

The construction and validation of a health-related quality of life measure for women with endometriosis

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DECLARATION

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ABSTRACT

The purpose of this study was to construct and validate a health-related quality of life (HRQOL) measure for patients with endometriosis. The study employed an exploratory, sequential mixed methods research design, consisting of a qualitative phase, followed by a quantitative phase. The study consisted of three aims.

The first aim was to describe and understand the QOL-related experiences of women with endometriosis. This qualitative phase of the study involved in-depth, semi-structured interviews with 25 women diagnosed with endometriosis. I recorded and transcribed the interviews. I used thematic analysis to code the data and identify themes. Eleven themes emerged from the data, namely psychological functioning, sexual functioning, financial impact and considerations, healthcare and medical treatment, reproductive functioning, information and knowledge, interpersonal functioning, menstrual characteristics, occupational functioning, somatic features and physical functioning.

The second aim of the study was to construct items for the instrument based on data collected during the first phase. The initial item pool consisted of 314 items. I then consulted with two experts in psychometry, who provided feedback relating to the clarity, conciseness, wording and ambiguity of items. This process resulted a reduced pool of 184 items.

I asked five endometriosis experts to review the items in terms of relevance. Items that the experts regarded as highly relevant were retained in the measure and items that were not regarded as highly relevant were removed from the measure. The review resulted in the retention of 64 items. I piloted these items among seven women with endometriosis in order to assess the readability of the items.

The final aim of the study was to determine the test reliability, validity and factor structure of the measure. This formed the quantitative component of the study. I administered the 64-item HRQOL measure, Endometriosis Health Profile 30, Short Form Health Survey,

World Health Organization Quality of Life Brief scale and the Beck Depression Inventory to 203 patients with endometriosis. I conducted an item analysis and removed 16 items that displayed corrected item total correlations below .35. I then conducted an exploratory factor analysis (EFA) on the remaining 48 in order to establish the factor structure of the measure. The factor analysis identified thirteen items that either cross-loaded on more than one factor or that did not significantly load on any factor. These items were removed. The remaining 35 items produced an eight-dimension factor structure. A second EFA produced the same factor structure. I named the measure the Stellenbosch Endometriosis Quality of life (SEQOL) measure and named the dimensions as follows: (1) Psychological well-being; (2) Income; (3) Sexual functioning and romantic relationships; (4) Reproductive functioning; (5) Vitality; (6) Occupational functioning; (7) Menstrual characteristics and (8) Support.

The SEQOL and its subscales demonstrated excellent internal consistency reliability. The SEQOL produced a Cronbach's α of .92 and the Cronbach's α for the subscales ranged from .72 to .88. Correlations between scores on SEQOL, its subscales and other measures indicated promising validity. The initial validation indicates that the SEQOL may be a useful assessment of HRQOL in women with endometriosis, both in research and clinical practice.

OPSOMMING

Die doel van hierdie studie was om 'n meetinstrument saam te stel om die gesondheidsverwante lewensgehalte (GVLG) van pasiënte met endometriose te meet. Die studie het gebruik gemaak van 'n ondersoekende, sekwensiële gemengde metode-ontwerp bestaande uit 'n kwalitatiewe fase, gevolg deur 'n kwantitatiewe fase. Die studie het drie doelstellings nagestreef.

Die eerste doelstelling was om die KVL-verwante ervaringe van vroue met endometriose te beskryf en te verstaan. Hierdie kwalitatiewe fase van die studie het in-diepte, semigestruktureerde onderhoude met 25 vroue wat gediagnoseer is met endometriose behels. Ek het die onderhoude opgeneem en getranskribeer. Ek het tematiese analise gebruik om die data te kodeer en temas te identifiseer. Ek het elf temas uit die data geïdentifiseer, naamlik sielkundige funksionering, seksuele funksionering, finansiële gevolge en oorwegings, gesondheidsorg en mediese behandeling, reprodktiewe funksionering, inligting en kennis, interpersoonlike funksionering, menstruele eienskappe, werksverwante funksionering, somatiese kenmerke en fisiese funksionering.

Die tweede doelstelling van die studie was om items vir die meetinstrument te identifiseer op grond van die data wat gedurende die eerste fase ingesamel is. Ek het 'n aanvanklike kombinasie van items saamgestel bestaande uit 314 items. Ek het daarna twee kenners in psigometrie geraadpleeg en hulle het terugvoer verskaf rakende die duidelikheid, bondigheid, bewoording en dubbelsinnigheid van items. Die proses het uitgeloop op 184 items.

Ek het vyf endometriose-kenners gevra om die items te hersien met betrekking tot relevansie. Die items wat die kenners beskou het as hoogs relevant is behou as deel van die meetinstrument en items wat nie beskou is as hoogs relevant nie, is verwyder. Dit het die

behoud van 64 items tot gevolg gehad. Hierdie items is getoets tydens 'n toetsopname onder sewe vroue met endometriose om die leesbaarheid van die items te toets.

Die finale doelstelling van die studie was om die toetsbetroubaarheid, geldigheid en faktorstruktuur van die meetinstrument te bepaal en te toets. Dit het die kwantitatiewe komponent van die studie uitgemaak. Ek het die 64-item GVLG meetinstrument, die EHP 30, die SF12v2, die WHOQOL Bref en die BDI by 203 pasiënte met endometriose afgeneem. Ek het 'n item-analise gedoen en 16 items wat gekorrigeerde itemtotaal-korrelasies onder .35 vertoon het uitgehaal. Daarna het ek 'n ondersoekende faktoranalise (OFA) gedoen van die oorblywende 48 om die faktorstruktuur van die meetinstrument vas te stel. Die faktoranalise het dertien items uitgewys wat hetsy met meer as een ander faktor oorkruis gelaai het, of wat nie beduidend gelaai het op enige faktor nie. Hierdie items is verwyder. Die oorblywende 35 items het 'n agt-dimensie faktorstruktuur gelewer. 'n Tweede OFA het dieselfde faktorstruktuur gelewer. Ek het die meetinstrument die Stellenbosch Endometriose Lewensgehalte (SELG) genoem en die dimensies soos volg benoem: Psigologiese welstand; (2) Inkomste; (3) Seksuele funksionering en romantiese verhoudings; (4) Reproductiewe funksionering; (5) Vitaliteit; (6) Werksverwante funksionering; (7) Menstruele eienskappe; en (8) Ondersteuning.

Die SELG en sy subskale het uitstekende interne internekonsekwentheid getoon. Die SELG het 'n Cronbach α van .92 gelewer en die Cronbach α vir die subskale het gewissel van .72 tot .88. Korrelasies tussen tellings op SELG, sy subskale en ander meetinstrumente het belowende geldigheid getoon. Die aanvanklike geldigheid het aangedui dat die SELG 'n bruikbare meting van GVLV in vroue met endometriose kan wees in beide navorsingkontekste en kliniese praktyk.

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GLOSSARY OF MEDICAL TERMS

Bilateral salpingo-oophorectomy	Hysterectomy involving removal of the uterus and ovaries
Bowel resection	Surgery to remove part of the bowel
Danazol	Synthetic steroid used to treat endometriosis
Deep-infiltrating endometriosis	Endometriosis that is not located in superficial tissue
Dienogest	Steroid progestin used to treat endometriosis
Dysmenorrhoea	Painful menstruation
Dyspareunia	Painful sexual intercourse
Endometrioma	Blood-filled ovarian cyst
Endometriosis	Presence of endometrial tissue outside the womb
Excision	Specialised surgical removal of endometriosis
Laparoscopy	Surgical procedure used to diagnose and treat various diseases in which a laparoscope (telescope-like instrument) is inserted into the abdomen through a small incision
Menorrhagia	Heavy menstrual bleeding
Nulliparity	Not bearing offspring
Uterosacral ligament	A major ligament attached to the uterus that contains a significant amount of nerve tissue

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Chapter 1

Introduction

1.1 Background

Doctors have traditionally evaluated chronic diseases by using physiological measurements that assess organ functioning and measure the extent of the disease. However, these measurements correlate poorly with functional capacity and patients' subjective well-being (Guyatt, Feeny, & Patrick, 1993). There is increasing recognition of the fact that approaching chronic illness using only a biomedical framework is insufficient and thus the focus has subsequently shifted to improving quality of life (QOL) in patients living with a chronic illness (Singh & Dixit, 2010).

Quality of life is a multidimensional concept, consisting of dimensions such as family support, financial resources, access to health and social services. Health-related quality of life (HRQOL) deals specifically with psychological, social and physical aspects during and following treatment (Greer, 1984; Han, Lee, Lee, & Park, 2003) and is concerned with the impact that health, illness and treatment have on an individual's well-being (Bullinger, Anderson, Cella, & Aaronson, 1993; Bullinger, 2002; Padilla, Grant, Ferrell, & Presant, 1996). The concept of QOL has gained recognition as an important factor to consider when evaluating medical therapies, especially therapies aimed at pain management (Katz, 2002). This recognition is due to the biomedical perspective viewing health interventions as solely providing cures for diseases and not taking into account patients' own psychological perspectives (Singh & Dixit, 2010). Conceptualising chronic illness within the context of health-functioning, spiritual well-being, psychological well-being, economic status and societal roles allows practitioners to gain insight into background factors that contribute to QOL for patients with chronic illness (Schirm, 2009).

1.2 Health-related quality of life and chronic illness

Multiple social, psychological and health-related factors are associated with QOL in chronically ill patients (Han et al., 2003). HRQOL has been investigated in chronic illness such as heart disease (Vigl et al., 2011), HIV (Peltzer & Phaswana-Mafuya, 2008), arthritis (Khanna et al., 2011; Tomasevic-Todorovic et al., 2011) and endometriosis (Marques, Bahamondes, Aldrighi, & Petta, 2004; Nnoaham et al., 2011; Petrelluzzi, Garcia, Petta, Grassi-Kassisse, & Spadari-Bratfish, 2008; Siedentopf, Tariverdian, Rücke, Kentenich, & Arck, 2008). These studies assessed HRQOL among persons living with specific chronic disorders such as HIV (Peltzer & Phaswana-Mafuya, 2008) and arthritis (Tomasevic-Todorovic et al., 2011) or compared HRQOL in people with a specific chronic illness and the general population (Khanna et al., 2011).

1.2.1 Measuring health-related quality of life.

The interest in investigating HRQOL among patients living with a chronic illness has led to the development of various assessment measures. HRQOL has been studied by psychologists for many years and remains a major topic in health psychology. Scale development is an activity unique to psychology and these scales play a role in gathering research data (Foxcroft & Roodt, 2005).

HRQOL measures aim to differentiate between people with better or worse HRQOL or to determine a change in a person's HRQOL (Guyatt et al., 1993). HRQOL instruments can therefore play a role in decision-making with regard to patient treatment. According to Schirm (2009), HRQOL instruments can be used to examine the appropriateness of treatments and provide an indicator of progress towards achieving treatment goals and responses to therapy. These instruments can also be used to evaluate the specific problems and needs of patients and to gauge the extent to which patients' needs in terms of service delivery are being met (Schirm, 2009).

HRQOL instruments are classified as generic or disease specific. Generic scales are useful for investigating the effect of a wide variety of diseases on quality of life, whereas disease-specific scales focus on the effects of a specific disease on QOL. Generic scales are valuable to researchers as they allow comparison among patients with different diseases and conditions in terms of QOL (Bowling, 2001). However, their shortcoming is that they are unable to detect specific health-related concerns that are unique to particular diseases. Disease-specific scales therefore play an important role in monitoring the effect of treatment of specific illnesses as they may be more clinically and socially significant and may be more sensitive to changes in health status than generic scales (Bowling, 2001; Jones, Jenkinson, & Kennedy, 2004a). Examples of generic HRQOL instruments include the World Health Organization Quality of Life short form (WHOQOL-Bref), the Research and Development Corporation's (RAND) 36-item health survey (SF-36) and the Functional Assessment of Non-Life Threatening Conditions (FANLTC).

HRQOL instruments therefore play a role in assessing the impact of various chronic illnesses on patients' lives. These instruments are particularly useful in tracking the progression of diseases that lack biomedical markers as indicators. Endometriosis is a chronic illness for which no biomedical markers have been conclusively identified to track disease progression (Barlow & Kennedy, 2005; Galazis, Athanasias, & Pisal, 2014) and medical professionals rely on HRQOL instruments for this purpose.

1.3 Endometriosis

Endometriosis is marked by the presence of tissue that usually only lines the uterus, in other regions of a woman's body, including the pelvic organs such as the ovaries, colon and bladder, and in extreme cases the lungs or brain. It is associated with fatigue, lethargy, chronic pain, insomnia and depression (Huntington & Gilmour, 2005; Lorençatto, Petta, Navarro, Bahamondes, & Matos, 2006). Endometriosis can result in severe and in some cases

debilitating pain that can impact all spheres of a woman's life and lead to social dysfunction (Peveler, Edwards, Daddow, & Thomas, 1996). A multi-disciplinary approach that includes psychological support has therefore been recommended (Giudice, 2010). Doctors have also endeavoured to establish global consensus regarding the management of endometriosis in patients (Johnson & Hummelshoj, 2013).

1.3.1 Prevalence.

Endometriosis affects 10-15% of women of reproductive age (Denny & Mann, 2007). Adamson, Kennedy and Hummelshoj (2010) estimate that 176 million women worldwide may be living with endometriosis. As much as 47% of women experiencing infertility have endometriosis (Meuleman, d'Hoore, van Cleynenbreugel, Beks, & d'Hooge, 2009). The true prevalence of endometriosis in African countries is unknown as the disease may be under-reported and diagnosis not readily available due to the need for specialist knowledge and a laparoscopy (Kyama et al., 2007).

1.3.2 Symptoms and disease stages.

The primary symptom indicating endometriosis is chronic pelvic pain. In most cases pain is cyclical and patients experience periods of pain and relief based on their menstrual cycle (Denny, 2004a). Other symptoms leading to diagnosis include dysmenorrhoea (painful periods), sub-fertility, ovarian cysts and dyspareunia (painful sexual intercourse) (Mao & Anastasi, 2010; Sinaii et al., 2008). Women with endometriosis also experience nausea, diarrhoea, constipation, abdominal bloating, vomiting, fever, menorrhagia (heavy menstrual bleeding) and headaches (Jackson & Telner, 2006; Mao & Anastasi, 2010). While these are regarded classic symptoms of endometriosis, the combination of symptoms and severity are highly variable in individual cases (Fraser, 2008). Although the disease has been linked to infertility, findings on the extent of the relationship between endometriosis and fertility have

been largely inconclusive. Some studies have shown that fertility decreases with disease severity (Ventolini, Horowitz, & Long, 2005), whereas others found no association between these variables (Hassa, Tanir, & Uray, 2005).

According to Denny (2004b), endometrial tissue bleeds in response to ovarian stimulation, forming scar tissue (lesions), adhesions and ovarian cysts, resulting in pain. Endometriosis presents as lesions, adhesions, nodules and ovarian cysts known as endometriomas (Kennedy et al., 2005; Mao & Anastasi, 2010). Lesions may vary from small and superficial and appearing as a powder-burn, to darker raised spots, red implants, clear vesicles, white plaques or scarring or a yellow-brown discolouration on otherwise normal pelvic organs (Kennedy et al., 2005; Mao & Anastasi, 2010). Adhesions may cause pelvic organs to adhere and become distorted. Endometriomas are ovarian cysts that contain a thick tar-like fluid (Kennedy et al., 2005).

The American Society for Reproductive Medicine (ASRM) has proposed a classification system for the disease (ASRM, 1997). It consists of a scoring system for endometrial implants, adhesions and endometriomas based on size, number and location. A score of 1-5 indicates stage I (minimal) endometriosis. Stage II (mild endometriosis) is diagnosed when a score ranges between 6 and 15, whereas stage III (moderate) endometriosis is diagnosed when scores range between 16 and 40 points. A score above 40 indicates stage IV (severe) endometriosis (ASRM, 1997).

1.3.3 Pathogenesis.

The aetiology of endometriosis is presently unknown, although several theories have been postulated about the origin of this disease (Giudice & Kao, 2004; Donnez, 2012). While these theories may account for some cases of endometriosis, no theory can fully account for all presentations of the disease (Laufner, Sanfilippo, & Rose, 2003).

The most widely-accepted theory is known as transplant theory or retrograde menstruation. Retrograde menstruation is the process during which the endometrium (lining of the uterus) flows back into the abdomen, instead of leaving the body as menstruation. According to this theory, retrograde menstruation may cause the endometrial tissue to be implanted in the peritoneum (membrane that lines the abdominal cavity) (Farquhar, 2007; Fraser, 2008; Siedentopf et al., 2008). Transplant theory or retrograde menstruation may explain how the endometrial cells are placed at sites in the abdomen. Retrograde menstruation occurs in 76-90% of all women, yet the much lower prevalence of endometriosis among women of reproductive age indicates that additional factors play a role in the development of this disease (Seli, Berkkanoglu, & Arici, 2003).

A second theory is metaplasia theory, which states that pluripotent coelomic cells (stem cells) differentiate into endometrial cells (Siedentopf, et al., 2008). Vascular and lymphatic systems may also play a role in proliferation of endometrial tissue (Jackson & Telner, 2006; Laufner et al., 2003; Mounsey, Wilgus, & Slawsom, 2006). Metaplasia theory may account for these cells growing in areas outside the abdominal cavity, such as the lungs and brain.

In addition to these theories, a number of factors such as genetics, immunity and hormones have been linked to endometriosis (Crosignani, Olive, Bergqvist, & Luciano, 2006; Hompes & Mijatovic, 2007; Laufner et al., 2003; Saha et al., 2015). The higher prevalence rates of endometriosis among first-degree relatives and twins than control groups indicate the presence of a genetic component (Barlow & Kennedy, 2005; Dalsgaard, Hjor dt-Hansen, Hartwell & Lidegaard, 2013; Hompes & Mijatovic, 2007; Treolar, O'Connor, O'Connor, & Martin, 1999). However, the specific genes implicated have not been identified (Fraser, 2008). Agents related to immunity have also been associated with endometriosis. Women with endometriosis have more peritoneal fluid and therefore more peritoneal macrophages

(white blood cells) than women without endometriosis (Donnez, 2012; Gazvani, & Templeton, 2002). These macrophages release cytokines (immunomodulating agents), prostaglandins, and interleukins (multifunctional cytokines) into the peritoneum and high levels of these substances have been associated with the disease (Child & Tan, 2001; Gazvani & Templeton, 2002). Hormones such as oestrogen (oestradiol and progesterone) play a role in the maintenance of endometriosis (Gazvani & Templeton, 2002). Recently, Canis et al. (2015) hypothesized that trauma, such as vaginal birth and caesarean sections, may trigger endometriosis, but further research is required to explore this claim.

1.3.4 Diagnosis of endometriosis.

Definitive diagnosis can only be made upon laparoscopic investigation (Denny, 2004b; Farquhar, 2007). A laparoscopy is a surgical procedure used to diagnose and treat various diseases in which a laparoscope (telescope-like instrument) is inserted into the abdomen through a small incision. This option may not be readily available to many women, especially those seeking medical treatment in the public health sector, mainly due to the costs associated with it (Prentice, 2001). The true prevalence of this disease is consequently difficult to assess precisely (Dancet et al., 2011). Research is underway to develop non-surgical methods to diagnose endometriosis. This research explores the possibility of using biomedical markers, imaging techniques and questionnaires (Moragianni, 2012).

Endometriosis is seldom diagnosed early in the disease process, as the symptoms are often trivialized and normalized (Cox, Henderson, Andersen, Cagliarini, & Ski, 2003; Denny, 2004a). Women with endometriosis reported that friends and family members downplayed the pain they experienced as normal and as something that simply had to be endured (Cox, Henderson, Andersen et al., 2003; Denny, 2004b). Doctors frequently prescribed oral contraceptives and told patients that the pain is normal and part of the physiological process of menstruation, denying that there is anything medically wrong with them (Denny, 2004b).

Women with endometriosis also reported feeling as though they were over-reacting or not taken seriously or as if doctors refused to provide referrals or offer any further investigation into the sources of pain they experienced (Cox, Henderson, Andersen et al., 2003a). These factors may contribute to diagnostic delay. The mean length of time between the onset of symptom-related pain and diagnosis via laparoscopy is eight years in the United Kingdom (UK) and 12 years in the United States of America (Hadfield, Mardon, Barlow, & Kennedy, 1996). Norway reports a similar diagnostic delay of 6.7 years (Husby, Haugen, & Moen, 2003).

Researchers have attempted to identify the factors associated with a positive diagnosis of endometriosis in order to make decisions regarding the urgency to operate. Calhaz-Jorge, Mol, Nunes, and Costa (2004) found that dysmenorrhea, chronic pelvic pain, primary sub-fertility, regularity of menstrual cycles, smoking and the use of contraceptives predicted the presence of endometriosis. This finding led these researchers to assert that medical histories of patients can be used to predict the presence of endometriosis and to decide on the urgency of laparoscopic surgery to diagnose endometriosis. However, this assertion should be interpreted with caution, as predictors may be able to identify those at risk, but cannot yield conclusive diagnosis.

1.3.5 Treatment of endometriosis.

Several treatment options are available for endometriosis, yet they remain controversial (Donnez, 2012). A few levels of treatment are available to women with endometriosis. These include oral contraceptives, non-steroidal anti-inflammatory drugs, synthetic androgens and gonadotrophin-releasing hormone analogues and conservative surgery (Brown & Farquhar, 2015).

The first level is oral contraception, which aims to prevent ovulation and may be used to suppress menstrual periods, and non-steroidal anti-inflammatory drugs (Laufner et al.,

2003). The second level is the use of synthetic androgens and gonadotrophin-releasing hormone (GnRH) analogues. Synthetic androgens such as Danazol are used, but produce side-effects such as acne, weight gain and hirsutism. GnRH analogues are another second level form of treatment that works by inducing the symptoms of menopause (Lessey, 2000). These treatments are short-term (6-9 months) and have a reported recurrence rate of 50% in the 12-24 months after termination of treatment (Farquhar, 2007; Jackson & Telner, 2006). The third level involves patients undergoing conservative surgery to remove endometrial tissue and adhesions. More aggressive surgery may involve a hysterectomy and even this may have limited effectiveness in overcoming the symptoms associated with the disease. Radical surgical excision is now regarded as the most effective means of treating endometriosis and it results in reduced expression of symptoms, improved HRQOL and improved psychological functioning in patients with deep infiltrating endometriosis (Fritzer, Tammaa, Salzer, & Hudelist, 2012). However, there are very few doctors who are experienced in providing this radical surgery. The European Society of Human Reproduction and Embryology (ESHRE) developed guidelines for the management of endometriosis (Dunselman et al., 2014). The guidelines consist of 83 recommendations that deal with areas such as diagnosis, pain management, infertility and more.

In addition to these allopathic approaches to endometriosis, alternative treatments such as Chinese herbs and acupuncture as well as dietary changes have been proposed for symptom alleviation (Flower, Liu, Chen, Lewith, & Little, 2009; Highfield et al., 2006; Lundeberg & Lund, 2008). Empirical evidence for these interventions is emerging. A Cochrane review of randomized controlled trials relating to the use of Chinese herbal medicine in the treatment of endometriosis was conducted (Flower et al., 2009). Even though 196 studies relating to Chinese herbal medicine as a form of treatment of endometriosis were found, all but two were excluded from the review as they did not meet the methodological

requirements deemed necessary for a Cochrane review. Of these studies only one demonstrated statistically significant benefits for the use of Chinese herbal medicine in treating symptoms of endometriosis. Fifty-eight participants were assigned to one of three groups. The first group received Chinese herbal medicine endometriosis pills, the second group received Chinese herbal medicine endometriosis pills and enemas and the third group received Danazol. Patients in groups that received Chinese herbal medicine endometriosis pills and Chinese herbal medicine endometriosis pills in combination with Chinese herbal medicine enema experienced greater symptomatic relief than patients treated with Danazol (RR 5.06, 95%CI 1.28 to 20.05; RR 5.63, 95%CI 1.47 to 21.54, respectively). However, the large confidence intervals bring into question the reliability of the study. Fewer patients in the Chinese herbal medicine groups reported side-effects such as acne and weight gain than patients in the Danazol group (Flower et al., 2009). More recently, physical therapy has been recommended to patients with pelvic pain and pelvic floor dysfunction in order to improve QOL and decrease pain (Sarrel, 2013).

1.3.6 Prognosis of treatment efficacy for endometriosis.

The effectiveness of treatments can be limited as it may work for some and not for others. Symptoms are generally thought to resolve with menopause (Jackson & Telner, 2006), but research indicates that symptoms may still persist following total abdominal hysterectomy with bilateral salpingo-oophorectomy, in other words hysterectomy involving removal of the uterus and ovaries (Prentice, 2001; Sutton, 2001). Medical treatment results in temporary relief and a high rate of recurrence (Jackson & Telner, 2006). Surgery to remove endometriosis may provide more long-term results, but recurrence rates remain high (Crosignani et al., 2006). Recently there has been an increase in research on endometriosis among adolescent females to gain information regarding the progression of endometriosis (Brosens et al., 2016; Brosens, Gordts, & Benagiano, 2013).

1.4 Psychological aspects of endometriosis

Research on endometriosis has been gaining momentum internationally. A study by Denny and Khan (2006) revealed 12 546 citations related to endometriosis. However, these studies mainly reported clinical trials and medical and surgical interventions. In addition, a recent systematic review and synthesis of qualitative research by Young, Fisher and Kirkman (2015) found only 11 qualitative studies that reported on women's experiences with endometriosis. These studies were all conducted in high income, primarily English-speaking countries.

Endometriosis has far-reaching ramifications for those who endure it as it negatively affects their relationships with families and partners, social participation, sexual relationships, education and work (Denny, 2004a; Gilmour, Huntington, & Wilson, 2008). Depression is also associated with endometriosis (Lorençatto et al., 2006). Endometriosis can therefore be seen as a pervasive disease as it permeates many aspects of a patient's life.

1.5 Health-related quality of life and endometriosis

The vast majority of research relating to QOL in women with endometriosis focuses on surgical and medical treatment options. QOL research indicates that women with endometriosis and chronic pelvic pain demonstrate higher levels of perceived stress and poorer QOL than women without these problems (Petrelluzzi et al., 2008). A multicentre study across ten countries demonstrated that women with endometriosis displayed poorer HRQOL and work productivity than women without the disease across ethnicities and countries (Nnoaham et al., 2011). Similarly, Siedentopf et al. (2008) found that patients with endometriosis reported lower QOL than women without endometriosis when assessed using the SF-36, as well as increased perceived stress when assessed using the Perceived Stress Questionnaire. Furthermore, results of the Allgemeine Depressionsskala (general depression

questionnaire) indicated that women with stage 3 and 4 endometriosis reported more depressive symptoms than women with stage 1 and 2 endometriosis and women without endometriosis. However, this research was limited by the relatively small sample size. The studies referred to above used generic HRQOL instruments that were not specifically developed for endometriosis.

1.6 The Endometriosis Health Profile-30

The Endometriosis Health Profile-30 (EHP-30) is the only validated disease-specific HRQOL instrument for patients with endometriosis (Jia, Leung, Shi, Sun, & Lang, 2012; Jones, Kennedy, Barnard, Wong, & Jenkinson, 2001; Jones et al., 2004a; Khong, Lam, & Luscombe, 2010; Vincent, Kennedy, & Stratton, 2010). This instrument was developed from data collected by Jones, Jenkinson and Kennedy et al. (2004b), who sought to explore and describe the impact of endometriosis on QOL. In the development of the instrument, interviews were conducted with 24 women in the United Kingdom diagnosed with endometriosis and thereafter analysed. This research resulted in the development of 15 thematic categories.

These categories were subsequently used to develop categories for the EHP-30. The core scale consists of 30 items spanning five scales including pain, control and powerlessness, emotional well-being, social support and self-image (Jones et al., 2001). In addition, six modules accompany the core questionnaire. These modules include aspects such as work, sexual intercourse, relationship with children, feelings regarding the medical profession, treatment and infertility. The modules may not be applicable to all patients diagnosed with endometriosis. For example, not all patients with endometriosis are employed and therefore items in this module are not applicable to them.

The advantage of an endometriosis-specific HRQOL instrument is that it is likely to be more responsive to changes in endometriosis-related health status than generic instruments. Aspects pertinent to endometriosis such as dyspareunia are contained in the EHP-30, but not in generic instruments such as the SF-36 (Jones et al., 2001). Other areas specific to endometriosis that the EHP-30 addresses that are not accessible via generic scales include feelings of control and powerlessness, self-image, lack of social support and concerns regarding infertility (Jones et al., 2001).

1.7 Problem identification

The EHP-30 focuses primarily on physical, psychological and social aspects of QOL relating to endometriosis. The domains assessed in the EHP-30 provide detailed accounts of the effect that endometriosis has on QOL. However, these domains are too detailed and only cover a limited range of factors that affect HRQOL in women with endometriosis. For example, the physical domain concentrates on the effect that pain has on the woman's ability to function. Even though the physical domain is assessed in detail—it contains 11 items—it does not assess the effect that other endometriosis symptoms such as nausea, menorrhagia, lethargy, constipation and diarrhoea have on the QOL of endometriosis patients.

Another shortcoming of the EHP-30 is that it completely ignores environmental factors that influence QOL in women with endometriosis. For example, even though one of the EHP modules covers treatment, it only includes personal feelings and side-effects associated with treatment and ignores other important factors such as access to treatment, patient care and choice regarding treatment. This omission may be because the EHP-30 was developed specifically for use in clinical trials and therefore only focuses on aspects that may be directly affected by medical treatment. Since environmental factors such as financial resources, health and social care, and physical environment can be seen to have no bearing on

a particular medical treatment, they may have been overlooked. However, it is important to assess whether these factors play a role as they may contribute to the overall QOL in women with endometriosis. It is therefore appropriate to develop a new HRQOL instrument for women with endometriosis that encompasses a broader range of factors that affect the HRQOL of women with endometriosis than the EHP-30 does. A further limitation of the EHP-30 relates to access. The instrument may only be used after obtaining a license, which is granted at a fee. The EHP-30 is therefore not currently used in South Africa.

A number of challenges have become apparent in the South African (SA) healthcare system, including low doctor-to-patient ratios in the public health and private sectors (Strachan, Zabow, & van de Spuy, 2011). Women's health is a neglected concern in SA, with endometriosis being a below-the-radar phenomenon. No prevalence rates exist for endometriosis in SA. However, informal discussions with doctors in the private and public sector revealed that some doctors perform two to three endometriosis surgeries per week and the disease affects a diverse sample of women with varying contextual backgrounds (T. Matsaseng, personal communication, February 1, 2013).

In terms of practical utility, Dr T. Matsaseng, the Head of Reproductive Medicine at Tygerberg Hospital, has indicated the need for a free HRQOL that contains simple language and is easy to administer so that physicians can monitor on an ongoing-basis the HRQOL in women with endometriosis treated at the hospital (T. Matsaseng, personal communication, February 1, 2013). The development of such an instrument may play a pivotal role in helping doctors and patients manage the health and improve QOL in women with endometriosis.

The goal of this study was to construct and validate a new endometriosis QOL instrument for South African women. This goal was achieved by pursuing the three aims described below and utilising a sequential exploratory mixed methods research design. The

design consisted of a qualitative phase and a quantitative phase, with results from the qualitative phase informing the quantitative phase (Creswell, 2009).

1.8 Research aims

Aim 1: To describe and understand the QOL-related experiences of women with endometriosis.

Aim 2: To construct items for the instrument based on data collected while pursuing the first aim.

Aim 3: To determine the test reliability, validity and factor structure of the instrument.

1.9 Impact of the study

Monitoring HRQOL in patients with endometriosis is paramount to managing the condition. The availability of a measurement instrument that can be used freely and with ease by patients and doctors can play a key role in the management of symptoms related to endometriosis. Such a measure will contribute towards understanding patient experience and will contribute to understanding the factor structure of HRQOL. The new HRQOL measure for patients with endometriosis can also be used for future research in this area.

1.10 Organization of the dissertation

Chapter 1 consists of the introduction to the dissertation. The introduction consists of basic definitions of key concepts used in the study and the problem identification. The aims of the study are outlined, followed by a brief note on the impact of the study. The organization and overview of the dissertation is provided.

Chapter 2 contains the literature review and commences by detailing studies relating to HRQOL and the measurement of HRQOL. This is followed by a review of psychosocial

research regarding endometriosis. Finally, the chapter outlines the theoretical framework utilized in the study.

Chapter 3 presents the methodology, results and discussion of the first aim of the study, which was to understand HRQOL in a sample of women with endometriosis.

Chapter 4 details the process of item construction used to develop the measure.

Chapter 5 presents the methodology, results and discussion related to the finalization and initial validation of the new HRQOL measure for women with endometriosis.

Chapter 6 offers a summary of the study, implications for patients and for practice, and discusses the research limitations.

Chapter 2

Literature review

2.1 Introduction

The aim of this thesis is to present a HRQOL measure for patients with endometriosis. The literature review presented in this chapter informs this process. It addresses two themes that come into play, and as such, it divides into two sections. The first section deals with HRQOL and the measurement of HRQOL, while the second examines psychosocial research on endometriosis. The chapter concludes with an introduction to the theoretical framework employed in the study.

Section 1: HRQOL and the Measurement of HRQOL

2.2 Health-related quality of life and chronic illness

The term ‘quality of life’ (QOL) was first used in reference to dying patients, especially in cases where patients were being kept alive with the aid of respirators (Romney, Jenkins, & Bynner, 1992). The concept of QOL was used to determine whether a patient’s life was worth prolonging. QOL has since become an important concept in medical decision-making and is no longer restricted to life-and-death situations (Romney et al., 1992). Improvements in surgery and medical technology have shifted the focus away from survival rates in favour of assessing QOL (Jenkins, Jono, Stanton, & Stroup-Benham, 1990). Chapter 1 offers a distinction between QOL and HRQOL (see Section 1.1).

HRQOL is a multidimensional concept and multiple social, psychological and health-related factors have been associated with QOL in chronically ill patients (Han et al., 2003). HRQOL is concerned with the impact that health, illness and treatment have on an individual’s well-being (Bullinger et al., 1993; Bullinger 2002; Padilla et al., 1996) and deals

specifically with psychological, social and physical aspects during and following treatment (Greer, 1984; Han et al., 2003). HRQOL is a subjective and dynamic concept (King, 2012).

HRQOL studies cover three broad areas. First, some studies assess HRQOL among persons living with specific chronic disorders such as HIV (Peltzer & Phaswana-Mafuya, 2008) and arthritis (Tomasevic-Todorovic et al., 2011) to determine how the illness affects HRQOL. Second, some studies have compared HRQOL in people with a specific chronic illness and the general population. For example, Khanna et al. (2011) found that patients with arthritis reported poorer HRQOL than the general population. Third, the relationship between the number of chronic illnesses a patient has been diagnosed with and HRQOL has also been of interest to researchers. Hayworth, Hazel, Linehan and Frank (2009) found a negative correlation between HRQOL and the number of chronic illnesses. The research reported above indicates the importance of HRQOL in relation to numerous chronic illnesses and demonstrates the utility of measuring HRQOL.

2.3 Measuring health-related quality of life

As discussed in Chapter 1, the measurement of HRQOL serves numerous purposes, including providing a subjective assessment of patients' perceptions regarding their health. HRQOL measures can be used to examine patient experiences related to medical care and to describe experiences related to chronic illness (Bowling, 1995). Both generic and disease-specific measures of HRQOL are valuable, depending on the purposes for which they are used. The distinction between general and disease-specific measures was made in Chapter 1. However, there is no gold standard for assessing HRQOL (Grant & Dean, 2012; Haberman & Bush, 2012).

2.4 Methodology employed in the development of HRQOL measures

In the context of clinical trials, the HRQOL measures completed by patients are regarded as patient-reported outcomes (PRO's) (Anthoine, Moret, Regnault, Seville, & Hardouin, 2014; Lasch et al., 2010). The United States Department of Health and Human Services Department of Food and Drug Administration (FDA) has published recommendations for the development of PRO's (FDA, 2009). The FDA acknowledges that PRO development is an iterative process and their guidelines include the use of mixed-methods research for instrument development. The current study employed a mixed-methods design that is in line with these recommendations. Lasch et al. (2010) contend that rigorous qualitative data are key to the development of PRO's with content that is meaningful and relevant for patients. The measures discussed below were developed using mixed methods.

2.5 Comparing generic and disease-specific measures

Comparisons between generic and specific measures reveal that there are differences in the constructs being measured. For example, a comparison of the WHOQOL-Bref and the SF-36 in patients with coronary artery disease found that the instruments appeared to measure different QOL constructs, with the SF-36 focusing chiefly on health-related QOL and the WHOQOL-Bref focusing on general QOL. General QOL included environmental aspects such as the home environment, financial resources, health and social care, physical environment, freedom, physical safety and security, etcetera (Cruz, Camey, Fleck, & Polanczyk, 2009).

Studies comparing generic and specific HRQOL measures indicate that both may be useful. Among patients with breast cancer, the generic SF-36 with the disease-specific Functional Living Index – Cancer (FLIC) assessed different aspects of HRQOL (Wilson, Hutson, & Van Stry, 2005). Both measures contained similar domains such as mental, social

and physical well-being, but the global conceptualization of HRQOL differed. Moreover, the FLIC demonstrated greater sensitivity to differences in emotional well-being than the SF-36 (Wilson et al., 2005). In contrast with these findings, a study comparing the SF-36 with the disease-specific Asthma Quality of Life Questionnaire (AQLQ) found that the former instrument discriminated better than the latter among patients with different severity levels of asthma (Puhan, et al., 2008).

HRQOL instruments are particularly useful in tracking the progression of diseases that lack biomedical markers as indicators. Endometriosis is a chronic illness for which researchers have not yet conclusively identified biomedical markers to track disease progression (Barlow & Kennedy, 2005) and medical professionals rely on HRQOL instruments for this purpose. Both generic and specific HRQOL measures are used in patients with endometriosis. A systematic review of HRQOL and endometriosis found that both the EHP-30 and SF-36 are commonly used as measures of HRQOL in women with endometriosis (Jia et al., 2012).

2.6 Generic HRQOL measures

Examples of well-known generic HRQOL instruments include the World Health Organization Quality of Life short form (WHOQOL-Bref); the RAND 36-item health survey (SF-36); the Nottingham Health Profile (NHP); the Duke Health Profile (DHP); the McMaster Health Index Questionnaire (MHI); the Sickness Impact Profile (SIP); the Quality of Well-being scale; the Health Utilities Index (HUI) and the Euro Qol EQ 5 D scale. The next section discusses the construction, domains/dimensions and basic psychometric properties of three of these measures (namely the WHOQOL, the SF36 and the NHP).

2.6.1 The WHOQOL and WHOQOL-Bref.

The WHO group in collaboration with 15 international field centres developed the WHOQOL-Bref so that the instrument would be cross-culturally applicable. This was in line with the WHO's aim of developing an international QOL measure that upholds the organization's holistic approach to health and health care (WHO, 1997).

The process of developing the WHOQOL began with researchers reaching consensus on the conceptual definition of QOL. QOL was defined as an individual's perceived position in life with regard to his/her expectations, goals, standards and concerns in life within the context of the value systems and culture in which they live (WHO, 1996). Following this definition, the researchers explored the construct 'QOL' in 15 culturally diverse field centres to identify agreed-upon factors deemed relevant to the assessment of QOL. Each centre generated a maximum of six items per factor and the questions from each centre were compiled to form a global pool of items. Semantically equivalent questions were clustered, resulting in the construction of an assessment measure covering 236 items and nine dimensions. This measure was administered to a minimum of 300 respondents at each field centre. The results of the field test led to the selection of 100 items to form the WHOQOL. The WHOQOL-Bref is the 26-item abridged version of the WHOQOL. The items cover four domains, namely physical, psychological, social relationship, environment and two additional general questions (Cruz et al., 2009; WHO, 1997). Each domain consists of a number of facets, with each facet comprising four questions. The measure also contains four items relating to overall QOL and general health (please refer to Table 2.1 to view the conceptual model of the WHOQOL). Higher scores on the measures indicate better QOL compared to lower scores. The WHOQOL is available in over 20 different languages and the WHOQOL-Bref is available in 19 different languages (WHO, 1997). In addition, the WHOQOL-Bref has

been used to measure HRQOL in patients with endometriosis (Altinbas, Tekin, Dilbaz, & Dilbaz, 2015; Souza et al., 2011; Tripoli et al., 2010).

Table 2.1 WHOQOL and WHOQOL-Bref dimensions and facets

Domain	Facets
Physical	Activities of daily living
	Dependence on medical substances and medical aids
	Energy and fatigue
	Mobility
	Pain and discomfort
	Sleep and rest
	Work capacity
Psychological	Body image and appearance
	Negative feelings
	Positive feelings
	Self-esteem
	Spirituality/religion/personal beliefs
	Thinking, learning, memory and concentration
Social relationships	Personal relationships
	Social support
	Sexual activity
Environment	Financial resources
	Freedom, physical safety and security
	Health and social care: accessibility and quality
	Home environment
	Opportunities for acquiring new information and skills
	Participating in and opportunities for recreation / leisure activities
	Physical environment (pollution / noise / traffic / climate)
	Transport

2.6.2 Nottingham Health Profile (NHP).

The NHP is one of the earliest health status measures. The measure was developed from interviews with 768 patients with acute or chronic illness. The interviews produced 2200 statements that described the effects of ill health. These statements were analysed and reduced to 138 statements. Item analysis resulted in the finalization of a 38-item measure,

consisting of six subscales, namely energy, pain, sleep, physical reactions, emotional reactions and social isolation (Hunt, McEwan, & McKenna, 1985). The measure is self-administered and provides test-takers with statements to which they respond either yes or no.

The NHP has been criticized as lacking discriminatory power. A study conducted by Kind and Carr-Hill (1987) found that the measure did not discriminate between people with poor and good health status. The researchers also claimed that items on the NHP were redundant and that results are difficult to interpret (Kind & Carr-Hill, 1987).

However, Jenkinson, Fitzpatrick and Argyle (1988) administered the NHP to patients with rheumatoid arthritis and migraines and found that the measure was indeed able to discriminate between patients. The authors further criticized Kind and Carr-Hill's (1987) study, stating that the measure was administered to a sample of the public and that the perceived inability of the NHP to discriminate between well and ill patients may have been due to the general good health of the sample rather than poor discriminatory power on behalf of the NHP. To my knowledge, the NHP has to date not been used as a measure of QOL among South Africans or among patients with endometriosis.

2.6.3 36-Item short form health survey (SF-36).

RAND Corporation developed the SF-36 and constructed it as an alternative to the longer assessment measures utilized in the Medical Outcomes Study (MOS) (McDowell, 2006; Ware, Gandek, & IQOLA Project Group, 1994). The measure is a compilation of the most frequently used concepts in health surveys and the concepts deemed most affected by disease and treatment (Ware et al., 1994). The MOS consisted of a number of assessment measures, including the Health Perceptions Questionnaire, the General Psychological Well-Being Inventory and various physical and role functioning measures. Items from these questionnaires were adapted to form the SF-36 (Ware et al., 1994). The MOS measures consist of 40 scales, of which eight scales were chosen to formulate the SF-36. These scales

include physical functioning, bodily pain, role physical, general health status, vitality, social role functioning, emotional role functioning and mental health (Cruz et al., 2009).

The original SF-36 had a dichotomous response format, whereas the later version utilizes a five-point Likert response format (McDowell, 2006). The measure takes five to ten minutes to complete and higher scale scores indicate better QOL compared to lower scores. The SF-36 has also been used in several studies to assess HRQOL in patients with endometriosis (De Graaff et al., 2013; Jia et al., 2012; Nnoaham et al., 2011; Bodner, Garratt, Ratcliffe, Macdonald, & Penney, 1997; Lövkvist, Boström, Edlund, & Olovsson, 2012). The internal consistency reliability of the SF-36 subscales ranged from 0.79 to 0.91 in a sample of endometriosis patients (Bodner et al., 1997). The SF-36 is commonly used in endometriosis research (Gao et al., 2006) and has been validated in this sample (Stull et al., 2014). However, one study found that the SF-36 underestimated QOL (Laas et al., 2015).

2.7 Endometriosis-specific HRQOL measures

As mentioned in Chapter 1, the EHP-30 is the only validated endometriosis-specific HRQOL measure (Jia et al., 2012; Jones et al., 2001; Jones et al., 2004a). Chapter 1 outlines the process through which the EHP-30 was developed and its limitations. The five-factor structure of the original study was confirmed and internal consistency reliabilities for the scales ranged from .80 to .96 in a sample of women in the U. K. (Jones, Jenkinson, Taylor, Mills, & Kennedy, 2006).

The EHP-30 consists of a core module containing 30 questions. There are five modules in addition to these 30 questions. These modules cover aspects such as infertility (4 items), treatment (3 items), medical profession (4 items), sexual relationships (5 items), relationship with children (2 items) and work (5 items). The total number of modular items is 23, but test-takers only complete the modules that are applicable to them.

The EHP-30 has demonstrated good reliability in patients with endometriosis. The measure has been used in an American sample and the study reported internal consistency reliabilities for the subscales ranging from 0.84 to 0.91 (Jenkinson, Kennedy, & Jones, 2008). The Dutch version of the EHP-30 confirmed the 5-factor structure and reported internal consistency reliabilities for the sub-scales ranging from .75 to .97 (Van de Burgdt, Hendriks, & Kluivers, 2011). The short form, the EHP-5, contains five items and has been adapted and validated among patients with endometriosis in Iran (Goshtasebi, Nematollahzadeh, Hariri, & Montazeri, 2011).

In conclusion, the measurement of HRQOL forms an important aspect of QOL research among people living with chronic illnesses. The increasing emphasis on HRQOL in these patients indicates a shift in medicine. The measurement of HRQOL is therefore integral to assessing this construct. There are a number of measures of HRQOL and different methodologies were employed to develop these measures. Reliable and valid HRQOL measures are therefore necessary to facilitate research in this field.

Section 2: Psychosocial Research On Endometriosis

Understanding psychosocial experiences is vital to develop patient-centred measures. Psychosocial research among women with endometriosis has focused on (1) HRQOL, (2) pain and physical functioning, (3) psychological well-being, (4) interpersonal functioning, (5) sexual dysfunction, (6) infertility, (7) occupational functioning, (8) healthcare, and (9) control and powerlessness.

2.8 Research on HRQOL

The consensus in HRQOL literature is that patients with endometriosis have poorer QOL compared to their healthy counterparts (Friedl et al., 2015; Jia et al., 2012; Giuliani et al., 2015; Petrelluzzi et al., 2008; Nunes, Ferreira, & Bahamondes, 2014; Siedentopf et al.,

2008). For example, an Italian study among patients who underwent laparoscopic surgery reported lower total HRQOL in women with endometriosis compared to women with benign masses surrounding the uterus ($p=0.008$) (Laganà et al., 2015). Another study found that women with endometriosis reported significantly lower total HRQOL compared to that of US population norms (De Graaff et al., 2015). In addition, women with endometriosis also scored significantly lower than healthy controls on certain subscales, such as the physical role, general health and vitality subscales of the SF-36 (Lövkvist et al., 2012) and the physical, psychological and social domains of the WHOQOL (Giuliani et al., 2015).

A large multicentre study ($n=1,418$) across ten countries demonstrated that newly diagnosed women with endometriosis displayed poorer HRQOL and work productivity than women without the disease across ethnicities and countries (Nnoaham et al., 2011). The sample consisted of three groups: 1) patients with endometriosis; 2) patients who experienced pelvic pain without endometriosis (control group 1); and 3) women who presented themselves for sterilization (control group 2). Patients with endometriosis scored significantly lower than the first control group in the bodily pain domain ($p=0.02$). Patients with endometriosis also scored significantly lower than patients in the second control group in domains such as physical functioning ($p=0.02$), physical role limitation ($p=0.01$), mental role limitation ($p=0.02$), bodily pain ($p=0.04$) and health perception ($p=0.03$). Finally, a systematic review of 20 HRQOL studies conducted on women with endometriosis found that endometriosis had a negative impact on HRQOL domains, especially pain, psychological functioning and social functioning (Gao et al., 2006). The literature therefore indicates that a number of domains of HRQOL are negatively affected in women with endometriosis.

De Graaff et al. (2015) caution researchers that results of HRQOL studies among patients with endometriosis are influenced by recruitment strategies, as most endometriosis research takes place among patients at tertiary providers or via patient associations (e.g.

support groups). These authors compared the QOL among three groups of patients, namely, 1) patients with endometriosis recruited from a tertiary care centre, 2) patients with endometriosis recruited from secondary care centres, and 3) patients recruited from an endometriosis association. One difference between these groups is that patients from secondary and tertiary providers usually have laparoscopically confirmed diagnosed endometriosis, whereas patients from patient associations self-report their diagnosis, but the diagnoses have not been confirmed by a health professional. De Graaff et al. (2015) did not find significant differences in QOL scores between patients from tertiary and self-help groups. However, patients from self-help groups produced significantly lower QOL than patients from secondary facilities (De Graaff et al., 2015). The study demonstrates that differences exist in the QOL of patients recruited from different settings. This difference is likely because patients from tertiary centres may have been referred to those centres due to the severity of the disease, whereas patients belonging to self-help groups have a range of severity of endometriosis (De Graaff et al., 2015).

2.8.1 Pain and physical functioning

Pain, specifically pelvic pain, is one of the primary symptoms of endometriosis. While pain limits physical functioning and patients' lives on a daily basis (Jones et al., 2004a; Moradi, Parker, Sneddon, Lopez, & Ellwood, 2014; Petrelluzzi et al., 2008), research on the relationship between pain and HRQOL has shown mixed findings. Several studies found that pain was significantly associated with HRQOL in patients with endometriosis (Facchin et al., 2015; Marques et al., 2004; Nnoaham et al., 2011; Tripoli et al., 2011), which is consistent with the biopsychosocial model. Only one study failed to find a relationship between pain and QOL among women with endometriosis (Souza et al. 2011). However, Souza's study was limited by its small sample (n=57) and the fact that all participants in the endometriosis group were diagnosed with minimal or mild, but not severe endometriosis. Research

conducted on small samples are vulnerable to type 1 error and the failure to find significant results in the study may be a function of the small sample size rather than differences in QOL scores.

The consensus in the literature indicates that pain negatively affects HRQOL. Yet, factors associated with pain require further investigation. Among women with endometriosis, factors such as having had a hysterectomy, nulliparity (not having children) and catastrophizing pain were significant biopsychosocial predictors of pelvic pain (Martin, Johnson, Wechter, Leserman, & Zolnoun, 2011). Similarly, catastrophization and younger age were also found to be significant predictors of persistent pain following surgery (Carey, Martin, Siedhoff, Bair, & As-Sanie, 2014).

Chapter 1 outlines the medical interventions aimed at improving symptoms of endometriosis. Interventions aimed at reducing pain may be beneficial to patients with endometriosis. One study found that medical treatment (e.g. surgery, oral contraception, GnRH analogues) was effective in managing pain in patients with endometriosis who were diagnosed with endometriosis 15 years prior to participating in the study (Fagervold, Jenssen, Hummelshoj, & Moen, 2009).

In addition to pain, women with endometriosis reported feeling tired, lethargic and lacking energy (Jones et al., 2004; Petrelluzzi et al., 2008). They reported that fatigue, pain and preoccupation with pain resulted in their limiting their social interaction (Gilmour et al., 2008; Jones et al., 2004). Pain and fatigue can therefore be seen as contributing to impaired HRQOL in women with endometriosis, including social functioning.

2.8.2 Psychological well-being among patients with endometriosis.

Research regarding the psychological well-being of women with endometriosis has focused on (1) depression, (2) anxiety, (3) other psychiatric disorders, and (4) assessing interventions aimed at improving psychological well-being.

2.8.2.1 Depression

Most literature show that women with endometriosis report elevated symptoms of depression (Chen et al., 2016; Eriksen et al., 2008; Friedl et al., 2015; Laganà et al., 2015; Lorencatto et al., 2006; Roth, Punch, & Bachman, 2011; Sepulcri & Amaral, 2009). For example, among 104 women with endometriosis, 86.5% presented with depressive symptoms (mild in 22.1%, moderate in 31.7%, and severe in 32.7%) (Sepulcri & Amaral, 2009). Yet, among endometriosis patients reporting chronic pain, findings have been contradictory. Lorencatto et al. (2006) found a significant difference in symptoms of depression between subjects with and without pelvic pain, while Eriksen et al. (2008) failed to do so.

Studies comparing women with endometriosis and women with other conditions show mixed results on measures of depression. For example, a study comparing women with endometriosis to women without endometriosis, but with chronic pelvic pain due to either myofascial abdominal/pelvic pain or pelvic adhesions, found no differences in depressive symptoms and distress (Roth et al., 2011). However, Laganà et al. (2015) found significantly higher levels of depression ($p=0.01$) among patients undergoing laparoscopic surgery for endometriosis compared to patients undergoing laparoscopic surgery for benign masses. This result may be due to differences in the symptoms patients with endometriosis and patients with benign masses experience.

Researchers yet again produced contradictory results pertaining to the relationship between disease stage and symptoms of depression. In one study, women with stages 3 and 4 endometriosis manifested a greater number of depressive symptoms than women with stages 1 and 2 endometriosis and women without endometriosis (Siedentopf et al., 2008). However, another study failed to find a relationship between stage of endometriosis and symptoms of depression (Eriksen et al., 2008). In conclusion, the literature on depression and endometriosis is equivocal and warrants further investigation.

