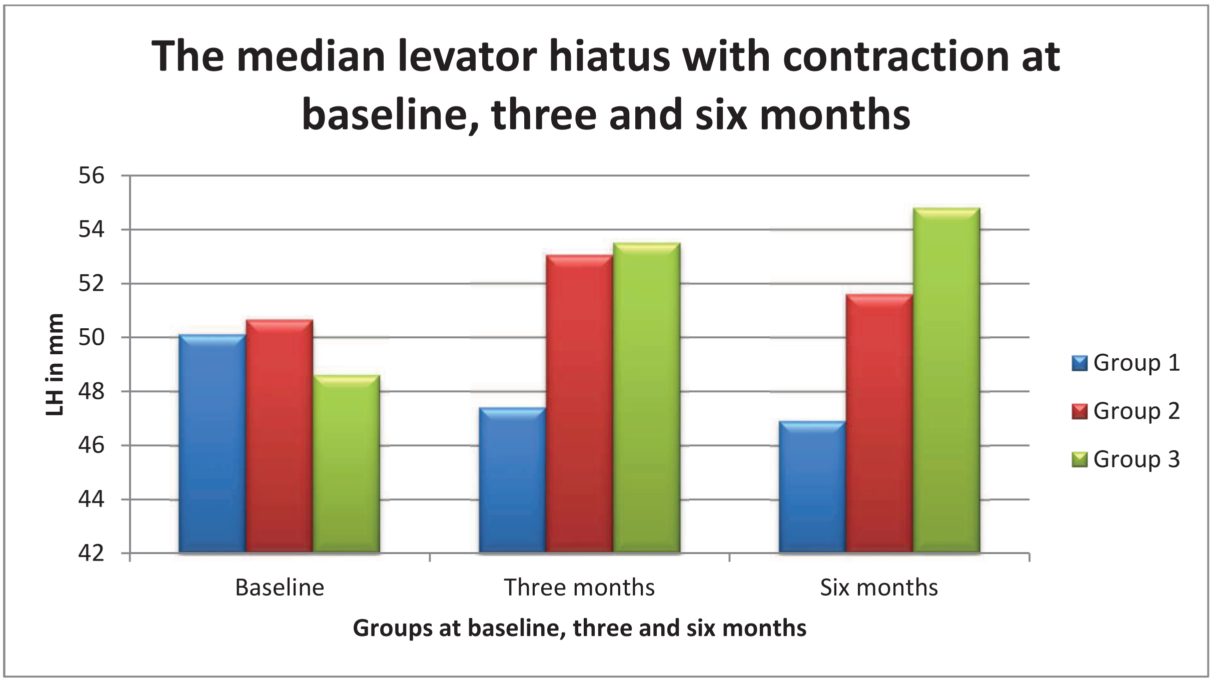
Contrary to the above findings, the median LH decreased with Valsalva in both intervention groups from baseline to three (3) months (median change of 4.1mm in group 2 and -3.5mm in group 1). However, it returned to approximately its pre-operative state, as observed with the six (6) months follow-up assessment. The control group showed an increase in its median at baseline to six (6) months follow-up (median change of -0.55mm) (Graph 9).



*95% CI indicating statistical significant difference within group 1 from baseline to three months

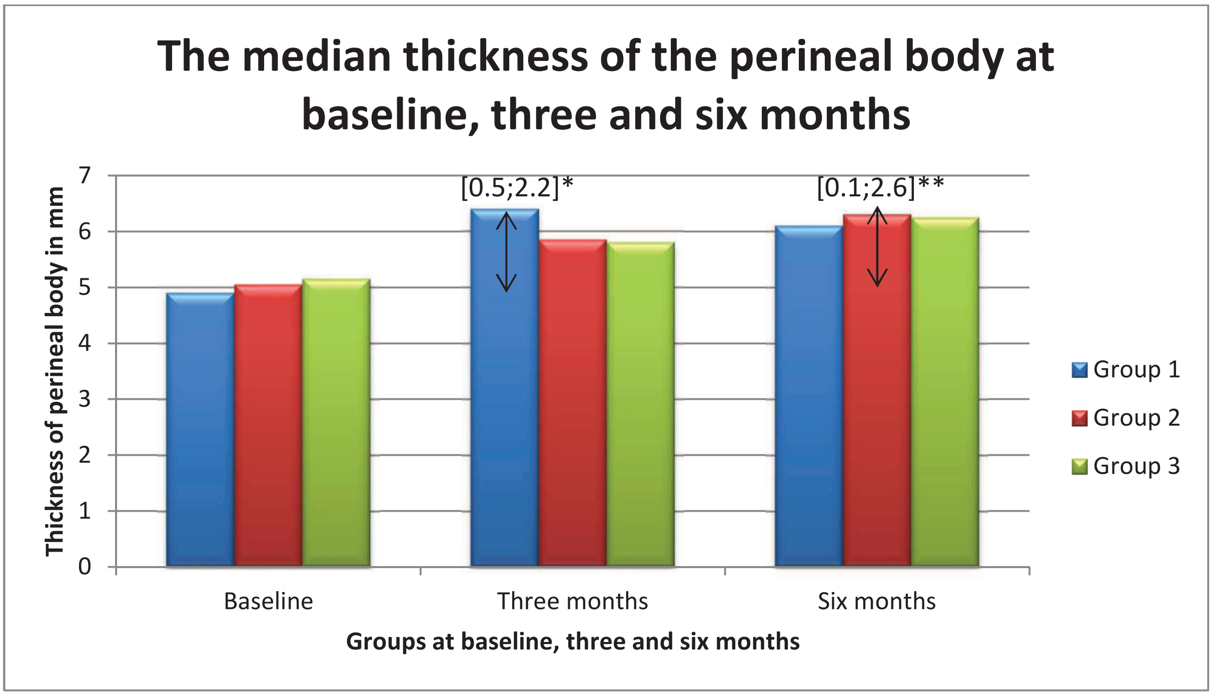
Graph 9. The median levator hiatus with Valsalva at baseline, three and six months post-operative.

If we look at the third variable measured for the LH, it was only group one who showed a continued decrease in median length with contraction at baseline, three (3) and six (6) months post-operative (median change of 0.5mm). Group two and three both increased in length at three (3) months, but it was only group three who continued this increase in length up to six (6) months (median change of 0.9mm over six months) (Graph 10).



Graph 10. The median levator hiatus with contraction at baseline, three and six months post-operative.

It was hypothesised from the literature that a decrease in LH might be associated with increased thickness of the musculature structures due to increased strength. Two variables were measured to investigate this hypothesis. Firstly, measurement of the perineal body showed an increased median in thickness in all three (3) groups at three (3) months, with group one showing the highest increase (median change of 1.5mm) (Graph 11).



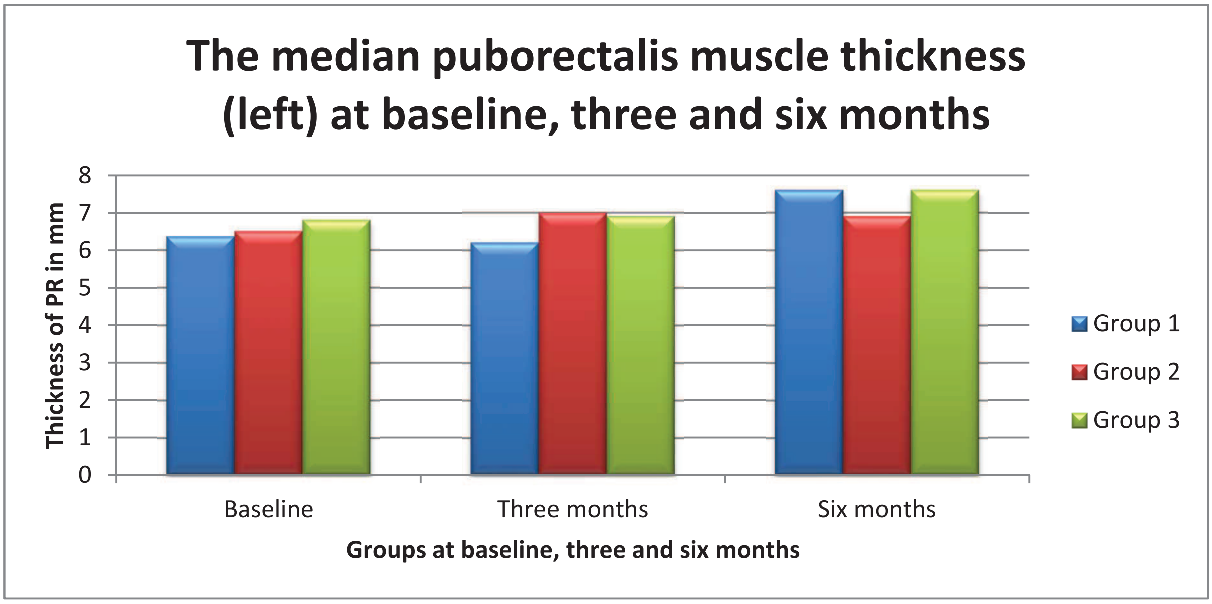
*95% CI indicating statistically significant difference for change in group 1 from baseline to three months

**95% CI indicating statistically significant difference for change in group 2 from baseline to six months

Graph 11. The median thickness of the perineal body at baseline, three and six months post-operative.

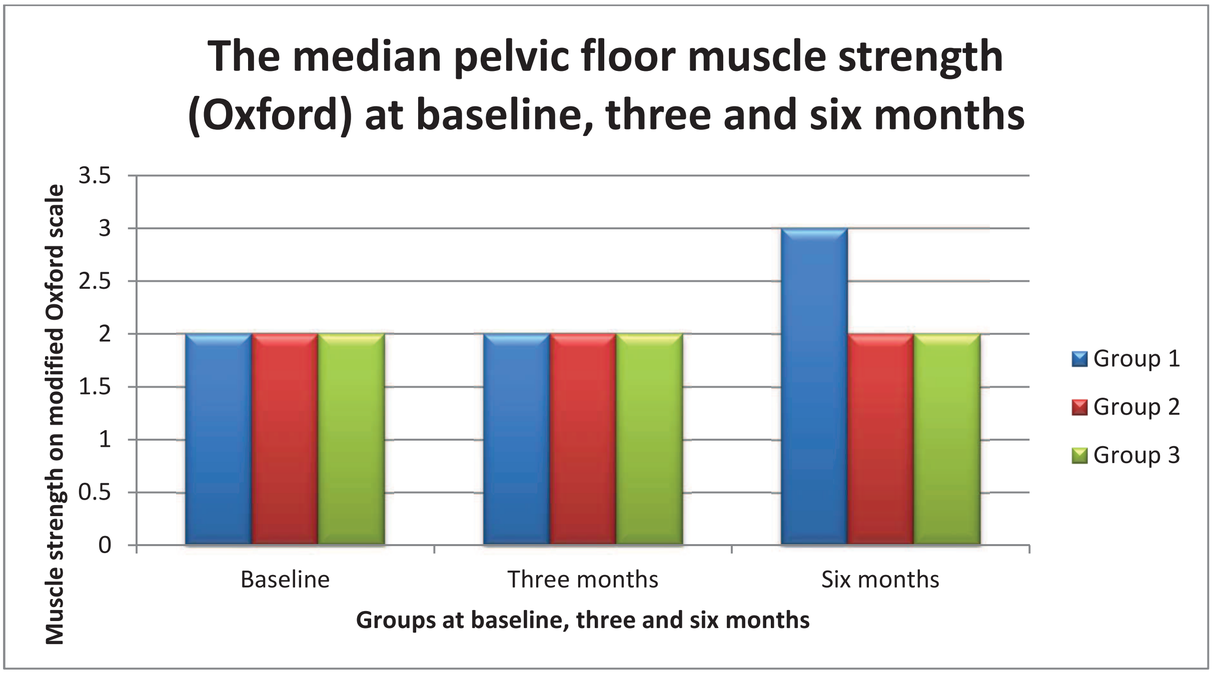
Secondly, the measurement of the PR muscle thickness first decreased in group one at three (3) months, but differed with more than a millimetre at baseline and six (6) months (median change of 1.3mm). Group two also indicated an increased median, which remained more or less constant at three (3) and six (6) months (median change of 0.35mm over six months). Group three showed only a slight increase at three (3) months, and continued this trend up to six (6) months (Graph12).

It was therefore only group one who showed a trend towards supporting the hypothesis of an increased muscle thickness to be associated with a decreased length of the LH.



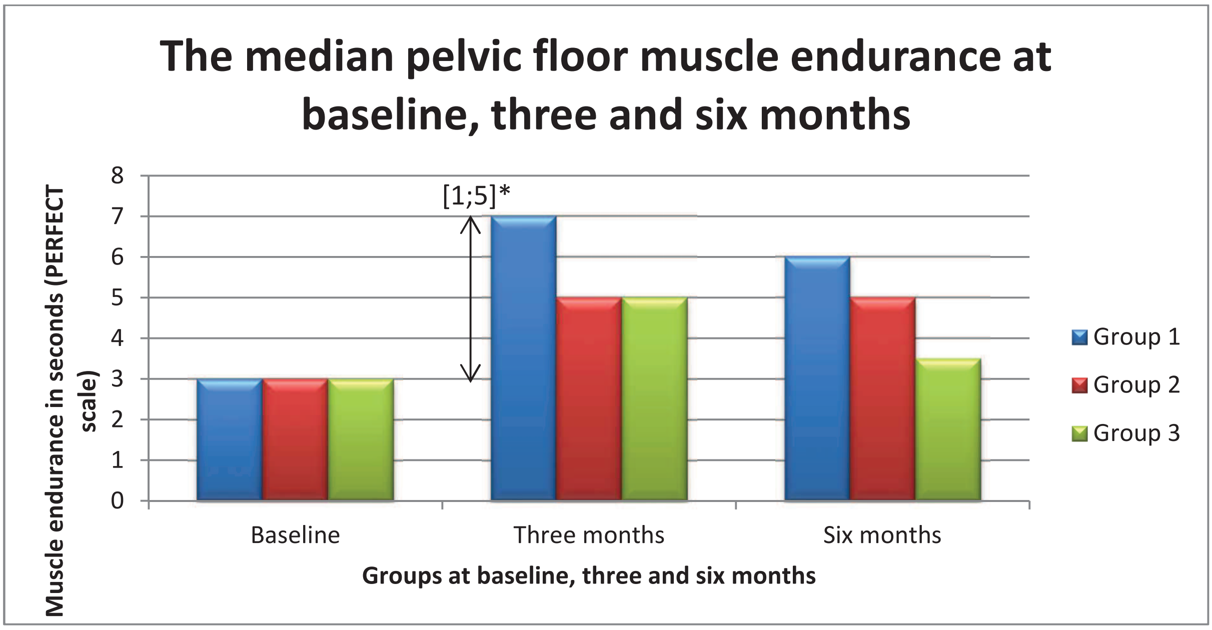
Graph 12. The median puborectalis muscle thickness (left) at baseline, three and six months post-operative.

Muscle thickness may be closely related to hypertrophy of muscles in response to strength training. The median Oxford scores however remained unchanged for the duration of the study. It was only group one who yielded an increase of one (1) level (from level 2 to 3) on the scale at six (6) months post-operatively (Graph 13).



Graph 13. The median pelvic floor muscle strength (Oxford) at baseline, three and six months post-operative.

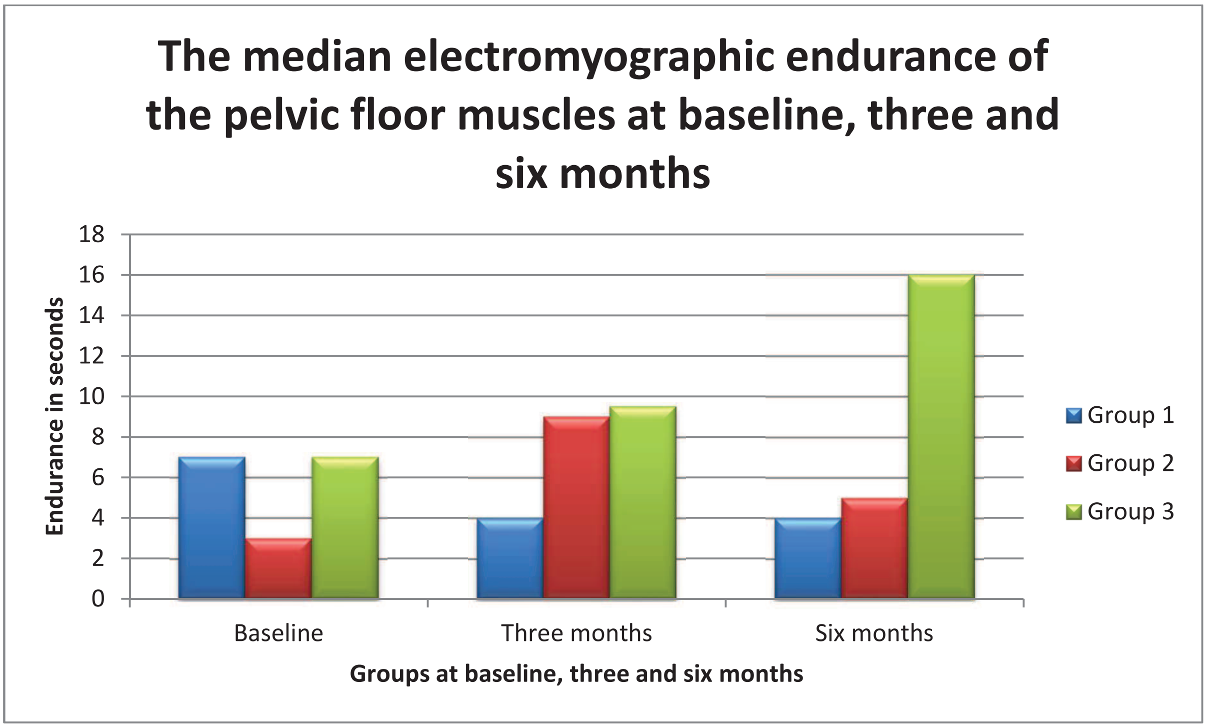
From the significant correlations found in the pre-operative data, a positive correlation could be expected between PFM strength and endurance. However, despite the median PFM strength remaining constant, the median endurance of the PFM increased in all the groups at three (3) months post-operative. This endurance again decreased in group one and three at six (6) months, while group two remained constant (see Table 38 and Graph 14).



*95% CI indicating statistically significant difference for change in group 1 from baseline to three months

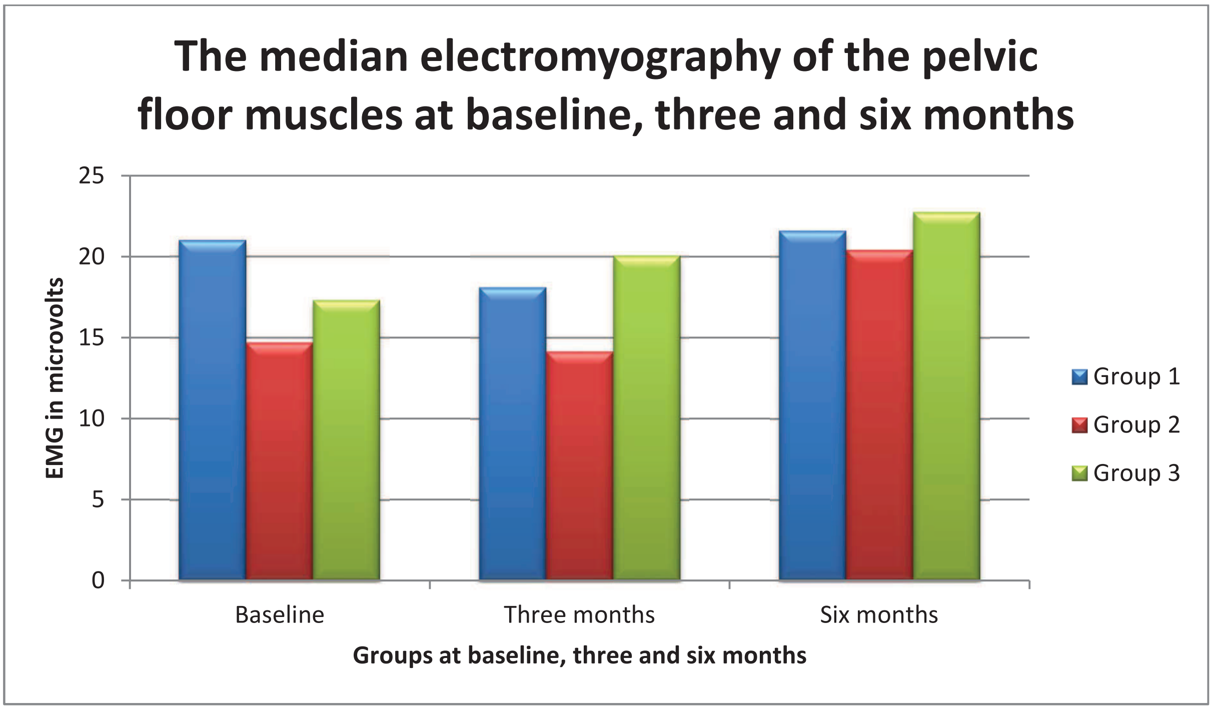
Graph 14. The median pelvic floor muscle endurance at baseline, three and six months post-operative.

Contrary to the median endurance as measured with the PERFECT scale above, endurance as measured with the EMG yielded a sustained decrease in median endurance in group one and a sustained increase in group three from baseline to six (6) months (median changes 0 sec in both groups) (Graph 15). However, interpretation of the EMG can be misleading due to the variety of factors that may cause an increase/decrease in the value.



Graph 15. Median electromyographic endurance of the pelvic floor muscles at baseline, three and six months post-operative.

The EMG measurement of the activation of the PFM must therefore also be interpreted with caution. Group three demonstrated a continued increased median EMG activity at baseline to six (6) months (median change of 3.7μV), while group one returned to its approximate pre-operative state at six (6) months (median change of 3μV from baseline to six months), and group two ended with an increased EMG activity at six (6) months when compared to the baseline measurement (median change of 5.2μV over six months) (Graph 16).



Graph 16. The median electromyography of the pelvic floor muscles at baseline, three and six months post-operative.

Table 50 presents the 95% CIs for the comparison between the groups in regards to the change in each variable from baseline to three (3) and six (6) months respectively. There was a significant difference between group one and two regarding the change in the LH at rest during the first three (3) months. Group one showed greater improvement, namely a median change of -4.1mm compared to group two with a median change of 4.4mm (95% CI [-12.8;-1.7]). A similar significant difference was found between group one (median change of -4.1mm) and three (median change of 3.35mm) regarding the same variable (95% CI [-12.6;-1.7]).

Comparing groups two and three, group two had statistically more improvement from baseline to three (3) months in regards to the number of repetitions (median changes of 3 and 0.5 respectively, 95% CI [1;4]), and more improvement in the number of fast contractions (median changes of 2 and 0 respectively, 95% CI [1;7]) from baseline to six (6) months.

Table 50. Ninety five percent CIs for the changes in the pelvic floor muscle function from baseline to three and six months – a comparison between groups.

	CHANGE FROM BASELINE TO THREE MONTHS	CHANGE FROM BASELINE TO SIX MONTHS	CHANGE FROM THREE MONTHS TO SIX MONTHS
VARIABLE	95% CI	95% CI	95% CI
COMPARISON BETWEEN GROUP 1 AND 2			
SONAR			
LH at rest (mm)	[-12.8;-1.7]*	[-10.9;5.5]	[-2;10.4]
LH during Valsalva (mm)	[-14.4;-0.7]	[-13.9;3.7]	[-3;9.8]
LH during contraction (mm)	[-8.2;3.7]	[-10;6.5]	[-5.7;7.1]
Thickness of perineal body (mm)	[-0.7;1.3]	[-1.3;1.4]	[-1.5;1.3]
Thickness of left PR (mm)	[-2.2;0.4]	[-0.9;2.3]	[-0.5;2.5]
Thickness of right PR (mm)	[-1.4;0.8]	[-1.3;1.6]	[-1.2;1.4]
Amount of movement (mm)	[-8.1;1.8]	[-5.8;2.3]	[-2.9;7.6]
PERFECT scale			
Power	[0;0]	[0;1]	[0;1]
Endurance (sec)	[-1;3]	[-1;4]	[-2;2]
Repetitions	[-5;0]	[-4;1]	[-1;4]
Fast contractions	[-4;1]	[-4;2]	[-1;2]
EMG OF PFM			
EMG at max contraction (µV)	[-8.8;1.9]	[-16.3;4.3]	[-13.1;5.3]
Endurance with EMG (sec)	[-11;3]	[-11;2]	[0;9]

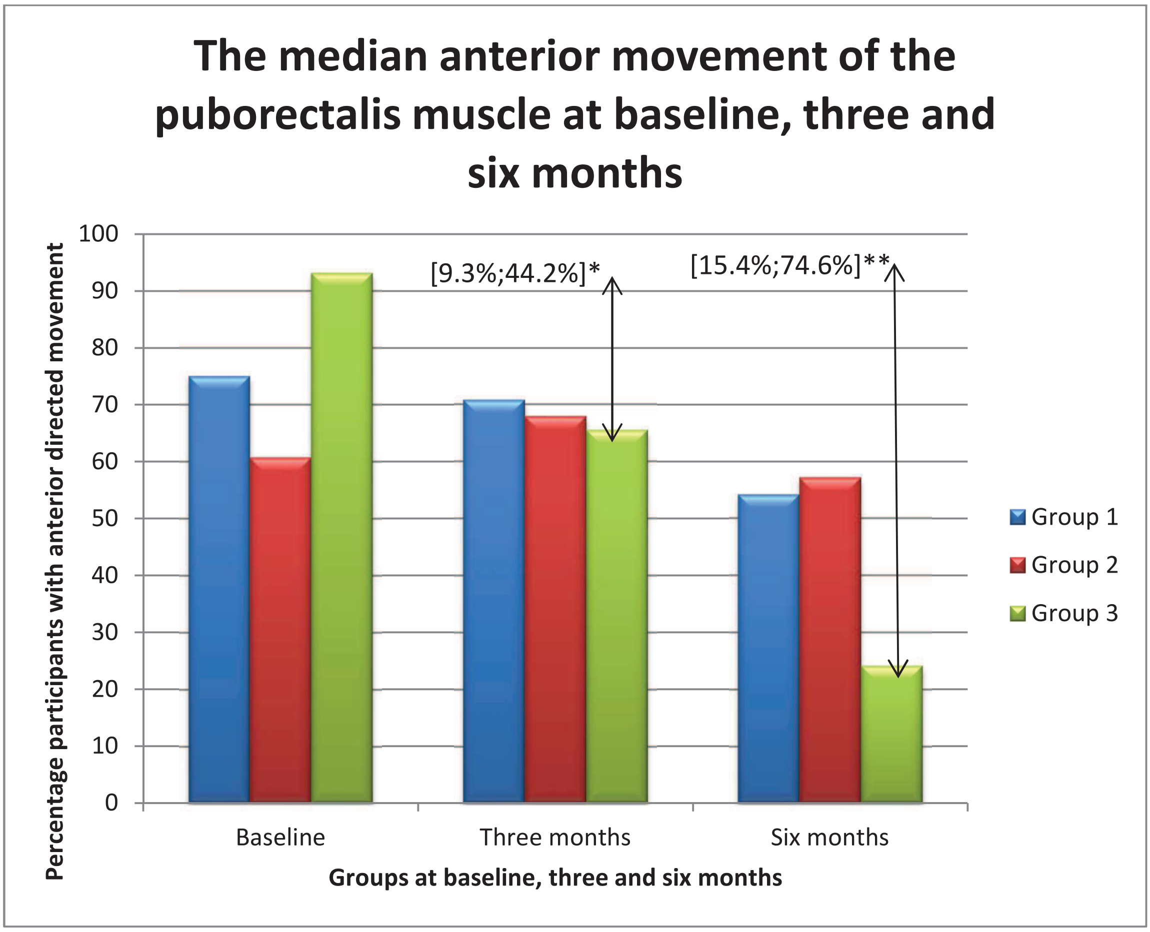
VARIABLE	CHANGE FROM BASELINE TO THREE MONTHS 95% CI	CHANGE FROM BASELINE TO SIX MONTHS 95% CI	CHANGE FROM THREE MONTHS TO SIX MONTHS 95% CI
COMPARISON BETWEEN GROUP 1 AND 3			
SONAR			
LH at rest (mm)	[-12.6;-1.7]*	[-11.1;7.6]	[-2.8;11]
LH during Valsalva (mm)	[-13.4;0.3]	[-13.5;3.6]	[-4.2;10.2]
LH during contraction (mm)	[-6.6;3.8]	[-14.2;4.5]	[-5.2;7.1]
Thickness of perineal body (mm)	[-0.2;2]	[-1.5;1.3]	[-2.6;0.4]
Thickness of left PR (mm)	[-2.1;0.4]	[-1.2;2.4]	[-1.2;1.9]
Thickness of right PR (mm)	[-1.2;1.4]	[-2.4;0.9]	[-2;0.2]
Amount of movement (mm)	[-6.4;2.5]	[-2.7;6.7]	[-1;9.8]
PERFECT scale			
Power	[0;1]	[0;2]	[0;1]
Endurance (sec)	[-1;3]	[-1;4]	[-2;4]
Repetitions	[-2;2]	[-2;4]	[-2;2]
Fast contractions	[-1;3]	[0;7]	[-1;5]
EMG OF PFM			
EMG at max contraction (µV)	[-9;1.7]	[-7.6;8.6]	[-5.5;7.6]
Endurance with EMG (sec)	[-14.4]	[-28;6]	[-26;9]
COMPARISON BETWEEN GROUP 2 AND 3			
SONAR			
LH at rest (mm)	[-4.7;5.2]	[-6.4;8.4]	[-5.2;5.7]
LH during Valsalva (mm)	[-5.7;7]	[-9.3;10.1]	[-6.9;6.9]
LH during contraction (mm)	[-3.5;6.2]	[-10.8;6.8]	[-6.7;5.2]

VARIABLE	CHANGE FROM BASELINE TO THREE MONTHS 95% CI	CHANGE FROM BASELINE TO SIX MONTHS 95% CI	CHANGE FROM THREE MONTHS TO SIX MONTHS 95% CI
Thickness of perineal body (mm)	[-0.6;1.8]	[-1.6;1.4]	[-2.5;0.4]
Thickness of left PR (mm)	[-1.1;1.4]	[-2.;1.5]	[-2.3;1]
Thickness of right PR (mm)	[-0.5;1.1]	[-2.5;0.9]	[-2.4;0.4]
Amount of movement (mm)	[-3.2;5.6]	[-0.9;8.1]	[-3.5;6.5]
PERFECT scale			
Power	[0;1]	[0;1]	[0;1]
Endurance (sec)	[-2;2]	[-2;2]	[-1;3]
Repetitions	[1;4]*	[0;5]	[-3;1]
Fast contractions	[0;5]	[1;7]*	[-1;4]
EMG OF PFM			
EMG at max contraction (µV)	[-5;4.8]	[-3.3;12.6]	[-2.7;12.3]
Endurance with EMG (sec)	[-7;7]	[-19;10]	[-15;1]

*Statistical significant difference

If we reflect back to the baseline measurements, the statistical significant differences that were observed regarding the direction and amount of movement were no longer present post-operatively. This could either be an indication of improvement in the intervention groups, or deterioration in the control group.

Graph 17 depicts the percentage change of anterior and posterior movement in each group from baseline to three (3) and six (6) months follow-up. Approximately 20% fewer participants in the control group (n=29) had anterior movement of the PR muscle at three (3) months, while the amount of participants with anterior movement in group two increased by 7.2% (n=28) from baseline. Group two was the only group who improved from baseline to three (3) months. All groups showed a tendency to have fewer participants with anterior directed movement at six (6) months, compared to three (3) months follow-up. This was however most evident in the control group. The decrease in the percentage of anterior movement was due to an increase in posterior-directed (paradoxical) movement.



*95% CI indicating statistically significant difference for change within group 3 from baseline to three months

**95% CI indicating statistically significant difference for change within group 3 from baseline to six months

Graph 17. The median percentage participants with an anterior movement direction of the puborectalis muscle at baseline, three and six months follow-up.

Lastly, the 95% CIs for the difference in continuous variables between groups on PFM function at three (3) months were rather narrow for all variables, indicating a good degree of accuracy. It was only the EMG measurements that demonstrated wider intervals (Table 51). The same pattern was observed at six (6) months, with no statistically significant differences between groups, apart from group two who showed a significantly higher number of fast contractions (median of 10) of the PFM when compared to group three (median of 4.5).

Table 51. Ninety five percent CIs for the absolute median differences in pelvic floor muscle function between groups at three and six months post-operative.

	ASSESSMENT 2 (three months)	ASSESSMENT 3 (six months)
VARIABLE	95% CI	95% CI
COMPARISON BETWEEN GROUP 1 AND 2		
SONAR		
LH at rest (mm)	[-8.4;1.1]	[-3.8 ; 7.4]
LH during Valsalva (mm)	[-10.5;3.8]	[-6.1 ; 6.8]
LH during contraction (mm)	[-7.8;2.2]	[-9.3 ; 3.3]
Thickness of perineal body (mm)	[-0.8;1.3]	[-1.0;0.8]
Thickness of left PR (mm)	[-1.7;0.3]	[-0.9 ; 1.4]
Thickness of right PR (mm)	[-1.3;0.5]	[-1.4 ; 0.5]
Amount of movement (mm)	[-4.7;3.0]	[-0.2 ; 9.1]
PERFECT scale		
Power	[0;1]	[0 ;1]
Endurance (sec)	[0;4]	[0 ; 4]
Repetitions	[-2;1]	[-2 ; 3]
Fast contractions	[-2;1]	[-2 ; 0]
EMG OF PFM		
EMG at max contraction (µV)	[-3.2;12.2]	[-5.4 ; 14.3]
Endurance with EMG (sec)	[-8;3]	[-4 ; 4]

VARIABLE	ASSESSMENT 2 (three months) 95% CI	ASSESSMENT 3 (six months) 95% CI
COMPARISON BETWEEN GROUP 1 AND 3		
SONAR		
LH at rest (mm)	[-8.2;1.1]	[-7.4 ; 5.8]
LH during Valsalva (mm)	[-11.0;3.1]	[-9.1 ; 5.2]
LH during contraction (mm)	[-7.4;3.7]	[-12.0 ; 3.2]
Thickness of perineal body (mm)	[-0.5;1.6]	[-1.0;0.9]
Thickness of left PR (mm)	[-1.4;0.4]	[-1.8 ; 1.6]
Thickness of right PR (mm)	[-1.0;0.6]	[-2.6 ; 0.1]
Amount of movement (mm)	[-5.8;0.5]	[-1.5 ; 11.1]
PERFECT scale		
Power	[0;1]	[0 ; 2]
Endurance (sec)	[0;4]	[0 ; 5]
Repetitions	[-1;2]	[0 ; 4]
Fast contractions	[0;3]	[0 ; 5]
EMG OF PFM		
EMG at max contraction (µV)	[-7.5;6.9]	[-5.3 ; 15.3]
Endurance with EMG (sec)	[-13;0]	[-26 ; 4]
COMPARISON BETWEEN GROUP 2 AND 3		
SONAR		
LH at rest (mm)	[-4.2;4.8]	[-7.9 ; 3.4]
LH during Valsalva (mm)	[-6.4;6.1]	[-7.4 ; 3.9]
LH during contraction (mm)	[-3.1;6.5]	[-10.1 ; 5.2]

	ASSESSMENT 2 (three months)	ASSESSMENT 3 (six months)
VARIABLE	95% CI	95% CI
Thickness of perineal body (mm)	[-0.7;1.1]	[-0.8;0.7]
Thickness of left PR (mm)	[-0.8;1.1]	[-1.9 ; 1.2]
Thickness of right PR (mm)	[-0.6;1.0]	[-2.2 ; 0.4]
Amount of movement (mm)	[-5.6;2.5]	[-4.7 ; 5.9]
PERFECT scale		
Power	[-1;1]	[0 ; 1]
Endurance (sec)	[-2;2]	[-2 ; 5]
Repetitions	[0;3]	[-2 ; 4]
Fast contractions	[0;3]	[1 ; 6]*
EMG OF PFM		
EMG at max contraction (µV)	[-10.6;1.3]	[-10.0 ; 10.6]
Endurance with EMG (sec)	[-9;2]	[-21 ; 2]

*Statistically significant difference

Hypothesis 6 (Objective 1.6.1.1-1.6.1.2)

"It is evident from the above descriptions that disruption of the fascia and musculature contributing to normal motor control and support of the pelvic viscera may lead to decreased function and coordination of the neuro-musculoskeletal system immediately post-surgery. Due to insufficient evidence, it is not clearly understood whether normal healing would be sufficient to return the tissue to its pre-operative state and motor control function. However, pre-operatively it is assumed that the patient has already decreased PFM function and motor control in most cases of POP. Should the tissue not return to its pre-operative state, the motor control and PFM function could be speculated to be worse

post-operatively due to suboptimal healing, therefore contributing to a poor surgical outcome."

4.6.4 Data analysis – Assessment of the abdominal muscles at three and six months post-operative

Investigation of the abdominal muscle function included comparisons of the groups at each assessment, as well as analysis of the change in the variables from baseline to three (3) and six (6) months. The median values and IQ ranges upon which calculations between and within group differences were based at three (3) and six (6) months are presented in Table 52.

Table 52. Median values and IQ ranges for abdominal muscle function per group at baseline, three months, and six months.

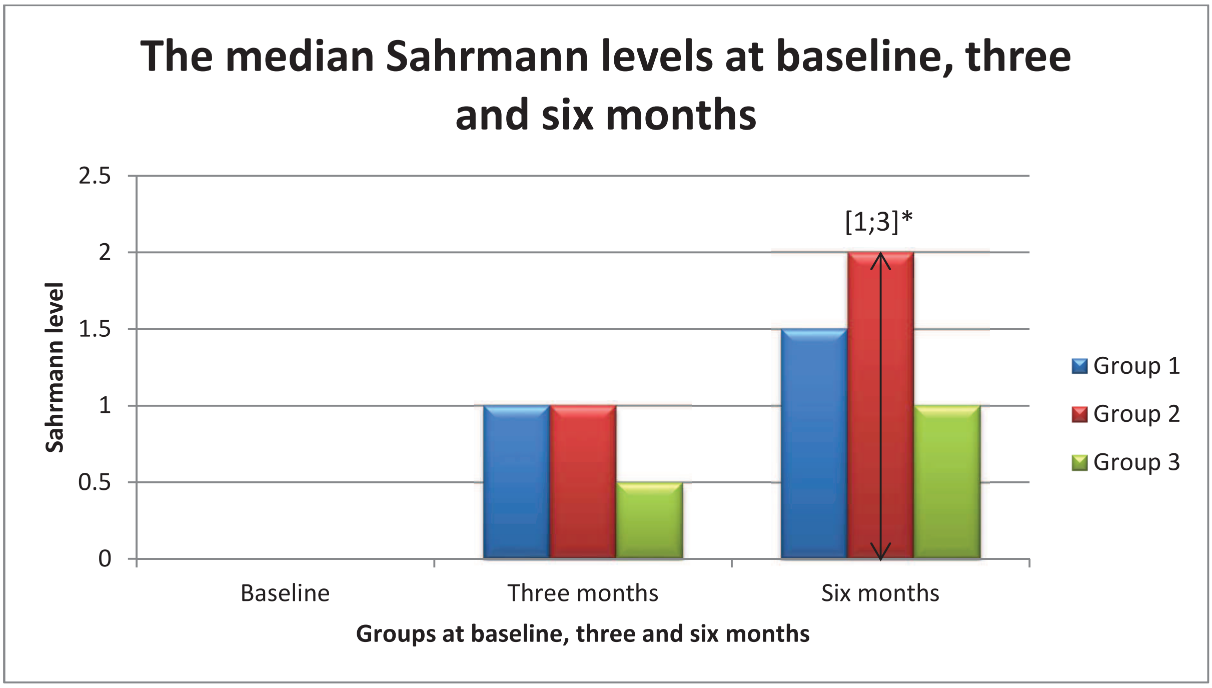
VARIABLE	BASELINE		THREE MONTHS		SIX MONTHS	
	n	Median (IQ range)	n	Median (IQ range)	n	Median (IQ range)
GROUP 1						
Sahrmann scale	24	0 (1.0-0)	21	1.0 (2.0-0)	14	1.5 (2.0-0)
EMG of IO/TrA	24	9.8 (15.95-6.55)	21	9.8 (14.7-6.1)	14	7.95 (13.1-7.2)
PBU of TrA	24	0 (6.5-0)	21	0 (8.0-0)	14	5.0 (10.0-0)
GROUP 2						
Sahrmann scale	28	0 (1.0-0)	24	1.0 (2.0-0)	22	2.0 (4.0-1.0)
EMG of IO/TrA	28	12.1 (16.9-6.7)	25	15.3 (18.6-10.6)	22	16.3 (23.0-10.4)
PBU of TrA	28	0 (1.5-0)	24	3.0 (10.0-0)	22	6.5 (10.0-0)
GROUP 3						
Sahrmann scale	29	0 (2.0-0)	26	0.5 (2.0-0)	12	1.0 (2.0-0)
EMG of IO/TrA	29	12.7 (18.2-9.3)	26	16.3 (23.7-10.0)	12	18.3 (20.55-14.85)
PBU of TrA	29	0 (3.0-0)	26	0.5 (4.0-0)	12	0 (1.5-0)

Dysfunction of the abdominal muscles was measured with the Sahrmann scale, the PBU and EMG to detect different aspects of muscle dysfunction. The Sahrmann scale was used to include observation of changes in the global stabilisers and strength of the abdominal muscles. All three (3) groups demonstrated a continuous increase in their median level on the Sahrmann scale up to six (6) months. This observation was mostly detected in group two, who increased by a statistically significant 40% (two levels) (95% CI [1;3]) from the baseline to six (6) months measurement (Table 53 and Graph 18).

Table 53. Ninety five percent CIs for the median changes in the abdominal muscles from baseline to three and six months within each group (paired data).

VARIABLE	CHANGE FROM BASELINE TO THREE MONTHS Median (IQ range) 95% CI	CHANGE FROM BASELINE TO SIX MONTHS Median (IQ range) 95% CI	CHANGE FROM THREE MONTHS TO SIX MONTHS Median (IQ range) 95% CI
GROUP 1			
Sahrmann scale	0 (0 – 1.0) [0;1]	0.5 (0 – 2.0) [-1;2]	0 (0 – 1.0) [-1;1]
EMG of IO/TrA	-0.1 (-2.2 – 3.2) [-2.2;3.2]	1.1 (0.3 – 2.8) [-0.3;4.1]	-0.2 (-3.7 – 2.1) [-5.2;2.5]
PBU of TrA	0 (0 – 0) [0;0]	0 (0 – 9.0) [0;0]	0 (0 – 10.0) [0;10]
GROUP 2			
Sahrmann scale	0.5 (0 – 2.0) [0;2]	2.0 (1.0 – 3.0) [1;3]*	1.0 (-1.0 -2.0) [-1;2]
EMG of IO/TrA	2.6 (-0.2 – 4.7) [-0.1;4.6]	2.15 (0 – 5.8) [0;5.8]	1.0 (-2.8 – 2.1) [-2.8;2.1]
PBU of TrA	3.0 (0 – 8.5) [0;8]	5.5 (0 – 8.0) [0;8]	0 (0 – 0) [0;0]
GROUP 3			
Sahrmann scale	0 (0 – 2.0) [0;1]	0 (0 – 2.0) [0;2]	0 (0 – 2.0) [-1;2]
EMG of IO/TrA	0.55 (-2.9 – 8.7) [-2.4;7.8]	4.1 (-1.5 – 6.1) [-1.6;6.2]	-2.3 (-8.0 – 6.8) [-16;7.2]
PBU of TrA	0 (-1.0 – 1.0) [0;1]	0 (-2.0 – 0.5) [-2;1]	0 (0 – 1.0) [-1;1]

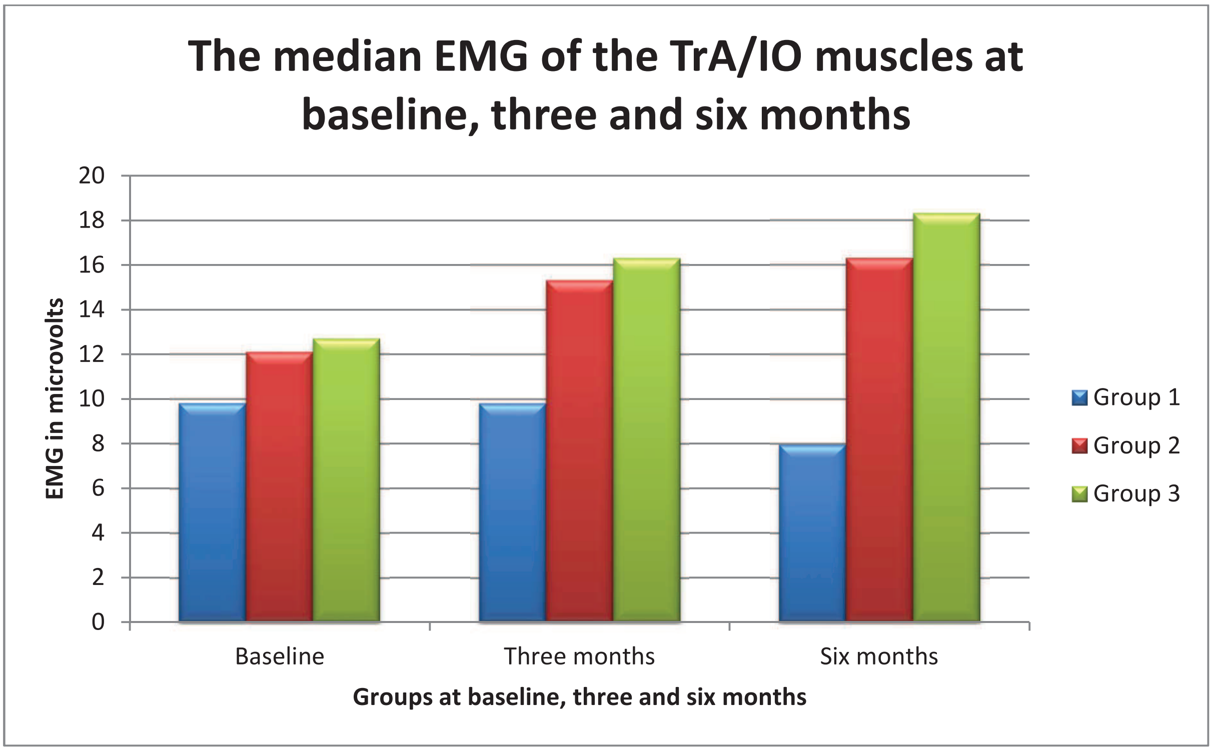
*Statistically significant difference



*95% CI indicating statistically significant difference for the change within group 2 from baseline to six months

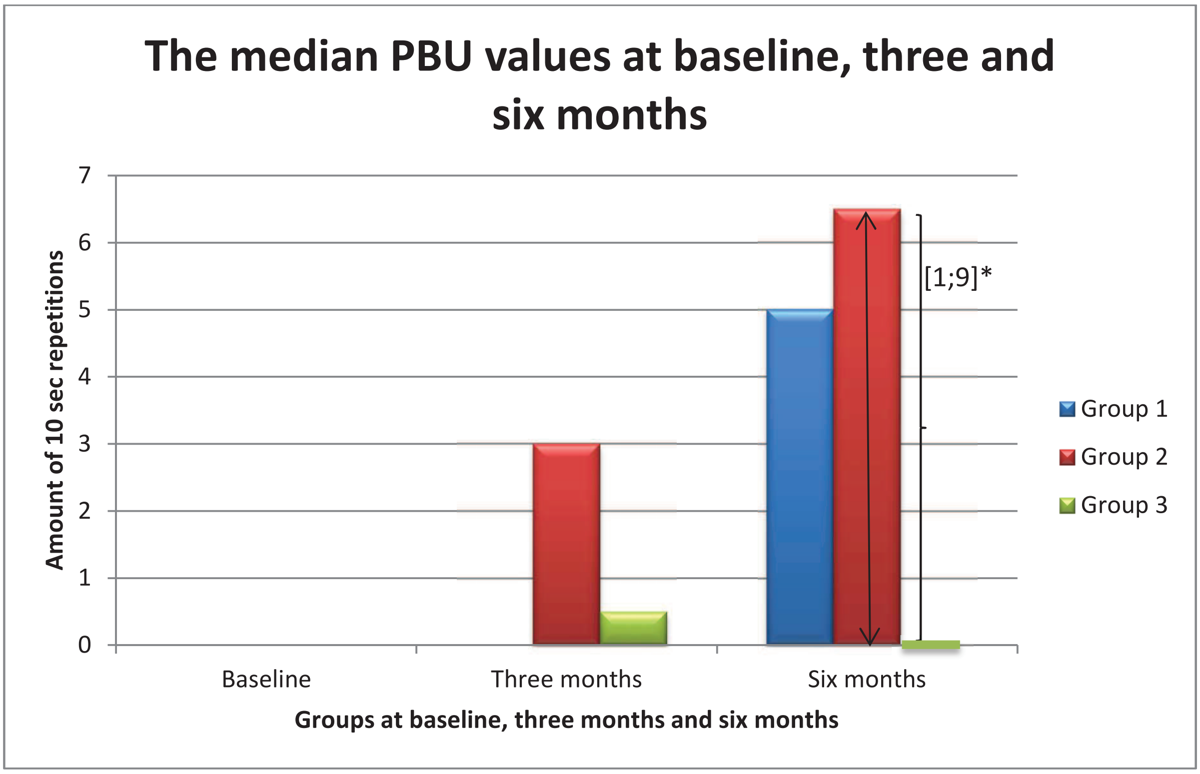
Graph 18. The median Sahrmann levels at baseline, three and six months post-operative.

When closely observing the local stabilisers, it is the EMG and PBU measurements which are important. The median EMG measurements in group two and three showed a continuous increased median over the six (6) month period, while group one showed a decrease (median changes of 2.15 and 0.5 in group two and three, and 1.1 in group one) (Graph19).



Graph 19. Median EMG of the TrA/IO muscles at baseline, three and six months post-operative.

However, the results from the PBU measurements only showed group two to increase drastically over the six month period (median change of 5.5), while group one had a sudden increased median at six (6) months, compared to no median activation at three (3) months (median change of 0 over six months). Group three still had no median activation, as measured with the PBU at six (6) months (Graph 20).



*95% CI indicating statistically significant difference for the difference in changes between group 2 and 3 from baseline to six months

Graph 20. The median Pressure Biofeedback Unit values at baseline, three and six months post-operative.

Comparing the changes between the groups (Table 54), it was only group two and three who differed significantly regarding the change in PBU measurements over a six (6) month period (Graph 20). Group two showed a median increase of 5.5 repetitions, while group three showed a median change of 0 (95% CI [1;9]).

Table 54. Ninety five percent CIs for the median changes in the abdominal muscles from baseline to three and six months – a comparison between groups.

	CHANGE FROM BASELINE TO THREE MONTHS	CHANGE FROM BASELINE TO SIX MONTHS	CHANGE FROM THREE MONTHS TO SIX MONTHS
VARIABLE	95% CI	95% CI	95% CI
COMPARISON BETWEEN GROUP 1 AND 2			
Sahrmann scale	[-1;1]	[-2;0]	[-2;1]
EMG of IO/TrA	[-5.6;0.6]	[-4.7;1.4]	[-4.9;2.4]
PBU of TrA	[-7;0]	[-6;1]	[0;9]
COMPARISON BETWEEN GROUP 1 AND 3			
Sahrmann scale	[-1;1]	[-1;1]	[-1;1]
EMG of IO/TrA	[-8;2.3]	[-5.4;1.9]	[-5.1;9.2]
PBU of TrA	[-1;1]	[0;9]	[-1;9]
COMPARISON BETWEEN GROUP 2 AND 3			
Sahrmann scale	[-1;1]	[0;2]	[-1;2]
EMG of IO/TrA	[-3.8;4.5]	[-4.7;3.1]	[-2.6;9.2]
PBU of TrA	[0;7]	[1;9]*	[-1;1]

*Statistically significant difference

Despite the difference in changes observed in the groups, a similar pattern to the values of the PFM among the three (3) groups was observed in the abdominal muscles at three (3) months. No statistical significant differences were observed between the groups at three (3) months. The 95% CIs were again rather narrow, indicating good accuracy, apart from the EMG measurements which had a wider interval (Table 55). However, it is the EMG measurement which yielded some statistically significant higher values at six months in group two (95% CI [-10.4;-0.4)] and group three (95% CI [-12.4;-3.0]), when compared to group one.

Table 55. Ninety five percent CIs for the median difference in abdominal muscle function between the groups at three and six months post-operatively.

VARIABLE	ASSESSMENT 2 (three months) 95% CI	ASSESSMENT 3 (six months) 95% CI
COMPARISON BETWEEN GROUP 1 AND 2		
Sahrmann scale	[-1;0]	[-2 ; 0]
EMG of IO/TrA	[-7.7;0.4]	[-10.4 ; -0.4]*
PBU of TrA	[-3;0]	[-4 ; 3]
COMPARISON BETWEEN GROUP 1 AND 3		
Sahrmann scale	[-1;1]	[-1 ; 1]
EMG of IO/TrA	[-9.5;0]	[-12.4 ; -3.0]*
PBU of TrA	[-1;1]	[0 ; 8]
COMPARISON BETWEEN GROUP 2 AND 3		
Sahrmann scale	[0;1]	[0 ; 2]
EMG of IO/TrA	[-6.1;3.7]	[-7.3 ; 3.3]
PBU of TrA	[0;5]	[0 ; 9]

*Statistically significant difference

In summary, it would appear that group two demonstrated clinically better and more consistent results with variables that included endurance and local stabiliser muscle function. Group one, however, tended to yield better outcomes, especially with localised PFM function such as control of the LH. Group three tended to show the most undesirable results regarding most muscle functions, although they did show improvement on some aspects. These findings and controversial aspects will be discussed further in Chapter 5.

Hypothesis 3 (Objective 1.6.1.1-1.6.1.3)

"According to the above explanation, it seems that dysfunction of the TrA muscle may lead to either increased tone of the PFM, or weakness, due to failure in response to sustained overload and compensation."

4.6.5 Data analysis – Exercise adherence at three and six months post-operative

A crucial factor to assist in interpreting the muscle response is exercise adherence and the number of contact sessions. The intervention programmes consisted of a median of four (4) contact sessions over a period of six months for both intervention groups, supplemented by a home-based exercise programme, while the control group attended no contact sessions.

Although there was no statistical difference between the number of contact sessions between group one and two, exercise adherence could affect the results in a similar manner as the amount of sessions could affect the results. Statistical analysis indicated no significant differences between the groups for exercise adherence at three (3) and six (6) months post-operatively. There was however a small tendency in the control group to be more compliant than the intervention groups at three (3) months (Table 56).

Table 56. Exercise adherence at three months post-operative.

	Group 1 (n=24)	Group 2 (n=28)	Group 3 (n=29)
Compliant	62.5%	60.7%	72.4%
Non-compliant	33.3%	39.3%	27.6%

However, this tendency was not evident at the six (6) months follow-up due to an almost 20% decrease in compliance rate in the control group (Table 57).

Table 57. Exercise adherence at six months post-operative.

	Group 1 (n=24)	Group 2 (n=28)	Group 3 (n=29)
Compliant	75%	57.14%	55%
Non-compliant	16.7%	35.7%	34.5%

Compliance rated as 3 or 4 was interpreted as '*compliant'*. If the score was 2 or less, it was interpreted as '*non-compliant'*. Even though a score of 2 meant that the participant exercised '*a little bit',* it could not be rated as compliant due to the fact that the exercises were not done as prescribed. The intensity/volume of the exercises was not applied correctly and would therefore influence the outcome. An argument should also be made for the interpretation of a score of 3, which meant that the participant exercised '*rather regularly'*. A participant was scored a 3 if she missed a session occasionally. A score of 4 was given if the participant indicated that the exercises were done every day, as indicated.

Removing the scores of the non-compliant participants from the data analysis would therefore yield a more accurate result as to the effect of the prescribed exercises.

However, external validity requires taking into account factors such as adherence and motivation during analysis, which is a more accurate perception of the real life situation of the population.

4.6.6 Data analysis – Assessment of quality of life at three and six months post-operative

Assessment of QOL reveals how the real life situation of the participant is affected by her health on a day-to-day basis. In the end, the effects of treatment should be to improve this main outcome of the treatment of POP.

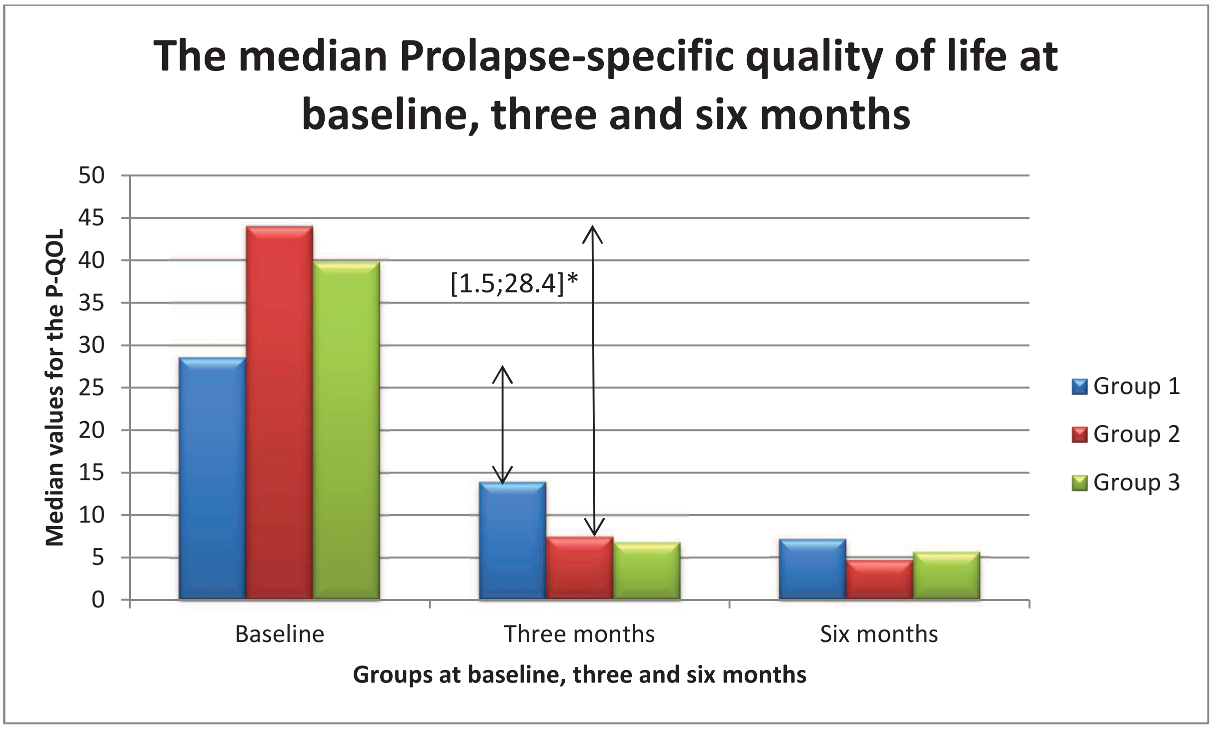
Hypothesis 13 (Objective 1.6.1.1-1.6.1.4)

"Based on theoretical biomechanical and exercise principles and guidelines, an effective exercise programme should lead to improvement of disease specific symptoms and bother, and therefore QOL."

