Validation of the Utian Quality of Life Scale in the Metro West region of Cape Town

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SPNTRE001

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Declaration by the candidate

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Declaration by the supervisors

We supervised the research undertaken by Trevi Alison Olga Spence and the presentation of this dissertation.

We are satisfied that this is the original work of Trevi Alison Olga Spence and that this dissertation should be submitted in partial fulfilment of the requirements for the degree, Master of Medicine (Obstetrics and Gynaecology) in the University of Cape Town.

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ABBREVIATIONS

European Regulatory Issues on Quality of Life Assessment	ERIQA
Groote Schuur Hospital	GSH
Gynaecology Out Patient's Department	GOPD
Health and Research Ethics Committee	HREC
Health Outcomes Committee of the Pharmaceutical Research and Manufacturers of America	PhRMA HOC
Health Related Quality of Life	HRQoL
Hormone replacement therapy	HRT
Hormone therapy	HT
International Society for Pharmacoeconomics and Outcomes Research	ISPOR
International Society for Quality of Life Research	ISOQOL
Kaiser-Meyer-Olkin measure of sampling	KMO
Mature Women's Clinic	MWC
Menopause-Specific Quality of Life Questionnaire	MENQOL
Menopause Quality of Life Scale	MQOL
Menopause Rating Scale	MRS

Mitchells Plain District Hospital	MPDH
New Somerset Hospital	NSH
Patient-reported outcomes	PRO
Quality of Life	QoL
Stages of Reproductive Ageing Workshop	STRAW
Utian Quality of Life Scale	UQOL
Women’s Health Questionnaire	WHQ
World Health Organisation	WHO
World Health Organisation Quality of Life-Bref	WHOQOL-BREF

ABSTRACT

Background: Menopause is a universal event and today most women are reaching the age when menopause occurs. Very little research has been done in South Africa about the perimenopausal period, particularly with regard to quality of life (QoL). The Utian Quality of Life Scale (UQOL) was designed to determine the QoL in peri- and postmenopausal women, and not just to measure their symptoms. The aim of this study was to validate the UQOL in a local urban population in State sector hospitals in Cape Town.

Methods: This was a prospective, cross-sectional study. Participants were recruited from the Mature Women's Clinic at Groote Schuur Hospital (GSH), and Gynaecology Out Patient Departments (GOPD) at GSH and New Somerset Hospital (NSH). Four questionnaires were administered- a demographics questionnaire, the UQOL, the WHOQOL-BREF and the Greene Climacteric Scale. Women were contacted telephonically after 3-14 days for retest of the questionnaires to establish reliability.

Results: Fifty two participants were initially recruited and 49 were retested. Results showed that the UQOL is a valid instrument with which to measure QoL in our study population. The test-retest reliability was good, with only 2 questions having significantly different answers (p-value < 0.05). Internal consistency (Cronbach's alpha) was >0.7 for the occupational domain of the UQOL only. The health, emotional, and sexual domains had alpha values of 0.673 and 0.691 and 0.634 respectively, which are acceptable. The Cronbach's alpha for the health domain improved to 0.739 when question 8 was removed from the health domain.

Construct validity was demonstrated by a statistically significant correlation between the domains of the UQOL and the WHOQOL-BREF. Secondary factor analysis confirmed the domain structure of the UQOL.

The scores from the domains seem to indicate that perceived QoL in our study population is not significantly impaired, with the sexual domain showing the most negative impact on QoL. The WHOQOL-BREF demonstrated good internal consistency in our study population.

Conclusions: The UQOL is a valid instrument to measure QoL related to the menopause in our patients. No questions were deleted from the original scale. Further research is needed in Afrikaans and Black African languages. The sexual experiences of peri- and post-menopausal women should also be explored. Menopause did not seem to adversely affect QoL in the women who participated in this study. The WHOQOL-BREF is a good tool to measure general QoL in our study population.