2.8.2.2 Anxiety

There are many fewer studies on anxiety among women with endometriosis than on depression. One study found that 29% of women with endometriosis reported symptoms of anxiety (Friedl et al., 2015). Women with endometriosis are more likely to develop anxiety disorders than women without endometriosis (Hazard Ratio: 1.44, 95% CI: 1.22–1.70) (Chen et al., 2016). Moreover, studies examining the relationship between pain, anxiety and endometriosis are contradictory. For example, among women diagnosed with endometriosis, Eriksen et al. (2008) failed to find significant differences in levels of anxiety between women with and without pain. Yet, in a study among Brazilian women with endometriosis, the relationship between pain intensity and anxiety symptoms as measured by the State-Trait Anxiety Inventory and the Hamilton rating Scale was found to be significant (Sepulcri & Amaral, 2009).

2.8.2.3 Other disorders

Along with research into levels of anxiety and depression in women with endometriosis, researchers have also explored other psychological symptoms and disorders. Laganà et al. (2015) found significantly higher scores in somatization ($p=0.02$), sensitivity (0.04) and phobic anxiety ($p=0.04$) among patients undergoing laparoscopic surgery for endometriosis compared to patients undergoing laparoscopic surgery for benign masses. In addition, Cavaggioni et al. (2014) found a significant difference in the prevalence of alexithymia between women diagnosed with endometriosis ($N=37$) and women without the disease ($N=43$) ($P < 0.05$). Another study found that women with endometriosis and chronic pelvic pain demonstrated higher levels of perceived stress than women without the disease (Petrelluzzi et al., 2008).

2.8.2.4 Distress reduction interventions for women with endometriosis

Studies have shown that symptoms of depression may be ameliorated by means of psychosocial (Kold, Hansen, Vedsted-Hansen & Forman, 2012; Zhao et al., 2013) and even surgical interventions (Van de Broeck et al., 2013) among patients with endometriosis. Surgery is one method used to treat endometriosis and to improve patient well-being. One study found that laparoscopic surgery for endometriosis resulted in an improvement in levels of depression post-surgery (Van de Broeck et al., 2013). However, this finding should be interpreted with caution. It may not indicate that the disease itself results in depression, but more likely that the surgery may have reduced symptoms of endometriosis, which in turn may have led to a decrease in symptoms of depression.

There are very few studies investigating psychological interventions in patients with endometriosis (Kold et al., 2012; Petrelluzzi et al., 2012; Zhao et al., 2013). Zhao et al. (2013) conducted a small randomized, controlled trial to investigate the impact of progressive muscle relaxation (PMR) on symptoms of depression, anxiety and quality of life in patients with endometriosis receiving GnRH therapy. The study indicated that patients in both the control and intervention groups experienced a significant improvement in their HRQOL due to the medical therapy. However, the intervention group (which received the PMR intervention) displayed a significant improvement in their levels of depression and anxiety, which was different to the control group (Zhao et al., 2013). These results are promising as they indicate that psychology-based interventions may be of value to patients with endometriosis who report distress. Kold et al. (2012) also found that a mindfulness-based psycho-educational programme improved the QOL in 10 women with endometriosis. While participants' QOL scores improved, the results should be interpreted with caution as the study was not a randomized controlled trial and therefore the design did not include a control group.

2.8.3 Interpersonal

The psychosocial impact of endometriosis is mainly evident in two domains, namely social participation and romantic relationships.

2.8.3.1 Social participation

Most research exploring the relationship between endometriosis and social functioning is qualitative and does not use measures to evaluate the extent of social participation. Culley et al. (2013) conducted a critical review of research relating to the social and psychological impact of endometriosis on women's lives and concluded that endometriosis had a significant negative impact in psychosocial domains. In addition, interviews with endometriosis patients revealed that the physical pain related to the disease restricted their social lives, as many women reported that they were often unable to attend social events or participate in sport (Cox, Henderson, Andersen et al., 2003a; Culley et al., 2013; Denny, 2004a; Jones et al., 2004; Gilmour et al., 2008). Women with the disease reported that chronic pelvic pain is an important contributor to social isolation (Mellado et al., 2016). Women further reported that these limitations meant that their social circle became restricted to close family and friends. In addition, women interviewed in the Jones et al. (2004) study also reported that endometriosis resulted in feelings of isolation, as they did not disclose their illness to others and dealt with the impact of the disease by themselves. Patients with endometriosis reported that they found online support groups beneficial as these groups provide a platform that allows patients to connect, learn and share experiences with one another (Shoebotham & Coulson, 2016). However, some women with endometriosis have reported negative aspects of online support groups, including privacy concerns, concerns regarding accuracy of information shared and conflict between group members (Shoebotham & Coulson, 2016).

2.8.3.2 Romantic relationships

Women with endometriosis report in numerous studies that their illness has had a negative impact on their romantic relationships (Cox, Henderson, Wood et al., 2003; Denny, 2004a, Denny, 2004b; Jones et al., 2004; Hudson et al., 2016; Huntington & Gilmour, 2005). Some women reported that endometriosis played a major role in their relationship break-up (Cox, Henderson, Andersen et al., 2003; Huntington & Gilmour, 2005). Women with endometriosis also reported that their pain, anger and mood swings related to endometriosis were responsible for difficulties within their relationships (Moradi et al., 2014).

The disease may also have an impact on partners of women with endometriosis. Male partners of women with endometriosis report experiencing anger upon partner diagnosis, low mood and feelings of isolation and powerlessness (Fernandez, Reid, & Dzuirawiec, 2006). However, some males in the same study reported that endometriosis provided the opportunity for growth in their relationships with their partners. In other words, even though endometriosis had had a negative impact on their relationships, there were some positive aspects related to it, such as emotional closeness (Fernandez et al., 2006).

In an attempt to understand relationships in couples affected by endometriosis, Butt and Chesla (2007) identified five relational patterns in couples affected by endometriosis, namely ‘together but alone’, ‘battling endometriosis together’, ‘conjoined through disability’, ‘totalized by caregiving’ and ‘engaged in mutual care’. These relational patterns range from the more disconnected relationships (together but alone), to a strong sense of companionship in managing the disease (battling endometriosis together), to all aspects of the relationship being focused on the partner with endometriosis (totalized by caregiving). Furthermore, Denny (2004a) found that while many women received support from partners, the experience of endometriosis caused strain within some relationships and contributed to relationship break-up with partners who were unable to cope with the impact of endometriosis (Denny, 2004a). Culley et al. (2013) reported similar findings, but also found that in some cases the

experiences relating to endometriosis strengthened the bond between couples. However, Culley et al. (2013) found that communication between couples regarding the disease tended to focus on medical care and treatment rather than feelings relating to the endometriosis experience.

Respondents reported that dyspareunia (painful sexual intercourse) was an additional source of strain in sexual relationships with partners and another contributing source of relationship break-up (Denny, 2004a). Dyspareunia is discussed in detail in section 2.8.6.

The treatment of endometriosis may result in improved social functioning, as one study found that patients with endometriosis who underwent laparoscopic surgery with bowel resection (i.e. patients who had part of their bowel removed) experienced a significant improvement in relationship satisfaction than patients who underwent laparoscopy without bowel resection (Van de Broeck et al., 2013). This finding indicates that radical surgery may be of more benefit to patients with endometriosis than conservative surgery.

In conclusion, research relating to psychosocial functioning in women with endometriosis is mostly qualitative and these studies have reported that patients with endometriosis experience challenges in their social functioning. More quantitative research is needed to determine factors that influence psychosocial functioning in women with endometriosis.

2.8.4 Occupational functioning

Research has both quantified and described the impact that endometriosis has on patients' ability to work (Gilmour et al., 2008; Hansen et al., 2013; Moradi et al., 2014; Seear, 2009a; Seear, 2009c; Fourquet, Báez, Figueroa, Iriarte, Flores, 2011; Nnoaham et al., 2011; Culley et al., 2013). In the study reported on earlier by Nnoaham et al. (2011), researchers concluded that patients with endometriosis lost an average of 11 hours per week at work due to reduced effectiveness. De Graaff et al. (2013) found that 51% of their sample

of women with endometriosis reported that the condition negatively affected their work. In Belgium, patients with endometriosis reported that on average the disease cost them €9872 (approximately R326 000) per annum, with 75% of this value being attributed to productivity loss (Klein, D'Hooghe, Meuleman, Dirksen, Dunselman, & Simoens, 2014).

Qualitative research describes the roles that endometriosis prevents patients from performing and the daily impact on their lives. For example, participants in the Jones et al. (2004a) study discussed previously stated that the disease left them unable to perform a number of roles in their lives relating to areas such as housework and motherhood. It also affected their ability to work professionally. Similarly, the data reported by Denny (2004a) also provide accounts of the difficulties that women with endometriosis experienced in the workplace when symptoms such as pain and gastrointestinal issues stemming from the disease meant that they were unable to perform their jobs as required and they needed to take sick leave. Women with endometriosis have reported feeling that their employers and colleagues trivialized or did not believe that their pain was related to endometriosis (Denny, 2004a). Another study found that some women with endometriosis did not disclose their diagnosis to employers and colleagues out of fear that they would be pressured to discontinue work or because they were unwilling to discuss symptoms with male employers due to the gendered-nature of the disease (Gilmour et al., 2008).

A number of women with endometriosis reported that symptoms related to the disease first emerged during their tertiary studies. Women also reported that endometriosis played a role in poor academic performance and in some cases, forced them to abandon their studies (Gilmour et al., 2008). The research cited above indicates that endometriosis can negatively affect women's ability to work, which may have far-reaching consequences for both their personal and professional development, as well as their ability to make a living.

2.8.5 Healthcare

2.8.5.1 *Diagnostic delay*

The diagnostic delay (i.e. time from onset of symptoms until diagnosis) among women with endometriosis is well-known (Ballard, Lowton, Wright, 2006; Cox Henderson, Andersen et al., 2003; Denny, 2004a; Denny, 2004b; Hadfield et al., 1996; Husby et al., 2003; Markovic, Manderson, & Warren, 2008). Interviews with women diagnosed with endometriosis highlight three reasons for this delay. Firstly, both patients and doctors tend to normalize painful periods. Secondly, women take hormone-based medication (i.e. birth control) that suppress the symptoms of endometriosis and therefore do not seek assistance. Finally, doctors opt to investigate symptoms of pain using techniques such as ultrasounds (sonograms), which are not efficient in diagnosing endometriosis, rather than laparoscopy (Ballard et al., 2006). Seear (2009b) offers a different perspective by stating that women do not disclose menstrual irregularities in order to avoid being stigmatized and actively try to conceal menstrual problems. This concealment occurs because of a certain etiquette regarding menstruation in society (Seear, 2009b). This etiquette includes the concealment of menstruation in society and the perception that women who disclose menstrual related irregularities are vulnerable to stigmatization (Seear, 2009b). Markovic et al. (2008) state that the diagnostic delay in women with endometriosis stems from both patients and doctors. In their study, the researchers reported on four factors that resulted in patients seeking medical advice. Women sought medical advice when close family members or friends prompted them to do so, when their daily lives were disrupted, when their ability to become pregnant was hampered, and when they recognized pathology (such as pain and dyspareunia) related to their periods (Markovic et al., 2008).

2.8.5.2 Dissatisfaction with healthcare

A number of studies found that patients with endometriosis were dissatisfied with the healthcare and medical treatment that they had received (Cox, Henderson, Wood et al., 2003; Denny, 2004a; Jones et al., 2004; Moradi et al., 2014). The patients with endometriosis who were interviewed spoke of their challenges to find doctors who believed that they were in pain and who paid attention to their symptoms. In addition, women described their search for doctors who were sympathetic to them (Cox, Henderson, Wood et al., 2003; Jones et al., 2005). Women have also reported that they endured a number of laparoscopies (keyhole surgeries), which provided temporary relief, but that symptoms usually reappeared (Cox, Henderson, Wood et al., 2003).

Another challenge relating to healthcare received by patients with endometriosis is that doctors and patients describe symptoms of endometriosis differently. Fauconnier, Staraci, Huchon, and Descamps (2013) interviewed 41 patients with endometriosis and nine gynaecological experts and found a mismatch between the description of symptoms by doctors and patients. Patients described 12 more themes relating to symptoms than doctors. In addition, the doctors described five themes that patients did not describe. This mismatch between descriptions of doctors and patients indicates a gap between these two parties. As a result of these findings, Fauconnier et al. (2013) emphasize that tools measuring symptoms of endometriosis should use words and phrases that are expressed by patients in their narratives of pain.

Satisfaction with healthcare is an important aspect of HRQQOL in women with endometriosis. The significance of this dimension is emphasized in the development of the Endometriosis Treatment Satisfaction Questionnaire (Deal, Williams, DiBenedetti, & Fehnel, 2010). As illustrated above, satisfaction with healthcare is an important aspect of illness. The inclusion of satisfaction with healthcare as a domain in various QOL measures indicates that this domain is pertinent to patients' experience of illness.

2.8.5.3 Cost of healthcare

Healthcare for patients with endometriosis can be costly. Simoens et al. (2012) performed a cost analysis to determine the cost of treatment for patients with endometriosis. The sample consisted of 909 women with endometriosis from 10 countries, namely Belgium, Denmark, France, Germany, Hungary, Italy, Netherlands, Switzerland, U. K. and U. S. A. Women reported an annual average healthcare cost of €3113 (approximately R51 000). These costs are attributed to surgery (29%), tests (19%), hospitalization (18%) and visits to doctors (16%) (Simoens et al., 2012). There are no data on the cost of endometriosis care in South Africa. Most research relating to healthcare received by patients with endometriosis indicate patient dissatisfaction with healthcare. Healthcare can therefore be seen as an important part of a patient's HRQOL.

2.8.6 Dyspareunia

Medical literature defines dyspareunia as painful sexual intercourse and lists it as a symptom of endometriosis. Research on dyspareunia and endometriosis largely focuses on physiological aspects of the disease and medical interventions. Levels of dyspareunia are typically assessed to determine the effect that endometriosis has on the quality of sex life and sexual functioning/dysfunction and to gauge the effectiveness of medical interventions.

Dyspareunia is common among patients with endometriosis and is associated with impaired sexual functioning, relationship problems and psychological distress (Fritzer et al., 2013). Sexual functioning contains the following domains: sexual desire, satisfaction with sex, orgasm frequency and pelvic problem interference with sex. Endometriosis has an effect on quality of sex life and partnership, with patients with endometriosis experiencing less satisfying sex lives and relationships than patients without endometriosis (Rossi et al., 2008). Pain and physical function negatively affect sexual functioning in women with endometriosis compared to healthy controls (Giuliani et al., 2015). In addition to dyspareunia, women with

endometriosis experience significantly poorer QOL and lower body image compared to health controls (Melis et al., 2015).

The location of endometriotic lesions has been investigated to determine if location of lesions play a role in the development / presence of dyspareunia. One study found no statistically significant difference between patients with endometriosis that infiltrated the uterosacral ligament (a major ligament attached to the uterus that contains a significant amount of nerve tissue), also referred to as DIE endometriosis, and those without in terms of quality of sex life (Ferrero et al., 2005). However, Di Donato et al. (2014) found that women with DIE endometriosis reported significant impairment in sexual functioning compared to healthy controls. In addition, no significant differences were found between patients with rectovaginal endometriosis (endometriosis in the rectum and vagina) and peritoneal/ovarian endometriosis (endometriosis on the ovaries) (Vercellini et al., 2012). The studies cited above indicate that a simplistic understanding of dyspareunia in terms of location of lesions is insufficient and other factors should therefore be taken into consideration.

As dyspareunia is a symptom of endometriosis, an improvement in this symptom may be an indicator that a specific treatment is effective. Studies have found that interventions such as Dienogest (a progestin) and laparoscopic surgery with and without excision of endometriosis significantly improved sexual functioning in women with endometriosis (Caruso et al., 2015; Ferrero, Abbamonte, Giordano, Regni, & Remorgiola, 2006; Lukic et al., 2016; Van de Broeck et al., 2013).

Dyspareunia is listed as a genitopelvic pain/penetration disorder in the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5) (American Psychiatric Association, 2013). According to the DSM-5, a patient may be diagnosed with genitopelvic pain/penetration disorder if they experience persistent or recurrent difficulties (for a minimum of six months) in one or more of the following: 1) difficulties with vaginal penetration during intercourse, 2)

pain during intercourse, 3) fear or anxiety in anticipation of or as a result of intercourse, and 4) tensing and tightening of the pelvic floor muscles (APA, 2013).

These diagnostic criteria outlined above allow for an improved understanding of dyspareunia compared to the simplistic one typically used in medical literature that defines dyspareunia as painful sexual intercourse. The DSM-5 acknowledges that most sexual dysfunctions may be caused by biological and psychological factors (Latif & Diamond, 2013). A pathogenic mechanism has been identified to explain dyspareunia. According to this mechanism, previous experiences of pain during sexual intercourse results in an altered awareness of pain (Fritzer et al., 2013). Focus shifts from pleasure/enjoyment to the sensation of pain. This shift may create anxiety in anticipation of sexual intercourse and result in tensing of the pelvic muscles resulting in further pain. Recurrent painful intercourse reinforces this cognitive scheme (Fritzer et al., 2013).

Recognizing dyspareunia as a psychological disorder and not merely a physical symptom has implications for treatment. Psychological interventions (such as cognitive-behavioural therapy) can play a role in alleviating dyspareunia (LoFrisco, 2011) and this recognition by doctors may be beneficial to patients with endometriosis.

2.8.7 Infertility

Endometriosis is associated with infertility (Carvalho et al., 2013; Fagervold et al., 2009; Fourquet et al., 2010; Giudice, 2010; Meuleman et al., 2009; Ozkan, Murk, & Arici, 2008; Ventolini et al., 2005). Many factors contribute to infertility in women with endometriosis, including mechanical (e.g. pelvic adhesions), genetic (e.g. epigenetic damage to the endometrium) and environmental factors (Macer & Taylor, 2012). The disease has a prevalence of 25-40% among women with infertility (Ozkan et al., 2008). A longitudinal study found that 75.6% of a sample of women diagnosed with endometriosis were able to produce a child within a 15-year period (Fagervold et al., 2009). In vitro fertilization (IVF) is

widely regarded as the most effective method to assist women with endometriosis to conceive (Macer & Taylor, 2012). Medical scientists previously believed that hormones associated with IVF result in disease progression in women with endometriosis, but recent studies have found that this is not the case (Benaglia et al., 2011; Santulli et al., 2016).

Infertility associated with endometriosis has far-reaching consequences for those who endure it. Affected women describe difficulty with conception as a source of distress in relationships with partners (Jones et al., 2004a). Women diagnosed with endometriosis are concerned about infertility, even when they are not yet seeking to reproduce (Denny, 2009; Markovic et al., 2008). This means that couples affected by endometriosis are forced to make premature decisions relating to the timing of starting a family and the spacing of children (Culley et al., 2013).

Women diagnosed with endometriosis have reported receiving conflicting information regarding fertility and endometriosis from doctors (Young, Fisher, & Kirkman, 2016). While some women were satisfied with the information they received from doctors regarding endometriosis and fertility, others were dissatisfied and stated that they received inappropriate and inefficient information and that doctors prioritized their fertility without consulting them (Young et al., 2016).

2.8.8 Control and power.

Patients with endometriosis have reported that uncertainty is a central psychological feature associated with the disease (Denny, 2009). Research conducted among women with endometriosis in Australia reported that this uncertainty was related to diagnosis, disease progression and women's futures (Denny, 2009). In addition, women with endometriosis have reported feeling a lack of control and feeling powerless, as pain dominated their lives (Jones et al., 2004). A qualitative Australian study described patients' attempts to gain control of their bodies through managing the disease (Cox, Henderson, Wood et al., 2003). In the

study, participants reported that managing their interaction with doctors was a key determinant of a sense of control. Participants stated that they became assertive during their interactions with doctors, forcing doctors to take note of their symptoms and carefully considering surgical procedures before agreeing to them. Patients reported that they meticulously noted their symptoms in diaries, which they presented to doctors to demand acknowledgement of their symptoms and proper treatment. This assertiveness and control allowed patients to feel empowered and in control of their bodies (Cox Henderson, Wood et al., 2003).

Women with endometriosis report that they set goals in their daily lives to manage their condition (Cox Henderson, Wood et al., 2003). These goals ranged from simply getting up in the morning to being able to manage pain, remaining drug free and getting out of the ‘medical roundabout’ (i.e. medical treatment) by resorting to alternate therapies such as Chinese Herbal Medicine, Reiki, acupuncture, naturopathy, meditation, vitamins, diet and exercise. Some patients used these therapies as complementary, meaning that they used them in conjunction with medical therapy, whereas others used them as alternate therapies to medical therapy, meaning that they did not continue to see doctors, use drugs or undergo surgery (Cox, Henderson, Wood et al., 2003). These findings indicate that patients were dissatisfied with medical therapy and sought alternatives that allowed them some feeling of control. Other studies reveal that patients attempt to gain control by consulting online resources and books (Seear, 2009a; Neal & McKenzie, 2011).

This literature review has indicated that endometriosis has a negative impact on many aspects of the lives of the women afflicted with the disease. These various aspects of patients’ lives can be conceptualized as dimensions of HRQOL. Trends in management of the disease have been changing, with leaders in the field advocating for patient-centred and problem-oriented approaches to managing the disease in patients (Vercellini, 2015). These approaches

include taking the needs and priorities of patients into consideration and offering counselling where necessary (Vercellini, 2015). Management of the disease should therefore be centred on the improvement of QOL in patients. The availability of endometriosis-specific HRQOL measures is therefore a crucial aspect of patient care.

There is a paucity of psychosocial endometriosis research from developing countries such as South Africa (Young et al., 2015). The only endometriosis-specific HRQOL measure, the EHP 30, was developed in the UK. The aim of this thesis was therefore to develop an alternate measure of HRQOL for patients with endometriosis for the South African context.

The research reported on in Section 2 of this chapter is related to QOL and can therefore be conceptualized as domains of HRQOL. The next section introduces the conceptual framework utilized in the study.

2.9 Initial conceptual framework for this study

There are a number of HRQOL conceptual frameworks. The most commonly used HRQOL frameworks were developed by Wilson and Cleary (1995), Ferrans, Zerwic, Wilbur and Larson (2005) and the World Health Organization (2007) (Bakas et al., 2012). The present study used the contextual model proposed by Ashing-Giwa (2005). Ashing-Giwa (2005) argues that HRQOL is subjective and that culture plays an important role in patients' experience of HRQOL. Therefore, the contextual model of HRQOL includes cultural context, socio-ecological context, and healthcare system context in addition to the aspects mentioned above. I chose this model of HRQOL as my initial conceptual framework because it was best suited to my aim, which was to develop a contextual HRQOL measure for patients with endometriosis.

2.9.1 The Contextual Health-related quality of life Model (CHM).

The CHM was developed using HRQOL research that spanned 10 years based on multi-ethnic and socially diverse samples of breast cancer survivors (Ashing-Giwa, 2005). The model was informed by a number of sources, including the biopsychosocial model, the traditional HRQOL model, research with breast cancer survivors, general literature on cancer and cancer survivorship, and psychological and multi-cultural literature. Figure 2.1 consists of a model representing Ashing-Giwa's (2005) contextual model of HRQOL.

Ashing-Giwa's (2005) contextual model consists of a macro/systemic level and an individual level. The macro/systemic level consists of factors such as socio-ecological, cultural and demographic factors and the healthcare system, whereas general health, medical factors, health efficacy and psychological well-being are seen as individual level factors.

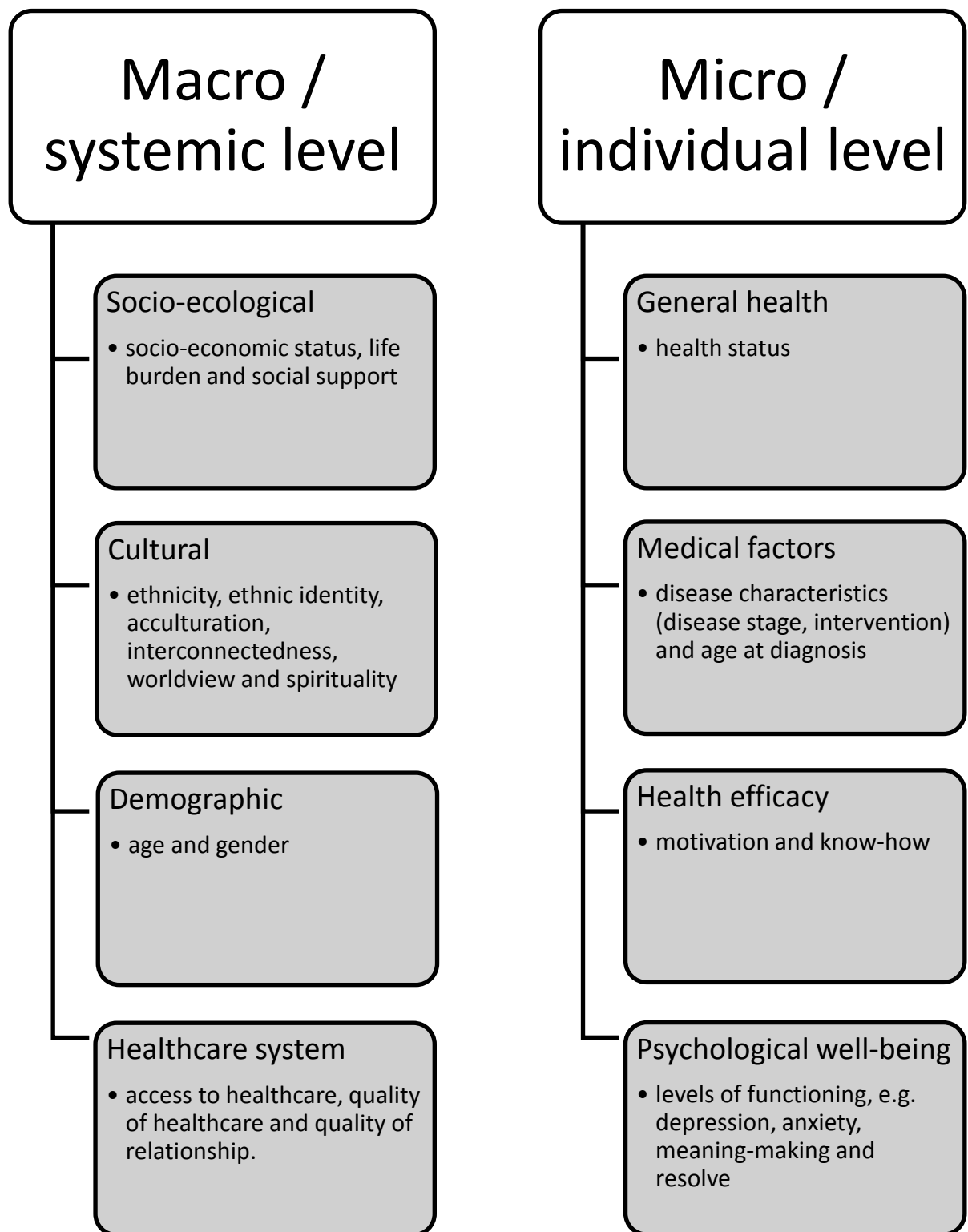
The socio-ecological factors consist of socio-economic status (income, education, and employment), life burden (living situation, neighbourhood character and resources, day-to-day strain) and social support (social and emotional networks). Cultural factors are ethnicity, ethnic identity, acculturation, interconnectedness, worldview and spirituality. Demographic factors include age and gender. Finally, the healthcare system includes components such as access to health care, quality of health care and quality of relationship.

General health comprises of health status, whereas medical factors include cancer characteristics (disease stage, intervention) and age at diagnosis. Health efficacy consists of motivation and know-how (health practices, perceived health efficacy, medical adherence). Psychological well-being refers to levels of functioning and is reflected in levels of depression, anxiety, meaning making and resolve.

Ashing-Giwa and Lim (2008) examined the relationship between variables in the contextual model using structural equation modelling and found that the model provided a

valid conceptualization of HRQOL. The model has been adapted for use by rural cancer survivors (Pedro, 2010). The application of this framework is outlined in Chapter 3.

Figure 2.1 The Contextual model of HRQOL



2.10 Chapter summary

This chapter presented the relevant literature pertaining HRQOL and its measurement. The discussion started off with the conceptual background of HRQOL and the measurement of HRQOL. The chapter continued with information on popular existing measures of HRQOL and outlined their development. The chapter reviewed psychosocial research on endometriosis. The discussion concludes with the introduction of the theoretical framework employed in this study.

Chapter 3

Describing and understanding HRQOL

3.1 Introduction

This chapter provides a brief overview of the research design of the overall study and then outlines the methodology used in the first part of Phase I of the study. The first part of Phase 1 describes and documents the QOL-related experiences in women with endometriosis. The chapter concludes with the results of the first aim and a discussion of these results.

3.2 Method

3.2.1 Research design for the overall study.

The overall aim of this thesis was to develop a HRQOL measure for patients with endometriosis. The choice of research methods was driven by the research question (Biesta, 2010). I employed a sequential mixed-methods research design to develop and validate the measure. The design consisted of an initial qualitative phase, followed by a quantitative phase. Results from the qualitative phase informed the quantitative phase (Creswell, 2009). The qualitative phases consisted of in-depth, individual interviews with patients with endometriosis and consultations with expert panels and patients. During the quantitative phase a battery of measures, including the newly developed measure, was administered to patients with endometriosis. Table 3.1 presents a summary of the research methodology for the study.

Table 3.1

Summary of research design

Phase	Aim	Methodology
1. Qualitative (Development of measure)	To describe and understand the QOL-related experiences in women with endometriosis	<ul style="list-style-type: none"> ▪ Interviews with 25 patients ▪ Thematic analysis
	To construct and refine items for the instrument based on data collected in the first aim	<ul style="list-style-type: none"> ▪ Consultation with psychometric experts ▪ *Item reduction with endometriosis experts ▪ Pilot with 7 patients
2. Quantitative (Validation of measure)	To determine the test reliability, validity and factor structure of the instrument	<ul style="list-style-type: none"> ▪ Administered instrument battery to 200 patients

*Quantitative section embedded in Phase I

3.2.2 Qualitative Phase

I conducted interviews with patients diagnosed with endometriosis to understand the influence of endometriosis on patient HRQOL. Qualitative interviews with patients provide greater insight into the disease experience than expert opinions and literature reviews and are therefore useful in instrument development (Williams et al., 2013). Qualitative research can play a role in ensuring that patient report outcome measures have meaning and are relevant to patients (Lasch et al., 2010). By first conducting qualitative interviews, researchers are able to access local knowledge and develop instruments that are both meaningful and consist of items that are relevant and intelligible to the target population (Hammersley, 1997; Kelle, 2006). For these reasons, I decided that interviews with patients with endometriosis would be an appropriate technique to explore the impact of the disease on the patients' HRQOL.

3.2.3 Research sites

As research in the field of endometriosis in South Africa is new, no sampling frame was available from which to select participants. I therefore decided to approach sites that offer reproductive health services to women to recruit participants from these research sites.

The study initially involved two research sites. The Health Research Ethics Committee (HREC) at Tygerberg Hospital approved the study (please refer to Appendix A).

Obstetrics and Gynaecology Unit, Tygerberg Hospital.

Tygerberg Hospital is a tertiary academic hospital in Cape Town. In 2012, the medical staff at the unit included 18 specialists, 22 registrars, 14 medical officers and 12 interns. These doctors attended to 10 105 obstetrics in-patients, 21 704 obstetrics outpatients; 3 907 gynaecology in-patients; and 16 751 gynaecology outpatients during that year (Western Cape Government, 2013). Fifteen cases of severe endometriosis were reported in 2012 (Western Cape Government, 2013).

In 2014, the medical staff was made up of only eight specialists in addition to 22 registrars, 15 medical officers and 13 interns. The doctors attended to 13 409 obstetric in-patients, 27 541 obstetric outpatients, 17 319 gynaecology out-patients, 8 986 day theatre patients and 636 elective surgery patients (Western Cape Government, 2015). This state-run facility offers healthcare to all, and is usually accessed by those who cannot afford private medical care. The Western Cape Department of Health (WCDOH) granted me permission to conduct the study at Tygerberg hospital (please refer to Appendix B).

Cape Fertility Clinic.

The Cape Fertility Clinic is a private fertility clinic located in Cape Town. The clinic has the largest in-vitro fertilization (IVF) clinic in South Africa, with its own IVF procedure room, laboratory and embryo transfer room. The medical team consisted of five specialists in reproductive medicine, five IVF coordinators, six embryologists, four theatre staff, eight receptionists and a psychologist. The doctors perform 240 surgeries per year and handled 1062 IVF cases in 2013. At the time of this writing, the practice saw on average 80 patients per day (S. Heylen, personal communication, June 23, 2014).

Inclusion of additional research sites.

Six months into the recruitment process no patients had been recruited at Cape Fertility Clinic, mainly due to the unwillingness of administrative support staff to assist with the recruitment process. In addition, even though participants were being recruited at Tygerberg Hospital, it became clear that the site would be unable to provide an adequate number of participants for the study. The decision was taken to add more research sites and to extend the timelines of the study. One additional state hospital (Karl Bremer Hospital) and five private gynaecological practices were added as secondary research sites.

In addition to the inclusion of new sites, the data collection of this phase of the study was extended by 6 months. The HREC granted ethical clearance for the addition of these new research sites (please refer to appendices C and D). In addition, the WCDOH granted permission to access patients at Karl Bremer Hospital (please refer to appendix E). WCDOH approval is not required for private clinics.

3.2.4 Sampling procedure

I used flyers to recruit participants for this phase of the study (please see appendix F). These flyers were placed in doctors' offices and handed to patients by either the doctors, nurses or receptionists. Patients were informed that they could contact me directly or complete a contact permission form (please refer to appendix G) should they wish to receive more information regarding the study. The contact permission forms provided consent from patients for me to contact them. The completed forms were left with receptionists. I visited the sites every three to four weeks to collect contact permission forms and contacted the potential participants based on the information provided.

When I contacted potential participants, I explained to them the nature of the study, its aims and ethical issues. Patients were then asked to consent to an interview, and if they agreed, an appointment was set up at a suitable time and place for the participant.

3.2.5 Data collection

Individual interviews were used to collect data for this phase of the study. Initially I proposed conducting interviews with 30 patients with endometriosis. However, data saturation was reached after 19 interviews. Data saturation occurs when no new concepts or sub-concepts emerge from the data (Strauss & Corbin, 1998). I continued with interviews until the sample consisted of 25 participants to ensure that all the relevant information was captured and no new themes were discovered. Lasch et al. (2010) assert that data produced in qualitative interviews represent the experience being investigated and not the sample. After 25 interviews, I was certain that the interviews represented the HRQOL experience of patients with endometriosis.

The 25 interviews were semi-structured and took place at either my offices, the participants' homes or locations selected by the participants, such as places of employment. The interviews at participants' places of work were conducted in private meeting rooms. Semi-structured interviews are generally organized around a set of pre-determined open-ended questions (DiCicco-Bloom & Crabtree, 2006; Glesne, 2006; Patton, 2002). More questions emerged during the course of the interviews from the dialogue with the interviewees. Semi-structured interviews are the most widely used format of qualitative interview (DiCicco-Bloom & Crabtree, 2006).

An interview schedule was used to guide the interview (please see appendix H). The interview schedule was based on an adapted version of Ashing-Giwa's (2005) contextual HRQOL framework. The interview commenced with my asking participants the following

question: ‘Can you tell me about your experience with endometriosis?’ A further 13 questions on the interview schedule explored participants’ experiences with endometriosis in terms of medical factors, psychological well-being, socio-ecological context, healthcare systems and more.

Rigid interview scripts fail to produce the meaning of experience related to illness (Lasch et al., 2010). Therefore, the questions on the interview schedule were not always asked in the same sequence as indicated on the interview schedule or asked in the exact same way, but were rather adapted to suit the interview conversation. In addition to the questions listed on the schedule, I also made use of follow-up, probing, direct, indirect, specifying and interpreting questions (Kvale, 2007).

I conducted the interviews in either English or Afrikaans, depending on the preference of the participant. The interviewing and coding processes were conducted simultaneously. This approach allowed me to analyse my interviewing skills and adapt the interview questions as required. Initially, interviews were structured according to the schedule and this elicited responses where women spoke of their entire experience with endometriosis from symptoms prior to diagnosis, the process of diagnosis, treatment and HRQOL. The interviews therefore yielded information that described the impact of endometriosis on patients’ HRQOL in a very factual manner. I then made a concerted effort to explore the psychological and emotional aspects associated with living with endometriosis in addition to the impact on HRQOL, resulting in richer and more meaningful interviews.

The interviews ranged between 31 and 84 minutes. All interviews were audio-recorded, with the permission of participants. At the end of the interviews, participants were debriefed about their experience of being interviewed and asked if they required any further information or support. Most participants reported that it was the first time they were able to

speak about the impact the disease had on their lives and that they enjoyed the interview as it provided them with the opportunity to share their experiences with someone who was willing to listen. Some participants requested support and were referred to an organization that arranges peer support for those with endometriosis. Participants received a R50 gift voucher as a token of appreciation for being part of the study. The interviews were transcribed on conclusion of the interview process.

3.2.6 Data analysis

I checked the transcriptions for accuracy and completeness and then entered the transcribed data into the qualitative data management program, Atlas Ti version 7.1.3. Listening to the recordings and checking the interviews allowed me to become immersed in the data. I used thematic analysis to analyse the interviews. The guidelines provided by Braun and Clarke (2006; 2015a; 2015b) were followed to identify and analyse themes within the data.

I analysed the data in the following way:

I first immersed myself in the data by listening to the recorded interviews, reading interview notes and reading the transcriptions. This immersion allowed me to become familiar with the content of the data. Once I was familiar with the data, I generated initial codes. The coding process and interviews occurred in tandem, allowing me to keep track of codes and themes that were generated.

The first five interviews were used to generate an initial codebook. I assigned free codes for the first five interviews. These interviews produced over 300 codes, which were then refined, organized and reduced to 150 codes. At this stage, an independent research psychologist was recruited to code the same five interviews and to develop an independent codebook. We then compared our codes. The interviews were coded very similarly and we

debated the codes that differed until we reached consensus regarding the naming of codes. The agreed-upon codes from the first five interviews then formed the basis of the codebook (please refer to appendix I for the codebook).

I continued coding the remaining interviews using the codebook as a basis for codes, but adding new codes as the need arose. My supervisor checked samples of the coded interviews and made recommendations. The number of codes continued to increase until there were 365 codes. After 19 interviews, no new codes emerged and data saturation had therefore been reached. Data collection subsequently ceased at 25 interviews. Once all 25 interviews had been coded, I checked the coding of each interview and changed codes or added codes where necessary before proceeding onto the next phase. During this process, the number of codes was decreased to 344.

I grouped similar codes together to form overarching themes. Each theme and its corresponding codes and relevant quotations were carefully examined. In so doing, I ensured that the codes and data extracted for each theme formed a coherent pattern and fit meaningfully to the theme, and that each theme reflected the entire dataset accurately. More importantly, the themes reflected contextual HRQOL factors. The analysis produced a number of main themes, each containing smaller sub-themes that reflected the HRQOL in patients with endometriosis.

3.2.7 Trustworthiness

I employed a few strategies to enhance trustworthiness in the data collection and analysis during this phase of the study (Babbie & Mouton, 2001; Birks, 2014; Lincoln & Guba, 1985). In terms of data collection, I received interview training from my supervisor to ensure that I was competent to conduct interviews. Throughout the interviewing process, I reported to my supervisor after each interview and received feedback from him. I made notes

about the interviews and these notes were used during data analysis to ensure that the analysis captured important aspects of the interview. An independent coder was employed to construct the initial codebook. The coder and I produced very similar codes, indicating trustworthiness of data analysis. After all the interviews had been coded, I re-coded all interviews to ensure that no codes had been omitted. The coding was also checked by my supervisor, who inspected samples of the data.

3.2.8 Epistemological stance

My epistemological stance is similar to that of Hammersly (1997) who contends that qualitative and quantitative methods can be combined without adhering to a philosophical view. My opinion is that methodology should be put before epistemology for the sake of pragmatism. This study is a good example of the benefits of mixing qualitative and quantitative methods. To develop a patient report outcome measure that is relevant to patients with endometriosis it was important for me to understand women's experiences living with the illness. The best way for me to understand these experiences was with qualitative interviews. Similarly, the process of item construction, reduction and initial validation of a measure was best executed using a quantitative sub-study. I therefore also concur with Burke Johnson and Onwuegbuzie (2004) that methodological pluralism provides superior results that nomo-method research.

3.2.9 Ethical considerations

The Health Research Ethics Committee (HREC) of Stellenbosch University granted permission for the research and the Western Cape Department of Health granted permission for the research to be conducted in their jurisdiction. Additional sites were only accessed after approval by the HREC.

The nursing and reception staff handling the contact permission forms, individuals responsible for transcription and the independent coder all signed confidentiality agreements. When I initiated contact with potential participants, I informed them that they had a right to decline participation and that the study was independent from the hospital and would not affect their ongoing treatment. I also informed them that the study was confidential and that they would remain anonymous.

Before starting the interview, I reminded participants of their rights with regard to the research and told participants that they may terminate the interview at any time or refuse to answer any question that made them uncomfortable. Patients granted written consent to participate in the interviews (please refer to appendix J). All information containing participants' particulars were carefully stored in my office and pseudonyms were used to ensure their anonymity.

3.3 Results

3.3.1 Description of the sample

The sample in Phase 1 consisted of 25 patients with endometriosis between the ages of 25 and 42 years (average age = 33 years). Fifteen participants indicated their relationship status as married, three as divorced and seven as single. In terms of first language, 19 participants spoke Afrikaans, five participants spoke English and one spoke Xhosa. One participant stated that her highest level of education was completing primary school; four participants stated they had entered high school, but did not complete; 10 participants stated that they completed high school and 10 participants completed tertiary education. A large number of participants did not have any children ($n=12$), while six participants had one child each, another six participants had two children, and one participant had three children. Of the participants, one was a full-time student, five were unemployed, five were employed part-

time and 14 were employed full-time. The household income of participants per annum was generally low, with three participants stating that they did not know their household income. One participant listed her income as less than R5 000, another participant stated that the income was between R5 001 and R20 000, six households earned between R20 000 and R80 000, six participants earned between R80 001-R110 000, another six earned between R200 001-R300 000, and two participants earned more than R300 001.

The majority of participants (n=16) did not know the stage of their endometriosis. One patient was diagnosed with stage three endometriosis and five others were diagnosed as having stage four endometriosis. Seven participants had been diagnosed less than six months prior to the interview, seven participants had been diagnosed between 6 months and a year prior to the interview, three participants had been diagnosed between one and three years prior to the interview and nine had been diagnosed more than three years prior to the interview. In terms of treatment or medical management of endometriosis, 11 participants stated that they were not using any form of treatment, one reported recent surgery, 10 stated they were using contraceptives to control symptoms of endometriosis, two reported taking Dienogest (a hormone) and one participant said she was using alternate therapies. Please refer to Table 3.2 below for a summary of participant characteristics.

Table 3.2

Demographic characteristics of Phase I participants

Description	Number
Age (years)	
Range	25-42
Mean	33
Relationship status	
Single	7

Married	15
Divorced	3
Home language	
Afrikaans	19
English	5
Xhosa	1
Highest level of education	
Completed primary school	1
Started high school but did not complete	4
Completed grade 12	10
Completed tertiary	10
Number of children	
0	12
1	6
2	6
3	1
Employment status	
Student	1
Unemployed	5
Employed (part-time)	5
Employed (full-time)	14
Income (household income per year)	
Does not know	3
Less than R5 000	1
R5 001-R20 000	1
R20 000-R80 000	6
R80 001-R110 000	6
R200 001-R300 000	6
R300 001 and above	2
Time since diagnosis	
Less than 6 months	7
1 year	6
Between 1 and 3 years	3

More than 3 years	9
Disease stage	
Does not know	19
Stage 3	1
Stage 4	5
Treatment	
None	11
Surgery	1
Contraceptives	10
Dienogest	2
Alternate therapies	1

3.3.2 Outline of categories

A total of 10 categories emerged from the data, namely psychological functioning, sexual functioning, financial impact and considerations, healthcare and medical treatment, reproductive functioning, information and knowledge, interpersonal functioning, limited physical functioning, occupational functioning and medical factors.

3.3.3 Medical factors

Two themes emerged from the data that are related to the medical aspects of endometriosis and they were therefore categorized as such. These themes are (1) Somatic features and (2) Characteristics of the menstrual cycle.

3.3.3.1 Somatic features

Participants discussed both the pain that they experienced due to endometriosis and other symptoms such as fatigue, nausea and bloating. Pain and additional symptoms therefore formed two sub-themes that comprised the theme of somatic features.

Pain was the most widely reported symptom of endometriosis. Participants reported experiencing pain at different times during their menstrual cycle. They described both the pain that they experience and the specific body areas where their pain occurred.

Participants stated that their pain was difficult to describe. They used words such as *intense, constant but dull, excruciating, extremely sore, cramping, severe, numbing, sudden, shooting, sharp, stabbing* and *crippling* to describe the pain sensations they experienced. Some participants equated their pain to labour pains, whilst others said that the pain was worse than labour pain. Janine, a 41-year-old woman with endometriosis, reflected this sentiment in the following statement:

You know, it's almost like it's a period pain, but a labour pain which is ten times worse.

Participants furthermore described their pain as intense and that it made them want to *scream, climb walls* or *pull their hair out*. Some participants stated that their pain nauseated them or precipitated in emesis. The following statement by Jody, a woman diagnosed with endometriosis four years prior to the interview, described her pain:

With the pain I mean when I had period cramps without -- and there was no pain killers around I would be climbing the walls with pain, it would be just -- I couldn't function, I couldn't do anything I would be screaming and crying so naturally I would want to be alone, there was nothing else you can do at that time and once the pain killers kicked in usually I just got drowsy and then fell asleep.

Participants stated that the body areas where they most commonly felt pain were the uterus and ovaries. Many participants also reported experiencing pain in their backs, abdomen and rectum. Some participants experienced sciatic pain, which was pain that radiated down their thighs.

Participants stated that at times, they were overwhelmed by pain and they would feel that they could not manage it. When this would happen, participants stated that they would

feel powerless and helpless against endometriosis and would retreat socially and isolate themselves until the pain subsided. Participants would feel forced to live with the pain at times when they are unable to manage it. Many women stated that they hid their pain from other people and endured the pain in silence as they did not want others to know about their illness. Most participants reported that they only disclosed their illness to very few people, such as immediate relatives. They therefore felt compelled to pretend to be well in front of others. Participants also reported that they hid their pain as they did not want to worry family members and did not want to be seen as complaining. In the following statement Janine described how she hid the pain from her daughters:

When I do get home I try to first sort them out, make supper make sure the homework and things are done and then make it not obvious that I'm tired or in pain and then just say I had a long day at work, I'm gonna get early into bed, going to take a bath and get into bed.

The women interviewed also mentioned other symptoms that they thought negatively affected their HRQOL. Common symptoms reported by participants include bloating, nausea or vomiting, lethargy, lack of energy and feeling weak, faint or generally ill. Some participants also reported that they experienced periods of constipation or diarrhoea and a loss of appetite. Painful sexual intercourse is another commonly reported symptom (please refer to section 3.3.6). Women reported recurring fevers and headaches or migraines. Some participants also reported that they did not like others touching their skin at times. Rashieda, a 27-year-old married woman, who stated that she was hoping to conceive at the time of the interview, described her symptoms with the following statement:

Well it's basically just this tiredness, the migraine, the lower back pain, my tummy is never on a level you see if I'm not constipated I've got diarrhoea you see so it goes like that.

The range of symptoms and the intensity of symptoms varied between participants, but all viewed the symptoms as negative contributors to their HRQOL.

3.3.3.2 Characteristics of the menstrual cycle

Participants reported being burdened with many aspects regarding their menstrual cycle. The theme named *menstrual characteristics* consisted of two sub-themes, namely *concerns related to menstruation* and *concerns related to pain and menstruation*.

Participants reported a number of symptoms related to menstruation that caused difficulty or discomfort for them. These symptoms included clotting during menstruation, irregular menstrual cycles, menorrhagia, spotting and prolonged menstruation. Participants stated that their clotting caused worry and anxiety as many reported that they had thought it signalled that something was wrong with their reproductive health. Some participants reported having regular menstrual cycles (i.e. roughly 28 days), and others reported irregular menstrual cycles and prolonged periods of menstruation.

Some participants' menstrual cycles were highly irregular which meant they could not plan activities around them. This concern is addressed in detail in 3.3.3.2. Prolonged menstruation was also problematic for participants, some of whom reported that they menstruated for weeks. Participants stated that the prolonged menstruation was both physically and emotionally draining.

Most participants reported menorrhagia (heavy menstrual bleeding), which affected them in a number of ways. First, participants spent a great deal of time taking care of their feminine hygiene and spent what they considered to be a large amount of money on feminine hygiene products. Some participants reported that the heavy bleeding frequently disturbed their sleep. They also stated that they felt embarrassed when their heavy bleeding resulted in stained clothing. Many of the patients interviewed said that they were concerned about their

heavy bleeding. Another menstrual-related issue for participants was spotting. Some participants reported that they experienced spotting throughout their menstrual cycles. Participants reported that they found spotting inconvenient as it resulted in their feeling as if they were never free of menstruation. Madeline described her menorrhagia and clotting during menstruation in the following account:

So now when the klonte (clots) – literally it's nothing you know you actually get a fright as well because when you get off the toilet and you turn around to flush it you can't help but look or see and it's just its red it's like completely dark red that's how my – and I think for myself am I not bleeding to death here.

The second theme related to menstrual characteristics was related to the pain experienced during participants' menstrual cycle. For some participants, the pain was confined to their menstrual cycles, especially the first two to three days of menstruation. Other participants stated that the pain is intense and would result in their having to stay home and in bed. Participants stated that they would be alone in the privacy of their rooms and relied on large amounts of analgesics to alleviate the pain. Amina, a 36-year-old woman with endometriosis, described the timing of her pain in the following statement:

Okay I don't really have pain outside of my period duration...But the minute when I got my period I would start having pain like immediately.

Other participants stated that they experienced a build-up of pain prior to the onset of menses. For these participants the pain onset usually occurred mid-cycle and would gradually increase in intensity. Participants stated that the pain reached its peak at the beginning of menstruation and then decreased. The duration of pain for these participants was on average two to three weeks per four-week cycle. The following passage from Rashieda's interview describes the cycle of pain that she reported:

Well most of the time I don't have -- it's fine, not most of the time but there is (sic) times when I don't even feel that there's something wrong with me but then out of a month I'll say half of the month I'll be under pain and then I'm undergoing pain and then when it's my periods, close to my periods that is the worse.

Finally, for some participants the pain was chronic and occurred mostly among participants whose menstrual cycles were irregular in length. Some participants stated that they experienced pain every day and relied a great deal on analgesics. The intensity of the pain also changed throughout their menstrual cycles, but they reported a constant presence of pain. Amy, a 31-year-old married woman, described her chronic pain with the following statement:

I'm in pain every day. Sometimes it will be in the morning, sometimes in the afternoon, sometimes at night. Sometimes whole day, especially after I had my period then I will have the full day.

Participants stated that the characteristics mentioned above, namely duration of menstruation, spotting, and menorrhagia were affected their QOL.

3.3.4 Limited physical functioning

The pain and symptoms associated with endometriosis impaired participants' physical functioning. Participants stated that the functions that they were unable to perform due to endometriosis, which ranged from basic physical movement to more complex activities.

Participants reported they were unable to perform simple movements such as bending, lying down, sitting, standing and walking. They stated that being unable to perform these functions severely impacted their mobility. Participants also reported that they were unable to accomplish basic activities such as eating or sleeping because of pain and symptoms

associated with endometriosis. For example, the pain resulted in participants struggling to fall asleep or waking up during the night. Other activities that participants were unable to perform due to endometriosis included caring for themselves (i.e. dressing, bathing, going to toilet), driving, lifting heavy objects or partaking in sports.

Participants stated that the limitations to their physical functioning made them feel restricted and often resulted in their resorting to bed rest. For some, bed rest lasted a few hours at a time and for others it lasted a few days. The following statement by Cathleen illustrates how restricted she felt when she was in pain.

You know it does make me feel like I can't do things and I don't want to... my body feels like it wants to run, wants to walk fast, but I just can't. I feel like I'm trapped sort of.

3.3.5 Psychological functioning

The category Psychological Functioning consisted of three themes. The first theme probed the emotions that patients with endometriosis experienced. The second theme comprised thoughts associated with endometriosis, and the final theme dealt with coping with the disease.

3.3.5.1 Emotions associated with endometriosis

Participants reported that a number of emotions accompanied their endometriosis, such as distress or sadness, moodiness and short temper, anxiety, feeling emotional and uncertain, frustration, hopelessness, helplessness, regret, embarrassment, self-consciousness, low self-esteem and feelings of isolation.

Almost all participants reported feeling distressed or sad, with some going as far as labelling this emotion as depression. Accompanying this feeling of sadness were feelings of isolation, tiredness, uncontrollable crying, loss of appetite and irregular sleeping. A small number of participants were previously diagnosed as having depression and received

psychotherapy and / or medication to treat the depression. At the time of the interviews, none of these participants were receiving any form of treatment for depression. Some participants described their distress or sadness as a ‘darkness’ that would not go away, while others referred to it as a ‘heaviness’ that would not lift. Many participants said that they did not know why they felt sad, while others linked their sadness to their difficulties with trying to conceive. Two participants reported that their sadness and infertility led them to contemplate suicide. Chelsea, a 23-year-old woman diagnosed less than a year prior to the interview, described her sadness with the following statement:

But for a while, I felt like, this deep, deep, deep sadness. I don't know why I feel this way... I feel like I don't have a reason to be sad... it's as if there's this heaviness over me that... It's like there's times in my life where it's not so heavy and then there's other times where it feels like its sucking me in. It feels like I can't overcome it. I can't explain the feeling. But it's just this... To put it more simply, like a dark cloud or something.