Changes in the total median scores of the P-QOL revealed a noticeable decrease in all three groups over a six (6) month period. Group two yielded the most significant change from baseline to three (3) and six (6) months respectively, followed by group one. The change in group two was statistically significant when compared to group one from baseline to three (3) months post-operative (95% CI [1.5;28.4]) (Graph 21).

Changes in the domain scores did not reveal any statistically significant differences. The most clinical significant changes were observed in group two from baseline to three (3) months regarding the prolapse impact domain [median change = -66.67, IQ range = 9-33.3-(-100)]. A similar clinically significant change was observed in group one, also in regards to the prolapse impact domain from baseline to three (3) months follow-up [median change = -66.67, IQ range = -33.3-(-66.7)]. A negative value indicated improvement of the domain score due to better QOL being indicated by a smaller value on the scale.

Statistical regression however has to be considered as a reason for no changes being detected from three (3) to six (6) months post-operatively per domain. Large improvements were detected from baseline to three (3) months follow-up which yielded small changes, if any, from three (3) to six (6) months follow-up (Table 58).



n-values for Group 1=24, Group 2=28, Group 3=29

*95% CI indicating statistically significant difference between the changes for group 1 and 2 from baseline to three months

Graph 21. The median P-QOL at baseline, three and six months post-operative.

The median values per group for each domain at baseline, three (3) and six (6) months post-operative are presented in Table 58. Clinically, group two demonstrated *no impairment* in any of the domains at three (3) months follow-up. This was maintained at six (6) months follow-up. Group one and three also showed continuous improvement in these domains, although it was not noticeable in all the domains. Group one returned to its pre-operative state regarding prolapse impact at six (6) months follow-up.

Table 58. Median values and IQ ranges per group for the P-QOL domains at baseline, three and six months.

	BASELINE	THREE MONTHS	SIX MONTHS
	Median (IQ range)	Median (IQ range)	Median (IQ range)
	GROUP 1		
	n=24	n=23	n=22
General health	-	-	-
Prolapse impact	66.67 (83.33-33.33)	0 (66.67-0)	66.67 (66.67-0)
Role limitations	50.0 (83.33-8.33)	0 (33.33-0)	0 (33.33-0)
Physical limitations	33.33 (83.33-8.33)	0 (33.33-0)	0 (16.67-0)
Social limitations	8.33 (58.33-0)	0 (33.33-0)	0 [16.67-(16.67)]
Personal relationships	0 (16.67-0)	0 (0-0)	0 (0-0)
Emotions	27.78 (61.11-0)	0 (55.56-0)	0 (22.22-0)
Sleep/energy	33.33 (50.0-16.67)	16.67 (33.33-16.67)	16.67 (50.0-0)
Severity measures	29.17 (50.0-16.67)	8.33 (16.67-0)	0 (0-0)
	GROUP 2		
	n=28	n=28	n=26
General health	-	-	-
Prolapse impact	66.67 (100.00-66.67)	0 (16.67-0)	0 (66.67-0)
Role limitations	33.33 (66.67-33.33)	0 (25.0-0)	0 (33.33-0)
Physical limitations	33.33 (66.67-0)	0 (0-0)	0 (0-0)

	BASELINE	THREE MONTHS	SIX MONTHS
	Median (IQ range)	Median (IQ range)	Median (IQ range)
Social limitations	33.33 (66.67-0)	0 (0-0)	0 (0-0)
Personal relationships	33.33 (66.67-0)	0 (0-0)	0 (0-0)
Emotions	50.0 (77.78-16.67)	0 (33.33-0)	0 (22.2-0)
Sleep/energy	33.33 (6.67-16.67)	0 (25.00-0)	0 (33.33-0)
Severity measures	25.00 (45.83-16.67)	0 (20.83-0)	0 (0-0)

GROUP 3

	n=29	n=29	n=26
General health	-	-	-
Prolapse impact	66.67 (100.0-33.33)	0 (33.33-0)	0 (66.67-0)
Role limitations	33.33 (66.67-0)	0 (33.33-0)	0 (0-0)
Physical limitations	33.33 (83.33-0)	0 (0-0)	0 (0-0)
Social limitations	16.67 (66.67-0)	0 (0-0)	0 (0-0)
Personal relationships	0 (66.67-0)	0 (0-0)	0 (0-0)
Emotions	44.44 (66.67-11.11)	0 (11.11-0)	0 (11.11-0)
Sleep/energy	33.33 (50.0-16.67)	16.67 (33.33-0)	8.33 (33.33-0)
Severity measures	25.00 (41.67-16.67)	0 (16.67-0)	0 (0-0)

Highlighted results indicate important findings referred to in text.

Comparison of the median values for each domain of the P-QOL between the different groups at three (3) and six (6) months post-operatively revealed no significant differences (Table 59).

Table 59. Ninety five percent CIs for the median difference between groups regarding the P-QOL domains at three and six months.

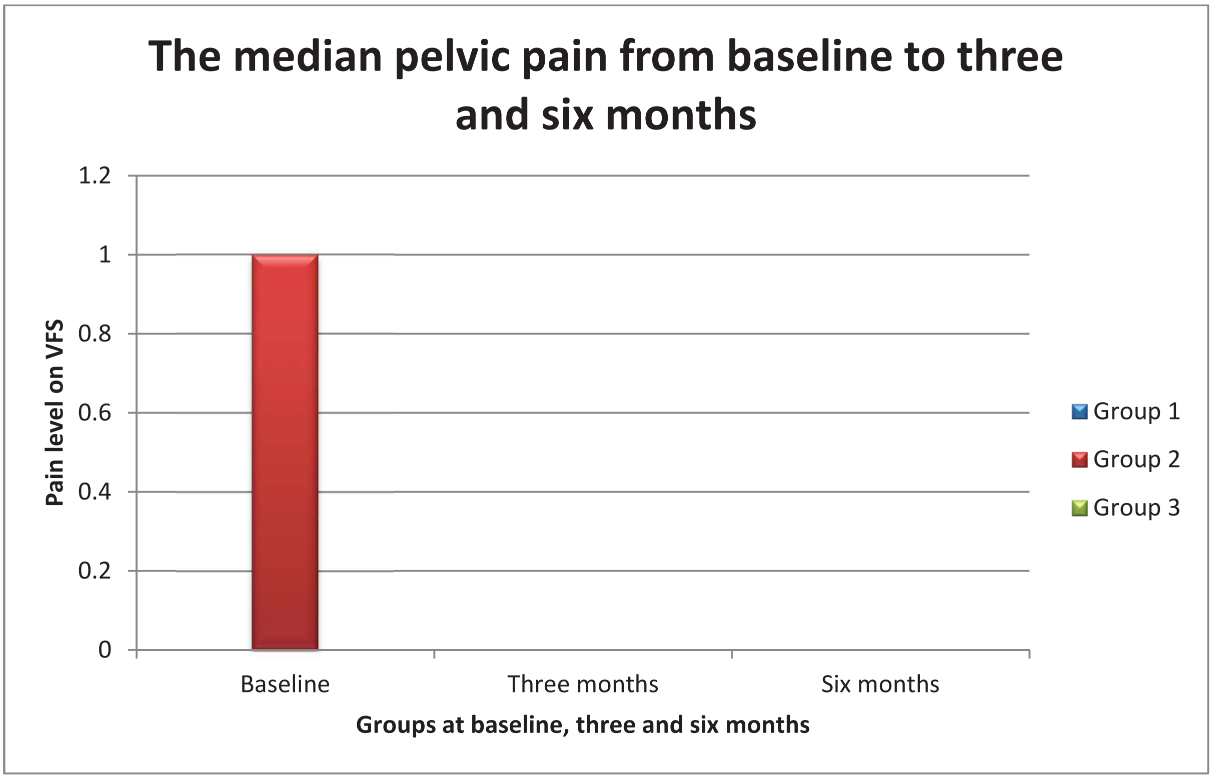
	ASSESSMENT 2 (at three months)	ASSESSMENT 3 (at six months)
DOMAIN	95% CI	95% CI
COMPARISON BETWEEN GROUP 1 AND 2		
General health	[-21.4;29.4]	[-22.0;20.0]
Prolapse impact	[0;33.3]	[0;66.7]
Role limitations	[0;0]	[0;16.7]
Physical limitations	[0;0]	[0;0]
Social limitations	[0;0]	[0;16.7]
Personal relationships	[0;0]	[0;0]
Emotions	[0;11.1]	[0;0]
Sleep/energy	[0;16.7]	[0;16.7]
Severity measures	[0;8.3]	[0;0]
COMPARISON BETWEEN GROUP 1 AND 3		
General health	[-16.5;33.5]	[-26.3;16.8]
Prolapse impact	[0;33.3]	[0;66.7]
Role limitations	[0;0]	[0;16.7]
Physical limitations	[0;0]	[0;16.7]
Social limitations	[0;0]	[0;16.7]
Personal relationships	[0;0]	[0;0]
Emotions	[0;11.1]	[0;11.1]
Sleep/energy	[0;16.7]	[0;16.7]
Severity measures	[0;8.3]	[0;0]

DOMAIN	ASSESSMENT 2 (at three months) 95% CI	ASSESSMENT 3 (at six months) 95% CI
COMPARISON BETWEEN GROUP 2 AND 3		
General health	[-19.2;28.2]	[-24.7;17.2]
Prolapse impact	[0;0]	[0;33.3]
Role limitations	[0;0]	[0;0]
Physical limitations	[0;0]	[0;0]
Social limitations	[0;0]	[0;0]
Personal relationships	[0;0]	[0;0]
Emotions	[0;0]	[0;0]
Sleep/energy	[-16.7;0]	[-16.7;0]
Severity measures	[0;0]	[0;0]

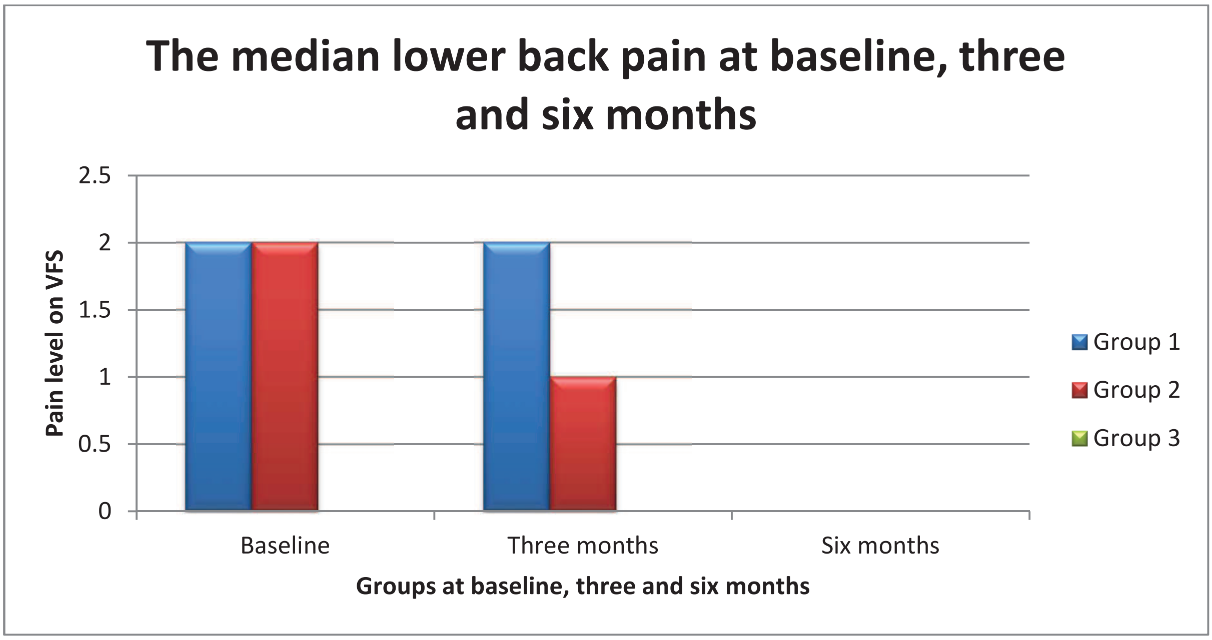
More specific analysis of individual questions indicated some significant differences. At three (3) months it was noted that significantly more participants in group one complained of tiredness when compared to group two (95% CI [-49.1%;-0.4%]). Another interesting and significant finding was that more participants in group one were still using preventative measures, such as tampons and underwear, to assist with the symptoms, when compared to the control group (95% CI [-50.9%;-2.2%]).

At six (6) months more significant differences were detected in the specific analysis compared to three (3) months. Significantly more participants in group one still complained of UUI and incomplete emptying when compared to the control group (95% CI [-50.1%;-5.3%] and [-51.3%;-0.8%] respectively). Regarding bowel habits, it seemed that the control group had fewer complaints regarding constipation and incomplete emptying when compared to both intervention groups. There was a statistically significant difference between the control group and group two regarding both of these symptoms (95% CI [-52.1%;-4.0%] and [-52.1%;-4.0%] respectively). Both intervention groups showed a tendency to not digitalise with defecation when compared to the control group. There was a statistically significant difference between group one and three regarding this symptom (95% CI [1.6%;45.7%]). However, the frequency of defecation (namely more than once a day) seemed to be statistically more significant in the control group when compared to group two (95% CI [-43.1%;-1.3%]).

Bowel habits, amongst other reasons, are important to be considered when participants complain of abdominal or pelvic discomfort. Significantly more participants in group two complained of an uncomfortable feeling in the pelvic region when compared to group one (95% CI [3.9%;42.1%]) and 3 (95% CI [-42.1%;-5.4%]) respectively. However, there was no statistical difference between the groups regarding pelvic or lower back pain, as measured by the VFS (Graph 22 and 23). At three (3) months, the median values were zero for all groups regarding this variable, apart from a median of 2 for lower back pain in group one. It therefore appeared unlikely that pain would be a significant reason for limiting certain physical aspects of QOL and motor control.



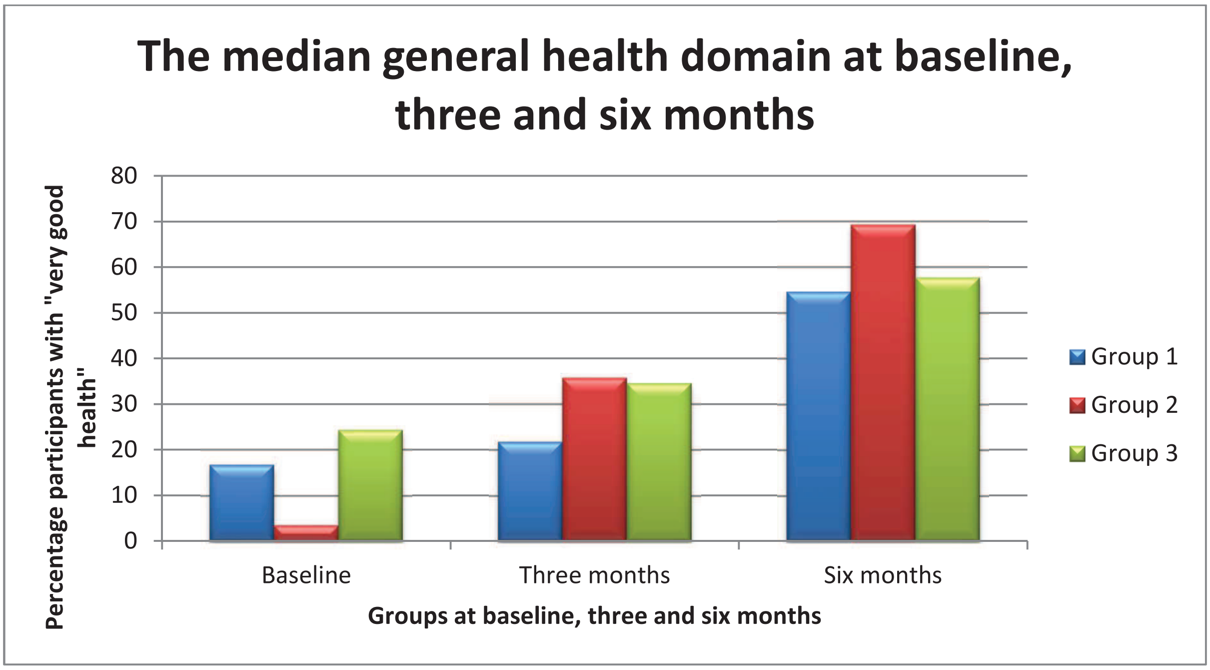
Graph 22. **The median pelvic pain at baseline, three and six months post-operative.**



Graph 23. **The median lower back pain at baseline, three and six months post-operative.**

Some aspects regarding role, physical and social limitations, however, differed significantly only between group one and three at six (6) months. It was interesting to note that group three complained less of POP affecting their daily household tasks (95% CI [-46.8%;-0.7%]), their ability to travel (95% CI [-50.1%;-5.3), and their ability to socialise with friends (95% CI [-51.0%;-0.3%]). Aspects such as UUI and incomplete emptying, which was statistically more significant in group one at six (6) months (compared to group three), might be related in this regard.

In summary, group two showed the most clinical improvement in prolapse-specific QOL from pre-operative assessment to six (6) months post-operative. This was also reflected in their improvement in the general health domain (Graph 24). Their improvement was of such a magnitude that they had no impairment at three (3) and six (6) months follow-up. However, group one and three also showed improvement and no statistically significant differences could be detected between groups regarding the domain scores.



Graph 24. The median general health domain (P-QOL) at baseline, three and six months post-operative.

Whether the assumed improvement in QOL was due to the surgical intervention and/or due to the adjunctive exercise programmes the participants received remains the topic to be discussed in the following chapter.

4.7 CONCLUSION

This chapter presented the results on variables that were investigated to determine the characteristic QOL, symptoms, signs and co-morbidities, biomechanical properties and muscle function in women with POP scheduled for pelvic floor reconstructive surgery. Then the changes in these variables were analysed in response to different approaches to PFM rehabilitation, in conjunction with pelvic floor reconstructive surgery.

The results indicated decreased QOL regarding the domains of general health, prolapse impact and the social, emotional, sleep and severity measures in the participants prior to surgery. The participants were also characterised by poor physical activity levels and some cardiovascular/depressive co-morbidities, which reflected in their poor achievement in regards to muscle testing of the PFM and abdominal muscles, which possibly contributed to symptoms and signs such as OAB and constipation. Certain significant correlations between muscle functions were identified.

Limited significant changes were observed in variables in response to the intervention programmes. However, some tendencies were identified and it would appear as if isolated PFM exercises yielded better results in regards to the function of the PFM, while an integrated motor control programme resulted in better abdominal muscle function and specifically local stabiliser muscle function of the PFM.

QOL improved in all groups during the six (6) month period, although it was group two who demonstrated no affected QOL at three (3) and six (6) months post-operatively.

This completed the cycle of analysing characteristics in women with POP scheduled for pelvic floor reconstructive surgery and whether rehabilitation could eventually affect their QOL (Figure 34).

The next chapter will discuss the reasoning around certain assumptions and will provide explanations for certain findings in order to reach a conclusion regarding a proposed model for rehabilitation in women undergoing pelvic floor reconstructive surgery.

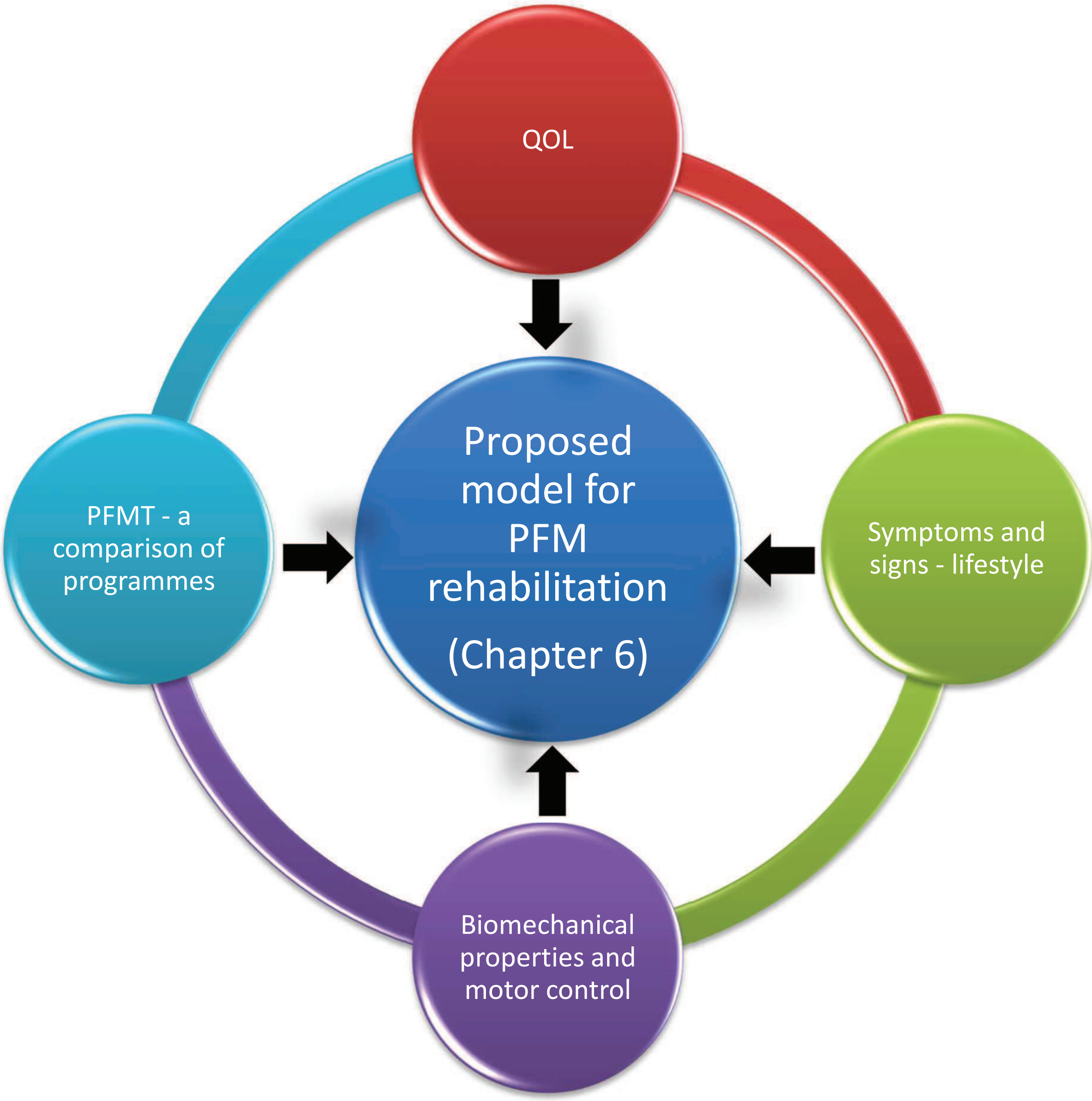


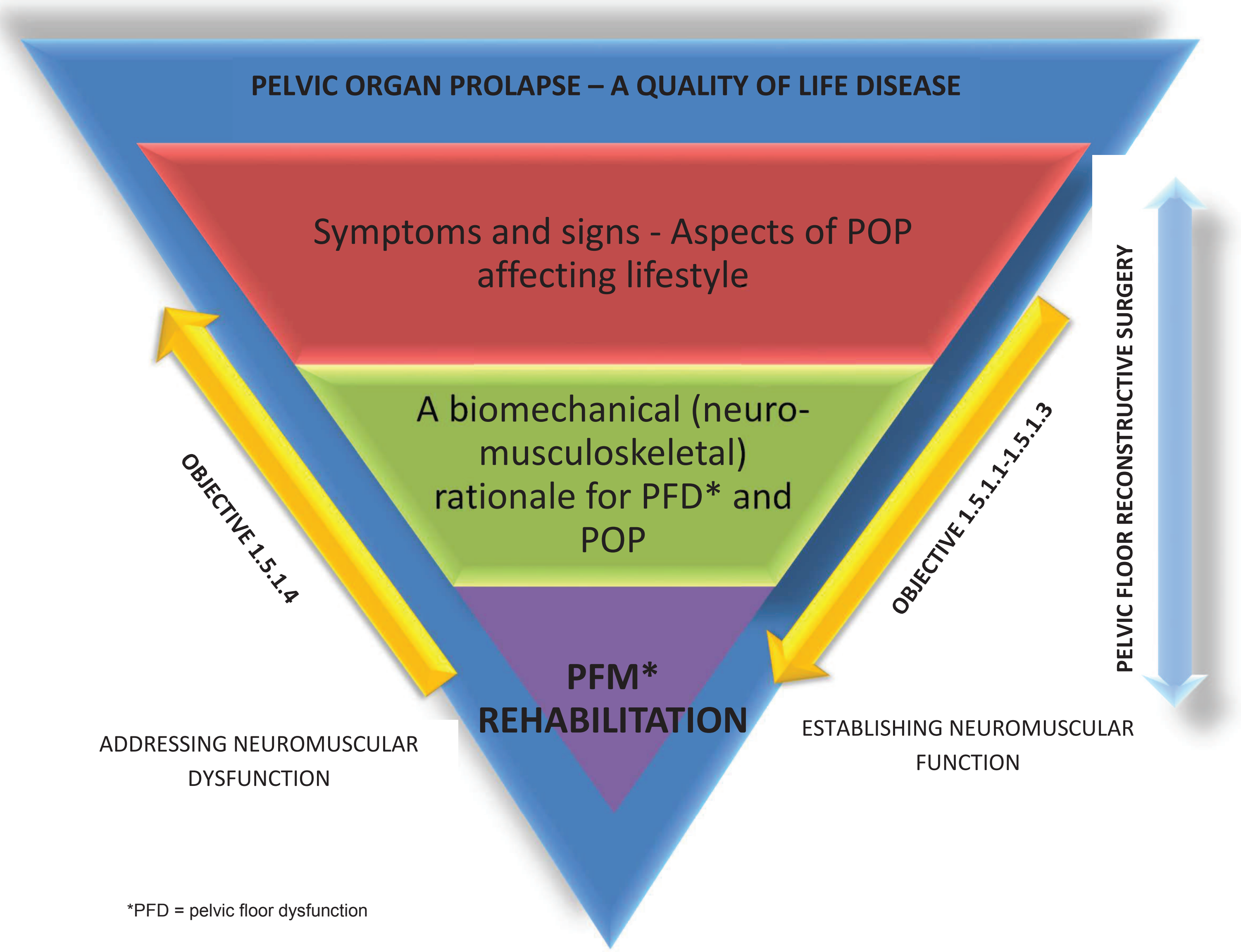
Figure 34. Cycle of analysis of variables.

CHAPTER 5

PELVIC ORGAN PROLAPSE AND RECONSTRUCTIVE SURGERY – EVIDENCE AND GUIDELINES FOR AN INTEGRATED MODEL FOR REHABILITATION

5.1 INTRODUCTION

Chapter 1 and 2 introduced the reader to the themes of QOL and motor control, biomechanics and exercise therapy as related to POP and reconstructive surgery. These chapters indicated how these concepts were integrated into the development of the aims and objectives of this research study (Figure 1).



*PFD = pelvic floor dysfunction

*PFM = pelvic floor muscles

Figure 35. A conclusive discussion of themes posed in Chapter 1 and 2.

The aim of this chapter is to provide a discussion of the findings of this study and how it can be integrated into a model of rehabilitation for POP pre- and post-operatively, based on current and new evidence as set within a framework of QOL. The discussion will be based on the outline of themes and hypotheses identified in Chapter 1 and 2 (Figure 35). The chapter will also critically reflect on the process that was followed to answer the research question and the current literature.

Furthermore, it will raise new questions and problems and give an indication of the clinical value of this research (Figure 36).

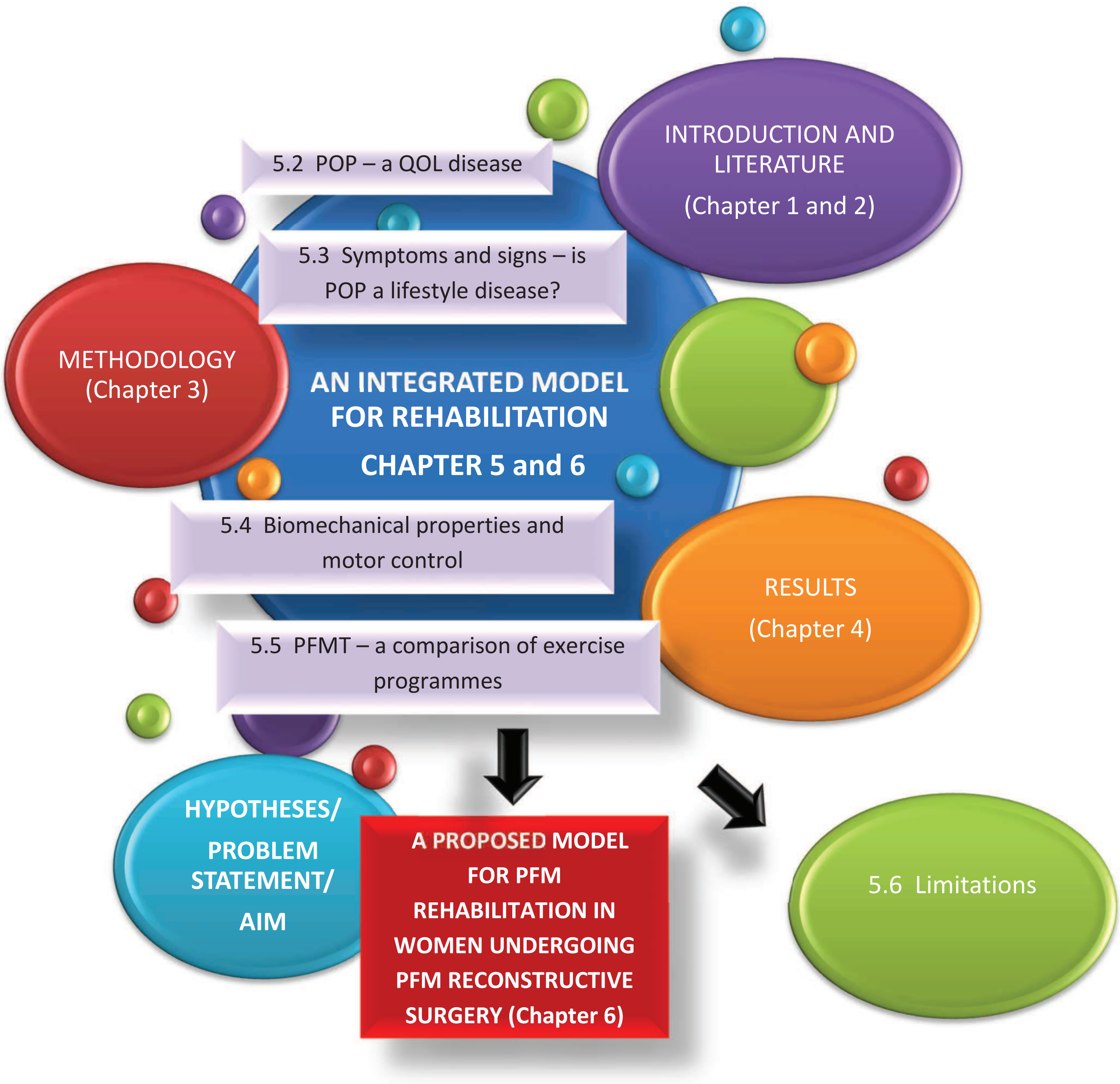


Figure 36. The interrelated discussion of concepts within the study context.

5.2 PELVIC ORGAN PROLAPSE – A DISCUSSION OF QUALITY OF LIFE IN WOMEN SCHEDULED FOR PELVIC FLOOR RECONSTRUCTIVE SURGERY

QOL has been the main focus of outcome measurement in studies investigating the effect of PFMT (see 1.1). Previous studies investigating the management of POP and QOL used a variety of condition-specific or general health questionnaires, whilst only one study made use of a combination of condition-specific and general health questionnaires (Doaee *et al.* 2014:156). Although domains of general and specific QOL questionnaires measure similar aspects of QOL, questions need to be specifically constructed for a particular pathology to ensure construct validity.

A small pre-test study conducted during this research process indicated an acceptable validity and reliability of the P-QOL in a South African population (n=40). Most kappa values were greater than 0.5, apart from six questions from different individual domains (see 4.3.2). Reliability testing of the SF-36 on a smaller sample of 21 participants however raised concern regarding the reliability and interpretation of this questionnaire in this study's population with kappa values which were mostly below 0.5 and the percentage agreement less than 70% (see 4.3.3). Larger trials are needed to determine normative data and conclusive reliability values in a South African population to draw valid conclusions. The researchers therefore had to rely on sensitive interpretation of QOL findings, relating it to results from other populations, but also relating it to demographic data found in this study.

The QOL domains that were mostly affected according to the P-QOL in this study were impact (median score of 66.67%, IQ range [33.33-100.00]) and severity of the prolapse (median score of 25%, IQ range [12.5-41.67]), emotional (median score of 44.4%, IQ range [11.1-72.2]), social (median score of 33.3%, IQ range [0-66.7]), and sleep/energy (median score of 33.3%, IQ range [16.67-50.0]). It should be reiterated that the sleep/energy domain raised some concern regarding the reliability of the interpretation of this domain due to the fact that two questions yielded a percentage reliability of 53.8% and a kappa value below 0.5. Similar to this study all previous studies found prolapse impact to be mostly affected (see Table 60). However, in their studies, the emotional, social and sleep/energy domains were much less affected when compared to their scores on physical, personal and role limitations. Table 60 can be consulted for a summary of authors and their findings regarding the domains (Claerhout *et al.* 2010:572; Manchana & Bunyavejchevin 2010:987; Svihrova *et al.* 2010:55; De Oliveira *et al.* 2009:1194; Cam *et al.* 2007:134; Digesu *et al.* 2003:187).

Table 60. Table of medians (%) for symptomatic and asymptomatic patients – P-QOL domains.

Domain	Sympto= matic	Asymp= tomatic	Sympto= matic	Asymp= tomatic	Sympto= matic	Asymp= tomatic	Sympto= Matic	Asymp= tomatic	Sympto= matic	Asymp= tomatic	Sympto= matic	Asymp= tomatic
General health	25	25	50	50	36	28	50	25	50	25	75	25
Prolapse impact	67	0	100	0	57	0	67	0	100	0	67	0
Role limitations	67	0	67	0	16	0	50	0	67	0	67	0
Physical limitations	67	0	50	0	19	0	50	0	67	0	50	0
Social limitations	17	0	22	0	16	0	22	0	56	0	33	0
Personal relationships	50	0	67	0	14	0	0	0	67	0	50	0
Emotional problems	44	0	67	0	16	0	44	0	56	0	67	0
Sleep/energy disturbance	33	0	33	0	23	0	17	0	67	0	33	17
Severity measures	33	0	33	0	11	0	25	0	42	0	33	0
	Claerhout *et al.* 2010:572		De Oliveira *et al.* 2009:1194		Svihrova *et al.* 2010:55		Manchana & Bunyavejchevin 2010:987		Digesu *et al.* 2003:187		Cam *et al.* 2007:134	

A reason for the difference in findings from previous studies might be the difference in environmental, social, educational and economic factors affecting QOL and physical/emotional well-being in the different populations. All of the aforementioned studies were done in First World countries where resources and social, educational and economic factors might have less of an impact on patients and how they feel, when compared to the resource-restricted health system in which this study`s participants were mostly placed (Eleje *et al.* 2015:798). The setting of a primary and public health care system and environment in which this study mainly took place could therefore have had a significantly larger effect on the outcomes of this study than the researcher originally anticipated. Seventy four percent of the participants were enrolled in the public health care system, while only 24% of the participants belonged to medical aids. The effect of these socio-economic factors on motivation, behaviour and physical well-being, relating to the biopsychosocial approach to rehabilitation, will be discussed further in sections 5.3 to 5.6.

Similar to our findings for the general health domain (median of 25%), most previous studies found general health (according to the P-QOL) not to be an affected domain (median ranges from 25% to 50%), except the study by Cam *et al.* (2007:134) who found a median score of 75% in the general health domain, indicating concern regarding the participants' QOL (Table 60). Their study did not differ from the other studies in regards to methodology or demographic variables. The reason for the difference in findings remains unanswered. The results from this study regarding the general health domain were also rather low (namely, a median of 25%). Low scores in this domain, compared with the high scores obtained by all the other studies in the prolapse impact domain (median ranges from 57% to 100%), might be an indication of the sensitivity of the P-QOL where findings can be contributed to the prolapse impact rather than poor general health (Claerhout *et al.* 2010:572; Manchana & Bunyavejchevin 2010:987; Svihrova *et al.* 2010:55; De Oliveira *et al.* 2009:1194; Cam *et al.* 2007:134; Digesu *et al.* 2003:187) (Table 60).

This should also be reflected in the results obtained from a general health questionnaire such as the SF-36. If a general health questionnaire is sensitive enough, it should reflect decreased QOL due to any pathology, including POP and emotional state. An assumption cannot therefore be made that a good general health domain in the P-QOL would be associated with a good score on the SF-36, or other general health questionnaires. It may be postulated that this was reflected in the findings of the reliability calculation of the SF-36 (with a percentage agreement below 70% and most kappa values of below 0.5), leading to what could be interpreted as poor reliability of the Afrikaans version in this study. It was specifically the questions comprising the mental health domain which were found to be unreliable, with disagreement varying between 45% and 65% (see Table 21). However, instead of interpreting it as poor reliability, it could also be an indication of the sensitivity of the SF-36 that detected differences in the mental health domain at the different testing occasions. This assumption would actually support the findings of the demographic data and P-QOL on the emotional well-being of our participants. This will be discussed further in the following paragraphs.

In this study, demographic results contributed to the concern regarding the participants' general health, including physical and emotional well-being. It was interesting to note that 80% (n=100) of the participants were unemployed at the time of the study and did not participate in any physical activity (76%, n=100). According to the P-QOL, physical activity did not seem to be limited by the impact of the POP (a median of 33.3%). Questions in the P-QOL relating to physical activity included sport, as well as daily activities (Digesu *et al.* 2005b:180).

For the purpose of discussion, differentiation of physical activity was warranted as relating to exercise, or as relating to activities of daily living as stated above. Physical inactivity relating to exercise can be defined as less than 150 minutes of moderate-intensity exercise per week, or less than 60 minutes of vigorous intensity exercise per week (Bernard *et al.* 2015:485). Lack of physical activity has been identified by several authors as a risk factor for depressive symptoms, as well as for cardiovascular disease (Bernard *et al.* 2015:486). The latter is dealt with in 5.3.

The prevention of major depressive disorder, minor depression, or sub-threshold depressive symptoms have become a priority especially in post-menopausal women. Many of the impairments the participants in our study experienced were similar to the symptoms and risk factors for depression. These factors related to the phenomena of unemployment amongst the participants in this study (80%), inactivity (76%), an increased BMI (28.67 kg/m^2), as well as the prevalence/treatment of depression symptoms (13%) and insomnia (3%). The most commonly reported symptoms for subsyndromal depression are insomnia, hypersomnia, a feeling of constant tiredness, trouble with concentrating and thinking, weight gain, and recurring thoughts of death (Savoy & Penckofer 2015:361). Risk factors for the development of depressive symptoms include social isolation, lower education, and physical inactivity (Bernard *et al.* 2015:486).

Increasing physical activity could therefore help to lower depressive symptoms in post-menopausal women, despite the cause of these symptoms (Bernard *et al.* 2015:486). Bernard *et al.* (2015) conducted a randomised controlled trial in post-menopausal women investigating the effect of a six (6) month walking intervention programme on depressive symptoms in this population. They established that three sessions per week of moderate-intensity walking (supervised and home-based) decreased depressive symptoms in this sample, even with a minimal adherence of 50% to their programme (Bernard *et al.* 2015:490).

The minimal adherence found in the aforementioned study could be further explained by the study by Savoy and Penckofer (2015:361-369). They found that subsyndromal depressive symptoms in women are significantly inversely related to health-promoting lifestyle behaviours and general QOL. Depressive symptoms interfere especially with compliance to alter lifestyle behaviour and other treatment plans, although the participants in our study appeared to have had better compliance when compared to the other studies (see 5.5.1). Feelings of tiredness, hypersomnia, and the consequence of insomnia would influence the physical capability of the participant to do exercises; in other words, the input and output mechanisms related to sensorimotor control would be influenced by fatigue. On a cognitive (processing) level (CNS), it would also have an effect due to trouble concentrating and thinking. The effect of cognitive and emotional factors on the sensorimotor system has been described in 2.8.1.5 (Jull *et al.* 2015:54-55).

QOL assessment relates mostly to environmental, emotional or psychosocial factors that could influence the delicate balance of the sensori-/motor control system, as defined by Mottram *et al.* (2005:4-3) and Jull *et al.* (2015:53), especially at a CNS level. These factors were reflected by the outcomes of the above domains of the P-QOL. The social (median score 33.3%), emotional (median score 44.4%), and sleep/energy domains (median score 33.3%) were all classified as symptomatic scores (see 4.3.4). However, as described in 2.8.1.5, environmental, emotional and psychosocial factors can also influence the input and output mechanisms of sensorimotor control. The effect of environmental/psychosocial factors on the sensorimotor control system would be expected to change normal PFM function, which usually helps to prevent the symptoms and signs of POP. The symptoms and signs are the cause of the decreased QOL in patients with POP, therefore a cycle of dysfunction may exist between QOL and sensorimotor control (see 1.2 and Figure 37). It may be postulated that improving QOL is not only important as an outcome for patients with POP, but also to improve sensorimotor control. This relationship is referred to in 5.4 and 5.5.

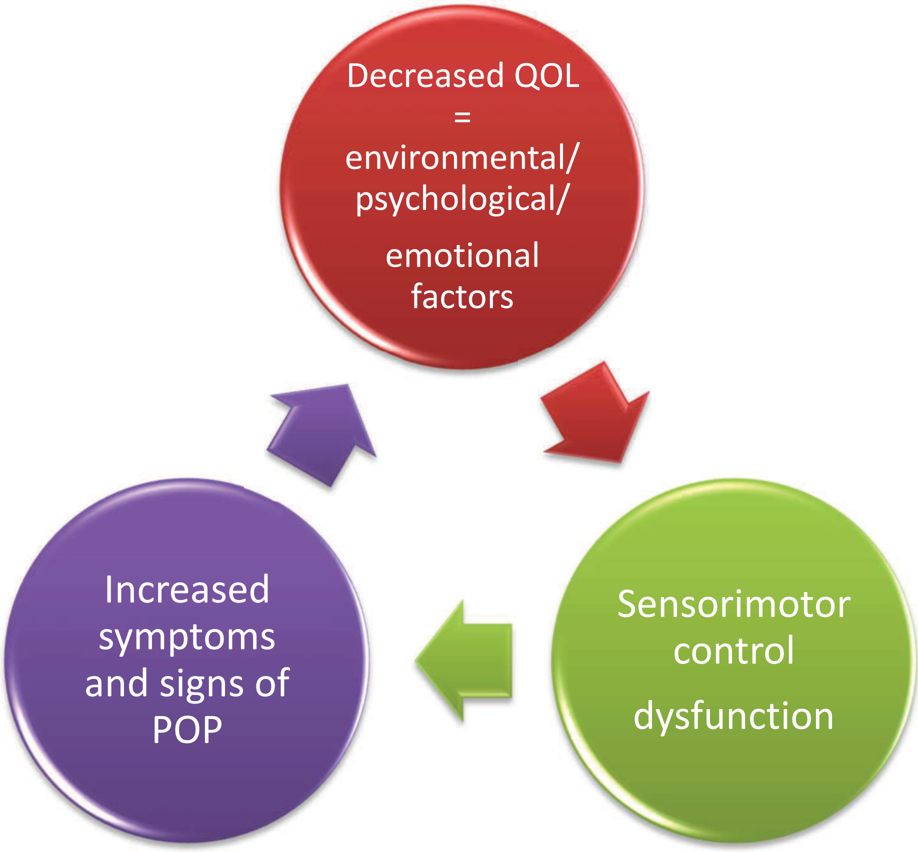


Figure 37. Relationship between quality of life, sensorimotor control, symptoms and signs of POP.

The learning strategy to educate and teach patients with decreased QOL and/or depressive symptoms exercises and lifestyle behaviour would therefore need to be adapted by the therapist so as to be effective (see 2.8.2.4). It is especially the learning context and environment, namely a lower socio-economic class, as well as the life stages and life events, namely unemployment and retirement in this study's sample, which would be important when designing learning for these patients (Massyn 2009:49-50). Exercise self-esteem and efficacy, as well as self-efficacy, should thus be emphasised. Improving the latter factors are some of the mechanisms causing the anti-depressant effects of exercise (Bernard *et al.* 2015:490). Early detection and treatment of depressive symptoms might therefore be important as part of a management plan to improve adult learning and adherence to a rehabilitation programme involving change in lifestyle behaviour and sensorimotor control (Savoy & Penckofer 2015:369).

It is evident from the discussion in this section that there might be a close relationship between the symptoms and signs of POP, QOL, lifestyle changes and behaviour, as well as neuro-musculoskeletal function. Authors have indicated that although lifestyle advice often forms a part of the management of patients with POP, there is still a lack of evidence and definition on lifestyle-related environmental factors and their role in patients with POP (Miedel *et al.* 2009:1089; Weber & Richter 2005:621). The following section defines this concept based on the results and framework of this study.

5.3 IS PELVIC ORGAN PROLAPSE A LIFESTYLE DISEASE? A DISCUSSION OF THE SYMPTOMS, SIGNS, AND CO-MORBIDITIES

The lack of physical activity was raised in the above section as a concern regarding not only the development of POP, but also as an aspect which may affect the general health and emotional well-being of the participants. However, many of the risk factors for POP and UI, namely pregnancy and childbirth, deficient connective tissue (varicose veins, hernia, haemorrhoids), hormonal factors, poor diet, smoking, obesity, lack of exercise, ageing and menopause (Grewar & McLean 2008:375-376; Weber and Richter 2005:616), are also risk factors for the development of lifestyle diseases such as hypertension and cardiovascular disease (Leuzzi & Modena 2011:16). A more specific analysis and discussion of demographic variables and risk factors in patients with POP might therefore help to define POP in the context of lifestyle changes and diseases.

The analysis of the socio-demographic data in the 100 participants scheduled for pelvic floor reconstructive surgery in community-based clinics in this study revealed several results that raised concern regarding lifestyle issues and disease, as were also established from their QOL assessment (see 5.2). Most participants were either unemployed or pensioners (80%, n=100). Although the sample could not be classified as obese (BMI>35kg/m^2), the participants' BMI (median 28.58 kg/m^2 (n=97)) showed a tendency toward the upper limit of the spectrum. Concern was also raised regarding the high percentage of participants who were physically inactive, nor participated in sport-related activities (76% and 85% respectively, n=100). Heart disease (14%, n=100), vascular disease (17%, n=100), and inflammatory conditions (19%, n=100) were the most common diseases the participants complained of. These findings were confirmed by the fact that 47% of the sample (n=100) was receiving drug treatment for hypertension, 18% for cholesterol, and 17% was receiving hormone replacement therapy, which is also used to treat hypertension in post-menopausal women, although the latter does not reflect accepted clinical practice (Leuzzi & Modena 2011:16). A higher percentage of participants also received medication for hypothyroidism (18%) and depression (12%), although the latter two findings were not reflected in their documented disease state. Approximately half of the participants (45%, n=100) had a history of previous surgery, while birth history indicated a mean of three (3) deliveries in the sample.

Despite the association with lifestyle diseases, several studies have indicated demographic variables such as older age, menopause, BMI, birth history and a history of previous surgery to be associated with POP (Fialkow *et al.* 2002:1444). The statement by Fialkow *et al.* (2002:1444) was supported by similar demographic findings from this study and other research done on patients receiving PFMT and pelvic floor reconstructive surgery (Pauls *et al.* 2013:273-274; Frawley *et al.* 2010:722; Jarvis *et al.* 2005:302; Vakili, Yong, Loesch, Karolynn, Franco & Chesson 2005:1593). Most women had a parity of two to three normal deliveries, and half or more of the sample in all studies had a history of previous hysterectomy or reconstructive surgery, compared to the 45% (n=100) found in our study. The most common types of previous reconstructive/gynaecological surgery in our participants were anterior repair (25%) and hysterectomy (18%). Different classification of surgical interventions among studies made it difficult to make direct comparisons of the results obtained. The BMI range was in the vicinity of 27kg/m^2. The latter was slightly higher in this study, with a median of approximately 29kg/m^2 due to increased weight. The mean age in all studies was approximately 60 years (compared to the mean of 59 years in our sample), which explains why the majority of the samples were classified as post-menopausal.

The mean age of the sample in the current study was approximately 59 years, which was to be expected when looking at the documented menopausal status of the women. Most women were post-menopausal (54%), while 31% (n=100) were peri-menopausal. Menopause occurs at a median age of 51.4 years. The menopausal transition (peri-menopause) begins approximately four (4) years before the final menstrual period. It occurs at a mean age of 47 years, therefore participants were classified as pre-menopausal if they were younger than 45 years of age, and post-menopausal if they were older than 55 years of age (Nygaard, Betschart, Hafez, Lewis, Chasiotis & Doumouchtsis 2013:2072).

Data from previous studies indicate that approximately 50% of post-menopausal women have hypertension or are taking anti-hypertensive therapy. This was reflected in our results where it was indicated that 47% of our participants were receiving medication for hypertension and 31% had a history of cardiovascular disease. Hypertension has been labelled as one of the major cardiovascular risk factors in post-menopausal women (Leuzzi & Modena 2011:13).

The pathophysiology of post-menopausal hypertension related to the post-menopausal stage can firstly be explained by the lack of oestrogen during this period. However, it was interesting to note that only 17% of our sample was receiving hormone replacement therapy at the time of the study. In 2.5.1 it was mentioned that a decrease in oestrogen and progesterone receptor density in the cardinal and uterosacral ligaments has been observed with increasing age in post-menopausal women (Reay Jones *et al.* 2003:470). Simplifying the explanation, the normal function of oestrogen is to inhibit the renin-angiotensin system (RAS) and suppress endothelin, which is a strong vasoconstrictor. A lack of oestrogen would therefore lead to an increase in endothelin, which in turn can lead to an increased sodium reabsorption in the kidneys and increased blood pressure. The RAS system can also cause increased blood pressure and fluid retention due to a lack of oestrogen, which leads to an upregulation of angiotensin II receptors and a downregulation of angiotensin I receptors (Cohen & Townsend 2011:331-332; Leuzzi & Modena 2011:14).

A second cause of hypertension in post-menopausal women can be endothelial dysfunction, which has been indicated as a predictor for the development of hypertension in this group of women. Post-menopausal status is also associated with reduced arterial nitric oxide activity, which can induce and therefore contribute to an increase in arterial resistance (Cohen & Townsend 2011:331-332; Leuzzi & Modena 2011:15).

Obesity in post-menopausal women is the third factor that could contribute to the development of hypertension in this specific group of patients. Obesity is also associated with an increased sympathetic activity, specifically in the kidney, and an increased renin release, which could be a contributing factor to the hypertension (Leuzzi & Modena 2011:15). This explanation could relate to the increased BMI (28.67 kg/m^2), as well as prevalence of hypertension/cardiovascular disease, which was found in our sample (n=100).

Raising the concern, however, is that depressive symptoms, as identified in our sample (see 5.2), are also defined as an independent risk factor for cardiovascular disease and is often under-diagnosed. It is the adverse effect of depressive symptoms, even if it is not clinically diagnosed, on the compliance to health style behaviour changes that contribute to the risk of developing cardiovascular disease (see 5.2). Approximately 70% of the participants in our sample who had depression/were treated for depressive symptoms (n=13), also had cardiovascular disease. None of these participants did any form of exercise which reflects upon the above statement regarding the compliance to health lifestyle behaviour changes in patients with depressive symptoms. These participants' BMI was also seemingly higher (namely 33.23 kg/m^2) than the average of the whole sample (28.67 kg/m^2). However, it must be taken into account that an increased BMI as well as lack of exercise are also independent risk factors for cardiovascular disease.

Despite evidence for the link between depression and cardiovascular disease, it has not been included in the most recent report of heart disease statistics by the American Heart Association (Savoy & Penckofer 2015:361). There is a link between increased cardiovascular morbidity and mortality and depressive symptoms, especially in women. More than 15% of people with cardiovascular disease have depressive symptoms. Women are twice as likely to have these symptoms, when compared to men (Savoy & Penckofer 2015:360-361).

The same problem of under-diagnosis applies to subclinical hypothyroidism. Only 19 of the participants in our study were diagnosed with hypothyroidism or were taking medication for it. Sixty three percent of these participants also had cardiovascular disease, or were treated for it. Subclinical or mild hypothyroidism occurs in approximately 5-20% of post-menopausal women and is associated with cardiac disease, and often seen in patients with POP. However, in a large case-cohort study on 736 cases who had myocardial infarction and a sub-cohort of 2927 members, no significant association was found between myocardial infarction and subclinical hypothyroidism in post-menopausal women. The authors suggested that inclusion of women with higher thyroid stimulating hormone levels and who were younger might yield different results (LeGrys *et al.* 2013:2309; 2317).

To further relate POP to lifestyle diseases, it could also be mentioned at this stage that of the 19 participants in our study who had or were treated for hypothyroidism, 94.73% had stage III POP. A cross-tabulation of hypertension with the stage of POP, however, revealed that participants with cardiovascular disease or who were treated for cardiovascular disease (n=58) had a similar prevalence of stage III POP (86.21%) than those without cardiovascular disease (85.71%, n=42). It could therefore be speculated that it is not the heart disease itself, but rather the similar associated and risk factors that contribute to the development of POP and heart disease. Such assumptions, however, need to be tested in large epidemiological studies.

Based on the discussion above, the proposed treatment for hypertension would be dietary and lifestyle changes, with or without drug therapy. Lifestyle changes would include aspects such as weight control, increased physical activity, moderate use of alcohol, decreased sodium intake and increased consumption of fresh fruit and vegetables and low-fat dairy products (Leuzzi & Modena 2011:16). These lifestyle changes are similar to those which are proposed for women with POP, due to the overlap of etiological and risk factors, as mentioned before (Bo *et al.* 2007:244). The emphasis should be on self-directed goals, self-management plans and further education, as indicated in a study on health-related behaviour in women with lifestyle-related diseases (Kozica, Deeks, Gibson-Helm, Teede & Moran 2012:71).

The administration of drug therapy might also be indicated. Drug therapy for hypertension in post-menopausal women may include administration of ß-blockers, diuretics or hormone replacement therapy, although the latter is still a controversial issue in the literature. Sixty four percent of our sample were on medication for cardiovascular disease, including hormone replacement therapy. Hormone replacement therapy has been indicated to have adverse or no significant effects against cardiovascular disease, while more recent literature indicates that it may suppress the incidence of cardiovascular disease in post-menopausal women (Cohen & Townsend 2011:335; Leuzzi & Modena 2011:16). The adverse effect of α-receptor blockers, ß-blockers and diuretics on associated symptoms in women with POP should also be considered. OAB and urgency/frequency are associated with a pressure drop in the urethra that can be considered as the initial motor event in micturition, involving the smooth musculature. Relaxation of the smooth musculature in the lower urinary tract may be affected by drug administration, which may worsen the symptoms related to POP (Bo *et al.* 2007:204). Diuretics will also lead to increased frequency of voiding and adversely affect the reflex mechanism of voiding by affecting bladder volume and fullness. The competent sphincter mechanism, which includes the coordinated function of the PFM, will therefore be disturbed (Bo *et al.* 2007:37). In addition to this, α- and ß-blockers may also cause muscle weakness as side-effects, adversely affecting bladder control and contributing to the over activity (Snyman 2012:111-146). Drug administration for hypertension could therefore possibly decrease QOL and contribute to PFM dysfunction by worsening symptoms of incontinence and OAB. This could also be a partial explanation for the prevalence of OAB (57%), SUI (37%) and UUI (31%) in our sample pre-operatively, other than the PFD (n=100).

In 1.2 it was stated that patients with POP adapt their lifestyle and physical activities due to the symptoms they experience; for example, patients with OAB or UUI may start limiting their fluid intake in order to reduce frequency of voiding (Vimplis & Hooper 2005:387; Mouritsen & Larsen 2003:122). Taking the above discussion into consideration, the question could therefore be asked whether POP should be defined as a disease of lifestyle and not only of QOL. The argument for this question is based on the assumption that patients with POP adapt their lifestyle to the symptoms they experience, and also that there is an overlap of risk factors for the developing of POP and cardiovascular disease. It is mainly the similarity of the risk factors that relate to lifestyle changes for both diseases.

5.4 BIOMECHANICAL PROPERTIES AND MOTOR CONTROL OF THE PELVIC FLOOR AND ABDOMINAL MUSCLES IN WOMEN SCHEDULED FOR PELVIC FLOOR RECONSTRUCTIVE SURGERY

The lack of physical activity and exercise could therefore possibly be due to an interrelationship between lifestyle behaviour, as discussed in 5.3, and symptoms and signs of POP. One of the most common adaptation strategies encountered is avoidance of physical activity that might cause or worsen the symptoms a patient experience (Jull *et al.* 2015:341; Comerford & Mottram 2001b:23). In the case of POP or incontinence, this would mean avoidance of activity in an upright position, or any moderate strenuous activity that could increase the IAP and therefore worsen the symptoms. Thus, instead of strengthening the core muscles to prevent symptoms and signs, it can be speculated that patients might get caught up in a vicious cycle of fear avoidance, which leads to even weaker muscle function (Jull *et al.* 2015:55). The domain in the P-QOL on physical and role limitations did not appear to reflect this assumption with median values below that expected for a symptomatic patient (see Table 23). However, if exercise and sport participation is not part of the patient's lifestyle, it would not be reflected in the answering of those questions, nor be indicated as "*affected*" by POP. The reason for a lack of sport participation and physical activity, and the effect it may have on POP, should rather be the aspect of concern. The effects of the emotional state, cognition, fatigue, motivation and pain on muscle function and compliance have been referred to in the previous sections (see 5.2 and 5.3).