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

Menopause is defined as the final menstrual period, a single point in time, followed by 12 months of amenorrhoea. It is due to a loss of ovarian function, resulting in a state of oestrogen deficiency. Menopause can either be natural, or induced as a result of bilateral oophorectomy (surgical menopause), chemotherapy or pelvic radiation. Natural menopause is a gradual process (the perimenopausal period, or climacteric), whereas surgical menopause results in an abrupt onset of symptoms. The mean age of menopause worldwide is 51 years, with a range between 48-55 years. The age of menopause has remained stable over time, while the age of menarche has declined. With the increase in the average life expectancy, most women may expect to spend a third of their lives in the postmenopausal period.[1-3]

The symptoms associated with menopause are due to a decrease and subsequent lack of circulating oestrogen levels. Vasomotor symptoms such as hot flushes, night sweats and insomnia occur early in the climacteric period, often before the menopause, and often continue for a prolonged length of time into the postmenopausal period. Later, psychosomatic symptoms such as headache, irritability, mood swings, and poor memory and concentration develop. The vasomotor and psychosomatic symptoms often subside and improve with time.[1-3]

Symptoms due to atrophy secondary to hypo-oestrogenism include urogenital complaints, changes in skin appearance and aching joints and muscles. These symptoms occur later than the onset of the vasomotor symptoms. There is an increased risk, post-menopause, of cardiovascular disease and osteoporosis. The increase in cardiovascular disease is due to a combination of factors, including the normal ageing process, lifestyle choices (smoking, poor diet, lack of exercise, obesity) and the presence of co-morbid conditions such as diabetes and hypertension which also increase with age. The role of hypo-oestrogenism in the development of cardiovascular disease is controversial.[1-5]

Women across the globe experience menopausal symptoms. Whether women experience these symptoms as positive or negative, and how often they seek medical attention depends on the society in which they live, as well as cultural factors.[6] Generally, in societies where ageing is regarded as a normal part of life and the elderly are treated with respect and valued, perimenopausal women do not associate this period of their lives with a decline in worth. In the Western world, however, the perimenopausal period is often anticipated with dread and an expected decline in quality of life (QoL), particularly among younger women.[7]

The Stages of Reproductive Ageing Workshop (STRAW) was held in 2001 to address the absence of a staging system for female reproductive ageing, to revise the then current classification pertaining to menopause at the time, and to recognize potential problems regarding knowledge that could be addressed by future research. The initial STRAW was only applicable to healthy women and excluded smokers, women with a BMI less than 18 or over 30, women with irregular menses, women who had hysterectomies or abnormal uterine or ovarian anatomy, and women who exercised more than 10 hours per week.[8]

STRAW was revised in 2011 to include advances in our understanding of ovarian ageing, and what influences this, including ethnicity, BMI and smoking.[8]

STRAW divides adult female life into 3 phases centred around the final menstrual period (FMP): reproductive, menopausal transition and postmenopausal. The three phases are divided into seven stages, as seen in the accompanying figure.[8, 9]

Fig 1: The Stages of Reproductive Aging Workshop +10 staging system for reproductive aging in women

(Figure used with permission from *Fertility and Sterility (Appendix 1)*)

	Menarche						FMP (0)			
Stage	-5	-4	-3b	-3a	-2	-1	+1 a	+1b	+1c	+2
Terminology	**REPRODUCTIVE**				**MENOPAUSAL TRANSITION**		**POSTMENOPAUSE**			
	Early	Peak	Late		Early	Late	Early			Late
					Perimenopause					
Duration	*variable*				*variable*	1-3 years	2 years (1+1)		3-6 years	*Remaining lifespan*
PRINCIPAL CRITERIA										
Menstrual Cycle	Variable to regular	Regular	Regular	Subtle changes in Flow/ Length	*Variable Length* Persistent ≥7- day difference in length of consecutive cycles	Interval of amenorrhea of >=60 days				
SUPPORTIVE CRITERIA										
Endocrine FSH AMH Inhibin B			Low Low	Variable Low Low	↑ Variable Low Low	↑ >25 IU/L** Low Low	↑ Variable Low Low		Stabilizes Very Low Very Low	
Antral Follicle Count			Low	Low	Low	Low	Very Low		Very Low	
DESCRIPTIVE CHARACTERISTICS										
Symptoms						Vasomotor symptoms *Likely*	Vasomotor symptoms *Most Likely*			*Increasing* symptoms of urogenital atrophy

* Blood draw on cycle days 2-5 ↑ = elevated

**Approximate expected level based on assays using current international pituitary standard[67-69]

(9)

The menopausal transition is a time of physiological change as a woman reaches the end of her reproductive potential. The symptoms associated with this have an impact on quality of life, and these changes influence the general health of women, both in the short and long term.[8, 9]

Worldwide, the number of men and women aged 65 or older is expected to increase to nearly 1.5 billion in 2050. The highest increase is projected to occur in the developing world.