Participants reported often feeling ‘moody’ and stated that this moodiness was usually a result of feeling physical pain associated with endometriosis and struggling to manage that pain. Participants stated that their moodiness often resulted in being quick-tempered and expressed impatience and frustration at others. The patients reported that their moodiness was mostly directed at their partners and in some cases at other family members. Participants stated they often regretted their outbursts towards others. Many of the women interviewed stated that their moodiness was uncharacteristic of them and that when they were moody they did not feel like themselves. Emma, a 40-year-old single woman with endometriosis, described her moodiness as follows:

I'm very moody...It's like when my period start, two days before that, don't talk to me. I don't have lus. Just don't talk to me. I don't want anybody around me. I want to go in that little corner of me and just stay there until everything is finished.

Madeline, a 31-year-old mother of two, spoke of regretting her outbursts in the following statement:

But the moment it subsides a bit when it's not horrible for you to handle the pain then you'll go and I was actually very nasty, please forgive me and stuff like that.

A number of participants stated that they were generally anxious but felt that this anxiety was part of their personality and it had existed prior to their diagnosis with endometriosis. Participants also spoke of themselves as being emotional and one participant stated that she experienced panic attacks. She stated that her fear of experiencing a panic attack at work resulted in her resignation from work and subsequent unemployment. Participants also stated that they were anxious because they experienced much uncertainty regarding endometriosis (this concern is addressed in more detail on sections 3. 3.3.12) and because they did not know much about the disease and needed advice or guidelines to assist them to manage the disease. Lauren, a 34-year-old women, diagnosed with endometriosis more than three years prior to the interview, mentioned her anxiety in the following words:

I've always been a very anxious person yes. I get extremely anxious.

Frustration was another common emotion reported by participants. Reasons for frustration among participants varied but participants stated that it was usually due to a combination of aspects of the disease. In most cases participants experienced frustration when they could not manage their pain. Another cause of frustration was the impact of the disease on their daily functioning, their independence, their social functioning and their

interpersonal relationships. The final area that caused frustration for participants was related to healthcare and treatment (please refer to section 3.3.10). The frustration referred to by participants is evident from the following statement by Lauren:

You are partly in pain...I have physically knocked like this (knocks on knees) ... It's basically to ease that pain, but that pain does not go away... That is the wellbeing that you actually get physically. You build up a wall and physically you cannot do anything. It's almost like a, you just want to hit someone to get the pain away. (Translated)

Participants stated that when they were in pain they would limit their social activities, resulting in their feeling isolated. A number of participants stated that while friends and family members offered support they preferred to be alone when in pain. Participants also stated that they felt that no one truly understood what they were going through and that only people with endometriosis would understand. The vast majority of participants stated that they did not know anyone with endometriosis. This was an important observation as participants held the belief that only women with endometriosis could understand their pain. Such a mismatch of belief and experience may have contributed to their feeling socially isolated. Brenda, a 35-year-old divorced student, spoke about her feelings of isolation:

You begin to isolate yourself because you just feel people do not understand what you are going through...You cut yourself off. You do things on your own. I did not socialize a lot. I am not someone who socializes a lot. (Translated)

Participants stated that the pain they experienced left them unable to function or take care of themselves, resulting in feelings of helplessness and hopelessness. Participants often felt helpless when they could not complete simple tasks such as bathing by themselves and required the help of others. Patients dealing with infertility also reported feeling hopeless because of their often lengthy struggles to conceive. Even though participants expressed

hopelessness regarding their inability to conceive, they also indicated a willingness to seek treatment for infertility. Jeanette, a 42-year-old mother of one, referred to her feeling helpless with the following statement:

A person feels helpless. You can't do anything for yourself and you have to ask, bring me a bit of water, give me a sip of tea, do this and do that for me. (Translated)

Participants stated that endometriosis affected the way they felt about themselves. For example, many reported feeling embarrassed and self-conscious and having low self-esteem. Two symptoms of endometriosis in particular resulted in embarrassment for participants, namely menorrhagia and swelling/bloating. Participants stated that the menorrhagia would result in blood on clothing and cause embarrassment, while the bloating made participants appear to be pregnant when they were not. The excessive bleeding made participants highly self-conscious during menstruation. Participants stated that these symptoms negatively affected their self-esteem and caused them to feel self-conscious. Other factors reported by participants that affected their self-esteem included their inability to become pregnant, weight gain, and dyspareunia. Embarrassment due to menorrhagia was expressed in the following statement by Madeline:

More embarrassment towards yourself because if you going to walk in a shopping centre and you going to start bleeding people is going to look at you and you going to feel embarrassed you can't go.

Similarly, Nuraan, a 31-year-old patient diagnosed with endometriosis almost 10 years prior to the interview, spoke about her embarrassment due to bloating. She stated:

Like yesterday it was super swollen because I looked about like six to seven months pregnant and it's quite embarrassing to walk around like that and you know you have no kids, you've not done anything.

3.3.5.2 Thoughts associated with endometriosis

Participants also discussed common thoughts or concerns relating to their experience with the illness. These thoughts included concerns regarding living with chronic pain, concerns about the way in which the disease impacted their womanhood, thoughts about the way that endometriosis made them feel unlike themselves; concerns about limited future prospects, and thoughts related to constantly monitoring their bodies and symptoms.

Many participants regarded endometriosis as a chronic illness and were concerned about living with chronic pain and the impact that this would have on their future. Some participants spoke about how their doctors informed them that endometriosis is a lifelong, chronic illness and that they would have to manage the impact of the illness since there is no cure. The experience of living with a chronic illness combined with the difficulty of managing pain caused great concern among participants. Cathleen, a 35-year-old divorced mother of two, spoke about this concern by saying the following:

You know, so I'm thinking am I always going to have pain because, you know and that I think is the hardest thing to actually live with I would say.

Participants' perceptions of themselves as women were reported as negatively affected by endometriosis. The women in the study reported that endometriosis made them feel like less of a woman and that they compared themselves to other women and felt different to other women. Women reported that issues related to endometriosis such as dyspareunia (painful sexual intercourse), infertility and menstruation in particular were important areas for comparison with other women. Dyspareunia was one aspect of

endometriosis that made participants feel as if they were not good enough as women as they were not able to satisfy their partners sexually. Other women spoke about how infertility made them feel like less of a woman. Participants who experienced dyspareunia or infertility compared themselves to other women and stated that they felt inferior to them. Participants also compared their own menstruation with other women's and regarded their own menstrual characteristics as abnormal and even expressed envy of women whom they thought had painless, normal menses. Carol, a 40-year-old woman who was diagnosed with endometriosis a year prior to being interviewed shared the way in which her sexual dysfunction made her feel about herself in the following statement:

That is why I say I feel that I'm not feminine enough or I don't know how to put it. On a sexual level, I feel that I have a shortcoming because it feels like I could've done more or that I could've been more available at times, because you are in many ways, not just sex, but you are there for each other in many other ways. But then at times when – you know when your husband wants attention or whatever the case may be – because I'm the problem, I will then push him away or tell him – because it makes me feel that I'm driving him away, do you understand? I'm not saying that is the case, but I'm saying this because my marriage went through this.

Similarly, Emma spoke about how not having children made her feel like less of a woman:

And then the other thing is I'm the only one in the family. I've got a sister with three children. My mother had three children. My sister in law, she have [has] two. So what's wrong with me? ... Sometimes I feel like -- at the beginning stage, for me it's like I'm never going to be a mother. I'm not a complete woman if I don't have children.

The participants in the study also stated that endometriosis made them feel unlike themselves and that it restricted them as they wished to be able to do more with their lives, but felt that the disease restricted them. Participants said that the pain and other symptoms would result in their behaving in ways that they thought were out of character. Some participants stated that they felt moody, lacked energy and lacked appetite, which they considered out of character for them. Many participants considered themselves to be independent people who were forced to be dependent on others because of the impact that their endometriosis symptoms had on them. Not feeling like themselves and feeling dependent on others was also a source of frustration for participants. Cathleen spoke about her frustration at not being able to do more in the following statement:

Like I told you my body feels like it wants to run, wants to walk fast, but I just can't. I feel like I'm trapped sort of.

Similarly, Barbara, a 27-year-old women diagnosed with endometriosis three years prior to the interview, mentioned her frustration about losing some independence because of endometriosis. She stated:

I'm a very independent person, I'm a perfectionist, I want to do everything myself, and if I can't, then I'm upset with myself.

Participants also reported that they were preoccupied with monitoring their bodies and symptoms. They stated that they were vigilant of their symptoms and constantly questioned whether their actions would contribute to the impact of the disease. For example, participants reported questioning whether eating a particular food or engaging in a particular activity would result in pain or exacerbate symptoms. In addition, the slightest change in their bodies was cause for concern as participants wondered whether the change was related to

endometriosis or not. Participants also reported being preoccupied with the origins of their disease, as many stated they thought about why they had endometriosis, with some alluding to existential reasons for their illness. Cathleen demonstrated with the following statement her constant questioning with regard to the impact of her actions on her disease progression:

I do (question self). So now I'm telling myself that am I eating properly. Everything I eat, is like, is it going to be harmful to me? Is this going to make the cysts come out more?

3.3.5.3 Coping

A combination of problem-focused and emotion-focused strategies were utilized by participants to manage the impact of the disease and its symptoms on their lives. The problem-focused strategies included engaging in self-management, limiting physical activity, increasing knowledge about endometriosis, scheduling social and work activities around menstrual cycles and relying on social support. The emotion-focused coping strategies included accepting the disease, adopting a positive attitude, engaging in self-talk, mental preparation, and relying on their spirituality. In addition to the coping strategies, participants also shared their struggles in coping with the disease and some stated that they were unable to cope.

Self-management: Self-management was the most frequently used coping strategy reported by participants. Self-management refers to actions taken by participants in order to alleviate the symptoms of endometriosis. It included strategies aimed at alleviating pain and discomfort, such as taking analgesics or other home remedies. Other self-management techniques included certain types of relaxation or stretching activities, adopting positions that eased the pain such as the foetal position and changing their diets. Many participants associated feeling cold with experiencing pain. Therefore, they would keep warm using

layers of clothing and heating aids during menstruation. The following statement by Jeanette explicates this theme:

I did not actually receive treatment for it (symptoms). I managed it myself with Grandpa, Disprin. That is all that alleviated pain.

Limiting physical activity: Many participants reported that during painful periods they would limit their physical activity and schedule work and social activities around their menstrual cycle. Since the pain associated with endometriosis is mostly cyclical in nature participants were able to predict when the pain associated with endometriosis would be better or worse. The cyclical nature of their pain allowed them to plan their social and work activities so that during menstruation they did not have to work and could withdraw socially. During menstruation, participants limited their physical activity to cope with the pain they experienced. The following statement by Cathleen describes her limiting her physical activity:

Because when it was time for me to get my periods I would always make sure that I didn't have to go anywhere.

Finding out more about endometriosis was another important coping strategy. Most women in this study declared that they first heard of endometriosis when they were diagnosed with the disease and that they did not know anyone else with endometriosis. Patients reported that they therefore sought to increase their knowledge of endometriosis to cope with it. Participants reported seeking information from a variety of sources, including books and the internet. In the following statement, Leona describes the benefit of researching endometriosis:

It [researching endometriosis] does (help) in the way that I don't feel that I'm the only one that is struggling with it, the things that I feel and the things that I'm going through, is the things that endometriosis is related to.

The last problem-focused coping strategy used was *relying on emotional support*. Participants often received support from close family members such as their partners, mothers and sisters. Family members often assisted participants by taking on some of their responsibilities in the home such as caring for children, cooking and cleaning or by providing them with analgesics or home remedies to alleviate pain. Participants stated that this helped them as it provided them with the opportunity to rest and care for themselves, without the added pressure of having to care for others.

In terms of emotion-focused strategies, participants stated that *accepting the disease* and *adopting a positive* attitude assisted them in coping with the effects that endometriosis had on their quality of life. Participants stated that they were forced to live with the disease as endometriosis has no cure. They added that they were forced to learn to live with the disease (i.e. accept the disease) and to adopt a positive attitude towards having the disease. The following statement by Leona, a 25-year-old women with endometriosis, explicates this point:

Because doctors have told me that there's not cure for it, so, in that way, it doesn't affect me, because I'm not going to sit in a corner and, ooh I've got endometriosis, I keep on living, I keep on going on. I'm a very, I must admit, I'm a very negative person, but in the endometriosis area in my life, I'm positive.

Leona's statement above also demonstrates a third emotion-focused coping strategy used by women in this study, namely *engaging in self-talk*. Women stated that they would often coach themselves by making self-statements during periods of pain. These statements

were often used to re-assure themselves that they would overcome the pain or to encourage themselves to relax in order to alleviate pain. Self-statements were employed because participants believed that their emotional responses could play a role in mediating pain, meaning that if they were calm or relaxed, they would experience less pain. Participants reported mentally preparing themselves for pain by using self-statements. They also stated that they mentally prepared themselves for pain and used self-statements to do so.

The last emotion-focused coping strategy was named *evoking spirituality*. Participants reported using several methods of relying on their spirituality such as using prayer or religious counselling. Prayer was commonly used and included participants praying for themselves or others praying for participants. Participants also reported seeking counsel from people associated with religious institutions such as churches. Some women reported that they often questioned God, spoke to God or read from the Bible to seek relief from pain. This theme is demonstrated by the following statement from Lauren, a 34-year-old single mother:

That moment when you're alone, you have to talk to God and then I do that and then I read verses from the Bible and I pray and ask the Lord to just relieve pain. (translated)

Finally, some participants shared their struggle to cope or inability to cope with the impact of the disease on their quality of life. Some participants stated that they were bed-ridden for the first couple days of their period and viewed this as an inability to cope. Others mentioned that the pain was severe and that they did not know what action to take to alleviate the pain and that this constitutes inability. The inability to cope also resulted in frustration amongst participants and this is evident from the statement below made by Melissa, a 33-year-old mother of two.

I don't think I really coped...especially when I got my period. The first two or three days I'll be in bed.

The three themes relating to psychological functioning (emotions, thoughts and coping) provide insight into the impact of endometriosis on patient's psychology. As is evident, psychological functioning is an important aspect of living with endometriosis.

3.3.6 Sexual functioning

The fourth area of participants' lives affected by endometriosis was their sexual functioning. Dyspareunia (painful sexual intercourse) is a symptom of endometriosis and almost all participants in this study reported were afflicted with this symptom. The themes associated with sexual functioning were: (1) Pain during sexual intercourse, (2) Pain after sexual intercourse, (3) Fear of sexual intercourse, (4) Avoiding sexual intercourse, (5) Avoiding relationships due to painful intercourse, (6) Negative impact on relationships, (7) Negative emotional consequences as a result of dyspareunia and (7) Improved sexual functioning as a result of treatment.

Participants reported experiencing pain during sexual intercourse and some stated that the pain would continue after. For some participants, the pain would last a couple of hours after intercourse, but others stated that the pain lasted an entire day after intercourse. One woman stated that the pain was so severe the next day that she struggled to walk. The pain associated with sexual intercourse resulted in a fear of sexual intercourse among some participants and subsequent avoidance of sex by many women. The fear associated with intercourse is evident in the following account by Courtney, a 33-year-old mother of two:

I was very scared of sex. (Translated)

Participants engaged in various actions to avoid having sexual intercourse with partners due to the pain experienced during intercourse and the subsequent fear. Some women reported that they their told partners about the pain, but others engaged in activities such as working late or "keeping busy" in order to avoid intercourse. Some participants stated

that their partners would question them regarding their avoidance of sexual intercourse.

Cathleen shared how she avoided sexual intercourse with her partner in the statement below:

Because of me not wanting to have sex I actually worked late hours so that I'd get home and he was sleeping already.

Dyspareunia negatively affected participants' relationships with their partners. In many cases participants stated that their partners were supportive and understanding, but other participants stated that their partners questioned them as to why they did not want to engage in sexual relations. Some women reported that their partners suspected that it was because they were being unfaithful. A few women stated that their sexual dysfunction contributed significantly to the breakdown of their relationships. One cited her sexual dysfunction as a reason for her husband's infidelity and their divorce. Other women stated that they were willing to divorce their partners as they felt unable to satisfy them sexually. The impact of dyspareunia on relationships is demonstrated with the following quotation from the interview with Cathleen:

You know so and trying to explain to him but I, it's painful you know how, but he doesn't understand because you are my wife and I want us to be intimate and you're always running away, so I would work late to avoid that. So and one day he just didn't come home, so you know and I think that is one thing also with relationships I have now that I want to avoid, but also how do you explain all the time that you have pain.

While most participants reportedly avoided sexual intercourse, some reported avoiding relationships altogether due to poor sexual functioning. These participants stated that they learnt from past relationships that relationships were difficult because of dyspareunia and they therefore found it easier to not be in a relationship. However, one

participant stated that she often thought about being in a relationship and wanted a partner, but was afraid of pain during sexual intercourse.

Participants also reported that their compromised sexual functioning resulted in negative emotional experiences. Many reported feeling inadequate as women as they were unable to satisfy their partners sexually. Participants reported that being unable to satisfy their partners negatively affected their self-esteem. The emotional consequences of dyspareunia are evident from the following statement by Gina, a 32-year-old married woman:

I do not feel satisfied, because I did not satisfy myself and I just did it because he wanted to and it's almost like he doesn't understand that I'm in pain. But alright, sometimes he asked me must he stop, am I in a lot of pain and then I tell him 'yes I am in pain' but I don't want to tell him no.

Finally, some participants reported that treatment, surgery in particular, improved their sexual functioning. Participants who had surgery said that the pain associated with sexual intercourse improved following surgery. However, some stated that as time progressed after surgery, the dyspareunia returned.

Sexual functioning is an important domain in the HRQOL in women with endometriosis. The findings above indicate that the impact of pain during sexual intercourse was a major concern for women in the study and that it affected their self-esteem and relationships.

3.3.7 Reproductive functioning

This category consisted of the following 11 themes: Constantly thinking about fertility, Strong desire to have a child, Impact of fertility on relationships, Frustration that doctors have not addressed fertility, Long wait for fertility treatment, Sacrificing having

children for symptom relief, Seeking alternatives to become parents, Side effects / complications of fertility treatment, Stigma associated with childlessness, Psychological and social aspects of infertility, and No treatment for those trying to conceive.

Infertility was a major concern for participants, both for those who were actively trying to conceive and for those who were not yet trying to conceive, but who want to in future. Some participants stated that when they were diagnosed with endometriosis their doctors advised them to fall pregnant as soon as possible, but at the same time the doctors told patients that it would be difficult for them to conceive. Both participants who were actively trying to conceive and those who planned to conceive in future reported that they constantly thought about their fertility. Some women stated that they were still in their teens when they were diagnosed with endometriosis and reported that they constantly thought about whether they would be able to conceive and felt pressured to conceive as soon as possible. Many participants reported a strong desire to have a child and felt added pressure to reproduce due to the presence of endometriosis. This pressure is reflected in the following statement by Leona, a 25-year-old women in a relationship:

I wish to have a baby one day, but the doctor told me that your chances of having children is, at that stage when they, they diagnosed me with it, when I was 16, the doctor told me, you've got less than two per cent chance of falling pregnant and his next words were, the older you get, the less the chance is for you to get pregnant. So, I mean, I've been living with it for ten years, so then I've got this thing in my head, at that stage it was two per cent or less than two per cent, what's the chances for me to get pregnant now.

Another participant stated that she was diagnosed with endometriosis at the age of 17 and was told by her doctor that conception would be very difficult for her. She stated that this information was a turning point in her life, and that since then she focused all her efforts on

becoming pregnant. She stated that had it not been for her diagnosis with endometriosis, she probably would not have gotten married as early in her life as she did.

Most participants reported a strong desire to have a child of their own. Some were trying to conceive around the time of participating in this study and others indicated an intention to conceive in the future. Participants stated that their ability to conceive was important to them as they viewed pregnancy and childbirth as essential aspects of womanhood. This is evident in the following statement by Leona, who was not yet ready to start a family at the time of the interview, but was still concerned with her fertility:

And then the other thing for me is the doctor say, ja you will be able to have babies and then one day when I want to start a family, that's the biggest issue for me, in this whole concept of endometriosis, is for me to dream, dream, dream I want to have a baby one day, and then I get there, and then they tell me, oh sorry, you can't have children.

According to the participants who were struggling to conceive, their infertility had a negative impact on their relationship with their husbands. Even though most women reported that their partners were supportive, they felt that infertility was an added pressure on their relationship. One woman stated that her inability to conceive was a contributing factor to her divorce, while another participant stated that if she could not conceive with her husband that she would allow him to take another wife. Another participant, Megan, stated that her husband had given her an ultimatum. She stated that she had no wish to receive IVF as she found it intrusive. However, her husband indicated that if she did not, he would leave the relationship. This reportedly made her feel emotionally distressed in the relationship as can be seen from the statement below by this 28-year-old married woman:

I'm very heartbroken and to me at the moment to be honest with you, I don't feel like being with him. Because he said that. Because he says he's making all the sacrifices and I'm

not willing to make this one for him. Just by going through with that. So I told him I'll do it once but I won't do it again. I won't go because you lose -- it's like you lose hope. Because you go all the time and it's expensive .

The women interviewed also spoke about their thoughts and feelings related to their infertility. Participants reported feeling frustrated with both their inability to conceive and their feeling that doctors are not doing enough to assist them to fall pregnant. Participants also stated that their infertility made them feel sad, broken and hopeless and that they did not feel like “real” women. One woman stated that she thought that her infertility was punishment from God. Participants also felt insecure, as is evident in the statement below by Evelyn:

I was in a long relationship then as well and then you have this fear at the back of your mind where you start getting to your early-20's, what if he leaves me for another woman because I can't give him a child? Then you start thinking about that and so the whole cycle starts.

According to participants, their inability to conceive affected their social interactions. Many reported that they did not like being around people with children as it was a constant reminder of their infertility. Participants therefore avoided going to events such as children's birthday parties or baby showers. For more information on this please refer to section 3.3.8 – Interpersonal functioning. Most women did not share their struggle with infertility with others and rather opted to manage this aspect of their lives in silence with their partners. Even though participants reported that they did not share their infertility with others, the absence of children made people question and discuss their childless status. Some participants reported feeling stigmatized by their childlessness, as can be seen in the following statement by Madeline:

It's like oh she can't have children you know things like that. People react differently towards it.

Participants also spoke of their thoughts and experiences related to infertility treatment. Those in the public healthcare system spoke of waiting long periods of time for fertility treatment. Participants discussed the side effects of fertility treatment such as the effect of hormones. Participants who were trying to conceive also stated that they struggled with symptoms related to endometriosis. There is no treatment to manage endometriosis for those trying to conceive, as most treatment options are contraceptive in nature. Other participants stated that they sacrificed having children for symptom relief. This theme is explicated in the following statement by Emma:

I was speaking to one of my sermons and I told them this is the situation and he said go for the loop it's going to help you and I believe him that it's going to help me but I won't have any children. It's going to make my pain better, but it's not going to make me a mother.

Finally, after prolonged struggles with infertility, some participants reported seeking alternative methods to become parents, such as adoption. Amina discussed her efforts to become a mother in the following statement:

Like after the ten years of our marriage when we decided okay we are going to apply for adoption.

For a number of participants, their ability to have children was the biggest problem associated with endometriosis. The impact of fertility issues affected the sense of womanhood and was reported as a major source of frustration and psychological distress. Reproductive functioning also influenced other domains such as relationships and interpersonal functioning and was considered an important contributor to QOL.

3.3.8 Interpersonal functioning

The category named interpersonal functioning consists of the ways in which endometriosis impacted on participants' engagement and relationships with others. This category consists of four themes, namely 1) feelings and interactions with others, 2) impact on social activities, 3) interpersonal relationships and 4) social support. Each of these themes contains a number of sub-themes, which are discussed below.

The first theme deals with participants' general feelings and interactions with other individuals. Participants stated that their experience of pain and symptoms often left them unable to do much for themselves and that during times of pain they became dependent on others, especially their partners and immediate family members. Many participants reported feeling that they were a burden to others, but did not want to be. Participants also reported that they did not want to be pitied by people. The following statement by Jeanette exemplifies these feelings of dependency on others:

It feels like, you are helpless, you can do nothing for yourself, or you have to ask, bring me some water, or give me a sip of tea, do this for me, open the covers (of the bed), do this and this. And, that is tiring.

When it came to disclosure, participants stated that they were selective about whom they disclosed their illness to. In general, participants disclosed their illness to very few people, in most cases only their partners and immediate family members such as parents or siblings. Selective disclosure is evident in the following statement by Cathleen:

I also feel, I don't like people, I don't want people to pity me and I don't want, do you know what I mean. So I feel that, like only my very close friends know and yet they also don't know what that is. It's not like they know cancer is. Do you know what I'm saying?

Some participants stated that they did not tell their friends and family about their condition as they considered it a private matter. When participants did disclose their illness it was mostly to their partners or people whom they thought might know of the disease, such as older women or people in the health profession such as nursing or physiotherapy. A few participants reported that they disclosed their illness to others easily and that this disclosure helped them cope with the disease. Disclosure allowed others to understand why they were in pain and behaved in certain ways, such as not wanting to leave their home. The women who were trying to conceive at the time of this study reported that they disclosed their illness to fewer people than women who were not actively trying to conceive.

Participants also stated that when they reported their pain to others, they were told it was normal, which frustrated them. Rashieda expressed her frustration with the following statement:

You know it frustrates me if people say oh you've got period pain and so why's your face hanging so but it's not like that, it's anything but.

Participants also stated that they found others intrusive when they enquired about their health and fertility. Women stated that this intrusiveness made them more determined not to discuss their diagnosis. The lack of general awareness regarding endometriosis was also reported to be a barrier to disclosing the illness to others. This lack of awareness is discussed in section 3.2.12 – information and knowledge. Participants reported that when they told others that they had been diagnosed with endometriosis, they were usually asked many questions regarding their condition, which they either did not want to or could not explain. Participants reported that questions about their health made them feel uncomfortable and that they did not tell others that they had endometriosis to avoid discomfort. Lack of awareness

regarding endometriosis was discussed under a previous theme and is described in the following statement by Cathleen:

No they don't, they don't and everyone's saying do you have cancer? Is it okay? Are you, you know and no I don't and I don't offer information, you know, like okay, is there anything we can help with, you know. No, no, I'm fine. You know because also and I am a very private person. I don't like people to know.

Underlying these feelings was a belief that only patients with endometriosis would truly understand what they were going through. Participants stated that they felt isolated and that people did not understand their experience. Barbara relayed her frustration with the following statement when people who did not have endometriosis gave her advice:

Sometimes when I have pain, they will tell me, no it will get better and I understand what you're going through but no one will understand what, what a person is going through, if they have endometriosis.

The second theme describes the impact of endometriosis on participants' social activities. Participants discussed the ways in which endometriosis affected their social lives. For most participants, during times of pain they would withdraw from social activities. A few participants, however, reported that they would attend social activities despite being in pain, but that their pain hampered their social interaction during these activities. In the following statement by Rashieda, she told me about her experience when she attended a social event despite being in pain.

If I'm going to have my periods I'd prefer to be at home but sometimes I would push, I would force myself to go...I would just sit.

As is evident in the above statement, participants who left their homes when in pain did not interact freely and felt restricted. These women stated that they focused on not moving and on managing their pain rather than their social interactions. Participants stated that when they withdrew from social activity due to pain they would become quiet and had no wish to interact with others. Participants said that they wanted to be alone and not be bothered so that they could focus on alleviating their pain. A few participants stated that they had outgoing personalities, but that when they were in pain, they would withdraw and become introverted. Many participants described their pain as being so intense that they would want to “climb the walls” of their rooms. Others described their isolation as being in a bubble. Participants also stated that they felt as though they were missing out when they were forced to socially withdraw. Janine discussed these feelings in the following statement:

(I feel) Definitely lonely because if I listen to my friends, some of friends going out and doing things with their kids or just in general then there are a lot of days that I feel lonely, most days but some days I'm okay with it and just some days it gets me down completely.

In addition to the pain, participants also stated that their moodiness and sadness contributed to their social withdrawal as they felt that they were bad company. In the following statement, Emma reflected on the impact her mood has on her willingness to interact with others:

Yes. Because if there is pain with that, even if I don't have my periods, I'm not very good company.

The third theme deals with relationships between participants and their friends, partners and family members. Most participants stated that they did not tell their friends that they had been diagnosed with endometriosis. However, some participants who informed their

friends of their diagnosis stated that they did not feel adequately supported by them. These participants stated that their friends did not understand why they were ill so often or why they could not go out and socialize. Some participants stated that their friends did not demonstrate compassion for symptoms such as pain and lethargy. Others stated they saw less of their friends or that they had lost friends because of endometriosis. Participants also struggled to decide if they should tell people that they had endometriosis out of fear that it would negatively influence the relationship. This notion is explicated by the following statement by Barbara:

I have friends that I actually lost because I can't socialize, I can't go with them, and then I've met new people, and then I just thought maybe I must tell them about my problem. I mean maybe they will understand, maybe they will stay my friends, but it's also not nice telling people about your private life.

Participants reported that endometriosis contributed negatively to their relationships with their partners. A number of participants reported conflict and difficulty within relationships due to their having endometriosis. The painful sexual intercourse experienced by participants and the infertility caused major struggles in some participants' relationships. Participant also reported that these factors led them to feel insecure in their relationships and that they compared themselves to other women and felt inadequate as partners. Two participants stated that their partners were unfaithful and attributed their relationship breakdown mainly to sexual dysfunction and infertility. On the other hand, a couple of participants reported that their partners were concerned that they were being unfaithful because they did not show sexual interest in their partners.

A few participants reported that their partners did not understand their pain and symptoms and that this also caused conflict in their relationships. Most participants admitted

that their moodiness contributed to difficulty in their relationships. Participants stated that their partners were the people who they interacted with the most and in many cases partners were the only people who knew about the pain that they were experiencing. Many participants acknowledged that their proximity to their partners and partners' knowledge of their health resulted in their directing their aggression at their partners. Many women stated that they regretted the way they treated their partners when they were in pain. Amy discussed her relationship with her partner by saying:

I will get home I will be in pain. I will go to the kitchen, I will cook food, I'll do everything I have to do. I will tell him I'm in severe pain. He won't help me in any way. He will go to bed tonight and he would still expect me to have intercourse with him.

Some participants stated that their difficulties in previous relationships due to endometriosis resulted in their choosing not get involved in a romantic relationship. As was previously discussed, one of the main concerns of participants related to the sexual functioning.

Participants also reported that endometriosis affected them as mothers, which in turn affected their relationships with their children. They felt that their children had to see the symptoms of endometriosis frequently. Participants stated that their children did not understand why their mothers were often in pain and could not take care of or play with them. Women reported that their children became anxious when they saw their mothers sick. Participants stated that they were unable to enjoy motherhood because of their endometriosis and that they tried to hide their pain from their children. Many participants reported that they could not care for their children when they were in pain and that their children took care of them when they reported pain. Some participants also stated that they would express anger at their children when in pain. Participants experienced feelings of guilt in relation to their

interaction with their children. Valerie, a 34-year-old mother of three discussed the impact that her illness had on her children with the following statement:

Yes, my children as well actually, the older ones, the two, because when I'm in so much pain, then they don't know which way to go, they also ask, 'mommy can we help, what can we do, my husband also looks like someone who's been traumatized, because he also asks me, if I can help you, if I can carry the pain with you, then I'll do it, stuff like that.

The last theme deals with social support. This theme overlaps with the coping strategy named 'relying on emotional support'. For the vast majority of participants their partners were their main source of support. These participants described their partners as being understanding, patient and supportive. Participants stated that their partners would care for them when they were in pain by providing them with analgesics, heating aids and massages. Partners also provided support by taking care of household chores and children to allow their wives time to rest. At times when participants wanted to be alone, their supportive partners gave them space.

Participants who shared their diagnosis with family often received support from their families. Mothers in particular were reported to be sources of support and would care for their daughters when they were in pain. Participants stated that they had disclosed their endometriosis to their mothers as they thought that their mothers were knowledgeable regarding 'women's issues'. Some participants stated that their mothers could tell when they were in pain and that they did not have to disclose pain and others stated that their mothers regularly asked them about their health. When they were in pain, their mothers would take care of them, which allowed them to bond with their mothers. Some participants stated that their mothers also suffered from menstrual pain when they were younger and therefore understood their pain. As some participants' mothers also experienced painful menstruation,

they told their daughters that these symptoms were normal. Participants reported that they also received support from other family members. These family members offered support by helping participants with domestic tasks and childcare and providing them with analgesics. Family members also illustrated concern by enquiring about participants' health. However, family members often realized that ultimately there was nothing that they could do to help the patients with endometriosis. Janine described the help provided by her mother in the following statement:

My mom will sometimes phone or she will just rock up and say I mustn't make supper because I can't stand long at the stove or whatever, she will come and she will maybe just bring supper or they will maybe do my washing for me.

For some participants, friends were a source of support. Participants stated that their friends demonstrated support for them by visiting them in hospital, praying for them, sending messages of support, and assisting them in their homes when they were unable to perform certain tasks like shopping or caring for their children. One participant who was a student stated that her friends would bring her notes from class so that she would not miss out on learning. The following statement by Leona illustrates how friends were a source of support:

They are a very good support network for me. The people who know about that, and who visited me in the hospital, kind of seen what I've been going through, no, I have a really good support group.

The earlier theme of coping discussed sources of support for participants in this study. However, many participants also reported instances where they felt that they lacked support. In these cases, participants reported that their partners and other close family members did not understand the severity of their pain and thought that they were over-reacting or faking

their pain. This was distressing for participants. Brenda, a 35-year-old divorced woman, discussed non-support in her statement below.

Especially when you lay there and you have so much pain and people do not understand. In particular, the two years that I was married, my husband definitely didn't understand and that affected my self-confidence a lot that he didn't understand at all.

Participants stated that they valued the concern and assistance from family members, but some thought that their family members were not supportive or understanding. Some family members did not understand why participants were always in pain and while they would encourage participants to seek help, participants interpreted this encouragement negatively.

A few participants reported that they sought emotional support from other patients with endometriosis or other gynaecological diseases as they thought that they could empathize better than those who did not have endometriosis or similar diseases. Knowing someone else with a similar illness made participants feel less alone. Evelyn discussed the comfort she felt when hearing about other people with endometriosis or similar conditions in the following statement:

You're not the only one, the only crazy fool, and you start questioning yourself, maybe it's in my mind, maybe it's not real. It helps bring a lot of info home when you start saying okay maybe I can get better, maybe I can heal and chatting to other people I think it lightens the situation as well. It's not so heavy and it's not just your cross to bear.

Some participants said that they read blogs of patients with endometriosis and that it helped them to understand their illness and to feel less isolated. However, most participants

did not know anyone with endometriosis and stated that they would like the support of other women who experienced what they were experiencing.

In summary, interpersonal functioning was identified as an important part of QOL. It was evident that patients with endometriosis in this study limited their interactions with others, especially when they struggled to cope with their symptoms. This limited interaction also contributed to patients feeling isolated in their experiences.

3.3.9 Occupational functioning

Participants discussed the impact that endometriosis had on their ability to work and their experiences in their work environments. The women stated that endometriosis negatively affected their work and work aspirations. They discussed the ways in which they managed interpersonal aspects of the illness, such as disclosure and treatment by colleagues. Participants also shared how they managed the disease at work and the challenges that they faced. The category was named “occupational functioning” and consisted of the following nine themes: Negative impact on schooling, Negative impact at work, Absenteeism due to illness, Fear of losing employment, Feeling pressured to work, Going to work despite pain, Limited aspirations, Able to talk about endometriosis at work, Difficulty discussing symptoms with men.

Many of the women interviewed discussed the ways in which endometriosis negatively affected their work and education. One participant was a student and spoke about missing several classes because of the pain. Participants reported that they felt pressured to work as their families relied on their income. In some cases, the women stated that they were the sole or main breadwinner in their homes. For these participants their employment was a constant worry when their symptoms related to endometriosis affected their ability to work.

Most of the participants who were working stated that they were regularly absent from work due to pain. Some of these women stated that they had exhausted their allotted sick leave for the year. In addition to monthly menstrual pain, which required participants to take leave, participants also stated that surgery had required them to use up to two weeks of sick leave. A number of participants were forced to take unpaid leave, which had further implications for their cost of living. Amina discussed the challenges she faced with regard to functioning at work in the following statement:

My type of work is no work, no pay so obviously if I don't go to work I don't get paid but the things is what happens is now I've got this backlog because now I've got to finish the work.

Some women reported having difficulty at work when colleagues or employers were unsympathetic to their pain. Participants also stated that the pain made it difficult for them to complete their work as they were physically unable to cope with the pain and were unable to concentrate on their work at times. Participants who had desk jobs stated that they struggled with sitting at their desk when they were in pain. Participants who had more physically demanding work struggled even more as they were unable to perform certain tasks. For example, Nuraan, a 31-year-old nanny, stated that she was unable to play with the children whom she looked after. Many participants reported that they struggled to go to work, but that they worked despite their pain. In the following statement, Amina discussed her process to prepare for work on mornings when she experiences pain:

If I have to go and work I would get up like four in the morning, crawl to the bathroom my husband would get me something to eat, I could take the tablets which will only take effect in another two or three hours if I can actually go to work.

Some participants stated that they went to work despite experiencing pain and did not want the pain to affect their ability to work. A number of participants reported that they tried to hide their pain from colleagues but that the colleagues noticed their pain. Most participants stated that they were unable to work when they were in pain. One participant stated that she could not work for two years because of her pain. Another participant stated that she resigned because she was unable to cope with her work because of her illness. Participants also reported that they feared they would lose their jobs because of time spent away from work due to endometriosis. In the following statement, Janine refers to her two years of unemployment after her diagnosis with endometriosis:

At the time (when diagnosed) I was told I won't be able to work again. I will be able to maybe do a desk job and then after my first operation after being diagnosed I was at home for two years and affected my whole life completely.

Participants stated that living with endometriosis limited their career aspirations. A couple of participants stated that they wanted to further their level of education, but were reluctant to do so because they were concerned that their symptoms of endometriosis would negatively impact their studies by causing them to miss classes due to feeling ill. Women who were employed at the time of the interviews and who claimed to have understanding and sympathetic employers stated that while they wished to further their careers they were hesitant to leave their place of work, as they were concerned that future employers may not be sympathetic to their condition. For these women this meant better career prospects and in many cases, better income or benefits were out of reach. This sentiment of limited career aspirations is expressed in the following statement by Janine:

I think currently I feel that I am stranded here I think I'm in a comfort zone. Because I know I have endometriosis and I don't know if another place or company will be so understanding.

Participants reported that colleagues and employers played an important role in their experience of the disease. Participants with supportive colleagues and employers reported that their occupational functioning was better than participants who did not have supportive colleagues and employers. Disclosure of illness to colleagues and participants was highly subjective. Some participants refused to disclose their diagnosis of endometriosis to colleagues. The reasons participants gave for not disclosing their illness to their colleagues included the discomfort in disclosing to male employers, difficulty discussing symptoms with males in the workplace, and a lack of awareness regarding endometriosis among their colleagues.

Other participants reported that they were comfortable disclosing their illness to colleagues. These participants reported that they thought that disclosure helped them cope and made it easier for colleagues as well. For example, participants stated that they would tell colleagues how to treat them or provide assistance when they were in pain. Carol spoke about telling her colleagues about her condition in the following way:

So, I informed them (colleagues) that when I'm like this, rather just leave me alone, speak to me about work stuff, what you know you have to tell me that concerns my work and that's it, I'll tell you yes or – but I'm not going to have a conversation, that is the understanding we have here at work. (translated)

A large number of participants stated that their colleagues provided support when they needed it. Actions such as not disturbing participants when they were in pain, encouraging participants to rest, providing analgesics and expressing sympathy or concern to participants

were interpreted as support. One participant stated that her employer sought information on endometriosis and then shared this information with the participant, which she interpreted as support. Janine shared with me how her colleagues supported her:

So I think that and like here at work people will do small things like for instance like if they know I'm in pain then they will get me a hot water bottle or they will do whatever or bring me a chocolate just to make me feel better. It's sounds so stupid now but it's important it helps actually, that people understand but a lot of people don't understand the illness so.

Other participants stated that their employers were not sympathetic to their experience with endometriosis, making their occupational functioning difficult. Some participants stated that their employers and colleagues did not recognize endometriosis as an illness and simply stated that pain during menstruation was normal. Employers therefore did not understand why participants took leave often or were in pain. Participants reported that their employers thought they were faking their symptoms. This negative experience at work can be seen in the following statement by Evelyn:

Well they think that you're faking it. You don't look like you're sick, you're not coughing, and you don't have spots all over your body. It's just like, oh well she calling in a sick today, she didn't feel like going to work. Which is concerning.

Work is essential to most participants, as they need the income. However, endometriosis affected their ability to work and their interactions with others in their workplace. Occupational functioning was therefore seen as a domain in HRQOL.

3.3.10 Healthcare and treatment

The category named “Healthcare and treatment” consisted of two themes, namely healthcare and treatment. Healthcare refers primarily to patients’ experience of the healthcare

system, whereas treatment refers to the range of treatment options available to patients and other treatment-related aspects that participants viewed as important. The category consists of seven codes, namely Satisfaction with information provided by healthcare professionals, Communication with healthcare professionals, Satisfaction with medical care, Healthcare professionals normalizing symptoms, Long wait for treatment, Long wait for diagnosis and Restricted access to analgesics.

3.3.10.1 Healthcare as theme

Participants reported varying reactions to receipt of their diagnosis from their healthcare providers (i.e. doctors and nurses). Some participants stated that they were unhappy with the information that they received, as doctors did not adequately explain the nature of their condition to them. Information was important to participants as most women stated that they had never heard of endometriosis prior to their diagnosis. Some participants reported that their doctors were unable to answer questions that participants posed to them regarding aspects of endometriosis, for example, identifying an optimal eating plan and elucidating the association between endometriosis and cancer. Other participants stated that they felt doctors did not know enough about endometriosis and were therefore unable to provide information to patients. Dissatisfaction regarding information provided by healthcare workers is explicated in the following statement by Madeline:

And so basically he didn't explain to me what endometriosis was, he was just explaining to me how he was going to do the procedure (referring to surgery).

Other participants reported that they were satisfied with the information that they received from healthcare professionals, stating that their doctors were well-informed and were able to explain the physiological aspects of the disease to them. Some participants stated

that doctors sketched the disease on paper, which was useful to them. Satisfaction with healthcare providers is demonstrated in the following statement by Rashieda:

This is the nicest thing that happened - when I went to Tygerberg the first time they (doctors and nurses) gave me like a diagram of the uterus and I think we did that in high school, like they showed me and they surround it where all this is happening.

Participants spoke about their communication with healthcare providers, in particular the barriers they experienced when communicating with doctors. These barriers were attributed to both the patients and the healthcare professionals. Participants expressed difficulty in describing their symptoms to doctors as they could not find the words to explain their symptoms and pain. Patients also stated that they avoided asking doctors questions as they felt that they would appear ignorant. One participant said that the doctor provided too much information at once and that she was unable to understand him. Other patients stated that they felt doctors did not understand what patients needed and were too busy attending to other patients to engage in discussions with them. Megan, a 28-year-old mother of one, mentioned in the following statement that she thought endometriosis was a new disease about which doctors knew very little:

It's when you ask questions it's almost like they (doctors) also don't really know what's going on because it seems like it's (endometriosis) new.

Satisfaction with medical care was also of importance to participants and mediated their experience with endometriosis. Many participants stated that they were happy with the care that they received from healthcare practitioners. They reported satisfaction with the way their doctors had examined them and described the doctors as *nice, friendly, helpful* and *supportive*. Some participants stated that their doctors' demeanour put them at ease. Many women reported satisfaction with the care they received from the doctors and that a few

doctors even gave them their personal phone numbers and responded to their messages. In public health settings in South Africa, patients do not see the same doctor at each visit, but rather see whichever doctor is on call. Therefore, participants usually receive treatment from different doctors at different visits. Participants expressed frustration with this aspect of the healthcare system. Two patients reported that doctors at state hospitals arranged for them to be treated by the same doctor at each visit. They viewed this as doctors going beyond their call of duty to care for their patients. Satisfaction with medical care is evident in the following statement by Megan:

The doctors I had was very nice...with everything that they did and she [doctor] knows I'm not a fan of pain. Because she was there actually yesterday and she promised me there will be no pain. We [doctor] will try to be as comfortable. But even the nurses and the doctors in [hospital] itself. They're awesome.

While many participants reported satisfaction with medical care, a large number of participants stated they were dissatisfied with medical care. These patients stated that they received impersonal care and that doctors were dismissive of them and in some cases patients felt that their dignity was impugned. Many participants, irrespective of whether they received medical care at private or state facilities, reported that the care they experienced was impersonal. Patients reported feeling frustrated by the medical care that they received. Their frustration related to their struggle to convince doctors to listen to them or provide them with access to a certain type of treatment. Participants stated that they were also frustrated when they were forced to consult with new doctors at each visit to state hospitals as it meant that they were required to explain their story and symptoms again. Participants reported feeling frustrated when different doctors gave them conflicting advice and recommended different treatments, leaving patients feeling uncertain about the best course of action. Participants reported that they were also dissatisfied that doctors and nurses normalized their symptoms

and made them feel that they were complaining for no reason or that the pain was “inside their heads”. Patients’ dissatisfaction with medical care is evident in the following account by Evelyn, a 38-year-old patient with endometriosis who sought treatment at private healthcare facilities:

It’s (medical care) been very negative, it’s not nurturing, it’s not caring. It’s not trying to fix a problem. I’m generalizing now, but a lot of professionals, in my experience, they don’t seem to have any empathy. They don’t care. You can explain a situation to them but you often wonder if they’re actually listening to you or just hearing me, and have already made their own diagnosis before.

Participants stated that they experienced long waiting times for diagnosis and treatment. Some participants reported having to wait up to a year for surgery to diagnose or treat endometriosis from the time that doctors suspected the presence of endometriosis. Women who sought fertility treatment also reported having to wait for treatment, which caused frustration for them and their partners. Prior to diagnoses, patients reported that they often sought healthcare from several places and were referred to other healthcare professionals or practices by doctors. Many participants reported that they were diagnosed and treated for recurrent urinary tract infections for lengthy periods of time and therefore felt that they were misdiagnosed. Participants stated that diagnosis offered a sense of relief for them and that receiving a diagnosis earlier than when they did would have positively affected their experience in relation to the disease. Participants also stated that they were not offered pain relief while awaiting surgery or treatment and other participants relied heavily on analgesics, which they reported as ineffective. Courtney spoke of seeking healthcare in the following statement:

I went to the doctor for probably a year straight, and then the doctor will give me a letter to go to the gynae (gynecologist) and then the gynae will discharge me and then when I have pain again, then I just go again – I went to the doctor regularly.

Participants also shared their difficulty with regard to gaining access to analgesics. For some participants, over-the-counter analgesics were ineffective and some participants reported that they experienced severe pain and required hospitalization as they could not manage the pain themselves. Patients who received treatment for the pain in hospital stated that they did not receive medication to take home to manage the pain when they were home. As patients did not have analgesics to treat pain at home, it meant that patients had to return to hospital for pain relief when the pain recurred. The participants using the new hormone (Dienogest) treatment available for the management of endometriosis also stated that the medication was not available at all pharmacies and that patients were required to order the medication beforehand. The logistical difficulty of access to the medication combined with the high cost of the medication made this new medication unfeasible for participants. Jeanette described her efforts to seek pain relief in the following statement:

I get pain killers for that moment. Like, I would go in now, then I would get the pain at that moment, that pill at the day hospital, then I'll drink it now, if the pain comes again, then I'll just go in again to fetch that pill, they don't give it to me.

3.3.10.2 Treatment.

Participants reported using a number of treatments to manage their endometriosis such as analgesics, contraceptive medication, hormonal medication and surgery. The women spoke about the side effects of these various treatment options, such as nausea, weight gain, headaches and hot flushes. Participants stated that the side effects associated with treatment also affected their well-being and functionality. Participants also spoke about medical

treatment as being ineffective and their resulting dissatisfaction with the medical and surgical treatments. Evelyn spoke as follows about her dissatisfaction with medical treatment:

I would be taking a whole box of Myprodol plus Buscopan plus Grandpa plus everything on top of that and it still wouldn't even take away half the pain. It got to a point where nothing was actually working anymore, I had prescribed medication, I had suppositories and eventually I thought I was going to die, my kidneys are going to pack up, my body is going to pack up.

Participants also voiced their dissatisfaction with the limited treatment options available to them. Some participants requested certain treatment options that they were denied by healthcare providers. Other participants stated that they were not provided with options, but were forced to accept treatment that the doctor deemed appropriate. Dissatisfaction with treatment options is illustrated in the following statement by Carol, who was given contraceptive treatment without being asked if it was what she wanted and without being presented with treatment alternatives:

And the nurse came and then the nurse gave me the injection and I asked her what injection is this, and she told me this is just a contraception injection. And the thing for me is I feel that I have a choice, the choice is mine.

A few participants stated that they were refused treatment such as intrauterine contraceptive devices (IUD) and hysterectomies, and that this resulted in feelings of frustration as they thought that these treatments would relieve their pain and ameliorate their symptoms. While some of these refusals were viewed as valid by the participants themselves (for example in patients who were too young to have hysterectomies), the refusal of treatment continued to cause unhappiness in patients. Leona, a 25-year-old women diagnosed with endometriosis ten years prior to the interview discussed her struggle to get an IUD inserted.

The doctors who helped me, there were some doctors, my last visit before the day she inserted the Mirena, was not that good because the one doctor that saw me before they inserted the Mirena, she didn't want to insert the Mirena, she told me that it's not necessary for me to get that and this and that and what, what.

Many participants reported positive changes as a result of medical treatment. Surgery in particular was reported by patients to have resulted in symptom relief for periods as long as two years. The improvement of symptoms affected participants in many areas of their lives, such as their social functioning, occupational functioning, relationships and sexual functioning. Anna Marie, a 33-year-old woman who was diagnosed with endometriosis a year prior to the interview, discussed the positive changes in her life following hormonal treatment in the following statement:

I have discomfort, little bit sometimes but I don't have that pain where I have to lie down. So the Visanne (treatment) is helping quite a lot because I don't have that severe pain where I can't do nothing or I have to lie down or I have to rest, or something like that.

Healthcare and treatment were regarded as important aspects of HRQOL in the sample. For participants the type of care and information that they received from doctors were associated with QOL. The type of treatment and access to treatment was also central in managing the effect that symptoms had on participants' QOL.

3.3.11 Financial considerations and impact

Participants reported that endometriosis had a considerable effect on their financial resources. This category consisted of five themes, namely the Cost of treatment, Cost considerations in planning treatment, Financial impact of endometriosis, Associated costs and Rejection from medical insurance.

The first theme, namely treatment cost, was viewed as negatively contributing to HRQOL in participants who stated that these costs placed strain on their financial resources. Most participants stated that they relied heavily on analgesics to manage the pain associated with endometriosis. For some participants the pain was cyclical and for others it was chronic, meaning that they required analgesics throughout their menstrual cycle. Many participants stated that they struggled to afford analgesics due to their limited financial resources and that paying for analgesics meant that they would use money earmarked for other spending. One woman spoke of how she would tolerate the pain until she had been paid and could then afford analgesics. Patients also reported struggling to afford contraceptive medication meant to manage endometriosis. Other patients stated that they were recommended a new hormone that was expensive. Some participants reported buying the medication despite the cost. Others simply stated that they could not afford the medication prescribed and therefore had to endure the pain associated with endometriosis. Surgery was also costly for patients. The cost of surgery in the public health sector is determined on a sliding scale and participants reported having to pay between R2000 and R13 000 for surgery, which they struggled to afford. Carol referred to the high cost of treatment in the following statement:

Let me tell you, okay, they always say for your health, you should either cut somewhere to get something done – understand? So, I'll say, remember, I am alone, I only have my income and I have to be responsible for everything. I rent a place, I have to travel to work, I'm responsible for everything and with my income, you cover everything and then there isn't much left, do you understand what I mean? So I'll say I feel those expenses - I should probably not say this but perhaps there were people who actually tried to help, but I felt that I didn't really receive any help.

The second theme, namely cost considerations in planning treatment, refers to the considerations that both doctors and patients make when planning treatment for

endometriosis. As previously mentioned, the cost of treatment was reported by participants as an important factor and participants stated that they would use treatment when they could afford to do so. Consequently, if a patient could not afford treatment at a particular time, the treatment was deferred to a time at which the patient would be able to afford it.

In addition, the public healthcare system operates with limited financial resources, making diagnosis and treatment of endometriosis difficult as surgery is necessary for diagnosis. Participants who sought care at state facilities reported that they often waited long periods for a diagnostic laparoscopy and for the surgery required to treat endometriosis. Participants stated that they thought doctors were more concerned with costs associated with treatments than with treating patients. One participant, Carol, felt very strongly that her level of income determined treatment and that she was discouraged from having surgery because she did not fall into the correct income bracket. Carol discussed how she felt when doctors told her that she that she could not afford surgery because of her income level in the following statement:

Let me tell you how I felt, I'll say I felt that because I couldn't afford what should've actually been done, I wasn't helped, that's how they made me feel, do you understand what I'm saying? That's how I see it, perhaps I could be wrong, I'm not saying it is like that, but that is how they made me feel.