Evidence for speculation on poor muscle function was reflected in the pre-operative results gathered on general activity levels, PFM and abdominal muscle function, and morphology. Compared to values that have been found in the literature in asymptomatic patients (see Table 35), the PFM demonstrated very poor function at all levels, except endurance as measured by EMG.

The results of this study display similar trends to findings from previous studies which investigated the function of the PFM by means of different variables and correlations in patients with PFM dysfunction (see below). The LH in our study had a mean length of 56.38mm with rest, 60.71mm with Valsalva, and 53.19mm with contraction. PFM function and morphology was further defined by the mean thickness of the perineal body (5.1mm), a mean diameter of 6.0-6.7mm of the PR muscle, and a mean of 4.28mm of movement of the PR muscle. However, comparison regarding the LH, movement and thickness of the PFM are complicated due to different imaging techniques and measuring points being used in the different studies. Measurements among studies vary from MRI, to three- and two-dimensional US measurements; the latter also varies between abdominal and perineal measuring techniques.

The LH as measured with two-dimensional US in this study (56.38mm) was approximately 10mm larger when compared to values previously found in the literature in asymptomatic subjects (aged 18 to 24 years) using a similar two-dimensional technique (Dietz *et al.* 2005:583). This corresponds with the findings of Clark *et al.* (2010:595.e19) who found the LH to be 0.8cm larger in women with PFM dysfunction, when compared to women without dysfunction ($P<0.01$) as measured with MRI. Majida *et al.* (2012:710) found significantly larger dimensions (with three- and four-dimensional US) of the LH during rest and contraction when they compared a group of patients with pubovisceral muscle dysfunction to a group of patients without pubovisceral muscle dysfunction. In the anterior-posterior direction they found a mean LH of 6.4-7.0cm during rest and during contraction a mean anterior-posterior diameter of 5.8-5.9cm in women with the dysfunction. During Valsalva the LH increased to 7.1-7.3cm, although the latter did not differ significantly from the dimensions in the women without pubovisceral muscle dysfunction. In general, the diameters for patients with dysfunction in their study (as well as in the study by Clark *et al.* 2010) are larger than the anterior-posterior values that were found in this study (see Table 34).

Despite the use of different measuring instruments among these studies, reasons for the differences in findings may include that both previous studies defined pubovisceral muscle dysfunction as trauma sustained during labour or other significant incidents, as measured by the presence of a unilateral or bilateral defect. Major defects may have a greater implication for muscle diameters and strength when compared to dysfunction of intact muscles. Only 13% (n=100) of the current sample was diagnosed with a unilateral defect and may therefore illustrate a better mean muscle strength and tone with a smaller LH. The percentage defects observed in this study are similar to the 15% which Dietz & Steensma (2006:227) observed in a sample of 338 women referred for urodynamic assessment. Another reason which necessitates exploration may be the history and effect of previous pelvic floor reconstructive surgery. Surgery may lead to narrowing of the LH due to formation of connective tissue post-operatively, which may be an explanation for smaller diameters when measuring the LH (Majida *et al.* 2012:711-713). According to the length-tension curve (see 2.5.1, Figure 14), a decreased length of skeletal muscle will result in a decreased force output and thus strength generation (Verelst & Leivseth 2004b:664). Approximately 50% of the current sample had previous reconstructive or gynaecological surgery (see Table 26). This was different from previous studies which excluded patients with previous POP surgery from their sample (Majida *et al.* 2012:708).

However, when the data in our study was analysed in regards to women with previous gynaecological surgery (45%, n=100) and without previous surgery (55%, n=100), no difference was observed in their median muscle strength (namely, a median Oxford score of 2). Usually an increased LH and weakened PFM are associated with POP.

The LH is the opening between the levator ani muscles through which the urethra, vagina, and rectum pass. Contraction of the PR muscle narrows this opening and prohibits herniation of the pelvic organs. With weakening of the deep PFM and PR muscle, the LH widens and the connective tissue support system is placed under stress (Figure 38). If this tension is sustained over a period of time (see 2.5.1), it leads to failure of the connective tissue, and consequently POP and associated symptoms (Shobeiri *et al.* 2013:205-209; Clark *et al.* 2010:595:e; Vakili *et al.* 2005:1593).

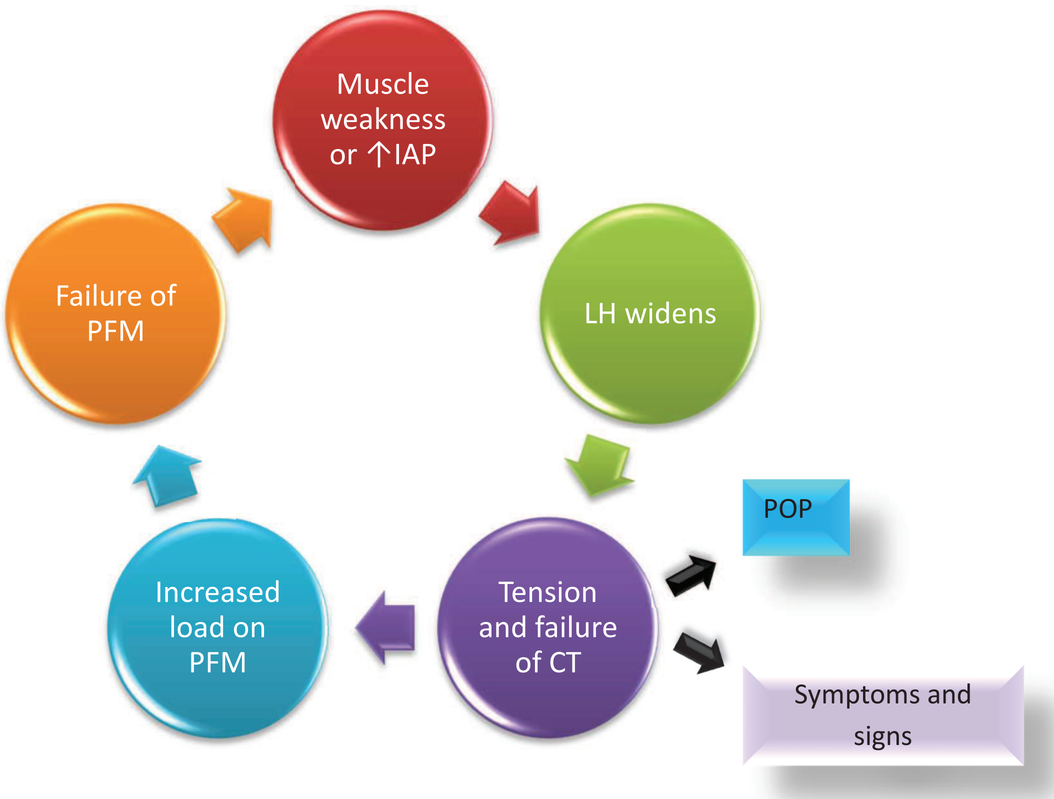


Figure 38. Pelvic organ prolapse due to muscle weakness and an increased levator hiatus.

Sustained lengthening of the muscle and fascia may lead to a loss of energy associated with the visco-elastic response of the tissue (see 2.3 and 2.5.1), and therefore strength of contraction and movement (Hunter 1998:4). Decreased strength and movement with contraction of the deep PFM and the PR muscle were found in this study. Approximately 72% of the sample (n=100) had a muscle strength of two or less on the PERFECT scale. A statistically significant positive correlation and medium effect size were found when the amount of movement was correlated with the PFM strength and EMG activity respectively (r_s=0.427 and r=0.427, p<0.001) (see Table 38).

Considering the above discussions on the deep PFM and the LH, increased strength of the PR muscle may lead to a decreased LH due to more overlap of actin and myosin which occurs in stronger muscles. Since muscle strength is defined in terms of the amount of muscle fibres stimulated, an increased activity would be expected in stronger muscles (Petty & Moore 2008:159-161). A correlation between the PFM strength and EMG activity in this study did reveal a significant positive correlation between these two variables (r_s=0.594, p<0.001) (see Table 38). This correlation differs from the finding of Quartly *et al.* (2010:313) who did not find PFM strength and activity to be correlated (r=0.21, p=0.290). However, in their study a perineometer was used for measurement of muscle strength and not the Oxford scale, which as previously discussed (see 2.9.2), can be influenced by variables such as IAP.

Correlation of the LH at rest with PFM strength and EMG activity did not reveal any significant correlation and only a small effect size respectively (see Table 38). An increased LH at rest has previously been associated with increased resting activity of the PFM (Stuge *et al.* 2012:154). The correlation made in this study between the LH and EMG activity was however based on the maximum EMG activity, and not the resting activity. Comparison is therefore difficult and interpretation of the EMG can be misleading if not interpreted correctly (also see 5.5).

The approach to analysis of EMG activity in this study was rather based on the comparison of the values obtained in each group over time. It will be discussed in 5.5. Discrepancy in strength between participants and controls exist, and therefore the baseline and sequential measurements should be taken as the reference voluntary contraction for the follow-up measurement in each group (Jull *et al.* 2015:171). If we only consider the baseline values of the whole group, it can be compared to findings such as those by Aukee *et al.* (2003:255). They found a mean EMG value of 17.0μV in incontinent patients (compared to the median of 17.4μV in this study), which may indicate activity in PFM with dysfunction. It is also less than the values found by other authors in asymptomatic patients (see Table 35). Although the populations were different, the close relationship between PFM dysfunction, POP and incontinence was discussed in 2.5.2.3. The interpretation of "under-activity" of the PFM is also supported by the fact that the participants mostly presented with symptoms and signs associated with under-activity/weakness. These symptoms and signs include urinary frequency and urgency, urinary seepage, vaginal prolapse, SUI, UUI, and obstructed defecation (Sapsford 2004:6). Symptoms such as voiding dysfunction, dyspareunia, obstructed defecation (anismus) and perineal pain are usually associated with over-activity of the PFM. Very few participants in our study complained of these symptoms pre-operatively (see Graph 3). The reason for incomplete emptying of the bladder and obstructive defecation, found in this study, could be related to a mechanical displacement of the pelvic organs due to a lack of fascial and muscle support mechanisms (Sapsford 2004:6).

Recent literature states that muscle strength is associated not only with the amount of fibres stimulated, but with an increase in the fibre/cell size when exposed to mechanical overload (Jull *et al.* 2015:71). Morkved *et al.* (2004:388) found a strong correlation between PFM thickness and strength (r=0.703) in women with and without PFM dysfunction, although these measurements were related to the superficial PFM. In this study we found no significant correlation between the thickness of the PR muscle and PFM strength (r_s=0.0003, p>0.5 on the left side and

$r_s=0.078$, $p>0.2$ on the right side). Differences in populations between these two studies must be considered with comparison. Despite the fact that their study involved measurement of the superficial PFM, the study by Morkved *et al.* (2004:388) was done on continent and incontinent pregnant women. These differences complicate comparison due to effects such as menopause and age that could also affect muscle thickness and strength. With increased age, there is an increase in the proportion of the type I fibres, and an associated decrease in the amount of type II fibres. It is the latter fibres that mainly produce rapid, fast contractions, which would be expected to result in hypertrophy of the muscle (Quartly *et al.* 2010:313).

Contrary to the above expectations from the literature, we found a significant positive correlation between age and PFM thickness and strength ($r=0.157$, $p<0.01$ and $r_s=0.958$, $P<0.001$ respectively). Only the correlation with PFM strength had a large effect size. The age of the participants was also significantly negatively correlated with the EMG of the PFM ($r=-0.245$, $p<0.02$). It would therefore seem that rather increased muscle thickness than the amount of fibres activated would explain the strength component in this scenario. Although it is usually the type II fibres which show an increased tendency towards hypertrophy, it is also observed in type I fibres (Jull *et al.* 2015:71). If we refer to the direct correlations made between PFM strength, endurance and thickness at baseline (see Table 38), it is interesting to note that those calculations indicated the opposite, namely a significant correlation between strength and EMG activity, but not between strength and PFM thickness.

Weaker muscles would be expected to have a smaller diameter, while stronger muscles would be expected to have a larger diameter due to the effect of hypertrophy. The diameter of the PR muscle (namely between 6 and 7mm, n=100) was approximately 3mm less than what has been found in asymptomatic patients by other authors (see Table 35). It is also less than the 7.3mm diameter found in a study by Dietz and colleagues (2005:583) on young, healthy patients using a similar technique as was used in this study. Several factors, such as the lack of exercise, advanced age, and menopausal status in our sample, could therefore be considered as reasons for the observed atrophy when compared to normal indicators. However, age was positively correlated with PFM strength and thickness in our study (r_s=0.958 and r=0.157 respectively). This contradicts the findings of Zhu *et al.* (2005:403) who found a significant association between decreasing diameter of the type I and II muscle fibres with increasing age and menopause.

The perineal body consists of fascia and contributions of the perineal muscles, including the pubococcygeus (PR) muscle (Coffey *et al.* 2002:799; Haderer *et al.* 2002:245). Decreased muscle strength and thickness/diameter of the PFM and PR muscle would hypothetically result in decreased thickness/diameter of the perineal body. However, a correlation between the PFM strength and the perineal body thickness in this study did not reveal any significant correlation (r_s=0.03, p>0.5). This would be suspected due to the PFM strength also not correlating with the muscle thickness of the PR muscle, as stated above. Contrary to the latter finding, the assumption of an increased PR muscle thickness correlating with the perineal body thickness was supported by this study. The positive correlation of the perineal body and the muscle thickness of the PR muscle on the left and the right respectively was r=0.443, p<0.001 and r=0.357, p<0.001. The muscle thickness in the pre-operative stage therefore did not appear to be associated with muscle strength, but should rather be attributed to other factors, such as age and menopausal changes.

It could be speculated that the participants (mostly peri- and post-menopausal), despite age-related degeneration and atrophy, may have decreased ligamentous thickness, as has been significantly related to menopause by Reay Jones *et al.* (2003:469). Comparing the findings of this study with normal values, as well as with values found in patients with POP, the thickness of the perineal body was much less in our study (5.1mm compared to 20-30mm). The study by DeLancey *et al.* (2007:298) found the perineal body to have a mean thickness of 32mm in patients with POP. MRI investigation was used in their study, which is difficult to compare with findings from two-dimensional US. Comparison of demographic findings between the two studies indicated very similar results and no other confounding factor could be identified as a reason for the difference in thickness.

The important implication of the compromised PFM function and morphology that we found in our study lies in the fact that it disrupts the integrity of the PFM support and control mechanisms. Disruption of support may occur at various levels of the motor control system and can occur in the urethrovesical, uterovaginal, or anorectal system (2.5.2), explaining the complex pathology and co-existence of symptoms and signs such as OAB, constipation, or incontinence (Sapsford 2001:620).

As an integral part of the motor control system and core stability, the PFM co-contract with the other core muscles, such as the abdominal muscles, to control IAP. However, the uniqueness of the PFM is that it remains the only muscle group that can provide structural support for the pelvic organs, prevent descent of the pelvic organs during increased IAP, or increase urethral closure pressure by its isolated contraction. A lack of co-contraction, or delayed or weak co-contraction of the PFM with the other core muscles, may thus lead to UI and faecal incontinence, cystocele, rectocele, enterocele, pain and sexual dysfunction (Bo 2004:454).

The importance of the coordinated contraction of the abdominal muscles, the PFM and the rest of the core muscles in the control of IAP and the above control systems was discussed in detail in 2.5.2. A dysfunction in any one of the components, such as the PFM, may lead to altered function in some of the other components, such as the abdominal muscles – or the other way around (Grewar & McLean 2008:376; Comerford *et al.* 2005:3-10).

A correlation between PFM strength and the Sahrmann level indicated a statistical significant positive correlation between these two variables, but with a small effect size (r_s=0.199, $p<0.05$). No statistical correlation was found between PFM strength and the related PBU measure (r_s=0.125, $p>0.5$). This could be expected, due to two different types of muscle function, namely global mobility versus local stability, being correlated in the latter correlation. It would be more meaningful to correlate PFM endurance and measurements with the PBU, due to both functions being related to slow motor unit recruitment. This correlation revealed a statistically significant positive correlation (r_s=0.280, $p<0.005$), though it had a small effect size.

More than half of the sample in this study (56%, n=100) were not able to activate the TrA muscle correctly, as measured with the PBU. This finding related to the scores on the Sahrmann scale, where 57% (n=100) of the sample were also not able to perform the level 1 test correctly, and was thus scored a zero. According to Comerford *et al.* (2005:xxviii), Sahrmann level 1 measures the low load rotational control of the abdominal muscles (namely the TrA and IO muscle function), whereas rotational strengthening under higher loads (where the external obliques muscles are activated) is measured by a level 2 and 3. Participants also scored very weak on the higher levels of the Sahrmann scale (0% scored a level 4 and 2% scored a level 5), indicating poor sagittal strength of the abdominal muscles (Comerford *et al.* 2005:xxix). Comparison of these values to a similar population is limited due to a lack of research. However, it is interesting to note that in a population of healthy, young sportswomen a low mean value of level 1.3 was recorded for lumbo-pelvic stability using a similar method to the one used in this study.

A correlation between the levels on the Sahrmann scale and the values obtained for measurement with the PBU, supported the above interpretation in our study. A significant positive correlation with a medium effect size was found between these two variables (r_s=0.516, $p<0.001$), indicating poor activation and low load rotational control of the abdominal muscles in our sample.

It seems that although the sample had poor strength, the function of the local muscle system (associated with low load rotational control and activation) was also problematic. It is especially the slow motor units, which are fatigue-resistant, that are associated with low load stability dysfunction. Poor endurance could also therefore be expected in these muscles. Seventy three percent of the sample (n=100) was not able to activate their abdominal muscles correctly for longer than ten seconds under low load.

EMG findings supported the findings by the Sahrmann scale and the PBU, indicating a very low median value of only 10.95μV, which can be related to the activation of the TrA and overlying IO muscles (Sapsford *et al.* 2008:1742). Although comparison of EMG data is difficult, as mentioned before, it is interesting to note the comparison of the findings of this study, with a very high value of 127.1μV, which was found in patients with low back pain with supposedly decreased activation of the deep abdominal muscles (Lima *et al.* 2012:392).

A correlation between the EMG measurement of the TrA/IO muscles with the PFM did not yield any statistically significant results ($r=0.962$, $p>0.05$). The problem with EMG measurement is that a muscle can react to changes by either increased activity due to redistribution in the muscle, or failure due to overuse. Inconsistent findings might therefore be suspected when EMG data is analysed (see 5.5). Findings in this study actually support the inconsistency in literature regarding the activation and co-activation of these two muscles (see 1.5). This discussion and findings on EMG may be an indication to rather use other measuring instruments in future research, correlating specific muscle functions, as we used in this study (see 3.6).

Based on the measurement of abdominal muscle and PFM function in this study, it seems that the participants did not demonstrate measurable morphological changes, increased strength or endurance in any of the muscle groups, which can be argued to be due to adaptation. They are characterised more by poor muscle function in both the abdominal muscle and PFM. It might be partially explained by their low levels of physical activity and exercise, which is not sufficient to cause overload and adaptation of muscle fibres (Jull *et al.* 2015:69-71). However, coordinated function of the core muscles are essential for optimal strength, stability and control of IAP, as indicated by several authors (Grewar & McLean 2008:375-376; Sapsford 2004:4). The concern would thus be the increased IAP and its consequences due to poor motor control during the physical activities of daily life, as well as after surgery, where muscle function may be even more affected due to the surgical procedures. Control of IAP and protection of the healing tissue against excessive strain is required for optimal recovery.

In the presence of weak or poor muscle control, IAP can be raised during strenuous work, bending, or lifting. These activities have been identified as risk factors for the development of POP and SUI (Bo 2004:457). Mens *et al.* (2006:631) found that daily activities such as laughing, straining and leg lifting increase IAP the most. Maximum vertical ground reaction forces reach three (3) to four (4) times body weight for sport activities, such as running, and even more in the case of muscle dysfunction. This repeated increase in IAP in the presence of poor muscle control can chronically damage the already weakened cardinal and uterosacral ligaments, the PFM and the connective tissue of the perineum leading to, or worsening, POP (Bo 2004:456-457).

In conclusion, the literature regarding the interaction between the PFM and the abdominal muscles has been biomechanically orientated. Studies focussed on the activation patterns and co-contraction of the PFM and abdominal muscles, with contradictory results. No study has reported on the clinical prevalence and muscle function of the PFM and the abdominal muscles, as described in this study in a population of women with POP. The literature states that the pathophysiology and etiology of POP remains unclear and under-investigated (Miedel *et al.* 2009:1089).

The findings of this study may therefore uniquely contribute to further assist in understanding this complex pathology. We found that the abdominal muscle function, as measured by the Sahrmann scale, EMG and PBU, was almost absent in our sample. Considering the role the abdominal muscles play in controlling IAP, and the significant correlations we found between different aspects of PFM and abdominal muscle function, our findings might have a significant clinical implication in addressing risk factors and symptoms in patients with POP. PFM and abdominal muscle function and control, factors such as emotional and cognitive aspects, learning strategies and co-morbidities (see 5.2 and 5.3) are all integrated into the further discussion to help explain the pathophysiology and rehabilitation of POP relating to an integrated neuro-musculoskeletal model.

5.5 PELVIC FLOOR REHABILITATION IN WOMEN UNDERGOING PELVIC FLOOR RECONSTRUCTIVE SURGERY

Using the literature available prior to this study and hypothesising on certain theories regarding neuro-musculoskeletal control, two different intervention programmes were compiled and compared in this RCT to investigate the outcomes on the muscle function and QOL identified in 5.2 to 5.4.

5.5.1 Comparison of groups at baseline and other confounding factors

This section, on the comparison of the groups, begins with a discussion on general variables within and between groups in order to guide the interpretation of the findings on the different exercise programmes. For reference purposes, the reader is reminded that group three was the control group, whereas group one and two were the intervention groups receiving PFMT and abdominal muscle training (group two), as well as PFMT alone (group one).

There were limited, but significant, differences between the three (3) groups regarding dependent and independent variables at baseline. This included variables such as BMI, muscle strength, previous surgery, birth history, physical activity, exposure to exercise therapy and PFMT that could influence the outcome of exercise programmes and symptomatic responses. The use of hormone replacement therapy and antidepressants did however differ significantly at baseline between group two and three.

Hormone replacement therapy and antidepressants may cause gastro-intestinal symptoms, urinary disorders, sexual dysfunction, and emotional/psychiatric effects as side-effects (Snyman 2012:4-14; 348-350). However, no significant differences were found between these two (2) groups regarding gastro-intestinal, urinary, sexual, or emotional/psychiatric symptoms at baseline. The difference in the use of hormone replacement therapy and antidepressants between these two (2) groups was therefore not expected to cause a meaningful confounding effect. However, some participants were prescribed hormone replacement therapy after surgery, which could have had an effect on the prevalence of the aforementioned symptoms post-operatively.

Nygaard *et al.* (2013:2072-2074) found both hormone replacement therapy and BMI not to be confounding factors in the symptomatic improvement of menopausal women in response to a PFMT programme. They investigated the effect of a PFMT programme in pre- and post-menopausal women with incontinence. The participants in their study received a home-based exercise programme, in addition to one-to-one contact sessions. The number of contact sessions and the intensity, frequency and volume of exercise were not reported.

In this study, both intervention groups had a median amount of four (4) contact sessions over a period of six (6) months, which was alternated with a home-based exercise programme between visits. This correlated with the previous studies investigating PFMT pre- and post-reconstructive surgery (as described here). The number of exercise contact sessions over a period of three (3) months equalled two (2) to three (3) sessions (Pauls *et al.* 2013:271; Jarvis *et al.* 2005:301), while eight (8) contact sessions over a period of nine (9) months were recorded in the study by Frawley *et al.* (2010:720). In all of these studies, the contact sessions were supplemented by home-based exercise programmes between visits.

Home-based exercise programmes can be a tool to encourage the patient to participate in her own learning by promoting self-confidence and self-efficacy. Although supervised treatment sessions remain the ideal situation to improve compliance, most health care systems allow only for a certain number of individual sessions due to cost implications and restricted resources. These sessions are sometimes structured close together at the beginning of the treatment phase to help with activation and facilitation of contractions. They then become more spread out when the patient is able to perform the correct contractions. In this phase specifically, home-based exercise programmes become more important for the sustainability, progression and maintenance of the programme (Hagen *et al.* 2014:803).

A study by Chuter, Janse de Jonge, Thompson and Callister (2015:3-4) found that supervised core stability exercises had significant better outcomes when compared to home-based exercise programmes and a control group. However, the group receiving home-based exercises performed better than the control group on the static stability tests. The association in the home-based group between self-reported compliance and change in outcome measures from pre-test to follow-up was generally low. They attributed it to the smaller change in outcomes in this group or overreporting of compliance. Their findings indicated that supervised sessions seem especially important for tasks that require a higher level of neuro-muscular control. Comparing the compliance in this study, the control group, who received no supervised sessions between assessments, reported better compliance at three (3) months than both intervention groups (72.4% versus approximately 60% in the intervention groups). This compliance, however, dropped at six (6) months follow-up with 20%, while the compliance in the intervention groups increased or remained the same. This decreased compliance in the control group was also evident in the number of participants who came for their six (6) month follow-up assessment (only 41% of the group at baseline), when compared to specifically group two (79% follow-up at six months), who received the intervention programme which required the highest level of neuromuscular control. It could be speculated that over time some level of adult development and learning might have taken place in the participants in group two who received constant input and motivation, leading to better compliance and self-efficacy.

As discussed in 5.2, a variety of factors can affect compliance to exercise programmes, which in turn makes it a challenge for the therapist to apply the correct adult learning strategy. Most participants (>60%, n=81) in our study tended to exercise rather regularly, which was comparable to results from similar studies. The study by Frawley *et al.* (2010:721) found 22% of participants to train daily, 23% occasionally, and 22% would exercise less than once a week. The rather high compliance in our study could be contributed to strategies to improve compliance, such as regular reminders sent via SMS, attending follow-up visits, and the completion of the training diary. As mentioned in the previous paragraph, it was interesting to note that the control group in our study had a slight tendency to better compliance than group one and two (see Tables 56 and 57), although it was not significant. It should be taken into account that the control group only received lifestyle advice and basic advice on when and how to contract their PFM during daily activities. The literature has indicated that patients are less likely to adhere to the more complex and time-consuming exercises in their exercise programme, as was the case of the two (2) intervention groups, (Escolar-Reina *et al.* 2010:6). Unlike group one and two, the control group did not have to complete a training diary, and double checking their adherence was therefore not possible.

However, the compliance to completion of the training diary by groups one and two differed quite significantly from the 71% return of exercise diaries which was found in the study by Frawley *et al.* (2010:721). Mostly, participants neglected to complete their diaries and also forgot to bring them along to their appointments. The researcher resorted to testing participants' memory of the exercises, by letting them demonstrate and reflect on the exercises. It was argued that participants, who did their exercises regularly, would remember the exercise and show it with ease to the researcher. Based on this reflection strategy, the researcher would then confirm the score allocated by the participant for compliance.

Compliance was also reflected in the follow-up rate. The follow-up rate after the baseline assessment for QOL was 98.8% at three (3) months and 91.4% at six (6) months post-operatively. The follow-up rate for physical assessment was 90.1% and 59.3% respectively at three (3) and six (6) months post-operatively.

The follow-up rate was considered substantially higher when compared to the findings of previous follow-up studies on conservative treatment in women undergoing surgery for POP. Weber *et al.* (2000:1611) found a follow-up rate of 28% at six (6) months post-operatively. A study by Barber *et al.* (2002:284) on QOL pre- and post-surgical repair had a response rate of 89% at three (3) months and 76% at six (6) months respectively. Comparing the results from the current study with previous studies, it seems good when compared to 76% lost to follow-up *without* treatment of POP, which was found in a low resource setting (Elege *et al.* 2015:800). The reasons for participants being lost to follow-up, especially in a low resource setting, vary from characteristics such as low economic status, educational level, as well as cultural characteristics that affect the perception of the disease (Elege *et al.* 2015:800). Contrary to this, the study by Barber *et al.* (2002:284) did not find any baseline characteristics or therapeutic intervention, such as type of reconstructive surgery, to affect the response rate. Although both studies were conducted in a clinic setting, the difference was that the latter population was based in a First World country, while the study by Elege *et al.* (2015:800) was done in a Third World country.

The type of reconstructive surgery performed in this study, however, had to be considered in regards to confounding factors other than the effect it could have on response rate, as discussed in the previous paragraph. Analysis indicated that the difference between groups regarding the surgery they received were not statistically significant. There was also no statistical significant difference between the three (3) groups at baseline regarding previous surgery received. Clinical relevance should still be considered. The type of surgery could be considered as a confounding factor when the participants (group one and two) entered stage two of the intervention. Although the type of surgery did not influence the type of exercises that the participants received initially, the effect of the healing process and differences in pain levels (especially immediately post-operative) on muscle activation/inhibition should be considered, as well as the rate of progression through the exercise programme.

A correlation of participants who had had previous reconstructive surgery with those who did not have a history of previous surgery indicated that the latter group had significantly weaker PFM function when compared to the group who had had previous surgery at baseline. The opposite was observed regarding the abdominal muscle function, which in general showed better function in those without previous reconstructive surgery. However, it was only the EMG measurement of the abdominal muscles which showed a significant difference from the group who had had previous surgery (see 4.6.2). This phenomenon may have several explanations.

The above findings necessitate an elaboration on the initial discussion of the concept of motor control as discussed in the first two (2) chapters of this report, to a more contemporary theory of sensorimotor changes in the presence of pain and/or injury. Sensorimotor control is an interaction between input (sensory), processing (CNS), and output (motor) mechanisms, which is influenced by emotions, experiences and environmental context (see 2.8.1). The sensory nerve ending, the sensory nerve fibre, the afferent synapses and interneurons, and the ascending tracts composes the sensory component. The processing component involves the spinal cord, brain stem, and cerebral cortex, while the motor component includes the efferent pathways (upper motor neuron, efferent synapses and interneurons, the descending tracts, the lower motor neuron and the motor end plates). These components must be integrated to control coordinated activation of the skeletal muscles. It is therefore clear that a discussion on pain and the healing process, according to this model, cannot be limited to the physical component only, but needs to consider how factors such as adult learning (cognitive aspects) and psychological state, as assessed by the QOL questionnaires, can influence this integrated process (Jull *et al.* 2015:53, 54, 320).

The physical component of trauma due to surgery, as a cause of sensorimotor dysfunction, may firstly be explained by peripheral effects such as inflammation and central mechanisms (knowledge, fear, emotional state), which can cause sensitisation. Secondly, trauma to the PFM and abdominal muscle/ligaments/fascia during surgery, for example muscular incisions and ligamentous attachment sites, may compromise the passive and active control, as well as the sensory function of the tissue in which they are located. Thirdly, these changes may change the control of movement at spinal level or higher centres (Jull *et al.* 2015:55).

The adaptations that take place in participants, in response to pain and mechanical/nociceptive stimulation, may differ from subtle to major changes with individual variation. These major changes in movement have specifically been associated with psychosocial factors such as fear avoidance and catastrophising. Participants may modify their movement to avoid specific movements, participation, or function. The aim of this adaptation is to unload the painful/injured tissue. Participants who received abdominal surgery would therefore rather tend to avoid movements involving activation and contraction of the abdominal muscles. Contrary to this, participants who received surgery via the vaginal approach would rather compensate by using the abdominal muscles or diaphragm for stability in an attempt to unload the surgical area (Jull *et al.* 2015:56).

Subtle changes for adaptation include redistribution of muscle activity within or between muscles to enhance stability, alter the distribution of load on the structures, or modify the direction of force. Reduced variability, unloading of a limb, reduced amplitude of force/movement, and increased motion at adjacent segments to compromise for the lack of movement at the injured/painful area are more examples of subtle adaptations that can occur (Jull *et al.* 2015:56). The possibility that adaptation strategies might obscure differences between the control and intervention groups, as well as changes in muscle function within groups, must therefore be considered when limited changes in outcomes are observed.

Regarding the redistribution of muscle activity, evidence indicates that it is specifically the deeper muscle, such as TrA and multifidus in the spinal region, which demonstrates reduced activation patterns in the presence of pain and injury. These changes will manifest as delayed activation during contraction, reduced activation, or replacement of tonic activation with bursts of phasic activity (Jull *et al.* 2015:57). Muscle activity may also be redistributed to a more proximal region (Jull *et al.* 2015:171).

Reduced redistribution of muscle activity in different regions of a muscle has been indicated in the presence of clinical pain and fatigue. Pain prevents muscle adaption of muscle activity during sustained or repetitive contractions. This could lead to overuse of the specific muscle region with accompanied fatigue which would be reflected in the EMG or other fatigue assessment (Jull *et al.* 2015:172). This could either be indicated as an increased EMG activity (in the case of increased contraction), or as a decreased EMG reading in the case of failure of the region due to overuse and fatigue. However, much more specific assessment of myoelectric manifestations is required to analyse fatigue with EMG. This include the analysis of mean or median power spectral frequencies, the signal amplitude estimates such as the average rectified value or root mean square, and muscle fibre conduction velocity which was beyond the scope of this study (Jull *et al.* 2015:170).

It could therefore be speculated that the TrA muscle might have had poorer activation immediately post-operatively, especially in participants who received surgery via the abdominal approach or in patients who experienced abdominal or lower back pain, although the latter had a very low prevalence in our study. This confounding factor could have led to a decrease in the expected outcomes of the patients in response to PFMT/core training as measured by the EMG or PBU. These participants could also present with a false positive (type II error) due to redistribution of muscle activity and the fact that phasic activity might increase in response to delayed tonic activity of the muscles. This would be reflected as a false improvement of the Sahrmann levels.

Causing a cycle of dysfunction and pain, sensorimotor dysfunction might again contribute to the development of secondary pain or injury. Other tissue could be overloaded due to the strategy of movement or muscle activation. Contrary to this, the muscles might be unable to meet or sustain the requirements of the task, while the inaccurate sensory information might lead to inaccurate control, or excessive/lack of movement variability. Redistribution of activity between muscles could even lead to disuse of specific muscles important in the integrated continence or pelvic organ support system (Jull *et al.* 2015:56). In the case of sustained nociceptive peripheral input, such as prolonged inflammation, it could continue to drive the post-operative pain, and maintain central sensitisation. In these cases, the maintained sensorimotor dysfunction might directly influence recovery and outcomes post-operatively due to a motor dysfunction of the integrated action between the PFM and abdominal muscles controlling IAP and continence (Jull *et al.* 2015:56). Factors such as maintained incontinence or recurrence of POP post-surgery could underpin reduced confidence, anxiety, or depression in participants, and therefore lead to an interaction between adapted motor behaviour and psychosocial issues (Jull *et al.* 2015:59). Examples of the latter effects on motor control in this study could relate to group one, who experienced significantly more UUI and incomplete emptying of the bladder at six (6) months post-operative when compared to the control group. The same could account for group two, who experienced significantly more problems with constipation, incomplete emptying of the bowels and an uncomfortable feeling in the pelvic region six (6) months post-operatively.

Other reasons (than pain, fatigue and injury response) for maintenance of sensorimotor dysfunction should also be investigated over a longer term. For example, when a participant recovers from her pain/incision later in the post-operative stage, it does not necessarily mean that the adaptation will return to its initial strategy. Changes in PFM or abdominal muscle capacity, fatigability, mobility, or in the functioning of sensory information in these areas post-operatively might preclude resolution of adaptation of the sensorimotor control (Jull *et al.* 2015:61). Findings in the control group in this study might be of value for interpretation in this regard, due to the fact that they were the only group not receiving specific intervention. If we look at the length of the LH of the control group, it either remained the same as its pre-operative state, or increased over time, indicating poorer muscle function (see Graphs 8 to 10). This was also reflected in the increased percentage of paradoxical movement that was observed in this group over time (see Graph 6). The EMG and endurance of the PFM in this group however appeared to have increased over time (see Graphs 14 to 16), maybe due to adaptation strategies to very poor abdominal muscle function (see Graphs 18 to 21), or due to a testing or demand effect that could have threatened internal validity.

Although the above changes were observed clinically, comparison to the intervention groups yielded limited statistical significant differences for possible reasons indicated in this section.

5.5.2 Pelvic floor muscle training – A comparison of different exercise programmes from a neuro-musculoskeletal point of view

Comparison of the findings from this study with the outcomes of three (3) previous studies investigating the effect of physiotherapy intervention pre-and post-pelvic floor reconstructive surgery were limited to subjective measurements such as QOL. Amongst the three (3) previous studies, the only muscle assessment done was EMG and manometry, which makes the findings of this study unique in the field.

Physical components investigated in this study included the measurement of the LH, movement, strength, endurance, activity and thickness of the PR and PFM, as well as measurements of the abdominal muscles with EMG, PBU and the Sahrmann scale. However, an increase in variables is usually accompanied by an increase in confounding factors, which poses a challenge for interpretation. A summary of the most statistical significant findings in the three (3) groups can be structured as follows.

Comparison of the absolute values per group at baseline, three (3) and six (6) months, yielded a statistical significant higher value in group two compared to group three for the amount of fast contractions (95% CI [1;6]). Group one also had a statistical significant lower EMG value of the TrA/ IO compared to both group two and three (see Tables 51 and 55). However, if we look at the median changes within each group, a different outcome was found. The most significant changes occurred in group one during the first three (3) months regarding PFM function in terms of improvement of the LH during Valsalva, increased thickness of the perineal body, and improved endurance as measured by the PERFECT scale. Group two also yielded a significant change from baseline to six (6) months regarding improved thickness of the perineal body (see Table 49). Regarding changes in abdominal muscle function, it was only group two who demonstrated a significant change (95% CI [1;3]) in the Sahrmann level at six (6) months follow-up. Comparing the changes between groups yielded a more significant improvement of the LH at rest in group one for the first three (3) months when compared to both other groups. Compared to group three, group two had better improvement in the amount of repetitions of the PFM at three (3) months (95% CI [1;4]) and the amount of fast contractions at six (6) months (95% CI [1;7]). Group two also had a significant improvement in the values of the PBU when compared to group three at six (6) months. It can therefore be speculated that group one yielded better results regarding localised PFM function, while group two had more significant improvement in PFM function compared to the control group. Group two seemed to yield more statistical significant improvement regarding abdominal muscle function compared to both group one and the control group (group three).

Regarding the subjective measurement of QOL, it was only group two who yielded a statistical significant improvement in the total P-QOL score compared to group one from baseline to three (3) months post-operative (95% CI [1.5;28.4]).

The studies by Pauls *et al.* (2013) and Frawley *et al.* (2010) did not find significant improvement in subjective measurements, while some of the studies did find physical improvement in EMG activity and manometry of the PFM respectively when compared to a control group (Pauls *et al.* 2013:271; Frawley *et al.* 2010:720; Jarvis *et al.* 2005:301) (Table 61). The study by Frawley *et al.* (2010:723) found a significant improvement in the treatment group regarding muscle strength and exercise frequency when compared to the control group. Jarvis *et al.* (2005:302) reported a significant increase in vaginal squeeze pressure compared to the control group. The intervention group in their study also significantly improved regarding complaints of urinary symptoms, diurnal frequency, and general QOL. Limitations and confounding factors identified in these studies were discussed in detail in 1.4. Table 61 summarises the main findings from these studies compared to the findings of similar variables in our study.

Table 61. Significant findings from studies investigating physiotherapy management in conjunction with reconstructive surgery.

STUDY	n	QUALITY OF LIFE	ACTIVITY OF PELVIC FLOOR MUSCLES	PELVIC FLOOR MUSCLE STRENGTH
Pauls *et al.* (2013)	49	No significant difference between groups (World Health Organisation Quality of Life-BREF).	**Significant lower resting tone** post-operatively in treatment group (surface EMG).	-
Frawley *et al.* (2010)	51	No significant difference between groups (UDI, IIQ, and AQOL).	-	**Statistical significant difference between groups** favouring treatment group (Oxford scale). No significant difference detected with manometry between groups.
Jarvis *et al.* (2005)	60	**Significant difference in QOL** favouring treatment group (questionnaire not specified).	-	Results for Oxford scale not reported, although it was used. **Significant difference between groups** with manometry.
Current study (2016)	81	**Significant improvement in treatment group** (motor control) at three months post-operative (P-QOL).	No significant differences within or between groups (surface EMG).	No significant differences within or between groups (Oxford scale).

UDI = Urinary Distress Inventory; IIQ = Incontinence Impact Questionnaire; AQOL = Assessment of Quality of Life; P-QOL = Prolapse Specific Quality of Life questionnaire; EMG = electromyography

The major concern regarding the previous studies was the fact that the PFMT programmes were not scientifically based, and according to current guidelines for training and motor control, despite increasing research in this field (Sapsford 2004:3). There was also a lack of physical assessment regarding muscle function and morphological changes in muscles in response to the intervention programmes. Substantial evidence indicates that motor learning is an integrated process that involves input, processing, and output mechanisms which requires a variety of physical, behavioural and environmental factors that need to be addressed during rehabilitation (Jull *et al.* 2015:62). Surgical procedures affect these factors even more, which could explain the poor outcome of this "isolated" approach to PFMT that has been investigated up to date.

Section 5.6.1 introduced the reader to the possible effects of post-surgical pain immediately post-operatively on sensorimotor control. In this section, we focus on the anatomical and functional effects of the surgery on the control mechanisms to relate it more specifically to the development of symptoms and signs associated with POP. As extensively discussed in 2.5, it is specifically the modifiable factors of the integrated continence system that could be affected by surgery. This includes the motor control system, the musculoskeletal factors, and behavioural factors (Grewar & McLean 2008:375-376). Firstly, surgery could cause a momentary loss of the anticipatory response of the stabiliser muscles, leading to a lack of control of IAP and thus the control mechanisms (Sapsford 2004:4). This initial dysfunctional effect on motor control might be an explanation for the median PFM strength that remained exactly the same from the pre-operative to three (3) months post-operative assessment (see 4.6.3). The affected tissue would have poorer function immediately post-operative when compared to pre-operative assessment, due to swelling and the normal inflammatory response. As the healing progressed, the tissue would regain some/all of its function, until reaching its pre-operative level. It could be argued that the load of the training given during this timeframe was below the level necessary for hypertrophy to occur in the muscle. Overloading during the first six (6) weeks could damage the healing structures. The muscle response for the remaining six (6) weeks (of the three month period) would rather be due to neural adaptation, than due to hypertrophy (Comerford *et al.* 2005:4-3), although a study by Partner *et al.* (2014:314) demonstrated increases in muscle thickness of the TrA muscle after only one session of training. The assumption of neural adaptation being responsible for the changes in muscle function was evident in the changes that occurred in the endurance and EMG readings of the muscles, rather than changes in the muscle strength and thickness (see 4.6.3). The only change in PFM strength was observed in group one at six (6) months, who received only PFMT (see 4.6.3). A reason for this could be that, compared to the motor control programme of group two, their exercise programme included isolated contractions of the PFM. According to the model of motor control, the latter type of exercises should result in improved mobility function of the muscle (see 2.8.1) which would result in localised increased muscle strength.

Secondly, disruption of the ligaments and fascia during surgery might have led to laxity (see 2.5.1). This laxity might continue for a few weeks as the healing process progresses through all its phases. Due to the interrelationship between the fascia, ligaments, pelvic organs and musculature, muscle function might be affected in such a manner that the anal/urethral tubes cannot open, leading to problems such as retention (Petros & Woodman 2008:35-37). These effects were specifically observed in the intervention groups who still had symptoms of UUI, incomplete emptying of the bladder, constipation, and incomplete emptying of the bowels six (6) months post-operative. It should be considered that relatively more cases of rectocele repair were performed in the control group (although not statistically significant compared to the other groups), which might have contributed to them having less complaints of bowel symptoms post-operatively compared to the other two (2) groups (see 4.6.2). Also, according to the literature reconstructive surgery might lead to significant improvement in urgency, frequency, and UUI, but it might also result in the development of new urinary symptoms after surgery (De Boer *et al.* 2010:35; Maher *et al.* 2007:1). A study by Cronje and De Beer (2007:87) indicated no change in urinary nor bowel symptoms post-operatively.

Surgery may provide immediate relief of symptoms such as OAB and defecation problems due to restoration of the anatomical position of the pelvic organs, which might explain the limited differences regarding symptoms between the groups at three (3) months post-operative and the improvement observed in the control group. Restoration of the anatomical position also eliminated the strain put on the levator ani muscle by the descended pelvic organs. Surgery might therefore lead to improved (reduced) muscle length, and thus muscle strength of the PFM immediately post-operative, which might be observed in measurement of the LH or IAP (Clark *et al.* 2010:595e17). This could also be an explanation for the good PFM muscle function found in participants with a history of previous reconstructive surgery, when compared to the group without such a history (see 4.6.2 and Table 42).

Limited improvement in the LH at rest were noticed in group one during the six (6) month period, while group two and three showed an increase in LH at rest. It was only group one who showed improvement with the LH length during contraction (see Graph 10). This might again be related to the assumed increase in mobility function and strength of the local PFM in this group. Reasons for increased LH length in group two might be the slight increase in IAP due to their much more functional abdominal muscles at three (3) and six (6) months, which would put more strain on the PFM (Thompson *et al*. 2005:148). Especially immediately post-operative, the slightest increase in IAP might cause a load that is just above the threshold of the PFM strength at that stage of healing, leading to fatigue and poor function. This reasoning might be supported by the fact that control of the LH at rest improved again at six (6) months in group two, maybe due to improved motor control and therefore improved control of IAP. Regarding the control group, increased IAP due to the absence of abdominal muscle function, might have caused strain and overload on the PFM leading to poor function and control of the LH.

Different theories exist regarding the control of IAP by the abdominal muscles and PFM. Shafik *et al.* (2003:309) stated that IAP activated specifically the type II fibres. If considered that a Valsalva manoeuver increased the IAP more than when contracting the TrA and IO muscles (Mens *et al.* 2006:628,633), it could be speculated that there was a chance of finding reasonable muscle strength of the PFM in the presence of weak local abdominal stabilisers. This was observed in several instances in this study. Correlation of age with PFM strength in our study showed a statistical significant positive correlation (r_s=0.958, $p<0.001$), contrary to the findings of previous studies (Zhu *et al.* 2005:403). It was also reflected in the positive correlation between the Sahrmann levels and PFM strength that this study found pre-operatively. This was also observed during the intervention period in this study where groups who did not improve in their local abdominal stabiliser muscle function (PBU), still maintained a reasonable PFM strength. However, sustained load on the PFM due to increased IAP might eventually lead to failure of the PFM. Hodges *et al.* (2007:366-368) proposed a second theory, namely that the PFM responded to the phase where the abdominal muscles were active, instead of the breathing phase or changes in IAP. Considering both theories, they were actually interrelated due to the abdominal muscles which could modify IAP, which in turn could modify PFM behaviour. An association would thus be expected between the abdominal muscle function and PFM function.

Group two in this study, in particular, demonstrated clinical improvement in PFM endurance (as measured by the EMG), together with improvement of the local abdominal stabiliser muscle function (measured by PBU and EMG). This observation was despite the finding that group two received relatively more abdominal surgical procedures when compared to the other two (2) groups (see 4.6.2 and Graph 19). This could mean that these participants would have better control of their IAP during daily activities, and therefore decreased risk for fatigue of the PFM, especially if the PFM also demonstrated better endurance.

An effective rehabilitation programme, addressing all aspects that could influence muscle function and IAP, is important if the aim is to help prevent recurrence of POP, optimise the recovery process, and ultimately improve QOL. A retrospective study on surgical failure in an American population post-reconstructive surgery found a recurrence rate of 34.6% within a five (5) month follow-up period (n=451). The study found an association between an increased genital hiatus (≥5cm) and recurrence of prolapse, while increased levator contraction (as measured with the Oxford scale) was associated with a decreased re-operation rate (Vakili *et al.* 2005:1592-1595).

As mentioned, it was especially group one in this study who demonstrated most improvement in the LH length and PFM strength, when compared to the other groups (see 4.6.3). This finding correlates with a more specific observational, morphological study by Bo *et al.* (2009:29), who found that the LH decreased significantly more with contraction of the PFM alone, when compared to PFM and TrA muscle co-contraction. Comparison of their results to this study is limited due to the fact that their participants did not receive any training/intervention in TrA activation prior to measurement. Their measurements were also done in a standing position compared to the supine position in this study. In standing, the IAP is increased due to visceral weight and can trigger the straining-levator reflex, causing an improved response of contraction in the PFM (Shafik *et al.* 2003:311-313). However, it is studies similar to Bo *et al.* (2009:29) and Vakili *et al.* (2005:1592-1595) that are needed to find evidence and solutions in order to improve recovery and help decrease re-operation rates after pelvic floor reconstructive surgery.

From this study's results, it would appear that isolated PFMT (group one) had a good effect on local PFM function, such as LH length, perineal body thickness, PFM strength and endurance, whereas the combination of PFMT and abdominal muscle training had better outcomes regarding endurance capacity and activation of the abdominal muscles, associated symptoms and signs, and QOL. Considering that PFM strength, thickness, movement (causing LH narrowing) and even endurance could involve functioning of both the type I and II fibres of the PFM, it would seem likely that these functions would respond better to isolated muscle exercise, as in group one, than when compared to a core stability programme as in group two. These findings are supported by the improvement in a more stability type of function that were more observed in group two, which would be expected in response to a core stability programme targeting these functions. Limited statistical significant differences between group one and two regarding changes in abdominal muscle function could be related to the possibility of an involuntary co-activation of the abdominal muscles in group one in response to activation of the PFM (Sapsford *et al.* 2001:31-42). This study also supported the related hypothesis by finding a statistical significant positive correlation between PFM endurance and abdominal muscle function as measured by the PBU (see 5.4). The additional benefits of a core stability programme (especially in the long term) regarding control of IAP, improvement in and prevention of lower back and pelvic pain, and additional improvement in symptoms and signs have to be considered with an improved local muscle response also resulting in beneficial effects (Thompson *et al.* 2006a:268-269,273-275; Bo *et al.* 2003:587; Sapsford *et al.* 2001:31-42).

Viewed from a primary health care perspective, pre- and post-operative management should emphasise recovery, and eventually prevention of recurrence of POP. The primary aim of PFM rehabilitation as a conservative treatment, and in conjunction with reconstructive surgery, might differ slightly. Conservative management would concentrate more on treating and preventing worsening of the prolapse by shifting the emphasis to certain components of the rehabilitation programme. Due to the limited research on rehabilitation for POP in conjunction with pelvic floor reconstructive surgery, studies done on rehabilitation as a conservative management for POP were also consulted. However, the same problems arose as with studies done on rehabilitation in conjunction with pelvic floor reconstructive surgery.

Firstly, only one randomised controlled trial by Bo (2006:263) was identified to be supportive of the effect of PFMT in the treatment of POP. A Cochrane review in 2009 by Hagen *et al.* found only three randomised trials of conservative treatment to be insufficient for the drawing of any conclusions (Hagen *et al.* 2009:2). In 2010, Braekken *et al.* published the results from a randomised controlled trial finding significant improvement in pelvic organ position, symptoms, and muscle strength and endurance in a group of patients who received PFMT. Similar to other studies, exercise programmes were limited to the investigation of strength training of the PFM only (Braekken *et al.* 2010:170.e2), despite the fact that indications were that strength and endurance were both important factors in the treatment and prevention of POP and incontinence (Grewar *et al.* 2008:380-381; Sapsford 2004:5).

Secondly, the importance of the morphological change and hypertrophy in the muscle for support of the pelvic organs were also emphasised (Bo 2006:266), but no study investigated or evaluated these changes in the PFM in response to exercise. In our study, group two demonstrated better improvement in the thickness of the PR muscle, while group one showed better improvement in the thickness of the perineal body at three (3) months. As discussed in the literature review, the perineal body is a crucial structure where IAP passes through (see 2.5.2). It is also known that contraction of the local stabilisers might cause a slight increase in IAP, which could cause some strain on the perineal body and adversely affect improvement in its structure. However, other factors such as the formation of connective tissue in response to healing could also lead to an increased diameter. Prevention of the formation of excessive connective tissue post-operatively was however a desired effect for optimal healing and could be achieved in response to exercise. Due to the PFM strength that did not increase from pre-operative assessment to three (3) months post-operative assessment, it was unlikely that the increase in the thickness of the perineal body was due to muscle hypertrophy. The same argument could be raised for the increased thickness that was observed in the PR muscle in group two at three months post-operative.

Thirdly, although guidelines indicate the importance of motor control, lifestyle changes and behavioural therapy in the treatment of POP and incontinence (Grewar & McLean 2008:378-381; Sapsford 2004:4, 7), not a single study investigating the effects of PFM rehabilitation included all of these aspects. Outcomes were mainly based on subjective questionnaires, neglecting the physical assessment of the musculature. The endurance components of the PFM and the abdominal muscles, in particular, showed a positive response to motor control training in this study, when compared to group one and the control group. The amount of repetitions of the PFM, as measured by the Oxford scale, as well as the amount of fast contractions improved significantly in group two compared to the control group from baseline to three and six months respectively (95% CI [1;4] and [1;7]). The same accounted for the improvement in the amount of repetitions as measured by the PBU from baseline to six months (95% CI [1;9]). This finding was also supported by the significant positive correlation (r_s=0.280, p<0.005) found pre-operatively between PFM endurance and PBU measurements.

A systematic review by Bo and Herbert (2013:162-163), investigating evidence on PFMT, found three (3) studies that included abdominal muscle exercises in conjunction with PFMT in the conservative treatment of UI. The dilemma is that different aspects of muscle function are important for POP and continence respectively (namely strength versus endurance), making the comparison of exercise regimes and outcomes in different populations difficult. The type of abdominal exercises was also not based on contemporary evidence for motor control training, neither was there a differentiation in the type of muscle function when the outcome was measured. The evidence provided by these three (3) studies was thus insufficient to draw any conclusions due to these and other methodological limitations identified by the reviewer.

The purpose of our analysis and other studies should be to find the most effective combination of exercises and rehabilitation in order to prevent, cure, promote and improve the symptoms and signs of POP in order to improve the main outcome of QOL. But for that we need substantial evidence on muscle function and how it affects each of the related factors (Figure 39).

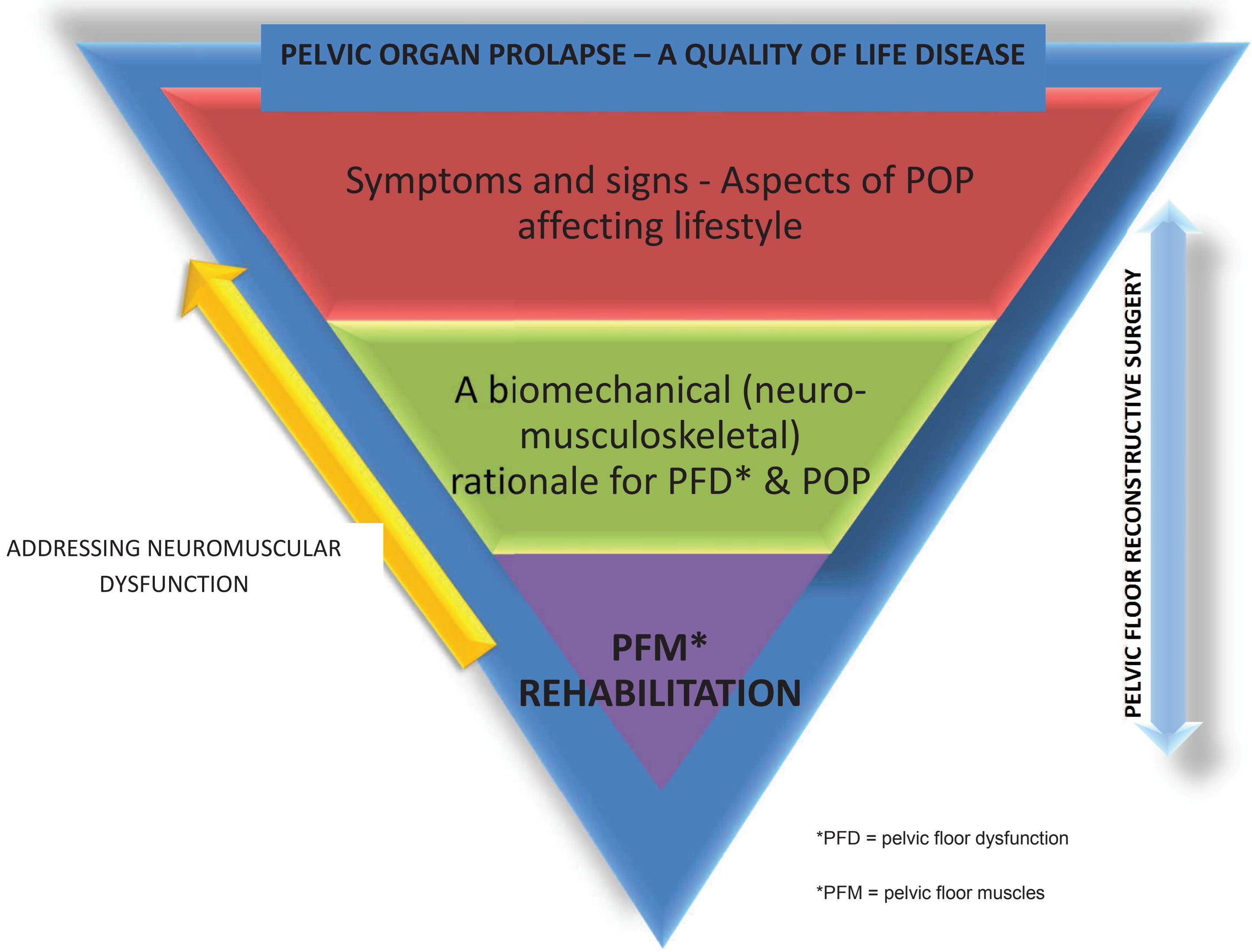


Figure 39. Establishing the role of pelvic floor muscle rehabilitation on muscle function, symptoms and signs, and quality of life.

5.5.3 Pelvic floor muscle training – A comparison of different exercise programmes in regards to the effect on quality of life

As previously mentioned, it is mainly the effect of the symptoms and signs that is responsible for the patient's decreased QOL. Should intervention programmes be able to improve muscle function, motor control and control of IAP contributing to improve these symptoms and signs, an increase in QOL might be postulated (Figure 39).