Changes in the causes of disease and death from infectious to non-infectious, improvements in living conditions and health-seeking behaviour, advances in modern medicine (the advent of antibiotics, immunisation and screening programmes) and access to healthcare facilities are among the main reasons for this increased life expectancy. Data from reviews of life expectancy between 1840 and 2007 shows a gradual, but persistent increase (10). As a result the upper limit of life expectancy is not clear. What is certain is that the world's population is ageing. There is convincing evidence from cross national data that if people can remain healthy, independent and well into old age they can make a meaningful contribution to their communities and families.[10]

Quality of life (QoL) is difficult to define, and therefore attempts to measure it are often challenging. The patient-reported outcomes (PRO) Harmonization Group (a group consisting of The European Regulatory Issues on Quality of Life Assessment [ERIQA] Group, International Society for Quality of Life Research [ISOQOL], International Society for Pharmacoeconomics and Outcomes Research [ISPOR], and Health Outcomes Committee of the Pharmaceutical Research and Manufacturers of America [PhRMA HOC]) defines it as: "Health Related Quality of Life (HRQL) represents the patients' evaluation of the impact of a health condition and its treatment on daily life". [5] Health–related quality of life (HRQoL) can be broadly defined as the "effect of a medical condition and/or its consequent therapy on a patient.[13]

The World Health Organisation (WHO) defines health as “a state of complete physical, mental, and social well-being not merely the absence of disease”.[11] It defines QoL as “an individual’s perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, standards and concerns.” The WHO definition includes 6 domains: physical health, psychological state, levels of independence, social relationships, environmental features, and spiritual concerns. The WHO currently has 2 QoL questionnaires available: the WHOQOL-100 and its shortened form the WHOQOL-Bref. Both these questionnaires can be used in different cultures and are available in over 20 languages.[11, 12]

The WHOQOL-100 was developed by conducting QoL research in 15 WHOQOL centres around the world in the 1990’s. Developed and developing nations were included in the research population. The researchers realised that it was important to determine whether similar aspects affected people’s perceived quality of life despite differences in culture, age, sex or wealth. First, a list of aspects that define QoL was made, and then questions were developed that tested how these aspects affected participants’ QoL. Information gained from patients, their families and health care workers at the 15 centres helped develop these questions. The final WHOQOL-100 was generated by applying these questions to a population in a large pilot field study. The WHOQOL-BREF is a shortened version of the WHOQOL-100. It has 4 domains (as opposed to the 6 in the WHOQOL-100), and 26 items. Each item is the best match from each of the 24 facets of the WHOQOL-100. Two items addressing health and quality of life were also kept in the WHOQOL-BREF. Skevington et al showed that the WHOQOL-BREF is a “sound, cross-culturally valid assessment of QOL, as reflected by its four domains: physical, psychological, social and environment.” [14, 15]

Quality of life questionnaires can either be general (as the WHO questionnaires are) or specific to a particular disease. Regardless of whether they are general or disease specific, they need to be objective, reliable and valid, to ensure they properly assess QoL.[16]

Health related QoL does not always equate to general QoL, as a person with a major physical handicap may still perceive their general QoL to be excellent. Assessment of QoL in the menopause often relies on symptom reporting, and while these symptoms may negatively affect QoL, they must be recognised together with global aspects of QoL, as outlined in the WHO definition. Menopause is not a disease, but a physiological process, and therefore QoL in the menopause is related to more than just health, and includes multiple factors which may affect a woman’s wellbeing.[3, 18]

It is important to assess the QoL in, and the state of health of, peri- and post-menopausal women because of the increasing number of women seeking healthcare who experience the menopause. Adequate care must be addressed and provided to them within a healthcare system. Quality of life in symptomatic menopausal women is often improved by the administration of hormone therapy (HT) which improves the oestrogen deficiency symptoms.[3, 18]