The third theme was named “financial impact of endometriosis”. Participants stated that endometriosis affected them financially in a number of ways. The cost of treatment often resulted in their being forced to use money earmarked for their household spending. Participants stated that this re-allocation of financial resources created difficulty in their day-to-day lives. Participants also stated that endometriosis affected their ability to earn an income. Some women stated that they were unable to work due to ill health (i.e. they resigned

from employment or did not feel well enough to seek permanent employment). Other participants stated that they did not get paid for days that they did not work, either because their sick leave was already used or because they were contracted workers who were only paid for the hours that they worked. Participants who were contract workers also stated that they did not receive benefits such as medical insurance and pension, which added further financial pressure. Another participant stated that her income was limited by the disease as she felt forced to take a job that paid far less than what she previously earned. The limited income security left some participants concerned about taking care of their children's financial needs in future. The financial impact of endometriosis can be seen in the following statement by Janine, a 41-year-old divorced mother of two:

Before I got ill I know I earned much more money than what I'm earning now. I had to seriously work up my way to earn a good salary here...I feel there are times like I don't have medical aid, like the only benefits it's like your pension fund that they have and housing maybe, not really but I feel if I had to work somewhere else.

In addition to treatment-related costs for endometriosis, participants discussed other associated costs not related to treatment. Participants reported having menorrhagia and prolonged menstruation and therefore purchasing large amounts of tampons and sanitary towels each month. A few participants with very limited household income said that they struggled to afford this. This theme is explicated in the following statement by Madeline:

So ja basically but the tampons are working out much more that's a lot of money the tampons so obviously ja and obviously you have to have the pads as well because night times I normally use the pads...I think I worked out the one day that I basically spent R300 on tampons and pads if not more.

The final theme deals with medical insurance. One participant spoke about her struggle to attain healthcare insurance. Despite completing the necessary paperwork and meeting the qualifying criteria, she was told that her diagnosis with endometriosis made it difficult for her to gain access to healthcare insurance. Participants also spoke about the limited funds provided by healthcare insurance and the need for them to pay extra despite having insurance. The following statement by Rashieda is an exemplar of this theme:

I even applied for medical aid at work ... on the form medical form so they ask you do you know of any conditions and there was something about the cyst and I tick yes, I'm honest about it, it's a cyst. And then I was waiting for feedback and they didn't want to assist me... Probably because they don't cover for that (endometriosis) or they know it can go on long, so I left it there and so I have to go through the government hospitals.

Challenges associated with obtaining optimal treatment due to financial constraints were regarded by participants as an important aspect of HRQOL. This is because optimal treatment could play a role in reducing symptoms and therefore improve physical functioning and a number of other HRQOL domains.

3.3.12 Information and knowledge regarding endometriosis

Information regarding endometriosis was important to participants and played a role in mediating their experience of the disease. This category consisted of nine themes namely, 1) The empowering nature of diagnosis, 2) The novelty of endometriosis before diagnosis, 3) Conducting research into the nature of endometriosis, 4) Negotiating conflicting information about endometriosis, 4) Inability to process information, 5) Having insufficient information to explain to others, 6) Lack of public information on endometriosis, 7) Concern regarding links between endometriosis and cancer, and 8) The need for additional information and 9) Guidelines on endometriosis.

Almost all the participants stated that they had never heard of endometriosis prior to diagnosis. Participants also stated that they felt empowered when they were diagnosed, as giving the cluster of symptoms a name validated their experience. Diagnosis meant that they could tell others that they had a condition and therefore the symptoms they were reporting were real. Participants also stated that diagnosis gave them peace of mind, knowing that they were not exaggerating or inventing their symptoms. Some participants stated that being diagnosed allowed them to deal with their symptoms better than before diagnosis. For other patients, the diagnosis of endometriosis was reassuring as they were concerned that they might have cancer. The relief that diagnosis offered participants is evident in the following statement by Evelyn:

I think it (diagnosis) helped. Knowing why I had such bad pain which was different to other people. Why I sometimes had to miss two days of school, and I couldn't go to school or I'd miss a test or something like that. It almost gave me peace of mind knowing that this is what's wrong and we can try and help you fix it. So I wouldn't have to suffer with it, it wasn't just we don't know, it's just how it is – deal with it.

As participants reported that they did not know about endometriosis prior to diagnosis and received basic information regarding the disease upon diagnosis, some stated that they resorted to researching endometriosis for themselves to learn about the disease. Some women reported that while their doctors tried to explain endometriosis to them, they could not process the information relayed to them at the time of diagnosis, as they were overwhelmed. Participants stated that they sought information from sources such as family members whom they thought might know about the disease, books, and internet sources such as Google and YouTube. A few participants stated that they sought information and support from online forums dealing with endometriosis and infertility. One of the challenges reported by participants in sifting through the information was that participants came across large

amounts of conflicting information that left them feeling uncertain pertaining aspects of the disease, such as the aetiology and prognosis of endometrioses. Participants also asked me for information regarding the disease and stated that part of their motivation for participating in the study was to find out more about endometriosis. Participants stated that they were concerned regarding the relationship, if any, between endometriosis and cancer. Some women stated that the information on online sources regarding the relationship between endometriosis and cancer were not consistent and that this uncertainty caused them to feel anxious. The uncertainty regarding information available on the internet can be seen in the following statement by Leona:

If you go on to the internet and read on certain sites, the different sites tell you different things. There is sites that tell you that if you don't get it removed, in a few years time it can turn into cancer. And you can, it can cause infertility and then there's other sites that tell you that it doesn't cause cancer and you can still get pregnant, things like that.

Similarly, Anna Marie discussed the way in which the information she received via the internet helped her:

Ja this is me, this is what's happening to me all the symptoms, all this -- because I went to google and there was one lady, I watched the clip on You Tube where the lady she describes because she's actually busy with also some type of research and then she was like explaining how it will affect your lifestyle and all of these things and it was like she was talking about me so I understood more.

Even though participants stated that they learned about endometriosis or understood the disease, they did not tell others about their endometriosis as they felt that they did not know enough about endometriosis to explain the disease to others. Therefore, a lack of

confidence in their knowledge of endometriosis was a barrier to disclosing their illness to others. This theme is explicated in the following declaration by Courtney:

I couldn't even spell the word. And that is probably also why I have never told anyone else about it, because I didn't even know what it was, what caused it and where it comes from and all that.

Participants also stated that a lack of public awareness regarding endometriosis was another barrier to disclosing their illness to others. Endometriosis is not a well-known disease and that if they told people that they had been diagnosed with endometriosis, they would not know what the illness was and would ask questions regarding the disease, which participants were unwilling to answer. Rashieda conveyed her reluctance to disclose her illness to others because of the lack of public awareness regarding endometriosis in the following statement:

It's no use of giving someone a name they don't know what it is, you understand. Like my line managers they know but they still don't really know what it is, you understand? If they ask me what it is then I'll say not it's just - or what does it cause no it cause pelvic pain and so on, then they also see it as periods, you understand.

Even though participants reported researching endometriosis for themselves, almost all stated that they required additional information regarding endometriosis, such as the explanations of the causes or contributing factors of the disease and guidelines for managing the disease. Participants experienced uncertainty about their condition and stated that they had many unanswered questions. Participants also stated that the provision of guidelines for managing the disease would ease their anxiety. The usefulness of guidelines for patients with endometriosis is evident in the following statement by Cathleen:

So, yes, maybe if I had more answers then you know you'd be at peace. You'd feel okay, this is what I'm allowed to be doing and even if I do this, that and the other it's not the reason why I have pain. Do you know what I'm saying? So if I knew that maybe then life will be better.

Knowledge about endometriosis was considered an important part of endometriosis management and as a part of QOL in the sample.

3.4 Discussion

The data from the qualitative interviews described the impact that endometriosis had on patients' QOL. More specifically, it outlined 10 categories that patients with endometriosis regarded as affecting their HRQOL. Many of these categories were reported by patients with endometriosis in other studies (Cox, Henderson, Anderson et al., 2003; Culley et al., 2013; Denny, 2004; Gao et al., 2006; Gilmour et al., 2008; Jones et al., 2004; Marques et al., 2004; Siedentopf et al., 2008). Figure 3.1 at the end of the chapter represents a conceptual map of the themes and their relationships with one another.

As anticipated, women reported marked impairment to their HRQOL because of their endometriosis. *Medical factors* (e.g. pain and symptoms) was a core category, as pain and symptoms impacted on other categories. For example, women reported that the pain and symptoms influenced their *Interpersonal functioning*, *Sexual functioning*, *Occupational functioning* and more. A number of categories were also inter-related. For example, sexual dysfunction (i.e. *Sexual functioning*) often influenced romantic relationships with partners (*Interpersonal functioning*). Women who were struggling to conceive (*Reproductive functioning*) often associated this category with challenges regarding *interpersonal* and *psychological functioning*. Therefore, while each category represents a specific dimension of

HRQOL affected by endometriosis, these categories do not exist in isolation and were integrally related to one another.

Most of the categories that emerged from this study were consistent with the Contextual Model of HRQOL (Ashing-Giwa, 2005). Aspects of Ashing-Giwa's socio-ecological dimension are expressed in this study. For example, interpersonal functioning, psychological functioning, occupational functioning and financial considerations and impact can be viewed as categories of Ashing-Giwa's socio-ecological dimension. Five other dimensions of the Contextual Model, (i.e. the healthcare system, general health, medical factors, health efficacy and psychological well-being) matched the categories that emerged from the data that emerged in this study, namely healthcare and treatment, limited physical activity, medical factors, information and knowledge and psychological functioning, respectively. Furthermore, two unique categories emerged from this study in comparison with the original Contextual Model, namely sexual functioning and reproductive functioning. Finally, two dimensions of the Contextual Model (demographic characteristics and culture) did not emerge in the current study. Overall, the contextual model provided a comprehensive framework for me to explore HRQOL in women with endometriosis. However, the model required adaptation.

In addition to the conceptual fit of the data from this phase of the study to the Contextual Model, the data from Phase I contain many parallels to other endometriosis findings. The findings of this phase of the study are in keeping with those of other studies, namely that pain and symptoms impacted HRQOL (Nnoaham et al., 2011; Souza et al., 2011; Tripoli et al., 2011; Facchin et al., 2015; Marques et al., 2004). Furthermore, the finding that physical functioning is regularly negatively affected in women with endometriosis is in line with previous research (Jones et al., 2004; Moradi et al., 2014; Petrelluzzi et al., 2008).

Even though studies regarding the relationship between endometriosis and depression/depressive symptoms provide conflicting findings with regard to the relationship between these two variables (Eriksen et al., 2008; Lorencatto et al., 2006; Sepulcri & Amaral; 2009; Siedentopf et al., 2008), the patients in the present study reported feeling symptoms of distress or anxiety. However, these symptoms were not assessed or screened for in this phase of the study. Other emotions reported in the current study, such as moodiness, frustration, self-consciousness, etc., were also found in women with endometriosis in other studies (Cox, Henderson, Andersen et al., 2003; Gilmour et al., 2004; Melis et al., 2014; Whelan, 2003).

As dyspareunia is a primary symptom of endometriosis, it was not surprising that patients reported poor sexual functioning. While most studies exploring sexual dysfunction in women with endometriosis have done so quantitatively (Di Donato et al., 2014; Ferrero et al., 2005; Fritzer et al., 2013; LoFrisco, 2011; Rossi et al., 2008), the findings of this phase of the study provide deeper insight into the experience of sexual dysfunction and its consequences for women, e.g. contribution to relationship breakdown.

The finding that endometriosis had a negative impact on romantic and interpersonal relationships among participants in this study was similar to earlier research, which found that patients with endometriosis reported feeling isolated (Culley et al., 2013; Jones et al., 2004; Mellado et al., 2016), reported limiting their social interaction (Cox, Henderson, Andersen et al., 2003; Denny, 2004a; Jones et al., 2004a; Gilmour et al., 2008) and reported that their interpersonal relationships (including romantic relationships) were challenging (Butt & Chesla, 2007; Cox, Henderson, Andersen et al., 2003; Fernandez et al., 2006; Huntington & Gilmour, 2005; Moradi et al., 2014).

Infertility was a major concern for many participants in this study, as in other studies (Denny, 2009; Jones et al., 2004; Markovic et al., 2008). While research in Australia found

that doctors prioritized fertility treatment in women with endometriosis (Young et al., 2016), the opposite was found in my study, where women often reported frustration when doctors ignored their desire to conceive. Some aspects of fertility highlighted in this study (e.g. complications with fertility treatment, sacrificing having children for symptom relief) have not been explored in prior research.

Women in this study reported that endometriosis influenced their experiences at work, as other studies report (Denny, 2004; Gilmour et al., 2008; Seear, 2009b). Unwillingness to disclose a diagnosis of endometriosis to employers and colleagues has been found in other studies (Gilmour et al., 2008). Women in this study, as in other studies, reported experiencing a lack of compassion and understanding for their condition in the workplace (Seear, 2009b). The impact of endometriosis on women's employment was a major concern for women in this study, although the current study did not measure loss of work productivity as other research has (Klein et al., 2014; Nnoaham et al., 2011). Women in this study spoke about the practical ways in which endometriosis affected their work, including not having enough sick leave available and not being able to earn an income due to their illness.

Financial aspects associated with endometriosis were emphasized by participants in this study, as they had impacted on other domains of HRQOL, such as access to healthcare. Very little research has been conducted on the financial impact of endometriosis on patients' lives from patients' perspectives (Klein et al., 2014; Simoens et al., 2012). The findings of the current study highlight areas regarding financial aspects that have not been described in detail in previous research, such as cost considerations in planning treatment, the associated costs and rejection from medical insurance. These themes may well have emerged due to the context of the research. As previously mentioned, most endometriosis research has been conducted in high income countries (Young et al., 2015) where financial aspects may not be an issue for patients with endometriosis as it was for patients in this study.

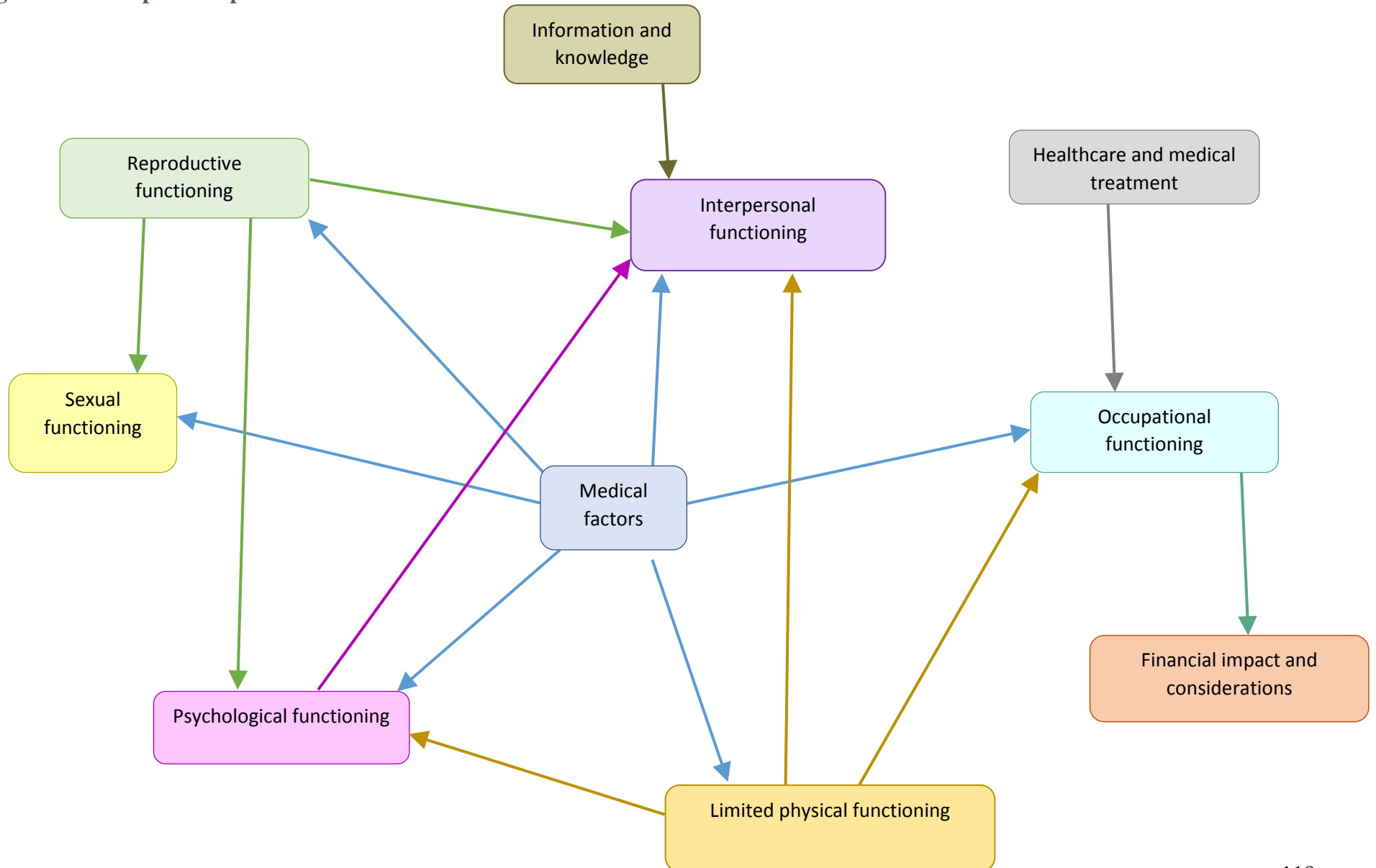
Healthcare was another key category reported by women in this study that has not been fully explored in previous research. While other research has documented the delay in diagnosis and treatment (Ballard et al., 2006; Cox, Henderson, Andersen et al., 2003; Denny, 2004a; Denny, 2004b; Hadfield et al., 1996; Husby et al., 2003; Markovic et al., 2008), this delay has been largely attributed to doctors and patients (Ballard et al., 2006; Manderson et al., 2008; Seear, 2009b). These causes of delayed diagnosis did emerge in this study, but delays in diagnosis was mostly attributed to structural issues within the healthcare system, which is quite disconcerting. For many women seeking healthcare at state facilities, doctors acknowledged their need for surgical diagnosis and treatment. However, due to financial constraints it took months for patients with endometriosis to receive adequate care. These sorts of constraints have not been reported in other studies and are unique to this sample and context.

Information regarding endometriosis is not widely available for women in South Africa. Women in this study knew very little about endometriosis and most were dissatisfied with the amount and accuracy of information that they received from healthcare professionals. In the current study, as in other research (Ballard et al., 2006), participants reported feeling relieved when they were diagnosed with endometriosis, as some feared that they had cancer. This concern is valid as research indicates that women with endometriosis are at a higher risk than the general female population to develop certain types of ovarian cancers and certain types of breast cancers (Giudice & Kao, 2004; Gourley, 2012; Vlahos, Kalampokas, & Fotiou, 2010). While women in international studies reported using online support groups to learn more about endometriosis (Shoebotham & Coulson, 2016), very few women in this study researched endometriosis to learn more about the condition. Women in the current study may not have felt empowered enough or may not have known how to access information that they needed.

3.5 Summary of Phase 1

The aim of this phase of the study was to gain first-hand knowledge of the domains of HRQOL affected in patients with endometriosis. I asked participants questions based on the Contextual Model of HRQOL about the impact of endometriosis on their lives. Participants spoke about the ways in which endometriosis affected their HRQOL. Analysis of the data revealed a total of 10 categories representing participants' HRQOL experiences. The categories consisted of themes, which in turn consisted of individual codes. The codes from Phase 1 of the study were used to create items for the measure. The next chapter describes the process of item construction for a HRQOL measure for patients with endometriosis.

Figure 3.1 Conceptual map of themes



Chapter 4

Item development

4.1 Introduction

The second aim of the study was to construct items for the measure based on the data that were collected and analysed in pursuit of the first aim. This chapter details the process of item development for the HRQOL measure for women with endometriosis. The process consisted of five steps and the methodology and results of each step are reported in this chapter.

4.2 Research design in item analysis

The process of item development formed part of the qualitative phase. Most of the steps in the process involved discussions with experts. However, this qualitative phase contained an embedded quantitative component (Plano Clark & Ivankova, 2016), where experts were asked to rate items in terms of relevance. Even though the qualitative phase contained a quantitative component, the research design of the study is still classified as a sequential mixed methods design, as the quantitative phase developed from the qualitative phase (Creswell, 2010). A mixed methods design is particularly suited to the development of measures (Onwuegbuzie, Bustamante, & Nelson, 2010).

4.3 Methodology for measure development

The previous chapter documents the interviews with women with endometriosis. These interviews contained the personal accounts of the impact of endometriosis on patients' HRQOL. The open-ended nature of interviews allowed me to explore HRQOL for participants. I then used this qualitative data collected to construct the items for the measure. In addition to constructing items for the measure, I also had to decide on a format for the

measure. I therefore selected the response format prior to constructing items. After a pool of items was constructed, the items underwent a number of reviews aimed at assessing the phrasing of items and reducing the number of items. The process included (1) selecting a response format, (2) construction of a pool of items, (3) review of measure format and item pool, (4) review of relevance of each item, and (5) piloting the measure. Each of these steps are recommended by DeVellis (2012) and Foxcroft and Roodt (2005, 2012). The following sections detail the steps in the construction of the measure.

4.3.1 Step 1: Selecting a response format

There were several tasks involved in selecting the response format of the measure.

These tasks included the following:

1. Deciding on the response format: In keeping with the generally accepted format for self-report measures, I chose to construct the measure using a Likert scale containing a stem and five response options. The response options were a gradation of the extent to which the item affected their HRQOL.

2. Deciding on the response period: The measure asks patients to reflect on their HRQOL over a specified period of time and to respond to the questions with that period in mind. The appropriate timeframe had to be sufficient to produce results that would give a good indication of the effect of endometriosis on HRQOL, without introducing recall bias (Martin, 2005). Eight weeks was selected as the timeframe in consultation with experts in the field of psychometry and gynaecology, since it spans two menstrual cycles. Respondents were subsequently instructed to relate their answers to the past eight weeks.

3. Deciding on the appropriate item stem: I also decided on the appropriate stem that grounded all statements in the measure. The stem was “Because of my endometriosis...”

I consulted with experts in the field of endometriosis and psychometry to make these decisions. The first version of the measure contained the following statement: “Below is a list of statements that other people with endometriosis have said affects their quality of life. Please indicate if these statements related to your experience of endometriosis affects your quality of life. Please circle or mark one number per line to indicate your response as it applies to the past 8 weeks.” The response format was a Likert scale, containing five response options ranging from “not at all” to “very much”.

4.3.2 Step 2: Construction of a pool of items

The codes developed in the first part of the study were used to develop the items for the measure. Items were phrased in the form of a statement and required participants to select a response from the options. For example, the code “lethargy” became the item “I did not have energy”. The initial item pool consisted of 314 items, each representing codes produced from analysis of the qualitative interviews.

4.3.3 Step 3: Review of measure format and item pool

I sought the expertise of two psychologists with experience in scale development to review the items. Both psychologists were female and had obtained doctoral degrees in the field of instrument development and adaptation. The review took place over the course of three meetings. The first meeting was held at the psychology department at Stellenbosch University and was attended by both reviewers. Subsequent meetings were held individually with each reviewer at her office.

I asked reviewers to evaluate each item on the measure for its clarity, conciseness and to provide feedback on item wording and ambiguity (DeVellis, 2012). I also asked them to identify any awkwardly phrased or confusing items and to provide suggestions to improve items. I asked reviewers to provide input on how specific items should be worded and to

identify redundant items. When presented with redundant items, I asked reviewers to select the best item. For some items, reviewers reached consensus fairly quickly. Other items were debated and I ultimately decided on the final wording and choice of items.

I reduced the item pool from 314 items to 184 items following the first review panel. The original item pool consisted of a number of items that assessed symptoms related to endometriosis. When conceptualizing the content of the scale, I decided to exclude the specific symptoms and instead focus on the impact that those symptoms had on HRQOL. For example, items such as “I have rectal pain”, “I experience bloating” and “I am constipated” were not included in the measure, as my focus was on the way in which symptoms affected participants’ day to day living, rather than the symptoms themselves.

Similarly, each coping strategy was not listed, but rather the perceived ability to cope was assessed. The reviewers provided input on the instructions for completing the measure, the tense of items and the stem that applied to each item.

4.3.4 Step 4: Review of relevance of each item

Once items were revised, the next step was to reduce the number of items contained in the measure. I consulted with five experts in the field of endometriosis to reduce the number of items on the scale. The experts included three medical fertility specialists who frequently worked with women diagnosed with endometriosis and two expert patients. The expert patients were women who have endometriosis but who also offered support to other women with the disease. The patient experts could therefore assess items based on their own experience of the disease and their knowledge of the impact that endometriosis has on other women’s HRQOL. I relied on experts in this part of the study because, according to DeVellis (2012), using experts in a particular field maximizes content validity of instruments.

Each expert assessed the measure independently. I met with each expert and explained the purpose of the review and the review process to them. One expert resided outside the Western Cape and I provided this information to her telephonically. The experts were provided with a definition of the construct HRQOL and were asked to rate the relevance on each item. The response options were as follows: “not at all relevant to patients’ experience of endometriosis”; “a little bit relevant to patients’ experience of endometriosis”; “moderately relevant to patients’ experience of endometriosis” and “highly relevant to patients’ experience of endometriosis”. The experts assessed each item on the measure using these response options.

In the absence of a suitable inter-rater statistic, I decided to score each item and remove items that obtained the lowest mean scores based on the ratings assigned by raters. Each response option was scored as follows: “not at all relevant to patients’ experience of endometriosis” =1; “a little bit relevant to patients’ experience of endometriosis” =2; “moderately relevant to patients’ experience of endometriosis” =3 and “highly relevant to patients’ experience of endometriosis” =4. The scores obtained for each item from each reviewer were tallied and items with the lowest combined mean scores were removed as they were deemed less relevant than items containing higher scores.

The reviewers’ responses were analysed using IBM SPSS version 23 (Statistical Package for Social Sciences). I calculated the minimum score, maximum score, range, mean and standard deviation for each item. Items were eligible to receive mean scores ranging from 0 to 4. Please refer to table 4 for the results. I retained items with a mean above 3.00 and standard deviation below 1. Large standard deviations indicated a lack of consensus regarding the relevancy of items. Therefore, items with a standard deviation below 1 indicated good consensus among reviewers regarding relevancy. Nine items received a mean score of 4 (maximum attainable score) with a standard deviation of zero. Fifteen items

received mean scores of 3.8, all with standard deviations of 0.447. Fifteen items received mean scores of 3.6; one item received a mean score of 3.5; 15 items received mean scores of 3.40, one item received a mean score of 3.25 and eight items obtained mean scores of 3.2. Therefore, a total of 64 items met the inclusion criteria and these were included in the next round of analysis. The next step in the procedure was conducting the pre-pilot.

Table 4.1 *Summary of reviewer scores*

Items description	Rating	Range	Min	Max	Mean	Standard deviation
Symptoms affect day-to-day	5	0	4	4	4.00	0.00
Periods drain	5	0	4	4	4.00	0.00
Speak to others with endo	5	0	4	4	4.00	0.00
Frustrated people say pain normal	5	0	4	4	4.00	0.00
Need guidelines	5	0	4	4	4.00	0.00
Worried not falling pregnant	5	0	4	4	4.00	0.00
Missed work	5	0	4	4	4.00	0.00
Unsure about pain management	5	0	4	4	4.00	0.00
Worried endo worsen	5	0	4	4	4.00	0.00
Pain week prior to menses	5	1	3	4	3.80	0.45
Pain during menstruation	5	1	3	4	3.80	0.45
Pain all the time	5	1	3	4	3.80	0.45
Partner support	5	1	3	4	3.80	0.45
Diagnosis makes it easier	5	1	3	4	3.80	0.45
Researched endo	5	1	3	4	3.80	0.45
Prefers people don't ask re children	5	1	3	4	3.80	0.45
Around others with children	5	1	3	4	3.80	0.45
Infertility affected relationship	5	1	3	4	3.80	0.45

Items description	Rating	Range	Min	Max	Mean	Standard deviation
Treatment results in improvement	5	1	3	4	3.80	0.45
Unsure about different advice	5	1	3	4	3.80	0.45
Difficulty describing pain	5	1	3	4	3.80	0.45
Fears sexual intercourse	5	1	3	4	3.80	0.45
Struggled to cope	5	1	3	4	3.80	0.45
Concern re living with endo	5	1	3	4	3.80	0.45
Unable to work when in pain	5	1	3	4	3.60	0.55
No support from colleagues	5	2	2	4	3.60	0.89
People at work did not believe pain	5	2	2	4	3.60	0.89
Absent from work/school	5	1	3	4	3.60	0.55
Worried that pain is not normal	5	2	2	4	3.60	0.89
Clots	5	2	2	4	3.60	0.89
Partner did not understand pain	5	1	3	4	3.60	0.55
Difficulty in romantic relationship	5	1	3	4	3.60	0.55
Withdrew from social activities	5	1	3	4	3.60	0.55
Anxiety re dealing with endo	5	1	3	4	3.60	0.55
Diagnosis empowering	5	1	3	4	3.60	0.55
Pressure to conceive	5	1	3	4	3.60	0.55
Unpaid leave	5	1	3	4	3.60	0.55
Researched endo	5	1	3	4	3.60	0.55
Lost hope	5	1	3	4	3.60	0.55
Not enough sick leave	4	1	3	4	3.50	0.58
Diff treatment options from docs	4	2	2	4	3.50	1.00
No energy	5	2	2	4	3.40	0.89
Live with pain	5	3	1	4	3.40	1.34

Items description	Rating	Range	Min	Max	Mean	Standard deviation
Hesitant to enter new work environ	5	1	3	4	3.40	0.55
Partner not believe ill	5	2	2	4	3.40	0.89
Partner did not believe illness	5	3	1	4	3.40	1.34
Telling others made it easier	5	1	3	4	3.40	0.55
Did not understand	5	2	2	4	3.40	0.89
Gave up hope to have child	5	1	3	4	3.40	0.55
Would like to have child in future	5	3	1	4	3.40	1.34
Would like to have child soon	5	3	1	4	3.40	1.34
Limits ability to earn	5	2	2	4	3.40	0.89
Resigned	5	2	2	4	3.40	0.89
Doctors told me its normal	5	3	1	4	3.40	1.34
Doctors considered needs	5	2	2	4	3.40	0.89
Doctor did not understand	5	1	3	4	3.40	0.55
Doctor knew enough to explain	5	3	1	4	3.40	1.34
Dyspareunia affected relationship	5	2	2	4	3.40	0.89
Avoided sexual intercourse	5	2	2	4	3.40	0.89
Scheduled activities	5	3	1	4	3.40	1.34
Adopted positive attitude to cope	5	1	3	4	3.40	0.55
Only person with endo	5	1	3	4	3.40	0.55
Helpless	5	2	2	4	3.40	0.89
Missing out on life	4	1	3	4	3.25	0.50
Had to stay in bed	5	2	2	4	3.20	0.84
Colleagues say that pain is normal	5	3	1	4	3.20	1.30
Hides pain from colleagues	5	3	1	4	3.20	1.30
Negative impact on work / school	5	3	1	4	3.20	1.30

Items description	Rating	Range	Min	Max	Mean	Standard deviation
Needs more support	5	2	2	4	3.20	0.84
Not good company	5	2	2	4	3.20	0.84
Anxious about contradicting info	5	3	1	4	3.20	1.30
Frustrated trying to conceive	5	2	2	4	3.20	0.84
Can't stop thinking about children	5	3	1	4	3.20	1.30
Insurance not adequate	5	3	1	4	3.20	1.30
Rejected insurance	5	3	1	4	3.20	1.30
Satisfied with medical care	5	2	2	4	3.20	0.84
Struggled describing symptoms docs	5	3	1	4	3.20	1.30
Avoids relationships dyspareunia	5	2	2	4	3.20	0.84
Pain after sexual intercourse	5	3	1	4	3.20	1.30
Mentally prepared for pain	5	2	2	4	3.20	0.84
Wants to be normal	5	3	1	4	3.20	1.30
Wants to do more but can't	5	3	1	4	3.20	1.30
Anxious	5	2	2	4	3.20	0.84
Unable to manage pain	5	3	1	4	3.00	1.23
Hides pain from others	5	3	1	4	3.00	1.23
Tries not to let endo affect work	5	3	1	4	3.00	1.23
Absence from work affected income	5	3	1	4	3.00	1.23
Cannot take care of children	5	2	2	4	3.00	1.00
Does not let pain affect social activities	5	2	2	4	3.00	1.00
Wants to start fertility treatment	5	3	1	4	3.00	1.23
Infertility sad	5	3	1	4	3.00	1.23

Items description	Rating	Range	Min	Max	Mean	Standard deviation
Cost of feminine hygiene products	4	2	2	4	3.00	1.16
Cannot afford prescribed medication	5	2	2	4	3.00	1.00
Tried to tolerate pain due to cost	5	2	2	4	3.00	0.71
Household money for treatment	5	2	2	4	3.00	1.00
Cannot afford medical treatment	5	3	1	4	3.00	1.41
No choice	5	3	1	4	3.00	1.41
Hot flushes	5	3	1	4	3.00	1.23
Cannot describe endo to docs	5	3	1	4	3.00	1.23
Doctor answered questions	5	3	1	4	3.00	1.41
Doctor explained	5	3	1	4	3.00	1.41
Satisfied with amount of info	5	3	1	4	3.00	1.41
Dyspareunia not real woman	5	2	2	4	3.00	0.71
Pain during intercourse	5	3	1	4	3.00	1.23
Support from others	5	2	2	4	3.00	0.71
Prayer	5	3	1	4	3.00	1.23
Stuck	5	3	1	4	3.00	1.23
Unsure about managing symptoms	4	3	1	4	3.00	1.41
Afraid may lose job	5	3	1	4	2.80	1.10
Needs more support at work	5	3	1	4	2.80	1.30
Unable to sit at desk	5	3	1	4	2.80	1.10
Impact on ability to earn a living	5	3	1	4	2.80	1.30
Menstruates longer than a week	5	3	1	4	2.80	1.64
Avoids relationships due to endo	5	3	1	4	2.80	1.30
Fears partner will leave	5	3	1	4	2.80	1.30

Items description	Rating	Range	Min	Max	Mean	Standard deviation
Friends understand	5	3	1	4	2.80	1.30
Hides pain from others	5	3	1	4	2.80	1.10
Headaches	5	3	1	4	2.80	1.30
Doctors/nurses respect dignity	5	3	1	4	2.80	1.30
Cope alone	5	3	1	4	2.80	1.64
Limits physical activity	5	3	1	4	2.80	1.10
Accepted	5	3	1	4	2.80	1.30
Thinking about reason for endo	5	3	1	4	2.80	1.10
Not normal woman	5	3	1	4	2.80	1.10
Isolated	5	3	1	4	2.80	1.10
Pain two weeks prior to menstruation	4	3	1	4	2.75	1.50
Cannot do anything	5	3	1	4	2.60	1.14
Partner thinks patient not interested	5	3	1	4	2.60	1.34
Uncomfortable when out	5	3	1	4	2.60	1.14
Only those with endo will understand	5	3	1	4	2.60	1.14
Burden	5	3	1	4	2.60	1.14
Does not like answering questions	5	3	1	4	2.60	1.34
Does not like people asking	5	3	1	4	2.60	1.34
Fertility treatment worsens symptoms	5	3	1	4	2.60	1.14
Infertility not real woman	5	3	1	4	2.60	1.14
Cannot afford proper dosage	5	3	1	4	2.60	1.14
Gained weight	5	3	1	4	2.60	1.34
Side effects	5	3	1	4	2.60	1.52

Items description	Rating	Range	Min	Max	Mean	Standard deviation
Did not understand doctor	5	3	1	4	2.60	1.14
Unable to satisfy partner sexually	5	2	2	4	2.60	0.89
Monitor body for changes	5	3	1	4	2.60	1.14
Thinking about actions	5	3	1	4	2.60	1.14
Distress	5	1	2	3	2.60	0.55
Nervous	5	1	2	3	2.60	0.55
Sad	5	2	2	4	2.60	0.89
Uncomfortable discussing endo work	5	3	1	4	2.40	1.14
Motherhood	5	3	1	4	2.40	1.14
Finds others intrusive	5	3	1	4	2.40	1.14
Selective disclosure	5	3	1	4	2.40	1.14
Long wait between fertility treatment	5	3	1	4	2.40	1.14
Others thought less infertility	5	2	1	3	2.40	0.89
Nausea	5	3	1	4	2.40	1.52
Frustrated re wait for fertility treatment	5	3	1	4	2.40	1.14
Self-conscious	5	3	1	4	2.40	1.14
Angry	5	2	1	3	2.40	0.89
Cannot work at all	4	3	1	4	2.25	1.26
Hesitant to further career	5	2	1	3	2.20	0.84
Pressure to work	5	2	1	3	2.20	0.84
Self-conscious re bleeding	5	3	1	4	2.20	1.30
Heavy bleeding	5	3	1	4	2.20	1.30
Pity	5	3	1	4	2.20	1.30

Items description	Rating	Range	Min	Max	Mean	Standard deviation
Cannot explain to others	5	2	1	3	2.20	1.10
Side effects	5	2	1	3	2.20	1.10
Doctor cares	5	2	1	3	2.20	0.84
Scared to look stupid	5	3	1	4	2.20	1.30
Improved sexual functioning	5	3	1	4	2.20	1.30
Did not feel like self	5	3	1	4	2.20	1.10
Snapped at others	5	3	1	4	2.20	1.10
Irregular cycle	5	3	1	4	2.00	1.41
Guilty mother	5	2	1	3	2.00	1.00
Felt restricted when out	5	2	1	3	2.00	1.00
Treatment refused	5	3	1	4	2.00	1.23
Doctor went beyond	5	2	1	3	2.00	0.71
Doctor gave too much info	5	2	1	3	2.00	1.00
Moody	5	2	1	3	2.00	0.71
Dependant on others	5	2	1	3	1.80	0.84
Doctors more concerned about cost	5	1	1	2	1.80	0.45
Difficulty getting pain relief	5	3	1	4	1.80	1.30
New doctor each time	5	2	1	3	1.80	0.84
Embarrassed	5	2	1	3	1.80	0.84
Bleeding when not menstruating	5	2	1	3	1.60	0.89
Not woman enough	5	1	1	2	1.60	0.55
Control of body	5	1	1	2	1.60	0.55
Could not play with children	4	1	1	2	1.50	0.58

4.3.5 Step 5: Piloting the measure as a means of assessing the readability of the measure

Once the final items were selected I conducted a small pre-pilot study among seven women with endometriosis. The aim of the pilot was to determine whether the measure was acceptable to patients with endometriosis and to identify any problems with the measure prior to validation.

4.3.5.1 Procedure

Participants were recruited from the database of endometriosis patients. I contacted participants and informed them about the study. Two research assistants assisted me in gathering data for this phase of the study. We met with participants individually and administered the measure to them. After the participants completed the measure, I asked them a number of questions relating to the readability of the items and the appearance of the measure. Participants were prompted to provide feedback on the suitability of the response format, the stem, the difficulty of questions, the suitability of instructions, and whether they thought the items tapped health-related quality of life. Please refer to appendix L for the data collection form for this part of the study.

4.3.5.2 Participants

The participants consisted of seven women with endometriosis. Please refer to Table 4.2 below for a summary of participant characteristics. Participants were recruited using the same strategy employed in the first phase of the study. Participants were between the ages of 21 and 37 years (average age = 29 years). Five participants listed their relationship status as single, one as divorced and one as married. In terms of first language, two participants spoke Afrikaans as first language and five spoke English. One participant had completed high school, one participant attended university, but did not graduate and five participants went on to graduate from tertiary education. Most participants did not have any children (n=5), while

one participant had one child and another participant had two children. Of the participants, four were employed full-time, one was employed on a part-time basis, one was a student and one was unemployed. In terms of household income of participants per annum, two participants stated that they did not know their household income, one participant earned between R80 001-R110 000, one earned between R110 001-R200 000, another earned between R200 001-R300 000, and two participants earned more than R300 001.

When it came to disease staging, one participant did not know the stage of her condition of endometriosis, three participants indicated that they were diagnosed with stage 3 endometriosis and another three participants indicated that they were diagnosed with stage 4 endometriosis. One woman was diagnosed one month prior to participating in the study, one participant was diagnosed less than six months prior to participating, four participants were diagnosed less than a year prior to the interview, and one was diagnosed more than three years prior to the interview. In terms of treatment or medical management of endometriosis, the majority of participants (n=5) stated that they were not getting any form of treatment. One was using contraception and one reported taking Dienogest.

Data were collected using a form that required short, qualitative answers from participants. Participants completed these forms themselves and I analysed the data. The data gathered from the participants when completing the measure were not used as they were not sufficient for quantitative analysis. As the objective of this part of the study was to gain information on how participants viewed the measure, the completion of the measure was only necessary so that participants could form an opinion about it.

Table 4.2

Participant characteristics

Description	Number
Age (years)	
Range	21-37
Mean	29
Relationship status	
Single	5
Married	1
Divorced	1
Highest level of education	
Completed Grade 12	1
Started tertiary but did not complete	1
Completed tertiary	5
Number of children	
No children	5
One child	1
Two children	1
Employment status	
Student	1
Unemployed	1
Employed (part-time)	1
Employed (full-time)	4
Income level (household income per year)	
Does not know	2
R80 001-R110 000	1
R110 001-R200 000	1
R200 001-R300 000	1

R300 001 and above	2
Time since diagnosis	
Less than one month	1
Less than 6 months	1
Less than 1 year	4
More than 3 years	1
Disease stage	
Does not know	1
Stage 3	3
Stage 4	3
Treatment	
None	5
Surgery	1
Contraceptives	1

4.3.5.3 Analysis.

I analysed the qualitative responses using content analysis. Content analysis allows researchers to systematically code and categorize qualitative data (Grbich, 2013; Wilkinson, 2015). I coded the data and then created a table that summarized the responses of all seven participants (please refer to table 4.3). Each column in the table consists of responses from participants regarding the comprehension of items, appropriateness of the stem, suitability of response options, the identification of any difficult questions, unfamiliar words and problematic phrasing of items. The table also contains comments relative to the relevance of items, an indication of whether any additional items should be added and general comments from participants.

4.3.5.4 Results.

Table 4.3 contains a summary of comments. The table shows that all the participants were satisfied with the comprehensibility of items and the stem. Participants did not identify any unfamiliar words and reported that the questions were all relevant. The vast majority of participants stated that they were satisfied with the phrasing of items (n=6) and did not suggest any items be added to the measure (n=6). Few participants reported issues relating to the response options (n=3); question difficulty (n=3); phrasing of items (n=1) and the inclusion of additional items (n=1). The general comments from participants indicated that participants were satisfied with the measure and the overall aims of the study.

Table 4.3

Summary of responses from participants

Comprehensibility	Stem	Response options	Difficult questions	Unfamiliar words	Phrasing	Relevance	Add	Verbatim comments
Satisfied	Satisfied	Should be at the start of each page.	None identified	None identified	Satisfied	Yes	None	Reconsider the 8-week time-frame. Make it wider.
Satisfied	Satisfied	Satisfied	“I feel pain all the time” conflicted with “only during menstruation” and “a week before”.	None identified	Satisfied	Yes	None	Should be interesting to see what bowel effects as it seems to be quite common. And depression if any women are treated for that.
Satisfied	Satisfied	Satisfied	Work should be changed to work/schooling	None identified	Satisfied	Yes	None	Good research that can help women with endo

Satisfied	Satisfied	Reduce to 3 options	None identified	None identified	Satisfied	Yes	How long does the pain last on a daily basis?	None
Satisfied	Satisfied	Satisfied	None identified	None identified	Satisfied	Yes	None	This is an excellent study as most young women are completely in the dark
Satisfied	Satisfied	Satisfied	Questions 53-55 may be contradictory	None identified	Satisfied	Yes	None	Very good questions.
Satisfied	Satisfied	Should be at the start of each page.	None identified	None identified	Combine questions 13 and 15.	Yes	None	None

Table 4.4 contains the concerns raised by participants in this part of the study, the changes made to items, and the rationale for these decisions. Two changes were made to the measure based on the feedback from participants. The first change was that the response options were added to the top of each page, whereas prior to this they were only provided on the first page. The second change was that “work” was replaced with “work/schooling” so that it would be more appropriate for students.

A few suggestions were made by participants that did not result in changes. I discussed all recommendations with my supervisor, who agreed that these recommendations should not result in changes. Firstly, two participants suggested that the timeframe be extended beyond 8 weeks. I consulted on this matter with both medical experts in endometriosis and experts in test construction. All agreed that the timeframe should not be extended as this may introduce recall bias. Secondly, one participant recommended that the response options be narrowed to three options, but I decided not to change this because all the other participants were satisfied with five response options. Thirdly, another participant requested that an item detailing pain duration be added to the scale, but I did not add it as the measure is a HRQOL scale and not a pain scale. The focus is therefore not on how long the pain lasts, but the impact of the pain on HRQOL. Two participants stated that they found some questions contradictory, but the items remained in the measure for further analysis. Finally, one participant indicated that two items relating to sexual dysfunction were redundant. I did not change these items because the one deals with avoidance of sex and the other deals with avoidance of relationships due to sexual dysfunction.

Even though very few changes were made to items based on the feedback obtained from this part of the study, the pilot study was helpful as participants were optimistic about the measure and reported very few concerns. This optimism was reassuring as I proceeded with the initial validation of the newly developed measure.

Table 4.4

Concerns raised during pilot and responses

Comment	Decision	Reason
Reconsider the 8-week time-frame. Make it broader.	Time frame was not changed	I consulted with doctors and experts in measurement construction who agreed that the 8-week time frame is appropriate. Any longer would introduce recall bias.
Work should be changed to work/schooling.	“Schooling” has been added	The comment was valid.
I think it should be narrowed down to only 3 options	Response options will not be reduced	Only one participant requested fewer response options.
How long does the pain last on a daily basis?	No items added	The measure deals with HRQOL and is not a pain scale.
Questions 53-55 seem contradictory	No changes were made to items	The items deal with the timing of pain and each item refers to different times within the menstrual cycle at which women experience pain.
Some of the questions seemed similar. Could be made one like questions 13 and 15.	No changes were made to items	The questions are different because the one relates to avoidance of sex and the other relates to avoidance of relationships due to sexual dysfunction
Put headings on other pages too.	Response options added to each page	The comment was valid.

4.4. Summary of chapter

This chapter outlined the process of item construction used to develop a HRQOL measure for patients with endometriosis. The process consisted of five steps that took place in consultation with experts in psychometry, experts in endometriosis and patients. The process led to the development of a HRQOL measure containing 64 items. Chapter 5 reports on the initial validation of this measure.

Chapter 5

Initial validation of a HRQOL measure for patients with endometriosis

5.1 Introduction

The third aim of the study was to finalize the items in the measure, determine the factor structure of the measure and establish the measure's psychometric properties. This chapter contains the methodology and results of this endeavour. The chapter concludes with a discussion that compares the newly developed measure with other measures of HRQOL.

5.2 Determination of sample size

Validation studies of patient-report outcome measures consist of subject-to-item ratios ranging from 1:1 to 10:1 (Anthoine et al., 2014). Furthermore, less than 10% of studies that made use of PRO measures provide a justification of the sample size. Kline (2013) argues that a sample of 200 is defensible in studies using EFA. However, it was challenging to recruit a large enough number of participants for the study and I carefully considered the sample size. I decided to use a sample of 200 participants before I commenced with this phase of the study as this was adequate for the statistical analyses. It took 11 months to collect the data for the final phase of the study.

5.3 Data collection

5.3.1 Overview

The finalization of items and validation of the measure was achieved by administering a battery of measures, including the newly developed HRQOL measure, to a large sample of women with endometriosis and analysing the resultant data. The quantitative analysis consisted of item analysis, exploratory factor analysing and correlation.

5.3.2 Research assistants

Five research assistants were recruited to assist with the data collection given the large size of the sample. The research assistants were postgraduate students in psychology who received training prior to data collection. The training included information about endometriosis and HRQOL, the construction process, orientation to research sites, administration of measures and ethical considerations. Each research assistant collected data for 1-8 hours each week and reported to me on a weekly basis. The group also met once a month to discuss participant recruitment and any issues that arose during data collection. The research assistants captured the data in Microsoft Excel and forwarded the file to me on a weekly basis. They also submitted the hard copies of completed measures at the monthly meeting.

5.3.3 Procedure

Participants were recruited using the participant database that I developed during the earlier phase of the study. New participants were also recruited at two state hospitals and a private infertility clinic. At this stage of the study I added a new research site, Groote Schuur Hospital. The addition of a new site was necessary to obtain an adequate sample size. The HREC approved the addition of this new site (please refer to appendix M) and the WCDOH granted permission for data collection at the hospital (please refer to appendix N).

5.3.3.1 Data collection with database participants.

I re-established contact with participants from the participant database when the instrument battery was ready to be administered. Women who remained interested in participating in the study and who still met the inclusion criteria were given three options for completing the measures - post, email or in person, administered by me or a research assistant. We administered an information and data collection pack to each participant. This pack consisted of informed consent forms (please refer to appendix O) and the instrument

battery. The information and data collection pack were posted to participants who indicated a preference to complete the instrument battery via mail. They each received an envelope with paid postage for participants to return the information. Those who opted to complete the measure via email were emailed a PDF version of the battery, which they printed, completed, scanned and emailed back. Finally, I made appointments to meet with participants who preferred to complete the information and data collection packs in person. When I received all the completed forms I checked each form to ensure that the data were complete and then gave participants a token of appreciation (a R40 gift card).

5.3.3.2 Data collection with new participants from Groote Schuur and Tygerberg Hospitals.

During the data collection phase one research assistant was placed at each research site. Research nurses contacted patients with endometriosis and asked if they would like to participate in the study. The nurses scheduled a time for patients to meet with the research assistants. The research assistants informed participants about the purpose of the study and the ethical considerations. Patients were then asked if they wished to participate in the study and were informed that participation would entail their completion of a battery of measures. The research assistants read through the informed consent forms and demographic questionnaire with participants and asked them to complete it. Participants were handed an envelope containing the battery of measures and a pen and were asked to complete the measures by themselves. The research assistant was present to answer any questions regarding the items in the measure that participants had. The assistants noted these questions and forwarded them to me. Participants handed the battery of measures back to the research assistants on completion. The research assistants checked the completed measures and handed participants the token of appreciation and a transportation voucher. The research assistants captured the completed measures electronically and forwarded the information to me.

5.4 Instruments

The new endometriosis QOL questionnaire, WHOQOL-Bref, SF-12, EHP-30, Beck Depression Inventory (BDI) and a demographic questionnaire were administered to participants to measure the validity of the new endometriosis QOL questionnaire.

5.4.1 The Endometriosis HRQOL measure.

The newly developed measure consisted of 64 items. The response format was outlined in section 4.3.1. However, in addition to these options, a sixth option, “not applicable”, was included. This option was added based on suggestions by the experts and patients with endometriosis (focus group). The items were scored as follows: “not applicable” =0; “not at all” =1; “a little bit” =2; “somewhat” =3; “quite a bit” =4; and “very much” =5. The measure is presented in Appendix K.

5.4.2 WHOQOL-Bref.

The WHOQOL-Bref consists of 26 items covering domains such as physical aspects, psychology, social relationship, environment and two additional general questions (Cruz et al., 2009; WHO, 1997). Higher scores indicate better QOL compared to lower scores. I derived scores for each dimension and each participant as per the instructions outlined in the manual. The instrument produced an internal consistency reliability of 0.92 in general samples of ill and well participants in the U.K. (Skevington & McCrate, 2011). The study also found that the WHOQOL-Bref demonstrated good concurrent validity with the SF-36 in the physical and psychological domains, but weak validity on the social domain. Only one study utilized an adapted and translated Portuguese version of the WHOQOL-Bref to assess HRQOL in patients with endometriosis (Tripoli et al., 2010). The reliability and validity of the instrument in patients with endometriosis are unavailable. However, the WHOQOL-Bref was selected as an instrument in this study as it encompasses a broader range of scales than

the SF-36. The WHO gave permission for the use of the WHOQOL-Bref (please refer to appendix P).

5.4.3 SF-12v2.

The SF-12v2 is the short form version of the SF-36 and covers the same eight domains, namely physical functioning, bodily pain, role physical, general health status, vitality, social role, role emotional and mental health (Cruz et al., 2009). It is a self-report measure that utilizes a Likert response format. Higher scale scores indicate better QOL compared to lower scores. The SF-36 has been used in many studies to assess HRQOL in patients with endometriosis (Jia et al., 2012; Nnoaham et al., 2011; Bodner et al., 1997). A study assessing the reliability, validity and responsiveness of the SF-12 among patients with lower back pain in the U. S. produced internal consistency reliabilities of 0.77 on the physical scale and 0.80 on the mental scale (Luo et al., 2003).

The eight domains on the SF12v2 can be clustered to general scores for two domains, physical and psychological domains. I used the software provided, Optum (Optum smart measurement system scoring solution), to generate scores for these domains of the SF12v2. I received permission to use the SF-12v2 from Optum (please refer to Appendix Q). No copy of the SF12v2 has been attached due to copyright restrictions.