The group receiving motor control training and PFMT (group two) in this study demonstrated a marked improvement in total QOL over a six (6) month period. The median improvement was -30.8641975 in the total P-QOL score (IQ range [-53.5493827-(-12.0370370)]). The speculation raised in 5.5.2 regarding motor control training improving control of IAP and therefore symptoms and signs, might be a contributing factor to this improvement in QOL in this group. Although lower back and pelvic pain did not seem to be a significant factor to influence any outcomes in this study, it should be mentioned that it was group two who showed a marked improvement in the moderate pelvic pain and low back pain they complained of pre-operatively. This could be due to the improvement they showed in abdominal muscle function (PBU) post-operatively. Correction of motor patterns and performance could induce changes in motor behaviour and normal motion, and thereby improve lumbar/sacro-iliac joint function, neural control and muscle tissue (see 2.5.2.2). The effects of improved local stability on lower back and pelvic pain, and therefore also psychological state by addressing fear avoidance beliefs, anxiety, and depression for example, have been reported by several authors in the literature (Bystrom *et al.* 2013:E350; Mens *et al.* 2002:627-634; Hodges & Gandevia 2000:972).

At three (3) months, group one reported statistically significant more complaints of tiredness and the use of preventative measures for symptoms of POP when compared to group two. Referring to group two, a comprehensive exercise programme might have helped to improve energy levels and psychological state, together with the improved symptoms themselves (Savoy & Penckofer 2015:360-361). The improvement might also have had a motivating effect on the participant and therefore sensori-motor control yielded in the good follow-up rate in this group at six (6) months.

The bother of symptoms in group one continued and was evident at the six (6) month follow-up in the form of UUI and incomplete emptying when compared to the control group. As discussed above, a lack of motor control and IAP may contribute to dysfunction in the continence mechanism. However, this would not make sense in this case as group three had poorer abdominal and PFM function when compared to group one. Other reasons, such as medication (for example hormone replacement therapy) prescribed post-operatively, could also have affected urinary symptoms.

The other significant difference was regarding bowel symptoms, such as constipation, and incomplete emptying, that group three complained less of when compared to the intervention groups at six (6) months. This was also evident in their increased frequency of defecation, compared to the intervention groups. However, findings such as poorer abdominal muscle control and increased paradoxical movement of the PFM in this group might be responsible for this finding.

As mentioned in 5.2, interpretation of QOL results remain problematic due to a lack of normative data in South Africa, as well studies using a variety of QOL measuring instruments. The latter statement is supported by a systematic review investigating the effect of surgery, surgery in conjunction with PFMT, or only conservative treatment with PFMT, on QOL in women with POP. The review found that patients receiving surgery for POP indicated significant improvement in especially the social, physical and mental components of QOL. Surgery involving mesh repair was emphasised as having a superior effect on QOL when compared to other type of surgical repairs. The improvement after surgery may be contributed to the immediate mechanical effect of the surgery on symptoms such as UI, faecal incontinence, dyspareunia, and pelvic pain. An individual study on PFMT in conjunction with surgery found a significantly better effect on QOL, when compared to surgical intervention alone, while another study did not correlate with these findings (see 1.4). Meta-analysis was limited to two studies in total due to the lack of homogeneity and a limited number of trials qualifying for inclusion. The trials included for meta-analysis were on conservative treatment of POP alone, but no significant difference could be found in QOL measurements between baseline and 16 week follow-up using the International Consultation on Incontinence Questionnaire (ICIQ) (Doaee *et al.* 2014:161). However, it must be noted that these trials did not use the P-QOL for measurement of QOL, but an incontinence questionnaire. They also did not include PFMT, as applied in our or other comparable studies. The Colpexin sphere was used for PFMT (Doaee *et al.* 2014:160).

A study by Stüpp, Resende, Oliveira, Castro, Girão and Sartori (2011:6), investigating the effect of a home-based exercise programme in women with stage II POP on QOL, as measured by the P-QOL, found a significant improvement in the role, physical, personal, prolapse impact and severity domains over a 14 week period ($p<0.05$). A study by Sivaslioglu, Unlubilgin and Dolen (2008:470), investigating the pre- and post-operative results on QOL (by means of the P-QOL) after mesh surgery for cystocele, also found a significant improvement in the total mean score. However, it has been recommended that the total score must not be taken as the value for interpretation, but rather the scores of the individual domains (G.A. Digesu, personal communication, 2011). Individual domains were not reported in their research (Sivaslioglu *et al.* 2008:470). The improvement in QOL after POP surgery, as measured by the P-QOL, was also supported by the findings of Feldner, Castro, Cipolotti, Delroy, Sartori and Girao (2011:1061). They found a significant improvement in all the domains of the P-QOL, apart from the general health domain, after anterior vaginal wall repair.

Only one study investigating PFMT as an adjunct to surgery used the P-QOL for outcome measurement (Jarvis *et al.* 2005:301). Although it found a significant improvement in the treatment group versus the control group in QOL after three (3) months ($p<0.0001$), the domains of improvement were also not specified (Jarvis *et al.* 2005:302).

Regarding general QOL measurement, a limited number of studies included these measures as a measurement of QOL (Doaee *et al.* 2014:156). Only one study (Pauls *et al.* 2013:272) on PFMT (in conjunction) after reconstructive surgery included such a measure. It found a positive Pearson correlation between EMG resting tone and the physical domain on the World Health Organisation Quality of Life-BREF. No significant differences were found between the intervention and control groups.

Ward and Hilton (2008:231) investigated the effect of surgery on QOL using the SF-36 as a general health survey outcome. They compared the outcomes of tension-free vaginal tape and colposuspension. No significant change from baseline was observed in any domain of the SF-36 over a five (5) year period from pre- to post-operative (Ward & Hilton 2008:231).

However, the findings from the systematic review by Doaee *et al.* (2014), and also individual studies as discussed above, indicated that improvement in QOL could be suspected after surgery and in some instances after conservative treatment (the latter depending on the stage of the POP), while the effect of exercise programmes in conjunction with surgery still needed some more investigation. These findings were supported by this study, indicating good improvement, but with limited statistical significant differences between the intervention and control groups.

Sections 1.4 and 1.5 highlighted the limitations and lack in research regarding PFMT as a conservative treatment and in conjunction with pelvic floor reconstructive surgery. Recommendations for improvement on the research methodology used in this study would be beneficial to improve the quality of the results of future studies done on conservative treatment for POP.

The next section reflects on limitations identified in the methodology and discussion chapters and poses suggestions for improvement.

5.6 LIMITATIONS

This randomised, double blind, controlled clinical trial was the first to investigate abdominal and PFM exercise programmes, compared to a control group in a population of women with POP scheduled for PF reconstructive surgery. The choice of study design contributed to the level of evidence the researcher was aiming for. However, methodological limitations were identified throughout the research process and must be considered in order to draw valid conclusions.

5.6.1 Limitations regarding the study sample and population

Reflecting upon the whole research process, a critical discussion of the sample follows firstly. Strengths included randomisation and blind, concealed allocation of participants to the experimental and control groups. This helped to limit performance, attrition, and detection bias (The Cochrane Collaboration: online 2016). Randomisation ensured similarity at baseline regarding the demographic variables. However, group sizes were limited to between 20 and 30 participants per group. Although this fell within the suggested power calculations of previous studies and also correlated with the sample sizes of similar previous research, larger samples might yield more statistical and clinical significant results and provide for the loss to follow-up (Frawley *et al.* 2010:722-723).

Participants were lost for similar reasons across the groups and the missing data regarding physical assessments were balanced in numbers across the groups. Missing data was handled with an intention-to-treat analysis (ITT) to lower the risk of bias. ITT reflects the practical and clinical scenario, preserves the sample size, and limits inferences based on ad hoc or arbitrary subgroups of patients in the trial. ITT therefore helps to limit type I errors and allows for the greatest generalisability (Gupta 2011:110-111).

ITT helped to address the limitation of the relative small sample sizes and the effect it could have on generalisability. The sample size was the result of poor referral rates. Referral rates were not problematic, due to the continuous involvement of the researcher and one surgeon in the medical assessment. Recruitment rates however were lower than expected, which could have affected the generalisability of the results. This might be attributed to the strict inclusion and exclusion criteria, as well as matching of participants, which were necessary to limit variables between groups and thus type II errors.

A problem encountered was the amount of variables that could affect the outcome, versus the small group size. Although matching provided a solution for some of these variables, not all variables could be accounted for by this method due to the small sample. The heterogeneity of surgical procedures among the groups had to be considered in regards to the effect it could have on the outcomes and motor control system. This issue has been discussed comprehensively in 5.5. However, groups were similar at baseline regarding this variable, limiting the confounding effects on the results. Internal validity also has to be weighed up against external validity. In a real-life situation, patients are referred from different surgeons using different surgical procedures and techniques. A model for rehabilitation should make provision for heterogeneity to be effective (Gupta 2011:110-111).

Another reason for low recruitment rates could be the relatively small population size in a restricted area, if it is considered that approximately 40% of women present with POP, of which only 11% may need surgery (Cronje 2011: online; Vakili *et al.* 2005:1592). In a primary health care setting where limited resources and transport are concerns, the question can also be raised as to how many symptomatic women (from the estimated 40%) do reach the clinic for intervention.

As stated in 5.5, socio-economic circumstances and lack of transport were two of the main reasons for loss to follow-up. Specific efforts were made by the researcher to remind participants about follow-up visits and to make it as convenient as possible for them to attend. This helped to prevent poor follow-up rates. The study yielded a follow-up rate which was better/similar to previous studies (see 5.5).

5.6.2 Limitations regarding the intervention

Follow-up rates relate closely to intervention parameters and number of treatment sessions, which was designed as patient-specific. The ideal number of contact sessions needed by each participant to improve adherence and motivation to lead to optimal outcomes were therefore not accomplished under all circumstances. In the initial phases of intervention, participants might need more sessions in order to help with facilitation and activation of inhibited muscle contractions. These factors might have been critical in the intervention yielding some non-significant results.

Participants did not seem to identify with the completion of a training diary as a method of motivation and adherence. There was an approximate 90% non-return of exercise diaries. This related poorly to previous research and adversely affected the calculation of exercise adherence in this study. The reasons might include that participants found it time-consuming and that it did not relate to the previous educational experiences of the participants. Most participants were unemployed and from a lower educational and social background. Job satisfaction, self-esteem, and QOL are internal motivators, which if not present, may lead to poor adherence (Massyn 2009:26; Fidishun 2000:15). Adaptation of the exercise diary to a calendar, which can be ticked off every day, might be a more effective strategy to advocate self-efficacy in these participants than completion of an exercise diary (McGrane *et al.* 2015:10; Basset 2012:1000e124). Use of an alternative adult learning theory, such as reflection during follow-up consultations, could also be proposed.

Contrary to the response to training diaries, participants responded very well to SMS messages as reminders to do their home exercises. Reasons could include that the use of cellular telephones formed part of the participants' everyday activities and required no effort to respond to. The use of social media should be explored as a motivational strategy to improve exercise adherence.

The control group attended no contact sessions and received no home-based exercise programme which, according to the principles underlying andragogy, could lead to decreased compliance and motivation (Plack & Driscoll 2011:221; Escolar-Reina *et al.* 2010:6). This was indicated by the group's 20% drop in exercise adherence at six (6) months. However, bound by ethical conduct, participants received an information leaflet regarding lifestyle factors (Addendum 3). This leaflet was similar in all three (3) groups. Depending on the health behaviour of the participant, it might have led to self-directed PFMT or motor control training causing a confounding effect in the control group. Similar reasoning could be applied to the fact that prior measurement of all the muscles (PFM and abdominal muscles) might have led to a learning effect in the groups who were not receiving specific muscle training. However, the same assessors were used during all follow-up measurements and were blind in regards to group allocation. Similar instructions were given to all groups, limiting bias regarding a possible learning effect (Frawley *et al.* 2010:724).

Contrary to the above statement, attempts to teach participants in the intervention groups the correct PFM and abdominal muscle contractions, still led to incorrect contractions. Bo (2004:454) reported on different studies in different countries that found that more than 30% of women were unable to do a correct PFM contraction, even after proper instruction during their first consultation. Women tended to strain, especially when performing the exercises, instead of contracting the muscles (Bo 2004:454). This was evident in the US measurement where 21% of the women in the study (pre-operatively during their first consultation) had a paradoxical movement of the PR muscle when instructed to contract the muscle. It is specifically in this group of participants that regular follow-up visits were of greater importance as a confounding factor.

Participants with paradoxical movement and a low/zero value on the PERFECT scale are the individuals who needed more methods of facilitation and adjunctive therapy, such as NES in the case of an absent or weak PFM contraction. Adjunctive therapy reflects normal clinical and ethical practice, and coinciding with the objective of our study to investigate rehabilitation and not only isolated PFMT, it was included as a management option for these participants. Should the aim be to only investigate isolated, non-supervised/home-based exercise programmes, adjunctive therapy would need to be excluded from intervention programmes (Frawley *et al.* 2010:724).

The surgical intervention that the participants in our study received was also a reason for inclusion of adjunctive therapy. Provision had to be made for possible adverse effects/complications that surgery could have on muscle activation, function or strength. The effect of pain and inflammation on muscle function and motor control is well-known (see 2.4 and 2.5.1), and would need to be addressed in the case of an effective rehabilitation programme and optimal recovery.

The opposite effect of the surgical intervention, namely the improvement in participants due to the intervention, might have been of such magnitude that it could obscure improvement in symptoms and signs due to physiotherapeutic intervention. Neuro-musculoskeletal physiotherapy, especially in the early post-operative stages, has to be limited to protect injured tissue and optimise the healing process (Hunter 1994:16). However, this would only be an explanation for the immediate improvement in QOL and symptom severity. The assessment of muscle function, morphology and motor control made it possible to assess the effects of the surgical procedure and intervention independently due to inclusion of a control group. This has been a major limitation in previous studies which did not include physical and objective measures of muscle function.

Limited changes from three (3) to six (6) months post-operative might be attributed to several factors. The magnitude of change in symptom severity from pre-operative to three months post-operative due to surgery might have obscured the detection of further significant changes due to conservative intervention. However, again this would only be applicable for the QOL measures. Improvement in muscle function should become more prominent from three to six (6) months as the healing process progresses and exercise intensity can be increased. This is where this study differs from studies on the conservative treatment of POP. Studies investigating the conservative treatment of POP in patients not scheduled for reconstructive surgery would be able to progress quicker to a higher intensity and volume of exercise due to the absence of the healing process. Results from such studies might therefore yield more significant findings than when comparing it with a population undergoing pelvic floor reconstructive surgery.

The ideal situation would thus be for a longer follow-up period, for example between one and two (2) years, to reach the optimal potential effect of a complete rehabilitation programme. Patients undergoing pelvic floor reconstructive surgery might suffer from associated surgical symptoms up to one year post-operatively, which limits optimal functional return. Culligan *et al.* (2002:1478) found surgical failure to occur mostly in the first six (6) months after abdominal sacral colpopexy surgery, but recurrence of POP could occur up to two (2) years or longer after initial surgical repair. There is however a lack of scientific evidence regarding the long-term subjective and objective cure rates (Culligan *et al.* 2002:1473). As explained earlier, follow-up rate would pose a challenge if such a study is undertaken. In a long term study, variable factors regarding measurement would also be confounding, which could be controlled in a shorter term study. Using the same surgeon, assessors or therapist in the long term might not be feasible and could introduce bias and inter-rater reliability issues due to research mortality.

5.6.3 Limitations regarding the measuring instruments

Despite the reliability issues of measuring instruments, this study identified a few other problems in regards to this issue. Firstly, a problem encountered was to select a reliable, objective and practical measure of general health outcome, which is vital for the assessment of health levels and changes in health in a low resource and primary health care system in South Africa (Jenkinson, Coulter & Wright 1993:1437). With the proposal of a holistic approach to treatment and prevention of POP in this study's population, this would be an important issue to address in future research (Frempong-Ainguah & Hill 2014:8-9; Hopman *et al.* 2000:270).

Secondly, statistics regarding health status in developing countries are scarce and often incomplete. General health questionnaires are also more applicable to and have mainly been standardised for developed countries, while such approaches have not been implemented in African or developing countries (Frempong-Ainguah & Hill 2014:8-9).

The above literature supports the argument and findings regarding the reliability of the Afrikaans version of the SF-36, as found in this study (see 5.2). The SF-36 was chosen as it is known for its use across age, disease, and treatment group. POP being a complex pathology, with some unknown etiology, the SF-36 was deemed a suitable questionnaire to detect a variety of health and functional factors in our population. The categorisation of the domains of the SF-36 and the P-QOL showed similarities which would have benefited the interpretation of the validity of the findings in QOL. Table 62 indicates the similarity in domains of the disease-specific and general QOL questionnaires. It could also mean that exclusion of the analysis of the SF-36 for interpretation would still yield a comprehensive analysis of all aspects of QOL, covered by analysis of the P-QOL.

Table 62. Comparison of the domains of the SF-36 and the P-QOL.

P-QOL DOMAINS	SF-36 DOMAINS
General health perceptions	General health
Prolapse impact*	-
Role limitations	Role-Physical
Physical limitations	Physical functioning
Social limitations	Social functioning
Personal relationships*	-
Emotions	Role emotional and Mental Health
Sleep/energy	Vitality
Severity measures*	-
-	Bodily pain

*Indicates disease-specific domains

A small pilot study, as included in our analysis, is insufficient to determine the true reliability and validity of the SF-36 in a South African population. A full-scale validation and standardisation of such a questionnaire is imperative if reliable results are to be obtained to base management strategies and outcomes upon (Hopman *et al.* 2000:270). A lack of normative data complicates the choice and implementation of a general health questionnaire in a South African population.

Other confounding factors regarding measuring instruments and the choice of measuring techniques were discussed extensively in 2.9 and 3.6. All measuring instruments included in this study were found to be valid and reliable, with a good correlation to other assessment techniques. Techniques such as needle EMG, three- or four-dimensional US, or MRI might yield more advanced and accurate measurements. For example, measurement with the ultrasound did not measure the levator plate angle, compared to some other studies investigating the movement of the levator plate during contraction and Valsalva. In this study, however, we used a similar method to establish the direction of the anterior-posterior movement of the levator plate relative to a horizontal reference line (Shobeiri *et al.* 2013:209). The same argument accounts for EMG where detailed analysis of myoelectric manifestations gives a more accurate reflection of aspects, such as muscle fatigue and timing (see 5.5).

Mills *et al.* (2005:65) provided evidence that the stabiliser PBU is a sensitive instrument to detect impairment of stability and subsequent improvement in response to abdominal muscle training. Their study was done in an athletic population. The researcher used a similar method to their study, and as proposed by other authors, where a change of 10mmHg was taken as effective activation of the abdominal stabiliser muscles. Recent literature, however, proposed that a change of 2-4mmHg might be sufficient to indicate activation of the abdominal stabilisers (Park & Lee 2013:528) (see 2.9.3). This could have led to a more sensitive detection of change in the participants' ability to contract the abdominal stabilisers. This reasoning might account for the high prevalence of zero activation of the abdominal muscles (57% and 56% respectively on the Sahrmann scale and with the PBU) that was found in this study's population of mainly older, physical inactive women.

PFM (which includes the superficial part as well) and abdominal muscle palpation, as proposed by Devreese *et al.* (2004:192) and Lovegrove-Jones (2016: online), could be included as improvement of the methodology to assess timing and coordination of muscle contraction. A comprehensive assessment should include assessment of breathing patterns, posture, and the lumbo-pelvic-hip region, which could all affect motor control or be affected by dysfunction of the motor control system related to POP. Inclusion of these aspects are proposed in the model for rehabilitation based on previous literature (see 5.6) (Sapsford 2004:7-9).

However, a comprehensive assessment and management with inclusion of all suggested components and measurements is very time consuming, and has to be considered to prevent participant/patient drop-out and poor adherence. Monitoring patient adherence is therefore important to ensure optimal outcomes, not only regarding research, but also in clinical practice. Outcome measures such as exercise diaries, logbooks, physical activity recall interviews and questionnaires are popular methods to assess participant/patient adherence. Different forms of bias may however have an effect on interpretation of such measures. Reporting, recall, dilution, regression, extreme response and attention bias (the 'Hawthorne effect') may all have an effect. It is therefore suggested that both objective and self-reported measures, as were implemented in this study, are used to limit interviewer and observer expectation bias (McGrane *et al*. 2014:10). It is also suggested, in order to improve adherence in future research studies, that only some, and not all assessment and management components, be investigated at the same time. Although this may limit clinical relevance, it might produce more statistical significant results. Inclusion of some aspects can be investigated in comparative populations, in order to compare and determine the effect on similar outcome measures.

In conclusion, the choice of measuring instruments and techniques has to be suitable for the population being investigated for the purpose of clinical relevance and external validity. Using MRI or advanced EMG to assess muscle function in a resource restricted population and environment would be of limited clinical value in a primary health care centre where it is not available. Choosing two-dimensional US, superficial EMG and palpation techniques would be of much more clinical value in a setting where it could be used on an everyday basis with limited cost implications.

Physiotherapy intervention, on all levels of health care and under all circumstances, should be evidence-based and patient-centred – therefore the need for research in a variety of populations and health care settings.

5.6.4 Summary

To summarise the quality of the study, a self-assessment of risk of bias was done by the researcher according to Cochrane Collaboration's risk of bias tool. Table 63 depicts the risk of bias assessment and scoring for this study. The criteria for scoring for reviewers can be seen in Addendum 17.

Table 63. The Cohcrane Collaboration tool for assessing risk of bias within a study (http://ohg.cochrane.org/sites/ohg.cochrane.org/files/uploads/Risk%20of%20bias%20assessment%20tool.pdf).

DOMAIN	DESCRIPTION	REVIEW JUDGEMENT Low/unclear/high risk of bias
Sequence generation	Computer random number generation was used for random allocation.	Low
Allocation concealment	Participants nor investigators could foresee assignment due to group allocation being concealed	Low
Blinding of participants, personnel and outcome assessors	Blinding of participants and key study personnel ensured, and unlikely that blinding could have been broken. Outcome assessment was blinded.	Low
Incomplete outcome data	Missing outcome data was balanced in numbers across intervention groups, with similar reasons for missing data across groups reported. Missing data has been imputed using appropriate methods.	Low
Selective outcome reporting	The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest have been reported in the pre-specified way.	Low
Other sources of bias	There was no potential source of bias related to the specific study design used, nor did the study end early due to some data-dependent process (including a formal-stopping rule). There were also no imbalances at baseline assessment. Ethical principles of voluntary participation and no reimbursement were applied.	Low

The main challenge thus remained to find an effective clinical guideline for PFMT/rehabilitation for patients with POP and scheduled for reconstructive surgery, considering the strengths and limitations posed by this study and other evidence (Riss & Aigmueller 2014:855; Hagen, Stark & Cattermole 2004:24). The combining of the objectives and findings of this study, with existing evidence and theories, led to a comprehensive proposal (Chapter 6) of a holistic approach to PFM rehabilitation in women undergoing pelvic floor reconstructive surgery (Figure 40).

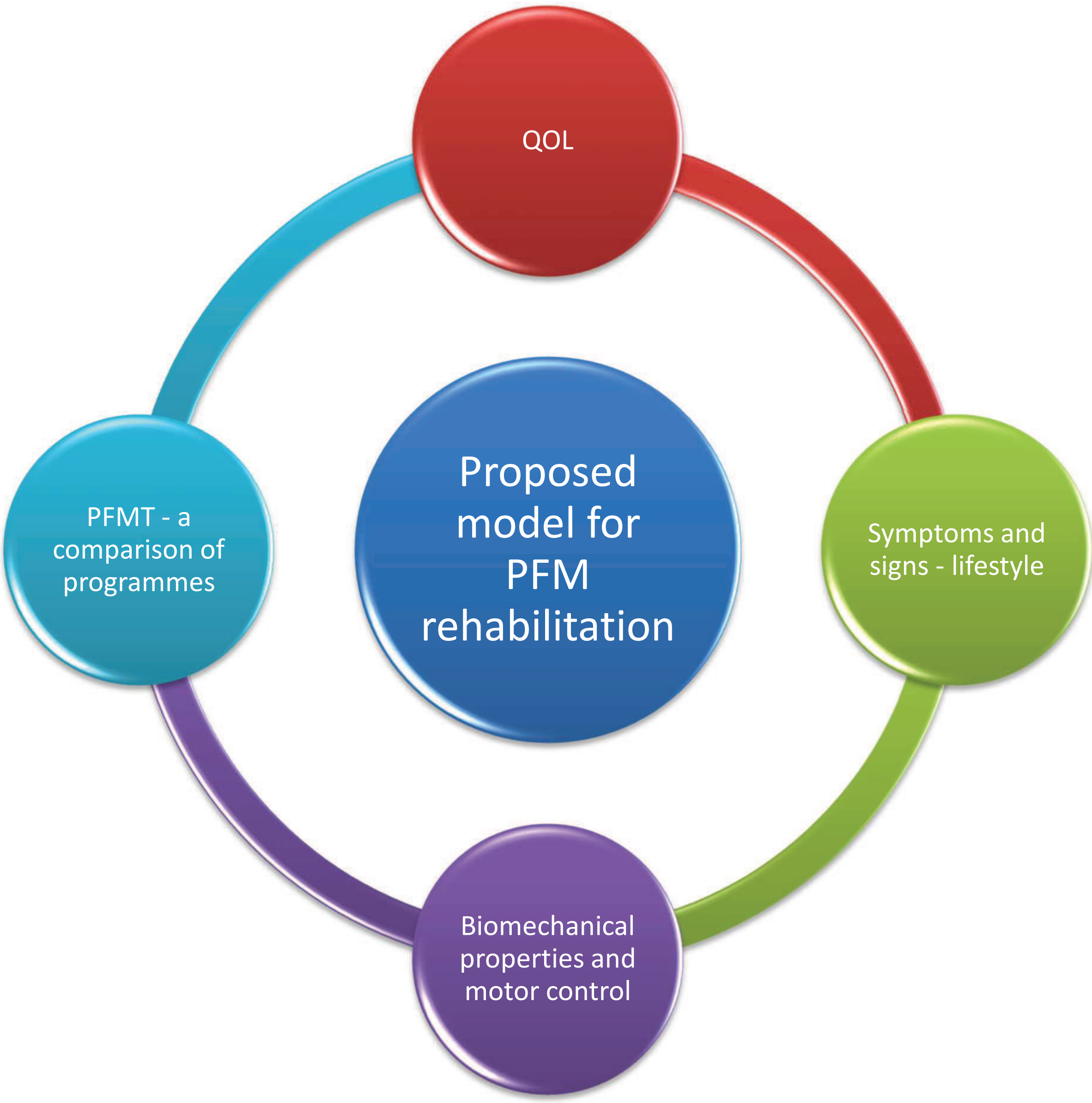


Figure 40. Completing the circle of quality of life and integrated themes.

CHAPTER 6

RECOMMENDATIONS AND IMPLEMENTATION: A PROPOSED MODEL FOR PELVIC FLOOR MUSCLE TRAINING IN WOMEN UNDERGOING PELVIC FLOOR RECONSTRUCTIVE SURGERY

6.1 INTRODUCTION

This study was the first to describe the clinical manifestations of activation of local and global stabiliser muscle function of the abdominal muscles and PFM in a population of patients with POP. It was also the first randomised control trial to investigate the effect of a scientifically-based intervention programme in regards to the training of the PFM and abdominal muscles in this population. Due to the effects that pelvic floor reconstructive surgery could have on muscle function and sensorimotor control, and the incidence of recurrence of POP post-operatively, this population was considered clinically relevant for the investigation. Furthermore, although it was not part of the original objectives, the study developed into one of the first studies to describe intervention for POP in a primary health care system/resource-restricted population.

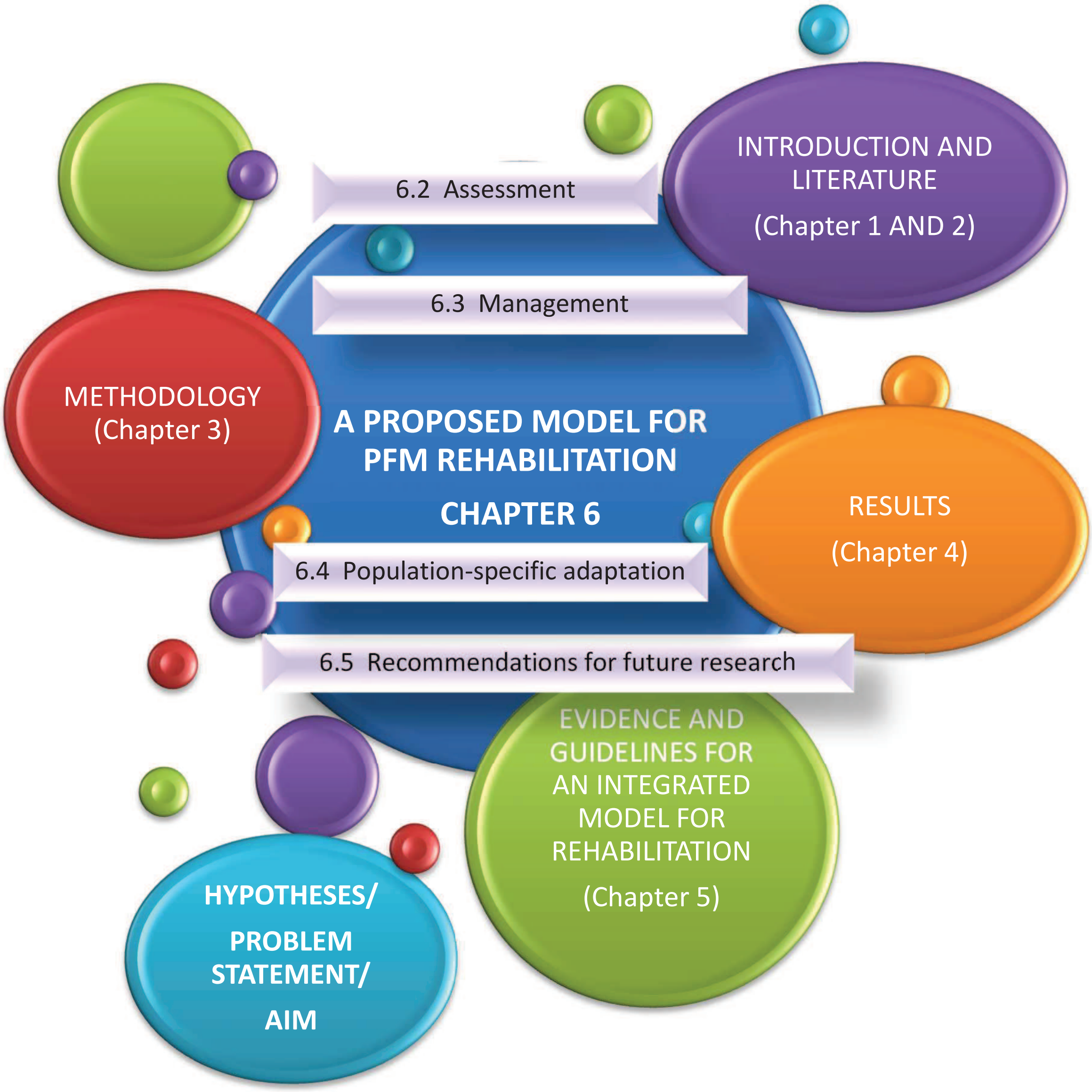


Figure 41. The integration of study concepts into a model for rehabilitation.

This study is only the first of many studies that should explore the effectiveness of PFM rehabilitation in women with POP. Based on the limited research available, this chapter is a summary of evidence and theories combined to propose a model for rehabilitation in women with POP undergoing pelvic floor reconstructive surgery (Figure 41).

Evidence from the findings for the first objective of this study indicated that decreased physical activity, depressive symptoms and other co-morbidities such as cardiovascular disease might be factors to be considered in a rehabilitation programme (see 5.2 and 5.3). It also indicated the need for rehabilitation in these patients as the majority of the participants had never received any PFM or core training. The correlations made from baseline data regarding PFM and abdominal muscle function, together with the findings of the effects of the intervention programmes, indicated that both localised PFMT, as well as core training, might have a beneficial effect on different aspects of the pathology and muscle function respectively (see 5.4 and 5.5). It therefore seems, as stated by Falla, Whitely, Dardinale and Hodges (in Jull *et al.* 2015:306), that both motor control and strength training may play a profound and significant role in the neuro-musculoskeletal system, and therefore treatment of pathologies, symptoms and signs, and QOL (Figure 42).

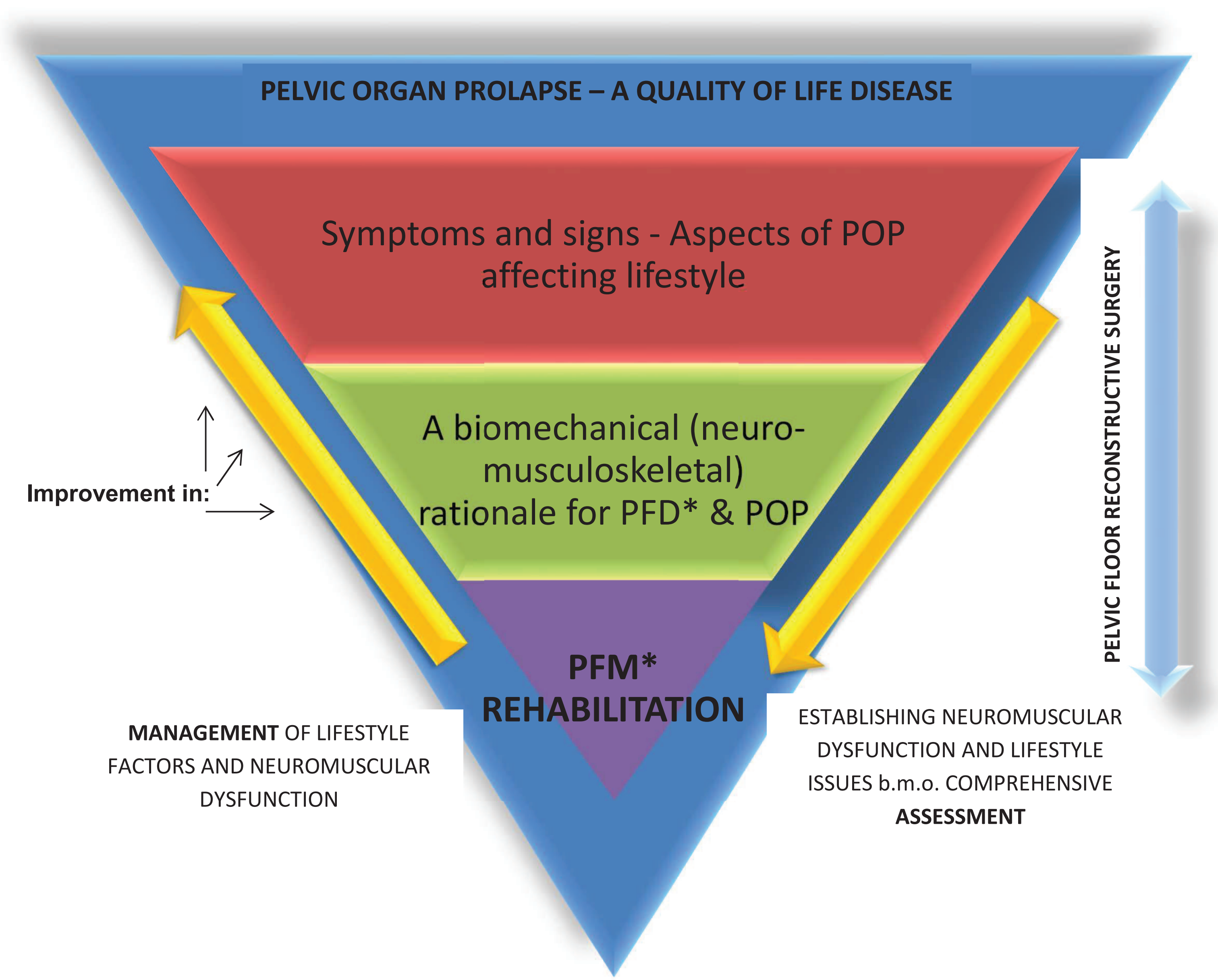


Figure 42. Proposed outcomes of a rehabilitation model for POP pre- and post- reconstructive surgery.

In this chapter, the results from this study are integrated into a proposed model for rehabilitation. The model that follows has been structured in such a manner that it can also be adapted for the conservative treatment of POP. The model for assessment and management of neuromuscular control is applicable to all neuromuscular dysfunction as related to PFM dysfunction. Based on the findings of this study and the literature study, the model must include exercise programmes based on scientific guidelines and biomechanical principles in regards to motor control. The specifics of these guidelines and the evidence were however discussed comprehensively in the previous chapters and will not be included in this discussion (see 2.8, 3.5, 3.6, 5.4, 5.5 and Addendum 1 to 4).

6.2 ASSESSMENT

Every rehabilitation plan for POP should be based on a proper assessment of the patient. Comprehensive assessment in neuro-musculoskeletal therapy consists of an interview/subjective part, followed by clinical reasoning and the substantiating/rejection of the hypotheses by a physical assessment (Petty 2011:127). Assessment from a neuro-musculoskeletal point of view should therefore include a detailed medical history, assessment of QOL, lifestyle, motor control, active, passive and neural aspects of the neuro-musculoskeletal system (Figure 43), and environmental, psychological, behavioural as well as social factors. Based on these findings, a rehabilitation programme can then be compiled to address all the aspects that could influence neuro-musculoskeletal function.

These aspects are depicted in Figure 43, which is an adaptation of the original version of the motor control system, as presented in 1.3. Pathological, physiological, epidemiological, as well as neuro-musculoskeletal concepts derived from this study and literature, and related to POP and reconstructive surgery, were integrated into this model of motor control, as described by Comerford et al. (2005:1-3). This model will be further elaborated on in 6.3, where the concepts of management will be discussed.

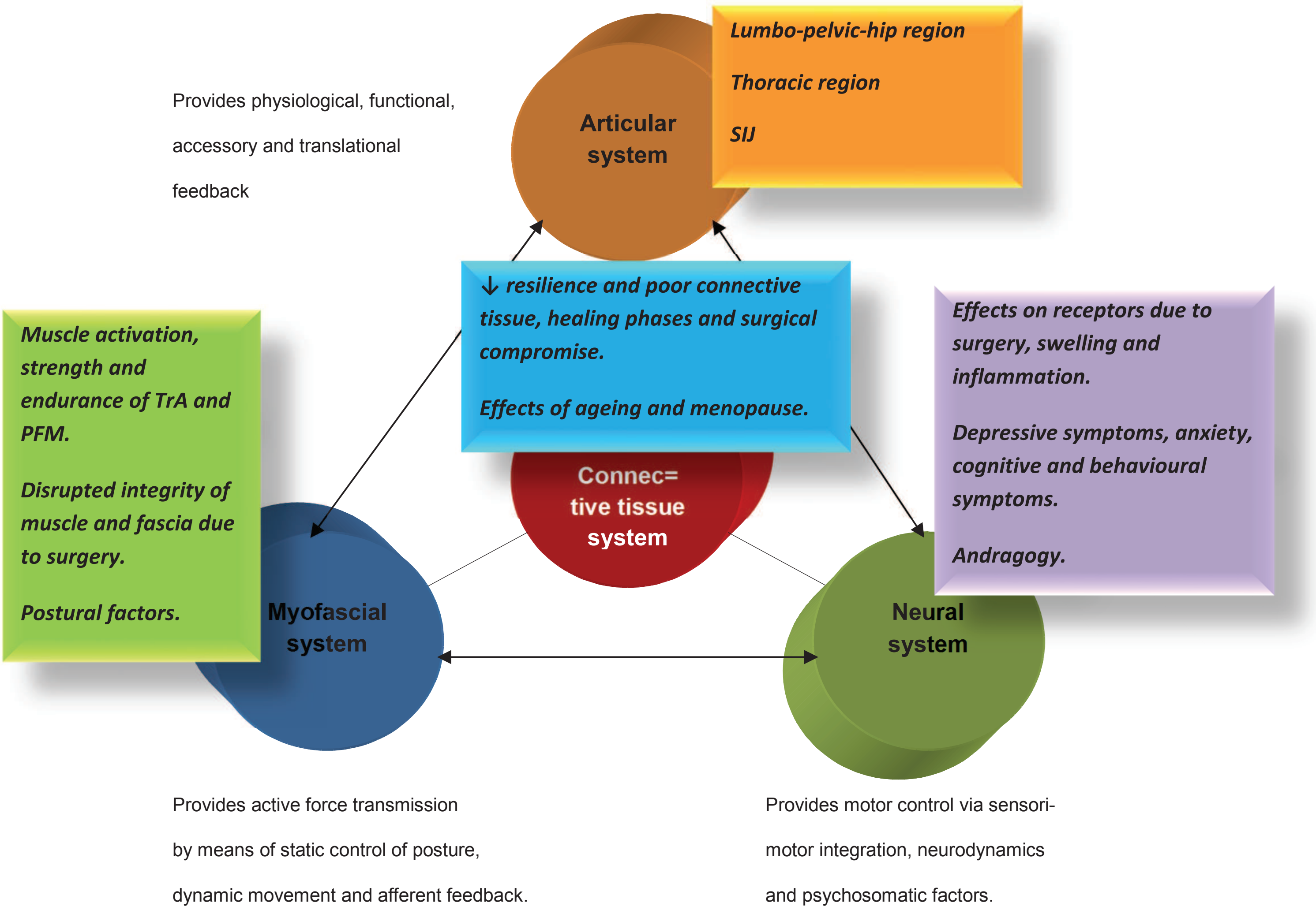


Figure 43. The neuro-musculoskeletal control system as applicable to the assessment and rehabilitation of POP in women undergoing pelvic floor reconstructive surgery.

The ICF, as originally depicted in 2.9 (Table 4), appeared suitable to accommodate all of these factors; however, some changes had to be made to the original table to incorporate the new information gathered during this research process. Table 64 illustrates the recommendation for assessment in future studies within this field. One of the main concerns regarding previous studies investigating muscle function and treatment was the lack of detailed and specific assessment of the different neuro-musculoskeletal components and biopsychosocial factors, which are now included in the recommended assessment structure.

Table 64. A proposed ICF for outcome measurement in patients with POP.

ICF LEVEL	DESCRIPTION	OUTCOME MEASUREMENT TOOLS
Body function	**Decreased physical activity.* **Lumbo-pelvic-hip/SIJ joint function.* **Posture.* **Co-morbidities such as hypertension and depressive symptoms.* POP stage. Decreased PFM strength and endurance, movement, activation and coordination. TrA activation (local stability). Global stability and mobility of the abdominal muscles. Any associated bladder or bowel dysfunction.	POP-Q PERFECT scale, perineal US, EMG PBU, EMG Sahrmann P-QOL **Incontinence questionnaires*
Activity	Activities that result in a rise in IAP, e.g. handling heavy objects, running long distances, walking, coughing, sneezing, **laughing*, *bending*, obstructive defecation, etc. Any activities that cause increased dysfunction of bladder or bowel. Sexual functioning.	P-QOL, SF-36 **Disease specific questionnaires.*
Participation	Cannot participate in any physical activity that causes rise in IAP. Social activities with family and friends. Intimate relationships.	P-QOL, SF-36

Environmental factors	**Resource-limited health care.* *Unemployment.* *Manual labour.* *Lack of transport.*
Personal factors	**Lack of health-related education.* *Poor lifestyle and co-morbidities.* *Depressive symptoms and poor emotional state.* *History of multiple normal deliveries and previous surgery.* *No experience in PFM or abdominal training.* *Age and menopausal status.*

*Adapted according to information gathered during the research process for a proposed model of rehabilitation.

A variety of questionnaires and techniques are available to asses QOL and symptom severity more objectively. However, a lack of standardisation in other languages, other than English, still exists amongst QOL questionnaires. General as well as disease-specific QOL should be measured. Examples of general health questionnaires include the Nottingham Health Profile dimensions, which has been used in previous studies on POP (Fritel *et al.* 2009:615), and the SF-36 (see 2.9.1). Disease-specific questionnaires for POP include the PFDI, the PFIQ and the P-QOL. The decision on the most appropriate measuring instrument should be based on reported validity and reliability measures and the sensitivity to the characteristics of the population being investigated. From this study it would appear that the P-QOL could be used effectively in a resource-restricted (and Afrikaans-speaking) population (see 5.2).

Assessment with a structured questionnaire should be supported by a thorough medical history to detect any co-morbidities, risk or lifestyle factors such as age, BMI, level of physical activity, diet, medication, hypertension, depressive symptoms, hypo-thyroidism, pulmonary disease, birth history, surgical history, menopausal status, the presence or history of pelvic or low back pain, associated sexual, urinary, or bowel symptoms, and social and economic status. This information should then be analysed and the effect on the input, processing, and output mechanisms of the sensorimotor control system established. It is recommended that future research should focus on the development of a screening tool for early identification of lifestyle factors that could be a risk for development of co-morbidities and POP (Jull *et al.* 2015:375-377).

The aim of the physical assessment is to substantiate or reject the hypotheses formulated by the therapist based on the interview and medical history and to determine what structures/factors are responsible for the symptoms (Petty 2011:39). Due to the complex and interrelated pathology of POP, there are a variety of neuro-musculoskeletal and motor control aspects that need assessment (see Figure 43). Aspects such as diaphragmatic breathing patterns should be confirmed in lying and sitting to exclude compensation strategies. It should be followed by assessment of functional expiratory patterns such as coughing, sneezing, nose blowing, and laughing (which is known to increase IAP) by observing the sequence of breathing and muscle activation. The activation, timing, co-contraction, endurance, strength and power of the superficial and deep PFM and the abdominal muscles should be established as relating to local and global stability, or as relating to global mobility (Comerford *et al.* 2005:4-4; Devreese *et al.* 2004:192; Sapsford 2004:7-9). It should also include assessment of postural awareness, muscle weakness, pain and range of motion in the lumbo-pelvic-hip region (Grewar & McLean 2008:383) due to the effect it may have on POP and associated symptoms (see 2.5.2).

Referring to the assessment of the lumbo-pelvic-hip region, a study by Nguyen, Lind, Choe, McKindsey, Sinow and Bhatia (2000:333-335) can be mentioned. This author found an association between advanced POP and a decreased lumbar lordosis. The biomechanical consequence of the decreased lordosis may be an increased fraction of the downward IAP reaching the PFM, leading to overexertion and eventually failure. The presence of the decreased lordosis may be due to ageing or as coupled with an increased kyphosis. Mens *et al.* (2006:633) also indicated that increased IAP is sufficient to cause pain in patients suffering from pelvic girdle pain. It would therefore be important to help limit osteoporotic changes in ageing and post-menopausal women by means of lifestyle and exercise intervention strategies to limit these consequences.

Sapsford *et al.* (2008:1746) found significant differences in EMG activity in slumped and upright sitting postures. In an upright sitting posture, greater PFM and abdominal muscle activity was recorded when compared to a slumped sitting posture. Posture correction in the workplace and at leisure could therefore contribute to enhanced coordination and control of the PFM and abdominal muscles. Including posture correction in the rehabilitation programme of a patient with POP could therefore be beneficial for improvement of incontinence and POP. This data also supports the finding of Nguyen *et al.* (2000:333-335) where a decreased lordosis (together with a kyphosis) was indicated to lead to possible failure of the PFM. Relating this evidence to the prevalence of manual labour, and therefore a chance of increased IAP (Mens *et al.* 2006:627-634) during such activities in this study's population, aspects such as kinetic handling and posture seem indicated to be included in a comprehensive rehabilitation programme. This suggestion supports the proposed model focussing on interrelating QOL, lifestyle and biomechanical principles and exercise specificity.

Exercise specificity is only possible if it is based on the accurate and continuous assessment of each patient (Falla *et al.* in Jull *et al.* 2015:298). For example, the therapist must establish whether the reason for the poor posture is primarily related to neuro-musculoskeletal dysfunction, or whether the primary cause is related to a biopsychosocial component. Patients with poor self-esteem or depressed emotions have been found to demonstrate poor body language and posture as a result of their emotional state. Canales, Cordás, Fiquer, Cavalcante and Moreno (2010:378-379) found in a controlled study significant increase in head flexion, thoracic kyphosis, pelvic retroversion and scapula abduction in patients during a depressive episode. Treatment of the cause and the symptoms, whether neuro-musculoskeletal or biopsychosocial, should therefore be included in the rehabilitation programme as behavioural, manual or exercise therapy, based on the comprehensive assessment of the neuro-musculoskeletal and biopsychosocial components.

Continuing the focus on physical assessment, different assessment tools to measure the PFM and the abdominal muscles, as described in 2.9.2 and 2.9.3, have been identified and investigated for validity and reliability over the years. As problems are identified during an assessment and the interrelationship between factors explored, other specific assessment tools might also be needed. The assessment might therefore be directed towards a complete and comprehensive neuro-musculoskeletal assessment of the spine or pelvic regions, if indicated. Guidelines for such assessments are thoroughly described in the literature, such as by Jull *et al.* (2015:460-500), Petty (2011:283-322), and Maitland (1998:259-318). It is important however to choose the correct instrument or technique to measure the correct component of suspected muscle, fascial, or joint dysfunction causing or contributing to the symptoms and signs (Grewar & McLean 2008:384).

Symptom severity can be measured by objective measurements such as the pad-test for incontinence (or continence-specific questionnaires), or the POP-Q scale/US (two- or three-dimensional) for the stage of POP. Bladder diaries can be used to determine fluid intake and voiding patterns in the case of OAB or urgency/UI (Grewar & McLean 2008:384). This physical measurement is important to relate to the subjective assessment of QOL. A patient's perspective and physical findings may sometimes not correlate. Differences in findings might give an indication of factors other than those due to POP, that affect the patient's QOL or lifestyle.

It is therefore evident that a comprehensive assessment should be conducted prior to surgery, as well as after surgery, to determine the function of the different neuro-musculoskeletal systems before and after it is affected by the surgical procedure. This further implies that as problems are identified during assessment, other, additional assessment tools might be needed as indicated in the comprehensive neuro-musculoskeletal assessment. Surgical intervention would immediately limit the assessment that could be conducted due to precautionary measures. It would also change the symptoms, signs and neuro-musculoskeletal behaviour due to the intervention, adaptation strategies and physiological changes that follows surgery.

As time lapses after surgery, and healing occurs, re-assessment would be indicated to determine the changes in the neuro-musculoskeletal and biopsychosocial system. Adaptation of the intervention or management strategies are therefore necessary to stay relevant to the dysfunction/reason for dysfunction which might change from pre-operatively to post-operatively.

6.3 MANAGEMENT

Always considering the principles of individuality and specificity, a rehabilitation model based on findings of significance in this and previous studies can be proposed to be used as a guideline. However, when implementing a programme for a specific patient or population (see 6.4), it should always be based on the specific findings from a comprehensive assessment to be effective. The discussion on the proposed management therefore refers to general as well as specific guidelines of neuro-musculoskeletal rehabilitation, taking into account environmental, social and personal factors which may affect the outcome of such a programme in patients with POP (see 5.3 to 5.6).

An effective exercise programme, based on scientific principles, does not necessarily imply an effective outcome. Effective treatment is also based on compliance and adherence from the patient and proper teaching skills from the therapist. Counselling women about rehabilitation, surgery and outcomes should be described by using a patient's perspective to decide on a mutually agreeable and acceptable outcome for both parties (Barber *et al.* 2009:608). The patient should be encouraged to be self-efficient and involved in her own rehabilitation. This implies that each rehabilitation programme should be individualised and specific to the patient's needs with a component including home-based exercise programmes. Patients can take responsibility for example by completing an exercise diary or calendar. These and other principles are underpinned by the assumptions of andragogy described in 2.8.2.3 (Plack & Driscoll 2011:204-205).

The exercise programmes should not only include specific motor control exercises, but also exercises relating to lifestyle adaptation. It seems that a rehabilitation model for women with POP should include lifestyle changes, as discussed in 5.2 and 5.3. Ideally women should be screened for any cardiovascular or thyroid dysfunctions/other co-morbidities and risk factors (such as an increased BMI, birth history, amongst others), during their first consultation (see 5.3). Based on these findings, a basic programme to improve lifestyle should be prescribed, or the patient must be referred to an appropriate member of the interdisciplinary team to address identified problems. These members may include physicians, dieticians or psychologists, amongst others.

Important components to include in a lifestyle programme are specifically education, weight loss strategies and increased physical activity which have proven efficient to reduce the risk of developing lifestyle diseases (Jull *et al.* 2015:365-375; Crouch, Wilson & Newberry 2011:240-241; Pettee, Storti, Conroy & Ainsworth 2008:428-429). The programmes need to be population-specific for intervention to be effective, which poses a challenge in resource-restricted populations by adapting the model to improve outcomes (see 6.4). Rural communities who depend on primary health care delivery mostly have restricted resources for education and transport is usually a major problem for them to reach the clinics. An Australian study investigating the effects of primary health education and intervention programmes in improving rural women's knowledge on risk factors and changing lifestyle behaviours found it to be of marginal benefit, especially in women at low risk (Crouch *et al.* 2011:237-238). It is therefore important to use any opportunity to implement intervention. Although follow-up visits are important for motivation and the progression of treatment, other strategies such as home-based exercise programmes, visual aids, or frequent reminders (using available technology) can be used as an alternative to maintain adherence to the intervention programme.

Adherence to lifestyle changes may lead to decreased depressive symptoms and co-morbidities, such as hypertension, which in turn have been associated with improved compliance and adherence. However, initially proper teaching skills from the therapist and the choice of adult learning strategies may play a major role in adherence to initiate the lifestyle programme with the patient. Lonsdale *et al.* (2012:2) have proposed that physiotherapists should set their management plans within a framework based on the self-determination theory to increase patient adherence and improve outcomes (see 2.8.2).

Improved compliance and adherence due to the lifestyle changes can have a positive effect on the improvement of sensorimotor control and muscle training pre- and post-operatively. Improved lifestyle may specifically have a beneficial effect on the processing mechanisms and therefore improve the output mechanism (see 2.8.1.5 and Figure 44).

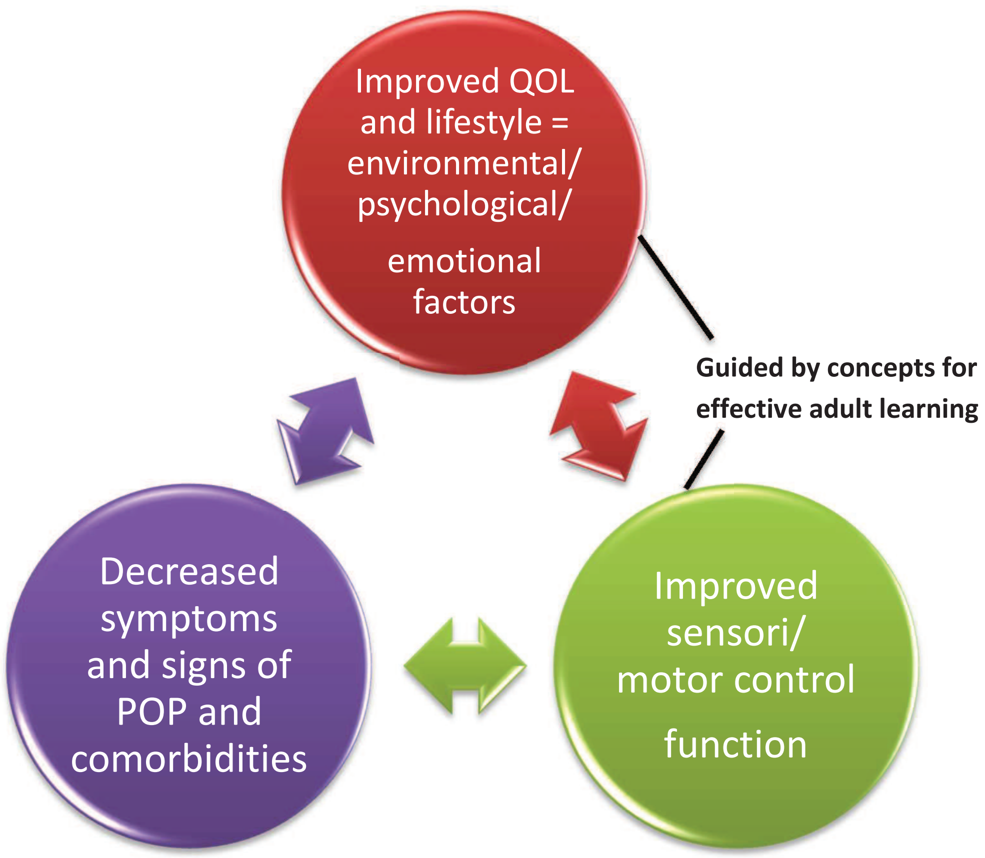


Figure 44. Components to be addressed in a rehabilitation programme for POP.

Although the motor control system, as described by Comerford *et al.*, Janda, Sahrmann, Richardson, Hodges, Jull, Hides and O`Sullivan (see 2.8.1.1), has been used to define and guide rehabilitation of motor control in this study, recent suggestions by Sahrmann (2014:1038) may provide an additional perspective on the concept of motor control and the management thereof, as applicable to the participants in our population receiving surgery.

Not only the type of surgery, pain and the healing process may change the active, passive and neural subsystems' contribution to symptoms from pre- to post-operatively, but also changes in the physiological systems (see Figure 43). Sahrmann recently proposed an adapted model of the human movement system (Sahrmann 2014:1038) where the endocrine, pulmonary and cardiovascular systems are integrated into the human movement model (Figure 45). These systems are important for the uptake and delivery of oxygen and metabolic substances for maintaining and generating movement and also emphasise the importance of immediate post-operative care, as incorporated in this study. Reflecting on the general model proposed by this study, it seems to be supported by Sahrmann's model. Firstly, the physiological effect that, for example, depressive symptoms can have on sensorimotor control would fit into the endocrine system. Secondly, the participants in this study seemed to be prone to being hypertensive and physically inactive which would involve all three (3) systems. The same would account for the changes or the effect that surgery can have on all three (3) systems. These systems help with the physiological control of movement; however, they are just as much influenced by movement. A lack of movement and physical activity would cause them to deteriorate (Sahrmann 2014:1038).