Most studies focusing on menopausal challenges are limited to developed countries. There is a paucity of data regarding QoL in menopausal South African women. Ramakuela *et al* investigated menopausal challenges faced by women in Limpopo province, a rural province in South Africa, as there had been little attention focused on this group. They reviewed vasomotor symptoms, psychological symptoms, gastrointestinal symptoms and psychosomatic symptoms. The participants were divided according to age to analyse certain variables, while menopausal status was used to analyse other variables. They found that the younger women suffered from severe menopausal symptoms (hot flushes, excessive sweating, insomnia, urinary frequency and avoiding intimacy), and that most women were not aware of the menopausal challenges they would encounter. The authors felt that interventions concerning menopausal symptoms among these women needed to be strengthened, particularly at a primary care level.[19]

Smith *et al* conducted a survey among patients in a private practice in Cape Town about their perceptions of the menopause. The authors concluded that most women were well informed regarding the indications for hormone replacement therapy (HRT), and developments concerning HRT, with the prescribing doctor being the key factor regarding information and decision-making.[20] This study did not address QoL issues and assessed the perceptions of a group of women who accessed private healthcare. A further study by the same group using the Utian Quality of Life (UQOL) Scale in a similar population was done as part of the above survey to assess QoL between patients on HT and those not on HT, and whether the use of HT influenced patients' QoL. The UQOL was not validated for this study. Most of the responders (78%) were using HT, with 69% having concurrent comorbidities (hypertension, thyroid disease, osteoporosis/osteopaenia, depression, other cardiac disease, breast cancer and diabetes). The survey showed that women on HT reported a better perceived QoL in the occupational, sexual and emotional domains of the UQOL Scale. The authors reported that women who were receiving treatment for depression, and who were also taking HT reported the best QoL across all domains of the UQoL.[21]

Mashiloane *et al* investigated the awareness and attitudes of black African women about the menopause and treatment. They found that the age of menopause in black African women is slightly lower than the average age (49.5 years vs 51). Seventy nine percent of women interviewed knew about the menopause, and all of these women felt that it was a normal part of ageing, and had a positive attitude towards it. More than half of these women had heard about the menopause from members of their community. Twenty eight percent were aware of treatment options available to manage menopausal symptoms. This study also found that the more educated the women interviewed were, the more likely they were aware of the symptoms of menopause. Despite the fact that nearly half the women interviewed experienced menopausal symptoms, very few of them were aware of the relationship between the symptoms and the menopause.[22] This study did not, however, assess QoL.

In comparison, a study done in Nigeria by Ozumba *et al* assessing similar factors, reported a mean age of menopause of 49 years, the same as in the South African study. In contrast, they showed that 70% of participants had a negative attitude towards the menopause, and that these women experienced vasomotor symptoms, had very little support, and had very little knowledge of the menopause. Of professional women interviewed, 90% had a negative attitude towards the menopause.[23]

In a review of the literature in Quality of Life Research, Zollner *et al* reviewed a number of HRQoL questionnaires to determine if there were any instruments that addressed menopausal symptoms and effects of hormone replacement therapy (HRT).[5] The 8 health related quality of life instruments they reviewed were the Greene Climacteric Scale, the Women's Health Questionnaire (WHQ), Qualifemme, the Menopause-Specific Quality of Life Questionnaire (MENQOL), the Menopausal Symptoms List (MSL), the Menopause Rating Scale (MRS), the Menopausal Quality of Life Scale (MQOL) and the Utian Quality of Life Scale (UQOL). The review concluded that an existing questionnaire would have to be modified, or a new questionnaire would have to be developed to analyse the effect of HRT on HRQoL, as none addressed all the aspects of the impact of HRT on HRQoL.[5]

The Greene Climacteric Scale was initially developed in 1976 to determine if there was a relationship between symptoms present in the climacteric, and to create a sensible means of evaluating menopausal symptoms than was available at the time. It was revised in 1998 in order to create a standardised climacteric scale. The Greene Climacteric Scale is essentially a symptom list, and it was not designed to be used as an instrument to assess QoL or the effects of HT. The domains covered are psychological, somatic and vasomotor, with 21 questions posed to participants.[5, 24-26]