5.4.4 EHP-30.

The core EHP-30 covers five domains including pain, control and powerlessness, emotional well-being, social support and self-image, and six modular components as outlined previously (Jones et al., 2001). It is a self-report measure that utilizes a Likert response format. Higher scores indicate better QOL compared to lower scores. The internal consistency of the scales ranged between 0.80 and 0.96 in a sample of patients with endometriosis in the U. K. The EHP-30 has not been used as an assessment measure on

patients in South Africa. I obtained permission to use the EHP30 from ISIS Innovation Limited (now known as Oxford University Innovation) (Please refer to Appendix R for the license).

5.4.5 Beck Depression Inventory (BDI).

The BDI is a self-report measure used to assess depression. It consists of 21 items that utilize a four-point rating scale. Scores range from 0 to 63, with scores above 10 indicating clinical depression. The scale has been adapted and standardized for various cultural groups within South Africa. An internal consistency reliability of 0.85 was found in a sample of South African patients living with chronic illness (Kagee, 2008). Please refer to Appendix U for a copy of the BDI.

5.4.6 Demographic questionnaire

I used a demographic questionnaire in order to obtain general information from participants relating to their age, relationship status, living situation, education, employment and income. In addition, the questionnaire contained items relating to their health such as date of diagnosis, disease stage, number of surgeries, medical treatment, comorbid chronic illnesses and fertility treatment.

5.5 Data analysis

The data were captured using Microsoft Excel and imported into Statistical Package for the Social Sciences (IBM SPSS), version 23. I cleaned and analysed the data using SPSS. Cleaning the data comprised of removing any duplicate participants, coding all data (including missing data), including variable names and labelling variables. The data collected were analysed using a number of statistical methods. First, I reduced the number of items in the new measure by conducting an item analysis. I then conducted a factor analysis to determine the final items to be included in the measure. I conducted a second factor analysis

after removing items. When the measure was finalized I assessed its internal reliability using Cronbach's alpha and assessed the initial validity by correlating the scores from the new questionnaire with scales from the SF-12, WHOQOL-Bref, EHP-30 and BDI. Each method of analysis is discussed below:

5.5.1 Item analysis.

I conducted an item analysis to reduce the number of items (Field, 2013; Spector, 1992). Item analysis results in the production of a tentative version of a measure, prior to validation (Spector, 1992). The item analysis was conducted on all the items of the new HRQOL measure. I calculated five item-total statistics, including (1) scale mean if item deleted, (2) scale variance if item deleted, (3) squared multiple correlation, (4) Cronbach's alpha if item deleted, and (5) corrected item total correlation. These results enabled me to assess the contribution that each item made to the measure. The result that I was most interested in was the corrected item-total correlations. The item-total correlation represents the correlation between the score on an item and on the entire measure. In accordance with the guideline provide by Field (2009), I deleted items with corrected item-total correlations below .35.

5.5.2 Factor analysis.

I conducted an exploratory factor analysis (EFA) to assess factor validity. Factor analysis seeks to determine latent factors present in scales. EFA was the appropriate type of factor analysis (as opposed to confirmatory factor analysis) as one of the purposes of conducting a factor analysis was to further reduce the number of items (Hinkin, Tracey, & Enz, 1997; Netemeyer, Bearden, & Sharma, 2003). In addition, confirmatory factor analysis was not appropriate during this stage of instrument development, as there was no established factor structure to test.

I used a Varimax rotation as it yields an easily interpretable factor structure (Field, 2014). Jones et al. (2004b) used a Varimax rotation when determining the factor structure of the EHP30. Considering that HRQOL is a multidimensional concept with most models containing at least four dimensions, Varimax rotation is appropriate. In order for the item to load significantly on a factor the following criteria had to be met:

- A minimum loading of 0.40 was required (Field, 2009; Hair, Anderson, Babin, & Black, 2009).
- Items that loaded on more than one factor were regarded as poor items and removed.
- At least three items were required to load on a factor for it to be considered a stable factor (Costello & Osborne, 2005)

5.5.3 Assessing reliability using correlation.

Reliability refers to the consistency of scores (Foxcroft & Roodt, 2005, 2012). Items on a scale are required to intercorrelate with one another as these items should be assessing the same latent variable. This intercorrelation is known as internal consistency (DeVellis, 2012). I assessed the internal consistency reliability for each of the subscales of the measure and the entire measure. Cronbach's alpha is a commonly used indicator of internal consistency. A reliability coefficient above .8 is considered a good indicator of reliability (Anastasi & Urbina, 1997).

5.5.4 Validity.

Validity refers to whether a test measures what it purports to measure. There are three types of validity, namely content validity, criterion-related validity and construct validity (Allen & Yen, 2002). One way of evaluating validity is to correlate the new measure with an existing, valid measure for the same trait. This is known as concurrent validity (Foxcroft &

Roodt, 2005). This measure was intended to be a measure of HRQOL. I therefore correlated scores from the sample on the new measure with other measures of HRQOL (i.e. the WHOQOL-Bref, the SF-36 and the EHP-30). Scores obtained using the new measure were also correlated with scores obtained from the BDI. The BDI is a measure of symptoms of depression, not HRQOL. Even though both measures evaluated different constructs, these constructs are theorized to be related. Therefore, I expected to see a weak, positive correlation between scores on these measures. I assessed the correlations using the criteria put forth by Field (2013), which categorises correlations as follows: ± 1 represents a small effect; ± 3 represents a medium effect; and ± 5 represents a large effect.

5.6 Results

5.6.1 Description of sample.

The sample in Phase 1 consisted of 203 patients with endometriosis between the ages of 19 and 64 years (average age = 35 years). One hundred and twenty-one participants indicated their relationship status as married, 15 as divorced/separated, 63 as single and 2 as widowed. In terms of the most common first language, English was spoken by 52.7% participants, Afrikaans was spoken by 25.4% participants and 15.7% spoke Xhosa. The level of education among participants varied. Two participants stated that they received no formal education, 5 participants stated they only completed primary school (grade 7), 34 participants stated that they entered high school, but did not graduate from high school (i.e. complete grade 12) and 58 participants stated that they completed high school. A number of participants received some tertiary education, with 25 women reporting that they commenced tertiary studies, but did not complete it, and 75 women reported that they completed tertiary education. A large number of participants did not have any children ($n=123$), while 34 participants had one child each, another 20 participants had two children. Most of the

participants were employed on a full-time basis (n=126), while 18 were employed on a part-time basis, 10 were full-time students and 29 were unemployed. Table 5.2 also contains data related to the reported income of participants, but this data should be interpreted cautiously as it became evident to me that patients struggled to calculate their income.

Table 5.1 contains the medical information of participants. The majority of participants (n=93) did not know the stage of their endometriosis. A large number of participants reported having stage 4 endometriosis (n=66), while fewer participants reported having stages 1 (n=7), 2 (n=13) and 3 (n=15). In terms of treatment or medical management of endometriosis, most participants stated that they were not receiving any form of treatment (n=113). Of the participants who used treatment (n=85), most stated that they received surgery in the past year (n=31). A number of patients reported that they were using contraception to manage their endometriosis (n=19), while other participants reported that they were using Visanne (n=16). Please refer to table 5.2 below for more details of participant characteristics.

Table 5.1

Demographic characteristics of validation participants

Description	Number
Age (years)	
Range	19-64
Mean	35
Relationship status	
Single	63
Married	121
Divorced/separated	15
Widowed	2
Missing	2
Home language	
English	107
Afrikaans	51

Xhosa	31
Other	12
Missing	2
Highest level of education	
None	2
Completed primary school	5
Started high school but did not complete	34
Completed grade 12	58
Attended tertiary but did not complete	25
Completed tertiary	75
Missing	
Number of children	
No children	123
One child	34
Two children	20
Three children	14
Four children	3
Five children	1
Missing	8
Employment status	
Employed (full-time)	126
Employed (part-time)	18
Unemployed	29
Student	10
Homemaker	9
Disabled	7
Retired	1
Missing	3
Income (household income per year)	
Does not know	34
Less than R5 000	28
R5 001-R20 000	33
R20 000-R80 000	15
R80 001-R110 000	12
R110 001-R200 000	18
R200 001-R300 000	15
R300 001 and above	30
Missing	18
Time since diagnosis	
One month	11
Six months	25
One year	27
Three years	41

More than 3 years	85
Cannot remember	11
Missing	3
Disease stage	
Stage 1	7
Stage 2	13
Stage 3	15
Stage 4	66
Does not know	93
Missing	9
Treatment	
None	113
Surgery	31
Contraceptives	26
Dienogest (Visanne)	16
GnRH Analogues	4
Danazol	1
Hysterectomy	2
Missing	10

5.6.2 Screening data for missing values.

I screened the data collected using the new HRQOL measure for completeness. The analysis indicated that the amount of missing data was negligible (0.75%) and random. I decided to impute the mean score for missing data, as missing data would affect the number of cases processed during factor analysis.

5.6.3 Results of item analysis.

The item analysis was conducted on all 64 items of the new HRQOL measure. The results of the item analysis can be found below in Table 5.2. Sixteen items displayed corrected item total correlations below .35, indicating that these items did not correlate with the score for the entire measure. These items (i.e. item 1, 3, 9, 10, 11, 18, 19, 20, 21, 26, 33, 34, 35, 39, 45 and 54) were removed prior to conducting the factor analysis. The factor analysis was therefore conducted on 48 items.

Table 5.2

Results of item analysis

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Q1	224.441	2250.639	.304	.679	.937
Q2	223.294	2243.203	.421	.674	.936
Q3	223.524	2256.985	.318	.681	.937
Q4	223.853	2229.061	.445	.719	.936
Q5	224.441	2221.053	.467	.607	.936
Q6	223.341	2241.634	.400	.688	.936
Q7	224.082	2212.088	.601	.735	.935
Q8	223.629	2218.483	.557	.672	.936
Q9	223.288	2266.124	.248	.545	.937
Q10	223.341	2284.463	.115	.528	.938
Q11	223.512	2273.589	.166	.661	.938
Q12	223.812	2202.923	.586	.859	.935
Q13	224.135	2205.928	.568	.846	.935
Q14	224.012	2209.515	.519	.776	.936
Q15	224.171	2199.338	.505	.709	.936
Q16	224.094	2221.506	.483	.679	.936
Q17	224.441	2213.751	.503	.679	.936
Q18	223.276	2309.515	-.082	.781	.939
Q19	223.176	2298.052	.002	.774	.938
Q20	223.388	2243.434	.341	.428	.937
Q21	223.324	2306.765	-.059	.451	.939
Q22	224.282	2202.370	.429	.696	.936
Q23	223.765	2220.086	.441	.683	.936
Q24	224.059	2190.789	.536	.777	.936

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Q25	224.371	2197.430	.516	.772	.936
Q26	222.771	2262.249	.247	.676	.937
Q27	223.465	2224.262	.414	.655	.936
Q28	223.747	2198.344	.512	.699	.936
Q29	222.794	2239.691	.366	.697	.937
Q30	223.488	2228.606	.384	.603	.937
Q31	224.076	2214.320	.446	.649	.936
Q32	223.253	2222.758	.427	.622	.936
Q33	222.935	2260.215	.308	.649	.937
Q34	223.494	2281.352	.114	.596	.938
Q35	223.618	2270.616	.190	.623	.937
Q36	223.159	2239.495	.471	.608	.936
Q37	223.982	2230.645	.412	.557	.936
Q38	223.659	2210.664	.635	.711	.935
Q39	223.971	2266.857	.199	.418	.938
Q40	223.000	2229.089	.501	.589	.936
Q41	224.124	2191.257	.637	.736	.935
Q42	224.082	2187.259	.695	.797	.935
Q43	223.965	2195.833	.631	.718	.935
Q44	223.865	2203.289	.566	.736	.935
Q45	222.747	2291.492	.060	.468	.938
Q46	224.029	2226.301	.414	.710	.936
Q47	224.459	2212.475	.461	.757	.936
Q48	223.894	2211.539	.540	.670	.936
Q49	223.582	2225.203	.484	.556	.936
Q50	223.088	2221.063	.550	.799	.936
Q51	222.982	2227.603	.552	.805	.936

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Q52	222.694	2244.107	.493	.629	.936
Q53	223.382	2228.226	.477	.640	.936
Q54	223.265	2287.734	.058	.401	.938
Q55	223.271	2225.252	.498	.646	.936
Q56	223.700	2211.442	.534	.735	.936
Q57	223.912	2194.022	.528	.737	.936
Q58	223.535	2211.173	.493	.702	.936
Q59	223.718	2226.251	.390	.633	.937
Q60	223.159	2237.874	.399	.634	.936
Q61	223.506	2180.322	.614	.676	.935
Q62	223.229	2226.497	.540	.650	.936
Q63	223.459	2202.984	.665	.806	.935
Q64	223.635	2213.121	.538	.738	.936

Note: Item-total correlations <.35 are in boldface.

5.6.4 Results of factor analysis.

5.6.4.1 Assessing assumptions.

Data have to meet three requirements to be considered suitable for factor analysis.

These requirements pertain to sample size, correlations between variables and distribution of data. I assessed the data using recommended criteria to determine if it was suitable to conduct an EFA

5.6.4.1.1 Sample size.

The issue of sample size has been addressed in the section 5.3. In this study the sample size of 203 was considered adequate for factor analysis. Furthermore, the subject-to-variable ratio was 1:4. Total sample sizes of 150 and item-to-subject ratios of 1:4 are adequate for conducting exploratory factor analysis (Hinkin et al., 1997). Higher subject-to-

variable ratios are recommended. However, finding participants who met the inclusion criteria for the study was challenging.

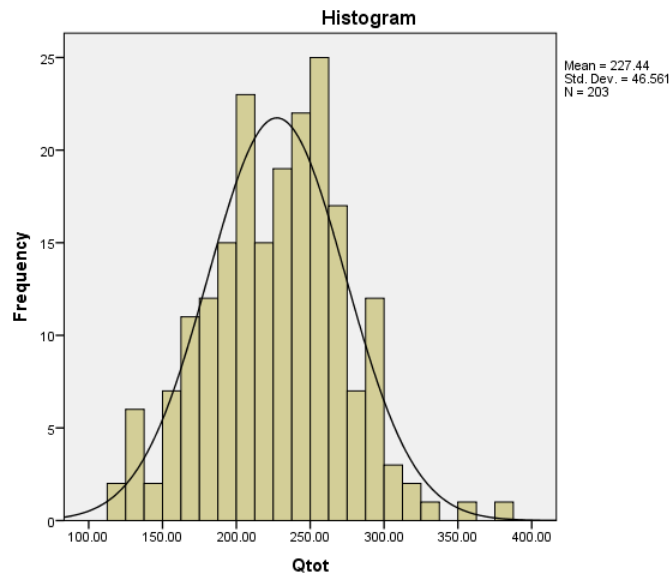
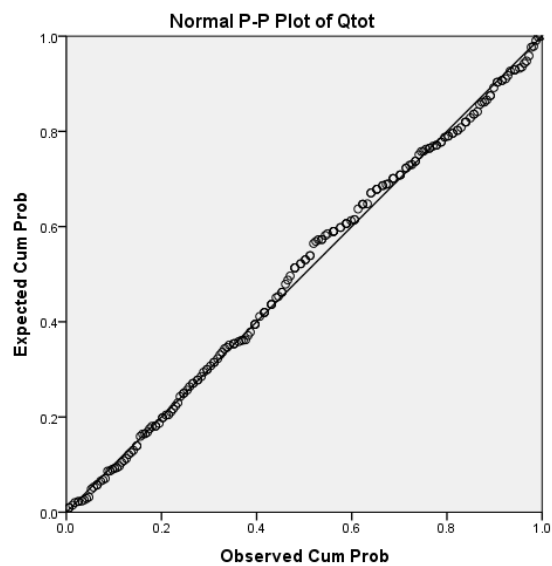
5.6.4.1.2 Correlation between variables.

In order to conduct a factor analysis, the variables should correlate with one another but the correlations should not be too high (multicollinearity) (Field, 2009, 2013). The contribution that a variable makes to the factor is almost impossible to determine when that variable correlates too highly with another variable (Field, 2003). I inspected the correlation matrix to assess the correlations between variables (please refer to appendix S). The correlation matrix showed that items met this assumption and that it was appropriate to conduct a factor analysis on this data. In addition, the Kaiser-Meyer-Olkin measure was 0.89, indicating excellent sampling adequacy (Field, 2009). Bartlett's test of sphericity $\chi^2(1128) = 5480,082$, $p < .01$ was significant and this indicated significantly large correlations between items.

5.6.4.1.3 Distribution of data.

A normal distribution of data is required to conduct factor analysis. I plotted a histogram (please refer to figure 5.1) and P-P plot (please refer to figure 5.2) to assess the distribution of scores. The normal distribution curve as presented in Figure 5.1 and Figure 5.2 shows that the points on the P-P plot were near the line, indicating that this requirement had been met. This assessment of normality was confirmed with a non-significant Kolmogorov-Smirnov test ($D = .060$, $p > .05$),

My inspection of the data concluded that the three assumptions required for factor analysis (i.e. the sample size was adequate, there were sufficient correlations between variables and the scores were normally distributed) had been met and that it was appropriate to conduct a factor analysis.

Figure 5.1 Histogram**Figure 5.2** P-P plot

5.6.4.2 Deciding on the number of factors to retain.

I inspected the scree plot and eigenvalues greater than 1 when determining the number of factors to retain. The results were contradictory, with the point of inflection occurring at Factor 2 (indicating one factor) on the scree plot (please refer to Appendix T),

and 11 items displaying eigenvalues greater than 1 (indicating 11 factors) (please refer to Appendix U). I therefore decided not to use this information in deciding the number of factors to retain, but to rather base this decision in inspection of items.

5.6.4.3 Factor structure of the new measure.

Table 5.3 displays the results of the factor analysis from the rotated factor matrix. Factor loadings that were .40 and above were considered significant (Hair et al., 2009). A factor also required a minimum of three significant loadings to be considered a factor. The factor analysis identified 13 items that either cross-loaded on more than one factor (items 42, 56 and 57) or that failed to significantly load on any factor (items 16, 17, 37, 40, 41, 43, 46, 47, 55 and 62). These items were removed from the measure.

Eight factors were extracted, each having a minimum of three items. Factor 1 consisted of seven items (item 2, 4, 5, 6, 7, 8 and 38), Factor 2 consisted of four items (item 22, 23, 24 and 24), Factor 3 consisted of five items (item 12, 13, 14, 15 and 44), Factor 4 consisted of six items (item 27, 28, 29, 30, 31 and 32), Factor 5 consisted of three items (item 53, 63 and 64), Factor 6 consisted of four items (58, 59, 60 and 61), Factor 7 consisted of three items (item 50, 51 and 52) and Factor 8 consisted of three items (item 36, 48 and 49). These items were considered the final items in the measure and the factors represented the subscales.

Table 5.3

Factor loadings for EFA with Varimax rotation

	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7	Factor 8
Q2	.662	.096	.101	.086	.028	.028	.059	.125
Q4	.677	.054	.059	.133	.060	.027	.047	.023
Q5	.514	.032	.073	.136	.113	.065	.103	.276
Q6	.547	.008	.206	.158	.095	.018	.035	.219
Q7	.649	.250	.127	.109	.188	.031	.116	-.012
Q8	.509	.124	.247	-.021	.346	.152	.195	.155
Q12	.240	.045	.819	.147	.139	.057	.100	.092
Q13	.129	.102	.855	.130	.104	.035	.114	.086
Q14	.116	.110	.761	.096	.098	-.011	.066	.049
Q15	.160	.181	.624	.049	.038	.159	.119	-.004
Q16	.384	.128	.233	.028	.095	.078	.211	.045
Q17	.397	.147	.257	.083	.100	.075	.095	-.032
Q22	.109	.683	.039	.104	.018	.127	-.029	.006
Q23	.160	.702	.050	.145	.166	.030	.061	.041
Q24	.101	.810	.136	.103	.069	.097	.062	.082
Q25	.070	.771	.145	.039	.075	.218	.021	.069
Q27	.273	.084	.060	.521	-.012	.047	.202	.078
Q28	-.077	.093	.326	.685	.110	.059	.012	.219

Q29	.106	.049	.087	.801	-.008	.027	.026	.032
	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7	Factor 8
Q30	.077	-.018	.161	.623	-.031	.081	.129	.051
Q31	.130	.209	.019	.562	.059	.078	.032	.039
Q32	.196	.135	-.022	.569	.093	.179	.126	-.021
Q36	.243	.089	.019	.134	.042	.159	.118	.624
Q37	.221	.030	.056	.059	.171	.167	.107	.375
Q38	.515	.129	.098	.166	.206	.117	.132	.372
Q40	.287	.042	.028	.233	.186	.171	.286	.012
Q41	.269	.389	.136	.107	.286	.241	.117	.143
Q42	.456	.241	.198	.145	.146	.135	.091	.257
Q43	.194	.212	.174	.097	.354	.206	.113	.128
Q44	.041	.103	.470	.219	.219	.031	.044	.187
Q46	-.027	.118	.188	.272	-.011	.111	.041	.143
Q47	-.011	.130	.243	.205	.045	.048	.068	.142
Q48	.219	.162	.170	.094	.136	.117	.150	.471
Q49	.290	.175	.177	.052	.161	.057	.139	.418
Q50	.146	.058	.179	.100	.133	.158	.730	.155
Q51	.158	.026	.179	.193	.177	.121	.850	.154
Q52	.177	.062	.069	.246	.268	.118	.437	.065
Q53	.182	.188	.209	-.054	.507	-.080	.234	.268
Q55	.007	.151	.168	.163	.303	.178	.150	.222

Q56	.057	.494	.131	-.037	.401	.302	.120	.225
	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7	Factor 8
Q57	.034	.520	.153	.149	.181	.441	.032	.179
Q58	.062	.128	.031	.100	.114	.712	.110	.141
Q59	-.013	.140	.015	.218	-.014	.636	.063	.124
Q60	.210	.252	.046	-.073	.228	.524	.099	-.033
Q61	.075	.291	.288	.137	.146	.483	.181	.104
Q62	.385	.112	.046	.092	.364	.367	.229	-.166
Q63	.208	.164	.186	.099	.633	.311	.163	.139
Q64	.279	.167	.102	.029	.749	.139	.154	.030

Note. Factor loadings > .40 are in boldface.

5.6.5 Presentation of the measure.

The final measure consists of 35 items and eight subscales. Table 5.4 contains the item number, a description of the item, the factor number and the name of the factor. Factor 1 is named “Psychological well-being” as the items that loaded on this subscale all related to psychological aspects of living with endometriosis such as coping, anxiety, concern, helplessness. I named Factor 2 “Income” as the items that loaded on this subscale were relevant to the ability to earn an income in the context of illness. Items that loaded significantly on Factor 3 were related to sexual functioning and romantic relationships and this factor is therefore named accordingly. I named Factor 4 “Reproductive functioning” as items referred to the pressure to have children, the social impact of infertility and concerns regarding infertility. The three items that loaded on Factor 5 deal with pain, day-to-day functioning and bed rest and this factor is therefore named “Vitality”. I named Factor 6 “Occupational functioning” as the items related to ability to work and the work environment.

I named Factor 7 “Menstrual characteristics” as all the items related to menstruation. Finally, the items on the last subscale all related to support and I therefore named the subscale “Support”. These eight subscales represent salient aspects of HRQOL in patients with endometriosis. The measure has been named the Stellenbosch Endometriosis Quality of Life measure (SEQOL).

Table 5.4

Description of items and factors

Factor	Item number	Item description
Factor 1: Psychological well-being	2	Worried condition would get worse
	4	Helpless
	5	Alone
	6	Concerned about living with endo
	7	Struggled to cope
	8	Unsure about managing pain
	38	Anxiety related to managing endo
Factor 2: Income	22	Resigned
	23	Missed work/school
	24	Took unpaid leave
	25	Limits income
Factor 3: Sexual functioning and romantic relationships	12	Scared of sexual intercourse
	13	Avoided sex
	14	Pain during sex affected relationship
	15	Avoided relationships because of painful sex
	44	Difficulty in romantic relationship
Factor 4: Reproductive functioning	27	Pressure to have a child
	28	Infertility caused relationship difficulties
	29	Frustrated trying to get pregnant
	30	Has given up hope of pregnancy
	31	Difficult being around people with children
	32	Prefer people not asking about childlessness

Factor	Item number	Item description
Factor 5: Vitality	53	Pain all the time
	63	Symptoms affecting day-to-day living
	64	Stayed in bed
Factor 6: Occupational functioning	58	Colleagues did not believe pain
	59	No support from colleagues
	60	Could not work when in pain
	61	Hesitant to find new work
Factor 7: Menstrual characteristics	50	Concerned about clots
	51	Worried that period was not normal
	52	Period draining
Factor 8: Support	36	Need guidelines to manage endometriosis
	48	Needed more support
	49	Need to speak with others with endometriosis

5.6.6 Second factor analysis with 35 items.

I conducted a second factor analysis after removing items that did not load on any of the above factors or that loaded on more than one factor (i.e. the final 35 items). The factor analysis was conducted using the same parameters as specified for the initial factor analysis. Table 5.5 below consists of the factor matrix of the second factor analysis. As is evident, the second factor analysis produced the same factor structure as above. The model explains 58.2% of the variance between the items.

Table 5.5

Factor loadings for second EFA with Varimax rotation

	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7	Factor 8
Q2	.074	.709	.069	.091	.062	.040	.001	.062
Q4	.067	.647	.151	.073	.045	.026	.082	.097

Q5	.077	.547	.148	.027	.107	.075	.109	.277
	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7	Factor 8
Q6	.175	.613	.123	-.008	.043	.047	.057	.091
Q7	.142	.607	.130	.259	.123	.036	.191	.068
Q8	.252	.554	-.025	.110	.217	.152	.286	.080
Q12	.825	.253	.149	.039	.126	.046	.094	.040
Q13	.859	.143	.134	.086	.127	.032	.079	.073
Q14	.781	.124	.110	.116	.060	.005	.072	.139
Q15	.620	.157	.058	.171	.125	.155	.043	.029
Q22	.069	.072	.119	.715	-.017	.142	.040	.078
Q23	.053	.170	.137	.684	.058	.047	.144	.061
Q24	.158	.095	.114	.810	.079	.112	.057	.092
Q25	.166	.076	.050	.762	.020	.247	.082	.120
Q27	.049	.282	.518	.071	.193	.043	-.024	.073
Q28	.346	-.038	.685	.084	.022	.074	.090	.265
Q29	.077	.118	.762	.037	.023	.001	-.019	.012
Q30	.183	.077	.648	-.012	.125	.084	-.053	.074
Q31	.048	.098	.598	.228	.022	.094	.074	.135
Q32	-.011	.173	.582	.139	.131	.178	.094	-.074
Q36	.031	.279	.137	.079	.144	.173	.010	.528
Q38	.125	.499	.189	.143	.155	.109	.185	.333
Q44	.513	.039	.248	.125	.027	.065	.211	.390
Q48	.187	.230	.106	.150	.141	.136	.130	.601
Q49	.183	.306	.051	.162	.144	.085	.124	.468
Q50	.184	.147	.107	.066	.773	.170	.095	.138
Q51	.179	.174	.204	.011	.812	.130	.149	.160

Q52	.075	.184	.257	.048	.459	.113	.236	.105
	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7	Factor 8
Q53	.228	.236	-.051	.165	.277	-.059	.425	.204
Q58	.048	.078	.121	.109	.105	.742	.111	.152
Q59	.023	.005	.218	.130	.061	.658	-.035	.107
Q60	.054	.192	-.065	.241	.106	.474	.215	-.030
Q61	.304	.081	.148	.279	.192	.482	.118	.175
Q63	.212	.211	.108	.162	.193	.316	.588	.230
Q64	.119	.275	.037	.161	.164	.152	.832	.061

Note. Factor loadings >.40 are in boldface.

5.6.7 Reliability analysis.

I calculated the Cronbach's alpha of the entire measure (35 items) and for each of the eight subscales. The results can be found below in Table 5.6. The entire measure displayed good reliability, Cronbach's $\alpha = .92$. The subscales also displayed good reliability, with Cronbach's α ranging from 0.72 to 0.88.

Table 5.6

Reliability statistics of measure and subscales

Scale/subscale	Cronbach's alpha
Entire measure	0.92
Subscale 1 (Psychological functioning)	0.85
Subscale 2 (Income)	0.87
Subscale 3 (Sexual dysfunction)	0.88
Subscale 4 (Reproductive functioning)	0.83

Subscale 5 (Vitality)	0.79
Scale/subscale	Cronbach's alpha
Subscale 6 (Occupational functioning)	0.75
Subscale 7 (Menstrual characteristics)	0.82
Subscale 8 (Support)	0.72

I also evaluated the reliability of the measures used to validate SEQOL. I calculated the reliability statistics of the scales and subscales (please refer to table 5.7). All the measures and subscales produced good reliability, with Cronbach's α ranging from .73 for the social support subscale of the WHOQOL-Bref social support subscale to .98 for the EHP core component. However, the scores on the SF12v2 were low, Cronbach's α = .49, indicating poor reliability. This means that subsequent results relating to the SF12v2 in this study have to be interpreted with caution.

Table 5.7

Reliability coefficients of measures used to validate SEQOL

Scale/subscale	Cronbach's alpha	Number of items
EHP30 core	.98	30
EHP work subscale	.97	5
EHP child subscale	.92	2
EHP sex subscale	.94	5
EHP medical profession subscale	.94	4
EHP treatment subscale	.93	3
EHP infertility subscale	.97	4

SF12v2	.49	12
Scale/subscale	Cronbach's alpha	Number of items
BDI	.93	19
WHOQOL Bref total	.96	26
WHOQOL-Bref physical subscale	.85	7
WHOQOL-Bref psychological subscale	.83	6
WHOQOL-Bref social support subscale	.73	3
WHOQOL-Bref environment subscale	.85	8

5.6.8 Validity results.

Construct validity was assessed by correlating scores on the new SEQOL with scores obtained from the EHP 30, WHOQOL-Bref, and SF12v2. Total scores and subscale scores were correlated. I expected moderate correlations between scores as similar constructs were measured. Correlations between measures assessing the same construct should be moderately high and not too high, as a high correlation indicates duplication of measures (Foxcroft & Roodt, 2005). I assessed the data from each measure and subscale to assess the normality of the distribution of scores. The data from a number of measures and subscales were normally distributed (e.g. SEQOL total score, SEQOL psychological functioning, SF12v2 mental functioning, etc.). However, the data from many other scales were not normally distributed (EHP30, BDI, SEQOL occupational functioning, etc.). Please refer to appendices V-ZQ for the histograms and P-P plots for each measure and subscale and appendix ZR for a table containing the results of the Kolmogorov-Smirnov test of normality for each measure and subscale. I calculated a Spearman's rank correlation between variables as all the scores were not normally distributed. Table 5.8 contains the correlations between the measures.

Table 5.8

Spearman's rank correlations between the SEQOL and EHP30, SF12v2, BDI and

WHOQOL-Bref

SEQOL subscale	Measure/ subscale	Spearman's rho correlation	P	
Entire scale	WHOQOL Bref – perception of QOL	-.283	.000	Weak
	WHOQOL Bref -Perception of health	-.202	.004	Weak
	EHP30 core	.508	.000	Moderate
	BDI	.406	.000	Strong
F1: Psychological well-being	BDI	.399	.000	Moderate
	EHP30 core	.548	.000	Strong
	WHOQOL Bref – Psychological scale	-.369	.000	Moderate
	SF12v2 – Mental subscale	-.348	.000	Moderate
F2: Income	EHP30 – Work module	.117	.096	Weak
F3: Sexual functioning	EHP30 – Sexual relationships subscale	.338	.000	Moderate
F4: Reproductive functioning	EHP30 – Infertility subscale	.038	.590	Weak
F5: Menstrual characteristics	No scale			
F6: Occupational functioning	EHP30 – Work module	.119	.091	Weak
F7: Vitality	EHP30 core	.583	.000	Strong
	WHOQOL Bref - Physical subscale	-.449	.000	Moderate
	SF12v2 Physical subscale	-.507	.000	Strong
F8: Support	BDI	.338	.000	Moderate
	EHP30 Core	.388	.000	Moderate
	WHOQOL Bref – Support subscale	-.198	.005	Weak

5.6.8.1 Validating the SEQOL.

I calculated the correlation coefficient between the total score of the SEQOL measure with the total scores of the EHP30, the WHOQOL-Bref Perception of QOL, the WHOQOL-Bref Perception of Health subscale and the BDI. As expected, the SEQOL was positively correlated with the EHP30 as high scores on both measures indicate low QOL. The SEQOL was negatively correlated with the WHOQOL-Bref Subscales (Perception of QOL and Perception of Health). This finding was also expected as high scores on the WHOQOL-Bref indicate better quality of life, whereas high scores on the SEQOL indicate poor QOL.

The SEQOL scores were weakly correlated with scores from WHOQOL-Bref Perception of QOL (Spearman's $\rho = -.283$, $p < .001$) and the WHOQOL-Bref Perception of Health questions (Spearman's $\rho = -.202$, $p < .001$). The strength of the correlations between the SEQOL and these subscales may be because items on these subscales are too broad and due to the fact that each subscale consists of one item.

Scores from the SEQOL were strongly correlated with scores from the EHP30 (Spearman's $\rho = .508$, $p < .001$) and the BDI (Spearman's $\rho = .406$, $p < .001$). I was satisfied with this correlation, as a higher correlation may indicate that the scales are too similar. Therefore, even though the SEQOL and the EHP30 are endometriosis-specific measures of HRQOL, the SEQOL is not a duplication of the EHP30. This is discussed at length later on. As expected, the correlation between the SEQOL and the EHP30 is stronger than the correlation between the SEQOL and BDI. This is because both the SEQOL and EHP30 measure HRQOL, whereas the BDI is a measure of depressive symptoms.

The EHP30 provides a more accurate assessment of HRQOL in patients with endometriosis than the WHOQOL-Bref Perceptions of QOL and Perceptions of Health subscales. The ability of the EHP30 to better assess HRQOL than the WHOQOL stems from

the EHP30 being an endometriosis-specific measure, whereas the WHOQOL is a generic QOL measure. The correlations indicate that the SEQOL is a measure of HRQOL.

5.6.8.2 Validating the Psychological Well-being subscale of the SEQOL.

The Psychological Well-being subscale was correlated with the BDI, the EHP core component (the core component contains a number of items relating to psychological functioning), the WHOQOL-Bref psychological subscale and the SF12v2 mental subscale. The Psychological well-being subscale of the SEQOL strongly correlated with the EHP30 core component (Spearman's $\rho = .548$, $p < .001$) and moderately correlated with the BDI (Spearman's $\rho = .399$, $p < .001$). The strong correlation between scores on the SEQOL Psychological well-being scale and the EHP30 maybe be due to the specificity of both measures. I correlated this subscale with the EHP30 core component, because this component contains items relating to psychological functioning such as coping, frustration, depression, anxiety, etc. The correlations between these two subscales were positive and strong (Spearman's $\rho = .548$, $p < .001$), indicating that they both measured similar constructs. The moderate correlation between scores on this subscale of the SEQOL and the BDI may be due to the BDI only measuring depression, whereas the SEQOL measures psychological well-being more generally. The subscale also produced moderate correlations with the WHOQOL-Bref psychological subscale (Spearman's $\rho = -.369$) and the SF12v2 mental subscale (Spearman's $\rho = .342$, $p < .001$). The correlation between the SEQOL psychological well-being subscale and the SF12v2 subscale should be interpreted with caution as the SF12v2 did not produce a convincing internal consistency reliability in the current sample.

5.6.8.3 Validating the Income subscale of the SEQOL.

I correlated scores on this subscale with scores from the EHP30 work module. The correlation was weak and not significant (Spearman's $\rho = .117$, $p > .001$). The subscales therefore do not measure the same construct and this subscale will require further validation.

5.6.8.4 Validating the sexual functioning and relationship subscale of the SEQOL.

The sexual functioning and relationship subscale of the SEQOL was correlated with the sexual relationships subscale of the EHP30. However, the scales were only moderately correlated (Spearman's $\rho = .338$, $p < .001$), indicating less than adequate construct validity. Therefore, while these subscales are similarly named, they may not assess the same construct. On inspection of items in both subscales, it was apparent that some questions were similar (e.g. experience of pain, avoidance of sexual intercourse and fear of sexual intercourse) and that other questions differed between the two subscales. For example, the SEQOL also asks patients if they avoided relationships because of painful intercourse, whereas items on the EHP30 ask patients if they experienced guilt and frustration in relation to sexual dysfunction. Considering that the items in the sexual dysfunction subscale of the SEQOL are in line with the diagnostic criteria for genito-pelvic penetration disorder, it may be useful to validate this subscale using a different measure of sexual dysfunction.

5.6.8.5 Validating the Reproductive functioning subscale of the SEQOL.

This subscale was correlated with scores from the Feelings about infertility subscale of the EHP30 and produced a moderate correlation (Spearman's $\rho = .031$, $p > .001$), indicating that both subscales measured different constructs. On inspection of items in these subscales it is apparent that while items measure aspects of fertility, the items on both scales are different. Items on the EHP30 subscale measure feelings of inadequacy, depression, worry and the impact of infertility on romantic relationships. However, items on the SEQOL were related to interpersonal aspects of infertility such as pressure to have a child, difficulty being around

people with children, questions regarding their childlessness in addition to relationship difficulties, frustration and hope.

5.6.8.6 Validating the menstrual characteristics subscale of the SEQOL.

I could not correlate this subscale of the SEQOL as none of the measures of HRQOL that I administered to participants contained this subscale.

5.6.8.7 Validating the Occupational functioning subscale of the SEQOL.

The work subscale of the SEQOL was correlated with the work modular component of the EHP30. The subscales were weakly correlated with one another (Spearman's $\rho = .119$, $p < .001$), indicating that although the subscales were named similarly, they do not measure the same constructs. On inspection of items I found that the both the EHP30 work modular component and the SEQOL work subscale ask participants about their ability to work and their absence from work. However, most of the items on the EHP30 component (3 out of 5 items) assessed feelings relating to work such as embarrassment, guilt and worry. Items on the occupational subscale of the SEQOL did not focus on these emotions, but instead focused on feelings of being supported in the workplace, ability to work when in pain and hesitance to find new employment. Even though this subscale was poorly correlated with a similar subscale, it did produce a high internal consistency value (Cronbach's $\alpha = .97$).

5.6.8.8 Validating the Vitality subscale of the SEQOL.

This Vitality subscale of the SEQOL produced strong correlations with the EHP30 core component (Spearman's $\rho = .583$, $p < .001$) and the SF12v2 Physical subscale (Spearman's $\rho = -.507$, $p < .001$); and moderate correlations with the physical subscale of the WHOQOL-Bref Physical subscale (Spearman's $\rho = -.449$, $p < .001$). These results indicated that the subscales measure similar constructs.

5.6.8.9. Validating the Support subscale of the SEQOL.

This subscale's scores produced moderate correlations with the BDI (Spearman's $\rho = .338$, $p < 0.05$) and the EHP30 core (Spearman's $\rho = .388$, $p < 0.05$). The subscale was also weakly correlated with the WHO Social subscale (Spearman's $\rho = -.198$, $p > .001$). The Social subscale of the WHOQOL-Bref consists of three items that assess the extent of support from friends, satisfaction with sex life and satisfaction with interpersonal relationships. The support subscale of the SEQOL consists of three items relating to support from others (including other women with endometriosis) and the need for guidelines to manage endometriosis. Therefore, while both measures assess interpersonal support, the subscale on the SEQOL is more specific than the Social subscale of the WHOQOL-Bref to patients with endometriosis.

In conclusion, the external validity of the SEQOL and its subscales were adequate for some subscales, but most of the subscales require further testing for validation.

5.7. Discussion

5.7.1 Summary of chapter.

This chapter describes the development of a contextual HRQOL measure for patients with endometriosis. The measure consists of 35 items in total that assess HRQOL. Factor analysis revealed eight subscales that represent the multidimensional concept of HRQOL. These subscales are (1) Psychological well-being, (2) Income, (3) Sexual dysfunction, (4) Reproductive functioning, (5) Vitality, (6) Occupational functioning, (7) Menstrual characteristics, and (8) Support. The subscales were derived from patients with endometriosis and therefore represent the domains that were pertinent to their HRQOL.

It was essential for me to define HRQOL prior to developing the measure. There is no universally accepted definition of HRQOL (Grant & Dean, 2012). Furthermore, most

measures do not clearly define HRQOL, but instead define HRQOL in terms the model's dimensions. These definitions and framing of HRQOL were outlined in Chapter 1. For this study HRQOL was defined as the impact that endometriosis and treatment related to endometriosis had on women's well-being (Bullinger et al. 1993; Bullinger, 2002). It was therefore necessary for the measure to conform to this definition of HRQOL. I presented this definition of HRQOL to participants and asked them to explore what HRQOL meant to them. Obtaining patient perspectives of HRQOL is considered best practice (Roop, Payne, & Vallerand, 2012).

The methodology employed in developing, refining and reducing the items on the SEQOL are described in Chapters 4 and 5. The process included (1) consulting with experts in psychometry regarding the phrasing of items and, (2) reducing the number of items in consultation with doctors who work extensively with patients with endometriosis and patient experts who offer support to other women with endometriosis. Finally, the measure was administered to a large number of patients with endometriosis for an initial validation of the measure. The process of item development, refinement and reduction was guided by the recommendations for scale development from DeVellis (2012) and Foxcroft and Roodt (2005). The SEQOL and its subscales demonstrated excellent reliability and the measure was validated against one disease-specific measure of HRQOL and two generic measures of HRQOL. The following sections will compare the SEQOL in relation to these HRQOL measures.

5.7.2 Comparing the SEQOL to generic HRQOL measures.

I used two generic HRQOL measures to validate the SEQOL. Jones et al. (2006) validated the EHP30 against the Rand SF36. I was unable to obtain permission to use the Rand SF 36 and therefore validated the SEQOL against the WHOQOL-Bref and the SF12v2. WHOQOL-Bref and the SF12v2 may have been more suitable in this study as they contained

fewer items than the WHOQOL and SF36 respectively. Considering the number of measures that participants were requested to complete, the use of these abbreviated measures may have reduced the impact of respondent fatigue compared to the longer versions.

Haase and Braden (2012) stated that measures of HRQOL are not comparable across dimensions. However, it is the standard practice to validate a new measure using established measures that evaluate the same construct. The validation of the SEQOL and its subscales using the WHOQOL-Bref and the SF12v2 was reported in section 5.6.8. The discussion below will qualitatively compare the SEQOL and its subscales and items with generic HRQOL measures.

While the items and subscales of the SEQOL share certain similarities with other HRQOL measures, important differences between these measures emerged. For example, most HRQOL measures contain subscales relating to physical functioning, vitality/energy, psychological wellbeing, social relationships and overall health status. This is in line with traditional models that view HRQOL as a multidimensional concept consisting of these dimensions (Greer, 1984; Han et al., 2003). Both the Rand SF36 and the WHOQOL contain these dimensions. Two of these dimensions, namely psychological functioning and vitality, are present in the SEQOL, WHOQOL and Rand SF-36. In addition, the Income subscale of the SEQOL contains similar items to the Environment subscale of the WHOQOL. However, on close inspection of these subscales it is evident that the income subscale of the SEQOL deals with the impact of endometriosis on patients' ability to earn an income, whereas the environment subscale of the WHOQOL is broader as it includes safety, the physical environment and access to healthcare services and transport. These broader items relating to the environment were not part of the SEQOL, indicating that it was not considered pertinent to patients with endometriosis QOL in the South African context.

The remaining five subscales of the SEQOL, i.e. sexual dysfunction and romantic relationships, reproductive functioning, occupational functioning, menstrual characteristics and support are not subscales found on generic HRQOL measures. In addition, a number of subscales contained in generic measures do not form part of the SEQOL. For example, the WHOQOL contains subscales relating to overall QOL and health and social relationships, and the Rand SF-36 contains subscales relating to physical functioning, bodily pain, physical role general health status and social role. None of these subscales appear in the SEQOL.

One aspect considered to be a central dimension of HRQOL is social functioning. The SEQOL does not contain a social subscale, even though this dimension is present in other generic measures. The absence of this subscale on the SEQOL indicates that the ability to interact with others socially was not considered an important aspect of HRQOL in the sample. However, three other subscales of the SEQOL contain items that can be considered to form part of a social subscale. First, the Sexual dysfunction and romantic relationships subscale contains items related to romantic relationships. Second, the Reproductive functioning subscale contains an item that pertains to being around other people with children. Finally, the Occupational functioning subscale contained an item specifically related to social functioning at work. Therefore, even though social functioning did not emerge as a dimension, the measure indirectly assesses social functioning through these other subscales. In conclusion, the SEQOL bears some similarities to generic HRQOL measures (e.g. all the measures contain dimensions pertaining vitality and psychological functioning), but for the most part the SEQOL contains subscales that are specific to patients with endometriosis, which generic measures do not.

5.7.3 Comparing the SEQOL to the EHP30.

The EHP30 is the only validated HRQOL measure developed specifically for patients with endometriosis. The EHP30 is a lengthy measure, containing a core component of 30

items and 6 additional subscales that are optional for participants. The optional subscales relate to (1) Work, (2) Relationships with children, (3) Sexual relationship, (4) Feelings about the medical profession, (5) Feelings about treatment and (6) Feelings about infertility. The entire measure (including the optional subscales) therefore contains 53 items. In contrast, the SEQOL consists of fewer items (35 items), but assesses similar domains. For example, both measures assess HRQOL in terms of patients' experiences relating to work, psychological functioning, sexual dysfunction, reproductive functioning, support and vitality. Six subscales from the EHP30 (this includes core and modular components) do not feature in the SEQOL. These subscales are (1) Relationships with children, (2) Feelings about the medical profession (3) Feelings about treatment, (4) Pain, (5) Control and powerlessness, and (6) Self-image. In addition, four subscales of the SEQOL do not feature on the EHP30. These subscales are (1) Income, (2) Vitality (3) Menstrual characteristics and (4) Support.

The EHP30 core module consists of four subscales that relate to (1) Pain, (2) Control and powerlessness, (3) Emotional well-being and (4) Self-image. The EHP30 core subscales are very different to the subscales of the SEQOL, indicating a conceptual difference of HRQOL in patients with endometriosis. The emotional well-being subscale of the EHP30 is congruent with the psychological functioning subscale of the SEQOL. However, other EHP dimensions, namely control and powerlessness, pain and self-image, did not emerge in this study as dimensions of HRQOL. In addition, the pain subscale of the EHP30 contains a number of items related to pain and symptoms of endometriosis. I deliberately excluded symptoms of endometriosis in developing the new measure as my conceptualization of HRQOL is related to the impact that symptoms have on the day-to-day functioning of patients and not the symptoms themselves. All items relating to symptoms were therefore removed and a separate Symptom Checklist was created (please refer to appendix ZS). The Symptom Checklist was not further developed in this study, but will be developed later.

The SEQOL contains one unique subscale named menstrual characteristics. The items on this subscale do not assess the presence or absence of menstrual characteristics such as dysmenorrhea and menorrhagia. Rather, the items assess thoughts or emotions associated with patients' menstruation. This subscale does not exist on any other measure of HRQOL, but emerged as an important dimension for participants in this study.

A strong correlation was found between scores on the core component of the EHP30 and scores of the SEQOL in the current study. Inspection of items in both measures illustrates that they view HRQOL somewhat differently. The differences between these two measures may be related to context. It is evident that aspects related to HRQOL differ from context to context. Even though both the EHP30 and the SEQOL measure HRQOL among patients with endometriosis, the measures are different. This difference may be attributed to context. The EHP30 was developed in the UK and the SEQOL was developed in South Africa. The present study was conducted in the Western Cape among middle to low income earners. For participants in this study, the impact that endometriosis had on their ability to work and earn an income was an important concern.

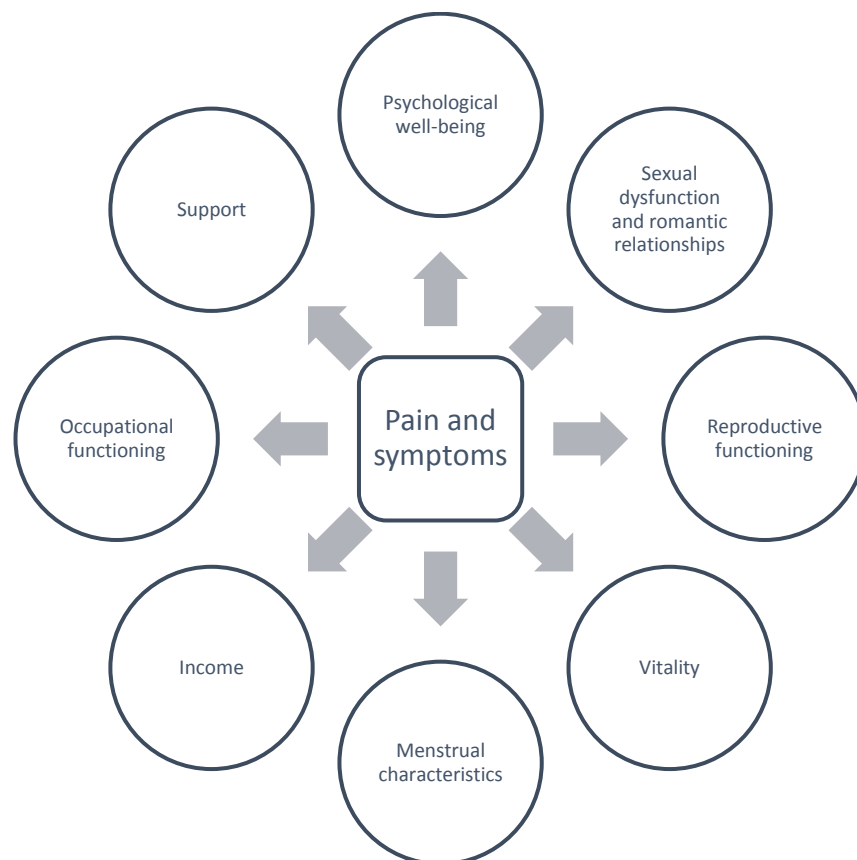
Successful QOL measures should be brief, easy to understand, easy to score and easy to analyse (King, 2012). The SEQOL is a much shorter measure compared to the EHP30. Although scoring criteria have not yet been established for the SEQOL, there are no indications that it would be a complicated scoring process. The SEQOL may therefore be suitable in circumstances where a short assessment of HRQOL in patients with endometriosis is necessary.

5.7.4 The SEQOL as a new model of HRQOL in patients with endometriosis.

The contextual model of HRQOL proposed by Ashing-Giwa (2005) was used to develop the interview schedule used in the first phase of the study. The model was used to

explore contextual HRQOL among women with endometriosis. During the first phase of this study, 10 categories emerged from the interviews with patients with endometriosis that described their HRQOL. In the second phase of this study these categories were reduced to eight subscales of HRQOL. Each of these subscales can be conceptualized as a dimension of HRQOL. Therefore, according to the SEQOL, HRQOL in patients with endometriosis consists of eight dimensions, namely (1) Psychological functioning, (2) Income, (3) Sexual dysfunction, (4) Reproductive functioning, (5) Vitality, (6) Occupational functioning, (7) Menstrual characteristics, and (8) Support. These dimensions indicate a very different conceptualization of HRQOL compared to dimensions traditionally employed in HRQOL research. A visual representation of this model can be found in figure 5.3.

Figure 5.3 Dimensions of HRQOL in women with endometriosis derived from the SEQOL



The above model differs considerably from the contextual model proposed by Ashing-Giwa (2005). Three dimensions on the SEQOL do not feature at all on the contextual model. These dimensions are (1) Sexual dysfunction and romantic relationships, (2) Reproductive functioning and (3) Menstrual characteristics. These dimensions are greatly associated with endometriosis and are therefore key dimensions on the SEQOL. The contextual model was originally developed for patients with breast cancer and these three dimensions are not leading features of the breast cancer experience.

In addition, four dimensions on the Contextual model did not emerge as dimensions on the SEQOL. These dimensions include the (1) Cultural dimension, (2) Demographic characteristics, (3) Healthcare system and (4) Medical factors. At the start of the study I expected the Cultural dimension to emerge during the development of the HRQOL. However, participants in Phase 1 of the study did not regard culture as an important aspect of HRQOL in terms of their experiences with endometriosis. One aspect of culture, namely spirituality, emerged in the first phase of the study. However, I framed spirituality as a coping strategy, and not as an aspect of culture. Therefore, the only items related to culture that were developed for the SEQOL were framed as coping strategies. Even though Spirituality surfaced as a coping strategy in Phase 1, there were insufficient items that could result in the development of a Cultural dimension on the SEQOL. There have been increasing calls for spirituality to be included as a dimension of HRQOL (Haase & Braden, 2012; Padilla, Kagawa-Singer, & Ashing-Giwa, 2012).

Similarly, in Phase 1 of the study, participants reported the healthcare system as pivotal to their experience of HRQOL. However, the healthcare system did not emerge as a dimension in Phase 2 of the study. Finally, both medical and demographic factors (dimensions of the CM) failed to emerge as dimensions of HRQOL in patients with endometriosis.

Certain dimensions on the contextual model and the SEQOL were congruent with one another. For example, the dimension named Income on the SEQOL was partially compatible with the Socio-ecological dimension of the CM. In addition, even though the SEQOL does not contain a Social support subscale (that also forms part of the socio-ecological dimension), the Occupational functioning dimension contains items relating to social support in the work setting. Another example of similarities between the two models is the Vitality subscale of the SEQOL and the General health dimension on the CM as both are indicators of health status. The support subscale of the SEQOL was similar to the Health efficacy dimension of the CM, as the SEQOL contained items relating to guidelines required and support from other women with endometriosis. Finally, the Psychological wellbeing dimension of the SEQOL was congruent with the Psychological functioning dimension of the SEQOL. In summary, while the CM provided a comprehensive framework for me to explore HRQOL in women with endometriosis, the resulting framework from this study was markedly different to that of the CM.