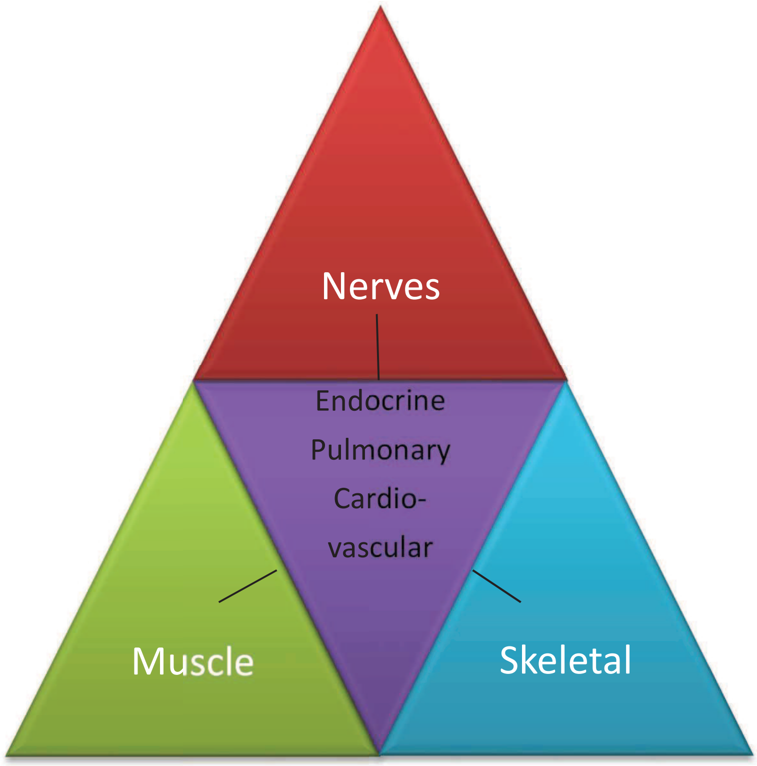


Figure 45. Proposed model of human movement, according to Sahrmann (2014:1038).

The latter connotation to Sahrmann's model may be an indication of the generalisability of the proposed model. At the opposite end of the spectrum, specificity is also a requirement for optimal rehabilitation. Therefore, the proposed model attempts to incorporate all of the mentioned aspects by individualising and specifying certain components as applicable to the population in this study. Some components affecting specificity were not original objectives of investigation of this study but developed from the results of this study and are used to demonstrate the adaptation of the model.

6.4 RELATING THE PROPOSED MODEL FOR REHABILITATION TO A POPULATION WITH LIMITED RESOURCES AND IN A PRIMARY HEALTH CARE ENVIRONMENT

Emotional, environmental and social factors appeared to feature in this study's population and therefore had to be considered in the discussion emanating from the results. The featuring of different biopsychosocial factors may not necessarily be the same in populations not situated in a primary health care system or with limited resources. This was evident when the QOL from this study's population was related to the findings of other studies (see 5.2). Other populations might have different aspects affecting QOL and lifestyle necessitating different adaptations in the model.

According to the World Health Organisation, the ultimate goal of primary health care is to provide better health for all patients, and consists of five (5) elements: reducing exclusion and social disparities in health (universal coverage reforms); organising health services around people's needs and expectations (service delivery reforms); integrating health into all sectors (public policy reforms); pursuing collaborative models of policy dialogue (leadership reforms); and increasing stakeholder participation. Although a previous study was done by Wiegersma *et al.* (2014:4) in a population within a primary health care system in the Netherlands, the limited resource component unique to this study remains the actual challenge to implement and ensure efficacy of a rehabilitation programme. This component was not applicable to their study and may change the focus of the rehabilitation programme.

Relating the aspects of neuro-musculoskeletal rehabilitation identified in this research study and proposed model to the pillars of primary health care in a resource-restricted setting can be explained as follows. Firstly, prevention strategies should be implemented at primary, secondary and tertiary level. At primary level, patients and communities should be educated on lifestyle changes in order to prevent POP and co-morbidities. Secondary prevention can be implemented as screening of patients who visit the gynaecology clinics. Early diagnosis and treatment of risk factors may prevent the worsening of developing symptoms and signs of POP, and even prevent surgery at a later stage. Tertiary prevention would include treatment of the infirmed, prevention of complications post-reconstructive surgery, and optimising the healing process of the neuro-musculoskeletal system to prevent recurrence.

Secondly, health promotion is closely related to adult learning, in order to equip patients to take responsibility to increase control over or improve their own health. This pillar would include strategies such as lifestyle changes, education, the use of training diaries and home-based exercise programmes, and providing a continuous service for follow-up visits and interdisciplinary care at the clinic.

Effective skills and treatment strategies by therapists, based on a comprehensive assessment, form the basis of curative care. Suggestions regarding treatment strategies based on the principles of motor control and rehabilitation have been made in this study (see 2.8). However, until further research has been done and high quality research has arrived at definite conclusions regarding the role of the motor control system in POP and the effect of exercise programmes on POP, all factors will need to be considered, as hypothesised in the literature.

Lastly, embracing the first three (3) components is the rehabilitation component. Rehabilitation is defined as the return of the patient to her highest functional level to participate in society. It is also defined as an improved QOL, which is the main outcome for patients with POP - thereby completing the correction of the cycle of dysfunction (see Figure 42).

Although the above aspects have been specifically described as imperative in a primary health care system, the literature indicates that the burden of POP in the general population might also be higher than suspected (Subak *et al.* 2001:649). This would imply the importance of an evidence base for early detection, prevention, and treatment of patients with POP (Smith, Holman, Moorin & Tsokos 2010:1098-1099).

Therefore, added to the above components of primary health care was also a research component. For a rehabilitation model to be effective, continuous research is needed for adaptation and improvement. The lack of literature regarding exercise interventions for patients with POP has been emphasised, as well as the need for development of screening tools to identify at-risk patients. The researcher therefore encourages clinicians to base intervention on recent evidence and to expand research in this field.

6.5 RECOMMENDATIONS FOR FUTURE RESEARCH: A NEW PERSPECTIVE

This study was done on patients with severe POP who needed surgery. A simple recommendation would be to repeat this study in patients with less severe stages of POP (not scheduled for surgery) and to compare the findings. The aims of conservative treatment for POP are similar to patients scheduled for reconstructive surgery. It also includes strengthening and improving endurance and support of the PFM. Other aims include prevention of the prolapse worsening, a decrease in the frequency or severity of symptoms caused by prolapse, and to avert or delay the need for surgery (Hagen *et al.* 2009:3).

A recent rigorous randomised control trial by Hagen *et al.* (2014:796) on conservative treatment involving 447 women with stage I to III POP across 23 centres in the United Kingdom indicated the same limitations as previous studies (see 5.5.2). An intervention group who received individualised PFMT was compared to a control group receiving only lifestyle advice. They found a significant improvement in the intervention group in regards to QOL and symptom severity when compared to a control group. The intervention was designed specific to the health care system in the United Kingdom. Similar to other reported studies, subjective measures were the only outcomes assessed. Similar comments can be made regarding a feasibility study by McClurg *et al.* (2014:885) investigating the effect of PFMT in conjunction with surgery. More specific assessment regarding muscle function and morphology, as described in this study, are important to establish the underlying reasons for symptomatic improvement. Depending on the population and environment, it would be interesting to see if there are differences in the underlying neuro-musculoskeletal and biopsychosocial factors affecting symptomatic improvement.

The above paragraph emphasises the scope of recommendations and limitations posed by this (see 5.5) and previous studies. In order to find valid answers and solutions to the controversial and under-investigated aspects of POP, researchers must build upon each other's findings and suggestions.

This chapter therefore concludes with a diagram (Figure 46A) which is a summary of the proposed model as compiled from this study's findings and the literature discussion. It incorporates general (coloured flow diagram) and patient-specific aspects (text boxes on the left and right hand side) of rehabilitation for women with POP scheduled for pelvic floor reconstructive surgery. It also gives an indication of how the model can be adapted to be population-specific, for example in a low-resource setting. However, as with most new suggestions, it creates an opportunity for improving rehabilitation in these women, and for further investigation.

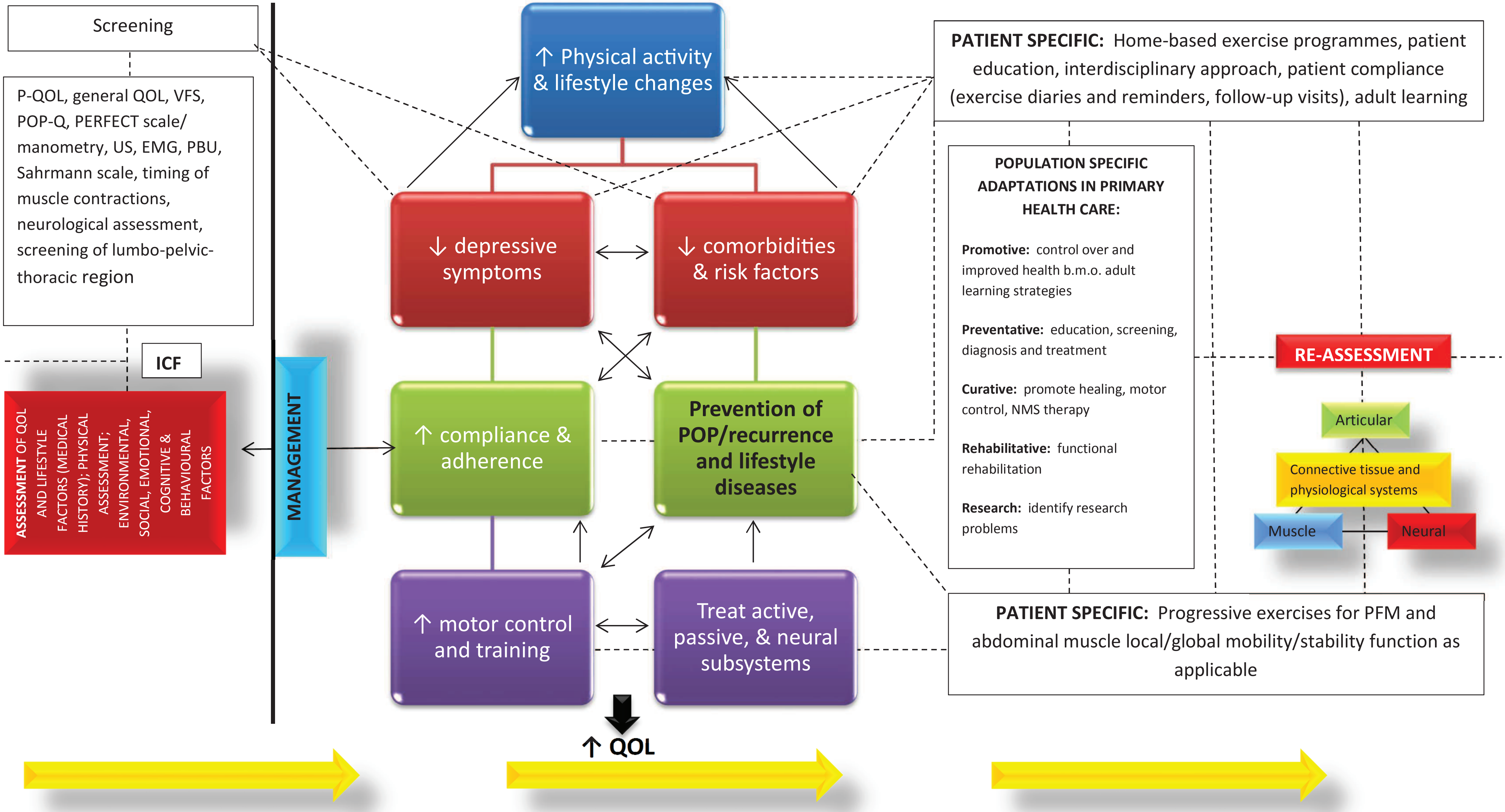


Figure 46A. A proposed model for rehabilitation for women with pelvic organ prolapse or scheduled for pelvic floor reconstructive surgery.

Figure 46B is a depiction of the scope for further research that this model synthesised. The aspects that should be further and more specifically investigated are circled in red.

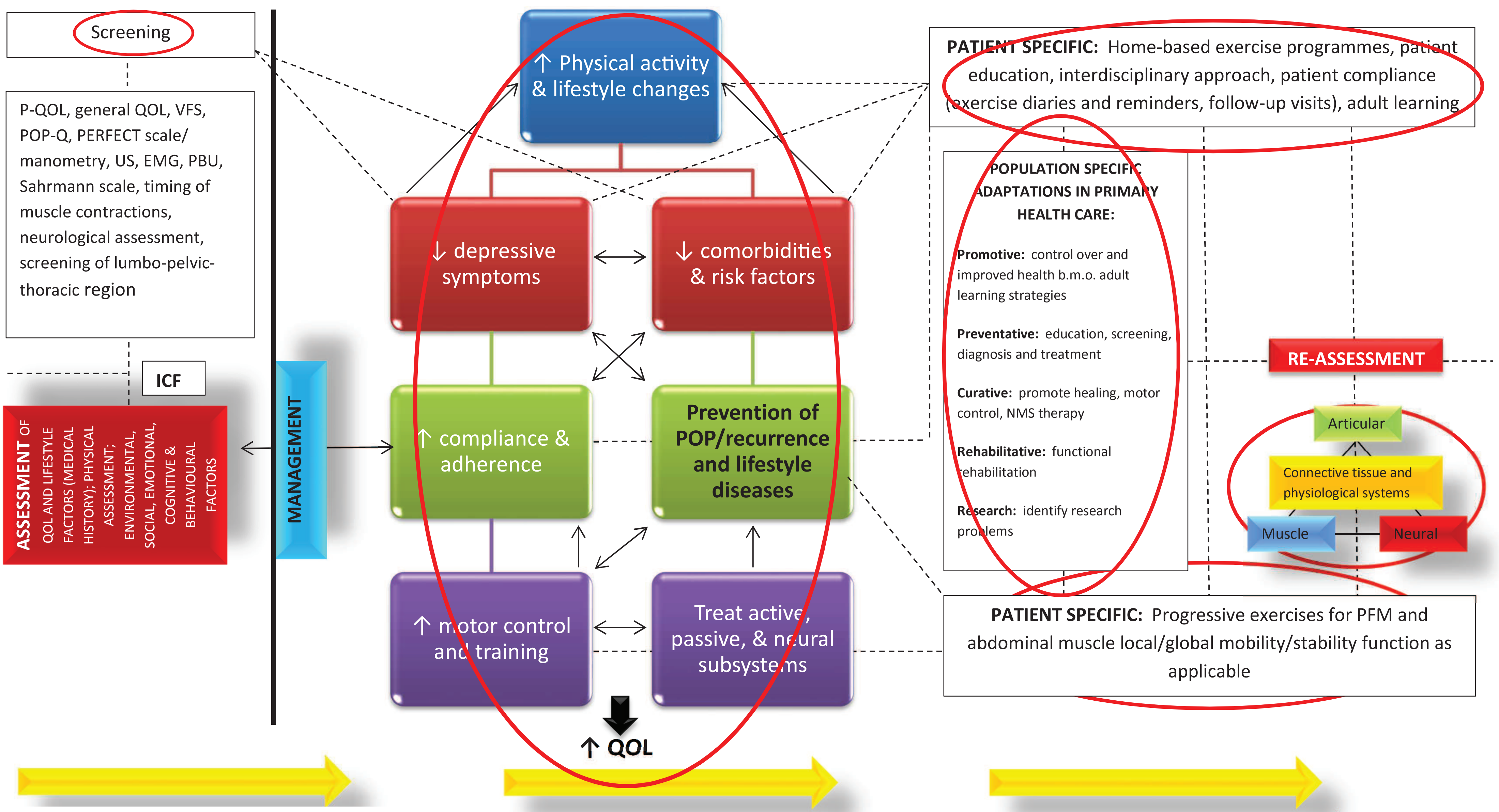


Figure 46B. Recommendations for future research.

6.4 CONCLUSION

This chapter integrated the concepts derived from this study to compile a proposed rehabilitation model for women with POP scheduled for reconstructive surgery. It was compiled in such a manner that it could also be adapted for conservative treatment and populations set in different environments.

The model encourages patient-centred rehabilitation and focuses on specific aspects of adult learning applicable to the population and patients with POP. The concepts included in the model are thus generalised, while the specifics and exercise prescription need to be individualised, scientifically-based and patient-centred, based on a comprehensive individual assessment.

The next chapter concludes the discussion and the thesis by summarising the research process and the hypotheses that were posed at the beginning of the study.

CHAPTER 7

CONCLUSION

This chapter concludes the research report on the process that was followed to answer the research questions and to investigate hypotheses from the literature. It is a conclusion on neuro-musculoskeletal and lifestyle concepts that were integrated into a framework of quality of life in patients with pelvic organ prolapse (Figure 47).

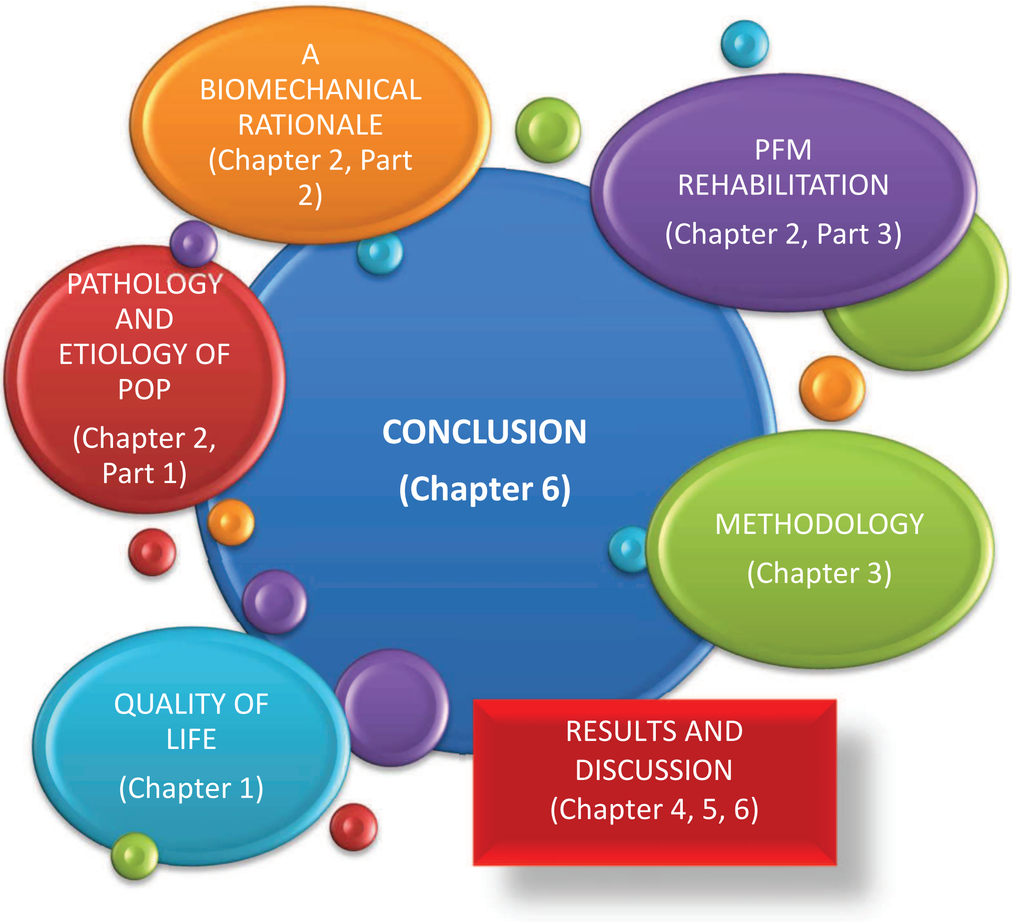
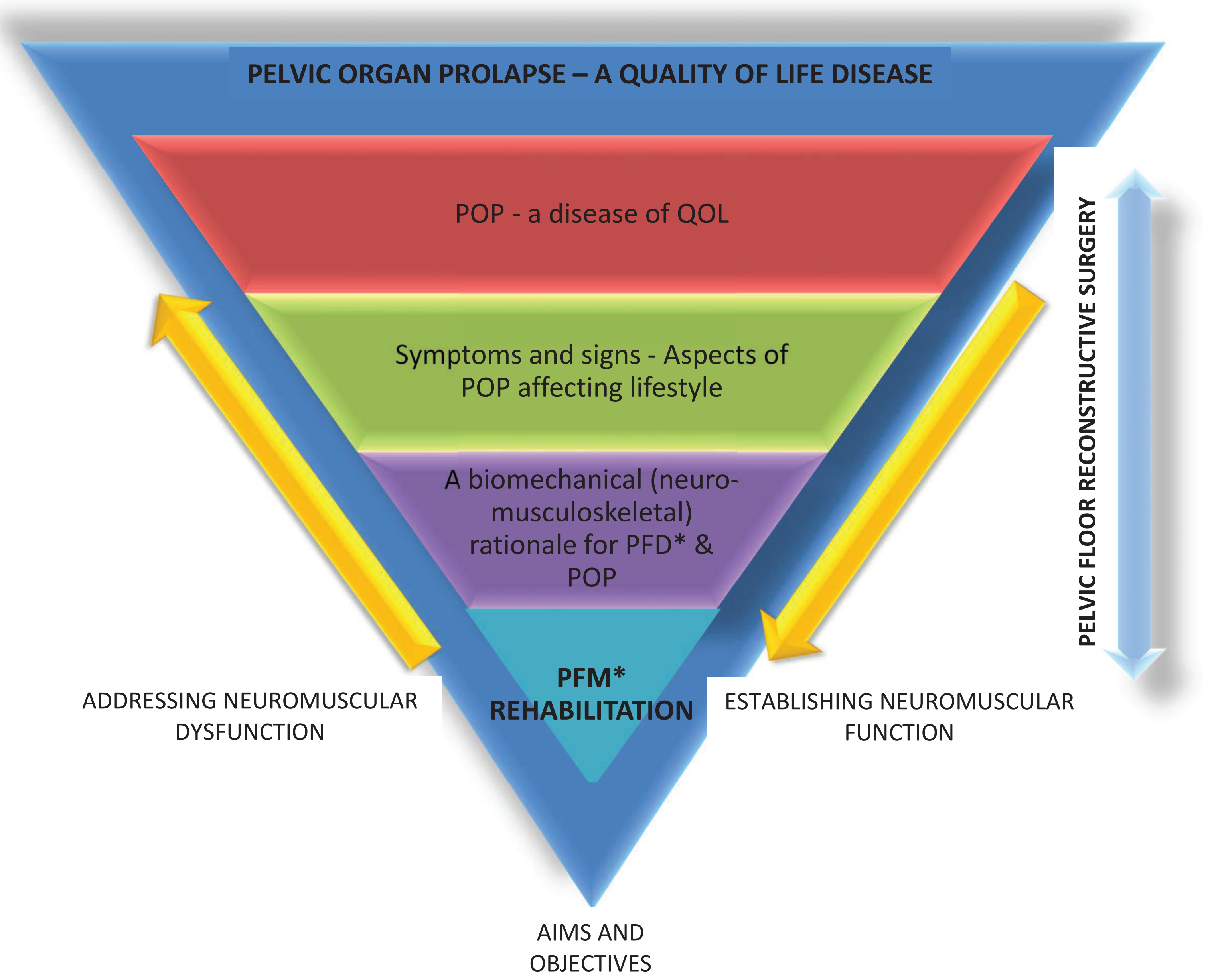


Figure 47. The interrelated conclusive chapter.

One of the most important outcomes in the treatment of POP is QOL (see 1.2). Surgical intervention has been proven to improve QOL immediately post-operatively. However, a poor long-term surgical success rate has been reported. The risk of women undergoing initial pelvic floor reconstructive surgery is estimated to double within the next 30 years due to the increasing ageing population (Doaee *et al.* 2014:154). The role of the PFM and core stability in the prevention and treatment of POP were found to be under-investigated and controversial, according to the literature.

The framework within which this study was conducted was therefore structured around the concept of QOL, the symptoms and signs causing this decreased QOL, the biomechanical and neuro-musculoskeletal components contributing to the pathology, and eventually the rehabilitation of these patients to address this interrelationship of concepts (Figure 48).



*PFD = pelvic floor dysfunction

*PFM = pelvic floor muscles

Figure 48. Conceptual framework of the research study.

Aims and objectives were identified to address these concepts and were related to hypotheses derived from the available literature (see Table 7).

This was the first double blind, randomised, controlled clinical trial to investigate and combine the subjective and physical outcomes of the management and prevalence of POP. No previous study on conservative management of POP, with or without surgical intervention, has combined and investigated the variety of biomechanical and rehabilitative components which were addressed in this study. Also unique to this study was the population who was from a resource-restricted, primary health care setting. This poses challenges to practitioners to find effective, but cost-effective and evidence-based intervention and assessment strategies, when compared to developed health care settings. Most previous studies were set in developed countries with better socio-economic and health care status.

Differences in affected QOL domains were therefore expected to be found, compared to other literature. Questionable reliability of the SF-36 and a lack of normative values for a South African population complicated the interpretation of the QOL data. Severity measures, prolapse impact, social limitations, sleep/energy and emotional limitations were mostly affected in our sample, according to the P-QOL. This was also reflected in the participants' demographic information, as well as symptoms and signs found on assessment. The sample consisted of women who were mostly unemployed, older, and mainly peri- and post-menopausal. The majority of participants were physically inactive and a relatively high percentage were either diagnosed with, or treated for heart/vascular disease, depression and hypothyroidism.

The main associated symptoms were OAB, constipation, UI and anal incontinence, as well as problems such as incomplete emptying of the bladder, which relates to poor muscle function and support mechanisms, as well as inherent bladder problems or a rectocele partially obstructing the urethra. In concordance with previous findings, participants did not complain of pelvic or lower back pain, which should raise concerns (Heit *et al.* 2002:27). Most participants were a stage III POP, according to the POP-Q system, which was expected due to the target population who was scheduled for pelvic floor reconstructive surgery.

Poor PFM and abdominal muscle function could relate to the symptoms and signs found in the sample pre-operatively. The LH at rest, thickness of the perineal body and PR muscle, amount of movement of the PR muscle, PFM strength and endurance were well below normal reported values for asymptomatic patients. Very poor abdominal muscle function was recorded with the PBU and Sahrmann scale (median values of 0 respectively), as well as with EMG. Pain did not seem to be a confounding factor of poor muscle function in participants, due to very low levels of pain recorded on the VFS.

Statistical significant positive correlations were found between PFM strength, endurance, and EMG activity. PFM strength and EMG activity also demonstrated a statistical significant positive correlation with the amount of movement of the PR muscle. Although PFM strength was not significantly correlated with PR muscle or perineal body thickness, the thickness of the PR muscle was significantly positively correlated with the thickness of the perineal body. This could indicate that decreased muscle and perineal body thickness might not necessarily be due to muscle dysfunction, but rather due to morphological and anatomical age-related changes of connective tissue. Since most participants presented with rectoceles, it may be possible that a rectocele stretches out a perineal body.

Regarding the controversial findings on PFM and abdominal muscle function, the correlations from this study showed a statistically significant positive correlation between PFM strength and the Sahrmann scale levels, as well as between the PBU measurements and the PFM endurance. These findings relate measurement of the slow and fast motor units respectively between the PFM and the abdominal muscles. The PBU measurements and the Sahrmann scale were also positively correlated, indicating the possible interrelationship and co-existence of local and global muscle activity – supporting the motor control theory. However, no significant correlation was found between the EMG measurements of the abdominal muscles and PFM, reflecting the existing controversy of co-activation patterns of these muscles found in literature. Due to different adaptation strategies and EMG patterns that can be expected in dysfunctional muscles, and therefore fluctuating outcomes, our recommendation would be to involve correlations of other aspects of PFM and abdominal muscle function, as was significantly done in this study.

Comparison of different intervention programmes yielded limited statistical significant findings regarding comparison of muscle function, QOL, and symptoms and signs. The explanation may be two-fold. Firstly, a variety of biomechanical and some confounding factors were identified as a reason for these findings. Clinically it would appear as if localised PFMT could result in improved global stability/mobility function of the PFM, while a combination of abdominal and PFMT could result in improved endurance capacity of the PFM and better control of IAP (and thus motor control) by improving the function of the abdominal muscles, resulting in improved associated symptoms and signs, and therefore QOL. Secondly, limited changes in response to an exercise programme and lifestyle advice alone may be an indication of the need for a more holistic approach to patients with POP, as indicated in our proposed model for rehabilitation.

In conclusion, a rehabilitation programme was proposed based on existing literature and the findings from our study. A holistic approach was recommended involving lifestyle issues, environmental and psychological factors, learning theories and specific training of the PFM and the abdominal muscles. The model of neuro-musculoskeletal therapy was incorporated in this proposal to follow established and current guidelines regarding muscle training and principles. The treating therapist is encouraged to use specific adult learning strategies to involve the patient in the rehabilitation process and to account for a variety of emotional and environmental factors that could affect effective training on a CNS level in the patient.

These aspects relate closely to the implementation of such a programme in a resource restricted and/or primary health care setting. Different needs might need to be addressed in such a population which can only be established by means of a comprehensive neuro-musculoskeletal examination of each individual, based on the biopsychosocial model.

A proposed model of rehabilitation should be able to adapt to a specific population or individual needs, without discarding the core components. This study aimed to provide groundwork for such a model, of which specific aspects need to be explored and further developed by means of high quality research.

This chapter concludes with a narrative summary in table format (Table 65) of the identified hypotheses in literature and the findings from this study. New hypotheses and recommendations for research are posed which emanated from this study.

Table 65. Summary of hypotheses and findings/new hypotheses and recommendations.

Objective 1.6.1.1 To determine baseline data regarding the abdominal muscles and the PFM, as well as QOL pre-operatively, in women undergoing corrective surgery for POP.
Objective 1.6.1.2 To determine the outcomes, within groups, of a i. PFMT programme, ii. core training programme, and iii. a control intervention, on the PFM, abdominal muscles and QOL post-operatively in women who have had corrective surgery for POP.
Objective 1.6.1.3 To compare the outcomes, between groups, of a i. PFMT, and ii. a core training protocol, versus no training (control group), on the PFM, abdominal muscles and QOL (pre-operatively and post- operatively in women with POP.

Objective 1.6.1.4

To compile a proposed model for rehabilitation for patients with PFD in the public and private sector, pre- and post-operatively.

OBJECTIVES	HYPOTHESES	FINDINGS
1.6.1.1	***Hypothesis 1*** *Factors such as increased age, menopause, BMI, vaginal delivery, or which cause an increased IAP (obesity, smoking, pulmonary disease, constipation, recreational or occupational activities), seem to be associated with POP.*	*The participants in our study were found to be of an increased age, mostly peri- or post-menopausal, with a history of mostly vaginal delivery. Their BMI was increased, but still within an acceptable range. Smoking and pulmonary disease were present in some participants, but more prominent were symptoms of constipation, OAB and a tendency for most participants to be unemployed and do manual labour.*
1.6.1.1	***Hypothesis 2*** *Decreased diameter and weakening of the PFM has again been associated with some of the above-mentioned factors, such as vaginal delivery, increased age and menopausal time. Together with the anatomical position and function of the PFM, the literature seems to indicate the importance of these muscles' function in the development of POP.*	*Although determining a causative relationship was not within the scope of our study, we did find decreased diameter of the puborectalis muscle and poor PFM strength, endurance and EMG activity compared to values found in asymptomatic patients in the literature.*
1.6.1.1-1.6.1.3	***Hypothesis 3*** *According to the above explanation, it appears that dysfunction of the TrA muscle may lead to either increased tone of the PFM, or weakness due to failure in response to sustained overload and compensation.*	*PFM endurance was significantly positively correlated with PBU measurements of the TrA/IO muscles. However, no significant correlation could be established between PFM strength and EMG activity of the TrA muscle, nor with PBU measurements. EMG activity of these two muscle groups also did not show a*

		significant correlation. It therefore seems that slow motor unit activity might be correlated with the PFM and TrA muscles.
1.6.1.1 and 1.6.1.2	***Hypothesis 4*** *The muscles, such as the levator ani, can therefore contribute to dynamic as well as static support of the pelvic organs. The dynamic support is provided by means of muscle activity, and the static support by means of the effect of the muscle activity on the connective tissue (such as ligaments and fascia) to which it is connected.*	*Measurements at baseline indicated a complete lack of proper PFM and abdominal muscle function. PFM strength was not correlated with muscle thickness or perineal body thickness. However, muscle thickness was correlated with perineal body thickness proposing a possible contribution of static structures to decreased thickness. Strengthening of the muscles did not cause a significant change in thickness of the perineal body and muscle morphology.*
1.6.1.1 and 1.6.1.2	***Hypothesis 5*** *Referring back to Figure 2 (see 1.2), namely the neuro-musculoskeletal control system, the discussion of the anatomy supports the hypothesis of the model where the connective tissue lies central to the whole system, connecting all the neuro-musculoskeletal components. Failure of the connective tissue at any level may contribute significantly to failure of the support mechanism of the pelvic organs.*	*The control group indicated limited significant differences in muscle function post-operatively when compared to groups who received PFMT. The lacking differences might be speculated to be due to connective tissue/fascia disruption during surgery or to muscle inhibition/adaptation being of such significance and leading to slow recovery and limitations on progression during retraining.*
1.6.1.1 and 1.6.1.2	***Hypothesis 6*** *It is evident from the above descriptions that disruption of the fascia and musculature contributing to normal motor control and support of the pelvic viscera may lead to decreased function and coordination of the neuro-musculoskeletal system immediate post-surgery. Due to insufficient evidence it is not clearly understood whether normal*	*Comparison of post-operative results at three and six months respectively in the control group yielded different results. Some aspects, such as LH at rest, were worse post-operatively, while other components, such as EMG, increased post-operatively. A variety of adaptation strategies or confounding factors should be considered in this regard.*

	healing would be sufficient to return the tissue to its pre-operative state and motor control function. However, pre-operatively it is assumed that the patient has already decreased PFM function and motor control in most cases of POP. Should the tissue not return to its pre-operative state, the motor control and PFM function could be speculated to be worse post-operatively due to suboptimal healing, therefore contributing to poor surgical outcome.	*Also see Findings of Hypotheses 4 and 5.*
1.6.1.2-1.6.1.4	***Hypothesis 7*** *However, due to the connection between the fascia, viscera and muscle, restoration of the mechanical and supportive properties of the pelvic floor muscles and fascia, as well as the abdominal muscles, may lead to improved mechanical properties of the more distant fascial, ligamentous, and visceral structures.*	*Although the study did not directly measure the mechanical properties of the fascia, ligaments and viscera, it may be depicted by the improved symptoms and QOL participants experienced post-operatively, as well as by relating findings in the function of the PFM and abdominal muscles.*
1.6.1.1-1.6.1.3	***Hypothesis 8*** *It therefore seems that, according to available studies, increased muscle thickness, strength and endurance could possibly contribute to a decreased levator hiatus which will prevent descent of the pelvic organs. EMG activity of the PFM however seems to be more complicated to interpret, due to reactions to adverse effects, such as increased IAP, as well as positive effects, such as increased activation of motor units in response to muscle training and improved neuromuscular control.*	*Our study did not find any significant correlation between PFM strength and EMG activity, and the size of the LH at rest, respectively. The same accounted for the relationship between muscle thickness and endurance, with the size of the LH respectively. Abdominal muscle function was also not correlated with the size of the LH at rest.*

1.6.1.2 and 1.6.1.3	***Hypothesis 9*** *The above explained mechanisms of motor control are in accordance with the accepted motor control mechanism, and may clinically implicate the importance of maintaining a "normal" IAP by coordinated muscle actions, and the inclusion of postural changes and normal functional movements of the limbs during the rehabilitation of PFM function.* *Also see findings of hypothesis 3.*	*Incorporation of motor control into the rehabilitation programme revealed some clinical differences compared with groups who received only PFMT or a control intervention. It was specifically the slow motor unit function of the PFM that responded well to this training. Motor control retraining also resulted in an improvement in this group and therefore an assumed improved control of IAP during activities of daily living.*
1.6.1.1-1.6.1.3	***Hypothesis 10*** *Similar to the case of pelvic floor dysfunction and pain, the stabiliser muscles exhibit disturbed motor control patterns and changed physiological properties in individuals with low back pain (Hodges & Richardson 1996:2647). On the other hand, altered postural activity and morphological changes in these muscles are related to the development and recurrence of low back pain (Cholewicki et al. 2005:2614). Pain may cause an inhibition of the stabiliser muscles, and therefore is hypothesised to contribute to PFM dysfunction such as POP, and even incontinence (Grewar et al. 2008:376).*	*Our population at baseline did not show any severe pain levels in the pelvic region or lower back. If it was present, however, the influence on muscle function would have to be considered.*
1.6.1.1-1.6.1.3	***Hypothesis 11*** *Relating to the neuro-musculoskeletal control mechanism (Figure 2, Chapter 1.2), continence requires the interaction of anatomical systems, which include muscular, fibrous and fascial systems. They provide the structure and support to keep the tissues in a normal*	*Positive correlations between aspects of PFM and abdominal muscle function found in this study support the above hypothesis. Also, poor muscle responses after surgery may indicate a disturbance in these systems due to the disruption of*

	functional relationship. Due to the close interaction between these systems, the failure of one may lead to the failure of one/all of the other components (Haderer et al. 2002:240).	*connective tissue and fascia during surgery, or even due to effects such as pain inhibiting normal muscle function.*
1.6.1.2 and 1.6.1.3	***Hypothesis 12*** *The question remains whether the programmes for PFMT, as suggested up to now in the literature, are optimal for patients with POP, and if more structured programmes based on sound rehabilitation principles and assessment findings could be more effective.*	*A comparison of different rehabilitation programmes in our study indicated the possible need for both localised PFMT as well as core stability training to most effectively improve the symptoms and signs, and therefore QOL, in patients.*
1.6.1.1-1.6.1.4	***Hypothesis 13*** *Based on theoretical biomechanical and exercise principles and guidelines, an effective exercise programme should lead to improvement of disease specific symptoms and bother, and therefore QOL.*	*QOL outcomes improved in all three groups. However, it was the group receiving motor control rehabilitation that showed the most clinical change in QOL.*

NEW HYPOTHESES		
SECTION IN THESIS	**HYPOTHESES**	**RECOMMENDATIONS FOR RESEARCH**
5.3	***Hypothesis 14***	*Epidemiological studies to determine risk in women with POP to develop lifestyle diseases.* *Determine the effect of rehabilitation, based on the proposed model, on risk factors and lifestyle diseases.*

	POP could possibly be considered as a lifestyle disease due to the similarity in risk factors and co-morbidities to other lifestyle diseases.	
4.5	***Hypothesis 15*** *Correlations between PFM and abdominal muscle function exist when distinguishing between the functional characteristics of these muscles.*	*Repeat correlation studies regarding specific components of muscle function in populations with different stages of POP, asymptomatic patients, and with different measuring instruments (e.g. three-dimensional US and fine-wire EMG).*
5.5.2 and 5.6	***Hypothesis 16*** *PFMT should possibly include both localised PFMT as well as motor control training to address all aspects of muscle function important for the prevention and treatment of POP.*	*Determine the effect of long-term motor control training versus localised PFMT (> 1 year) on QOL and recurrence rates.*
5.5.1	***Hypothesis 17*** *The low prevalence of pelvic and low back pain indicated that muscle response might only be affected by surgical pain in this population.*	*Determine the risk of patients with POP (and therefore poor motor control function) on developing lumbo-pelvic pain/pathology.*

A FINAL WORD

*"With the establishment of an evidence-base for pelvic floor muscle training for the management of prolapse, health-care providers will need to invest in extra resources to ensure that a similar service can be provided for women with prolapse. Additionally, beyond the clinical arena, the role of pelvic floor muscle exercises for alleviation of prolapse symptoms is an important public health message that should be shared widely among women of all ages" (*Hagen *et al.* 2014:804*).*

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ADDENDUM 1

THE REHABILITATION PROGRAMME – INSTRUCTIONS TO FIELD WORKERS

INFORMATION FOR FIELDWORKERS

LIFESTYLE INTERVENTION/ADVICE

(group 1,2 & 3)

The following aspects will be included in the participants home programme (together with their exercises and information on the condition):

1. Decreased levels of oestrogen at the time of menopause may cause the fascia to become less elastic and even the skin collagen content may reduce. Participants in their menopause will be assessed regarding this and advised appropriately.
2. Women will be advised on correct defecation techniques in order not to strain and increase potential weakness of the pelvic floor – associated with increased risk/ worsening of prolapse.
3. In the case of constipation, they will be advised on the correct diet/ referred appropriately to a dietician.
4. Smoking will be discouraged due to the chronic coughing it leads to. This chronic increase in IAP puts the already defected pelvic floor under more strain and increase the risk/worsen the POP.
5. Obesity may also lead to an increase in IAP. If deemed necessary, participants will be advised on this and referred to a suitable clinician e.g. a dietician/biokineticist.
6. Activities such as heavy lifting, weight lifting, high-impact aerobics, and long-distance running may increase the risk of POP due to the strain it places on the pelvic floor. Participants need to be appropriately advised and demonstrated the correct technique of lifting.
7. Bladder training as appropriate.

INFORMATION FOR FIELDWORKERS

PROGRAMME FOR EDUCATION AND ADVICE

(group 3)

INFORMATION REGARDING THE PELVIC FLOOR MUSCLES

1. Inform the patient regarding the disorder and the aims of the programme.
2. Opportunity for questions.
3. Use the skeleton to teach the role of the PFM and its function to the patient.
4. The patient should be motivated at all times.
5. The patient should be encouraged to pre-contract and hold the contraction daily before and during coughing, laughing, sneezing and lifting (‘the knack’) to improve the timing of the contraction.

INFORMATION FOR FIELDWORKERS

REHABILITATION PROGRAMME FOR THE PELVIC FLOOR MUSCLES (group 1 & 2)

ACTIVATION AND FACILITATION OF THE PELVIC FLOOR MUSCLES

1. Inform the patient regarding the disorder and the aims of the treatment.
2. Opportunity for questions.
3. Teach the patient proprioception of the pelvis by means of anterior-posterior tilt and lateral tilt. Also teach the patient a diaphragmatic breathing pattern.
4. Use the skeleton to teach the role of the PFM and its function to the patient.
5. Increase awareness of the perineal area by letting the patient sit on the armrest of a chair with her legs in abduction, feet on the floor, sitting with a straight back and hips in flexion. She is instructed to "squeeze and lift" the perineal area away from the chair without rising up, and then to relax again. The patient is then allowed to go to the toilet to empty her bladder.
6. Vaginal palpation and observation of contraction is then used to give proprioceptive input and feedback to the patient. Verbal instructions may include:
   - "squeeze and lift",
   - "it is similar to an elevator door closing (squeeze) and then moving upstairs (lift)",
   - action similar as when "eating spaghetti",
   - action similar to a vacuum cleaner.
7. The patient should be motivated at all times.
8. Thorough concentration is a prerequisite. The room should be without noise or any distractions.
9. The patient should practice on her own at home for one week. Exercises include the following:
   - sitting on the armrest (as described above), and

- stopping the dribble at the end of voiding.

10. Exercises should be done daily, three (3) sets during the day. The amount of repetitions determined by the onset of fatigue.
11. Substitution strategies should be avoided, e.g. contracting the adductor muscles, the gluteal muscles, or the global abdominal muscles (such as holding the breathe).
5. If she is still not able after one week to activate the PFM, fast stretch, tapping of the perineum/PFM, or NES may be used.

NEUROMUSCULAR ELECTRICAL STIMULATION (NES)

In women with an Oxford grading of a 0,1, or possibly 2, the following parameters are indicated to be most effective in producing a titanic muscle contraction:

Frequency = 35-50Hz

Pulse width = 0.25ms

Current type: bi-phasic, rectangular

Intensity: maximum, comfortably tolerated

Duty cycle: 5s on/ 10s off (for very weak muscles the 'off' time may be increased to 15s or even 20s to give enough time for recovery)

Daily treatment

Treatment time: 5 minutes, progressing to 20 minutes by increasing the time with 3 minutes each consecutive session.

THE PELVIC FLOOR MUSCLE TRAINING PROGRAMME

1. Exercises should be done daily, five times a week to allow for adaptation, with weekly follow-up visits to the physiotherapist during which re-assessments will take place and the training programme modified accordingly. During these sessions, exercises will be monitored by means of EMG biofeedback.
2. A treatment diary must be kept (see addendum 4).

3. Exercise prescription will be according to the findings on the PERFECT scale and re-assessed weekly.
4. Exercises should be done until muscle fatigue. Exercise for endurance should be performed at <25% of the MVC. It should be alternated with sessions of fast contractions according to assessment findings. The fast contractions should be as hard as possible (60-70% of the 1-repetition maximum).
5. Exercises will first be progressed by increasing the amount of the contractions (up to 10), and then by increasing the holding time until 8-12 repetitions can be done for 10s in the specific position (contraction:rest = 1:1).
6. If the patient is able to do this, the position can be progressed and the same regime followed (see table 5).
7. The patient should continue exercise in the former positions by decreasing the rest intervals until the ratio of contraction:rest equals 1:0.5.
8. If the patient has achieved all the progressions successfully and the time period of six (6) months has not passed, progression should be in the volume of the training, e.g. progressing to 1-3 sets at a time (8-12 contractions each), with a rest interval of 1-2 minutes between the sets.
9. In addition, the patient should be encouraged daily to pre-contract and hold the contraction before and during coughing, laughing, sneezing and lifting ('the knack') to improve the timing of the contraction.

   Nose blowing should be commenced first. The patient must sit upright, unsupported, in front of a mirror. The blow is commenced from full inspiration using a strong, cognitive abdominal muscle contraction. This should be repeated 5 to 6 times. The exercise can be progressed from lying to sitting upright, sitting in a slumped position, standing upright, and forward lean standing.

   Coughing can be practised, applying similar principles as for nose blowing. Progression to sneezing, should emphasize lower rib expansion and muscle action by placing the hands around the lower ribs. The exercise should be practised with increasing rapidity.

INFORMATION FOR FIELDWORKERS

Progression of pelvic floor muscle exercises.

Progression	Exercise position
1	Supine with hip and knee flexion. Prone with one hip in abduction, lateral rotation.
2	Four foot kneeling with hips in lateral rotation and supporting on elbows.
3	Sitting with crossed legs, supporting on the hands with the shoulder and elbow in extension.
4	Standing with feet in slight abduction.
5	Standing in a squat position.
6	Supine, hips and knees in flexion, contracting abdominal muscles as if in a ‘crunch’ exercise.
7	Standing, climbing a stair. Standing, squatting.

INFORMATION FOR FIELDWORKERS

REHABILITATION PROGRAMME FOR THE LOCAL AND GLOBAL STABILISERS (group 2)

1. Explain the anatomy and muscle function of the transversus abdominus and multifidus muscles to the patient.
2. The room must be quiet without disturbances and concentration by the patient is mandatory.
3. The patient is lying supine with the PBU positioned under the lumbar lordosis. The cushion is inflated to 40mmHg and should change no greater than 10mmHg during contraction/ exercise.
4. Train central and lateral costal breathing control (as to be maintained during the contractions).
5. Activation of the transversus abdominus and multifidus muscles begin in supine, prone and four point kneeling. The spine must be in neutral during training.
6. Muscles are first contracted and activated in isolation. When the patient is able to co-contract the transversus abdominus and multifidus muscles 10 times for 10s, exercises can be progressed firstly to the sitting and then to the standing position.
7. The contraction should be tonic and prolonged at <25% of MVC.
8. Prevent substitution strategies at all times (see next paragraph).
9. Facilitation techniques can be used to encourage contraction in patients who are unable to perform the setting actions (see next paragraph).
10. Contractions should be ceased if global muscle substitution occurs, breathing control is lost, muscle fatigue occurs or there is an increase in pain.
11. When able to hold the co-contractions in each position, the exercise can be progressed adding limb load and functional movements as described in table 6.
12. Isometric contraction time should be increased to 60s prior to integration into functional activities.

13. The patient will be prescribed 2-4 exercises during phases I and II of the study. These exercises should be done twice a day.
14. During phase III the amount of exercises will be increased to 6-8 at a time.

METHODS OF FACILITATION AND ACTIVATION

Transversus abdominus:

1. “Gently draw the lower abdomen up and in.”
2. “Pull the umbilicus inwards towards the spine.”
3. “Pull your navel up towards your spine.”
4. Deep, gentle manual pressure on the muscle (medial to the anterior superior iliac spines).
5. Combine the co-contraction with contraction of the PFM.
6. Use of the PBU.

Multifidus:

1. “Let the muscles bulge (swell) on the sides of the spine.”
2. Manual contact on the muscle.

THE FOLLOWING SUBSTITUTION STRATEGIES SHOULD BE PREVENTED:

1. The rib cage, shoulders, and pelvis must remain still at all times.
2. Normal breathing should be encouraged.
3. Prevent abnormal bracing using the external obliques muscles (depression of the rib cage and horizontal abdominal skin crease).

INFORMATION FOR FIELDWORKERS

THE IMMEDIATE POST-OPERATIVE PROGRAMME

The following programme equals the standard in-hospital intervention:

1. Circulation exercises of the upper and lower limbs to all participants until the participant is allowed to mobilize, including exercises for lung ventilation.

2. Chest physiotherapy as indicated.

3. Manual wound support as indicated.

4. Mobilization when allowed.

5. Teaching of method of defecation to minimize IAP and strain.

6. **Group 1 & 2:**
   PFM exercises as described above in the supine position (within pain limits) aiming for her pre-operative level of exercise.

   Group 2:
   Isolated transversus abdominus muscle contraction as described above, within pain limits and at the participant`s level of competence.

   Group 3:
   Revision of their lifestyle advice and education (standard in-hospital advice).

7. Applicable post-operative advice depending on the individual needs of the participant.

INFORMATION FOR FIELDWORKERS

Progressing exercise programme for local and global stability.

SUPINE	FOUR FOOT KNEELING	SITTING	STANDING
Lie with hip and knee flexion. Slowly raise one leg to 90° of hip flexion and return to the start position. Alternate the legs.	Slowly lift one arm to 180° of shoulder flexion. Return to the start position. Alternate arms.	Slowly lift one arm to 180° of shoulder flexion. Return to the start position. Alternate arms.	
In the above starting position, slowly straighten one leg (foot supported on the plinth) and return to the start position. Alternate the legs.	Slowly extend one leg into extension (approximately 12cm above the ground). Return to the start position. Alternate the legs.	Slowly lift one leg into 100° of hip flexion. Return to the start position. Alternate the legs.	
Lie with one leg bent. Lower the bent leg out to the side, keeping the foot supported beside the straight leg. Return to the starting position.	Slowly lift the opposite arm and leg (as described above). Return to the start position. Alternate the limbs.	The patient sits with the spine and pelvis in neutral alignment, the knee extended to the point where the lumbar spine starts to flex/ resistance is felt in the hamstrings. Support the leg passively in this position. Actively anterior tilt the pelvis and hold for 20-30s. Repeat 3-5 times.	
Raise one leg to 100° of hip flexion with 90° knee flexion. Slowly raise the other leg to a similar position.	Slowly reach with one arm under the trunk towards the opposite hip. Alternate the arms.		Palpate the multifidus muscle with one hand. Slowly lift and lower the opposite arm to 90° of shoulder flexion and back, maintaining the contraction.
From the above position, slowly lower one leg, sliding it out on the plinth (with the foot supported), and then back up to the starting position.			Maintain the co-contraction for sit to stand.
Repeat the exercise as above, but keep the heel approximately 12cm above the plinth.			Maintain the co-contraction for walking.
From the starting position, slide both legs out into extension (feet supported on the plinth), and then back to the starting position.			Maintain the co-contraction for bending 30° into lumbar flexion and into slight extension.

INFORMATION FOR FIELDWORKERS

SUPINE	FOUR FOOT KNEELING	SITTING	STANDING
Repeat the exercise as above, but keep the heels approximately 12cm above the plinth.			Maintain the co-contraction for lifting a light object.
SIDE LYING			Maintain the co-contraction for twisting.
Keeping the heels together and hips and knees flexed, slowly lift the uppermost knee by turning out at the hip. Hold this position for 10s and repeat 10 times.			Maintain the co-contraction during aerobic exercise such as walking.

Exercises in supine will be monitored with the PBU.
Exercises are considered successfully completed if co-contraction is maintained for at least 10 repetitions without compensatory movement or until it starts to feel familiar and natural.
When an exercise has successfully been completed, it should be progressed by introducing an unstable base.

'Red dot' integration.

The patient should place red dots in appropriate positions (e.g. wristwatch, clock, telephone, coffee/ tea making area, office drawer, bathroom mirror, on the refrigerator door, etc.) as a reminder to contract the transversus abdominus and multifidus muscles. The contraction should be held for several seconds and repeated several times, without interrupting their normal/ functional activities.

Exercise progression:

1. Isometric co-contraction in supine and four foot kneeling. Progress to sitting and standing. Progress then on an unstable base.
2. Add linear movement with spine in neutral. When completed, add an unstable base while progressing to the next level of exercise.
3. Add rotational control with spine in neutral. Progress to an unstable base.
4. Progress to directional control exercises.
5. Progress to normal physiological movements where the trunk and girdles move away from the neutral position.
6. Activation during normal functional activities ('red dot' exercises).
7. Activation during occupational, recreational or sport specific skills.

ADDENDUM 2

PRECAUTIONS AND CONTRA-INDICATIONS TO PHYSIOTHERAPEUTIC ASSESSMENT AND TREATMENT OF THE PELVIC FLOOR MUSCLES

PRECAUTIONS AND CONTRA-INDICATIONS TO PHYSIOTHERAPEUTIC ASSESSMENT AND TREATMENT OF THE PELVIC FLOOR MUSCLES

PRECAUTIONS WHEN ADMINISTERING BIOFEEDBACK/VAGINAL EXAMINATION:

- Pregnancy,
- patients who have been advised to avoid sexual intercourse,
- inflammation/infection of the vulva/vagina,
- pelvic surgery in the previous two to three months, and
- psycho-sexual problems (Norton *et al.* 2007:6; Laycock *et al.* 2001:22,31).

PRECAUTIONS AND CONTRA-INDICATIONS WHEN ADMINISTERING NEUROMUSCULAR ELECTRICAL STIMULATION (NES):

Precautions:

- Altered vaginal sensation,
- selection of appropriate parameters to avoid muscle damage, and
- patients with epilepsy should only be treated after consultation with their medical practitioners.

Total contra-indications:

- Unreliable/uncooperative patients,
- implanted pacemaker,
- electrode placement over active/suspected malignant tumours,
- allergic reactions to electrodes/electrode gel,

- inflammation/infection of the vulva/vagina,
- haemorrhage/haematoma in the area,
- open wounds/abrasion in the area of application,
- compromised circulation,
- atrophic vaginitis,
- pregnancy,
- abnormal/malignant cells in the pelvic/abdominal area, and
- patients on anticoagulation therapy, history of pulmonary embolism or deep vein thrombosis (Laycock *et al.* 2001:38-39; Ballanger *et al.* 2000:9).

THE FOLLOWING CONDITIONS SHOULD BE TREATED BEFORE PFM TRAINING:

- Active urinary infection,
- haematuria,
- vaginal infection (including vaginal pain, discharge, etc.),
- hypo-oestrogenism with pain on contact with the mucosa,
- vaginal pain on contact with scars,
- dermatosis, and
- stage IV POP (Ballanger *et al.* 2000:5).

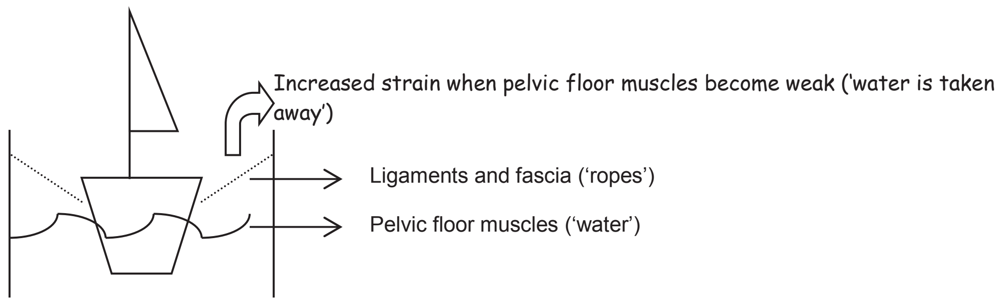
ADDENDUM 3

THE REHABILITATION PROGRAMME (patient copy)

THE REHABILITATION PROGRAMME (PATIENT COPY)

GROUP 1

The function of the pelvic floor muscles and their role in pelvic organ prolapse ("descending of the pelvic organs") can be explained by means of a 'boat in a dry dock'. The ship represents the pelvic organs, the ropes the ligaments and fascia, and the water the pelvic floor muscles. If the pelvic floor muscles ('water') provides good support, it will put little strain on the fascia and the ligaments. But when the muscles become weak, the strain on the ligaments and fascia increase and they will become stretched and damaged over time.



The pelvic floor muscles also have other very important functions despite the above supporting function. Dysfunction of the pelvic floor muscles may also lead to the following:

- Leaking of urine
- Leaking of faeces
- Problems with emptying of the bladder
- Problems with emptying of the rectum
- Sexual dysfunction
- Chronic pain

The following advice and exercises for the pelvic floor muscles may help to improve/prevent the above-mentioned problems.

LIFESTYLE ADVICE

1. Decreased levels of oestrogen (a hormone in women) at the time of menopause may cause the fascia to become less elastic and even the skin`s 'stiffness' may reduce.
2. Straining when emptying the bowels may put the pelvic floor muscles under strain and increase the risk of developing/worsening prolapse. The following advice may help to empty the bowels without straining:
   - *Sit with the knees higher than the hips.*
   - *Lift the heels or put a little bench/magazine etc. under the feet.*
   - *Keep the back straight.*
   - *Lean forward and support with the arms on the upper legs with the shoulders relaxed.*
   - *Expand the ribcage and breathe gently using the diaphragm (put the hand just below the sternum to facilitate the correct action).*
   - *Breathe superficial and with small volumes of air (as if in labour).*

   This position and mechanism help to open the sphincter and empty the bowels without applying any pressure.
3. In the case of constipation, it may also help to follow the correct diet. The best would be to consult a dietician for valuable advice.
4. Smoking may lead to chronic coughing. This chronic increase in the pressure in the abdomen puts the already defected pelvic floor under more strain and increase the risk/ worsening of the pelvic organ prolapse.
5. Obesity may also lead to an increase in pressure in the abdomen and thus put the pelvic floor muscles under more strain. If deemed necessary, a dietician should be consulted to help with the correct diet.
6. Activities such as heavy lifting, weight lifting, high-impact aerobics, and long-distance running may increase the risk of pelvic organ prolapse due to the strain it places on

the pelvic floor. Always bend your knees and keep the back straight when lifting up an object.

7. Bladder training will be necessary if you have a problem with the frequency of voiding or have an overactive bladder. The physiotherapist will advise and teach you how to use a bladder diary.

EXERCISES

Exercises should never cause any pain.
Exercise in a room without noise or distractions.
Thorough concentration is a prerequisite.