The Women's Health Questionnaire (WHQ), created in 1986 by Myra Hunter in England, covers 9 domains: depressed mood, somatic symptoms, vasomotor, anxiety/fears, sexual behaviour, sleep problems, menstrual symptoms, memory/concentration and attractiveness. These domains are assessed by 36 questions. The WHQ has been translated into many languages and has been extensively used internationally. It assesses both menopause-specific and non-specific symptoms, and is the first QoL questionnaire to be included in the International Quality of Life Outcomes Database (IQOD).[5, 18]

The Qualifemme questionnaire is a French tool developed in 1994 and revised in 1996 in a shorter form, to assess QoL before and after the initiation of HT. There are 5 domains: general, psychological, vasomotor, urogenital, pain and problems with skin and hair (covered as a single domain). There are 15 questions in the Qualifemme questionnaire, reduced from the original 32.[5]

The Menopause-Specific Quality of Life Questionnaire (MENQOL) was formulated in 1996 in Canada. Its population was post-menopausal women, who had not used hormone therapy (HT) in the preceding 6 months. The 5 domains covered by 29 questions are: physical, psychological, vasomotor, sexual and global QoL. The MENQOL covers both presence of symptoms and their impact on QoL.[5, 27, 28]

The Menopause Symptoms List, designed as a symptom list in 1997 in Australia, consists of 3 domains: psychological, vaso-somatic and general somatic. They are addressed by 25 items.[5]

The Menopause Rating Scale (MRS) was developed by the Menopause Association of German-speaking countries in 1996 and consists of 11 items covering 3 domains: psychological, somato-vegetative and urogenital symptoms. The MRS was developed with the aim to establish a standardised scale to measure QoL in menopausal women, to track menopausal symptoms over time, and the effects of HT. It has been translated into many languages and has been extensively used internationally.[5, 29]

The Menopausal Quality of Life Scale (MQOL) was formulated in 2000 in the United Kingdom to determine if there was a relationship between QoL and menopausal status, medical co-morbidities and lifestyle factors. It consists of 48 items covering 7 domains: energy, sleep, appetite, cognitions, feelings, interactions and symptom impact.[5, 30]

The Utian Quality of Life Scale (UQOL) was created to bridge the divide between existing menopause QoL questionnaires, which were mainly symptom inventories, and women's perceived QoL. The main objective was to provide an instrument to quantify QoL at baseline, as well as being able to monitor any changes over time, that would be consistent, practical and easy to use.[31] The UQOL began as an assessment in the 1960's of patients' response to oestrogen therapy, after surgical menopause as a result of total abdominal hysterectomy and bilateral salpingo-oophorectomy due to benign gynaecological conditions. The initial study only looked at the psychological and emotional response ("sense of wellbeing") of the patients to oestrogen or placebo, assessed by the patients and the principal investigator.[32]

The final UQOL is a result of revision of the initial questionnaire during subsequent studies. It consists of 23 items/questions. There are four domains in the UQOL: occupational (seven statements), health (seven statements), emotional (six statements) and sexual (three statements). Each question/statement is scored using a 5 point Likert-type score, ranging from 1- not true of me to 5- very true of me. Each domain is scored by adding the question scores, and the domain scores are added to achieve an overall score. The UQOL has been found to be reliable (shown by test-retest reliability estimates), and while validation proved to be challenging, it has been validated on a cross-sectional basis. The recommendation of the authors of the UQOL is to use the scale along with a symptom inventory such as the Greene Climacteric Scale to fully assess a woman's perceived quality of life as well her symptoms.[31]

The UQOL has been translated and tested in Portuguese- and Chinese-speaking populations. More recently it has been translated and validated in a Greek study where it was then used to assess the QoL in that same population, as well as validated in a Serbian population. It has been found to be a reliable and valid tool in these settings. It is a sound instrument to measure QOL during the menopause. [33-37]

The UQOL needs to be validated in our setting (an urban population in State sector hospitals) in order to use it in our clinical practice. The UQOL is freely available for use in research and clinical practice, without prior permission from the authors. The authors only ask that they be acknowledged.

We have undertaken the study to validate this potentially useful questionnaire in our clinical population with the aim to be able to include this assessment in the evaluation and management of women accessing our Mature Women's Clinic (MWC).