Other popular models of HRQOL include those developed by Ferrans et al. (2005) and Wilson and Cleary (1995). Wilson and Cleary's model (1995) consisted of five dimensions, namely (1) Biological function, (2) Symptoms, (4) Functional status, (4) General health perceptions and (5) General quality of life. The SEQOL has very little in common with these models of HRQOL. This difference may be due to the differences in specificity of the models and conceptualization of HRQOL. As previously mentioned, I did not conceptualize symptoms and functional status as dimensions of HRQOL, but rather as determinants of HRQOL. Similarly, pain was not regarded as a dimension of HRQOL, but as a cause of the dimensions. This is illustrated above in Figure 5.3. The conceptualization of the relationship between pain and HRQOL is similar to the City of Hope model of HRQOL (Roop et al., 2012) and is therefore not unique, but seldom used.

There is little theoretical basis for dimensions of HRQOL (Haase & Braden, 2012; King, 2012). This may be partially due to the lack of clear definitions of HRQOL and a tendency to define the concept in terms of its dimensions. The SEQOL only presents a conceptual model of HRQOL and further research should be conducted in order to develop this conceptual model into a theoretical model.

Furthermore, there are numerous conceptualizations of HRQOL. Bakas et al. (2012) claim that differing conceptualizations of HRQOL contribute negatively to developing the field of HRQOL research and practice, as they do not aid the development of a coherent body of HRQOL evidence. While I agree to some extent with this statement that it becomes challenging to develop a coherent body of research, I view these multiple conceptualizations of HRQOL as beneficial. The existence of differing HRQOL conceptions allow us to detect nuances of specific illnesses and alternate ways of viewing HRQOL. It is also important to note that HRQOL is highly subjective and it may therefore be extremely challenging to provide broad conceptualizations of the construct.

5.8 Conclusion

The SEQOL is a 35-item HRQOL measure that has been developed in the Western Cape, South Africa. The measure has demonstrated excellent reliability and good validity in the current sample. The SEQOL provides an alternate measure of HRQOL for patients with endometriosis.

Chapter 6

Conclusion, implications and limitations

6.1 Summary

HRQOL has become an important concept in research and practice with patients who are chronically ill (Katz, 2002; Schirm, 2009; Singh & Dixit, 2010). Patients with endometriosis often report poor HRQOL (Friedl et al., 2015; Jia et al., 2012; Giuliani et al., 2015; Petrelluzzi et al., 2008; Nunes et al., 2014; Siedentopf et al., 2008). Numerous measures of HRQOL have been developed to assess the HRQOL status of patients with chronic illnesses. Disease-specific HRQOL measures are useful in detecting specific health-related concerns that are unique to patients with a specific illness (Bowling, 2001). These measures may be especially applicable in assessing illnesses such as endometriosis of which the progression cannot be easily traced using biomedical markers (Barlow & Kennedy, 2005). However, to date only one disease-specific measure has been available for patients with endometriosis (i.e. the EHP 30).

In the present study, I used an exploratory, sequential mixed methods research design to develop a contextual HRQOL measure for patients with endometriosis (i.e. the SEQOL). The study stated three aims.

The first aim was to describe and understand the QOL-related experiences in women with endometriosis. The first aim therefore constituted Phase I of the project. During this qualitative phase, I conducted in-depth interviews with 25 women diagnosed with endometriosis to explore their HRQOL. I used a semi-structured interview schedule that explored HRQOL in terms of the contextual model of HRQOL proposed by Ashing-Giwa (2005). I explored participants' HRQOL in terms of these dimensions and I asked them to include additional dimensions of HRQOL that were not specified in the model. I recorded

and transcribed the interviews. I used thematic analysis to code the data and to identify themes. I identified 11 themes from the data, namely psychological functioning, sexual functioning, financial impact and considerations, healthcare and medical treatment, reproductive functioning, information and knowledge, interpersonal functioning, menstrual characteristics, occupational functioning, somatic features and physical functioning.

The second and third aims formed the quantitative phase of the study. The second aim of the study was to construct items for the instrument based on the data collected during the first phase. I used the codes from the 11 themes to construct the items for the measure. I decided on the response format, the appropriate response period and item stem at this stage of the study. I consulted with both subject experts (i.e. individuals who were knowledgeable about endometriosis) and methodological experts (i.e. individuals regarded as experts in psychometry) in making these decisions. I then constructed an initial item pool consisting of 314 items, with each item representing a code produced from analysis of the qualitative interviews. Two experts in psychometry who provided feedback relating to item clarity, conciseness, item wording and ambiguity (DeVellis, 2012), reviewed the item pool. During this process, I reduced the item pool to 184 items.

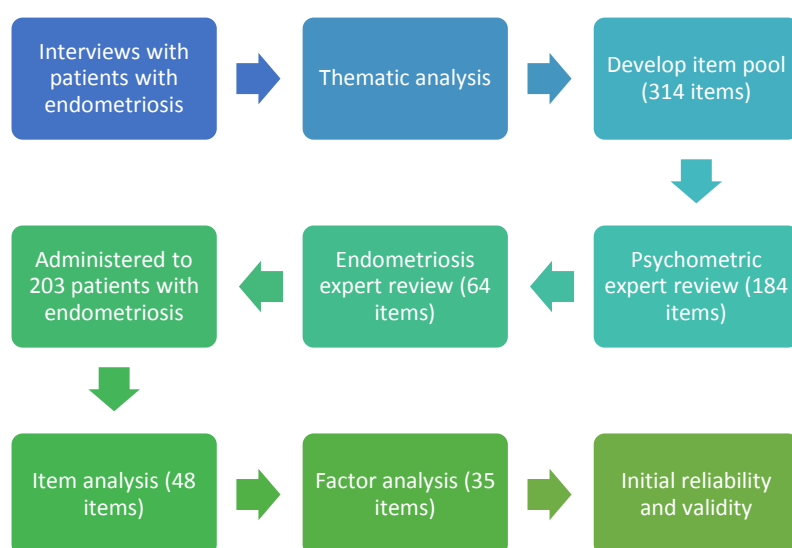
I then asked five endometriosis experts to review the items in terms of relevance. These experts were provided with the definition of HRQOL and were asked to rate each item for its relevance. Items that the experts regarded as highly relevant were retained in the measure and items that were not regarded as highly relevant were removed from the measure. The review resulted in the retention of 64 items. I piloted these items among seven women with endometriosis to assess the readability of the items.

The final aim of the study was to determine the test reliability, validity and factor structure of the measure. I administered the 64-item HRQOL measure, the EHP 30, SF12v2,

WHOQOL Bref and the BDI to 203 patients with endometriosis. I conducted an item analysis and removed 16 items that displayed corrected item total correlations below .35. I then conducted an EFA to establish the factor structure of the measure. The factor analysis identified 13 items that either cross-loaded on more than one factor or that did not significantly load on any factor. I removed these items from the measure. The remaining 35 items produced an eight-dimension factor structure. I named the measure the SEQOL and named the dimensions as follows: (1) Psychological functioning; (2) Income; (3) Sexual functioning and romantic relationships; (4) Reproductive functioning; (5) Vitality; (6) Occupational functioning; (7) Menstrual characteristics; and (8) Support.

The SEQOL and its subscales demonstrated excellent internal consistency reliability. The SEQOL produced a Cronbach's α of .92 and the Cronbach's α for the subscales ranged from .72 to .88. I then gathered information concerning the initial validation of the measure by correlating scores from the SEQOL and its dimensions with other validated measures. This initial validation indicated that the SEQOL measures HRQOL. Figure 6.1 is a flowchart depicting the creation and reduction of items for the SEQOL.

Figure 6.1. Flowchart indicating process of creation and reduction of number of items



6.2 Limitations

A number of methodological limitations may have influenced the outcome of this study. The first limitation relates to the qualitative phase of the study. I incorporated methods for enhancing the trustworthiness of the analysis by having my supervisor examine my coding and having an external coder independently code the first five interviews and assist with the development of the codebook. However, I did not conduct member checks by asking the participants of Phase I of the study for input on the findings. I do not believe this omission had a great impact on the outcome of the study as participants in the subsequent phase of the study stated that they could relate to the codes.

The second limitation relates to sampling bias. Most participants in endometriosis studies are recently diagnosed patients or patients from support groups (Fagervold et al., 2009). In addition, De Graaff et al. (2015) suggest that recruitment strategies may influence results in QOL studies, as participants recruited from tertiary hospitals and patient associations (e.g. support groups) typically experience worse QOL than those recruited through secondary hospitals. I recruited participants mostly via tertiary hospitals and infertility clinics and therefore patients in the study may have been experiencing worse symptoms of endometriosis than patients not seeking treatment at these sites. This selection strategy may have resulted in a skewed sample, as patients in this study may have been more likely to experience poorer HRQOL than patients at regular gynaecology practices.

A third limitation relates to sampling size. Sample sizes in endometriosis studies are generally small. No sampling frame of endometriosis patients exists and therefore finding and recruiting participants was the biggest challenge I experienced in this study. For example, it took me 11 months to collect the validation data from 203 participants. Ideally, I would have preferred a larger sample size.

The fourth limitation is generalizability, which is also related to sample size. The data were collected in the Western Cape, South Africa, and therefore should not be generalized beyond this population.

Finally, I developed the measure in English and only participants who spoke English either as a first or second language were able to participate in the study. I conducted the interviews in English and Afrikaans only. However, it should be worth noting that no patients were refused participation in this study due to language preferences. In addition, all patients reported being comfortable with the language options provided.

6.3 Implications for patients and recommendations for practice

This study found that patients diagnosed with endometriosis reported poor HRQOL. Many patients agreed to participate in this study in the hope of learning more about endometriosis. Those who participated in the study stated that they had not heard of endometriosis prior to their diagnosis. Participants also stated that they were not satisfied with the information that they had received from doctors. Endometriosis is not a well-known illness and it is therefore important that doctors provide the necessary information regarding the aetiology, pathogenesis and possible treatment options to patients affected by the disease. If doctors are unable to discuss the disease with patients, they should refer patients to accurate, reliable resources that can inform patients.

Furthermore, patients stated that doctors did not inquire about the effect of endometriosis on their HRQOL. It may be useful for doctors to inquire about patients' HRQOL to monitor disease progression and refer patients appropriately. The SEQOL may therefore be a useful tool in clinical practice as patients can complete the measure in order to show doctors the effect that endometriosis has on their quality of life. Doctors will then be able to make appropriate referrals or recommend suitable treatment for patients because they

would know which areas of a patient's life are most affected by endometriosis. For example, patients who score high on the sexual dysfunction subscale could be referred to psychologists and pelvic pain physiotherapists who can intervene to improve sexual functioning. Similarly, doctors can refer patients who report concerns regarding their fertility to doctors who specialize in fertility treatment.

Participants in the study also reported feeling isolated due to the impact of their illness. The vast majority of participants stated that they did not know anyone with endometriosis and many stated that they would like the support of other women who live with the disease. Patients with endometriosis may therefore benefit from support groups made up of patients with endometriosis. These support groups may be a source of both emotional support and informational support to women with this condition. In addition, most participants in this study stated that they experienced distress. These patients may benefit from referrals to psychologists.

In conclusion, it will be beneficial to patients if doctors take a multidisciplinary approach to managing symptoms in patients with endometriosis. A multidisciplinary approach may include doctors who specialize in surgery, fertility, endocrinology and healthcare professionals such as psychologists, pain management experts and physiotherapists. It is imperative that doctors enquire about and are aware of patients' HRQOL. Furthermore, doctors should take the needs and priorities of patients into account when deciding on suitable treatment. For example, if a patient tells her doctor that becoming pregnant is a priority for her, the doctor should be cognisant of this when recommending treatment.

6.4 Implications for research

Most research regarding the impact of endometriosis on patients' lives emanate from high income, primarily English-speaking countries (Young et al., 2015). The experiences of patients from these countries and developing countries such as South Africa may be different and it is therefore necessary to conduct further research to explore these differences and to provide more insight into living with endometriosis in developing countries. The current study indicates that HRQOL in patients with endometriosis differs between patients in the current sample and patients who participated in the development of the EHP 30 in the UK. It is therefore imperative that further research should be conducted to compare HRQOL in patients with endometriosis in developing and developed countries. Contextual factors such as income, cost of healthcare, access to healthcare, self-efficacy, informational support and social support and their relationship with HRQOL in different contexts, should be investigated. Such research will provide more information on the role of context in HRQOL.

The SEQOL requires further testing and validation, but can be used as a tool in assessing the HRQOL of patients with endometriosis in research. The SEQOL contains fewer items than the EHP 30 and may therefore be an alternative measure of HRQOL.

I would like to recommend areas for future research on endometriosis and HRQOL. First, further research on the SEQOL should be conducted. This research could include the development of scoring guidelines, determining of cut-off scores and assessing the responsiveness of the SEQOL, i.e. the ability to detect change. Further validation studies are also necessary. These include studies on other samples of patients with endometriosis, such as samples from other provinces in SA and outside SA.

It is necessary to conduct a confirmatory factor analysis (CFA) to test the factor structure of the SEQOL that was developed in the current study. A CFA is the next logical

step in this line of research, but it was beyond the scope of this study. A larger sample will be required to conduct a CFA to test the current factor structure. Finally, the SEQOL should be translated into other commonly spoken languages in the Western Cape, such as Afrikaans and isiXhosa.

It is imperative to conduct further psychosocial research on women living with endometriosis. Many studies describe HRQOL in patients with endometriosis or compare patients with endometriosis to other patient populations or healthy individuals (Culley et al., 2013; Friedl et al., 2015; De Graaff et al., 2015; Jia et al., 2012; Giuliani et al., 2015; Lövkvist et al., 2012; Petrelluzzi et al., 2008; Nunes et al., 2014; Siedentopf et al., 2008). More research should be conducted to identify predictors of HRQOL in patients with endometriosis. The identification of predictors of HRQOL may provide an indication of where to intervene to improve the QOL of women with endometriosis. Furthermore, the development and evaluation of psychosocial interventions may benefit patients with endometriosis. For example, many patients in the current study reported that fatigue negatively influenced their HRQOL. Yet, no interventions aimed at reducing fatigue have been applied to and evaluated in patients with endometriosis. Interventions aimed at improving patients' sexual functioning, psychological functioning and coping may be beneficial to patients with endometriosis. Studies, specifically randomised controlled trials, therefore need to be developed that test the effectiveness of chronic fatigue interventions in patients with endometriosis. Similarly, patients with endometriosis report poor sexual functioning and studies should be conducted that assess the effectiveness of psychological and physiological interventions aims at improving sexual functioning.

6.5 Conclusion

The overarching objective of the study was to develop a contextual HRQOL measure and therefore the setting in which the study took place was an important aspect of the research. The participants were patients and experts from the Western Cape, South Africa. The items on the SEQOL are different to the items on the EHP 30 (which was developed in the UK), indicating that the understanding and impact of HRQOL in women with endometriosis differs depending on context.

This study showed that endometriosis affected multiple areas of women's lives, such as their psychological well-being, income, sexual functioning and romantic relationships, occupational functioning, etc. This multifaceted impact has numerous implications. For example, participants considered income and the ability to work to be important aspects of HRQOL. Endometriosis may result in women being unable to work optimally, thereby affecting their income. In addition, when women are unable to work, there is a cost to the economic system as work productivity decreases. There may also be costs to social development as women withdraw from society and may not contribute despite having the necessary skills and knowledge to make valuable contributions. The impact of endometriosis therefore extends beyond patients to families, communities and the broader society.

Endometriosis falls within the ambit of reproductive health. Reproductive health research in Africa has largely focused on areas such as family planning, maternal mortality, sexually transmitted infections and unwanted pregnancy. These areas of research are prioritized because they affect communities and the broader society. Endometriosis is currently conceptualized as an individual issue, in other words something that only affects the women diagnosed with this condition. Further research is required to investigate the impact

that endometriosis has beyond the patient. Such research can be used to set a new agenda for reproductive health research.

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Appendix A

Health Research Ethics committee approval



UNIVERSITEIT•STELLENBOSCH•UNIVERSITY
jou kennisvennoot • your knowledge partner

Approval Notice New Application

24-Jul-2013
Roomaney, Rirwana R.

Ethics Reference #: S13/05/109
Title: The construction and validation of a health-related quality of life measure for women with endometriosis

Dear Ms Rirwana Roomaney,

The New Application received on 03-Jun-2013, was reviewed by members of **Health Research Ethics Committee 2** via Expedited review procedures on 05-Jun-2013 and was approved.

Please note the following information about your approved research protocol:

Protocol Approval Period: 02-Jul-2013 -02-Jul-2014

Please remember to use your **protocol number** (S13/05/109) on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:
Please note a template of the progress report is obtainable on www.sun.ac.za/rd and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.
Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.
For standard HREC forms and documents please visit: www.sun.ac.za/rd

If you have any questions or need further assistance, please contact the HREC office at 0219389207.

Included Documents:
IC VALIDATION
CHECKLIST
IC FORM
APPLIC FORM
CV KAGEE
TYGERBERG LETTER
POSTER AND FLYERS
PERMISSION FORM
SYNOPSIS
IC FORM

Appendix B

Western Cape Department of Health permission to conduct research



STRATEGY & HEALTH SUPPORT
Health.Research@westerncape.gov.za
tel: +27 21 483 6857; fax: +27 21 483 9895
5th Floor, Norton Rose House, 8 Riebeeck Street, Cape Town, 8001
www.capegateway.gov.za

REFERENCE: RP 124/2013
ENQUIRIES: Ms Charlene Roderick

**Psychology Department
Stellenbosch University
Private Bag X1
Matieland
7602**

For attention: Rizwana Roomaney and Prof SA Kagee

Re: The construction and validation of a health-related quality of life measure for women with endometriosis

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Please contact the following people to assist you with any further enquiries in accessing the following sites:

Paarl Hospital Dr B Kruger Contact No. 021- 918 1911

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final report within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. The reference number above should be quoted in all future correspondence.

We look forward to hearing from you.

Yours sincerely


DR NT Naledi

DIRECTOR: HEALTH IMPACT ASSESSMENT

DATE: 7/10/2013
CC **DR L PHILLIPS**

DIRECTOR: CAPE WINELANDS

Page 1 of 1

Appendix C

Health Research Ethics Committee approval of additional sites



Appendix D

Health Research Ethics Committee approval of additional site (Dr. Jansen)



UNIVERSITEIT-STELLENBOSCH-UNIVERSITY
jou kennisvennoot • your knowledge partner

Ethics Letter

14-Apr-2014

Ethics Reference #: S13/05/109

Clinical Trial Reference #:

Title: The construction and validation of a health-related quality of life measure for women with endometriosis

Dear Ms Rizwana Roomaney,

The HREC has granted permission to use the additional site of Dr L.Jansen to recruit participants for your research.


If you have any queries or need further assistance, please contact the HREC Office 0219389657.

Sincerely,

REC Coordinator
Franklin Weber
Health Research Ethics Committee 2

Appendix E

Health Research Ethics Committee approval of additional site (Karl Bremer hospital)



UNIVERSITEIT•STELLENBOSCH-UNIVERSITY
jou kennisvenoot • your knowledge partner

Approval Notice New Application

24-Jul-2013
Roomaney, Rizwana R

Ethics Reference #: S13/05/109
Title: The construction and validation of a health-related quality of life measure for women with endometriosis

Dear Ms Rizwana Roomaney,

The New Application received on 03-Jun-2013, was reviewed by members of **Health Research Ethics Committee 2** via Expedited review procedures on 05-Jun-2013 and was approved.

Please note the following information about your approved research protocol:

Protocol Approval Period: 02-Jul-2013 -02-Jul-2014

Please remember to use your **protocol number** (S13/05/109) on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:
Please note a template of the progress report is obtainable on www.sun.ac.za/hrs and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.
Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

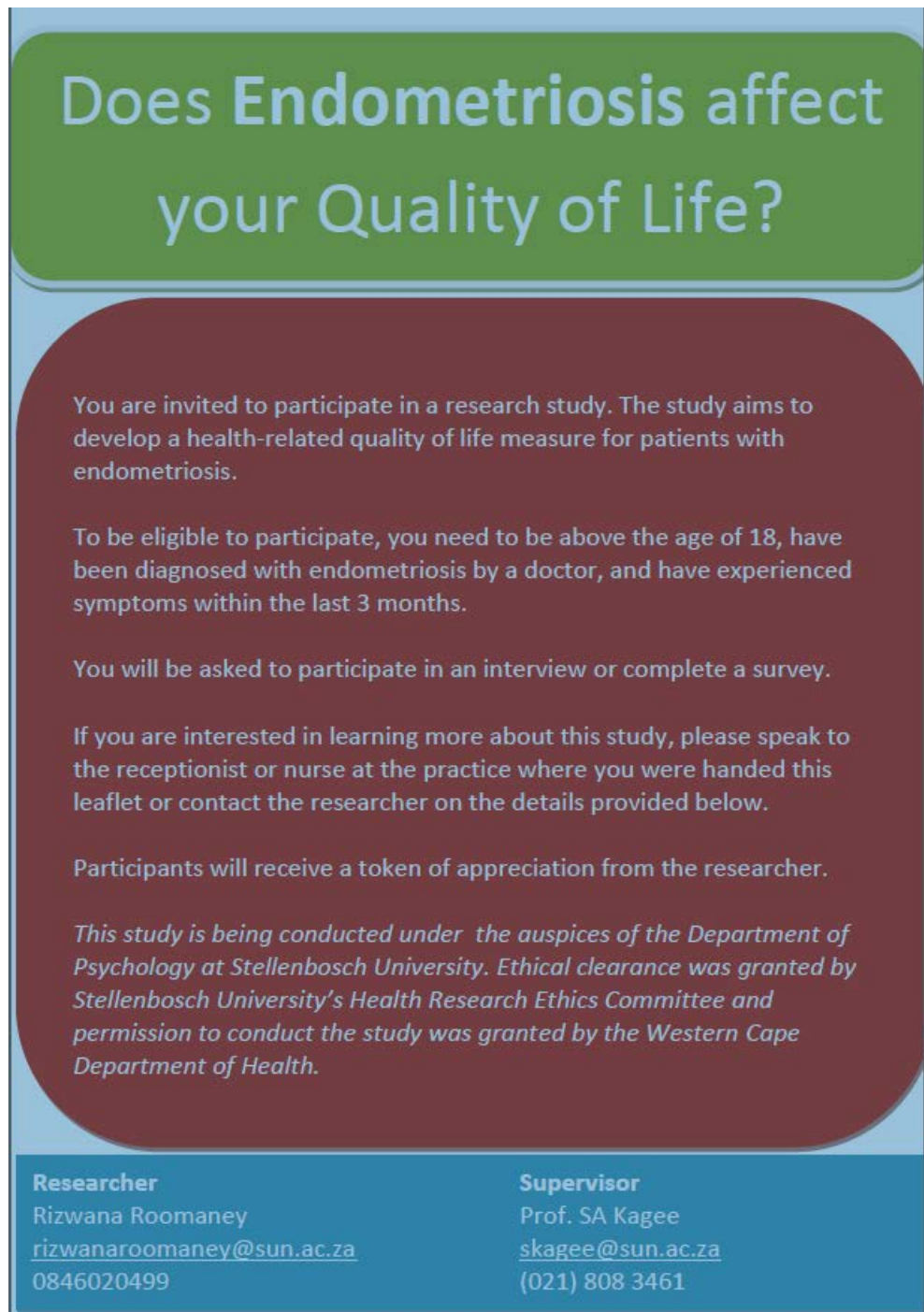
We wish you the best as you conduct your research.
For standard HREC forms and documents please visit: www.sun.ac.za/hrs

If you have any questions or need further assistance, please contact the HREC office at 0219389207.

Included Documents:
IC VALIDATION
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CV KAGEE
TYGERBERG LETTER
POSTER AND FLYERS
PERMISSION FORM
SYNOPSIS
IC FORM

Appendix F

Flyer



Does Endometriosis affect your Quality of Life?

You are invited to participate in a research study. The study aims to develop a health-related quality of life measure for patients with endometriosis.

To be eligible to participate, you need to be above the age of 18, have been diagnosed with endometriosis by a doctor, and have experienced symptoms within the last 3 months.

You will be asked to participate in an interview or complete a survey.

If you are interested in learning more about this study, please speak to the receptionist or nurse at the practice where you were handed this leaflet or contact the researcher on the details provided below.

Participants will receive a token of appreciation from the researcher.

This study is being conducted under the auspices of the Department of Psychology at Stellenbosch University. Ethical clearance was granted by Stellenbosch University's Health Research Ethics Committee and permission to conduct the study was granted by the Western Cape Department of Health.

Researcher Rizwana Roomaney rizwanaroomaney@sun.ac.za 0846020499	Supervisor Prof. SA Kagee skagee@sun.ac.za (021) 808 3461
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Appendix G

Contact Permission Form

TITLE OF THE RESEARCH PROJECT: The construction and validation of a health-related quality of life measure for women with endometriosis

I, (full name and surname), would like to learn more about this study relating to the health-related quality of life in women with endometriosis and how I may participate in this study.

I hereby grant permission for the investigator to contact me and explain this study to me. I may be contacted as follows:

Telephone number	
Cell phone number	
Home/postal address	
email	

I understand that by consenting to be contacted, I am not obligated to participate in the study.

DETAILS OF PRINCIPAL INVESTIGATOR

Name: Rizwana Roomaney

ADDRESS: Psychology Department, Wilcox Building, Ryneveld Street, Stellenbosch, 7600

CONTACT NUMBER: 0846020499

EMAIL: rizwanaroomaney@sun.ac.za

Appendix H

Interview schedule

I am going to ask you a few questions about the impact of endometriosis on your quality of life. Please take your time to answer the questions, providing as much or as little information as you feel comfortable sharing. The information that you share will be treated as confidential. If at any time you would like to end this interview you are free to do so.

1. Can you tell me about your experience with endometriosis?
2. Can you tell me about your diagnosis?
3. What were the events that lead up to the diagnosis?
4. What was your experience with doctors and the health care system?
5. Describe the support available to you?
6. Can you tell me how your symptoms of endometriosis affect your quality of life?
7. How does endometriosis affect your physical well-being or functioning?
8. How does endometriosis affect you psychologically or emotionally? Have you ever consulted a mental health professional for assistance?
9. How does endometriosis affect your social functioning?
10. How does endometriosis impact your personal relationships?
11. Do you ever experience sexual difficulties because of endometriosis? Do you mind telling me about it?
12. Are there any ways in endometriosis creates difficulties in your environment? For example what is its impact at work, school, and home and on financial resources?
13. Are there any other ways in which endometriosis affects your quality of life that we have not discussed in this interview?
14. Is there anything that you would like to gain from research into endometriosis?

Appendix I

Initial codebook

COPING

1. Coping_acceptance
2. Coping_distraction eases pain
3. Coping_humour
4. Coping_limit activities
5. Coping_positive attitude
6. Coping_research
7. Coping_scheduling activities according to menstrual cycle
8. Coping_self management
9. Coping_self talk
10. Coping_spirituality
11. Coping_venting

DYSPAREUNIA

12. Dyspareunia_avoidance
13. Dyspareunia_avoiding relationships
14. Dyspareunia_bleeding
15. Dyspareunia_disclosed to doctors
16. Dyspareunia_fear
17. Dyspareunia_impact on relationship
18. Dyspareunia_improved after treatment
19. Dyspareunia_negative emotional consequences due to dyspareunia
20. Dyspareunia_pain
21. Dyspareunia_pain after sex
22. Dyspareunia_painful penetration

HEALTHCARE

23. Healthcare_belief that private healthcare is better than state
24. Healthcare_communication_afraid to ask doc questions
25. Healthcare_communication_barriers in communicating to doctors
26. Healthcare_communication_doctor unable to answer questions
27. Healthcare_communication_doctors provide too much info at once
28. Healthcare_communication_information from doctor/nurse
29. Healthcare_communication_not satisfied with info provided by doc/nurse
30. Healthcare_communication_patient able to communicate with doctor
31. Healthcare_communication_satisfied with info provided by doctors/nurses
32. Healthcare_cost-effective pain relief
33. Healthcare_cost of treatment
34. Healthcare_dissatisfied with medical care
35. Healthcare_doc/nurse normalises symptom
36. Healthcare_doctor refers patient
37. Healthcare_doctors not proactive
38. Healthcare_does not seek healthcare unless absolutely necessary
39. Healthcare_impersonal care at state facilities
40. Healthcare_ineffective treatment

41. Healthcare_long wait for treatment
42. Healthcare_perceived misdiagnosis
43. Healthcare_restricted access to pain killers
44. Healthcare_satisfied with medical care
45. Healthcare_seeking medical care from several places
46. Healthcare_seeks information / assistance from doc / nurse
47. Healthcare_treatment refused

INFERTILITY

48. Infertility_constantly thinking about
49. Infertility_frustrated that doctors have not addressed this concern
50. Infertility_hides from others
51. Infertility_impact of
52. Infertility_no information provided by doctors
53. Infertility_planning treatment
54. Infertility_seeking alternatives
55. Infertility_strong desire to have a child
56. Infertility_working to afford IVF
57. Infertility_concern

INFORMATION

58. Information_conflicting info
59. Information_diagnosis empowering
60. Information_does not know enough to explain to others
61. Information_endo and cancer
62. Information_lack of public info on endo a barrier
63. Information_never heard of endo before diagnosis
64. Information_patient not able to process info
65. Information_requires additional information on endo
66. Information_requires guidelines
67. Information_researched endometriosis
68. Information_understanding of disease

INTERPERSONAL

69. Interpersonal_ambivalence to being alone
70. Interpersonal_caused conflict in relationship
71. Interpersonal_dependant on others
72. Interpersonal_disclosing illness to others
73. Interpersonal_does not want help from others
74. Interpersonal_does not want pity
75. Interpersonal_does not want to burden others
76. Interpersonal_friends
77. Interpersonal_impact on others
78. Interpersonal_impact on social life
79. Interpersonal_positive outcomes
80. Interpersonal_relationship with children
81. Interpersonal_relationships_difficult
82. Interpersonal_seeking other patients with endo
83. Interpersonal_selective disclosure / non-disclosure
84. Interpersonal_social support_additional social support required

- 85. Interpersonal_social support_family
- 86. Interpersonal_social support_partner
- 87. Interpersonal_social support_non-support
- 88. Interpersonal_social withdrawal
- 89. Interpersonal_support_relies on support from people in similar situations
- 90. Interpersonal_support_social media

MENSTRUAL

- 91. Menstrual_clots
- 92. Menstrual_irregular cycle
- 93. Menstrual_menorrhagia
- 94. Menstrual_prolonged menstruation
- 95. Menstrual_spotting

OCCUPATIONAL

- 96. Occupational_education_negative impact on schooling
- 97. Occupational_work_difficult discussion symptoms w men
- 98. Occupational_work_difficulty disclosing to employer
- 99. Occupational_work_fear of losing job
- 100. Occupational_work_goes to work despite pain
- 101. Occupational_Work_negative impact at work
- 102. Occupational_Work_pressure to work
- 103. Occupational_work_support
- 104. Occupational_Work_tries to not let it affect work
- 105. Occupational_Work_unable to work (home/work)
- 106. Occupational_Work_unwilling to disclose diagnosis at work
- 107. Occupational_Work_working alleviates pain

PAIN

- 108. Pain_activity_resting / lying down
- 109. Pain_activity_sitting
- 110. Pain_experience of pain
- 111. Pain_factor assoc_temp
- 112. Pain_hides pain from others
- 113. Pain_influences plans for the future
- 114. Pain_location_abdomen
- 115. Pain_location_back
- 116. Pain_location_bodily pain
- 117. Pain_location_ovaries
- 118. Pain_location_rectum
- 119. Pain_location_uterus
- 120. Pain_menstrual
- 121. Pain_non-menstrual / chronic
- 122. Pain_pre-menstrual
- 123. Pain_sciatic
- 124. Pain_unable to manage pain
- 125. Pain_unidentified

PHYSICAL LIMITATION

- 126. Physical limitation_bed rest

- 127. Physical limitation_feeling restricted
- 128. Physical limitation_unable to eat
- 129. Physical limitation_unable to lie down
- 130. Physical limitation_unable to lift heavy objects
- 131. Physical limitation_unable to partake in sports
- 132. Physical limitation_unable to play with children
- 133. Physical limitation_unable to run
- 134. Physical limitation_unable to sit
- 135. Physical limitation_unable to sleep
- 136. Physical limitation_unable to stand
- 137. Physical limitation_unable to walk

PHYSICAL SYMPTOM

- 138. Physical symptom_congested abdomen
- 139. Physical symptom_constipation
- 140. Physical symptom_dyspareunia
- 141. Physical symptom_endometrioma
- 142. Physical symptom_faint
- 143. Physical symptom_feeling ill
- 144. Physical symptom_fever
- 145. Physical symptom_ibs
- 146. Physical symptom_lethargy
- 147. Physical symptom_loss of appetite
- 148. Physical symptom_migraines or headaches
- 149. Physical symptom_nausea
- 150. Physical symptom_numbness in legs
- 151. Physical symptom_organs feeling loose
- 152. Physical symptom_tactile aversion
- 153. Physical symptom_tired
- 154. Physical symptom_unable to urinate
- 155. Physical symptom_vomitting
- 156. Physical symptom_weight loss
- 157. Physical symptom_reappearance of symptoms

PSYCHOLOGICAL/EMOTIONAL

- 158. Psychological/emotional_hope
- 159. Psychological/emotional_frustration
- 160. Psychological/emotional_concerned about living with chronic pain
- 161. Psychological/emotional_depressed
- 162. Psychological/emotional_diagnosis offers relief
- 163. Psychological/emotional_disoriented
- 164. Psychological/emotional_does not fear disease
- 165. Psychological/emotional_does not want pity
- 166. Psychological/emotional_does not want to be diagnosed with depression
- 167. Psychological/emotional_emotional
- 168. Psychological/emotional_endo makes her feel like a different person
- 169. Psychological/emotional_feeling disoriented
- 170. Psychological/emotional_fertility
- 171. Psychological/emotional_frustrated with healthcare
- 172. Psychological/emotional_frustrated with referrals

173. Psychological/emotional_frustration regarding diagnosis
174. Psychological/emotional_helplessness
175. Psychological/emotional_hopeless
176. Psychological/emotional_isolated
177. Psychological/emotional_loss of interest
178. Psychological/emotional_need to exert control over life
179. Psychological/emotional_neglects personal appearance
180. Psychological/emotional_pain makes her feel diff abnormal
181. Psychological/emotional_paranoia
182. Psychological/emotional_perfectionist
183. Psychological/emotional_psychological impact
184. Psychological/emotional_questions how actions will contribute to disease
185. Psychological/emotional_questions why she has the disease
186. Psychological/emotional_reaction to pain_moody
187. Psychological/emotional_reaction_anxiety
188. Psychological/emotional_regret actions
189. Psychological/emotional_self conscious
190. Psychological/emotional_self esteem
191. Psychological/emotional_stressful
192. Psychological/emotional_suicidal thoughts
193. Psychological/emotional_thoughts of harming others
194. Psychological/emotional_uncertainty
195. Psychological/emotional_vigilant of symptoms
196. Psychological/emotional_want to be able to do more

TREATMENT

197. Treatment_analgesics
 198. Treatment_contraceptives
 199. Treatment_disatisfied with treatment
 200. Treatment_hormones
 201. Treatment_results in positive outcome
 202. Treatment_side-effect
 203. Treatment_surgery
-
204. Changes in life
 205. Does not wish endo on other women
 206. Endo an invisible disease
 207. Existential reason behind illness
 208. Loss of normal life

Appendix J

Informed consent form for interviews

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT: The construction and validation of a health-related quality of life measure for women with endometriosis

REFERENCE NUMBER:

PRINCIPAL INVESTIGATOR: Rizwana Roomaney

ADDRESS: Psychology Department, Wilcox Building, Ryneveld Street, Stellenbosch, 7600

CONTACT NUMBER: 0846020499

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

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

What is this research study all about?

This study aims to develop and validate a health-related quality of life (HRQOL) measure for patients with endometriosis. This measure will be used to monitor the impact of endometriosis on patients' quality of life. The measure can therefore play a key role determining the effectiveness of treatment or identify areas in which quality of life has been impeded due to endometriosis. Identifying these areas will allow doctors to evaluate where interventions are needed.

The study will be conducted in the Western Cape. Participants will be recruited via public and private healthcare facilities. If you agree to participate, you will be interviewed about your experiences in relation to endometriosis.

Interviews will be conducted with 30 patients with endometriosis. Participants will be asked to speak about the impact that endometriosis has on their quality of life. The interviews will be conducted by the researcher who is a registered counsellor and has experience in conductive interviews of a sensitive nature. Interviews will last approximately an hour and be conducted in English or Afrikaans.

Who may participate in this study?

Any patient that has been laparoscopically diagnosed with endometriosis by a doctor and who experience symptoms of endometriosis may participate.

Will you benefit from taking part in this research?

There are no direct benefits associated with participating in this study. However, the construction and validation of a HRQOL measure for patients with endometriosis can assist patient, doctors and researchers in future.

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

There are no known risks to participating in this study. Should you have any concerns do not hesitate to contact the researcher.

Who will have access to your medical records?

The researcher will not have access to your medical records and will not discuss your case with your doctor. This study is being conducted independently of the healthcare facility through which you are recruited and does not in any way affect your ongoing treatment at the facility.

All information collected will remain confidential, with only the researcher, supervisor and research assistant having direct access to the data. All persons handling data will be required to sign confidentiality agreements. Any information that may lead to the identification of participants will be removed when disseminating the research.

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

Participants will receive a gift voucher as a token of appreciation for participating in the study.

Is there anything else that you should know or do?

- You can contact Rizwana Roomaney at 0716826454 if you have any further queries or encounter any problems.
- You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I agree to take part in a research study entitled (*insert title of study*).

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.

- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) on (*date*) 2014.

.....
Signature of participant

.....
Signature of witness

Declaration by investigator

I declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a interpreter. (*If a interpreter is used then the interpreter must sign the declaration below.*)

Signed at (*place*) on (*date*) 2014.

.....
Signature of investigator

.....
Signature of witness

Consent to confirm diagnosis

I hereby grant permission to the researcher to contact my doctor/nurse to confirm that I have been diagnosed with endometriosis.

Name of doctor(s).....

Clinic/hospital.....

Appendix K

Final measure prior to item reduction

Below is a list of statements that other women with endometriosis have said affects their quality of life. Please indicate if these statements relate to your experience of the impact of endometriosis on your quality of life.

Please circle or mark one number per line to indicate your response as it applies to the past 8 weeks.

Because of my endometriosis....

		Not at all	A little bit	Somewh at	Quite a bit	Very much	Not applicable
1.	I lost hope in the fight against my illness	1	2	3	4	5	NA
2.	I was worried that my condition would get worse	1	2	3	4	5	NA
3.	I felt anxious	1	2	3	4	5	NA
4.	I felt helpless	1	2	3	4	5	NA
5.	I felt like I am the only person with endometriosis	1	2	3	4	5	NA
6.	I was concerned about living with endometriosis for the rest of my life	1	2	3	4	5	NA
7.	I struggled to cope	1	2	3	4	5	NA
8.	I was unsure about how to manage my pain	1	2	3	4	5	NA
9.	I mentally prepared myself for pain	1	2	3	4	5	NA
10.	I adopted a positive attitude to cope	1	2	3	4	5	NA
11.	I researched endometriosis to cope	1	2	3	4	5	NA
12.	I was scared of having sexual intercourse	1	2	3	4	5	NA
13.	I avoided sexual intercourse	1	2	3	4	5	NA
14.	Pain during sexual intercourse affected my relationship	1	2	3	4	5	NA
		Not at all	A little bit	Somewh at	Quite a bit	Very much	Not applicable
15.	I avoided relationships because of painful sexual intercourse	1	2	3	4	5	NA

16.	I struggled to describe my pain to doctors	1	2	3	4	5	NA
17.	I did not think my doctor understood me	1	2	3	4	5	NA
18.	I was happy with the medical care I received	1	2	3	4	5	NA
19.	My doctor considered my needs	1	2	3	4	5	NA
20.	I felt unsure when different doctors gave me different advice	1	2	3	4	5	NA
21.	I felt better because of my treatment	1	2	3	4	5	NA
22.	I resigned/quit schooling because of my illness	1	2	3	4	5	NA
23.	I missed school/work because of my illness	1	2	3	4	5	NA
24.	I was forced to take unpaid leave because of my illness	1	2	3	4	5	NA
25.	My illness limited my ability to earn an income	1	2	3	4	5	NA
26.	I was worried about not falling pregnant	1	2	3	4	5	NA
27.	I felt pressure to have a child	1	2	3	4	5	NA
28.	My difficulty falling pregnant caused problems in my relationship	1	2	3	4	5	NA
29.	I felt frustrated trying to get pregnant	1	2	3	4	5	NA
30.	I gave up hope of having my own child	1	2	3	4	5	NA
31.	It was difficult for me to be around people with children	1	2	3	4	5	NA
32.	I preferred it if people did not ask me why I do not have children	1	2	3	4	5	NA

33.	I tried to find out more information about endometriosis	1	2	3	4	5	NA
34.	Being diagnosed made things easier for me	1	2	3	4	5	NA
35.	Being diagnosed was empowering for me	1	2	3	4	5	NA
36.	I needed guidelines on how to manage my endometriosis	1	2	3	4	5	NA
37.	I did not understand what endometriosis is	1	2	3	4	5	NA
38.	I felt anxious about not knowing how to deal with my endometriosis	1	2	3	4	5	NA
39.	Telling people that I have endometriosis made it easier to cope	1	2	3	4	5	NA
40.	I felt frustrated when people told me that period pain is normal	1	2	3	4	5	NA
41.	I withdrew from social activities	1	2	3	4	5	NA
42.	I felt like I was missing out on life	1	2	3	4	5	NA
43.	I was not good company	1	2	3	4	5	NA
44.	Endometriosis caused difficulty in my romantic relationship	1	2	3	4	5	NA
45.	My partner was supportive	1	2	3	4	5	NA
46.	My partner did not understand my pain	1	2	3	4	5	NA
47.	My partner did not believe that I was ill	1	2	3	4	5	NA
48.	I needed more support	1	2	3	4	5	NA
49.	I felt the need to speak to other women with endometriosis	1	2	3	4	5	NA

50.	I was concerned about the clots in my period	1	2	3	4	5	NA
51.	I was worried that my period was not normal	1	2	3	4	5	NA
52.	I felt that my period drained me	1	2	3	4	5	NA
53.	I experience pain all the time	1	2	3	4	5	NA
54.	I only experienced pain when I menstruated	1	2	3	4	5	NA
55.	I experienced pain a week prior to menstruation	1	2	3	4	5	NA
56.	I was often absent from work/school due to my endometriosis	1	2	3	4	5	NA
57.	I did not have enough sick leave to manage my endometriosis	1	2	3	4	5	NA
58.	People at work/school did not believe my pain	1	2	3	4	5	NA
59.	My colleagues did not support me	1	2	3	4	5	NA
60.	I could not work when I was in pain	1	2	3	4	5	NA
61.	I was hesitant to enter a new work environment as I am afraid that other employers may not understand my illness	1	2	3	4	5	NA
62.	I did not have energy	1	2	3	4	5	NA
63.	My symptoms affected my day-to-day living	1	2	3	4	5	NA
64.	I had to stay in bed	1	2	3	4	5	NA

Appendix L

Data collection form for pilot

What do you think about the measure you just completed?

Below are some questions relating to the measure you just completed. Your assessment of the measure will help me to improve it. Your input is greatly appreciated.

1. How long did it take you to complete the measure? _____

Questions about the format of the measure...

2. Were the instructions easy to understand? Please specify.

3. What do you think about the starting phrase of each question "Because of my endometriosis..."?

4. What do you think of the response options "Not at all"; "A little bit", "Somewhat", "Quite a bit" , "Very much" and "Not applicable"? Are they easy to understand and are there too little or too few options?

Questions about the wording of the measure...

5. Please identify if any questions are complicated / difficult to understand.

6. Please identify any words that are unfamiliar.

7. Please identify any questions that you think should be rephrased to make them easier.

Questions about the content...



8. Are the questions in the measure relevant to your experience of the impact of endometriosis on your quality of life?

9. Is there anything related to the impact of endometriosis on your quality of life that is not reflected in these questions? (Are there any questions that you think need to be added?)

10. Any other comments?

Appendix M

Health Research Ethics Committee approval for Groote Schuur Hospital

	UNIVERSITY OF CAPE TOWN Faculty of Health Sciences Human Research Ethics Committee	
Room E52-24 Old Main Building Groote Schuur Hospital Observatory 7925 Telephone [021] 406 6338 • Facsimile [021] 406 6411 Email: shuretta.thomas@uct.ac.za Website: www.health.uct.ac.za/fhs/research/humanethics/forms		

16 November 2015

HREC REF: 573/2015

Prof A Kagee
Psychology Department
Stellenbosch University
Wilcox Building
Ryneveld Street
Stellenbosch

Dear Prof Kagee

PROJECT TITLE: THE CONSTRUCTION AND VALIDATION OF A HEALTH-RELATED QUALITY OF LIFE MEASURE FOR WOMEN WITH ENDOMETRIOSIS-(PhD-candidate-R Roomaney)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th November 2016.


Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

We acknowledge that the PhD student, Rizwana Roomaney will also be involved in this study.

Yours sincerely




PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical


HREC 573/2015

Appendix N

Western Cape Department of Health approval to conduct research at Groote Schuur Hospital



**Western Cape
Government**
Health



GROOTE SCHUUR HOSPITAL
Enquiries: Dr Bernadette Eick
E-mail : Bernadette.Eick@westerncape.gov.za

Professor A. Kagee
Psychology Department
Stellenbosch University
Wilcox Building
Ryneveld Street
STELLENBOSCH

E-mail: rizwanaroomaney@sun.ac.za

Dear Professor Kagee

RESEARCH PROJECT: The Construction and Validation of A Health Related Quality of Life Measure for Women with Endometriosis (PhD Candidate R. Roomaney)

Your recent letter to the hospital refers.

You are hereby granted permission to proceed with your research.

Please note the following:

- a) Your research may not interfere with normal patient care.
- b) Hospital staff may not be asked to assist with the research.
- c) No hospital consumables and stationary may be used.
- d) **No patient folders may be removed from the premises or be inaccessible.**
- e) Please introduce yourself to the person in charge of an area before commencing.
- f) Please discuss the study with the HOD before commencing.
- g) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
- h) Confidentiality must be maintained at all times.

I would like to wish you every success with the project.

Yours sincerely

Signed by Dr B. Jacobs

DR BERNADETTE EICK
CHIEF OPERATIONAL OFFICER
Date: 18 December 2015

C.C. Mr. L. Naidoo, Dr H. Aziz, Professor S. Dyer

G46 Management Suite, Old Main Building,
Observatory 7925

Tel: +27 21 404 6288 fax: +27 21 404 6125

Private Bag X,
Observatory, 7935

www.capegateway.gov.za

Appendix O

Informed consent form for validation

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT: The construction and validation of a health-related quality of life measure for women with endometriosis

PRINCIPAL INVESTIGATOR: Rizwana Roomaney

ADDRESS: Psychology Department, Wilcox Building, Ryneveld Street, Stellenbosch, 7600

CONTACT NUMBER: 0716826454

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

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

What is this research study all about?

This study aims to develop and validate a health-related quality of life (HRQOL) measure for patients with endometriosis. This measure will be used to monitor the impact of endometriosis on patients' quality of life. The measure can therefore play a key role determining the effectiveness of treatment or identify areas in which quality of life has been impeded due to endometriosis. Identifying these areas will allow doctors to evaluate where interventions are needed.

The study will be conducted in the Western Cape. Participants will be recruited via public and private healthcare facilities. If you agree to participate, you will be required to complete a number of assessment measures (surveys). The measures will be in English and take approximately 40- 60 minutes to complete. 500 participants will be required for this part of the study. The measures will either be administered in person, through the post or electronically (web-based survey) depending on your preference.

Who may participate in this study?

Any patient that has been laparoscopically diagnosed with endometriosis by a doctor and who experience symptoms of endometriosis may participate.

Will you benefit from taking part in this research?

There are no direct benefits associated with participating in this study. However, the construction and validation of a HRQOL measure for patients with endometriosis can assist patient, doctors and researchers in future.

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

There are no known risks to participating in this study. Should you have any concerns do not hesitate to contact the researcher.

Who will have access to your medical records?

The researcher will not have access to your medical records and will not discuss your case with your doctor. This study is being conducted independently of the healthcare facility through which you are recruited and does not in any way affect your ongoing treatment at the facility. All information collected will remain confidential, with only the researcher, supervisor and research assistant having direct access to the data. All persons handling data will be required to sign confidentiality agreements. Any information that may lead to the identification of participants will be removed when disseminating the research.

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

Participants will receive a gift voucher as a token of appreciation for participating in the study.

Is there anything else that you should know or do?

- You can contact Rizwana Roomaney at 0716826454 if you have any further queries or encounter any problems.
- You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I agree to take part in a research study entitled (*insert title of study*).

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.

- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) on (*date*) 2016.

.....
Signature of participant

.....
Signature of witness

Declaration by investigator

I (*name*) declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a interpreter. (*If a interpreter is used then the interpreter must sign the declaration below.*)

Signed at (*place*) on (*date*) 2016.

.....
Signature of investigator

.....
Signature of witness

Consent to confirm diagnosis

I hereby grant permission to the researcher to contact my doctor/nurse to confirm that I have been diagnosed with endometriosis.

Name of doctor(s).....

Clinic/hospital.....

Appendix P

Permission to administer the WHOQOL-Bref

User Agreement for "WHOQOL-100" and/or WHOQOL-BREF and related materials

This agreement is between the World Health Organization ("WHO") and Rizwana Rcomaney. WHO hereby grants the User a nonexclusive, royalty-free license to use the World Health Organization Quality of Life Questionnaire and/or related materials (hereafter referred to as "WHOQOL-100" or "WHOQOL-BREF") in User's study outlined below. The term of this User Agreement shall be for a period of 1 year, commencing on (date) 1 September 2015

The approved study for this User Agreement is:

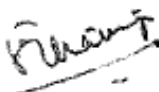
Study Title	The construction and validation of a HRQL measure for women with endo
Principal Investigator	Rizwana Rcomaney
Sample characteristics	Women with large uterine fibroids
Sample size	250
Treatment Intervention	None
Total number of assessments	250
Assessment time points	1
"WHOQOL-100" or WHOQOL-BREF version – Please specify language version(s) you would like to receive.	WHOQOL-BREF English
Other measures	HAS, BDI, SF-36

This User Agreement is based upon the following conditions:

1. User shall not modify, abridge, condense, translate, adapt, recast or transform the WHOQOL-100 or BREF in any manner or form, including but not limited to any minor or significant change in wording or organization, or administration procedures, of the WHOQOL-100 or BREF. If User thinks that changes are necessary for its work, or if translation is necessary, User must obtain written approval from WHO in advance of making such changes.
2. User shall not reproduce WHOQOL-100 or BREF, except for the limited purpose of generating sufficient copies for its own uses and shall in no event distribute copies of the WHOQOL-100 or BREF to third parties by sale, rental, lease, lending, or any other means. In addition, User agrees that it will not use the WHOQOL-100 or BREF for any purpose other than conducting studies as specified above, unless agreed in writing by WHO. In any event, the WHOQOL-100 or BREF should not be used for research or clinical purposes without prior written authorization from WHO.

Please confirm your agreement with the foregoing by signing and returning one copy of this letter to WHO, whereupon this letter agreement shall become a binding agreement between User and WHO.

WHO:



Dr. Somnath Chatterji
Health Statistics and Health Information Systems (HSI)
World Health Organization
Avenue Appia
Geneva 27
CH 1211 Switzerland

Date: 27-09-2015


USER:

By: Rizwana Reemjee
Title: MS
Institution: Stellenbosch University
Address: Private Bag 21
Matieland 7622 South Africa
Date: 27-09-2015

Appendix Q

Permission to administer the SF12v2

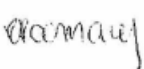
APPENDIX B



LICENSE AGREEMENT - DETAILS

Licensee: University of Stellenbosch
Rizwana Roomaney
Private Bag X1
Mateland
Stellenbosch, Western cape 7602

License Number: QM031521
Amendment to: N/A
Study Term: 09/02/15 to 09/01/16



Approved Purpose
The construction and validation of a HRQOL measure for women with endometriosis

Licensed Surveys (Modes) and Services:		Mode of Admin	Quantity
Item	Description		
PROJ01	License Fee	Paper	1
ADMINS	Administrations		300
ES0170	SF-12v2, Standard Recall	Paper	1

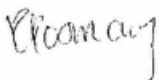
Approved Languages:
South Africa (English)

SS075	Scoring Software v4.5	1
SS079	SS v4.5 Key: SF-12v2	300
EM126	SF-12v2 User's Manual 3rd Ed.	1

Approved Languages:
United States (English)

Sign by October 1, 2015

TOTAL FEES: 0.00 USD



Appendix R

Permission from ISIS innovation to administer the Endometriosis Health Profile 30

Isis Project Number:	3735
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ISIS INNOVATION LIMITED COPYRIGHT LICENCE AGREEMENT FOR HEALTH OUTCOMES QUESTIONNAIRE

PARTIES:

(1) Licensor:	Isis Innovation Limited with a principal place of business situated at Ewert House, Ewert Place, Summertown, Oxford, OX2 7SG
(2) Licensee:	University of Stellenbosch, Psychology Department with a principal place of business situated at Private Bag X1, Matieland, 7602, South Africa

The Licensor and Licensee are together referred to as "Parties" and individually as "Party"

AGREEMENT

Commercial Terms:

Commencement Date	3 June 2013
Contact details for Licensee	Name of Manager: Ms Rizwana Roomaney Job Title: PhD Student Tel. No.: +2784 602 0499 E-Mail: rizwanaroomaney@sun.ac.za
Questionnaire	The health outcomes questionnaire titled: The Endometriosis Health Profile Questionnaire, the EHP-30, additional 23 modules and the short form questionnaire EHP-5
Required Quantity	The number of copies of the Questionnaire that as at the date of this Licence Agreement Licensee expects to make in connection with the Permitted Use, being: 500 ("Initial Quantity") plus any additional copies subsequently purchased on payment of the Supplemental Fee
Signing Fee	Free of charge
Study	The Licensee's survey study to be carried out in accordance with the study protocol titled: The construction and validation of a health-related quality of life measure for women with endometriosis at trial centres located in the Territory. Strictly for a non-commercial study to be completed by 30 June 2015.
Supplemental Fee	Free of charge for each additional 1-50 copies made above the Initial Quantity
Territory	University of Stellenbosch

This Licence Agreement comprises the Commercial Terms above and the General Conditions of Licence set out below.