The following exercises should be done at home for the first week:

1. Sit on the armrest of a chair with the legs wide, feet on the floor, straight back and hips flexed. "Squeeze and lift" the perineal area away from the chair without rising up, and then relax again. This exercise increase the awareness of the perineal area.
2. Stop the dribble at the end of voiding.
3. Perform three sets of _____ slow-velocity, close to maximum contractions of the pelvic floor daily. The following instructions may help to perform the correct muscle contraction:
   - *"squeeze and lift"*
   - *"it is similar to an elevator door closing (squeeze) and then moving upstairs (lift)"*
   - *the action is similar as when "eating spaghetti"*
   - *the action is similar to a vacuum cleaner suctioning…*
4. Avoid contracting the inner thigh, buttock, or abdominal muscles (such as holding the breathe). If this should happen, it might indicate that the muscles are tired and that they need a rest before continuing with the next set.
5. Pre-contract and hold the contraction of the pelvic floor muscles before and during coughing, laughing, sneezing, and lifting ('the knack') to improve the timing of the muscle contraction.
   - *Nose blowing should be commenced first.*
   - *Sit upright, unsupported, in front of a mirror.*
   - *The blow is commenced from full inspiration using a strong, voluntary abdominal muscle contraction.*
   - *Repeat 5 to 6 times.*
   - *Progress the exercise from lying to sitting upright, sitting in a slumped ('slouched') position, standing upright, and forward lean standing.*
   - *Coughing can also be practised, applying the same principles as for nose blowing.*
   - *Then progress to sneezing. Emphasize expansion of the lower rib cage by placing the hands around the lower ribs. Exercise this with increased rapidity.*

If you still struggle after one week to activate the pelvic floor muscles, the physiotherapist may then decide to use other modalities to help the muscle to contract. This will be explained to you during your next consultation with the physiotherapist.

THE PELVIC FLOOR MUSCLE TRAINING PROGRAMME:

1. Exercises should be done daily, five times a week to allow for adaptation, with two-weekly follow-up visits to the physiotherapist during which re-assessments will take place and the training programme modified accordingly. During these sessions, exercises will be monitored by means of an electromyography machine which shows the intensity of the muscle contraction.
2. Exercises should be done until the muscle fatigue. Exercise for endurance should be performed at <25% of your maximum effort for contraction of the muscle. It should be alternated with sessions of fast contractions. The fast contractions should be as hard as possible (60-70% of your maximum effort).
3. Exercises will first be progressed by increasing the amount of the contractions (up to 10), and then by increasing the holding time until 8-12 repetitions can be done for 10s in the specific position (contraction:rest = 1:1).
4. When you are able to do this, the position can be progressed and the same regime followed (see table below for the positions of the exercise).

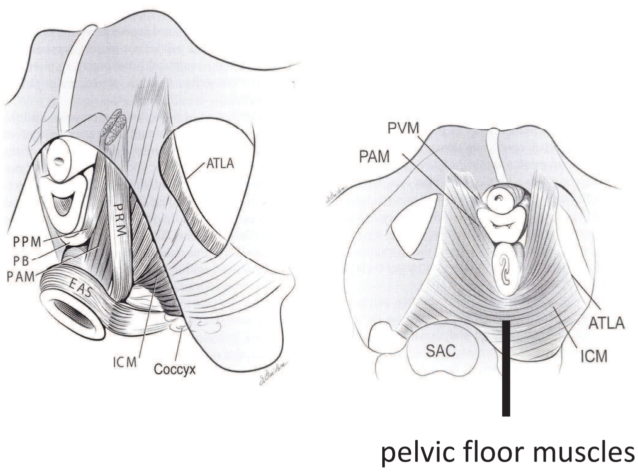
5. Exercises in the former positions should be continued by decreasing the rest intervals until the ratio of contraction:rest equals 1:0.5. In other words: the resting time should be half the contraction time.
6. If you achieve all the progressions successfully and the time period of six (6) months has not passed, progression should be in the volume of the training, e.g. progressing to 1-3 sets at a time (8-12 contractions each), with a rest interval of 1-2 minutes between the sets.

Progression of pelvic floor muscle exercises.

Progression	Exercise position
1	Supine with hip and knee flexion. Prone with one hip to the side, outward rotated.
2	Four foot kneeling with hips in outward rotation and supporting on elbows.
3	Sitting with crossed legs, supporting on the hands with the shoulder and elbow in extension.
4	Standing with feet slightly apart.
5	Standing in a squat position.
6	Supine, hips and knees in flexion, contracting abdominal muscles as if in a 'crunch' exercise.
7	Standing, climbing a stair. Standing, squatting.

Do not worry! Your therapist will tell you exactly what to do when! ☺

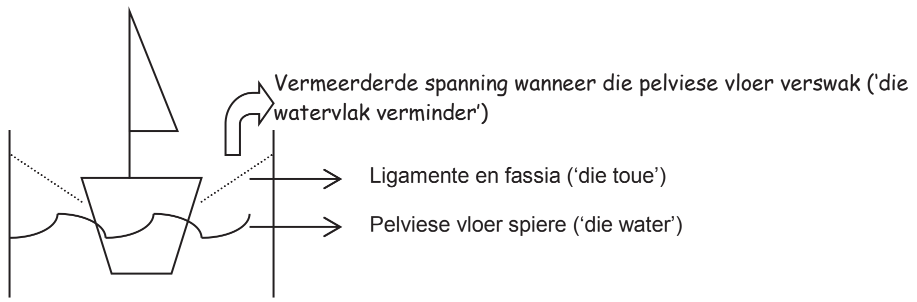
Keep an accurate training diary on the form provided!!



EXERCISE PRESCRIPTION CHART

WEEK	POSITION	CONTRAC= TION TIME	RESTING TIME	SETS	TIME BETWEEN SETS

Die funksie van die pelviese vloer spiere en hulle rol in pelviese orgaan prolaps ("afsakking van die pelviese organe") kan verduidelik word aan die hand van `n 'boot in 'n vlak hawe'. Die skip stel die pelviese organe voor, die toue die ligamente en fassia, en die water die pelviese vloer spiere. Indien die pelviese vloer spiere ('water') goeie ondersteuning bied, veroorsaak dit min spanning op die fassia en ligamente. Maar wanneer die spiere swak word, vermeerder die spanning op die fassia en ligamente en word hulle gestrek en al hoe swakker met die verloop van tyd.



Die pelviese vloer spiere het ook ander belangrike funksies as net die ondersteunende funksie. Verkeerde funksionering van die pelviese vloer spiere kan ook tot die volgende lei:

- Lek van urine
- Lek van stoelgang
- Probleme om die blaas te ledig
- Probleme om die rektum te ledig
- Seksuele disfunksie
- Kroniese pyn

Die volgende advies en oefeninge vir die pelviese vloer spiere kan help om al bogenoemde probleme te verbeter/voorkom.

ADVIES OOR LEWENSTYL

1. Verlaagde vlakke van estrogeen (die vroulike hormoon) tydens die menopouse kan veroorsaak dat die fassia minder rekbaar word en dat selfs die vel sy 'styfheid' kan verloor.
2. Deur te druk om die stoelgang te passeer, kan lei tot verhoogde spanning op die pelviese vloer spiere en 'n verhoogde risiko om prolaps te ontwikkel/vererger. Die volgende advies kan help om die stoelgang te passeer sonder om te druk:
   - *Sit met die knieë hoer as die heupe.*
   - *Lig die hakke of plaas `n klein bankie/tydskrifte onder die voete..*
   - *Hou die rug reguit.*
   - *Leuen vorentoe en ondersteun met die arms op die bobene terwyl die skouers ontspanne bly.*
   - *Laat die borskas uitsit en haal rustig asem deur die diafragma te gebruik (plaas die hande net onder die sternum om die korrekte aksie te fasiliteer).*
   - *Haal oppervlakkig en in klein volumes asem (soos tydens kraam).*

   Hierdie posisie en meganisme help om die sfinkter te open en om die stoelgang te passeer sonder om enige drukking toe te pas.
3. Indien u sukkel met konstipasie, kan dit ook help om 'n korrekte dieet te volg. Die beste opsie is om `n dieetkundige te konsulteer vir waardevolle advies.
4. Rook kan lei tot kroniese hoesbuie. Hierdie kroniese verhoogde druk in die abdomen plaas die alreeds verswakte pelviese vloer onder nog meer stremming en verhoog die risiko/vererger die pelviese orgaan prolaps.
5. Obesiteit kan ook lei tot 'n verhoogde druk in die abdomen en plaas dus die pelviese vloer spiere onder meer stremming. Indien dit nodig geag word, kan `n dieetkundige konsulteer word om te help met die korrekte dieet.
6. Aktiwiteite soos swaar voorwerpe optel, swaar gewigte oefen, hoë-impak aërobiese oefeninge, lang afstande hardloop kan die risiko om pelviese orgaan prolaps te

ontwikkel vermeerder as gevolg van die spanning wat op die pelviese vloer geplaas word. Buig altyd die knieë en hou die rug reguit wanneer `n voorwerp opgetel word.

7. Blaas ‘heropleiding’ sal nodig wees indien u `n probleem het met frekwensie van urinering of indien u `n ooraktiewe blaas het. Die Fisioterapeut sal u adviseer en leer hoe om `n blaasdagboek te gebruik.

OEFENINGE

Oefeninge moet nooit enige pyn veroorsaak nie.
Oefen in `n stil vertrek sonder versteurings.
Goeie konsentrasie is `n voorvereiste.

Die volgende oefeninge moet vir die eerste week tuis gedoen word:

1. Sit wydsbeen op die armlening van `n stoel, voete op die grond, reguit rug en die heupe gebuig. ”Knyp en lig” die perineale area weg van die stoel sonder om op te staan, en ontspan dan weer. Hierdie oefening verbeter die bewustheid van die perineal area.
2. Stop die druppeltjies wanneer u klaar die blaas geledig het.
3. Doen drie stelle van _____ stadige spoed, amper maksimale kontraksies van die pelviese vloer daagliks. Die volgende instruksies kan help om die korrekte spierkontraksie uit te voer:
   - *“knyp en lig”*
   - *“dit is soortgelyk aan `n hyser se deur wat toegaan (knyp) en dan boontoe beweeg (lig)”*
   - *die aksie is soortgelyk aan “spaghetti eet”*
   - *die aksie is soortgelyk aan `n stofsuier wat suig…*
4. Moet nie die binnebeen, boudspiere, of abdominale spiere (soos wanneer die asem opgehou word) saamtrek nie. Indien dit gebeur, is dit `n aanduiding dat die spiere moeg is en eers moet rus voor u weer kan voortgaan met die volgende stel.
5. Trek die pelviese vloer spiere saam en hou die kontraksie voor en tydens hoes, lag, nies, en die optel van voorwerpe (die ’knack’) om die tydsberekening van die spierkontraksie te verbeter.
   - *Begin deur dit te oefen wanneer u u neus moet blaas.*
   - *Sit regop, sonder ondersteuning en voor `n spieël.*
   - *Blaas die neus vanaf `n volle inspirasie deur `n sterk, willekeurige abdominale spiersametrekking te gebruik.*
   - *Herhaal 5 tot 6 keer.*
   - *Progresseer deur die posisie te verander vanaf lê na regop sit, sit in `n ‘slegte’ posisie, regop staan, en deur vorentoe te leun in staan.*
   - *Hoes kan ook so geoefen word deur dieselfde beginsels as vir die neus blaas toe te pas.*
   - *Progresseer dan na nies. Beklemtoon die uitsetting van die onderste deel van die borskas deur die hande op die onderste ribbes te plaas. Oefen hierdie dan al hoe vinniger.*

Indien u steeds na een week sukkel om die pelviese vloer spiere te aktiveer, kan die fisioterapeut besluit om ander modaliteite ook te gebruik om die spiere te help om saam te trek. Dit sal aan u verduidelik word tydens u volgende besoek aan die Fisioterapeut.

DIE PELVIESE VLOER SPIER OEFENPROGRAM:

1. Oefeninge moet daagliks gedoen word, vyf keer `n week om die spiere kans te gee om te verander (m.a.w. sterker te word), met twee-weeklikse opvolgbesoeke aan die fisioterapeut waartydens herevaluerings gedoen sal word en die oefeninge dienooreenkomstig aangepas sal word. Gedurende hierdie sessies, sal die oefeninge gemonitor word deur `n elektromiografie masjien wat die intensiteit van die spierkontraksies sal wys.
2. Die oefeninge moet gedoen word totdat die spiere uitgeput is. Oefeninge om die uithouvermoeë te verbeter moet teen <25% van u maksimale poging van spierkontraksie wees. Dit moet afgewissel word met sessies van vinnige spierkontraksies. Die vinnige kontraksies moet so sterk as moontlik (60-70% van u maksimale poging) uitgevoer word.

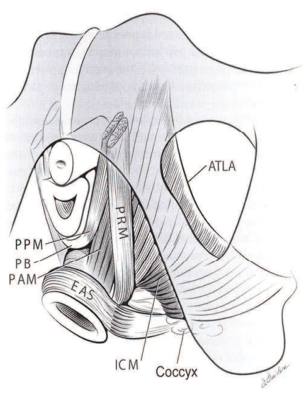
3. Die oefeninge sal eers geprogresseer word deur die hoeveelheid kontraksies te vermeerder (tot `n maksimum van 10), en dan deur die kontraksietyd te vermeerder totdat 8-12 repetisies vir 10s elk in die spesifieke posisie gedoen kan word (kontraksie:rus = 1:1).
4. Sodra u in staat is om dit te doen, kan die posisie waarin u die oefening doen geprogresseer word en dieselfde riglyne gevolg word (sien die onderstaande tabel vir die verskillende posisies van die oefeninge).
5. Oefeninge in die ‘makliker’ posisies moet egter mee voortgegaan word deur die rusintervalle te verminder totdat die kontraksietyd:rustyd gelyk is aan 1:0.5. Met ander woorde: die rustyd moet die helfte van die kontraksietyd wees.
6. Indien u al bogenoemde progressies suksesvol bereik het en die periode van ses (6) maande is nog nie verstreke nie, kan u begin om die volume van u oefeninge te vermeerder, bv. progresseer na 1-3 stelle op `n slag (8-12 kontraksies elk), met `n rusinterval van 1-2 minute tussen die stelle.

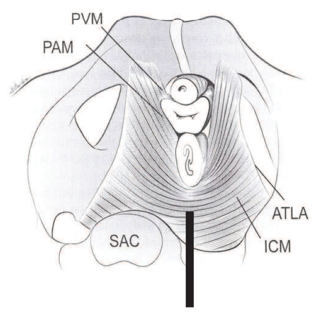
Progressie van die pelviese vloer spier oefeninge.

Progressie	Oefen posisie
1	Lê op die rug met die heupe en knieë gebuig. Lê op die maag met die been na buite en uitwaarts geroteer.
2	Handeviervoet met die heupe uitwaarts geroteer en ondersteun op die elmboë.
3	Sit met gekruisde bene, ondersteun op die hande met die skouer en elmboog reguit en na agter.
4	Staan met die voete effens uit mekaar.
5	Staan in `n ‘squat’ posisie.
6	Lê op die rug, heupe en knieë gebuig, abdominale spiere saamgetrek asof in `n ‘crunch’ oefening.
7	Staan, klim `n trappie. Staan, ‘squat’.

Moet nie bekommerd wees nie! U terapeut sal u presies vertel wat om wanneer te doen! ☺

Hou `n akkurate oefendagboek op die verskafte vorm!!





pelviese vloer spiere

OEFENVOORSKRIF KAART

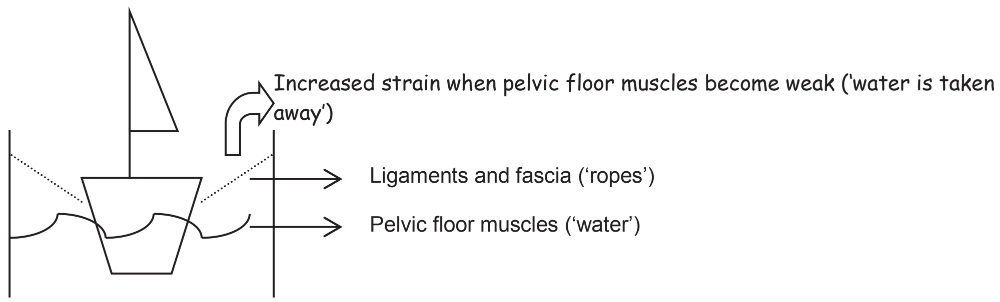
WEEK	POSISIE	KONTRAK= SIETYD	RUSTYD	STELLE	TYD TUSSEN STELLE

THE REHABILITATION PROGRAMME (PATIENT COPY)

GROUP 2

Pictures adapted from ExerPro™

The function of the pelvic floor muscles and their role in pelvic organ prolapse ("descending of the pelvic organs") can be explained by means of a 'boat in a dry dock'. The ship represents the pelvic organs, the ropes the ligaments and fascia, and the water the pelvic floor muscles. If the pelvic floor muscles ('water') provides good support, it will put little strain on the fascia and the ligaments. But when the muscles become weak, the strain on the ligaments and fascia increase and they will become stretched and damaged over time.



The pelvic floor muscles also have other very important functions despite the above supporting function. Dysfunction of the pelvic floor muscles may also lead to the following:

- Leaking of urine
- Leaking of faeces
- Problems with emptying of the bladder
- Problems with emptying of the rectum
- Sexual dysfunction
- Chronic pain

The pelvic floor muscles also function together with the deep abdominal muscles and the small, deep back muscles as well as the diaphragm to control the intra-abdominal pressure and act as your body`s own corset: protecting you from injuries and supporting important organs, joints and movements. Therefore it is important to exercise all of these muscles together in order to function as normal and optimal as possible.

The following advice and exercises for the pelvic floor and stabiliser muscles may help to improve/prevent the above-mentioned problems.

LIFESTYLE ADVICE

1. Decreased levels of oestrogen (a hormone in women) at the time of menopause may cause the fascia to become less elastic and even the skin`s 'stiffness' may reduce.
2. Straining when emptying the bowels may put the pelvic floor muscles under strain and increase the risk of developing/worsening prolapse. The following advice may help to empty the bowels without straining:
   - *Sit with the knees higher than the hips.*
   - *Lift the heels or put a little bench/magazine etc. under the feet.*
   - *Keep the back straight.*
   - *Lean forward and support with the arms on the upper legs with the shoulders relaxed.*
   - *Expand the ribcage and breathe gently using the diaphragm (put the hand just below the sternum to facilitate the correct action).*
   - *Breathe superficial and with small volumes of air (as if in labour).*

   This position and mechanism help to open the sphincter and empty the bowels without applying any pressure.
3. In the case of constipation, it may also help to follow the correct diet. The best would be to consult a dietician for valuable advice.
4. Smoking may lead to chronic coughing. This chronic increase in the pressure in the abdomen puts the already defected pelvic floor under more strain and increase the risk/ worsening of the pelvic organ prolapse.

5. Obesity may also lead to an increase in pressure in the abdomen and thus put the pelvic floor muscles under more strain. If deemed necessary, a dietician should be consulted to help with the correct diet.
6. Activities such as heavy lifting, weight lifting, high-impact aerobics, and long-distance running may increase the risk of pelvic organ prolapse due to the strain it places on the pelvic floor. Always bend your knees and keep the back straight when lifting up an object.
7. Bladder training will be necessary if you have a problem with the frequency of voiding or have an overactive bladder. The physiotherapist will advise and teach you how to use a bladder diary.

EXERCISES

Exercises should never cause any pain.
Exercise in a room without noise or distractions.
Thorough concentration is a prerequisite.

The following exercises should be done at home for the first week:

1. Sit on the armrest of a chair with the legs wide, feet on the floor, straight back and hips flexed. "Squeeze and lift" the perineal area away from the chair without rising up, and then relax again. This exercise increase the awareness of the perineal area.
2. Stop the dribble at the end of voiding.
3. Perform three sets of _____ slow-velocity, close to maximum contractions of the pelvic floor daily. The following instructions may help to perform the correct muscle contraction:
   - *"squeeze and lift"*
   - *"it is similar to an elevator door closing (squeeze) and then moving upstairs (lift)"*
   - *the action is similar as when "eating spaghetti"*
   - *the action is similar to a vacuum cleaner suctioning…*
4. Avoid contracting the inner thigh, buttock, or abdominal muscles (such as holding the breathe). If this should happen, it might indicate that the muscles are tired and that they need a rest before continuing with the next set.
5. Pre-contract and hold the contraction of the pelvic floor muscles before and during coughing, laughing, sneezing, and lifting ('the knack') to improve the timing of the muscle contraction.
   - *Nose blowing should be commenced first.*
   - *Sit upright, unsupported, in front of a mirror.*
   - *The blow is commenced from full inspiration using a strong, voluntary abdominal muscle contraction.*
   - *Repeat 5 to 6 times.*
   - *Progress the exercise from lying to sitting upright, sitting in a slumped ('slouched') position, standing upright, and forward lean standing.*
   - *Coughing can also be practised, applying the same principles as for nose blowing.*
   - *Then progress to sneezing. Emphasize expansion of the lower rib cage by placing the hands around the lower ribs. Exercise this with increased rapidity.*

If you still struggle after one week to activate the pelvic floor muscles, the physiotherapist may then decide to use other modalities to help the muscle to contract. This will be explained to you during your next consultation with the physiotherapist.

THE PELVIC FLOOR MUSCLE TRAINING PROGRAMME:

1. Exercises should be done daily, five times a week to allow for adaptation, with two-weekly follow-up visits to the physiotherapist during which re-assessments will take place and the training programme modified accordingly. During these sessions, exercises will be monitored by means of an electromyography machine which shows the intensity of the muscle contraction.
2. Exercises should be done until the muscle fatigue. Exercise for endurance should be performed at <25% of your maximum effort for contraction of the muscle. It should be alternated with sessions of fast contractions. The fast contractions should be as hard as possible (60-70% of your maximum effort).

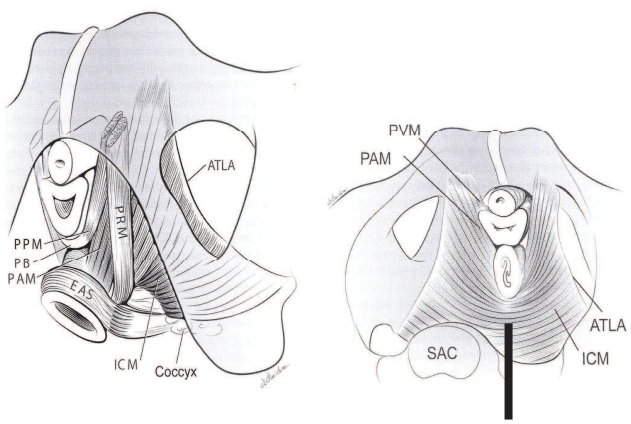
3. Exercises will first be progressed by increasing the amount of the contractions (up to 10), and then by increasing the holding time until 8-12 repetitions can be done for 10s in the specific position (contraction:rest = 1:1).
4. When you are able to do this, the position can be progressed and the same regime followed (see table below for the positions of the exercise).
5. Exercises in the former positions should be continued by decreasing the rest intervals until the ratio of contraction:rest equals 1:0.5. In other words: the resting time should be half the contraction time.
6. If you achieve all the progressions successfully and the time period of six (6) months has not passed, progression should be in the volume of the training, e.g. progressing to 1-3 sets at a time (8-12 contractions each), with a rest interval of 1-2 minutes between the sets.

Progression of pelvic floor muscle exercises.

Progression	Exercise position
1	Supine with hip and knee flexion. Prone with one hip to the side, outward rotated.
2	Four foot kneeling with hips in outward rotation and supporting on elbows.
3	Sitting with crossed legs, supporting on the hands with the shoulder and elbow in extension.
4	Standing with feet slightly apart.
5	Standing in a squat position.
6	Supine, hips and knees in flexion, contracting abdominal muscles as if in a ‘crunch’ exercise.
7	Standing, climbing a stair. Standing, squatting.

When you have reached level 6, the pelvic floor muscles should be contracted during the exercises for the stabiliser muscles.

Do not worry! Your therapist will tell you exactly what to do when! ☺



pelvic floor muscles

EXERCISE PRESCRIPTION CHART

WEEK	POSITION	CONTRAC= TION TIME	RESTING TIME	SETS	TIME BETWEEN SETS

EXERCISE PROGRAMME FOR THE STABILISERS:

1. The therapist is going to use a pressure biofeedback unit to teach you the correct contraction of the abdominal and back muscles. It consists of a cushion (inflated with air) that is placed underneath your lower back. You will then be asked to contract the muscles so that the pressure inside the cushion increases sufficiently. The cushion is inflated to 40mmHg and should change no greater than 10mmHg during contraction/ exercise.
2. During the contractions you should breathe normally: inhaling and exhaling the air to the lower parts of the lungs and also using the diaphragm.
3. Activation of the transversus abdominus and multifidus muscles begin in supine, prone and four point kneeling. The spine must be in neutral during training – in other words not hollow or rounded.
4. Muscles are first contracted and activated in isolation. When you are able to co-contract the transversus abdominus and multifidus muscles 10 times for 10s, exercises can be progressed firstly to the sitting and then to the standing position.
5. There should be no movement of the stomach or pelvis during contraction and it should be only <25% of your maximum effort.
6. Prevent substitution strategies at all times (see next paragraph).
7. Facilitation techniques can be used to encourage contraction if you are unable to perform the setting actions (see next paragraph).
8. Contractions should be ceased if muscle substitution occurs, breathing control is lost, muscle fatigue occurs or there is an increase in pain.
9. When able to hold the co-contractions in each position, the exercise can be progressed adding limb load and functional movements as described in your exercise programme.
10. Contraction time should be increased to 60s prior to integration into functional activities of your daily living.
11. You will be prescribed 2-4 exercises during the immediate pre-operative and post-operative phase of the study. These exercises should be done twice a day.
12. During the rehabilitation phase the amount of exercises will be increased to 6-8 at a time.

The following methods may help you to activate your muscles:

Transversus abdominus:

1. “Gently draw the lower abdomen up and in.”
2. “Pull the umbilicus inwards towards the spine.”
3. “Pull your navel up towards your spine.”
4. Deep, gentle manual pressure on the muscle.
5. Combine the co-contraction with contraction of the pelvic floor muscles.
6. Use of the pressure biofeedback unit.

Multifidus:

1. “Let the muscles bulge (swell) on the sides of the spine.”
2. Manual contact on the muscle.

The following substitution strategies should be prevented:

1. The rib cage, shoulders, and pelvis must remain still at all times.
2. Normal breathing should be encouraged.
3. Prevent abnormal bracing using the superficial stomach muscles (depression of the rib cage and horizontal abdominal skin crease).

Keep an accurate training diary on the form provided!!

LOCAL AND GLOBAL STABILITY PROGRAMME

The following flow chart will help to explain how you are going to progress through this exercise programme. However, your physiotherapist will always explain and demonstrate to you which exercises should be done and how you should do them.

The exercises are divided into five groups according to the position they are done in. When you start in a certain position, you will always first learn how to activate the muscle in that position. Once you can activate the abdominal muscles for 10 times x 10 seconds, you can start adding limb movement (in that position) and also progress to activation in the next position. However, you must continue with the basic activation exercise in each position until you can hold it for 60 seconds.

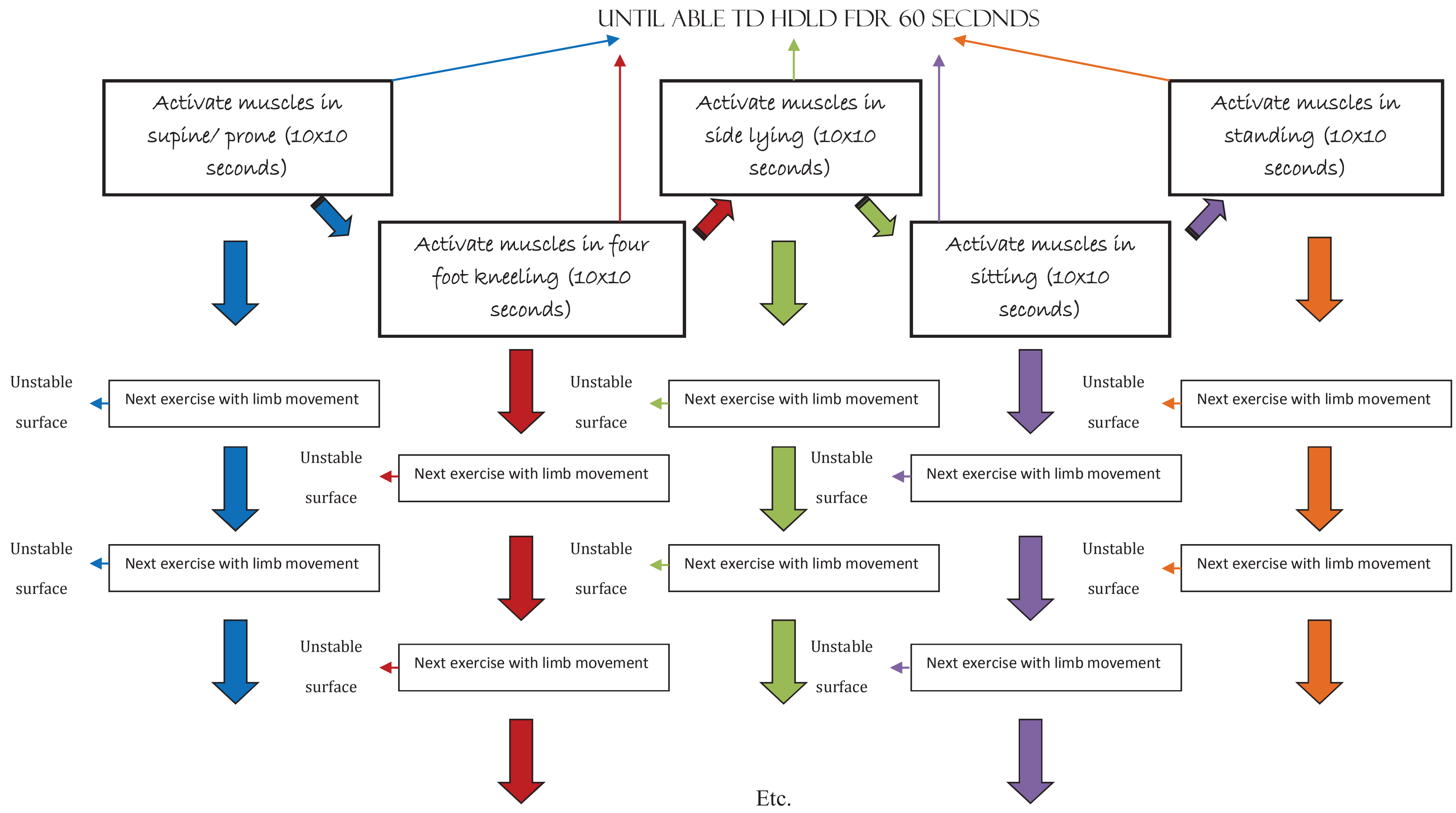
When you have mastered a certain exercise, you can progress it to an unstable surface as indicated in the flow chart; while you are also progressing to the next exercise in the list on a stable surface. When you have mastered the new exercise in the list, the same sequence must be followed as have just been described. This method must be followed until you have moved through all the exercises in the programme.

Always remember that the effort of contraction of the abdominal and back muscles should not exceed 25% of your maximum effort. Also be very cautious not to `cheat` by contracting the wrong muscles e.g. holding the breath, moving or `bracing` the rib cage, shoulders, or pelvis. The contractions must be ceased if breathing control is lost, muscle fatigue occurs or if there is an increase in pain.

Prior to surgery and during the first six weeks post-operatively, you will receive approximately **two to four exercises** which should be done **twice daily**. After six weeks you will receive **six to eight exercises** at a time.

Remember to keep your training diary!

Enjoy the exercises!



UNSTABLE SURFACES THAT YOU CAN USE AT HOME:

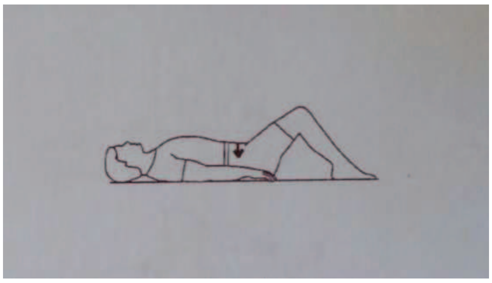
Lying supine – on an exercise mat/ mattress

Four foot kneeling – on an exercise mat/ mattress/ hard cushion under hands

Side lying – on an exercise mat/ mattress

Sitting – on a hard cushion

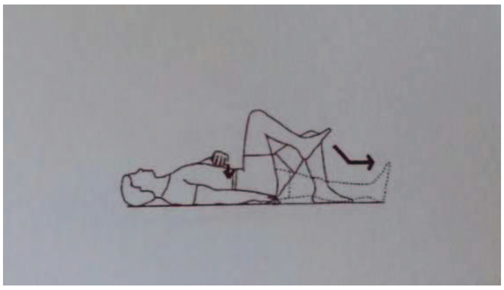
Standing – on a hard cushion/ mattress/ exercise mat



Gently draw the lower abdomen up and in. ("Pull your navel up towards your spine.")

The rib cage, shoulders, and pelvis must remain still at all times. Breathe normally the whole time. Prevent 'bracing'.

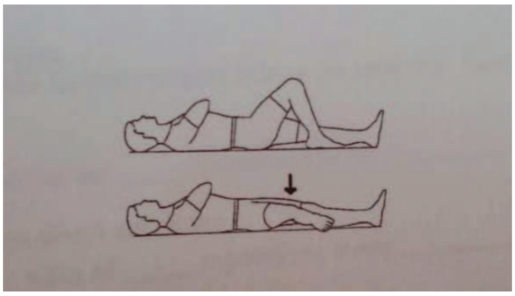
Amount of repetitions: **Amount of sets:** **Rest intervals:**



Lie with the hip and knees bent. Slowly straighten one leg (foot supported on the bed) and return to the start position. Alternate the legs.

Maintain a proper lumbar position throughout the exercise. Do not hold the breath.

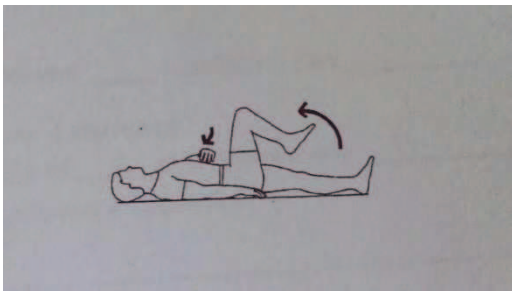
Amount of repetitions: **Amount of sets:** **Rest intervals:**



Lie on the back with the right leg bent, foot on the floor. Move the right leg outward, keeping the foot supported beside the straight leg. Keep pelvic bones flat on the floor. Return to the start position and repeat. Repeat with the left leg.

Keep the abdominal muscles contracted. Place hands on the pelvic bones to help ensure no movement.

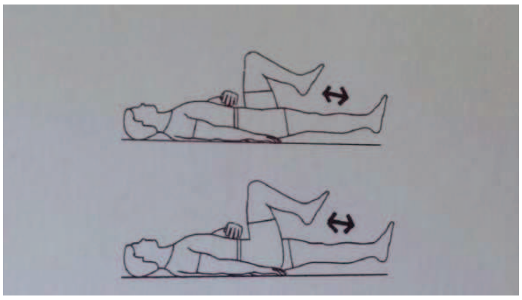
Amount of repetitions: **Amount of sets:** **Rest intervals:**



Lie on the back. Gently draw the lower abdomen up and in. While maintaining abdominal tension, lift one leg up to 100 degrees, with the knee bent at 90 degrees, as shown. Slowly raise the other leg up to a similar position. Hold for 10 seconds and then return the legs to the floor one by one. Repeat.

Do not hold the breath. The rib cage, shoulders, and pelvis must remain still at all times.

Amount of repetitions: **Amount of sets:** **Rest intervals:**

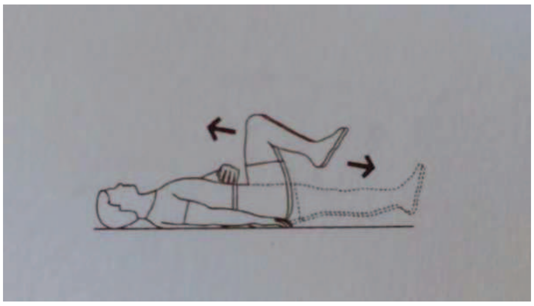


Lie on the back. While maintaining abdominal tension, lift both legs up to 100 degrees, with the knees bent 90 degrees.

1. Straighten one leg, by sliding it on the floor while keeping the other leg bent. When your physiotherapist is satisfied that you are doing the exercise correct, you can progress to the following level.
2. Straighten one leg, keeping the leg up off the floor (the heel approximately 12cm above the plinth) while keeping the other leg bent. Return this leg to the bent position and repeat with the other leg. Repeat this sequence.

Maintain a proper lumbar position throughout the exercise. Do not hold the breath.

Amount of repetitions:	**Amount of sets:**	**Rest intervals:**

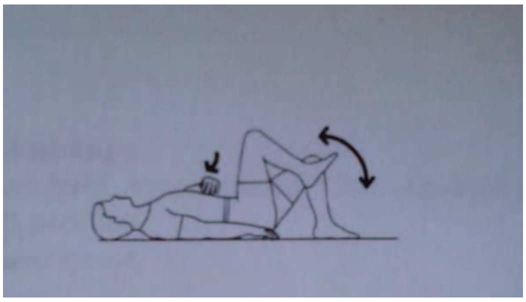


Lie on the back. While maintaining abdominal tension, lift both legs up to 100 degrees with the knees bent.

1. Straighten both legs, but keep them on the floor. Return the legs to the bent position and repeat. When your physiotherapist is satisfied that you are doing the exercise correct, you can progress to the next progression.
2. Repeat the exercise as above, but keep the heels approximately 12cm above the floor.

Maintain a proper lumbar position throughout the exercise. Do not hold the breath.

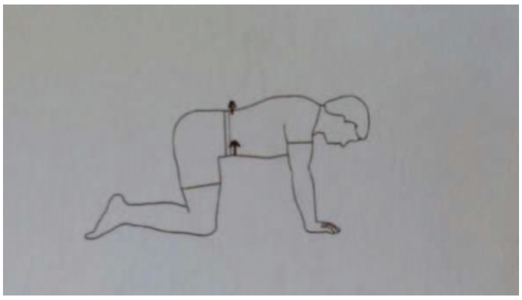
Amount of repetitions:	**Amount of sets:**	**Rest intervals:**



Lie with the hip and knee bent. Slowly raise one leg to 90 degrees of hip flexion and return to the start position. Alternate the legs.

Gently draw the lower abdomen in and up while you are doing the exercise.

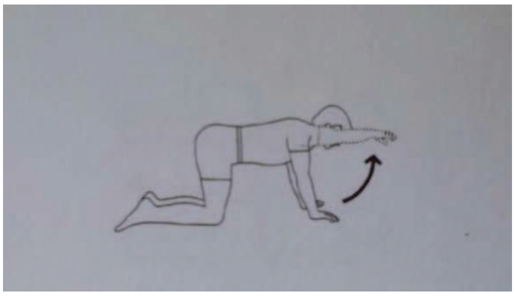
Amount of repetitions:	**Amount of sets:**	**Rest intervals:**



Begin on the hands and knees. The hands must be positioned underneath the shoulders and the knees underneath the hips. Gently draw the lower abdomen up and in. ("Pull your navel up towards the spine".) Also let the muscles bulge ("swell") on the sides of the spine. Hold for 10 seconds and relax for 10 seconds and repeat until fatigue.

Imagine balancing a glass of water or a cane on your back.

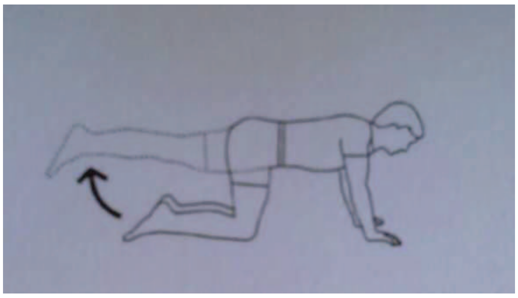
Amount of repetitions:	**Amount of sets:**	**Rest intervals:**



Kneel on all fours. Lift the arm up to 180 degrees, keeping the elbow straight. Return the arm to the start position. Lift the right arm. Lower and repeat.

Maintain a neutral spine and do not allow the lower back to twist. Keep the lower abdomen "up and in" and let the muscles bulge on the sides of the spine.

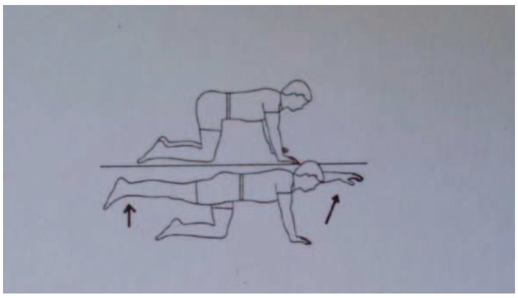
Amount of repetitions:	**Amount of sets:**	**Rest intervals:**



Begin with kneeling on all fours. Lift the right leg up and back approximately 12cm above the ground. Return to the start position. Lift the opposite leg and lower. Repeat.

Maintain neutral spine and do not allow the lower back to twist. Gently draw the lower abdomen "up and in" the whole time. Also remember to bulge the muscles on the side of the spine.

Amount of repetitions:	**Amount of sets:**	**Rest intervals:**



Begin on the hands and knees. Extend the right leg 12cm above the ground while lifting the left arm to 180 degrees. Hold 2-3 seconds. Return to the start position and repeat with the left leg and right arm.

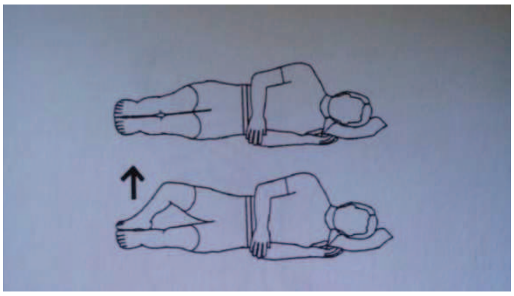
Maintain a neutral spine and do not twist. Remember to gently draw the lower abdomen 'up and in'. Also bulge the muscles on the side of the spine.

Amount of repetitions:	**Amount of sets:**	**Rest intervals:**

Kneel on the hands and knees. Lift the right arm out to the side and upwards, twisting to the right. Turn the neck to the right and follow the arm by looking at it. Then reach under the trunk towards the opposite hip. Return to the start position and repeat with the left arm.

Keep the lower abdominal muscles contracted.

Amount of repetitions:	Amount of sets:	Rest intervals:



Lie on the right side with the knees bent and the feet together. Lift the left knee upward by turning out at the hip. Lower and repeat. Repeat the exercise lying on the left side.

Keep the pelvis in a vertical position. Do not let it fall forwards or backwards when turning at the hip.

Amount of repetitions:	Amount of sets:	Rest intervals:

Sit with the back supported and knees at 90 degrees and feet flat on the floor. Place the hands on the chair at the side in a relaxed position, or let them hang down. Gently draw the abdomen "up and in" ("navel towards the spine") and bulge the muscles on the sides of the spine. Hold for 10seconds and repeat.

Make sure you sit in an upright position (neutral spine). Do not slump.

Amount of repetitions:	Amount of sets:	Rest intervals:

Sit on a chair with the arms relaxed by the side. Slowly lift one arm to 180 degrees. Return to the start position. Alternate the arms. As soon as 10 repetitions can be correctly executed, the exercise can be progressed to sitting on an exercise ball as shown.

Keep the back in a neutral position. When sitting on the exercise ball, sit slightly backward.

Amount of repetitions: **Amount of sets:** **Rest intervals:**

Sit on a chair with the feet on the floor. Slowly lift one leg to bend the hip 100 degrees. Return to the start position. Alternate the legs.

Sit in an upright position and gently draw the lower abdomen "up and in".

Amount of repetitions: **Amount of sets:** **Rest intervals:**

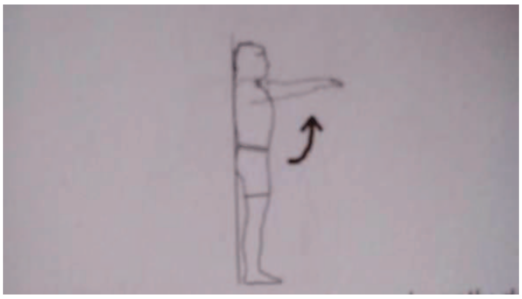
Sit in a chair with the spine and pelvis in a neutral alignment. Straighten the knee to the point where the lumbar spine starts to bend/ where resistance is felt in the leg muscles. Support the leg passively in this position (with the help of another person) or by means of a chair. Actively tilt the pelvis forward and hold for 20-30 seconds.

Amount of repetitions: **Amount of sets:** **Rest intervals:**

Stand with the feet shoulder distance apart. Gently draw the lower abdomen "up and in". Bulge the muscle on the side of the spine. Hold for 10 seconds and rest then for 10 seconds.

Do not hold the breath. The rib cage, shoulders, and pelvis should remain still at all times. Keep the spine in a neutral position.

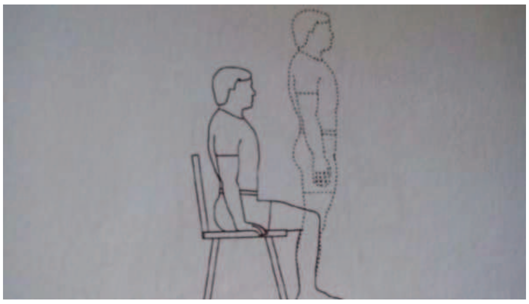
Amount of repetitions: **Amount of sets:** **Rest intervals:**



Stand against a wall. Bulge the muscle on the side of the spine and gently draw the lower abdomen up and in. Slowly lift and lower the opposite arm to 90 degrees and back again, maintaining the contraction of the back muscles. Alternate with the opposite arm.

Stand straight with a neutral spine and feet shoulder width apart.

Amount of repetitions: **Amount of sets:** **Rest intervals:**



Begin in a sitting position. Gently draw the lower abdomen "up and in" and bulge the muscle on the side of the spine. Maintain the co-contraction while slowly standing and sitting down again. Repeat.

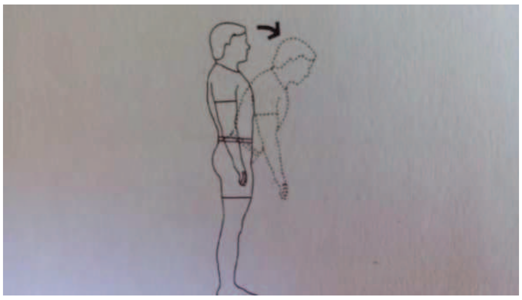
Keep the feet shoulder width apart and maintain a neutral spine.

Amount of repetitions: **Amount of sets:** **Rest intervals:**

Gently draw the lower abdomen "up and in" and bulge the muscles on the side of the spine. Maintain this contraction while walking at a comfortable pace.

Do not hold the breath. The shoulders, rib cage, and pelvis must not move excessively, nor be rigid.

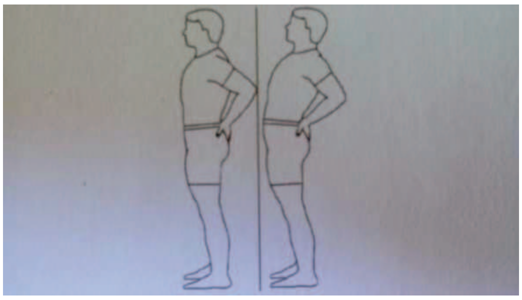
Amount of repetitions: **Amount of sets:** **Rest intervals:**



Stand with the hands at the sides. Gently draw the lower abdomen "up and in" and bulge the muscle at the side of the spine. Maintain this contraction and slowly bend forward (30 degrees), bending only at the hip joint. Allow the arms to hang in front as you bend. Return to the standing position by straightening at the hip joint. Repeat.

Do not bend or arch the lower back. Maintain a neutral spine. Do not hold the breath.

Amount of repetitions: **Amount of sets:** **Rest intervals:**



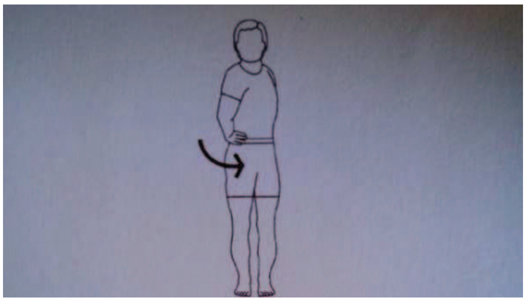
Stand with the feet shoulder width apart. Repeat the exercise as the previous, but just bending backwards.

Amount of repetitions: **Amount of sets:** **Rest intervals:**

Use a light object. Stand in front of the object. Bend the knees, keeping the back straight. Gently draw the lower abdomen "up and in" and bulge the muscles on the side of the spine. Maintain this contraction and grasp the object and lift it by straightening the knees. Carry the object for a few steps. Lower it and repeat the lift and carry.

Keep the object close to the body when carrying it. Do not twist the body while carrying, lowering or lifting.

Amount of repetitions: **Amount of sets:** **Rest intervals:**



Stand. Place the hands on the hips and keep the feet flat on the floor. Gently draw the lower abdomen "up and in" and bulge the muscles on the sides of the spine. Maintain this contraction and twist the trunk to the left and then to the right. Repeat.

Do not hold the breath. The shoulders, rib cage, and pelvis must not move excessively.

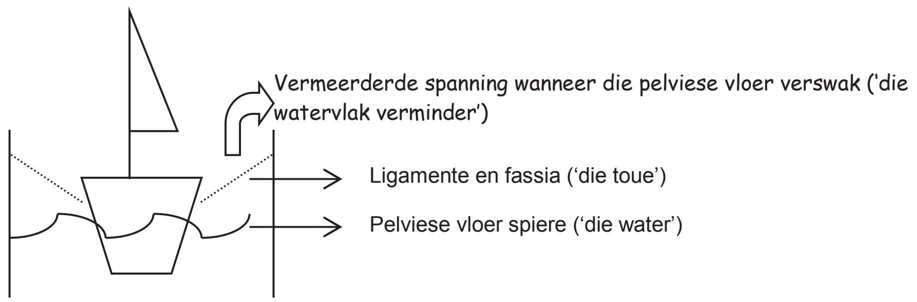
Amount of repetitions: **Amount of sets:** **Rest intervals:**

Gently draw the lower abdomen "up and in" and bulge the muscle on the side of the spine. Maintain this contraction while doing any aerobic exercise such as walking, cycling, on the cross trainer, jogging, etc.

Do not hold the breath.

Amount of repetitions: **Amount of sets:** **Rest intervals:**

Die funksie van die pelviese vloer spiere en hulle rol in pelviese orgaan prolaps ("afsakking van die pelviese organe") kan verduidelik word aan die hand van `n 'boot in 'n vlak hawe'. Die skip stel die pelviese organe voor, die toue die ligamente en fassia, en die water die pelviese vloer spiere. Indien die pelviese vloer spiere ('water') goeie ondersteuning bied, veroorsaak dit min spanning op die fassia en ligamente. Maar wanneer die spiere swak word, vermeerder die spanning op die fassia en ligamente en word hulle gestrek en al hoe swakker met die verloop van tyd.



Die pelviese vloer spiere het ook ander belangrike funksies as net die ondersteunende funksie. Verkeerde funksionering van die pelviese vloer spiere kan ook tot die volgende lei:

- Lek van urine
- Lek van stoelgang
- Probleme om die blaas te ledig
- Probleme om die rektum te ledig
- Seksuele disfunksie
- Kroniese pyn

Die pelviese vloer spiere funksioneer ook saam met die dieper abdominale en kleiner, diep rugspiere sowel as die diafragma om die intra-abdominale druk te beheer en u liggaam se eie korset te vorm. Hierdie spiere help om beserings te voorkom en ondersteun belangrike organe, gewrigte en bewegings. Dit is dus noodsaaklik om al hierdie spiere saam te oefen om hulle so normaal en optimaal as moontlik te laat funksioneer.

Die volgende advies en oefeninge vir die pelviese vloer en abdominale spiere kan help om bogenoemde probleme to verbeter/voorkom.

ADVIES OOR LEWENSTYL

1. Verlaagde vlakke van estrogeen (die vroulike hormoon) tydens die menopouse kan veroorsaak dat die fassia minder rekbaar word en dat selfs die vel sy 'styfheid' kan verloor.
2. Deur te druk om die stoelgang te passeer, kan lei tot verhoogde spanning op die pelviese vloer spiere en 'n verhoogde risiko om prolaps te ontwikkel/vererger. Die volgende advies kan help om die stoelgang te passeer sonder om te druk:
   - *Sit met die knieë hoer as die heupe.*
   - *Lig die hakke of plaas `n klein bankie/tydskrifte onder die voete..*
   - *Hou die rug reguit.*
   - *Leuen vorentoe en ondersteun met die arms op die bobene terwyl die skouers ontspanne bly.*
   - *Laat die borskas uitsit en haal rustig asem deur die diafragma te gebruik (plaas die hande net onder die sternum om die korrekte aksie te fasiliteer).*
   - *Haal oppervlakkig en in klein volumes asem (soos tydens kraam).*

   Hierdie posisie en meganisme help om die sfinkter te open en om die stoelgang te passeer sonder om enige drukking toe te pas.
3. Indien u sukkel met konstipasie, kan dit ook help om 'n korrekte dieet te volg. Die beste opsie is om `n dieetkundige te konsulteer vir waardevolle advies.

4. Rook kan lei tot kroniese hoesbuie. Hierdie kroniese verhoogde druk in die abdomen plaas die alreeds verswakte pelviese vloer onder nog meer stremming en verhoog die risiko/vererger die pelviese orgaan prolaps.
5. Obesiteit kan ook lei tot 'n verhoogde druk in die abdomen en plaas dus die pelviese vloer spiere onder meer stremming. Indien dit nodig geag word, kan `n dieetkundige konsulteer word om te help met die korrekte dieet.
6. Aktiwiteite soos swaar voorwerpe optel, swaar gewigte oefen, hoë-impak aërobiese oefeninge, lang afstande hardloop kan die risiko om pelviese orgaan prolaps te ontwikkel vermeerder as gevolg van die spanning wat op die pelviese vloer geplaas word. Buig altyd die knieë en hou die rug reguit wanneer `n voorwerp opgetel word.
7. Blaas 'heropleiding' sal nodig wees indien u `n probleem het met frekwensie van urinering of indien u `n ooraktiewe blaas het. Die Fisioterapeut sal u adviseer en leer hoe om `n blaasdagboek te gebruik.

OEFENINGE

Oefeninge moet nooit enige pyn veroorsaak nie.
Oefen in `n stil vertrek sonder versteurings.
Goeie konsentrasie is `n voorvereiste.

Die volgende oefeninge moet vir die eerste week tuis gedoen word:

1. Sit wydsbeen op die armlening van `n stoel, voete op die grond, reguit rug en die heupe gebuig. "Knyp en lig" die perineale area weg van die stoel sonder om op te staan, en ontspan dan weer. Hierdie oefening verbeter die bewustheid van die perineal area.
2. Stop die druppeltjies wanneer u klaar die blaas geledig het.
3. Doen drie stelle van _____ stadige spoed, amper maksimale kontraksies van die pelviese vloer daagliks. Die volgende instruksies kan help om die korrekte spierkontraksie uit te voer:
   - *"knyp en lig"*
   - *"dit is soortgelyk aan `n hyser se deur wat toegaan (knyp) en dan boontoe beweeg (lig)"*
   - *die aksie is soortgelyk aan "spaghetti eet"*
   - *die aksie is soortgelyk aan `n stofsuier wat suig…*
4. Moet nie die binnebeen, boudspiere, of abdominale spiere (soos wanneer die asem opgehou word) saamtrek nie. Indien dit gebeur, is dit `n aanduiding dat die spiere moeg is en eers moet rus voor u weer kan voortgaan met die volgende stel.
5. Trek die pelviese vloer spiere saam en hou die kontraksie voor en tydens hoes, lag, nies, en die optel van voorwerpe (die 'knack') om die tydsberekening van die spierkontraksie te verbeter.
   - *Begin deur dit te oefen wanneer u u neus moet blaas.*
   - *Sit regop, sonder ondersteuning en voor `n spieël.*
   - *Blaas die neus vanaf `n volle inspirasie deur `n sterk, willekeurige abdominale spiersametrekking te gebruik.*
   - *Herhaal 5 tot 6 keer.*
   - *Progresseer deur die posisie te verander vanaf lê na regop sit, sit in `n 'slegte' posisie, regop staan, en deur vorentoe te leun in staan.*
   - *Hoes kan ook so geoefen word deur dieselfde beginsels as vir die neus blaas toe te pas.*
   - *Progresseer dan na nies. Beklemtoon die uitsetting van die onderste deel van die borskas deur die hande op die onderste ribbes te plaas. Oefen hierdie dan al hoe vinniger.*

Indien u steeds na een week sukkel om die pelviese vloer spiere te aktiveer, kan die fisioterapeut besluit om ander modaliteite ook te gebruik om die spiere te help om saam te trek. Dit sal aan u verduidelik word tydens u volgende besoek aan die Fisioterapeut.

DIE PELVIESE VLOER SPIER OEFENPROGRAM:

1. Oefeninge moet daagliks gedoen word, vyf keer `n week om die spiere kans te gee om te verander (m.a.w. sterker te word), met twee-weeklikse opvolgbesoeke aan die fisioterapeut waartydens herevaluerings gedoen sal word en die oefeninge dienooreenkomstig aangepas sal word. Gedurende hierdie sessies, sal die

oefeninge gemonitor word deur `n elektromiografie masjien wat die intensiteit van die spierkontraksies sal wys.