Signed on behalf of Licensor:	Sign: _____ Print Name and Job Title: _____ Date: _____
Signed on behalf of Licensee:	Sign: _____ Print Name and Job Title: _____ Date: _____

Appendix S*Correlation matrix*

	Q2	Q4	Q5	Q6	Q7	Q8	Q12	Q13	Q14	Q15	Q16	Q17	Q22	Q23
Q2	1.000	.508	.386	.540	.483	.428	.285	.169	.160	.207	.266	.296	.124	.191
Q4	.508	1.000	.493	.376	.534	.394	.243	.195	.209	.154	.405	.394	.185	.177
Q5	.386	.493	1.000	.450	.425	.444	.225	.189	.256	.237	.372	.359	.102	.157
Q6	.540	.376	.450	1.000	.380	.425	.345	.273	.257	.204	.174	.159	.076	.195
Q7	.483	.534	.425	.380	1.000	.519	.325	.278	.302	.231	.458	.508	.286	.330
Q8	.428	.394	.444	.425	.519	1.000	.422	.367	.288	.341	.393	.348	.163	.260
Q12	.285	.243	.225	.345	.325	.422	1.000	.808	.708	.570	.386	.369	.130	.152
Q13	.169	.195	.189	.273	.278	.367	.808	1.000	.724	.625	.296	.342	.150	.178
Q14	.160	.209	.256	.257	.302	.288	.708	.724	1.000	.565	.298	.373	.164	.168
Q15	.207	.154	.237	.204	.231	.341	.570	.625	.565	1.000	.326	.345	.257	.220
Q16	.266	.405	.372	.174	.458	.393	.386	.296	.298	.326	1.000	.557	.215	.238
Q17	.296	.394	.359	.159	.508	.348	.369	.342	.373	.345	.557	1.000	.245	.214
Q22	.124	.185	.102	.076	.286	.163	.130	.150	.164	.257	.215	.245	1.000	.596
Q23	.191	.177	.157	.195	.330	.260	.152	.178	.168	.220	.238	.214	.596	1.000
Q24	.172	.167	.155	.119	.312	.232	.251	.258	.258	.233	.219	.259	.631	.596
Q25	.182	.124	.166	.090	.323	.262	.199	.247	.279	.317	.216	.263	.587	.581
Q27	.268	.309	.291	.180	.306	.210	.179	.213	.184	.194	.221	.224	.095	.203
Q28	.087	.131	.254	.154	.171	.129	.405	.421	.402	.258	.219	.265	.199	.201
Q29	.175	.187	.123	.232	.149	.054	.221	.181	.147	.155	.067	.097	.132	.198
Q30	.108	.221	.203	.150	.153	.133	.294	.265	.259	.138	.183	.249	.110	.113
Q31	.127	.190	.231	.116	.307	.093	.169	.182	.169	.174	.138	.189	.280	.233
Q32	.146	.150	.187	.236	.240	.162	.180	.152	.050	.132	.061	.144	.167	.188
Q36	.262	.207	.337	.312	.226	.254	.189	.170	.124	.125	.184	.189	.163	.171

	Q2	Q4	Q5	Q6	Q7	Q8	Q12	Q13	Q14	Q15	Q16	Q17	Q22	Q23
Q37	.150	.181	.260	.106	.204	.313	.251	.171	.157	.120	.276	.264	.190	.094
Q38	.372	.449	.449	.340	.488	.451	.351	.294	.225	.227	.384	.311	.220	.265
Q40	.188	.246	.266	.268	.336	.389	.196	.168	.128	.107	.316	.176	.093	.188
Q41	.229	.361	.285	.251	.474	.335	.284	.308	.281	.322	.346	.339	.379	.406
Q42	.376	.463	.418	.384	.531	.400	.389	.356	.330	.347	.436	.381	.353	.308
Q43	.193	.302	.321	.230	.381	.362	.320	.318	.325	.293	.349	.330	.326	.296
Q44	.135	.211	.260	.171	.280	.274	.510	.501	.579	.401	.314	.343	.230	.191
Q46	-.004	.093	.117	-.034	.071	.082	.284	.272	.327	.208	.120	.145	.250	.093
Q47	.039	.129	.161	-.010	.136	.152	.311	.357	.428	.224	.124	.231	.243	.107
Q48	.260	.275	.349	.231	.297	.315	.290	.306	.295	.277	.178	.210	.217	.235
Q49	.299	.230	.310	.330	.311	.341	.291	.323	.261	.236	.264	.220	.179	.283
Q50	.187	.206	.274	.193	.296	.343	.342	.309	.251	.293	.306	.260	.144	.131
Q51	.217	.218	.299	.229	.301	.395	.346	.337	.280	.278	.364	.262	.062	.183
Q52	.258	.227	.228	.195	.277	.342	.215	.220	.149	.228	.259	.245	.140	.164
Q53	.227	.214	.288	.251	.296	.445	.319	.321	.311	.211	.293	.298	.108	.244
Q55	.076	.096	.187	.193	.265	.286	.248	.236	.230	.206	.264	.230	.198	.172
Q56	.154	.095	.198	.131	.299	.400	.231	.247	.199	.268	.224	.157	.311	.497
Q57	.150	.134	.190	.129	.227	.308	.247	.264	.165	.270	.166	.082	.414	.415
Q58	.102	.119	.234	.153	.145	.293	.130	.128	.119	.242	.241	.226	.233	.158
Q59	.055	.085	.106	.086	.130	.135	.108	.097	.089	.066	.046	.130	.210	.156
Q60	.198	.185	.157	.105	.240	.248	.169	.116	.121	.212	.154	.163	.229	.299
Q61	.204	.187	.161	.153	.265	.254	.340	.408	.327	.406	.291	.256	.315	.292
Q62	.269	.333	.253	.213	.433	.410	.235	.182	.170	.240	.290	.325	.229	.246
Q63	.238	.278	.264	.253	.374	.449	.397	.314	.301	.279	.334	.291	.266	.315
Q64	.238	.288	.317	.265	.418	.498	.280	.263	.230	.232	.275	.299	.201	.304

	Q24	Q25	Q27	Q28	Q29	Q30	Q31	Q32	Q36	Q37	Q38	Q40	Q41	Q42
Q2	.172	.182	.268	.087	.175	.108	.127	.146	.262	.150	.372	.188	.229	.376
Q4	.167	.124	.309	.131	.187	.221	.190	.150	.207	.181	.449	.246	.361	.463
Q5	.155	.166	.291	.254	.123	.203	.231	.187	.337	.260	.449	.266	.285	.418
Q6	.119	.090	.180	.154	.232	.150	.116	.236	.312	.106	.340	.268	.251	.384
Q7	.312	.323	.306	.171	.149	.153	.307	.240	.226	.204	.488	.336	.474	.531
Q8	.232	.262	.210	.129	.054	.133	.093	.162	.254	.313	.451	.389	.335	.400
Q12	.251	.199	.179	.405	.221	.294	.169	.180	.189	.251	.351	.196	.284	.389
Q13	.258	.247	.213	.421	.181	.265	.182	.152	.170	.171	.294	.168	.308	.356
Q14	.258	.279	.184	.402	.147	.259	.169	.050	.124	.157	.225	.128	.281	.330
Q15	.233	.317	.194	.258	.155	.138	.174	.132	.125	.120	.227	.107	.322	.347
Q16	.219	.216	.221	.219	.067	.183	.138	.061	.184	.276	.384	.316	.346	.436
Q17	.259	.263	.224	.265	.097	.249	.189	.144	.189	.264	.311	.176	.339	.381
Q22	.631	.587	.095	.199	.132	.110	.280	.167	.163	.190	.220	.093	.379	.353
Q23	.596	.581	.203	.201	.198	.113	.233	.188	.171	.094	.265	.188	.406	.308
Q24	1.000	.719	.170	.236	.129	.107	.312	.278	.200	.156	.277	.131	.434	.366
Q25	.719	1.000	.144	.225	.082	.109	.250	.159	.213	.120	.241	.165	.494	.372
Q27	.170	.144	1.000	.407	.494	.336	.332	.396	.218	.135	.317	.276	.241	.275
Q28	.236	.225	.407	1.000	.586	.521	.450	.343	.264	.175	.256	.215	.278	.328
Q29	.129	.082	.494	.586	1.000	.519	.423	.458	.195	.075	.201	.232	.161	.202
Q30	.107	.109	.336	.521	.519	1.000	.461	.408	.192	.148	.220	.242	.176	.239
Q31	.312	.250	.332	.450	.423	.461	1.000	.553	.155	.165	.319	.221	.330	.374
Q32	.278	.159	.396	.343	.458	.408	.553	1.000	.159	.200	.294	.277	.209	.203
Q36	.200	.213	.218	.264	.195	.192	.155	.159	1.000	.411	.498	.165	.352	.427
Q37	.156	.120	.135	.175	.075	.148	.165	.200	.411	1.000	.490	.140	.164	.180
Q38	.277	.241	.317	.256	.201	.220	.319	.294	.498	.490	1.000	.321	.432	.546
Q40	.131	.165	.276	.215	.232	.242	.221	.277	.165	.140	.321	1.000	.330	.400

	Q24	Q25	Q27	Q28	Q29	Q30	Q31	Q32	Q36	Q37	Q38	Q40	Q41	Q42
Q41	.434	.494	.241	.278	.161	.176	.330	.209	.352	.164	.432	.330	1.000	.693
Q42	.366	.372	.275	.328	.202	.239	.374	.203	.427	.180	.546	.400	.693	1.000
Q43	.325	.381	.183	.348	.108	.208	.343	.135	.312	.192	.409	.312	.623	.654
Q44	.265	.278	.130	.525	.190	.312	.308	.152	.228	.165	.317	.244	.359	.531
Q46	.249	.222	.188	.368	.278	.377	.298	.237	.235	.211	.216	.149	.260	.319
Q47	.295	.263	.125	.409	.175	.355	.302	.265	.202	.258	.248	.125	.244	.293
Q48	.267	.278	.235	.299	.141	.156	.266	.160	.483	.239	.410	.187	.417	.539
Q49	.273	.245	.224	.212	.131	.116	.224	.137	.381	.228	.447	.217	.373	.463
Q50	.215	.169	.236	.230	.125	.222	.169	.224	.291	.293	.323	.321	.264	.292
Q51	.173	.147	.352	.270	.216	.300	.206	.268	.304	.252	.365	.408	.337	.344
Q52	.155	.143	.296	.292	.176	.297	.219	.309	.191	.153	.303	.352	.324	.327
Q53	.293	.225	.115	.146	.001	.084	.072	.082	.215	.290	.353	.204	.392	.353
Q55	.245	.184	.144	.298	.146	.183	.237	.132	.193	.237	.262	.171	.269	.268
Q56	.473	.522	.119	.180	.029	.048	.136	.122	.277	.166	.308	.255	.498	.359
Q57	.539	.541	.161	.267	.212	.135	.233	.238	.226	.131	.257	.206	.503	.427
Q58	.230	.324	.167	.222	.087	.179	.216	.254	.280	.203	.239	.283	.401	.336
Q59	.221	.297	.160	.271	.159	.232	.224	.252	.181	.187	.176	.181	.233	.171
Q60	.297	.309	.064	.012	.017	.037	.027	.183	.152	.208	.245	.190	.322	.259
Q61	.383	.435	.214	.312	.199	.183	.271	.217	.284	.196	.325	.251	.513	.405
Q62	.230	.227	.200	.101	.178	.116	.194	.237	.139	.200	.392	.351	.372	.387
Q63	.292	.322	.204	.276	.146	.167	.243	.207	.332	.268	.397	.307	.567	.517
Q64	.260	.289	.132	.182	.069	.044	.179	.220	.188	.243	.405	.321	.481	.396

	Q43	Q44	Q46	Q47	Q48	Q49	Q50	Q51	Q52	Q53	Q55	Q56	Q57	Q58
Q2	.193	.135	-.004	.039	.260	.299	.187	.217	.258	.227	.076	.154	.150	.102
Q4	.302	.211	.093	.129	.275	.230	.206	.218	.227	.214	.096	.095	.134	.119
Q5	.321	.260	.117	.161	.349	.310	.274	.299	.228	.288	.187	.198	.190	.234
Q6	.230	.171	-.034	-.010	.231	.330	.193	.229	.195	.251	.193	.131	.129	.153
Q7	.381	.280	.071	.136	.297	.311	.296	.301	.277	.296	.265	.299	.227	.145
Q8	.362	.274	.082	.152	.315	.341	.343	.395	.342	.445	.286	.400	.308	.293
Q12	.320	.510	.284	.311	.290	.291	.342	.346	.215	.319	.248	.231	.247	.130
Q13	.318	.501	.272	.357	.306	.323	.309	.337	.220	.321	.236	.247	.264	.128
Q14	.325	.579	.327	.428	.295	.261	.251	.280	.149	.311	.230	.199	.165	.119
Q15	.293	.401	.208	.224	.277	.236	.293	.278	.228	.211	.206	.268	.270	.242
Q16	.349	.314	.120	.124	.178	.264	.306	.364	.259	.293	.264	.224	.166	.241
Q17	.330	.343	.145	.231	.210	.220	.260	.262	.245	.298	.230	.157	.082	.226
Q22	.326	.230	.250	.243	.217	.179	.144	.062	.140	.108	.198	.311	.414	.233
Q23	.296	.191	.093	.107	.235	.283	.131	.183	.164	.244	.172	.497	.415	.158
Q24	.325	.265	.249	.295	.267	.273	.215	.173	.155	.293	.245	.473	.539	.230
Q25	.381	.278	.222	.263	.278	.245	.169	.147	.143	.225	.184	.522	.541	.324
Q27	.183	.130	.188	.125	.235	.224	.236	.352	.296	.115	.144	.119	.161	.167
Q28	.348	.525	.368	.409	.299	.212	.230	.270	.292	.146	.298	.180	.267	.222
Q29	.108	.190	.278	.175	.141	.131	.125	.216	.176	.001	.146	.029	.212	.087
Q30	.208	.312	.377	.355	.156	.116	.222	.300	.297	.084	.183	.048	.135	.179
Q31	.343	.308	.298	.302	.266	.224	.169	.206	.219	.072	.237	.136	.233	.216
Q32	.135	.152	.237	.265	.160	.137	.224	.268	.309	.082	.132	.122	.238	.254
Q36	.312	.228	.235	.202	.483	.381	.291	.304	.191	.215	.193	.277	.226	.280
Q37	.192	.165	.211	.258	.239	.228	.293	.252	.153	.290	.237	.166	.131	.203
	Q43	Q44	Q46	Q47	Q48	Q49	Q50	Q51	Q52	Q53	Q55	Q56	Q57	Q58

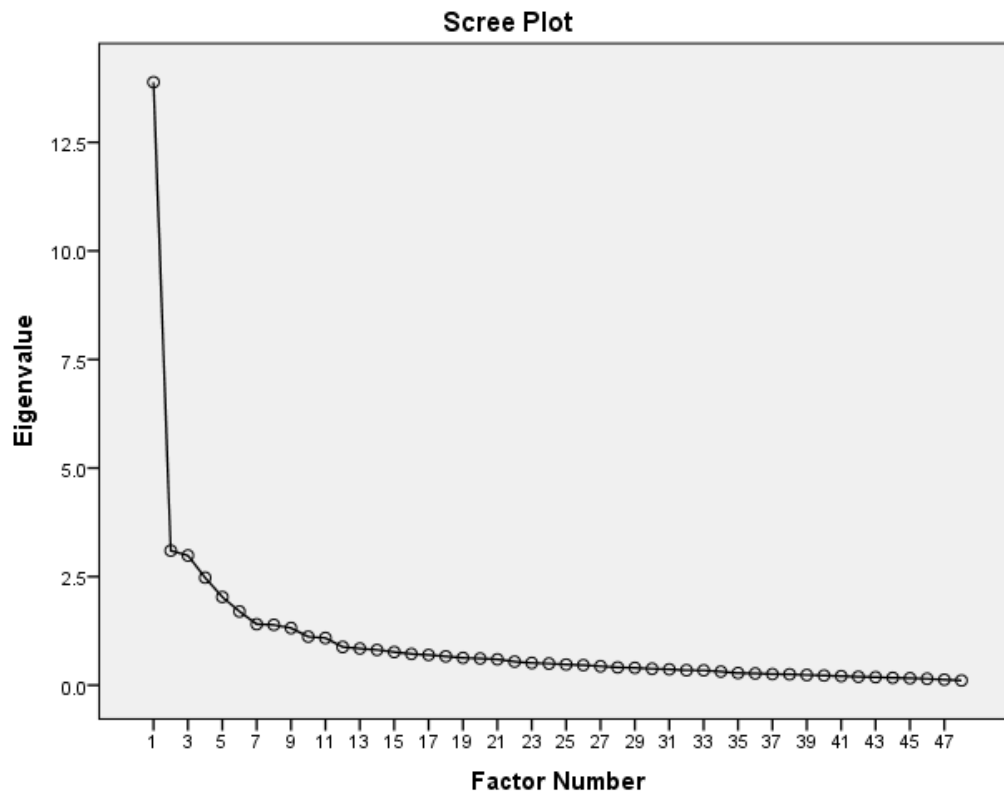
Q38	.409	.317	.216	.248	.410	.447	.323	.365	.303	.353	.262	.308	.257	.239
Q40	.312	.244	.149	.125	.187	.217	.321	.408	.352	.204	.171	.255	.206	.283
Q41	.623	.359	.260	.244	.417	.373	.264	.337	.324	.392	.269	.498	.503	.401
Q42	.654	.531	.319	.293	.539	.463	.292	.344	.327	.353	.268	.359	.427	.336
Q43	1.000	.535	.334	.390	.400	.317	.317	.338	.253	.321	.297	.399	.342	.379
Q44	.535	1.000	.349	.464	.441	.304	.219	.297	.243	.302	.371	.235	.248	.234
Q46	.334	.349	1.000	.681	.370	.213	.167	.173	.104	.134	.167	.115	.206	.169
Q47	.390	.464	.681	1.000	.388	.290	.240	.193	.207	.190	.103	.154	.131	.182
Q48	.400	.441	.370	.388	1.000	.528	.307	.347	.279	.281	.202	.350	.334	.226
Q49	.317	.304	.213	.290	.528	1.000	.298	.312	.210	.357	.206	.332	.254	.231
Q50	.317	.219	.167	.240	.307	.298	1.000	.771	.486	.337	.322	.205	.194	.268
Q51	.338	.297	.173	.193	.347	.312	.771	1.000	.529	.386	.303	.296	.211	.279
Q52	.253	.243	.104	.207	.279	.210	.486	.529	1.000	.335	.277	.247	.295	.217
Q53	.321	.302	.134	.190	.281	.357	.337	.386	.335	1.000	.472	.413	.263	.105
Q55	.297	.371	.167	.103	.202	.206	.322	.303	.277	.472	1.000	.340	.360	.245
Q56	.399	.235	.115	.154	.350	.332	.205	.296	.247	.413	.340	1.000	.596	.403
Q57	.342	.248	.206	.131	.334	.254	.194	.211	.295	.263	.360	.596	1.000	.444
Q58	.379	.234	.169	.182	.226	.231	.268	.279	.217	.105	.245	.403	.444	1.000
Q59	.188	.137	.174	.162	.232	.143	.203	.202	.166	.014	.264	.217	.389	.553
Q60	.304	.077	.178	.074	.234	.172	.219	.218	.108	.152	.153	.459	.432	.389
Q61	.451	.371	.256	.293	.348	.295	.385	.351	.328	.250	.344	.423	.489	.475
Q62	.390	.227	.151	.164	.198	.218	.313	.385	.353	.247	.276	.298	.296	.353
Q63	.572	.406	.156	.193	.412	.393	.396	.405	.420	.468	.377	.498	.432	.411
Q64	.497	.308	.086	.111	.306	.297	.317	.368	.359	.515	.274	.471	.301	.280

	Q59	Q60	Q61	Q62	Q63	Q64
Q2	.055	.198	.204	.269	.238	.238
Q4	.085	.185	.187	.333	.278	.288
Q5	.106	.157	.161	.253	.264	.317
Q6	.086	.105	.153	.213	.253	.265
Q7	.130	.240	.265	.433	.374	.418
Q8	.135	.248	.254	.410	.449	.498
Q12	.108	.169	.340	.235	.397	.280
Q13	.097	.116	.408	.182	.314	.263
Q14	.089	.121	.327	.170	.301	.230
Q15	.066	.212	.406	.240	.279	.232
Q16	.046	.154	.291	.290	.334	.275
Q17	.130	.163	.256	.325	.291	.299
Q22	.210	.229	.315	.229	.266	.201
Q23	.156	.299	.292	.246	.315	.304
Q24	.221	.297	.383	.230	.292	.260
Q25	.297	.309	.435	.227	.322	.289
Q27	.160	.064	.214	.200	.204	.132
Q28	.271	.012	.312	.101	.276	.182
Q29	.159	.017	.199	.178	.146	.069
Q30	.232	.037	.183	.116	.167	.044
Q31	.224	.027	.271	.194	.243	.179
Q32	.252	.183	.217	.237	.207	.220
Q36	.181	.152	.284	.139	.332	.188
Q37	.187	.208	.196	.200	.268	.243
Q38	.176	.245	.325	.392	.397	.405
Q40	.181	.190	.251	.351	.307	.321
Q41	.233	.322	.513	.372	.567	.481

	Q59	Q60	Q61	Q62	Q63	Q64
Q42	.171	.259	.405	.387	.517	.396
Q43	.188	.304	.451	.390	.572	.497
Q44	.137	.077	.371	.227	.406	.308
Q46	.174	.178	.256	.151	.156	.086
Q47	.162	.074	.293	.164	.193	.111
Q48	.232	.234	.348	.198	.412	.306
Q49	.143	.172	.295	.218	.393	.297
Q50	.203	.219	.385	.313	.396	.317
Q51	.202	.218	.351	.385	.405	.368
Q52	.166	.108	.328	.353	.420	.359
Q53	.014	.152	.250	.247	.468	.515
Q55	.264	.153	.344	.276	.377	.274
Q56	.217	.459	.423	.298	.498	.471
Q57	.389	.432	.489	.296	.432	.301
Q58	.553	.389	.475	.353	.411	.280
Q59	1.000	.355	.422	.236	.273	.115
Q60	.355	1.000	.391	.470	.379	.375
Q61	.422	.391	1.000	.394	.465	.319
Q62	.236	.470	.394	1.000	.547	.470
Q63	.273	.379	.465	.547	1.000	.697
Q64	.115	.375	.319	.470	.697	1.000

Appendix T

Scree Plot



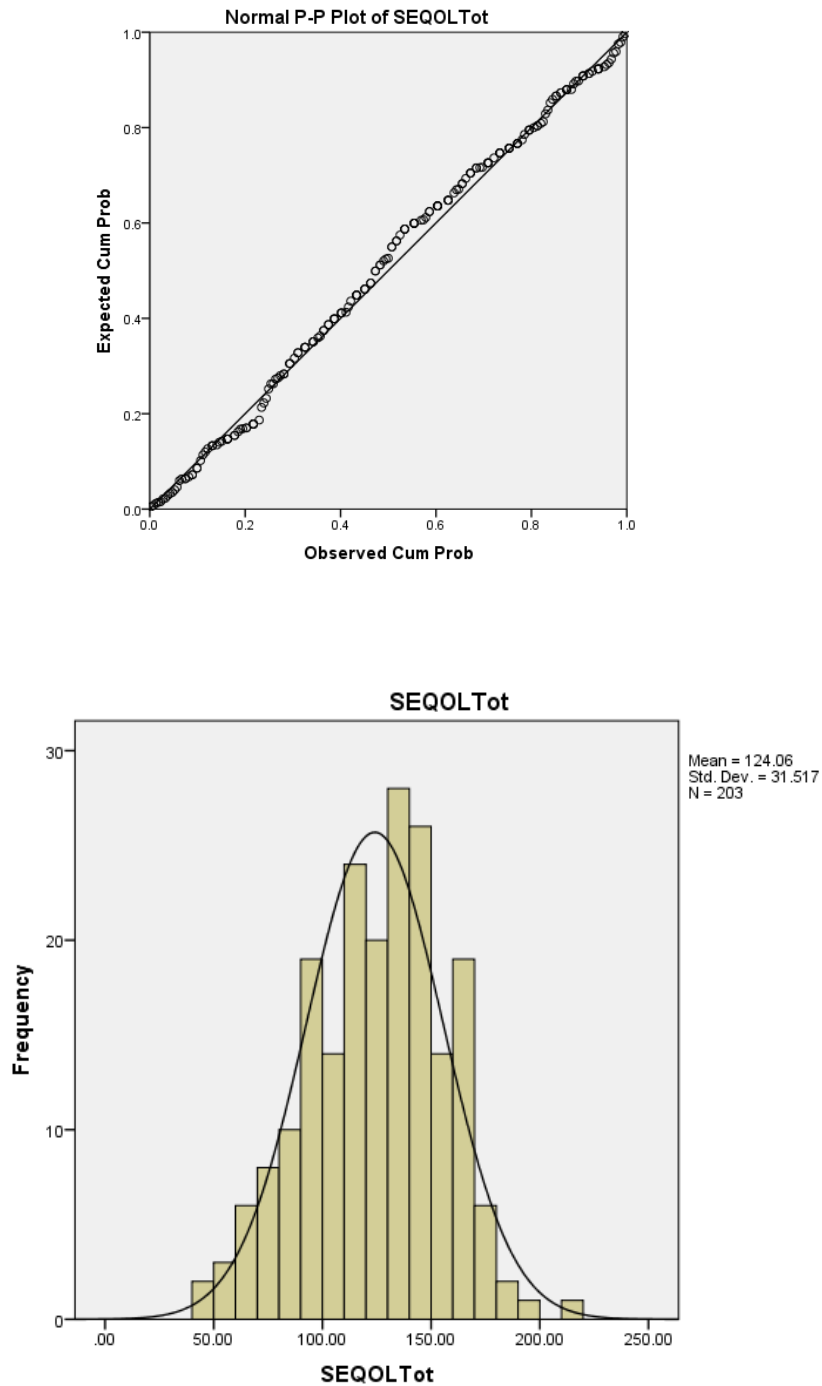
Appendix U

Total variance explained for first 20 factors

Factor	<u>Initial Eigenvalues</u>			<u>Extraction Sums of Squared</u>			<u>Rotation Sums of Squared</u>		
	Total	<u>Loadings</u>		Total	<u>Loadings</u>		Total	<u>Loadings</u>	
		% of Variance	Cumulative %		% of Variance	Cumulative %		% of Variance	Cumulative %
1	13.886	28.929	28.929	13.343	27.798	27.798	4.112	8.567	8.567
2	3.098	6.455	35.385	2.630	5.480	33.278	3.687	7.680	16.247
3	2.987	6.223	41.607	2.175	4.531	37.809	3.608	7.517	23.764
4	2.476	5.158	46.765	2.018	4.203	42.012	3.175	6.615	30.379
5	2.030	4.229	50.994	1.846	3.846	45.858	2.582	5.378	35.758
6	1.697	3.536	54.530	1.401	2.919	48.777	2.491	5.190	40.947
7	1.404	2.926	57.456	1.122	2.337	51.114	2.157	4.494	45.441
8	1.389	2.894	60.349	.809	1.686	52.799	1.854	3.861	49.303
9	1.317	2.743	63.093	.952	1.984	54.783	1.724	3.591	52.894
10	1.116	2.325	65.417	.968	2.016	56.799	1.481	3.086	55.980
11	1.087	2.264	67.682	.699	1.455	58.255	1.092	2.274	58.255
12	.880	1.833	69.515						
13	.844	1.759	71.274						
14	.813	1.693	72.967						
15	.763	1.590	74.557						
16	.720	1.500	76.058						
17	.696	1.451	77.509						
18	.664	1.383	78.892						
19	.630	1.313	80.205						
20	.614	1.279	81.484						

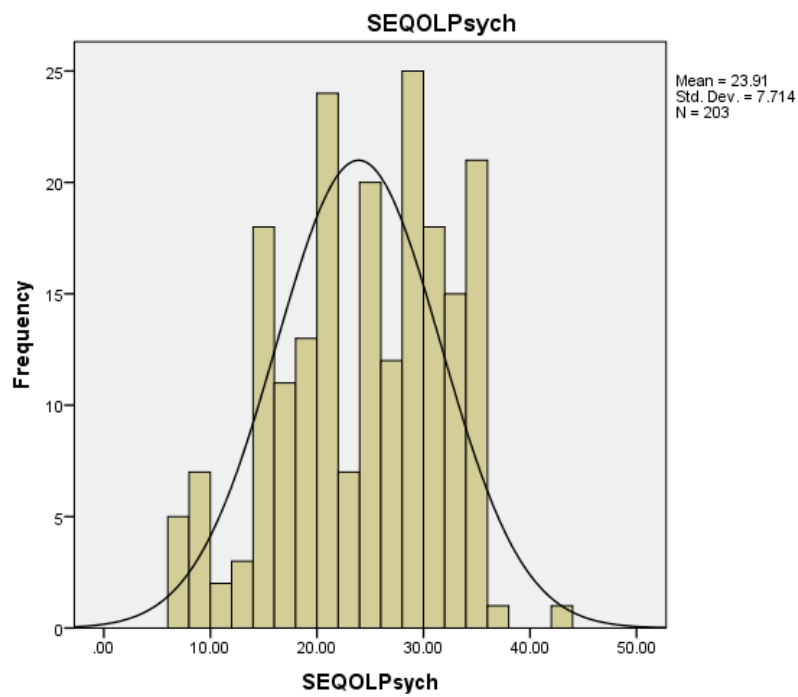
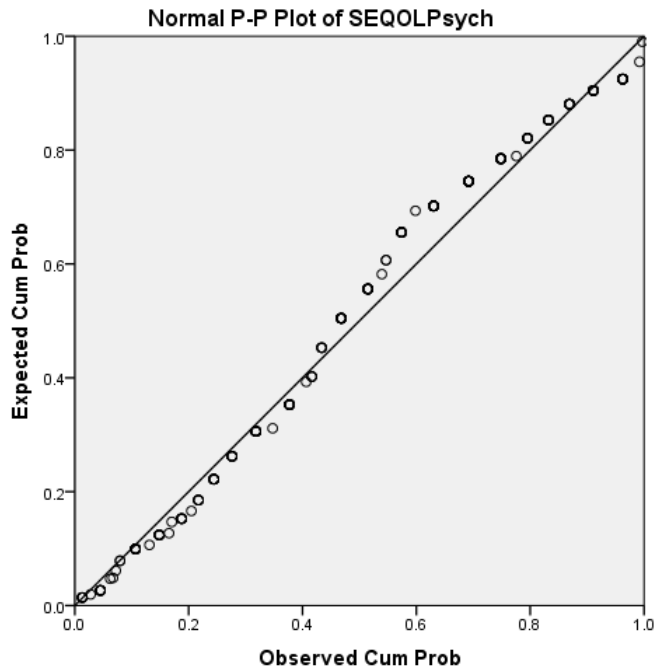
Appendix V

P-P plot and histogram of the SEQOL



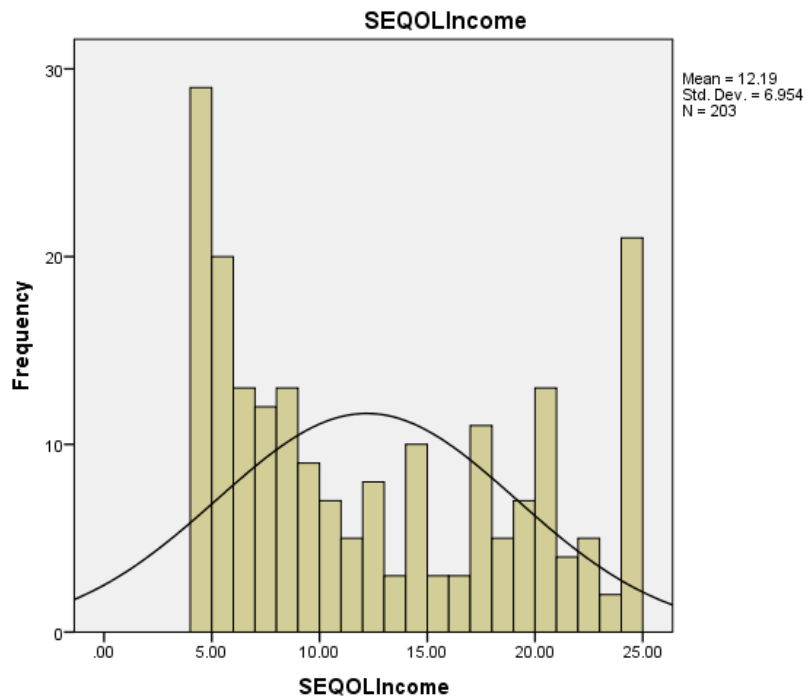
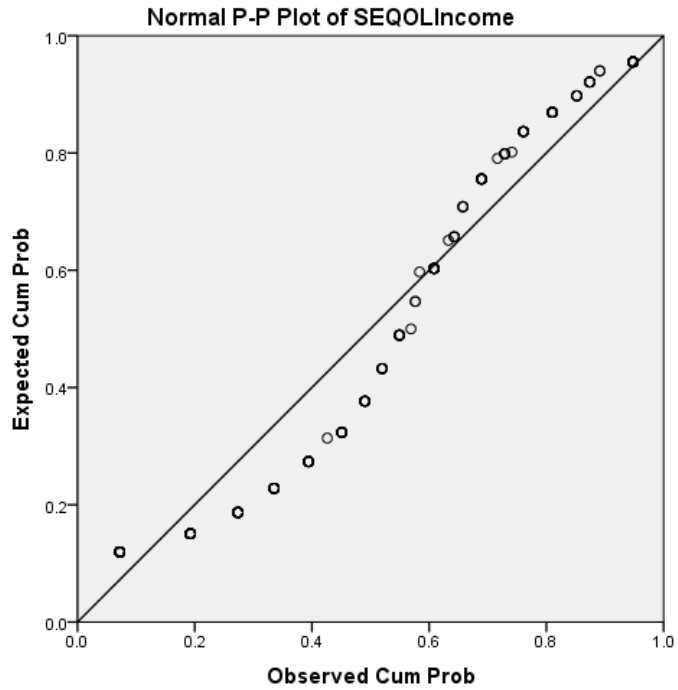
Appendix W

P-P plot and histogram of the SEQOL Psychological well-being scale



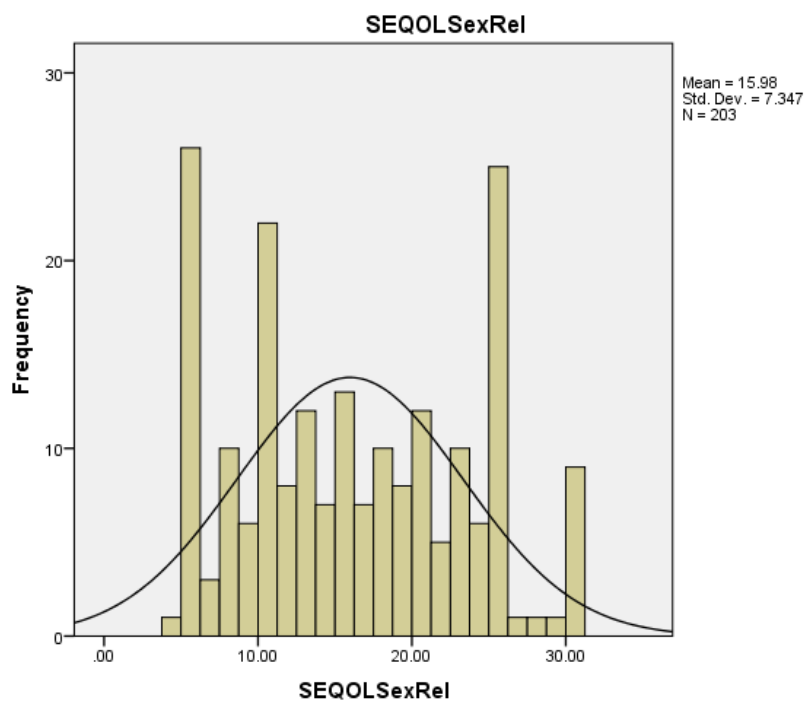
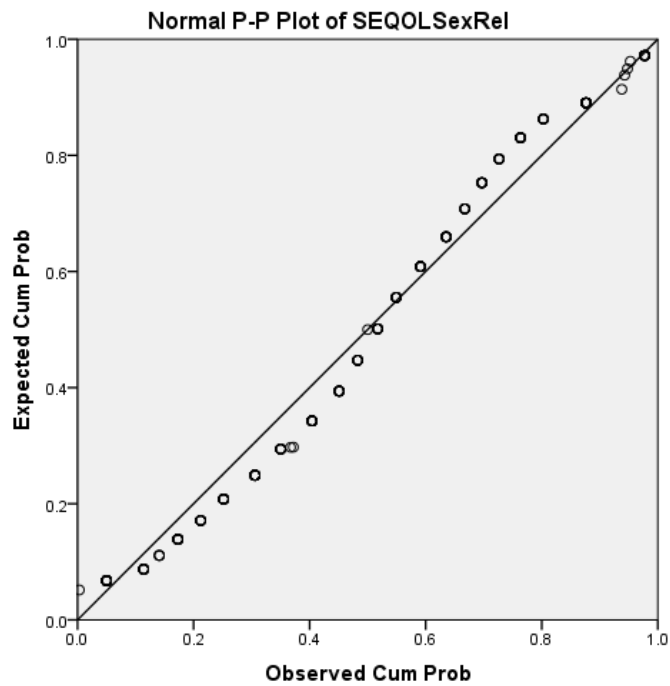
Appendix X

P-P plot and histogram of the SEQOL Income subscale



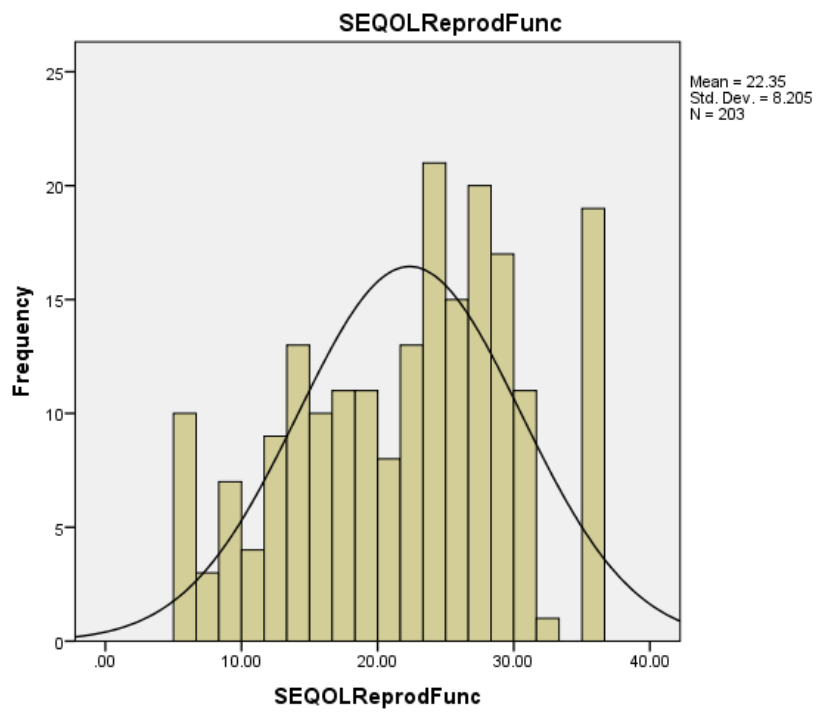
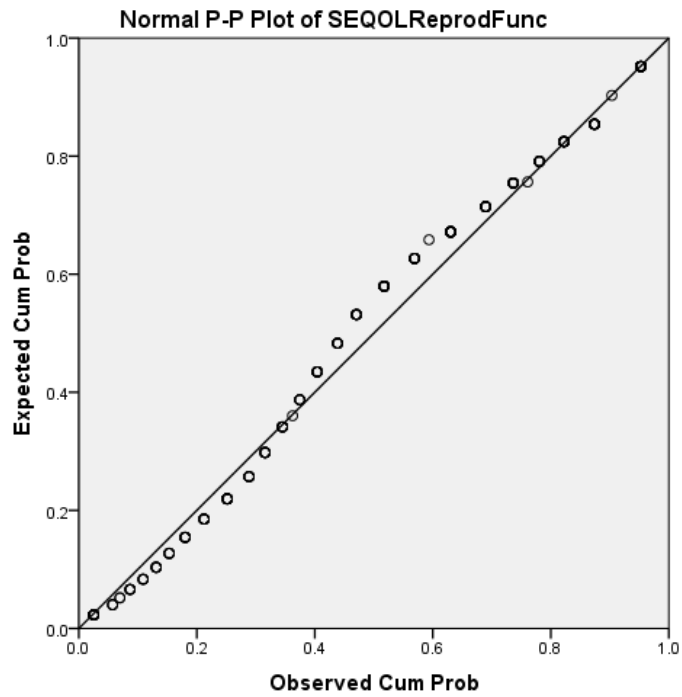
Appendix Y

P-P plot and histogram of the SEQOL Sexual functioning and romantic relationships subscale



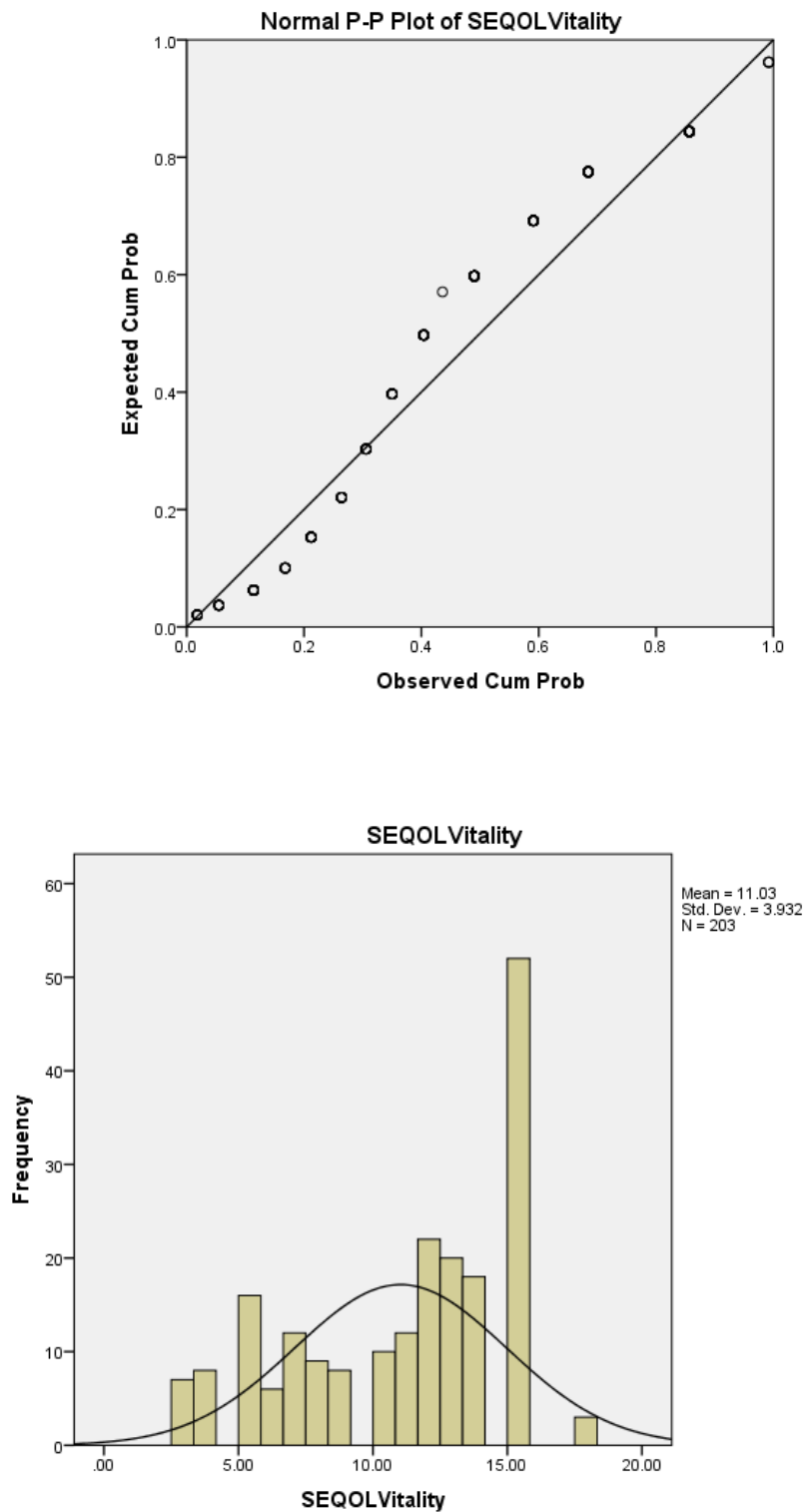
Appendix Z

P-P plot and histogram of the SEQOL Reproductive functioning subscale



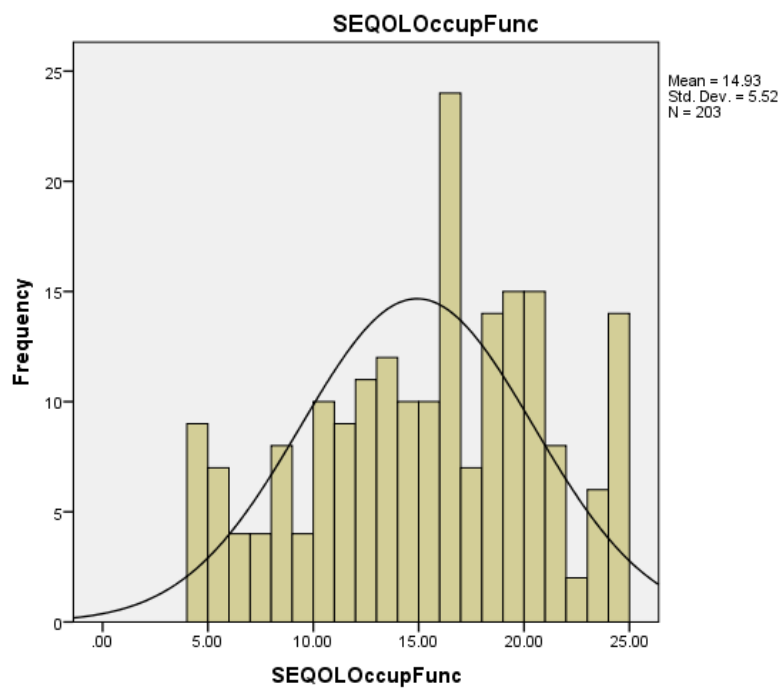
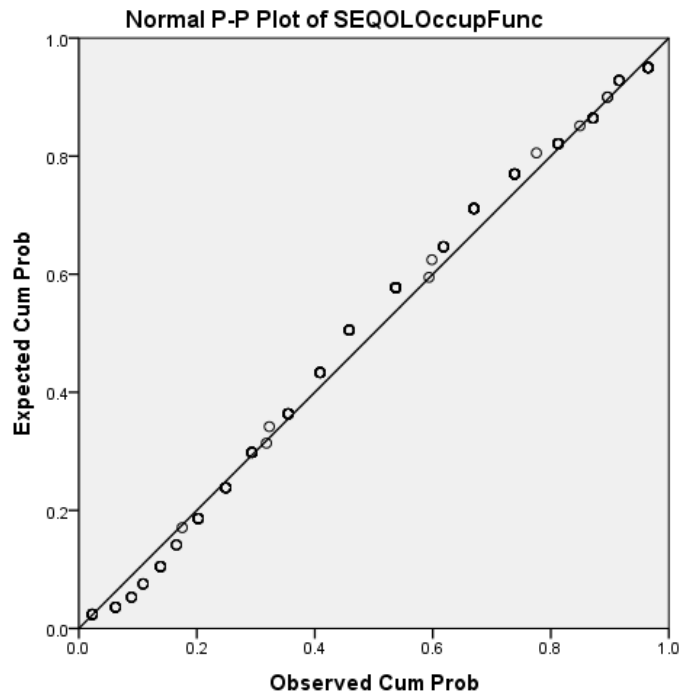
Appendix ZA

P-P plot and histogram of the SEQOL Vitality subscale



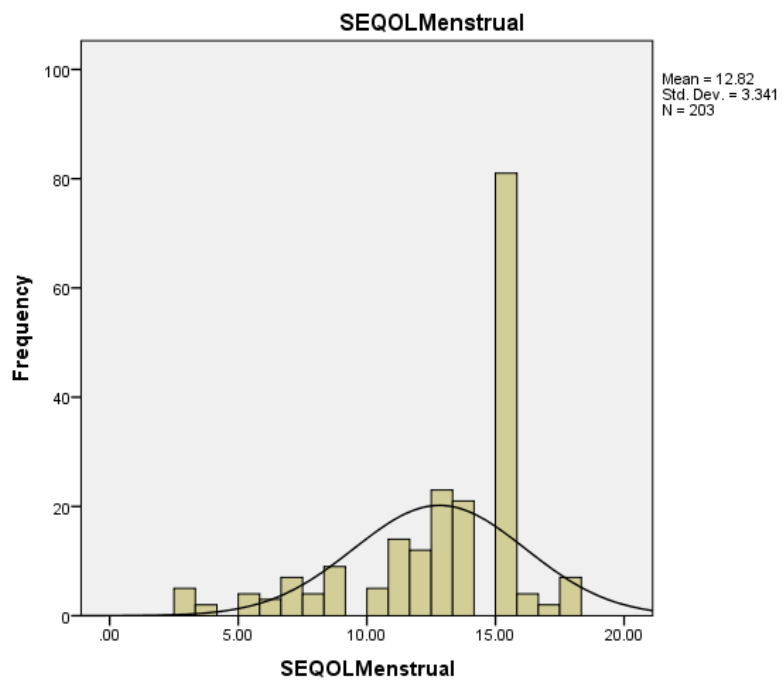
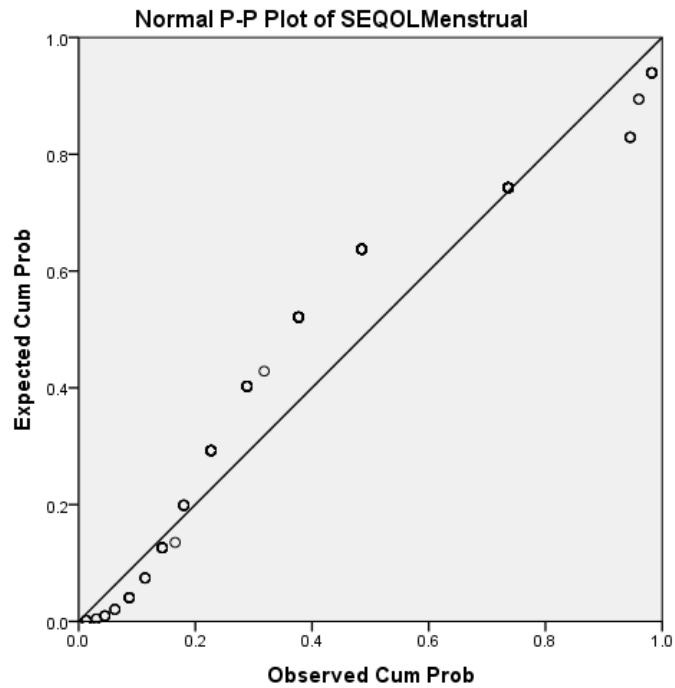
Appendix ZB