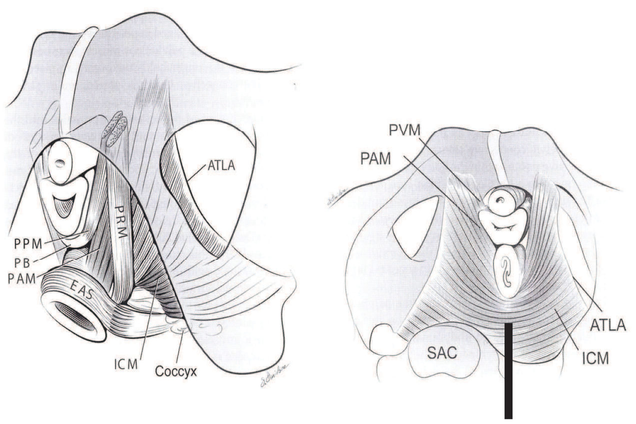
2. Die oefeninge moet gedoen word totdat die spiere uitgeput is. Oefeninge om die uithouvermoeë te verbeter moet teen <25% van u maksimale poging van spierkontraksie wees. Dit moet afgewissel word met sessies van vinnige spierkontraksies. Die vinnige kontraksies moet so sterk as moontlik (60-70% van u maksimale poging) uitgevoer word.
3. Die oefeninge sal eers geprogresseer word deur die hoeveelheid kontraksies te vermeerder (tot `n maksimum van 10), en dan deur die kontraksietyd te vermeerder totdat 8-12 repetisies vir 10s elk in die spesifieke posisie gedoen kan word (kontraksie:rus = 1:1).
4. Sodra u in staat is om dit te doen, kan die posisie waarin u die oefening doen geprogresseer word en dieselfde riglyne gevolg word (sien die onderstaande tabel vir die verskillende posisies van die oefeninge).
5. Oefeninge in die 'makliker' posisies moet egter mee voortgegaan word deur die rusintervalle te verminder totdat die kontraksietyd:rustyd gelyk is aan 1:0.5. Met ander woorde: die rustyd moet die helfte van die kontraksietyd wees.
6. Indien u al bogenoemde progressies suksesvol bereik het en die periode van ses (6) maande is nog nie verstreke nie, kan u begin om die volume van u oefeninge te vermeerder, bv. progresseer na 1-3 stelle op `n slag (8-12 kontraksies elk), met `n rusinterval van 1-2 minute tussen die stelle.

Progressie van die pelviese vloer spier oefeninge.

Progressie	Oefen posisie
1	Lê op die rug met die heupe en knieë gebuig. Lê op die maag met die been na buite en uitwaarts geroteer.
2	Handeviervoet met die heupe uitwaarts geroteer en ondersteun op die elmboë.
3	Sit met gekruisde bene, ondersteun op die hande met die skouer en elmboog reguit en na agter.
4	Staan met die voete effens uit mekaar.
5	Staan in `n 'squat' posisie.
6	Lê op die rug, heupe en knieë gebuig, abdominale spiere saamgetrek asof in `n 'crunch' oefening.
7	Staan, klim `n trappie. Staan, 'squat'.

Sodra u vlak 6 bereik het van hierdie oefenposisies, moet die pelviese vloer spiere ook geaktiveer word tydens die uitvoer van die stabiliserende oefeninge.

Moet nie bekommerd wees nie! U terapeut sal u presies vertel wat om wanneer te doen! ☺



pelviese vloer spiere

OEFENVOORSKRIF KAART

WEEK	POSISIE	KONTRAK= SIETYD	RUSTYD	STELLE	TYD TUSSEN STELLE

OEFENPROGRAM VIR DIE STABILISEERDERS:

1. Die terapeut gaan `n drukmeter gebruik om u te leer hoe om die korrekte kontraksie vna die abdominale en rugspiere uit te voer. Die meter bestaan uit `n lugkussing (opgepomp met lug) wat onder die lae rug geplaas word. Die spiere moet dan saamgetrek word totdat die druk in die kussing voldoende vermeerder het. Die kussing word opgepomp tot 40mmHg en die druk mag dan nie meer as 10mmHg gedurende die kontraksie/oefening verander nie.
2. Gedurende die kontraksies moet u normaal asem haal: asem in en uit deur middel van die onderste deel van die long te gebruik en ook deur die diafragma te gebruik.
3. Aktivering van die transversus abdominus en multifidus spiere begin in ruglê, maaglê en viervoetkniel. Die werwelkolom moet neutral gehou word gedurende die oefeninge – met ander woorde nie hol of rond gemaak word nie.
4. Die spiere word eers in isolasie geaktiveer en saamgetrek. Wanneer u die transversus abdominus en multifidus spiere kan ko-aktiveer vir 10 x 10 sekondes, kan dit geprogresseer word na die sit en dan na die staan posisie.
5. Daar mag geen beweging van die maag of die bekken wees gedurende die kontraksie nie. U mag slegs <25% van u maksimale inspanning gebruik.
6. Voorkom kulbewegings te alle tye (sien onderstaande riglyne).
7. Fasilitasietegnieke kan gebruik word om die kontraksie aan te help indien u sukkel om die sametrekkings reg te kry (sien onderstaande riglyne).
8. Kontraksies moet gestaak word indien kulbewegings voorkom, asemhalingsbeheer verloor word, die spiere uitgeput is of daar `n toename in pyn is.
9. Sodra u die ko-kontraksies in elke posisie kan volhou, kan die oefening geprogresseer word deur beweging van die ledemate en funksionele bewegings uit te voer soos beskryf in u oefenprogram.
10. Die kontraksietyd moet vermeerder word na 60 s voor integrasie na daaglikse funksionele aktiwiteite kan plaasvind.
11. U sal 2-4 oefeninge voorgeskryf word gedurende die onmiddelike pre-operatiewe en post-operatiewe fases van die studie. Hierdie oefeninge moet twee maal per dag gedoen word.
12. Gedurende die rehabilitasie fase kan die oefeninge vermeerder word tot 6-8 op `n slag.

Die volgende metodes kan u help om die spiere te aktiveer:

Transversus abdominus:

1. “Trek die laer abdomen versigtig op en in”.
2. “Trek die naeltjie in na die werwelkolom”.
3. “Trek die naeltjie op na die werwelkolom”.
4. Versigtige, diep manuele druk op die spier.
5. Kombineer die ko-kontraksie met kontraksie van die pelviese vloer spiere.
6. Gebruik die drukmeter.

Multifidus:

1. “Laat die spiere swel aan die kante van die werwelkolom”.
2. Manuele kontak op die spiere.

Die volgende kulbewegings moet voorkom word:

1. Die borskas, skouers en bekken moet te alle tye stil gehou word.
2. Normale asemhaling moet altyd aangemoedig word.
3. Moet nie die oppervlakkige maagspiere styf maak nie (depressie van die borskas en `n horisontale abdominale velvou).

Hou `n akkurate oefendagboek op die verskafte vorm!!

LOKALE EN GLOBALE STABILISERINGSPROGRAM

Die volgende vloeidiagram sal help om te verduidelik hoe u deur hierdie oefenprogram gaan progresseer. U fisioterapeut sal egter altyd aan u verduidelik en demonstreer watter oefeninge gedoen moet word, asook hoe hulle gedoen moet word.

Die oefeninge is opgedeel in vyf groepe na aanleiding van die posisie waarin hulle gedoen moet word. Wanneer u in `n sekere posisie begin, sal u altyd eers geleer word hoe om die spier in daardie posisie te aktiveer. Sodra u die abdominale spiere vir 10 x 10 sekondes kan aktiveer, kan u begin om ledemaatbeweging (in daardie posisie) by te voeg asook om te progresseer na aktivering van die spier in die volgende posisie. U moet egter met die basiese aktiveringsoefening in elke posisie voortgaan totdat u dit vir 60 sekondes kan hou.

Sodra u `n gegewe oefening bemeester het, kan u die oefening progresseer na `n onstabiele oppervlak soos aangedui word in die vloeidiagram. U moet terselfdertyd progresseer na die volgende oefening op die lys, maar wel op `n stabiele oppervlak. Sodra u die nuwe oefening op die lys bemeester het, moet dieselfde riglyne vir progressie gevolg word soos wat so pas verduidelik is. Hierdie metode moet gevolg word totdat u al die oefeninge in die program so bemeester het.

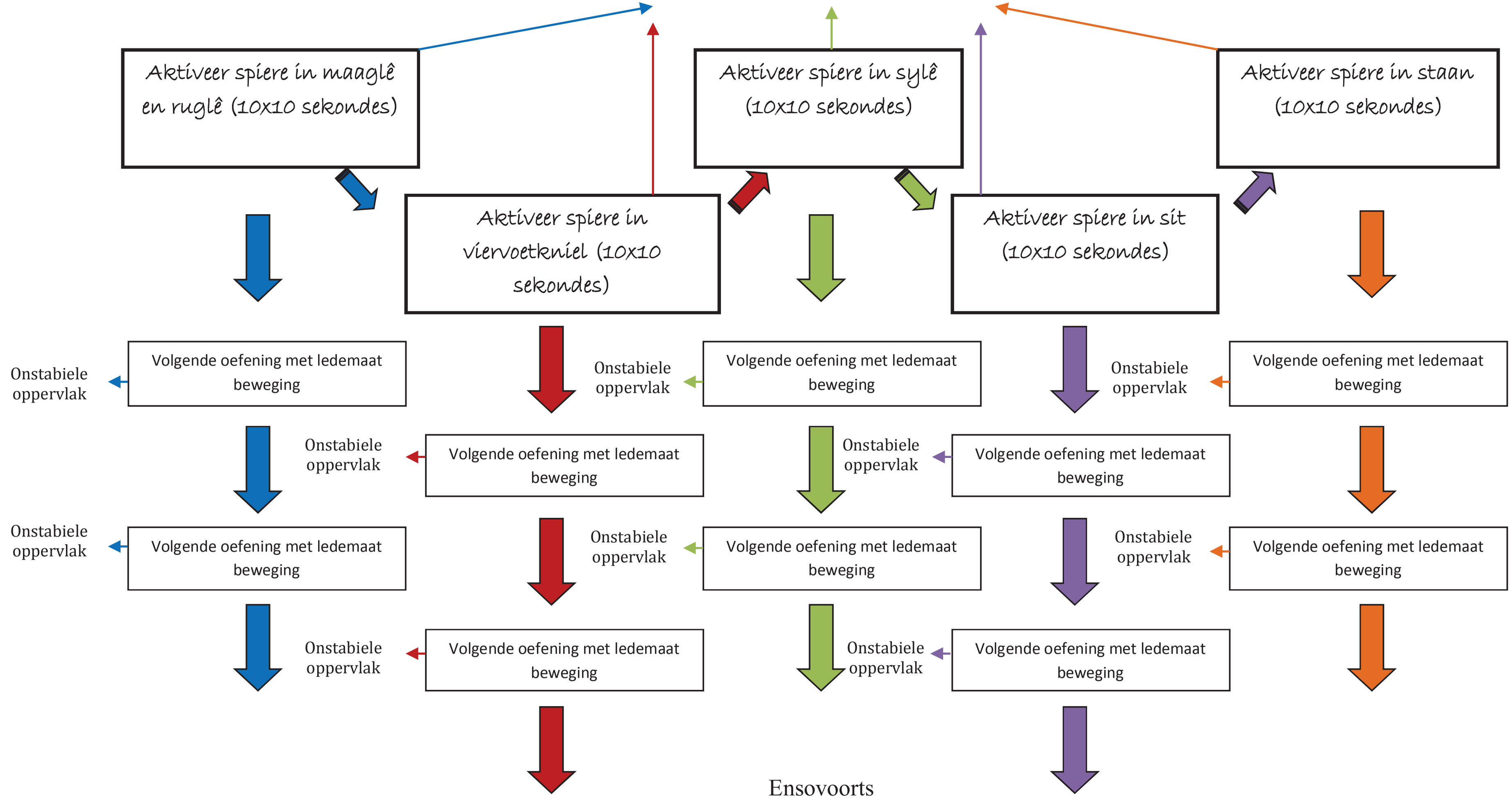
Onthou altyd dat die inspanning vir kontraksie van die abdominale en rugspiere nie 25% van u maksimum inspanning moet oorskry nie. Wees ook baie versigtig om nie te `kroek` deur die verkeerde spiere saam te trek nie bv. deur die asem op te hou, die borskas, skouers of pelvis te `brace` of oormatig te beweeg nie. Die spierkontraksies moet gestaak word sodra beheer van asemhaling verloor word, die spiere vermoei raak of as daar `n toename in pyn is.

Voor u chirurgie en gedurende die eerste ses weke post-operatief, sal u ongeveer **twee tot vier** oefeninge **twee maal per dag** moet doen. Na ses weke sal u **ses tot agt oefeninge** op `n slag gegee word om te doen.

Onthou om u oefeningdagboek op datum te hou!

Geniet die oefeninge!

HOU AAN MET OEFENING TOT VIR 60 SEKONDES GEHOU KAN WORD



ONSTABIELE OPPERVLAKTES WAT TUIS GEBRUIK KAN WORD:

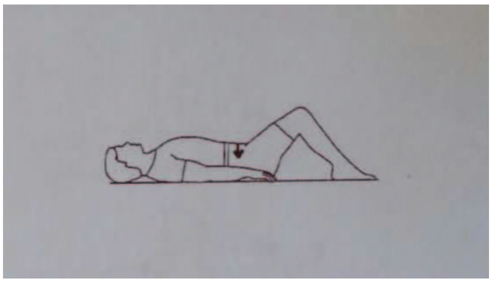
Ruglê – op `n oefenmat/ matras

Sit – op `n harde kussing

Viervoetkniel – op `n oefenmat/ matras/ harde kussing onder hande

Sylê – op `n oefenmat/ matras

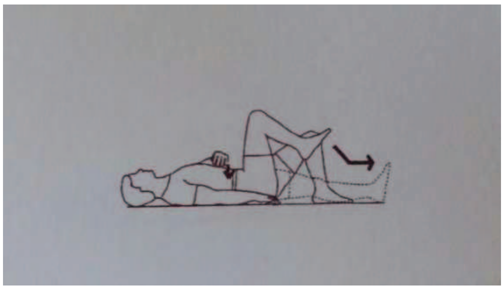
Staan – op `n harde kussing/ matras/ oefenmat



Trek die onderste deel van die maag versigtig in en op. ("Trek die naeltjie in na die ruggraat toe.")

Die borskas, skouers en bekken moet nie beweeg nie. Haal normaal asem terwyl u die oefening uitvoer. Moenie 'brace' nie.

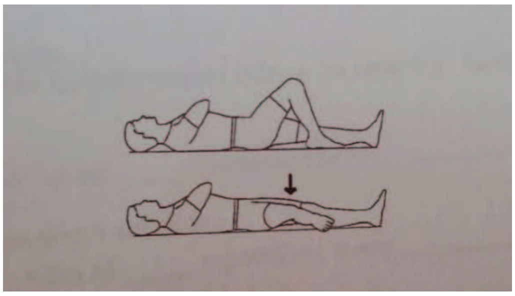
Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**



Lê met die heupe en knieë gebuig. Maak een been stadig reguit (met die voet ondersteun op die bed) en keer terug na die aanvangsposisie. Wissel die bene.

Handhaaf `n goeie posisie van die rug tydens die oefening. Moenie die asem ophou nie.

Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**

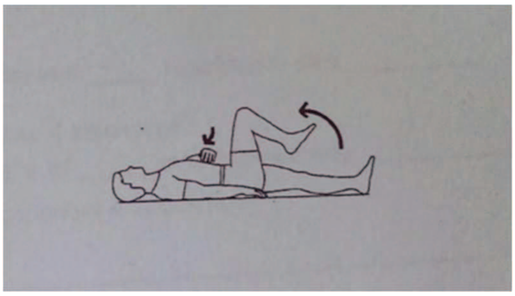


Lê op die rug met die regter been gebuig en die voet op die vloer. Beweeg die regter been buitentoe terwyl die voet ondersteun moet bly langs die reguit been. Hou die bekken plat op die vloer. Keer terug na die aanvangsposisie en herhaal. Herhaal met die linker been.

Hou die maagspiere saamgetrek. Plaas die hande op die bekkenbene om te erseker dat daar geen beweging plaasvind nie

.

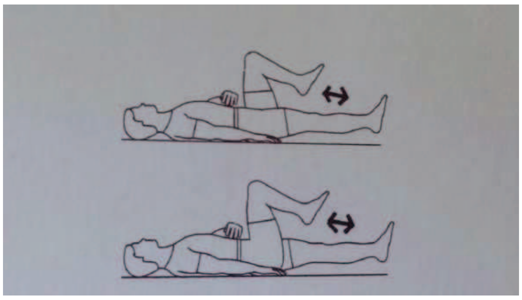
Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**



Lê op die rug. Trek versigtig die onderste deel van die maag in en op. Terwyl u die maagspiersametrekking volhou, lig een been op tot 100 grade met die knie 90 grade gebuig, soos aangedui. Lig die ander been stadig op tot in dieselfde posisie. Hou vir 10 sekondes en laat sak die bene terug na die vloer een vir een. Herhaal.

Moenie die asem ophou nie. Die borskas, skouers en bekken moet te alle tye stil gehou word.

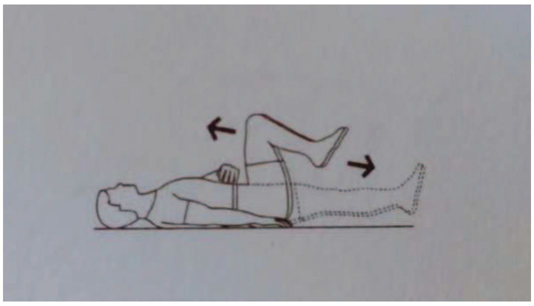
Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**



Lê op die rug. Terwyl u die maagspiersametrekking volhou, lig beide bene op tot 100 grade met die knieë 90 grade gebuig.
1. Maak een been reguit deur dit te gly op die vloer terwyl die ander been gebuig bly.
Wanneer u terapeut tevrede is dat u die oefeninge korrek uitvoer, kan u progresseer na nommer 2.
2. Maak een been reguit deur dit in die lug te hou (die hak ongeveer 12cm bokant die bed) terwyl die ander been gebuig bly. Laat die been dan terugkeer na die gebuigde posisie en herhaal met die ander been.
Herhaal hierdie hele oefening.

Handhaaf `n neutrale rugposisie tydens die oefening. Moenie die asem ophou nie.

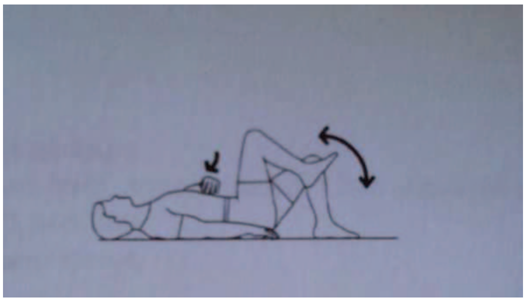
Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**



Lê op die rug. Terwyl u die maagspiersametrekking volhou, lig beide bene op tot 100 grade met die knieë 90 grade gebuig
1. Maak beide bene reguit terwyl u dit op die vloer hou. Keer die bene terug na die gebuigde posisie en herhaal. Wanneer u fisioterapeut tevrede is dat u die oefening korrek uitvoer, kan u progresseer na die volgende posisie.
2. Herhaal die oefening soos bo, maar hou die hake ongeveer 12cm bokant die vloer.

Handhaaf `n neutrale rugposisie tydens die oefening. Moenie die asem ophou nie.

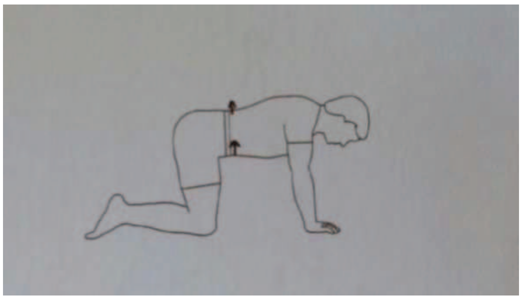
Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**



Lê met die heupe en knieë gebuig. Lig een been stadig op tot 90 grade en keer terug na die aanvangsposisie. Wissel die bene.

Trek die onderste deel van die maag versigtig in en op terwyl u die oefening doen.

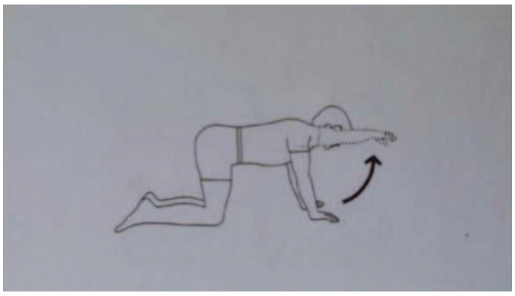
Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**



Begin in viervoetkniel. Die hande moet oner die skouers geposisioneer word en die knieë onder die heupe. Trek die onderste deel van die maag in en op. ("Trek die naeltjie na die ruggraat."). Bult ("swell") die spiere aan die kant van die ruggraat. Hou vir 10 sekondes en ontspan dan vir 10 sekondes. Herhaal tot vermoei.

Verbeel u dat u `n glas of `n kierie op u rug moet balanseer.

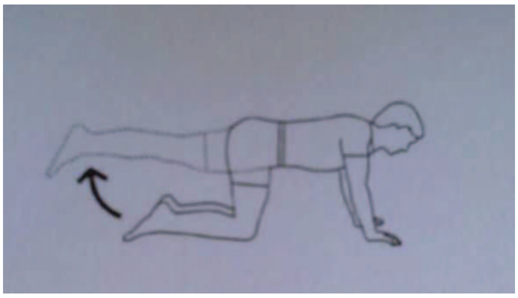
Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**



Staan in viervoetkniel. Lig die arm 180 grade vorentoe en hou die elmboog reguit. Keer terug na die aanvangsposisie. Lig die regter arm. Keer terug na die aanvangsposisie en herhaal.

Handhaaf `n neutrale werwelkolom en moet nie die rug draai nie. Hou die maag in en op getrek en bult die spiere aan die kant van die werwelkolom.

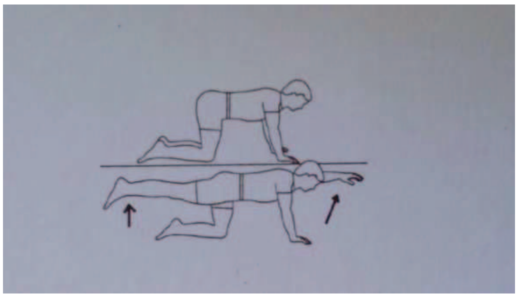
Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**



Begin in viervoetkniel. Lig die reger been agtertoe ongeveer 12cm bokant die grond. Keer terug na die aanvangsposisie. Lig die teenoorgestelde been en laat sak dit weer. Herhaal.

Handhaaf `n neutrale werwelkolom en moet nie die rug draai nie. Hou die maag in en op getrek en bult die spiere aan die kant van die werwelkolom.

Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**



Begin in viervoetkniel. Lig die regter been 12cm bokant die grond en lig die linker arm tot 180 grade. Hou vir 2-3 sekondes. Keer terug na die aanvangsposisie en herhaal met die linker been en die regter arm.

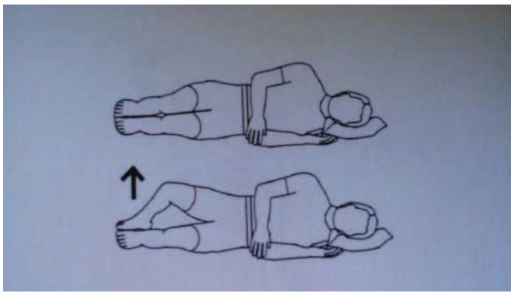
Handhaaf `n neutrale werwelkolom en moet nie die rug draai nie. Hou die maag in en op getrek en bult die spiere aan die kant van die werwelkolom.

Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**

Staan in viervoetkniel. Lig die regter arm na die buitekant deur te draai na regs. Draai ook die nek na regs en volg die arm deur te kyk daarna. Strek dan onderdeur die romp na die teenoorgestlde heup. Keer terug na die aanvangsposisie en herhaal met die linker arm.

Hou die onderste deel van die maag saamgetrek.

Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**



Lê op die regter sy met die knieë gebuig, voete bymekaar. Lig die linker knie op deur die been uit te draai by die heup. Laat sak die been en herhaal. Herhaal die oefening op die linker sy.

Hou die pelvis in `n vertikale posisie – moet nie dat die pelvis vorentoe of agtertoe beweeg wanneer die heup gedraai word nie.

Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**

Sit met die rug ondersteun en knieë 90 grade gebuig met die voete plat op die grond. Plaas die hande ontspanne op die kante van die stoel of laat hulle afhang. Trek die maag in en op (die naeltjie na die ruggraat) en bult die spiere aan die kant van die werwelkolom. Hou vir 10 sekondes en herhaal.

Maak seker u sit in `n regop posisie (met `n neutrale werwelkolom). Moet nie "slump" nie.

Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**

Sit op die stoel met die arms ontspanne langs die sy. Lig stadig een arm tot 180 grade. Keer terug na die aanvangsposisie. Wissel die arms af. Sodra u 10 repetisies korrek kan uitvoer, kan u die oefening progresseer na sit op `n bal – soos aangedui.

Hou die rug in `n neutrale posisie. Wanneer u op die oefenbal sit, leun effens terug.

Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**

Sit op `n stoel met die voete op die grond. Lig een been stadig totdat die heup ongeveer 100 grade gebuig is. Keer terug na die aanvangsposisie. Wissel die bene af.

Sit in `n regop posisie en trek die onderste deel van die maag in en op.

Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**

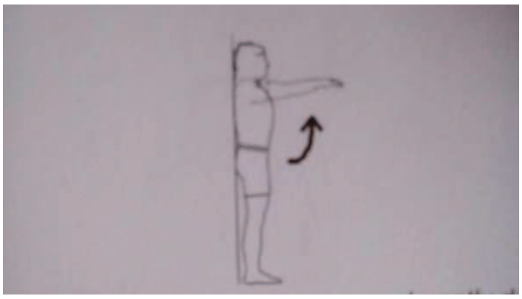
Sit op `n stoel met die werwelkolom en pelvis in `n neutral belyning. Maak die knie reguit totdat die lae rug begin buig/weerstand gevoel word in die bene. Onderstuen die been passief in hierdie posisie (deur `n ander persoon) of deur `n stoel. Kantel die pelvis aktief vorentoe en hou vir 20-30 sekondes.

Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**

Staan met die voete skouerwydte. Trek die laer deel van die maag in en op. Bult die spiere aan die kant van die werwelkolom. Hou vir 10 sekondes en rus dan vir 10 sekondes. Herhaal 10 keer.

Moet nie die asem ophou nie. Die borskas, skouers en bekken meot nie beweeg nie. Hou die werwelkolom in `n neutral posisie.

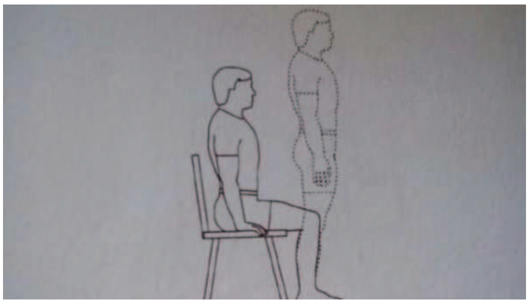
Aantal repetisies:	***Aantal stelle:***	**Rusintervalle:**



Staan teen `n muur. Bult die spiere aan die kant van die werwelkolom en trek die onderste deel van die maag in en op. Lig en laat sak stadig die teenoorgestelde arm tot 90 grade en weer terug terwyl die kontraksie gehou word. Wissel af met die teenoorgestelde arm.

Staan regop met `n neutrale werwelkolom en voete skouerbreedte uit mekaar.

Aantal repetisies: **_Aantal stelle:_** **Rusintervalle:**



Begin in `n sittende posisie. Trek die laer deel van die maag in en op en bult die spiere aan die kante van die werwelkolom. Hou die kokontraksie terwyl u stadig opstaan en gaan sit. Herhaal.

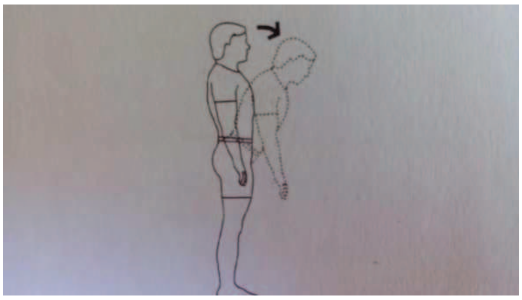
Hou die voete skouerbreedte uit mekaar en die werwelkolom neutraal.

Aantal repetisies: **_Aantal stelle:_** **Rusintervalle:**

Trek die onderste deel van die maag in en op en bult die spiere aan die kante van die werwelkolom. Hou hierdie kontraksie terwyl u teen `n gemaklike pas loop.

Moet nie die asem ophou nie. Die skouers, borskas en bekken moet nie oormatig beweeg of rigied gehou word nie.

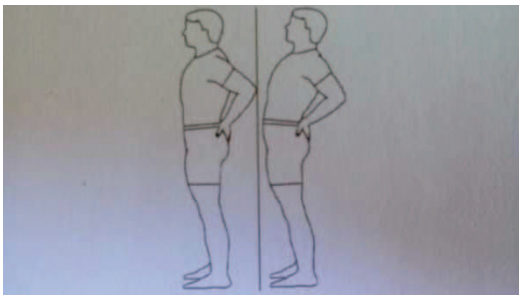
Aantal repetisies: **_Aantal stelle:_** **Rusintervalle:**



Staan met die hande langs die sye. Trek versigtig die laer maag op en in en bult die spiere aan die kant van die werwelkolom. Behou hierdie kontraksie en buig stadig vorentoe (30 grade) vanuit die heupe. Die arms moet ontspanne hang terwyl u beweeg. Keer terug na die staan posisie deur regop te kom vanuit die heupe. Herhaal.

Moet nie die lae rug buig nie. Hou die werwelkolom in neutraal. Moet nie die asem ophou nie.

Aantal repetisies: **_Aantal stelle:_** **Rusintervalle:**



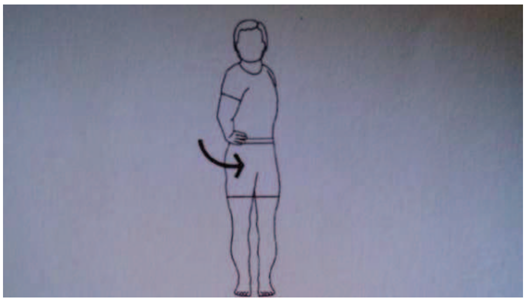
Staan met die voete skouerbreedte uit mekaar. Herhaal die oefening soos die voorafgaande, maar buig net agteroor.

Aantal repetisies:	*Aantal stelle:*	**Rusintervalle:**

Gebruik `n ligte voorwerp. Staan aan die voorkant van die voorwerp. Buig die knieë en hou die rug regop. Trek die onderste deel van die maag versigtig in en op en bult die spiere aan die kant van die werwelkolom. Behou hierdie kontraksie en tel die voorwerp op deur die knieë reguit te maak. Dra die voorwerp 10 treë vorentoe. Laat sak die voorwerp en herhaal die optel en dra aksie.

Hou die voorwerp naby aan u liggaam terwyl u dit dra. Moet nie die liggaam draai wanneer u die voorwerp optel, dra of laat sak nie.

Aantal repetisies:	*Aantal stelle:*	**Rusintervalle:**



Staan. Plaas die hande op die heupe en hou die voete plat op die grond. Trek die onderste deel van die maag versigtig op en in en bult die spiere aan die kant van die werwelkolom. Behou hierdie kontraksie en draai die romp na links en dan na regs. Herhaal.

Moet nie die asem ophou nie. Die skouers, borskas en bekken moet nie oormatig beweeg nie.

Aantal repetisies:	*Aantal stelle:*	**Rusintervalle:**

Trek die onderste deel van die maag versigtig in en op en bult die spiere aan die kant van die werwelkolom. Behou hierdie kontraksie terwyl u enige aërobiese oefening doen soos loop, fietsry, "cross-trainer", draf, ens.

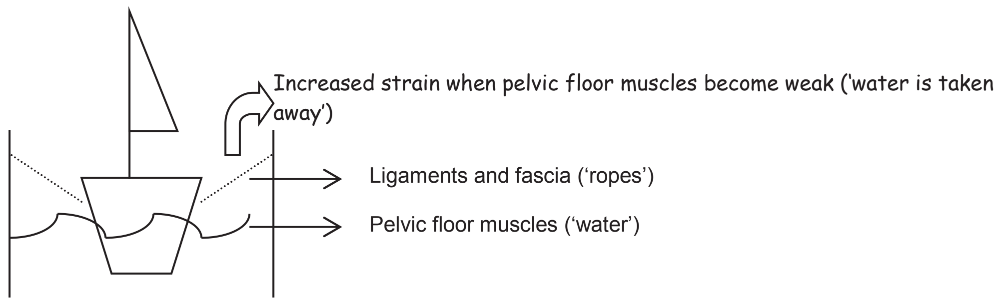
Moet nie u asem ophou nie.

Aantal repetisies:	*Aantal stelle:*	**Rusintervalle:**

THE REHABILITATION PROGRAMME (PATIENT COPY)

GROUP 3

The function of the pelvic floor muscles and their role in pelvic organ prolapse ("descending of the pelvic organs") can be explained by means of a 'boat in a dry dock'. The ship represents the pelvic organs, the ropes the ligaments and fascia, and the water the pelvic floor muscles. If the pelvic floor muscles ('water') provides good support, it will put little strain on the fascia and the ligaments. But when the muscles become weak, the strain on the ligaments and fascia increase and they will become stretched and damaged over time.



The pelvic floor muscles also have other very important functions despite the above supporting function. Dysfunction of the pelvic floor muscles may also lead to the following:

- Leaking of urine
- Leaking of faeces
- Problems with emptying of the bladder
- Problems with emptying of the rectum
- Sexual dysfunction
- Chronic pain

The following advice and exercises for the pelvic floor muscles may help to improve/prevent the above-mentioned problems.

LIFESTYLE ADVICE

1. Decreased levels of oestrogen (a hormone in women) at the time of menopause may cause the fascia to become less elastic and even the skin`s 'stiffness' may reduce.
2. Straining when emptying the bowels may put the pelvic floor muscles under strain and increase the risk of developing/worsening prolapse. The following advice may help to empty the bowels without straining:
   - *Sit with the knees higher than the hips.*
   - *Lift the heels or put a little bench/magazine etc. under the feet.*
   - *Keep the back straight.*
   - *Lean forward and support with the arms on the upper legs with the shoulders relaxed.*
   - *Expand the ribcage and breathe gently using the diaphragm (put the hand just below the sternum to facilitate the correct action).*
   - *Breathe superficial and with small volumes of air (as if in labour).*

   This position and mechanism help to open the sphincter and empty the bowels without applying any pressure.
3. In the case of constipation, it may also help to follow the correct diet. The best would be to consult a dietician for valuable advice.
4. Smoking may lead to chronic coughing. This chronic increase in the pressure in the abdomen puts the already defected pelvic floor under more strain and increase the risk/ worsening of the pelvic organ prolapse.
5. Obesity may also lead to an increase in pressure in the abdomen and thus put the pelvic floor muscles under more strain. If deemed necessary, a dietician should be consulted to help with the correct diet.
6. Activities such as heavy lifting, weight lifting, high-impact aerobics, and long-distance running may increase the risk of pelvic organ prolapse due to the strain it places on

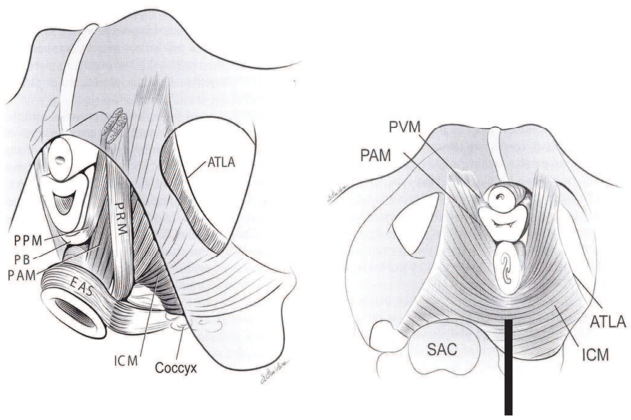
the pelvic floor. Always bend your knees and keep the back straight when lifting up an object.

7. Bladder training will be necessary if you have a problem with the frequency of voiding or have an overactive bladder. The physiotherapist will advise and teach you how to use a bladder diary.

ADVICE ON IMPROVING THE FUNCTION OF THE PELVIC FLOOR MUSCLES

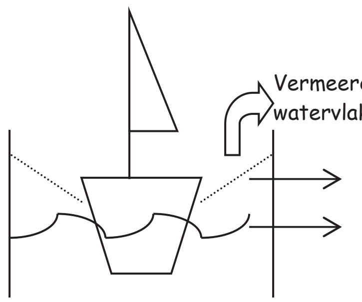
Exercises should never cause any pain.
Exercise in a room without noise or distractions.
Thorough concentration is a prerequisite.

1. Pre-contract and hold the contraction of the pelvic floor muscles before and during coughing, laughing, sneezing, and lifting ('the knack') to improve the timing of the muscle contraction.
   - *Nose blowing should be commenced first.*
   - *Sit upright, unsupported, in front of a mirror.*
   - *The blow is commenced from full inspiration using a strong, voluntary abdominal muscle contraction.*
   - *Repeat 5 to 6 times.*
   - *Progress the exercise from lying to sitting upright, sitting in a slumped ('slouched') position, standing upright, and forward lean standing.*
   - *Coughing can also be practised, applying the same principles as for nose blowing.*
   - *Then progress to sneezing. Emphasize expansion of the lower rib cage by placing the hands around the lower ribs. Exercise this with increased rapidity.*
2. Stop the dribble at the end of voiding.
3. Avoid contracting the inner thigh, buttock, or abdominal muscles (such as holding the breath).



pelvic floor muscles

Die funksie van die pelviese vloer spiere en hulle rol in pelviese orgaan prolaps ("afsakking van die pelviese organe") kan verduidelik word aan die hand van `n 'boot in 'n vlak hawe'. Die skip stel die pelviese organe voor, die toue die ligamente en fassia, en die water die pelviese vloer spiere. Indien die pelviese vloer spiere ('water') goeie ondersteuning bied, veroorsaak dit min spanning op die fassia en ligamente. Maar wanneer die spiere swak word, vermeerder die spanning op die fassia en ligamente en word hulle gestrek en al hoe swakker met die verloop van tyd.



Die pelviese vloer spiere het ook ander belangrike funksies as net die ondersteunende funksie. Verkeerde funksionering van die pelviese vloer spiere kan ook tot die volgende lei:

- Lek van urine
- Lek van stoelgang
- Probleme om die blaas te ledig
- Probleme om die rektum te ledig
- Seksuele disfunksie
- Kroniese pyn

Die volgende advies en oefeninge vir die pelviese vloer spiere kan help om al bogenoemde probleme te verbeter/voorkom.

ADVIES OOR LEWENSTYL

1. Verlaagde vlakke van estrogeen (die vroulike hormoon) tydens die menopouse kan veroorsaak dat die fassia minder rekbaar word en dat selfs die vel sy 'styfheid' kan verloor.
2. Deur te druk om die stoelgang te passeer, kan lei tot verhoogde spanning op die pelviese vloer spiere en 'n verhoogde risiko om prolaps te ontwikkel/vererger. Die volgende advies kan help om die stoelgang te passeer sonder om te druk:
   - *Sit met die knieë hoer as die heupe.*
   - *Lig die hakke of plaas `n klein bankie/tydskrifte onder die voete..*
   - *Hou die rug reguit.*
   - *Leuen vorentoe en ondersteun met die arms op die bobene terwyl die skouers ontspanne bly.*
   - *Laat die borskas uitsit en haal rustig asem deur die diafragma te gebruik (plaas die hande net onder die sternum om die korrekte aksie te fasiliteer).*
   - *Haal oppervlakkig en in klein volumes asem (soos tydens kraam).*

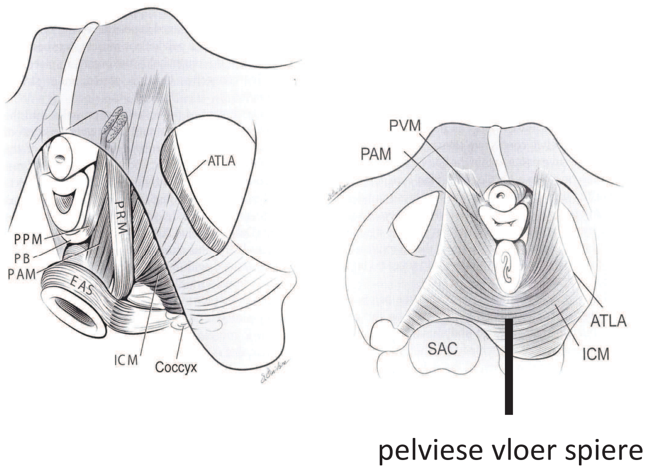
   Hierdie posisie en meganisme help om die sfinkter te open en om die stoelgang te passeer sonder om enige drukking toe te pas.
3. Indien u sukkel met konstipasie, kan dit ook help om 'n korrekte dieet te volg. Die beste opsie is om `n dieetkundige te konsulteer vir waardevolle advies.
4. Rook kan lei tot kroniese hoesbuie. Hierdie kroniese verhoogde druk in die abdomen plaas die alreeds verswakte pelviese vloer onder nog meer stremming en verhoog die risiko/vererger die pelviese orgaan prolaps.
5. Obesiteit kan ook lei tot 'n verhoogde druk in die abdomen en plaas dus die pelviese vloer spiere onder meer stremming. Indien dit nodig geag word, kan `n dieetkundige konsulteer word om te help met die korrekte dieet.
6. Aktiwiteite soos swaar voorwerpe optel, swaar gewigte oefen, hoë-impak aërobiese oefeninge, lang afstande hardloop kan die risiko om pelviese orgaan prolaps te

ontwikkel vermeerder as gevolg van die spanning wat op die pelviese vloer geplaas word. Buig altyd die knieë en hou die rug reguit wanneer `n voorwerp opgetel word.

7. Blaas 'heropleiding' sal nodig wees indien u `n probleem het met frekwensie van urinering of indien u `n ooraktiewe blaas het. Die Fisioterapeut sal u adviseer en leer hoe om `n blaasdagboek te gebruik.

ADVIES OM DIE FUNKSIE VAN DIE PELVIESE VLOER SPIERE TE VERBETER

1. Trek die pelviese vloer spiere saam en hou die kontraksie voor en tydens hoes, lag, nies, en die optel van voorwerpe (die 'knack') om die tydsberekening van die spierkontraksie te verbeter.
   - *Begin deur dit te oefen wanneer u u neus moet blaas.*
   - *Sit regop, sonder ondersteuning en voor `n spieël.*
   - *Blaas die neus vanaf `n volle inspirasie deur `n sterk, willekeurige abdominale spiersametrekking te gebruik.*
   - *Herhaal 5 tot 6 keer.*
   - *Progresseer deur die posisie te verander vanaf lê na regop sit, sit in `n 'slegte' posisie, regop staan, en deur vorentoe te leun in staan.*
   - *Hoes kan ook so geoefen word deur dieselfde beginsels as vir die neus blaas toe te pas.*
   - *Progresseer dan na nies. Beklemtoon die uitsetting van die onderste deel van die borskas deur die hande op die onderste ribbes te plaas. Oefen hierdie dan al hoe vinniger.*
2. Stop die druppeltjies wanneer u klaar die blaas geledig het.
3. Moet nie die binnebeen, boudspiere, of abdominale spiere (soos wanneer die asem opgehou word) saamtrek nie.



ADDENDUM 4

PATIENT TRAINING DIARY AND MEASUREMENT OF COMPLIANCE

PATIENT TRAINING DIARY

Trial stage:______ **Patient number:_________**

Mark the applicable block and state the reason if not exercised as prescribed. Please be honest and record exactly what you did./ *Merk die toepaslike blokkie en verskaf `n rede indien die oefeninge nie gedoen is soos voorgeskryf nie. Wees asseblief eerlik en noteer presies wat u gedoen het.*

Date/ ***Datum***	**Exercised as prescribed/** ***Geoefen soos voorgeskryf***	**Did not exercise/** ***Geen oefening gedoen***	**Exercised, but not as prescribed/** ***Oefeninge nie gedoen soos voorgeskryf***	**Clarify/** ***Verduidelik***

Please answer the following question as truthful as possible. Indicate your answer by placing an 'x' in the appropriate box./
Beantwoord asseblief die volgende vraag so eerlik as moontlik. Dui u antwoord aan deur `n 'x' in die toepaslike blokkie te maak.

Question: Did you manage to exercise regularly last week?/ *Vraag: Het u daarin geslaag om verlede week gereeld te oefen?*		
1		Not at all/ *Glad nie*
2		A little/ *`n Bietjie*
3		Rather regularly/ *Redelik gereeld*
4		Very regularly/ *Baie gereeld*

(Sluijs *et al.* 1993:773)

ADDENDUM 5

ETHICS APPROVAL DOCUMENTS

UNIVERSITY OF THE FREE STATE
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YUNIVESITHI YA FREISTATA
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UV

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E-mail address: StraussHS@ufs.ac.za

Ms H Strauss/hv

2012-03-07

REC Reference nr 230408-011
IRB nr 00006240

MS C BRANDT
DEPT OF PHYSIOTHERAPY
CR DE WET BUILDING
UFS

Dear Ms Brandt

ECUFS NR 25/2012
MS C BRANDT **DEPT OF PHYSIOTHERAPY**
PROJECT TITLE: PELVIC FLOOR REHABILITATION IN WOMEN UNDERGOING PELVIC FLOOR RECONSTRUCTIVE SURGERY.

- You are hereby kindly informed that the Ethics Committee approved the above project at the meeting held on 6 March 2012 on condition that:

  - ***The signed permission letters from the authorities have to be obtained and submitted to the Ethics Committee before the study may be conducted.***

- Committee guidance documents: Declaration of Helsinki, ICH, GCP and MRC Guidelines on Bio Medical Research. Clinical Trial Guidelines 2000 Department of Health RSA; Ethics in Health Research: Principles Structure and Processes Department of Health RSA 2004; Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition (2006); the Constitution of the Ethics Committee of the Faculty of Health Sciences and the Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines.

- Any amendment, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

- The Committee must be informed of any serious adverse event and/or termination of the study.

- A progress report should be submitted within one year of approval of long term studies and a final report at completion of both short term and long term studies.

- Kindly refer to the ECUFS reference number in correspondence to the Ethics Committee secretariat.

Yours faithfully

For CHAIR: ETHICS COMMITTEE

Cc Prof HS Cronje

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Ms H Strauss

2013-04-10

REC Reference number: REC-230408-011
IRB nr 00006240

MS C BRANDT
DEPT OF PHYSIOTHERAPY
CR DE WET BUILDING
UFS

Dear Ms Brandt

STUD NR 81/2011
PROJECT TITLE: VALIDATION OF THE PROLAPSE QUALITY OF LIFE QUESTIONNAIRE (P-QOL): AN AFRIKAANS VERSION IN A SOUTH AFRICAN POPULATION IN THE FREE STATE.

You are hereby kindly informed that the Ethics Committee approved the following at the meeting held on 9 April 2013:

- ***Extension of study period***
- ***Ms C Brandt will be the principal investigator who will continue with the study***

[Kindly inform the Ethics Committee until what date extension of the study period is requested]

Kindly note:

- that a progress report be presented not later than one year after approval of the project.
- that the student project number, i.e. Student Project No. 81/2011 has to be quoted in correspondence in the future.

Yours faithfully

....
PROF WH KRUGER
CHAIR: ETHICS COMMITTEE

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Ms H Strauss

2013-03-08

REC Reference number: REC-230408-011
IRB nr 00006240

MS C BRANDT
DEPT OF PHYSIOTHERAPY
CR DE WET BUILDING
UFS

Dear Ms Brandt

STUD NR 81/2011
PROJECT TITLE: VALIDATION OF THE PROLAPSE QUALITY OF LIFE QUESTIONNAIRE (P-QOL): AN AFRIKAANS VERSION IN A SOUTH AFRICAN POPULATION IN THE FREE STATE.

Your letter received on 7 March 2013 refers.

You are hereby kindly informed that the Ethics Committee approved your request to continue with the above mentioned study.

You are hereby reminded to notify the Ethics Committee of the extension of the study period.

The approval will be condoned at the meeting scheduled for 9 April 2013:

<u>**Kindly note**</u>:

- that a progress report be presented not later than one year after approval of the project.
- that the student project number, i.e. Student Project No. 81/2011 has to be quoted in correspondence in the future.

Yours faithfully

....
PROF WH KRUGER
CHAIR: ETHICS COMMITTEE

ADDENDUM 6

APPROVAL FROM INSTITUTIONS TO CONDUCT RESEARCH

health
Department of Health
FREE STATE PROVINCE

PHYSIOTHERAPY
UNIVERSITAS AND UNIVERSITAS ANNEXE HOSPITALS

Universitas
Logeman Street
Ground floor
Tel: 051-4053367
Fax: 051-4440792
E-mail: jvvuurenl@universitas.fs.gov.za

Universitas Annexe
Kolbe Street
(At the back of National Hospital)
Tel: 051-4052117
Fax: 051-4440792
E-mail:
jvvuurenl@universitas.fs.gov.za

8 March 2013

Dear Miss Brandt

Regarding : Permission to conduct a research study at the Uro-gynaecology clinic, Universitas hospital, with assistance of Mrs Penny Groenewald, Physiotherapist, Universitas Academic Hospital.

I hereby give permission for Mrs Groenewald, as an employee at our Physiotherapy department, to assist you in your study on the following conditions :

1. Mrs Groenewald herself must agree to this arrangement.
2. The time spent on this study must be suitable to the workload in our department.
3. In the absence of Mrs Groenewald, e.g. during leave or when at Annex, the study may be temporarily discontinued.
4. Information and results, after consultation with you, may be used for a clinical audit in our department, if Mrs Groenewald wishes to do so.
5. Mrs Groenewald and our patients participate voluntarily and may withdraw from the study at any time.
6. Informed consent must be obtained from all the patients.
7. For training purposes, briefing sessions should please be conducted with all the Physiotherapists in our department prior to commencement and at the end of the study to provide feedback.
8. With conclusion of the study, all information should be made available to our department.

It is unfortunately not in my power to give permission to conduct the study at the clinic itself. I refer you to Dr van Zyl/Rev Musapelo regarding this.

Best wishes for your study.

Yours sincerely

Louisa Jansen van Vuuren
Acting HOD, Physiotherapy department, UAH

health
Department of
Health
FREE STATE PROVINCE

7 March 2013

Me. C. Brandt
Dept Physiotherapy
University of Free State

Dear Me. Brandt

RESEARCH PROJECT: THE EFFECT OF REHABILITATION ON THE PELVIC FLOOR MUSCLES (PFM) AND QUALITY OF LIFE IN WOMEN WITH PELVIC ORGAN PROLAPSE THAT IS DUE FOR SURGERY.

Herewith permission for the mentioned project to be done at Universitas Academic Hospital on the following conditions:

1. The research should not expose the users and the Department to any avoidable harm.
2. Annual progress reports should be submitted and also a research report at the end of the research process.
3. Reporting of Adverse Events related to the research process must be done within 48 hours of discovery.
4. There shall be provision for obtaining informed consent from all patients/staff where appropriate.
5. Briefing sessions should be conducted with all stakeholders prior to commencement and at the end of the study to provide feedback where appropriate.
6. That approval is obtained from the Ethics Committee.

The Chief Executive Officer must be notified if the findings of the project will be published and a research report needs to be sent to the Head Clinical Services as soon as the study is completed.

Yours sincerely

DR NRJ VAN ZYL
2013 -03- 07
HEAD: CLINICAL SERVICES
UNIVERSITAS ACADEMIC HOSPITAL

DR N R J VAN ZYL
HEAD: CLINICALSERVICES
UNIVERSITAS ACADEMIC HOSPITAL

HEAD: CLINICAL SERVICES: DR NRJ VAN ZYL
Private Bag X20660, Bloemfontein, 9300. Tel. No.: 051-4052866,
Fax: 051-4053500, Room 1077, First Floor, Universitas Academic Hospital
Email: vanzylnr@universitas.fs.gov.za

ADDENDUM 7

PARTICIPANT TREATMENT RECORD

PATIENT TREATMENT RECORD

Trial stage:________ **Patient number:______**

Date	Re-assessment/ Treatment/ Modality	Exercise prescription

ADDENDUM 8

INFORMATION DOCUMENT AND CONSENT FORM

Dear Madam

I, Corlia Brandt, hereby invite you to participate in a research study, conducted for a doctoral degree at the University of the Free State, on the effect of exercise training on the pelvic floor muscles (PFM) and quality of life in women with pelvic organ prolapse.

The pelvic floor muscles are very important for structural support and functioning of the pelvic organs which include the bladder, anal sphincter and rectum, the vagina, cervix and uterus. Dysfunction of these muscles can contribute to problems such as urinary and faecal incontinence, pelvic organ prolapse, rectal dysfunction, and pelvic pain. Even after surgery exercises are important to restore normal muscle function and support; since pain and swelling prevent muscles from working effectively.

Participation in the study would entail that you come frequently for routine follow-up assessments of the PFM. It will form part of your routine gynaecological follow-up visits/ assessments at the Uro-gynaecology clinic, Universitas Hospital/ at the practice. This includes your first visit, as well as your visits at three (3) months, and six (6) months post-operative. These assessments will include a clinical assessment by the gynaecologist and physiotherapist, a sonar, and an electromyographic investigation of the pelvic floor muscles. These assessments will cause no discomfort or pain and your privacy will be respected at all times.

During the study you will receive exercises and advice to be done on a daily basis at home over a period of six (6) months. These exercises should not take longer than 20 minutes to do. A visit to the physiotherapist may be necessary every two weeks to progress and to monitor the exercises pre- and post-operatively; depending on the type of intervention programme you will be receiving. These visits will take approximately 45 minutes of your time. There is no costs or remuneration involved in the treatment.

Similar studies have reported some patients to feel a slight discomfort/ pain after exercise in distinguished cases, similar to what you feel after heavy exercise of the limbs. However, there are **no risks** involved in this treatment

Participation in the study is voluntary. At any time during the study you may withdraw without the fear of being penalised. If there should occur any complications (e.g. other illnesses, post-operative complications) that would affect your health, participation may be terminated by the investigator without your consent. With conclusion of the study, all results will be made available. All information will be kept confidential. Unfortunately absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law.

This study has been approved by the Ethics Committee of the Faculty of Health Sciences, UFS. If you have any questions, complaints or concerns regarding the research study, you may contact the Secretariat of the Ethics Committee of the Faculty of Health Sciences, UFS, at telephone number 051-4052812 or the researcher at 051-4013297.

If you are willing to participate, please complete the enclosed consent form.

Yours faithfully

Me C Brandt

Physiotherapist (M.Sc Physiotherapy)

Contact details:

Corlia Brandt

Department of Physiotherapy, UFS

Tel nr: 051-4013297

Cell nr: 0832640189

CONSENT TO PARTICIPATE IN RESEARCH

You have been asked to participate in a research study.

You have been informed about the study by **Corlia Brandt**.

You may contact **myself, Corlia Brandt** at **0832640189** any time if you have questions about the research or if you are injured as a result of the research.

You may contact the Secretariat of the Ethics Committee of the Faculty of Health Sciences, UFS at telephone number (051) 4052812 if you have questions about your rights as a research participant.

Your participation in this research is voluntary, and you will not be penalised or lose benefits if you refuse to participate or decide to terminate participation.

If you agree to participate, you will be given a signed copy of this document as well as the participant information sheet, which is a written summary of the research. All gathered information will be handled confidentially. Data, however, may be used for publication purposes.

The research study, including the above information has been verbally described to me. I understand what my involvement in the study means and I voluntarily agree to participate.

________________________ ____________________

Signature of Participant | Date

________________________ ____________________

Signature of Witness | Date

(Where applicable)

Geagte Mevrou/ Mejuffrou

Hiermee wil ek, Corlia Brandt, u graag nooi om deel te neem aan `n navorsingsprojek, uitgevoer as deel van `n doktorale graad aan die Universiteit van die Vrystaat, wat handel oor die effek van oefeninge op die pelviese vloer spiere (PFM) en lewenskwaliteit in vrouens met pelviese orgaan prolaps.

Die PFM is baie belangrik vir die strukturele ondersteuning en funksionering van die pelviese organe wat onder andere die blaas, anale sfinkter en rektum, die vagina, serviks en uterus insluit. Wanfunksionering van enige van hierdie spiere kan bydrae tot probleme soos urinêre en fekale inkontinensie, pelviese orgaan prolaps, rektale wanfunksionering en pelviese pyn. Selfs na chirurgie is dit belangrik om die spiere te oefen om weer hul normale funksie en ondersteunende rol te herstel; aangesien pyn en swelling voorkom dat spiere effektief kan werk.

Deelname aan die studie sal vereis dat u gereeld vir u roetine opvolg ondersoeke van die PFM sal moet kom. Dit sal egter deel uitmaak van die roetine ginekologiese opvolgbesoeke/ ondersoek aan die Uro-ginekologie kliniek by die Universitas Hospitaal/ praktyk. Dit sluit dus in u eerste besoek, asook u besoeke op drie (3) maande en ses (6) maande post-operatief. Hierdie ondersoek sal dus insluit `n kliniese ondersoek deur die ginekoloog en fisioterapeut, `n sonar en `n elektromiografiese ondersoek van die pelviese vloer spiere. Hierdie ondersoeke is egter glad nie ongemaklik of pynlik nie en u privaatheid sal te alle tye gerespekteer word.

Gedurende die studie sal u oefeninge en advies ontvang wat daagliks tuis gedoen moet word vir `n tydperk van ses (6) maande. Hierdie oefeninge behoort u nie langer as 20 minute besig te hou nie. `n Besoek elke tweede week aan die fisioterapeut sal moontlik nodig wees om die oefeninge te progresseer en te monitor pre- en post-operatief; afhangend van die tipe intervensie program wat u gaan ontvang. Hierdie besoeke sal ongeveer 45 minute elk duur. Daar is egter geen kostes of vergoeding verbonde aan die behandeling nie.

Soortgelyke studies wat voorheen gedoen is, het enkele uitsonderlike gevalle gerapporteer waar pasiënte `n effense ongemak/ pyn ervaar het na die oefeninge; soortgelyk aan wat `n mens voel na swaar oefening van die ledemate. Daar is **geen risiko`s** verbonde aan die behandeling nie.

Deelname aan die studie is egter vrywillig. U mag enige tyd van die studie onttrek sonder om gepenaliseer te word. Indien daar enige komplikasies intree (bv. ander siektetoestande, post-operatiewe komplikasies) wat u gesondheid mag benadeel, kan u deelname aan die studie deur die navorser gestaak word sonder u toestemming. Na die voltooiing van die studie sal al die resultate aan u beskikbaar gestel word. Alle inligting word konfidensieël gehou, maar ongelukkig kan volkome vertroulikheid nie gewaarborg word nie. Persoonlike inligting kan bekend gemaak word indien die wet dit vereis.

Hierdie studie is goedgekeur deur die Etiekkomitee van die Fakulteit Gesondheidswetenskappe, UV. Indien u enige navrae of probleme het aangaande die studie, kan u gerus die Sekretariaat van die Etiekkomitee van die Fakulteit Gesondheidswetenskappe, UV, skakel by telefoonnommer 051-4052812 of die navorser by 051-4013297.