P-P plot and histogram of the SEQOL Occupational functioning subscale



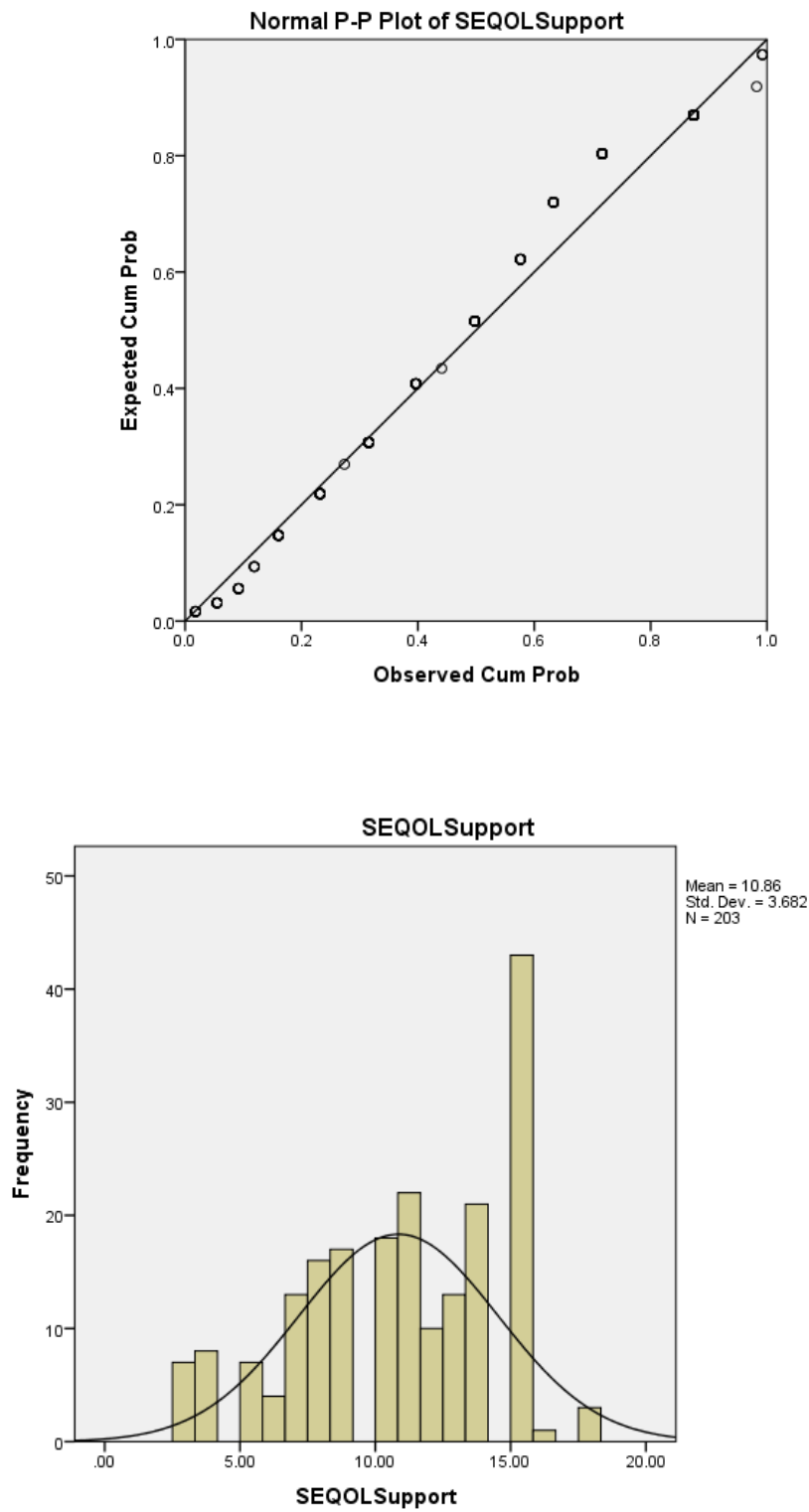
Appendix ZC

P-P plot and histogram of the SEQOL Menstrual characteristics subscale



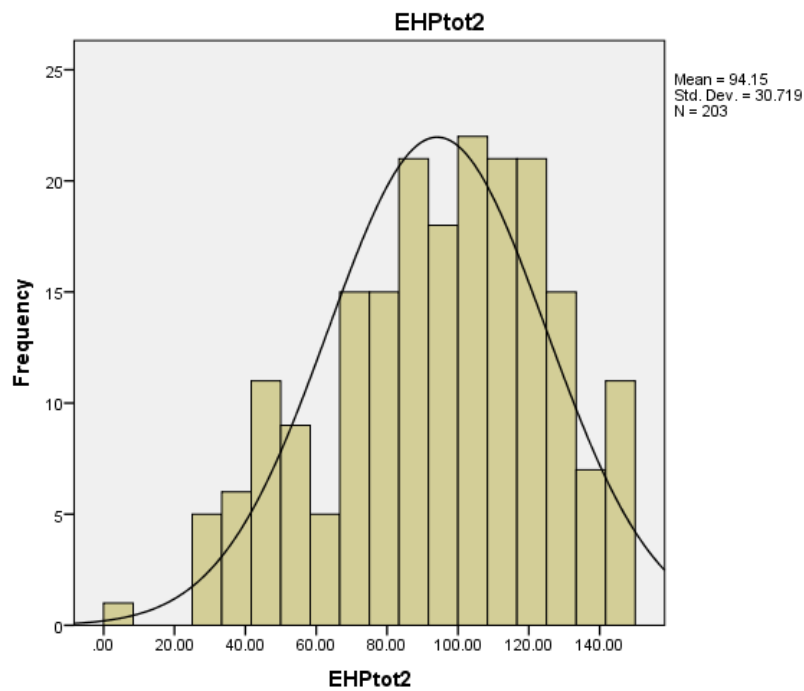
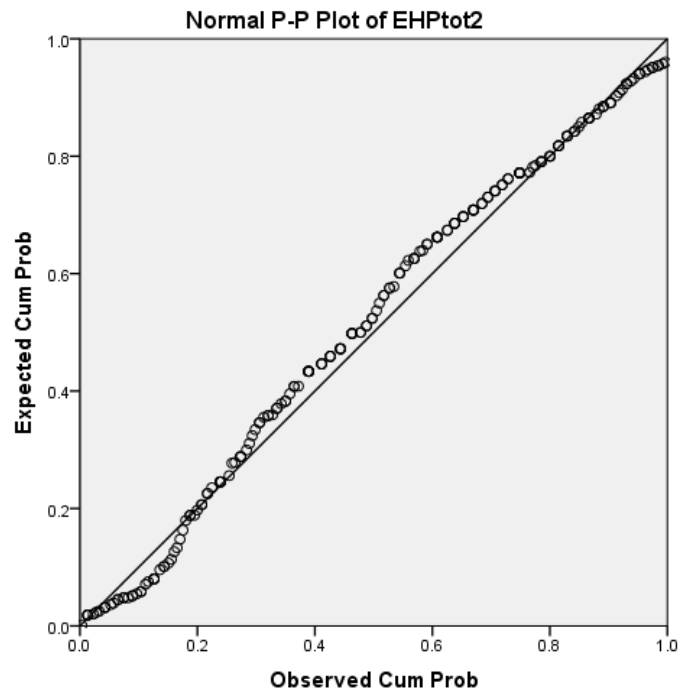
Appendix ZD

P-P plot and histogram of the SEQOL Support subscale



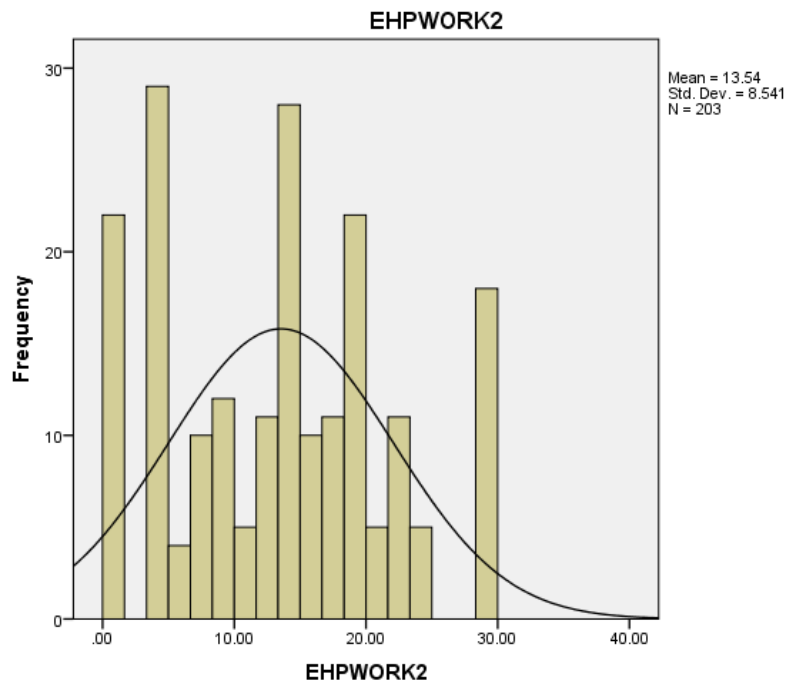
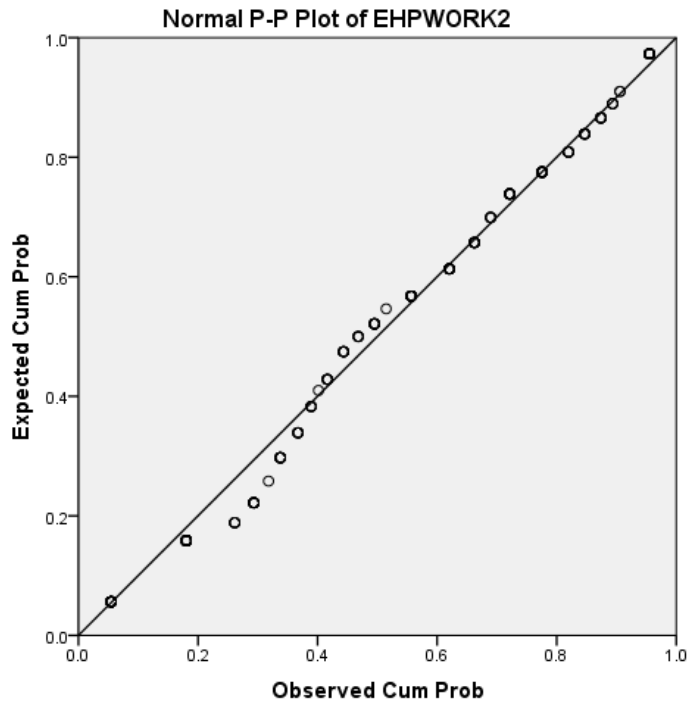
Appendix ZE

P-P plot and histogram of the Endometriosis Health Profile 30 core component



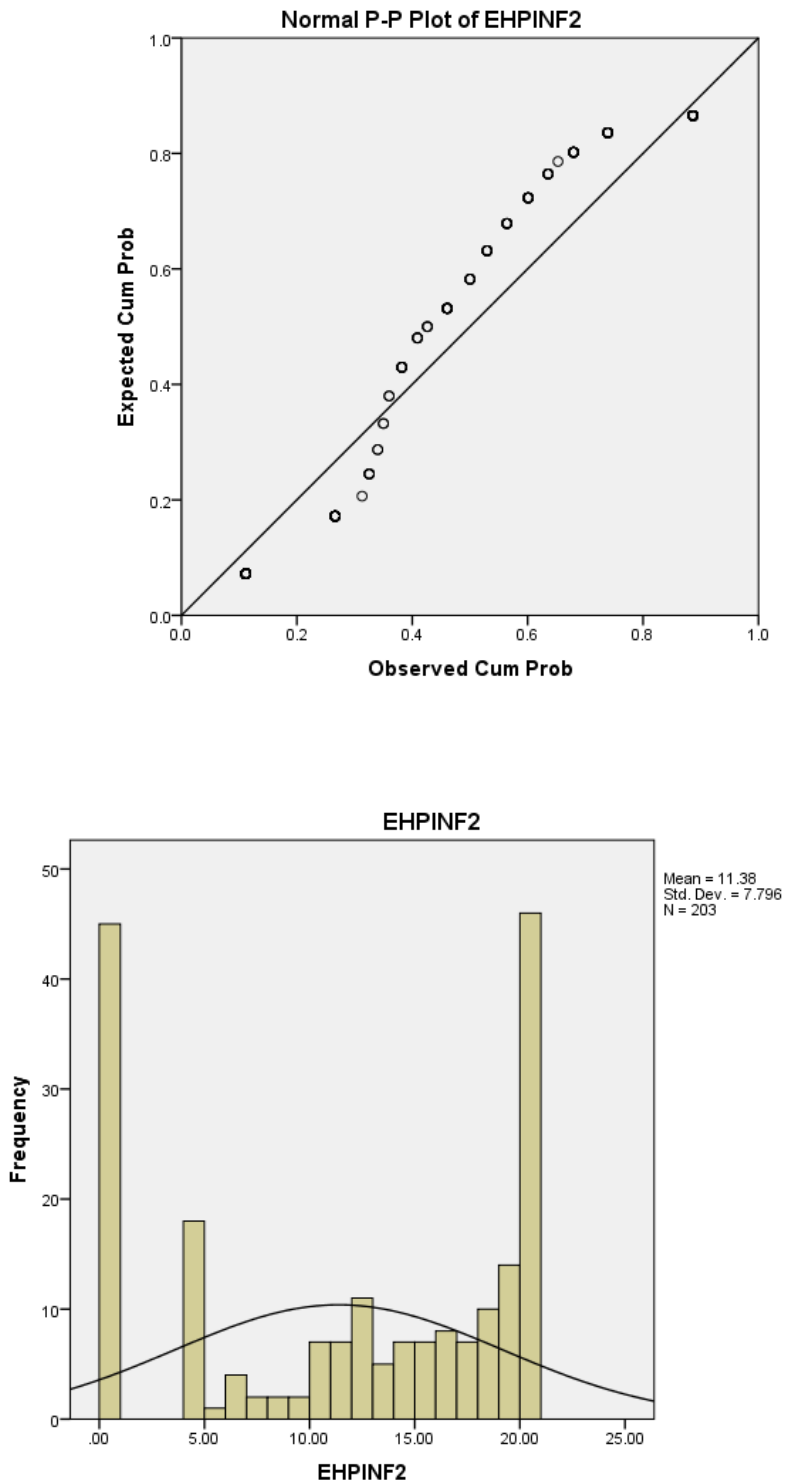
Appendix ZF

P-P plot and histogram of the Endometriosis Health Profile 30 Work module



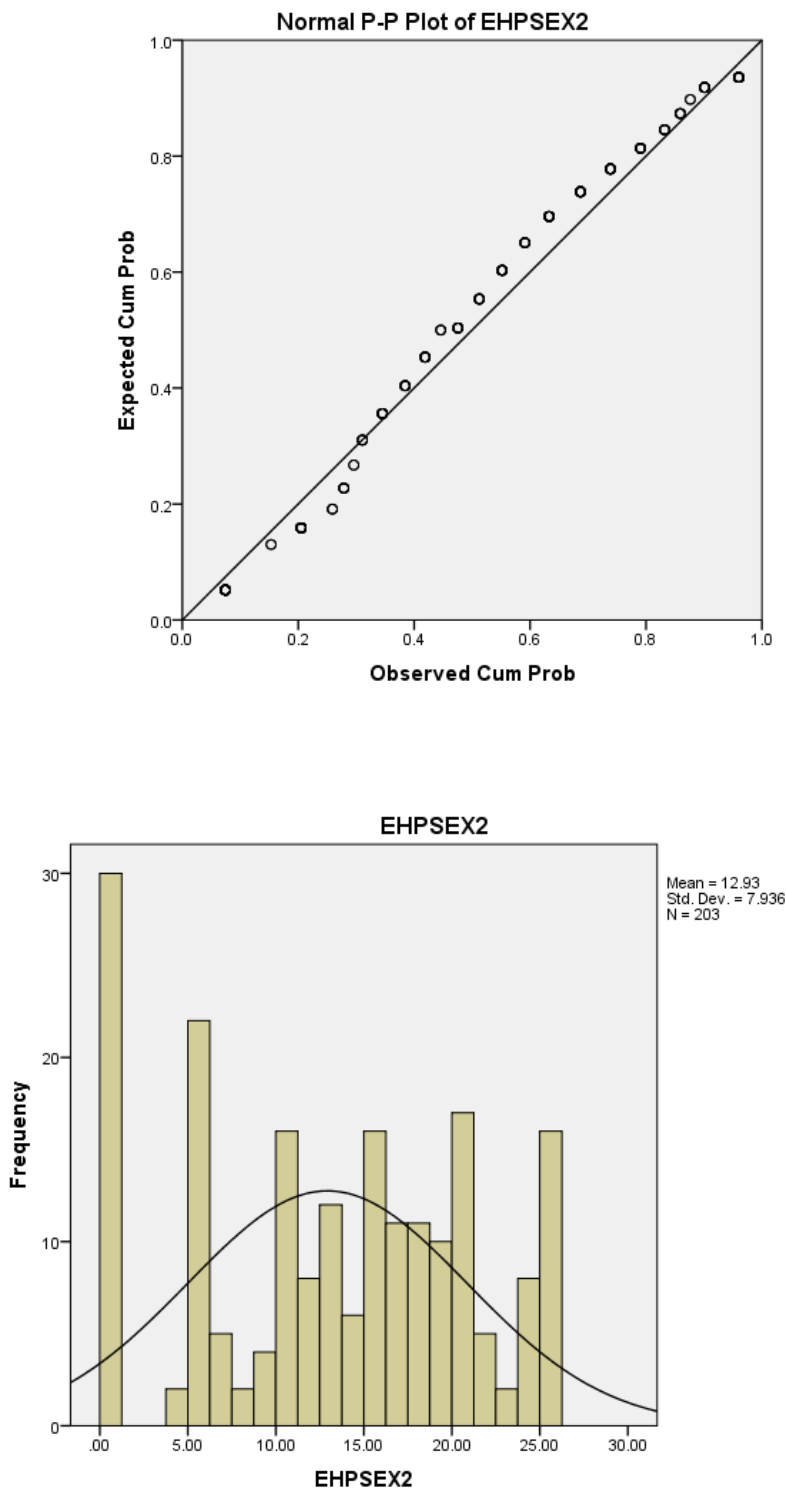
Appendix ZG

P-P plot and histogram of the Endometriosis Health Profile 30 Feelings about infertility module



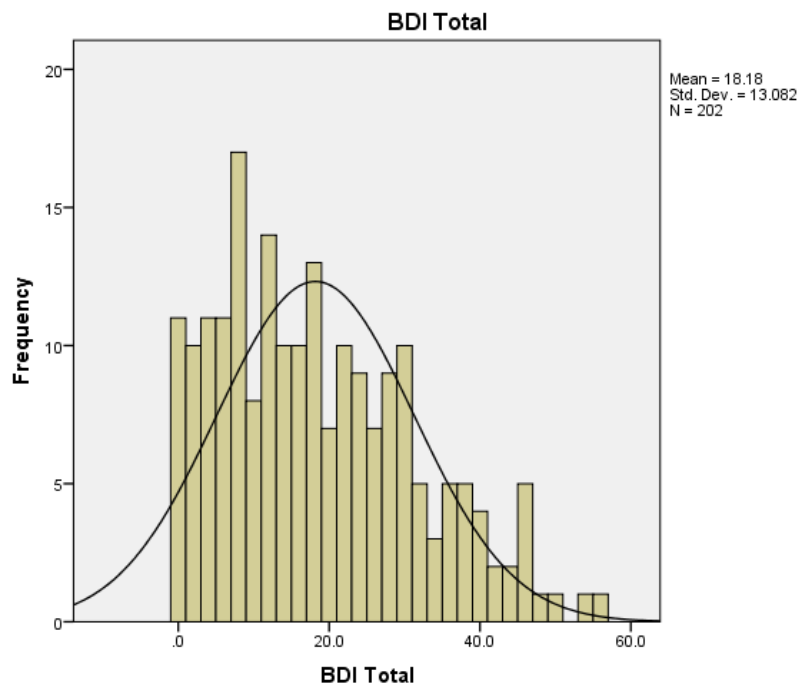
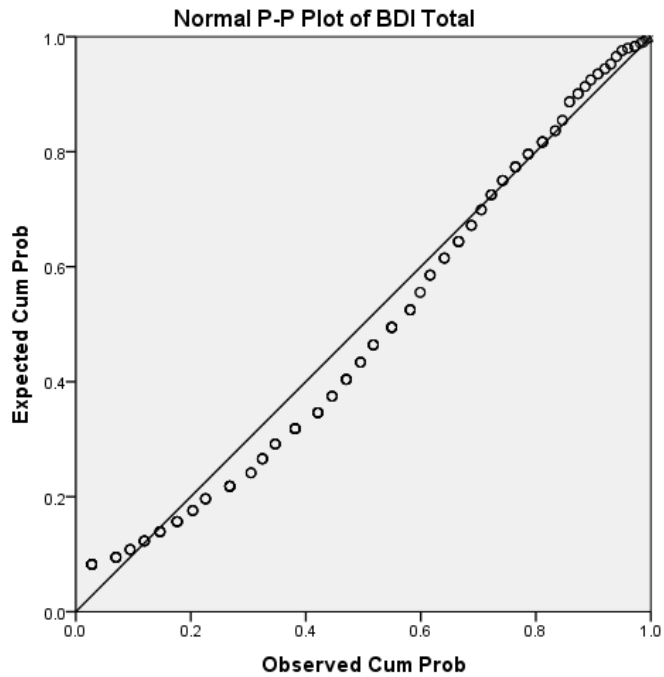
Appendix ZH

P-P plot and histogram of the Endometriosis Health Profile 30 Sexual relationships module



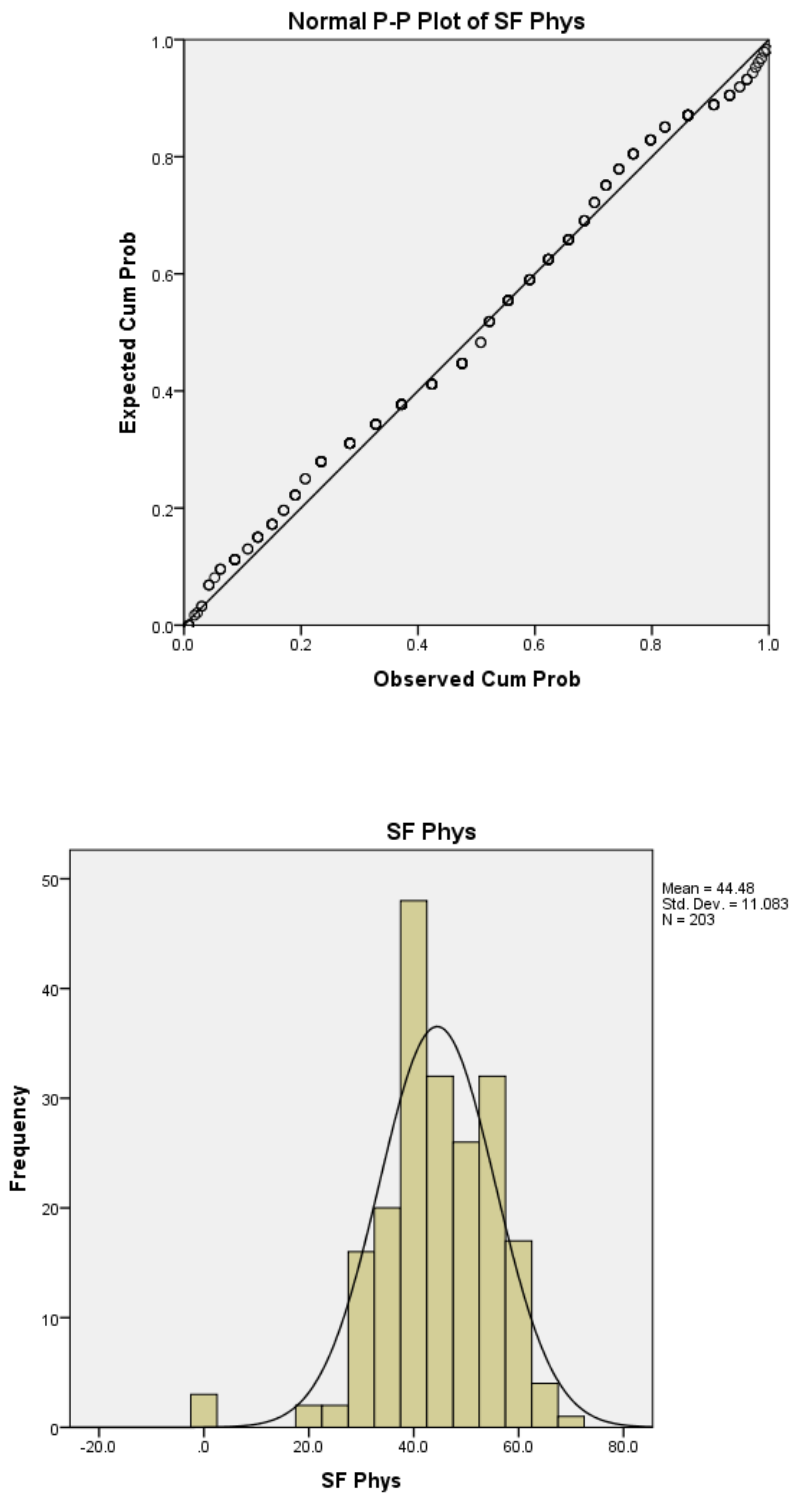
Appendix ZH

P-P plot and histogram of the Beck Depression Inventory



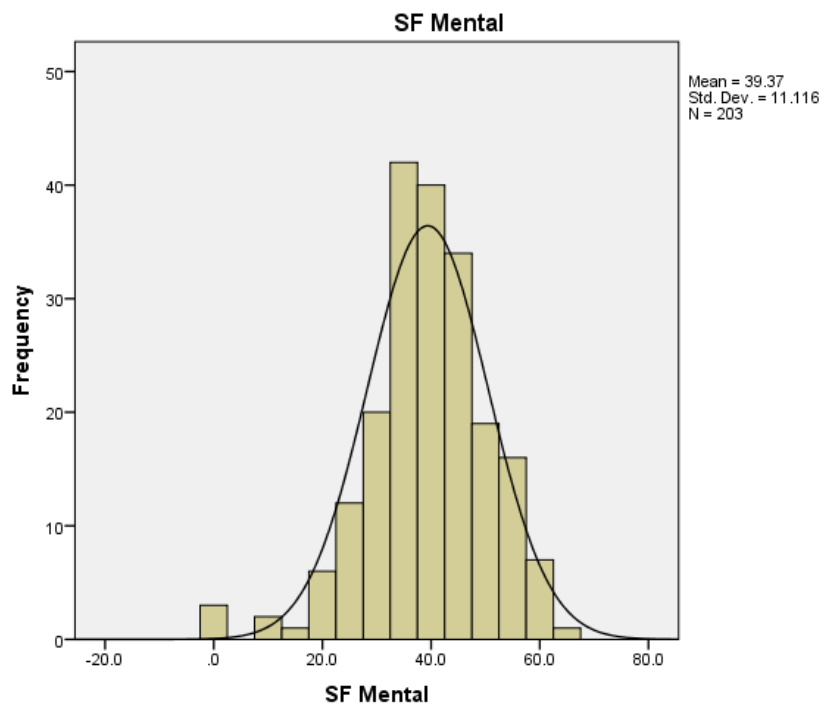
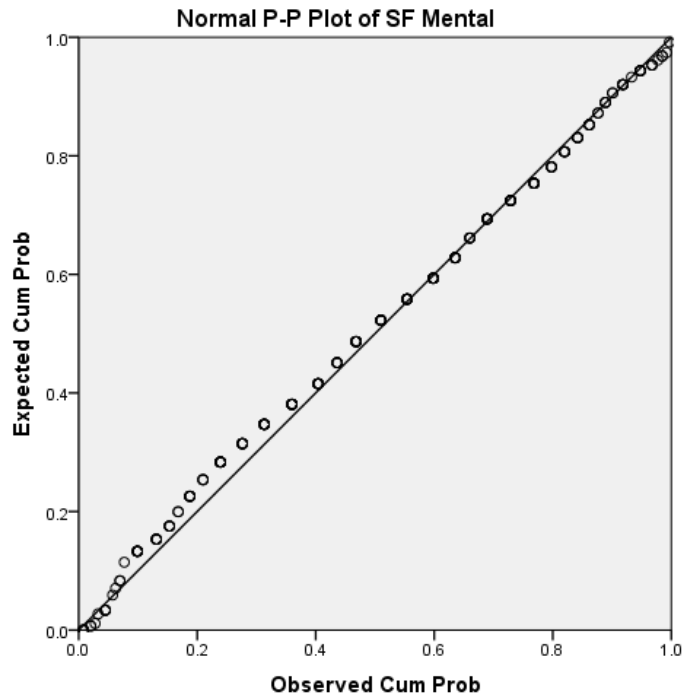
Appendix ZJ

P-P plot and histogram of the SF12v2 Physical subscale



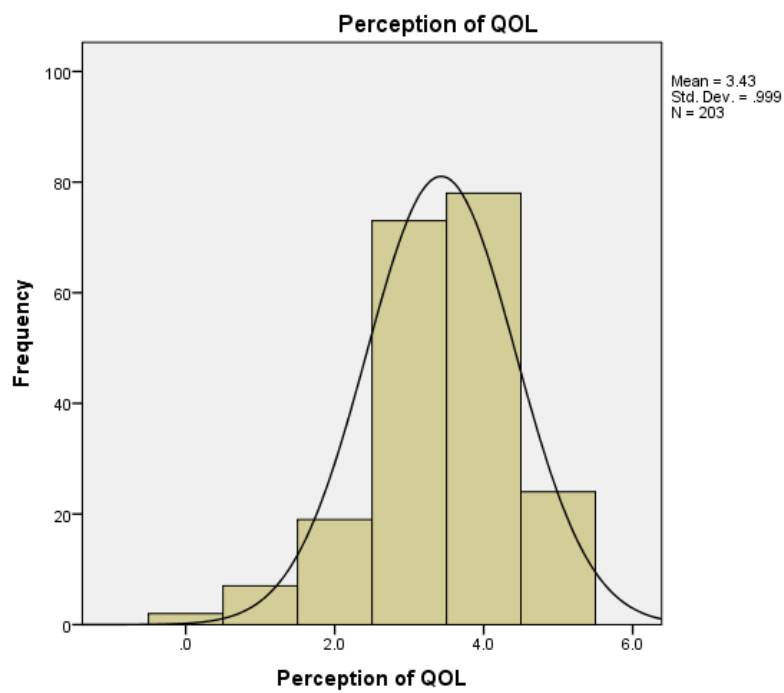
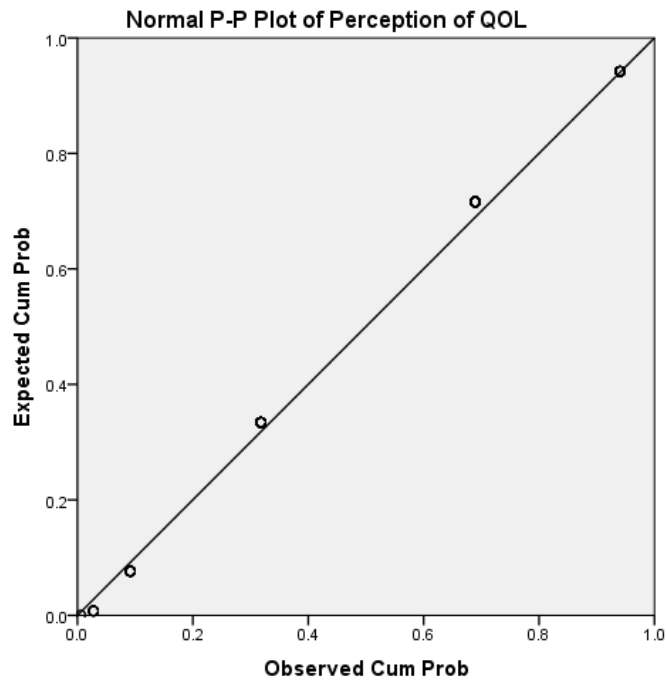
Appendix ZK

P-P plot and histogram of the SF12v2 Mental subscale



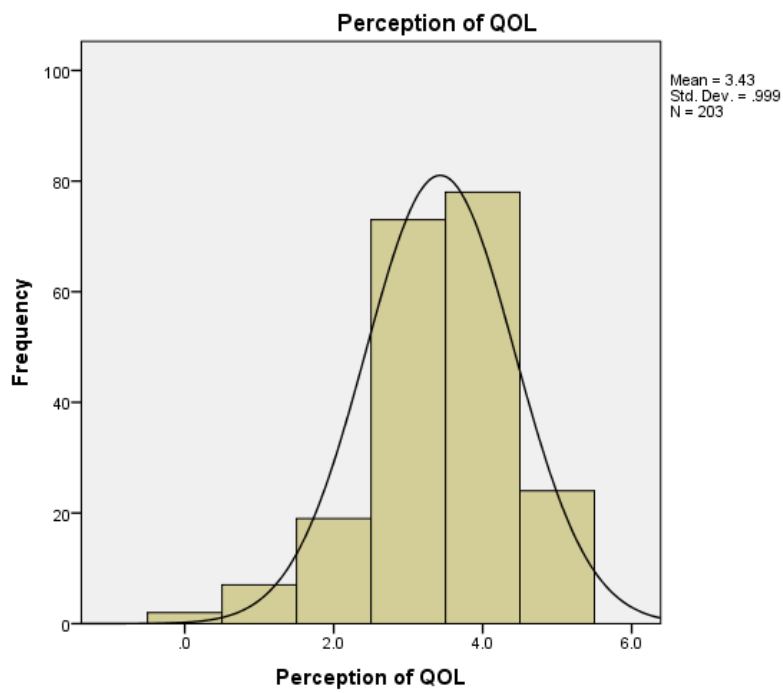
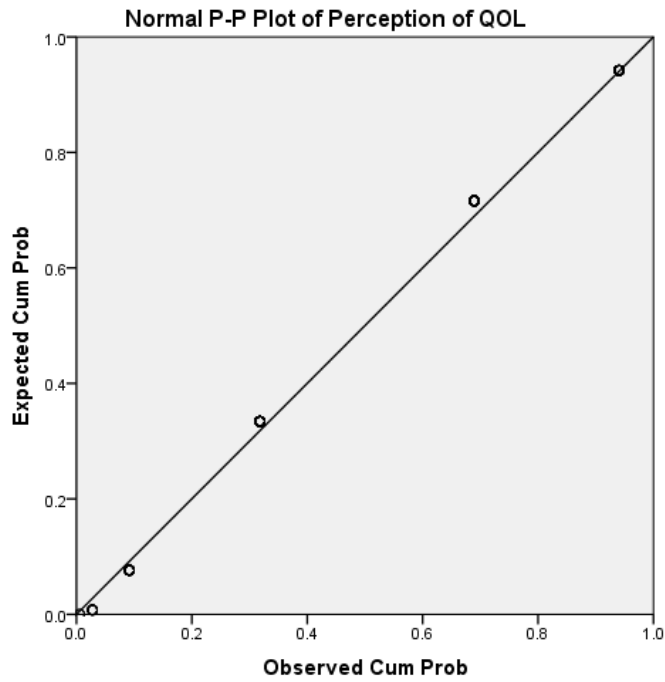
Appendix ZL

P-P plot and histogram of the WHO Perception of QOL



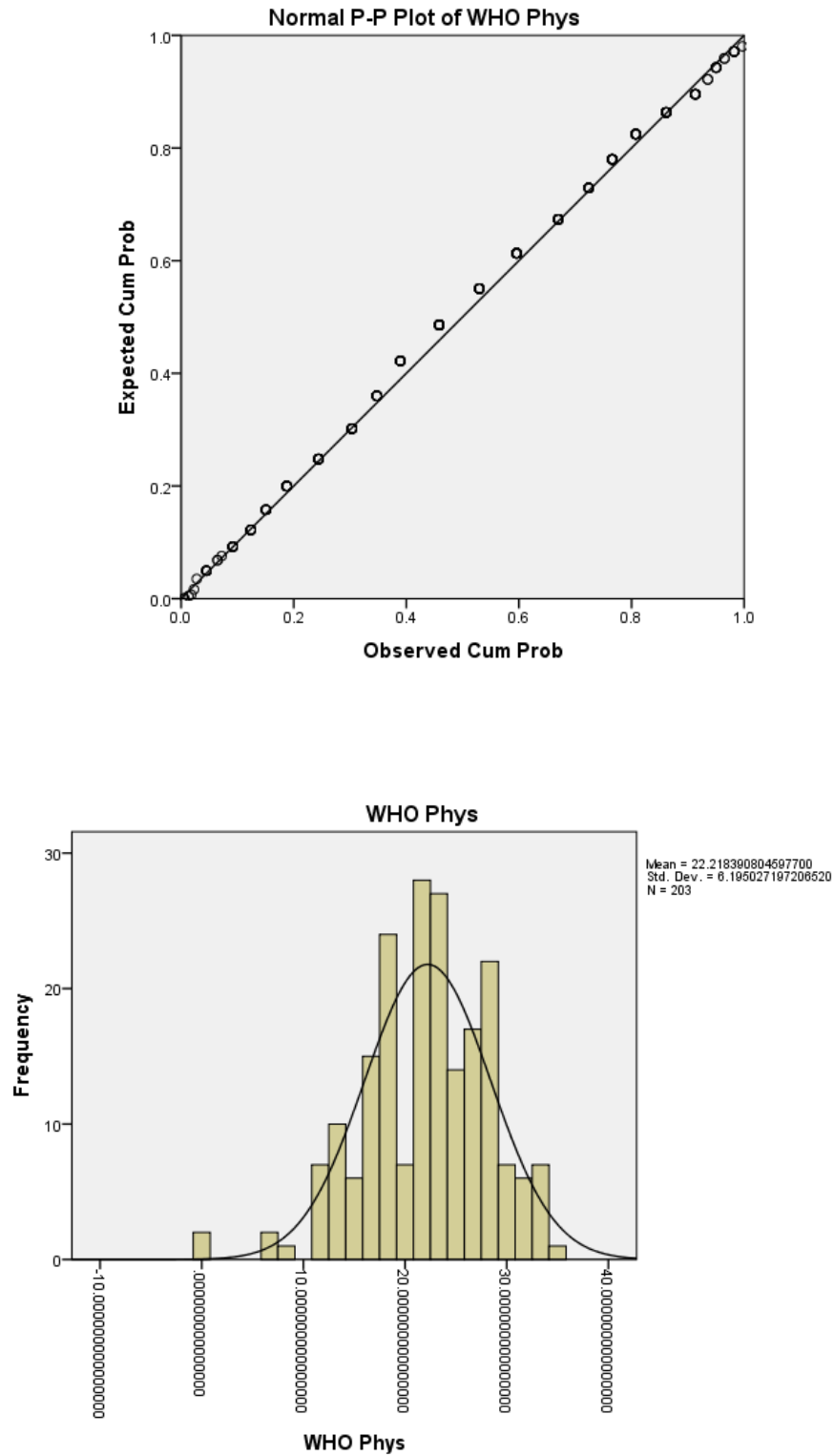
Appendix ZM

P-P plot and histogram of the WHO Perception of health



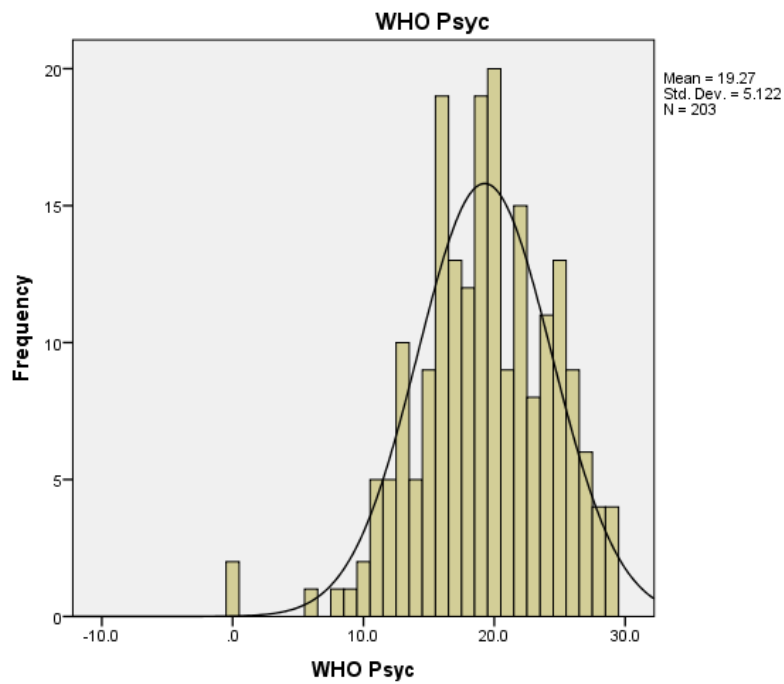
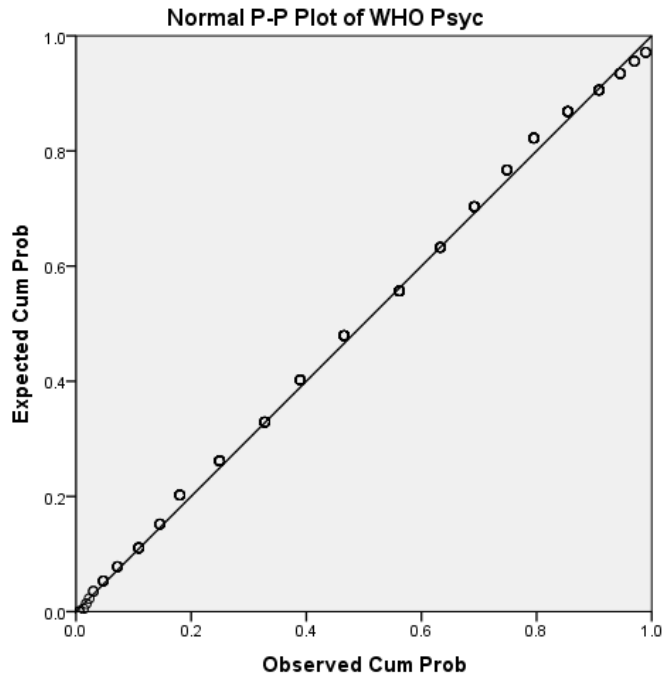
Appendix ZN

P-P plot and histogram of the WHOQOL-Bref Physical subscale



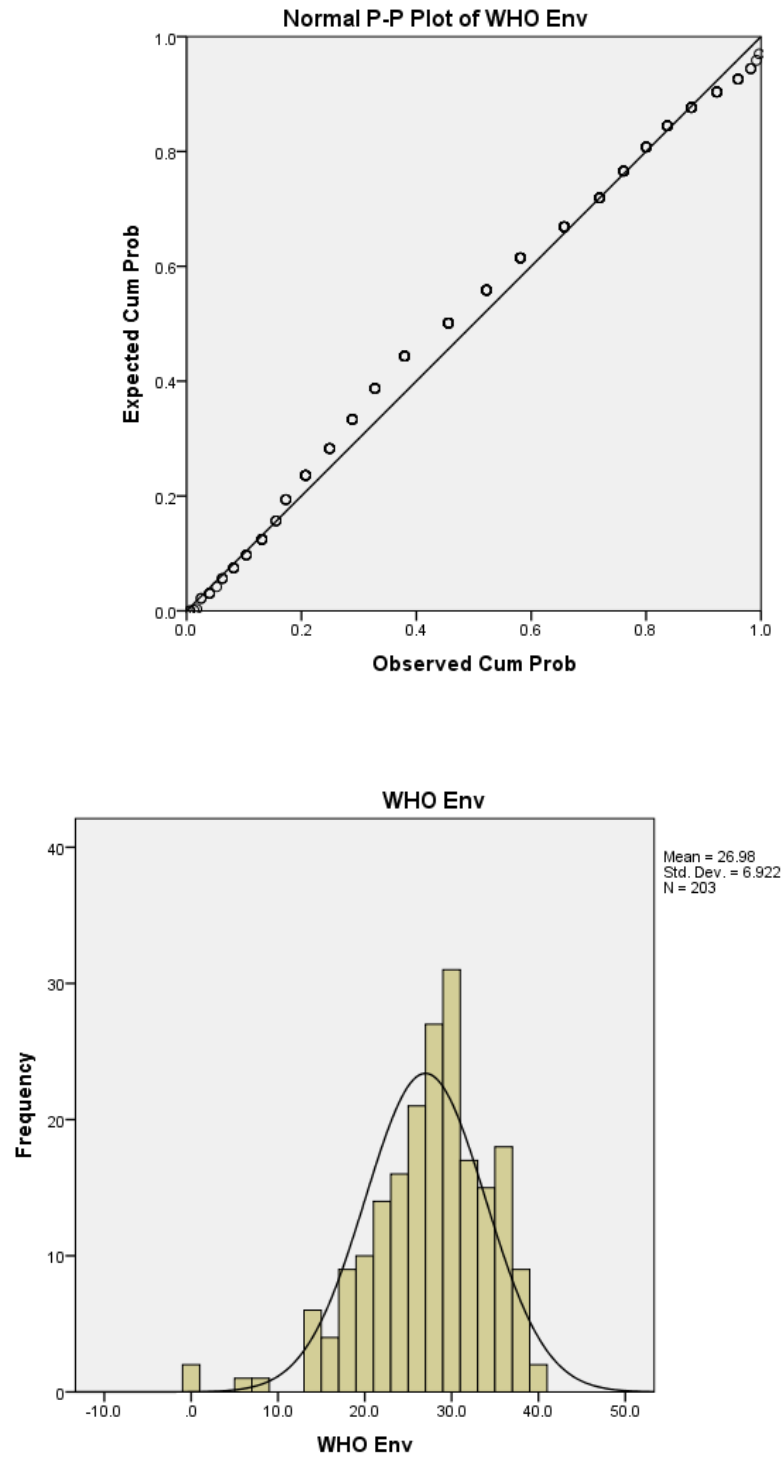
Appendix ZO

P-P plot and histogram of the WHOQOL-Bref Psychological subscale



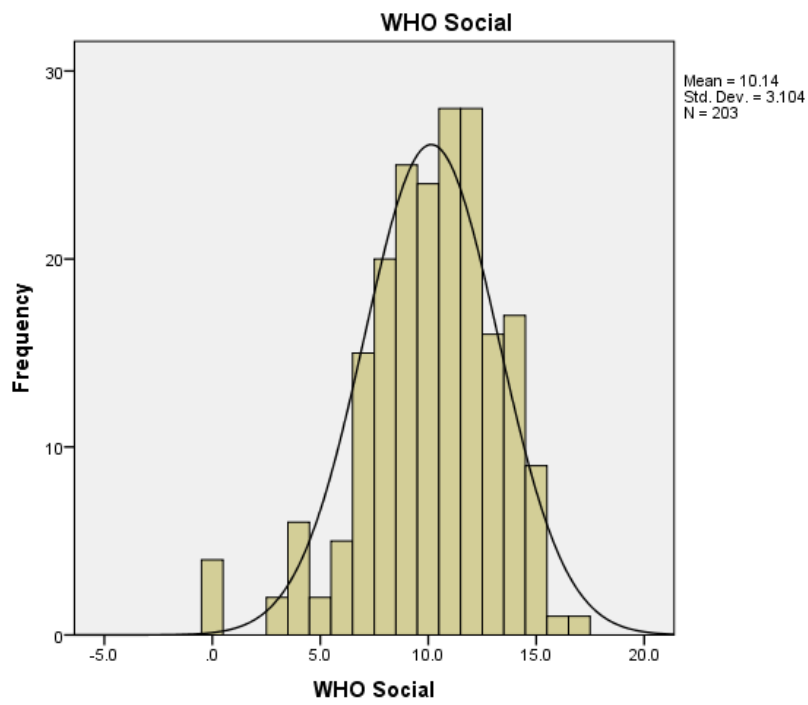
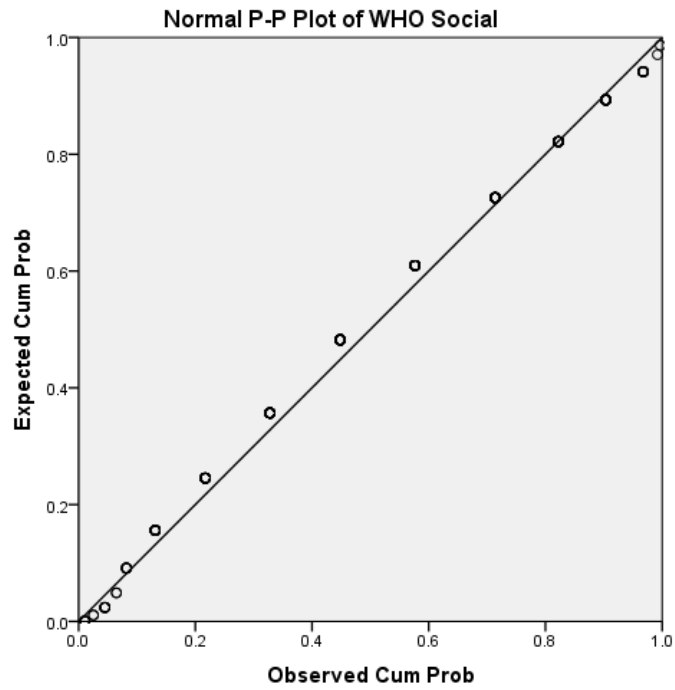
Appendix ZP

P-P plot and histogram of the WHOQOL-Bref Environmental subscale



Appendix ZQ

P-P plot and histogram of the WHOQOL-Bref Social subscale



Appendix Zr*Results of Kolmogorov-Smirnov test for normality for measures and subscales*

Scale/Subscale	K-S statistic	Significance
SEQOL	.060	.072
SEQOL Psychological well-being	.104	.000
SEQOL Income	.150	.000
SEQOL Sexual functioning and romantic relationships	.092	.000
SEQOL Reproductive functioning	.092	.000
SEQOL Vitality	.159	.000
SEQOL Occupational functioning	.094	.000
SEQOL Menstrual characteristics	.206	.000
SEQOL Support	.138	.000
EHP30 Core	.076	.000
EHP30 Work	.097	.000
EHP30 Feelings about infertility	.158	.000
EHP30 Sexual relationship	.096	.000
BDI	.090	.000
SF12v2 Physical	.086	.025
SF12v2 Mental	.067	.029
WHO Perception of QOL	.219	.000
WHO Perception of Health	.171	.000
WHO Physical	.072	.012
WHO Psychological	.061	.067
WHO Environmental	.099	.000
WHO Social	.102	.000

Note: p > .05 indicates a normal distribution

Appendix ZS

Endometriosis symptom checklist

Below is a list of symptoms reported by women who have endometriosis. Please indicate if you experienced the following symptoms:

		Yes	No
1.	I experienced pain during sexual intercourse	0	1
2.	I experienced pain after sexual intercourse	0	1
3.	I had clots in my period	0	1
4.	I had irregular periods / menstrual cycles	0	1
5.	I experienced heavy bleeding when I had my period	0	1
6.	My period lasted longer than a week	0	1
7.	I had some bleeding even when it was not my period	0	1
8.	I experience pain all the time	0	1
9.	I only experienced pain when I had my period	0	1
10.	I experienced pain a week prior to having my period	0	1
11.	I experienced pain two weeks prior to having my period	0	1
12.	I had pain in my abdomen	0	1
13.	I had pain in my ovaries	0	1
14.	I had pain in my uterus	0	1
15.	I had back pain	0	1
16.	I had rectal pain	0	1
17.	Pain shot down my leg	0	1
18.	I experienced bloating	0	1
19.	I was constipated	0	1
20.	I had diarrhea	0	1
21.	I felt faint	0	1

22.	I felt weak	0	1
23.	I felt ill	0	1
24.	I had a fever	0	1
25.	I did not feel like eating	0	1
26.	I felt tired	0	1
27.	I felt lethargic	0	1
28.	I did not have energy	0	1
29.	I experienced headaches	0	1
30.	I experienced migraines	0	1
31.	I was nauseous	0	1
32.	I did not like people touching my skin	0	1
33.	I vomited	0	1
34.	I struggled to bend	0	1
35.	I struggled to care for myself	0	1
36.	I struggled to bath myself	0	1
37.	I struggled to dress myself	0	1
38.	I struggled to go to toilet alone	0	1
39.	I struggled to drive	0	1
40.	It was difficult for me to eat	0	1
41.	I struggled to lie down	0	1
42.	I struggled to lift objects	0	1
43.	It was difficult for me to exercise	0	1
44.	I struggled to sit	0	1
45.	I struggled to sleep	0	1
46.	I struggled to stand	0	1
47.	I struggled to walk	0	1

Appendix ZT

External auditing

Publications:

Roomaney, R. & Kagee, A. Health related quality of life (HRQOL) among women diagnosed with endometriosis: A qualitative study. *Journal of Health Psychology*, in press.

Roomaney, R. & Kagee, A. Coping strategies employed by women with endometriosis in a public healthcare setting. *Journal of Health Psychology*, in press.

Conferences

Roomaney, R. & Kagee, A. Psychosocial predictors of quality of life in women diagnosed with endometriosis in the Western Cape. Paper presented at the 22nd Annual South African Psychology Congress, 20-23 September 2016.

Roomaney, R. & Kagee, A. Living with endometriosis: Coping strategies among women seeking treatment in a public healthcare setting in South Africa. Paper presented at the annual conference of the British Psychological Association - Division of Health Psychology, London, United Kingdom, 16-18 September 2015.

Roomaney, R. The effect of endometriosis on economic and social development. Paper presented at the Social Sciences for Development Conference, 9-10 September 2015, Stellenbosch, South Africa.

Roomaney, R., & Kagee, A. Living with endometriosis: What do patients need? Paper presented at the 9th Biennial Conference of the International Society of Critical Health Psychology, 12-15 July 2015, Grahamstown, South Africa.