Indien u bereid is om aan die studie deel te neem, voltooi asseblief die aangehegte toestemmingsvorm.

Die uwe

Me C Brandt

Fisioterapeut (M.Sc Fisioterapie)

Kontakbesonderhede:

Corlia Brandt

Departement Fisioterapie, UV

Tel nr: 051-4013297

Sel nr: 0832640189

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

TOESTEMMING TOT DEELNAME AAN NAVORSING

U is versoek om aan 'n navorsingstudie deel te neem.

U is oor die studie ingelig deur **Corlia Brandt**.

U kan **my, Corlia Brandt**, enige tyd kontak by **0832640189** indien u vrae oor die navorsing het of as gevolg van die navorsing beseer is.

U kan die Sekretariaat van die Etiekkomitee van die Fakulteit Gesondheidswetenskappe, UV by telefoonnommer (051) 4052812 kontak indien u enige vrae het oor u regte as 'n proefpersoon.

U deelname aan hierdie navorsing is vrywillig, en u sal nie gepenaliseer word of voordele verbeur as u weier om deel te neem of besluit om deelname te staak nie.

As u instem om deel te neem, sal 'n ondertekende kopie van hierdie dokument sowel as die deelnemersinligtingsblad, wat 'n geskrewe opsomming van die navorsing is, aan u gegee word. Alle inligting wat ingesamel word sal as vertroulik hanteer word. Data kan egter wel gebruik word vir publikasie doeleindes.

Die navorsingstudie, insluitend die bogenoemde inligting is verbaal aan my beskryf. Ek begryp wat my betrokkenheid by die studie beteken en ek stem vrywillig in om deel te neem.

__________________________ ____________________

Handtekening van deelnemer | Datum

_______________________ ____________________

Handtekening van getuie | Datum

(Waar van toepassing)

ADDENDUM 9

INFORMATION DOCUMENT AND LETTER OF COMMITMENT TO THE INVOLVED PRACTITIONER

Dear Dr __________________

Regarding: Involvement in the following research study – "Pelvic floor rehabilitation in women undergoing pelvic floor reconstructive surgery".

I, Corlia Brandt, hereby invite you to assist in a randomized, controlled, clinical trial undertaken by me as fulfilment of a doctoral degree at the University of the Free State. Approval for the study has been obtained from the Ethics committee of the Faculty of Health Sciences, UFS. The trial has also been registered with the NHREC.

The main aim of the study is to investigate the effect of rehabilitation on the pelvic floor muscles (PFM) and quality of life in women with pelvic organ prolapse that is due for surgery. Participation will entail frequent assessments of the PFM which will form part of their routine follow-up visits to the clinic/ pracitice pre- and post-operatively over a period of six (6) months.

Participants will be assigned randomly to one of three groups. The control group will be receiving the standard treating protocol as currently being given in the private and public sector pre- and post-operatively. The other two groups will be prescribed different exercise regimes for the PFM pre-operatively, receive routine physiotherapy treatment in hospital, and then again be prescribed exercises post-operatively. They will be requested to come for two weekly visits to the physiotherapist in order to progress and monitor their exercises which should be continued on a daily basis at home.

We request your involvement as an assessor. The following will be expected from you:

- Referral of eligible patients to partake in the study (see paragraph 4.2.2. in protocol).
- Measurement of the displacement and diameter of the m. puborectalis, thickness of the perineal body, and hiatal length with two-dimensional,

perineal ultrasound; according to a standardised procedure (see paragraph 4.4.1.1 and 4.4.2 in protocol).

- Measurement of the stage of the prolapse according to the Pelvic Organ Prolapse Quantification System (POP-Q) (see paragraph 4.4.2 in protocol).
- Measurement during the patient`s initial consultation, at their six weeks follow-up visit (post-operatively); and then again at three months and six months post-operatively.
- Your commitment for the duration of the study, which is expected to be two years.

You will be blind as an assessor and not be aware to which group the participant has been assigned.

You will also be provided with a protocol explaining the study and the measurement procedures.

All information will be strictly confidential and participation in the study is voluntarily. The patients can withdraw at any time from the study.

With conclusion of the study, all information will be made available to the involved institutions and submitted for publication.

I kindly request that you complete the enclosed consent form if you are willing to participate.

I appreciate your consideration.

Yours faithfully

Corlia Brandt
Physiotherapist (M.Sc Physiotherapy, UFS)

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CONSENT TO PARTICIPATE IN RESEARCH

You have been asked to participate in a research study.

You have been informed about the study by **Corlia Brandt.**

You may contact the researcher, **Corlia Brandt**, at **0832640189** any time if you have questions about the research.

You may contact the Secretariat of the Ethics Committee of the Faculty of Health Sciences, UFS at telephone number (051) 4052812 if you have questions about your rights as a research assistant/ assessor.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to terminate participation. Though we kindly request your commitment for the duration of the study.

If you agree to participate, you will be given a signed copy of this document as well as the protocol. All gathered information will be handled confidentially.

The research study, including the above information has been verbally described to me. I understand what my involvement in the study means and I voluntarily agree to participate.

_________________________ _____________________

Signature of Assessor Date

_________________________ _____________________

Signature of Witness Date

(Where applicable)

Contact details:
Corlia Brandt
Department of Physiotherapy, UFS
Tel nr: 051-4013297
Cell nr: 0832640189

ADDENDUM 10

PROOF OF SUBMISSION FOR PUBLICATION

Corlia Brandt

From: Dr Bridget Farham <ugqirha@iafrica.com>
Sent: 04 May 2016 10:05 AM
To: Corlia Brandt
Subject: [SAMJ] Submission Acknowledgement

Dear Corlia Brandt,

Thank you for submitting the manuscript, "Pelvic organ prolapse: a lifestyle disease or disease of quality of life?" to the South African Medical Journal. With the online journal management system that we are using, you will be able to track its progress through the editorial process by logging in to the journal web site:

Manuscript URL:
http://www.samj.org.za/index.php/samj/author/submission/10970
Username: gnftcb

If you have any questions, please contact me. Thank you for considering this journal as a venue for your work.

Kind regards

Dr Bridget Farham
South African Medical Journal
____
South African Medical Journal
Website: www.samj.org.za
Email: publishing@hmpg.co.za
Twitter: @samj_online
Phone: +27 (0)72 635 9825

Corlia Brandt

From: Dr William Edridge <william.edridge@gmail.com>
Sent: 12 April 2016 10:44 AM
To: Corlia Brandt
Subject: [SAJOG] Submission Acknowledgement

Corlia Brandt:

Thank you for submitting the manuscript, "Validation of the prolapse quality of life questionnaire (P-QOL): an Afrikaans version in a South African population." to South African Journal of Obstetrics and Gynaecology. With the online journal management system that we are using, you will be able to track its progress through the editorial process by logging in to the journal web site:

Manuscript URL:
http://www.sajog.org.za/index.php/SAJOG/author/submission/1077
Username: gnftcb

If you have any questions, please contact me. Thank you for considering this journal as a venue for your work.

Dr William Edridge
South African Journal of Obstetrics and Gynaecology ___________________ South African Journal of Obstetrics & Gynaecology www.sajog.org.za

ADDENDUM 11

PROLAPSE QUALITY OF LIFE QUESTIONNAIRES

PROLAPSE QUALITY OF LIFE (P-QOL)

Version 4

For office use only

ASSESSMENT _____ 1

Patient number: _______ 2-4

Age: _______ years 5-6

Today`s date: ____/____/____

A prolapse is a bulge coming down the vagina causing discomfort.
Please fill in this questionnaire even if you feel you do not have a prolapse.

1. How would you describe your health at present?
Please tick one answer.

Very good	
Good	
Fair	
Poor	
Very poor	

7

2. How much do you think your prolapse problem affects your life?
Please tick one answer.

Not at all	
A little	
Moderately	
A lot	

8

Please write down if you have any of the following symptoms and mark how much these affect you.

	Not applicable	None	A little	Moderately	A lot	
a. Going to the toilet to pass urine very often.						9
b. Urgency: A strong desire to pass urine.						10
c. Urge incontinence; urinary leakage associated with a strong desire to pass urine.						11
d. Stress incontinence: urinary leakage associated with coughing.						12
e. Feeling a bulge/lump from or in the vagina.						13

	Not applicable	None	A little	Moderately	A lot	
f. Heaviness or dragging feeling as the day goes on from the vagina or lower abdomen.						14
g. Vaginal bulge interfering with you emptying your bowels.						15
h. Discomfort in the vagina which is worse when standing and relieved by lying down.						16
i. Poor urinary stream.						17
j. Straining to empty your bladder.						18
k. Urine dribbles after emptying your bladder.						19

Please write down if you have any of the following symptoms and mark how much these affect you.

	Not applicable	None	A little	Moderately	A lot	
l. Bowels do not feel completely empty after opening.						20
m. Constipation: difficulty in emptying						21
n. Straining to open your bowels.						22
o. Vaginal bulge which gets in the way of sex.						23
p. Lower backache worsens with vaginal discomfort.						24
q. Do you help empty your bowels with your fingers?						25

r. How often do you open your bowels?

More than once a day	Once a day	Once every 2 days	Once every 3 days	Once a week or more	
					26

Below are some daily activities that can be affected by your prolapse problem. How much does prolapse problem affect you?
We would like you to answer every question.
Simply tick the block that applies to you.

ROLE LIMITATIONS	**Not at all**	**Slightly**	**Moderately**	**A lot**	
3. To what extent does your prolapse affect your household tasks (e.g. cleaning, shopping, etc.)					27
4. Does your prolapse affect your job or your normal daily activities outside the home?					28

PHYSICAL/SOCIAL LIMITATIONS	**Not at all**	**Slightly**	**Moderately**	**A lot**	
5. Does your prolapse affect your physical acitivities (e.g. going for a walk, run, sport, gym, etc.?)					29
6. Does your prolapse affect your ability to travel?					30
7. Does your prolapse limit your social life?					31
8. Does your prolapse limit your ability to see/visit friends?					32

PERSONAL RELATIONSHIPS	**Not applicalbe**	**Not at all**	**Slightly**	**Moderately**	**A lot**	
9. Does your prolapse affect your relationship with your partner?						33
10. Does your prolapse affect your sex life?						34
11. Does your prolapse affect your family life?						35

EMOTIONS	**Not at all**	**Slightly**	**Moderately**	**A lot**	
12. Does your prolapse make you feel depressed?					36
13. Does your prolapse make you feel anxious or nervous?					37
14. Does your prolapse make you feel bad about yourself?					38

SLEEP/ENERGY	**Never**	**Sometimes**	**Often**	**All the time**	
15. Does your prolapse affect your sleep?					39
16. Do you feel worn out/ tired?					40

Do you do any of the following to help your prolapse problem? If so how much?
Answer even if you do not feel you have a prolapse problem.

	Never	Sometimes	Often	All the time		
17. Use tampons/ pads/ firm knickers to help?						41
18. Do you push up the prolapse?						42

	Never	Sometimes	Often	All the time		
19. Pain or discomfort due to the prolapse?						43
20. Does the prolapse prevent you from standing?						44

Thank you, now check that you have answered all the questions.

PROLAPS KWALITEIT VAN LEWE (P-QOL)

Vierde weergawe

Slegs vir kantoorgebruik

EVALUERING_____ 1

Pasiënt nommer: _______ 2-4

Ouderdom: _______ jaar 5-6

Vandag se datum: ____/____/____ 7-12
dd /mm / yy

`n Prolaps is `n uitstulping vanuit die vagina wat afsak en ongemak veroorsaak.
Vul hierdie vraelys asseblief in, selfs al voel u nie u het `n prolaps het nie.

1. Hoe sou u, u gesondheid tans beskryf?
Merk asseblief een antwoord.

Baie goed	
Goed	
Redelik	
Swak	
Baie swak	

13

2. Hoeveel dink u affekteer u prolaps probleem u lewe?
Merk asseblief een antwoord.

Glad nie	
`n Bietjie	
Redelik	
Baie	

14

Skryf asseblief neer indien u enige van die volgende simptome het, merk hoeveel dit u affekteer.

	Nie toepaslik	Geen	`n Bietjie	Redelik	Baie	
a. Gaan gereeld badkamer toe om te urineer.						15
b. Dringendheid: `n sterk drang om te urineer.						16
c. Dranginkontinensie: Iek van uriene geassosieer met `n sterk drang om te urineer.						17
d. Stresinkontinensie: Iek van uriene geassosieer met hoes.						18
e. Voel `n uitstulping vanaf of in die vagina.						19

	Nie toepaslik	Geen	`n Bietjie	Redelik	Baie	
f. Swaar of `n trekgevoel soos die dag verloop vanaf die vagina of laer abdomen.						20
g. `n Vaginale uitstulping wat inmeng met u normale stoelgang lediging.						21
h. Ongemak in die vagina wat erger word wanneer u staan en beter word deur te gaan lê.						22
i. Swak urienvloei.						23
j. Sukkel om jou blaas leeg te maak.						24
k. Uriene drip nog nadat u, u blaas leeg gemaak het.						25

Skryf asseblief neer indien u enige van die volgende simptome het, en merk hoeveel dit u affekteer.

	Nie toepaslik	Geen	`n Bietjie	Redelik	Baie	
l. Die derm voel nie heeltemal leeg na stoelgang gepasseer is nie.						26
m. Hardlywigheid: sukkel met stoelgang ledeging.						27
n. Inspanning om u maag te laat werk.						28
o. Vaginale uitstulping wat in die pad is tydens seksuele omgang.						29
p. Lae rugpyn wat vererger met vaginale ongemak.						30
q. Help u, u stoelgang met u vingers?						31

	Meer as een maal per dag	Een maal per dag	Elke twee dae	Elke drie dae	Een keer per week/ meer	
r. Hoe gereeld werk u maag?						32

Hieronder is `n paar daaglikse aktiwiteite wat deur u prolapsprobleem geaffekteer kan word. Hoeveel affekteer u prolapsprobleem u?
Ons wil graag hê dat u elke vraag beantwoord.
Merk slegs die blokkie van toepassing op u.

ROLBEPERKINGs	**Glad nie**	**Effens**	**Redelik**	**Baie**	
3. Tot watter mate affekteer u prolaps u huishoudelike take (bv. skoonmaak, inkopies, ens.)?					33
4. Affekteer u prolaps u werk of u normale aktiwiteite buite die huis?					34

FISIESE/ SOSIALE BEPERKINGs	**Glad nie**	**Effens**	**Redelik**	**Baie**	
5. Affekteer u prolaps u fisiese aktiwiteite (bv. om te gaan stap, draf, sport, gimnasium, ens.)?					35
6. Affekteer u prolaps u vermoeë om te reis?					36
7. Beperk u prolaps u sosiale lewe?					37
8. Beperk u prolaps u vermoeë om u vriende te sien/ besoek?					38

PERSOONLIKE VERHOUDINGS	**Nie toepaslik**	**Geen**	**`n Bietjie**	**Redelik**	**Baie**	
9. Affekteer u prolaps u verhouding met u maat?						39
10. Affekteer u prolaps u sekslewe?						40
11. Affekteer u prolaps u gesinslewe?						41

EMOSIES	**Glad nie**	**Effens**	**Redelik**	**Baie**	
12. Laat u prolaps u depressief voel?					42
13. Veroorsaak u prolaps dat u angstig of senuweeagtig voel?					43
14. Veroorsaak u prolaps dat u sleg oor uself voel?					44

SLAAP/ENERGIE	**Nooit**	**Soms**	**Gereeld**	**Altyd**	
15. Affekteer u prolaps u slaap?					45
16. Voel u afgeleef/moeg?					46

Doen u enige van die volgende om u prolapsprobleem te help? Indien wel, hoeveel? Beantwoord selfs al dink u dat u nie `n prolapsprobleem het nie.

	Nooit	Soms	Gereeld	Altyd		
17. Gebruik u tamponne/ doekies/ stywe onderklere om te help?						47
18. Druk u die prolaps terug?						48

	Nooit	Soms	Gereeld	Altyd		
19. Pyn of ongemak weens die prolaps?						49
20. Verhoed die prolaps dat u kan staan?						50

Dankie, maak asseblief seker dat u al die vrae beantwoord het.

ADDENDUM 12

THE SF-36 HEALTH SURVEY QUESTIONNAIRES

SF36 HEALTH SURVEY

For office use

Participant number: ___________ 1-3

INSTRUCTIONS: This set of questions asks for your views about your health. This information will help keep track of how you feel an how well you are able to do your usual activities. Answer every question by marking the answer as indicated. If you are unsure about how to answer a question please give the best answer you can.

1. In general, would you say your health is: (Please tick **one** box.)
   - Excellent ☐
   - Very good ☐
   - Good ☐
   - Fair ☐
   - Poor ☐

☐ 4

2. Compared to one year ago, how would you rate your health in general now? (Please tick **one** box.)
   - Much better than one year ago ☐
   - Somewhat better now than one year ago ☐
   - About the same as one year ago ☐
   - Somewhat worse now than one year ago ☐
   - Much worse now than one year ago ☐

☐ 5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?
   (Please circle one number on each line.)

Activities	**Yes, limited a lot**	**Yes, limited a little**	**Not limited at all**	For office use
3.a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3	☐ 6
3.b. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3	☐ 7
3.c. Lifting or carrying groceries	1	2	3	☐ 8
3.d. Climbing **several** flights of stairs	1	2	3	☐ 9
3.e. Climbing **one** flight of stairs	1	2	3	☐ 10
3.f. Bending, kneeling or stooping	1	2	3	☐ 11
3.g. Walking **more than a mile** (1.6km)	1	2	3	☐ 12
3.h. Walking **several blocks**	1	2	3	☐ 13
3.i. Walking **one block**	1	2	3	☐ 14
3.j. Bathing or dressing yourself	1	2	3	☐ 15

4. During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health?</u> **(Please circle one number on each line.)**	**Yes**	**No**	
4.a. Cut down on the **amount of time** you spent on work or other activitites	1	2	☐ 16
4.b. Accomplished less than you would like	1	2	☐ 17
4.c. Were **limited** in the **kind** of work or other activities	1	2	☐ 18
4.d. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2	☐ 19
5. During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (e.g. feeling depressed or anxious)? **(Please circle one number on each line.)**	**Yes**	**No**	
5.a. Cut down on the **amount of time** you spent on work or other activities	1	2	☐ 20
5.b. Accomplished less than you would like	1	2	☐ 21
5.c. Did not do work or other activities as **carefully** as usual	1	2	☐ 22

6. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?
(Please tick **one** box)

Not at all ☐
Slightly ☐
Moderately ☐
Quite a bit ☐
Extremely ☐

☐ 23

7. How much <u>physical</u> pain have you had during the past 4 weeks? (Please tick **one** box.)

None ☐
Very mild ☐
Mild ☐
Moderate ☐
Severe ☐
Very severe ☐

☐ 24

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? (Please tick **one** box.)

Not at all ☐
A little bit ☐
Moderately ☐
Quite a bit ☐
Extremely ☐ ☐ 25

9. These questions are about how you feel and how things have been with you during the past 4 weeks. Please give the one answer that is closest to the way you have been feeling for each item. **(Please circle one number on each line.)**	**All of the time**	**Most of the time**	**A good bit of the time**	**Some of the time**	**A little of the time**	**None of the time**	
9.a. Did you feel full of life?	1	2	3	4	5	6	☐ 26
9.b. Have you been a very nervous person?	1	2	3	4	5	6	☐ 27
9.c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6	☐ 28
9.d. Have you felt calm and peaceful?	1	2	3	4	5	6	☐ 29
9.e. Did you have a lot of energy?	1	2	3	4	5	6	☐ 30
9.f. Have you felt downhearted and blue?	1	2	3	4	5	6	☐ 31
9.g. Did you feel worn out?	1	2	3	4	5	6	☐ 32
9.h. Have you been a happy person?	1	2	3	4	5	6	☐ 33
9.i. Did you feel tired?	1	2	3	4	5	6	☐ 34

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.) (Please tick **one** box.)

All of the time ☐
Most of the time ☐
Some of the time ☐
A little of the time ☐
None of the time ☐ ☐ 35

11. How TRUE or FALSE is each of the following statements for you? (**Please circle one number on each line.)**	**Definitely true**	**Mostly true**	**Do not know**	**Mostly false**	**Definitely false**	
11.a. I seem to get sick a little easier than other people	1	2	3	4	5	☐ 36
11.b. I am as healthy as anybody I know	1	2	3	4	5	☐ 37
11.c. I expect my health to get worse	1	2	3	4	5	☐ 38
11.d. My health is excellent	1	2	3	4	5	☐ 39

Thank you!

SF36 HEALTH SURVEY

Vir kantoorgebruik

Deelnemer nommer: ___________ 1-3

INSTRUKSIES: Hierdie stel vrae handel oor u siening oor u gesondheid. Hierdie inligting help om tred te hou met hoe u voel en hoe goed u in staat is om u gewone aktiwiteite uit te voer. Beantwoord elke vraag deur die antwoord te merk soos aangedui. Indien u onseker is oor hoe om `n vraag te beantwoord, moet u net asseblief die beste antwoord wat u kan, gee.

1. In die algemeen, sal u sê u gesondheid is: (Merk asseblief **een** blokkie.)

   - Uitstekend ☐
   - Baie goed ☐
   - Goed ☐
   - Redelik ☐   ☐ 4
   - Swak ☐

2. <u>In vergelyking met een jaar gelede</u>, hoe sal u u gesondheid <u>nou</u> gradeer? (Merk asseblief **een** blokkie.)

   - Baie beter as een jaar gelede ☐
   - Ietwat beter as een jaar gelede ☐
   - Omtrent dieselfde as een jaar gelede ☐
   - Ietwat slegter as een jaar gelede ☐   ☐ 5
   - Baie slegter as een jaar gelede ☐

3. Die volgende vrae handel oor aktiwiteite wat u gedurende `n tipiese dag mag doen. Beperk u gesondheid u nou in hierdie aktiwiteite? Indien wel, hoeveel? **(Omkring asseblief een nommer op elke lyn.)**

Aktiwiteite	Ja, baie beperk	Ja, bietjie beperk	Glad nie beperk	Vir kantoorgebruik
3.a. **Kragtige aktiwiteite**, byvoorbeeld hardloop, swaar voorwerpe optel, deelname in inspannende aktiwiteite	1	2	3	☐ 6
3.b. **Matige aktiwiteite**, byvoorbeeld om `n tafel te skuif, `n stofsuier te stoot, rolbal te speel, of gholf te speel	1	2	3	☐ 7
3.c. Optel of dra van inkopies	1	2	3	☐ 8
3.d. Klim van **verskeie** stelle trappe	1	2	3	☐ 9
3.e. Klim van **een** stel trappe	1	2	3	☐ 10
3.f. Buig, kniel of buk	1	2	3	☐ 11
3.g. **Verder as `n myl** loop (1.6km)	1	2	3	☐ 12
3.h. **Verskeie blokke** loop	1	2	3	☐ 13
3.i. **Een blok** loop	1	2	3	☐ 14
3.j. Uself bad of aantrek	1	2	3	☐ 15

4. Gedurende die afgelope 4 weke, het u enige van die volgende probleme met u werk of ander gewone daaglikse aktiwiteite ondervind as gevolg van u fisiese gesondheid? **(Omkring asseblief een nommer op elke lyn.)**	**Ja**	**Nee**	
4.a. Vermindering in die hoeveelheid tyd wat u bestee aan werk of ander aktiwiteite	1	2	☐ 16
4.b. Bereik minder as wat u graag sou wou bereik	1	2	☐ 17
4.c. Was beperk in die tipe werk of ander aktiwiteite verrig	1	2	☐ 18
4.d. Was moeilik om die werk of ander aktiwiteite uit te voer (byvoorbeeld, dit het ekstra inspanning geverg)	1	2	☐ 19
5. Gedurende die afgelope 4 weke, het u enige van die volgende probleme met u werk of ander gereelde daaglikse aktiwiteite ondervind as gevolg van enige emosionele probleme (bv. `n gevoel van depressie of angstigheid)? **(Omkring asseblief een nommer op elke lyn.)**	**Ja**	**Nee**	
5.a. Vermindering in die hoeveelheid tyd wat u bestee aan werk of ander aktiwiteite	1	2	☐ 20
5.b. Bereik minder as wat u graag sou wou bereik	1	2	☐ 21
5.c. Het nie werk of ander aktiwiteite so versigtig as gewoonlik gedoen nie	1	2	☐ 22

6. In watter mate het u fisiese gesondheid of emosionele probleme ingemeng met u normale sosiale aktiwiteite met familie, vriende, bure, of groepe die afgelope 4 weke?
(Merk asseblief slegs **een** blokkie.)

Glad nie ☐
Gering ☐
Matig ☐
Redelik baie ☐
Uitermatig ☐

☐ 23

7. Hoeveel fisiese pyn het u gedurende die afgelope 4 weke gehad? (Merk asseblief slegs **een** blokkie.)

- Geen ☐
- Baie lig ☐
- Lig ☐
- Matig ☐
- Erg ☐
- Baie erg ☐ ☐ 24

8. Gedurende die afgelope 4 weke, hoeveel het die pyn ingemeng met u normale werk (ingesluit werk buite die huis sowel as huiswerk)? (Merk asseblief slegs **een** blokkie.)

- Glad nie ☐
- Net `n bietjie ☐
- Matig ☐
- Redelik baie ☐
- Uitermatig ☐ ☐ 25

9. Hierdie vrae handel oor hoe u voel en hoe dit met u gegaan het gedurende die afgelope 4 weke. Gee asseblief die een antwoord wat die beste beskryf hoe u gevoel het vir elke item. **(Omkring asseblief een nommer op elke lyn.)**	**Al die tyd**	**Meeste van die tyd**	**`n Goeie deel van die tyd**	**Sommige van die tyd**	**Min van die tyd**	**Nooit nie**		
9.a. Het u vol lewe gevoel?	1	2	3	4	5	6	☐	26
9.b. Was u `n baie senuweeagtige persoon?	1	2	3	4	5	6	☐	27
9.c. Het u so sleg gevoel dat niks u kon opbeur nie?	1	2	3	4	5	6	☐	28
9.d. Het u kalm en rustig gevoel?	1	2	3	4	5	6	☐	29
9.e. Het u baie energie gehad?	1	2	3	4	5	6	☐	30
9.f. Het u neerslagtig en blou gevoel?	1	2	3	4	5	6	☐	31
9.g. Het u uitgemergel gevoel?	1	2	3	4	5	6	☐	32
9.h. Was u `n gelukkige persoon?	1	2	3	4	5	6	☐	33
9.i. Het u moeg gevoel?	1	2	3	4	5	6	☐	34

10. Gedurende die afgelope 4 weke, hoeveel van die tyd het u fisiese gesondheid of emosionele probleme ingemeng met u sosiale aktiwiteite (soos kuier saam met vriende, naasbestaandes, ens.) (Merk asseblief slegs **een** blokkie.)

- Al die tyd ☐
- Meeste van die tyd ☐
- Sommige van die tyd ☐
- Min van die tyd ☐
- Nooit nie ☐ ☐ 35

11. Hoe WAAR of VALS is <u>elk</u> van die volgende stellings vir jou? **(Omkring asseblief een nommer op elke lyn.)**	**Definitief waar**	**Meestal waar**	**Weet nie**	**Meestal vals**	**Definitief vals**	
11.a. Dit blyk of ek bietjie makliker siek word as ander mense.	1	2	3	4	5	☐ 36
11.b. Ek is so gesond soos almal wat ek ken	1	2	3	4	5	☐ 37
11.c. Ek verwag dat my gesondheid gaan versleg	1	2	3	4	5	☐ 38
11.d. My gesondheid is uitstekend	1	2	3	4	5	☐ 39

Baie dankie!

ADDENDUM 13

DATA FORMS

MEDICAL HISTORY

Please tick the appropriate answers or complete the blank space provided.

		For office use
Patient number:		1-3
Date:	dd / mm / yy	4-9
1. Age:	________years	10-11
2. Weight:	______.__kg	12-16
3. Length:	______.0cm	17-19

4. Language:

1	Afrikaans	20
2	English	

5. What type of work do you do?

1	Manual labour	21
2	Office work	
3	Other: specify ____________________	

6. Do you participate in any sport? (If yes, please answer question 6.1 and 6.2)

1	yes	22
2	no	

6.1 If yes, what type of sport do you participate in? (Tick all the applicable answers.)

1	Jogging	23
2	Swimming	24
3	Tennis	25
4	Aerobics	26
5	Weight training	27
6	Pilates/ Yoga	28
7	Other: specify ____________________	29

6.2 On what level do you participate in sport? Only indicate the highest level.

1	Social	30
2	Provincial	
3	National	

7. Do you suffer from any illness/ disease? Tick all the appropriate answers and specify the illness/ disease in the space provided.

1	Heart disease: specify	______	31
2	Vascular disease: specify	______	32
3	Pulmonary disease: specify	______	33
4	Cancer: specify	______	34
5	Allergies: specify	______	35
6	Previous surgery: specify	______	36
7	Inflammatory conditions: specify	______	37
8	Other: specify	______	38

8. What medication do you use? Please list them in the space provided.

______	39-40
______	41-42
______	43-44
______	45-46
______	47-48
______	49-50
______	51-52
______	53-54

9. Do you smoke?

1	yes	55
2	no	

10. Gynaecological history:

10.1 How many times have you been pregnant? __________ 56-57

10.2 How many times have you given birth? __________ 58-59

10.2 Please indicate the amount of normal deliveries and/or Ceasarian sections you have had. If you had any other type of delivery, please indicate in the space provided together with the amount.

Normal		60-61
Ceasarian section		62-63
Other: specify		64-65

10.4 Have you ever received pelvic floor muscle training from a physiotherapist before? 66

1	yes
2	no

10.5 Have you ever received any core stability training from a physiotherapist or biokinethicist? 67

1	yes
2	no

10.6 Tick the appropriate answer. I am ….. 68

1	Pre-menopausal
2	in my menopause
3	Post-menopausal

10.7 Have you had any abdominal or pelvic floor surgery before? If yes, please specificy in the space provided. 69

1	yes
2	no

Specify: ______________________________ 70-71

____

____

____

____

MEDIESE GESKIEDENIS

Merk asseblief die toepaslike antwoord of voltooi in die spasie wat voorsien word.

Vir kantoorgebruik

Pasiënt nommer: — 1-3

Datum: dd / mm / jj — 4-9

1. Ouderdom: ________jaar — 10-11

2. Gewig: ______.__kg — 12-16

3. Lengte: ______.0cm — 17-19

4. Taal: — 20

1	Afrikaans
2	Engels

5. Watter tipe werk doen u? — 21

1	Hande-arbeid
2	Kantoorwerk
3	Ander: spesifiseer ______________________

6. Neem u deel aan enige sport? (Indien ja, antwoord asseblief vraag 6.1 en 6.2) — 22

1	ja
2	nee

6.1 Indien ja, aan watter sportsoort neem u deel? (Merk al die toepaslike antwoorde.)

1	Draf	23
2	Swem	24
3	Tennis	25
4	Aërobiese oefeninge	26
5	Oefen met gewigte	27
6	Pilates/ Joga	28
7	Ander: spesifiseer ______________________	29

6.2 Op watter vlak neem u aan sport deel? Dui slegs die hoogste vlak aan.

1	Sosiaal	30
2	Provinsiaal	
3	Nasionaal	

7. Ly u aan enige siekte? Merk al die toepaslike antwoorde en spesifiseer die siekte in die spasie wat voorsien word.

1	Harttoestand: spesifiseer		31
2	Vaskulêre siekte: spesifiseer		32
3	Pulmonale siekte: spesifiseer		33
4	Kanker: spesifiseer		34
5	Allergieë: spesifiseer		35
6	Vorige chirurgie: spesifiseer		36
7	Inflammatoriese toestande: spesifiseer		37
8	Ander: spesifiseer		38

8. Watter medikasie gebruik u? Lys asseblief die medikasie in die spasie voorsien.

		39-40
		41-42
		43-44
		45-46
		47-48
		49-50
		51-52
		53-54

9. Rook u?

1	ja	55
2	nee	

10. Ginekologiese geskiedenis:

10.1 Hoeveel keer was u al swanger? __________ 56-57

10.2 Hoeveel keer het u al gekraam? __________ 58-59

10.2 Dui asseblief die hoeveelheid normale bevallings en/of Keisersnitte aan wat u al gehad het. Indien u enige ander tipe bevalling gehad het, dui dit, saam met die hoeveelheid, asseblief in die spasie voorsien aan.

Normaal		60-61
Keisersnit		62-63
Ander: spesifiseer		64-65

10.4 Het u al ooit vantevore pelviese vloer spier oefeninge van `n fisioterapeut ontvang? 66

1	ja
2	nee

10.5 Het al ooit enige oefeninge vir kernstabiliteit van `n fisioterapeut of biokinetikus ontvang? 67

1	ja
2	nee

10.6 Merk die toepaslike antwoord. Ek is….. 68

1	Pre-menopousaal
2	in my menopouse
3	Post-menopousaal

10.7 Het u al vorige abdominale of pelviese vloer chirurgie gehad? Indien wel, spesifiseer asseblief in die spasie voorsien. 69

1	ja
2	nee

Spesifiseer: ______________________________ 70-71

DATA FORM

ASSESSMENT ___

For office use

Patient number: 2-4 (office use: 1)

Date: dd / mm / yy 5-10

1. Surgeon/ gynaecologist: ______________________ 11

2. Pelvic organ prolapse:

2.1 Perineal sonar:

	Stage I	Stage II	Stage III	Stage IV	None	For office use
Cystocoele						12
Uterine prolapse						13
Vault prolapse						14
Enterocoele						15
Rectocoele						16

2.1 POP-Q:

	Stage I	Stage II	Stage III	Stage IV	None	For office use
Cystocoele						17
Uterine prolapse						18
Vault prolapse						19
Enterocoele						20
Rectocoele						21

2.2 POP-Q value: ______ 22-23

3. Symptoms:

		Yes	No	For office use
3.1	Overactive bladder	1	2	24
3.2	Stress incontinence	1	2	25
3.3	Urge incontinence	1	2	26
3.4	Fistula	1	2	27
3.5	Frequency	1	2	28
3.6	Constipation	1	2	29
3.7	Obstructive defaecation	1	2	30

	Yes	No	
3.8 Anal incontinence	1	2	31
3.9 Other: specify	1	2	32

4. Neurological examination:

4.1 Sensation:

		Normal	Absent	Abnormal	
4.1.1	S1				33
4.1.2	S2				34
4.1.3	S3				35
4.1.4	S4				36

4.2 Motor response:

		Normal	Absent	Weak	
4.2.1	S1				37
4.2.2	S2				38
4.2.3	S3				39
4.2.4	S4				40

4.3 Reflex:

1	Normal	41
2	Absent	

5. PFM assessment:

5.1.1 Hiatal length (rest): ________mm x ________mm = ___________mm² 42-44
5.1.2 Hiatal length (Valsalva): ________mm x ________mm = ___________mm² 45-47
5.1.3 Hiatal length (contraction): ________mm x ________mm = ___________mm² 48-50

5.2 Thickness of perineal body: _______________mm 51-52

5.3 Diameter of puborectalis:
5.3.1 Left: _______________mm 53-54
5.3.2 Right: _______________mm 55-56

5.4 External sphincter defect:

1	Yes
2	No

[ ] 57

5.5 Movement of puborectalis (direction):

Anterior	Posterior	Superior	Inferior
Ant-sup	**Post-sup**	**Ant-inf**	**Post-inf**

[ ] 58

5.6 Movement of puborectalis (distance): ______________mm [ ][ ] 59-60

5.7 PERFECT score:

5.7.1 Power: ______________ [ ] 61

5.7.2 Endurance: ______________seconds [ ][ ] 62-63

5.7.3 Repetitions: ______________ [ ][ ] 64-65

5.7.4 Fast contractions: ______________ [ ][ ] 66-67

5.8 EMG reading: __________.____цV [ ][ ][ ][ ][ ] 68-72

5.9 Endurance as measured with EMG: ______________seconds [ ][ ] 73-74

6. Lumbo-pelvic stability: Level [ ] [ ] 75

6.1 EMG reading: __________.____цV [ ][ ][ ][ ][ ] 76-80

6.2 PBU: _________ repetitions (x10sec) [ ][ ] 1-2

6.3 Sahrmann: _________ [ ] 3

7. Exercise compliance:

Not at all	1
A little	2
Rather regularly	3
Very regularly	4

[ ] 4

8. Surgery: ____________________________ [ ][ ] 5-6

9 Pain:

9.1 Pelvic pain: [ ] [ ] 7

9.2 Low back pain: [ ] [ ] 8

ADDENDUM 14

GUIDELINES FOR SCORING OF THE P-QOL

To Calculate Score

1. General Health Perceptions

Score = ((Score to GHPA – 1)/4) x 100

2. Prolapse Impact

Score = ((Score to GHPB – 1)/3) x 100

3. Role Limitations

Score = (((Scores to RLA + RLB) – 2)/6) x 100

4. Physical Limitations

Score = (((Score to PLA + PLB) – 2)/6) x 100

5. Social Limitations

Score = (((Score to PLC + PLD + PRC) – 3) /9) x 100 **

** if score to PRC > = 1, if 0 then … - 2) /6) x 100

6. Personal Relationships

Score = (((Score to PRA + PRB) –2) /6) x 100 ***

*** if score to PRA + PRB > = 2,

if PRA + PRB = 1; … -1) /3) x 100

if PRA + PRB = 0; … treat as missing value (not applicable)

7. Emotions

Score = (((Score to EMA + EMB + EMC) – 3) /9) x 100

8. Sleep / Energy

Score = (((Score to SEA + SEB) – 2) /6) x 100

9. Severity Measures

Score = (((Score to SMA + SMB + SMC + SMD) – 4) /12) x 100

GHPA:	question 1 page 1
GHPB:	question 2 page 1
RLA:	question 1 page 4
RLB:	question 2 page 4
PLA:	question 3 page 4
PLB:	question 4 page 4
PLC:	question 5 page 4
PLD:	question 6 page 4
PRA:	question 7 page 4
PRB:	question 8 page 4
PRC:	question 9 page 4
EMA:	question 1 page 5
EMB:	question 2 page 5
EMC:	question 3 page 5
SEA:	question 4 page 5
SEB:	question 5 page 5
SMA:	question 6 page 5
SMB:	question 7 page 5
SMC:	question 8 page 5
SMD:	question 9 page 5

The questions about urinary, bowel and sexual symptoms do not have score. They look at symptoms that can be related to the prolapse or not. The correlation between symptoms and prolapse has not been demonstrated yet. We presented a study in Birmingham for the 29th British Congress of O&G demonstrating a significant correlation between urinary symptoms and anterior vaginal wall prolapse only. Sexual symptoms correlate significantly with vaginal prolapse. No correlation was found between bowel symptoms and posterior vaginal wall prolapse. Same results have been published in July 2005 on the BJOG.
Digesu GA, Chaliha C, Salvatore S, Hutchings A, Khullar V. The relationship of vaginal prolapse severity to symptoms and quality of life. BJOG. 2005 Jul;112(7):971-6.
Thus we are not sure yet whether a scoring system for the symptoms will be accurate and correct.

The answers of the patient will have values that range between 1 to 4 (1 to 5 for the 1st question only). I will advise to use the SPSS as database.
The SPSS software will recognise 1 as not at all and 4 as a lot (1 very good 5 very poor). 0 will not be recognised from your computer or will be identify as missing item.
In fact when you compute your new variable using the scoring system if you type 0 you will have a negative score and this is not possible. If you type 1 your score will be 0 which means good quality of life or better that domain is not impaired.
In summary 1 to 4 (1 to 5 for the first question) are your variable (responses) values, 0 to 100 will be your score.

There is no overall score. A symptomatic woman might have only one domain impaired and an other one have all domain impaired. We consider both of them symptomatic but in different or same aspects of quality of life.
To differentiate different domains is important in the decision of our surgery (we will be careful in shortening and narrowing a vagina of a woman who had only a preoperative high (impaired) Personal relationships domain score and other domains in the normal range) The above woman is symptomatic, need a treatment as well as a woman with all domain impaired.
This will also help us in the follow up visits.

ADDENDUM 15

MANUSCRIPT: “VALIDATION OF THE PROLAPSE QUALITY OF LIFE QUESTIONNAIRE: AN AFRIKAANS VERSION IN A SOUTH AFRICAN POPULATION IN THE FREE STATE”

Validation of the prolapse quality of life questionnaire (P-QOL): an Afrikaans version in a South African population.

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Authors` contributions:

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Cronjè, HS: protocol, project development, manuscript writing

Van Rooyen C: data analysis

Word count: 2102

Abstract

Introduction: The Prolapse Quality of Life questionnaire (P-QOL) has been validated and translated into eight languages. The lack of an Afrikaans version of the P-QOL limits studies in Afrikaans speaking patients with Pelvic Organ Prolapse (POP). The aim was to validate an Afrikaans version of the P-QOL in a South African population.

Methodology: The P-QOL questionnaire was translated to Afrikaans by a medical translator and three gynaecologists. This descriptive study determined construct validity comparing 25 symptomatic (64.1% n=39) and 14 asymptomatic (35.9% n=39) participants` median domain scores. The POP stage was determined according to the Pelvic Organ Prolapse Quantification (POP-Q) scale and compared to their domain scores by means of percentages. A second P-QOL questionnaire was completed and the stability determined by the test-retest method. The cronbach alpha was used to determine internal consistency and the kappa value to determine measure of agreement.

Results: Symptomatic participants had higher median domain scores than asymptomatic participants. All asymptomatic participants had stage O POP and 33.3% of symptomatic participants had stage III POP. Stability was good with an average of above 50%. The mean Cronbach alpha value was 0.94 and the kappa value indicated moderate to good strength of agreement between items (κ = 0.41-0.80).

Conclusion: The Afrikaans P-QOL questionnaire was found valid and reliable to determine quality of life in women with POP, correlating with the findings of other validation studies and supporting the evidence that the P-QOL is a high-quality disease-specific quality of life questionnaire.

Word count: 244

Keywords:, Pelvic Organ Prolapse, Quality of Life (questionnaire), Uterovaginal prolapse, Validation

SUMMARY

An Afrikaans version of the P-QOL in a South African population was validated similar to methodology of previous validation studies of the P-QOL.

MANUSCRIPT

INTRODUCTION

Pelvic organ prolapse (POP) occurs in 46-73% of women in South Africa and may also be associated with other pelvic floor dysfunctions [1]. The assessment of quality of life is becoming increasingly important in determining the outcome of pelvic floor reconstructive surgery as well as other pelvic floor disorders [2].

POP is mostly benign, but it is distressing and disabling with a large effect on the patient`s quality of life (QOL) [3]. The multifactorial pathophysiology may be the cause of associated symptoms such as bladder, bowel, sexual, and even pain symptoms [4]. The symptoms may lead to physical, social, psychological, domestic, and/or sexual limitations in the patient`s acitivities of daily living [5]. A survey done by Muller [6] in the United States found that women with POP experienced compromised bladder and bowel control as most limiting quality of life. Secondly ranked was the inability to enjoy physical activities such as sport. They also emphasised satisfaction of conservative and surgical management as an important factor in determining quality of life [6].

Important is to validly and reliably determine the quality of life from a patient`s perspective, since it has been indicated that the validity of quality of life outcomes based on the physicians` perspective, should be interpreted with caution [7]. Changes in quality of life from the patient`s perspective is therefore important to consider when treatment and treatment outcomes of POP are determined [8].

The Prolapse Quality of Life Questionnaire (P-QOL) is one of only a few validated and reliable condition-specific questionnaires developed to assess the impact of urogenital prolapse on the quality of life in patients. The questionnaire covers various domains of life which include general health, prolapse impact, role limitations, physical limitations, social limitations, personal relationships, emotional problems, sleep/energy disturbances and prolapse severity [9].

The P-QOL has been successfully translated into eight languages, which include versions in Italian [5], Turkish [10], German [11], Portuguese [12], Dutch [2], Thai [8], and most recently Persian [13]. The lack of a validated prolapse quality of life questionnaire in Afrikaans limits studies and effective outcome measurement in Afrikaans speaking patients, which is the second most spoken language in South Africa [15]. The second problem is that the P-QoL was originally developed for a European population which might raise the question as to the validity in a multi-cultural, and mostly Afrikaans speaking population, as in South Africa.

The purpose of the study was therefore to validate the P-QOL in an Afrikaans-speaking South-African population.

METHODS

The observational, descriptive study was approved by the Ethics Committee of the Faculty of Health Sciences of the University of the Free State, South Africa. Written consent and permission was obtained from the participants and institutions where the study was conducted.

Translation of the P-QOL

The original English P-QOL questionnaire was translated to Afrikaans by an independent medical translator. The translated Afrikaans version (Appendix) was reviewed and translated back to English by three independent uro-gynaecologists. The uro-gynaecologists agreed that the original content was retained and that no ambiguity was present. No changes were made in the translated version.

Pilot study

The translation was followed by a pilot study (n=5) to confirm the readability and participants` comprehension of the questions. These participants were asked to complete the questionnaire and then interviewed by the researchers. No problems were identified and no changes were made to the translated Afrikaans version of the P-QOL. The same methodological procedures were followed as described for the main study in the following sections.

Sampling

A convenience sample was used, consisting of 40 women meeting the inclusion criteria (Table 1). The eligibility criteria was aligned with the validated versions of the P-QOL, and applied to the demographics of a South African population (Table 1).

Procedures

The eligible participants had to complete an informed consent document, a P-QOL questionnaire and a demographic data form after the study procedures were explained to them by the researchers. The same uro-gynaecologist determined the POP-Q score for all participants according to clinical and ultrasonography findings. The completed questionnaires and forms were checked by the researchers to ensure that all the information was gathered.

Following consultation each participant was given a second blank P-QOL questionnaire in an addressed envelope, to complete and mail back after two weeks in order to determine the stability of the questionnaire by a test-retest analysis. The date on which the questionnaire had to be completed was indicated by a note on the envelope. Reminders were sent to all participants to complete the second questionnaire.

Data analysis

Statistical analyses software was used for statistical analysis. The two questionnaires` construct validity was determined by assessing the domain scores of symptomatic and asymptomatic participants, and then comparing it to the POP-Q score to determine criterion validity be means of percentages. The test-retest method was used to indicate stability of the P-QoL, the kappa value to calculate the measure of agreement, and the Cronbach alpha to measure the internal consistency.

Descriptive statistics were used to explain the demographic data. Medians and percentiles were calculated for continuous data, and frequencies and percentages were calculated to describe categorical data.

RESULTS

A total of 40 women were enrolled into the study. Twenty five women (64.1%, *n*=39) were symptomatic and fourteen women (35.9%, *n*=39) were asymptomatic, with one data form incomplete with regards to the POP-Q score. Table 2 shows a summary of the demographic and clinical characteristics of symptomatic and asymptomatic participants.

Construct validity was determined by assessing the domain scores of symptomatic and asymptomatic participants, and then comparing it to the POP-Q findings to determine criterion validity. The P-QOL domain scores of symptomatic participants were mostly higher compared to asymptomatic participants, indicating a poorer quality of life (Table 3). Fourteen (35.9%) asymptomatic participants were classified as stage 0 on the POP-Q system and 64.10% of the symptomatic participants (n=25) had pelvic organ prolapse, ranging from stage II to IV. All asymptomatic participants (100%, n=14) were a stage O on the POP-Q system and the majority of the symptomatic participants (33.33%, n=13) were a stage III.

Stability was measured by means of the test-retest method to determine the consistency of the responses by participants (response rate = 65%, n=40). All the reliability percentages were above 50% (Graph 1). According to the interpretation of Birkimer and Brown [16], the median percentage of 69.2%, the sample size of 40, and the number of disagreements equalling less than three, indicates a non-chance agreement.

The measure of agreement between specific questions was determined by means of calculating the kappa value (Graph 2). The lowest kappa value was 0.12 for question 38, indicating poor strength in agreement. The highest kappa value was 0.65 for question 29, indicating good strength in agreement (ķ range 0.61-0.80). Four of the question's strength of agreement was fair (ķ range 0.21-0.40), eleven was moderate (ķ range 0.41-0.60) and two were good (ķ range 0.61-0.80) . The majority of questions, thirteen of twenty, therefore had a moderate to good strength of agreement.

The internal consistency was determined by means of the rhe Cronbach alpha. A Cronbach alpha > 0.7 is interpreted as acceptable. Table 4 shows that assessment one and two had a mean Cronbach alpha score of 0.94, indicating very high reliability.

DISCUSSION

Approximately half of the population in South Africa is female and mostly Afrikaans speaking [14], while POP can occur in up to three-quarters of this female population [1]. Pelvic floor disorders have been described as mainly being a quality of life disorder [16]. The subjective improvement and improvement in quality of life is one of the main goals of management of patients with POP (pre- and/or post-operatively) and needs to be clinically evaluated by means of a valid outcome measure [6,16].

This study determined validity and reliability aspects of an Afrikaans version of the P-QoL in a mainly Afrikaans speaking province in South Africa. Content validity was determined in a similar way as described by previous validation studies of the P-QoL [5]. The content was found to be valid after review by a medical translator, panel of experts and pilot study.

The construct validity was indicated by the median domain scores of the symptomatic patients being higher than the asymptomatic patients` scores, except for `general health perceptions` and `prolapse impact` scores. The results correlate with the findings of other validation studies which indicated statistical significant differences between the scores of symptomatic and asymptomatic patients. Lenz et al. [11] and De Oliveira et al. [12] also found the domain scores of `general health perceptions` to be similar for both groups, due to the fact that it consists of only one question and can be affected by symptoms or diseases not related to POP. A finding significant to this study was the lack in differences in scores relating to `prolapse impact`. The difference in the sample size for which each of these medians were calculated, may affect the interpretation of these results. Another possibility might be that POP is multi-factorial and can include an interaction and co-existence of several pelvic floor disorders affecting the experience of symptoms in even the minor (`asymptomatic`) stages of POP [2].

Lower domain scores also showed a relationship with less severe stages of POP, as assessed by the POP-Q system, indicating good criterion validity similar to the findings of previous studies.

The methods used in this study to calculate construct and criterion validity respectively, differed from most other studies which used the Mann-Whitney U test and the Spearman`s rho correlation respectively. This difference in methodology limits specific comparison of some of the validity findings of this study to those of the previous studies, though the conclusive findings were similar. The use of different statistical methods, all finding the same results, can however be seen as a strength to substantiate the findings from different validation studies.

Reliability measures correlate with previous findings on translated versions of the P-QoL [2,5,8,10,12,13]. Stability measures in this study indicated a non-chance agreement with the test-retest method, while the kappa value indicated moderate to good strength of agreement between questions, for the majority of the questions. A very high internal consistency was indicated by a mean Cronbach alpha of 0.94 during the first and second assessments.

Unfortunately the response rate for the second assessment was low due to poor compliance of the patients, even though patients were reminded of completing and sending back their questionnaires. Despite this limitation, a statistical analysis was still possible for this relatively small population from which the sample was drawn.

CONCLUSION

This study found the translated Afrikaans version of the P-QoL to have good content, construct and criterion validity, as well as very high stability, strength of agreement, and internal consistency. This correlates with the validity and reliability of other translated versions of the P-QoL, supporting the evidence that the P-QoL is a high quality disease-specific quality of life questionnaire. It can be recommended that the P-QoL be translated into other African languages, and especially to determine content validity in the different African cultures.

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ADDENDUM 16

THE VISUAL FACES SCALE

For office use

1

2-4

5-10

ASSESSMENT ____

Participant number:__________

Date:___/___/___ (dd/mm/yy)

Please indicate the intensity of your **PELVIC** pain (as you experience it today) by circling the number opposite to the face and explanation that best describes your pain.

11

WORST PAIN	5
VERY SEVERE PAIN	4
SEVERE PAIN	3
MODERATE PAIN	2
MILD PAIN	1
NO PAIN	0

Please indicate the intensity of your **LOW BACK** pain (as you experience it today) by circling the number opposite to the face and explanation that best describes your pain.

12

WORST PAIN	5
VERY SEVERE PAIN	4
SEVERE PAIN	3
MODERATE PAIN	2
MILD PAIN	1
NO PAIN	0

Vir kantoorgebruik

EVALUERING ____

1

Deelnemer nommer:____________

2-4

Datum:___/___/___ (dd/mm/jj)

5-10

Dui asseblief die intensiteit van u **PELVIESE** pyn aan (soos u dit vandag ervaar) deur die toepaslike nommer teenoor die gesiggie en verduideliking te omkring wat u pyn die beste beskryf.

11

ERGSTE PYN — 5

BAIE ERGE PYN — 4

ERGE PYN — 3

MATIGE PYN — 2

LIGTE PYN — 1

GEEN PYN — 0

Dui asseblief die intensiteit van u **LAE RUG** pyn aan (soos u dit vandag ervaar) deur die toepaslike nommer teenoor die gesiggie en verduideliking te omkring wat u pyn die beste beskryf.

12

ERGSTE PYN — 5

BAIE ERGE PYN — 4

ERGE PYN — 3

MATIGE PYN — 2

LIGTE PYN — 1

GEEN PYN — 0

ADDENDUM 17

THE COCHRANE COLLABORATION TOOL FOR ASSESSING RISK OF BIAS WITHIN A STUDY – CRITERIA FOR SCORING

The Cochrane Collaboration's tool for assessing risk of bias

Domain	Description	Review authors' judgement
Sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Was the allocation sequence adequately generated?
Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	Was allocation adequately concealed?
Blinding of participants, personnel and outcome assessors *Assessments should be made for each main outcome (or class of outcomes)*	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Was knowledge of the allocated intervention adequately prevented during the study?
Incomplete outcome data *Assessments should be made for each main outcome (or class of outcomes)*	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Were incomplete outcome data adequately addressed?
Selective outcome reporting	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Are reports of the study free of suggestion of selective outcome reporting?
Other sources of bias	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry.	Was the study apparently free of other problems that could put it at a high risk of bias?

Possible approach for *summary assessments* outcome (across domains) within and across studies

Risk of bias	Interpretation	Within a study	Across studies
Low risk of bias	Plausible bias unlikely to seriously alter the results.	Low risk of bias for all key domains.	Most information is from studies at low risk of bias.
Unclear risk of bias	Plausible bias that raises some doubt about the results	Unclear risk of bias for one or more key domains.	Most information is from studies at low or unclear risk of bias.
High risk of bias	Plausible bias that seriously weakens confidence in the results.	High risk of bias for one or more key domains.	The proportion of information from studies at high risk of bias is sufficient to affect the interpretation of the results.

Criteria for judging risk of bias in the 'Risk of bias' assessment tool

SEQUENCE GENERATION **Was the allocation sequence adequately generated? [Short form: *Adequate sequence generation*?]**	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	The investigators describe a random component in the sequence generation process such as: ▪ Referring to a random number table; Using a computer random number generator; Coin tossing; Shuffling cards or envelopes; Throwing dice; Drawing of lots; Minimization*. *Minimization may be implemented without a random element, and this is considered to be equivalent to being random.
Criteria for the judgement of 'NO' (i.e. high risk of bias).	The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: ▪ Sequence generated by odd or even date of birth; ▪ Sequence generated by some rule based on date (or day) of admission; ▪ Sequence generated by some rule based on hospital or clinic record number. Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example: ▪ Allocation by judgement of the clinician; ▪ Allocation by preference of the participant; ▪ Allocation based on the results of a laboratory test or a series of tests; ▪ Allocation by availability of the intervention.
Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	Insufficient information about the sequence generation process to permit judgement of 'Yes' or 'No'.
ALLOCATION CONCEALMENT **Was allocation adequately concealed? [Short form: *Allocation concealment*?]**	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: ▪ Central allocation (including telephone, web-based, and pharmacy-controlled, randomization); ▪ Sequentially numbered drug containers of identical appearance; ▪ Sequentially numbered, opaque, sealed envelopes.
Criteria for the judgement of 'NO' (i.e. high risk of bias).	Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: ▪ Using an open random allocation schedule (e.g. a list of random numbers); ▪ Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); ▪ Alternation or rotation; ▪ Date of birth; ▪ Case record number; ▪ Any other explicitly unconcealed procedure.

Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	Insufficient information to permit judgement of 'Yes' or 'No'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.
BLINDING OF PARTICIPANTS, PERSONNEL AND OUTCOME ASSESSORS **Was knowledge of the allocated interventions adequately prevented during the study? [Short form: *Blinding*?]**	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	Any one of the following: ▪ No blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding; ▪ Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken; ▪ Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.
Criteria for the judgement of 'NO' (i.e. high risk of bias).	Any one of the following: ▪ No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding; ▪ Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken; ▪ Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.
Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	Any one of the following: ▪ Insufficient information to permit judgement of 'Yes' or 'No'; ▪ The study did not address this outcome.
INCOMPLETE OUTCOME DATA **Were incomplete outcome data adequately addressed? [Short form: *Incomplete outcome data addressed*?]**	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	Any one of the following: ▪ No missing outcome data; ▪ Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); ▪ Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; ▪ For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; ▪ For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; ▪ Missing data have been imputed using appropriate methods.
Criteria for the judgement of 'NO' (i.e. high risk of bias).	Any one of the following: ▪ Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; ▪ For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; ▪ For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; ▪ 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization; ▪ Potentially inappropriate application of simple imputation.

Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	Any one of the following: ▪ Insufficient reporting of attrition/exclusions to permit judgement of 'Yes' or 'No' (e.g. number randomized not stated, no reasons for missing data provided); ▪ The study did not address this outcome.
SELECTIVE OUTCOME REPORTING **Are reports of the study free of suggestion of selective outcome reporting? [Short form: *Free of selective reporting*?]**	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	Any of the following: ▪ The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; ▪ The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for the judgement of 'NO' (i.e. high risk of bias).	Any one of the following: ▪ Not all of the study's pre-specified primary outcomes have been reported; ▪ One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; ▪ One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); ▪ One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; ▪ The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	Insufficient information to permit judgement of 'Yes' or 'No'. It is likely that the majority of studies will fall into this category.
OTHER POTENTIAL THREATS TO VALIDITY **Was the study apparently free of other problems that could put it at a risk of bias? [Short form: *Free of other bias*?]**	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	The study appears to be free of other sources of bias.
Criteria for the judgement of 'NO' (i.e. high risk of bias).	There is at least one important risk of bias. For example, the study: ▪ Had a potential source of bias related to the specific study design used; or ▪ Stopped early due to some data-dependent process (including a formal-stopping rule); or ▪ Had extreme baseline imbalance; or ▪ Has been claimed to have been fraudulent; or ▪ Had some other problem.
Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	There may be a risk of bias, but there is either: ▪ Insufficient information to assess whether an important risk of bias exists; or ▪ Insufficient rationale or evidence that an identified problem will introduce bias.