CHAPTER 2- METHODOLOGY

2.1 RECRUITMENT

Patients aged 45 years and older were identified by their date of birth on the clinic folders and recruited from the Mature Women's Clinic (MWC) and the general Gynaecology Out Patient's Departments (GOPD) at Groote Schuur Hospital (GSH) and New Somerset Hospital (NSH).

The folder of each participant was reviewed for additional clinical information. The study population included both women who were on hormone replacement therapy (HRT), and those who were not using HRT. The HRT was defined as the hormonal treatment they were on at the time of the study. The questionnaire was only administered in English, which unfortunately excluded some of the patients identified as suitable. There were however patients who were comfortable being interviewed in English even though it was not their home language.

2.2 AIMS AND OBJECTIVES

This study aimed to validate the Utian Quality of Life Scale (Appendix 2) in an urban population at public institutions in Cape Town. It will use the WHOQOL-BREF (Appendix 3) questionnaire as a comparison. The Greene Climacteric Scale for a South African population (Appendix 4) was used with the UQOL to evaluate menopausal symptoms in the study subjects.

2.3 STUDY DESIGN

The study was a prospective, cross-sectional study.

2.4 SAMPLE SIZE CALCULATION

A validation study has no universal recommendations for sample size, and 50-100 participants are suggested. The sample population used must represent the population being studied.[38] The sample size for this study was based on a 2:1 ratio of subjects to items in the questionnaire to be validated to reduce statistical error.[39] The UQOL has 23 items; therefore we needed a minimum of 46 participants to do the retest.

2.5 INCLUSION CRITERIA

- Women aged 45 years and older
- Women who were perimenopausal or had natural or surgical menopause
- Women who experienced menopausal symptoms or had elevated serum FSH levels

- Women willing to participate in the study and who understood and were comfortable completing the questionnaire in English

2.6 EXCLUSION CRITERIA

- Women who were younger than 45 years old (women who are younger than 45 are classified as having early menopause, and women younger than 40 are classified as having premature ovarian insufficiency)
- Women who did not understand English
- Women with other causes of secondary amenorrhoea
- Women who were not willing to participate in the study or were unable to consent to participation.

Potential subjects were counselled that non-participation in the study would not impact on their clinical care, as the research team would not be involved in their clinical management. All patients who agreed to participate had the study explained to them, were given a patient information sheet (Appendix 5), and asked to sign a consent form (Appendix 6) before completing the questionnaires.

2.7 DATA COLLECTION AND STATISTICAL ANALYSIS

The questionnaires (demographic, UQOL, WHOQOL-BREF and Greene Climacteric Scale) were administered by the principal investigator and by research staff of the Reproductive Medicine Unit (RMU). Another interviewer who was trained to administer the questionnaires assisted the principle investigator with interviews at NSH.

The questionnaires were readministered after 3-14 days, to assess test-retest reliability. This time interval was chosen to avoid recall bias (patients recalling their previous answers without reading the questions). The time interval used to validate the original UQOL scale was 3-7 days, as it was felt that this would improve compliance, that it was sufficient time as "QoL is a state rather than a trait construct" [31], and that there it was less likely that participants would remember their previous answers as the items were scaled on a 5-point Likert rating. It was also unlikely that QoL would change significantly in this short time frame.[31]

The follow-up arrangements were made at the time of the first interview, and the second interview was conducted telephonically. The principal investigator did most of the follow-up interviews, with assistance from a member of the Reproductive Medicine Unit. The interviewer who administered the initial questionnaire did not necessarily conduct the follow-up telephonic interview.

We controlled for interview bias by not explaining any of the questions to the participants. They answered the questions as they understood them.

Demographic information was obtained by using a general questionnaire (Appendix 7). Permission was obtained from the WHO to use the WHOQOL-BREF (Appendix 8) and from Corporate Translations to use the Greene Climacteric Scale (Appendix 9).

The two sets of questionnaires (UQOL and WHOQOL-BREF) were compared by correlational analysis, and reliability was assessed by internal consistency, and measurement, in the case of the UQOL, of its test-retest reliability.[16, 40]

Questionnaires are an important form of data collection, and have been widely used in a variety of studies. A good questionnaire needs to be valid and reproducible. The questionnaire to be used needs to be evaluated in terms of content validity (the questions are a correct and comprehensive reflection of the concept the questionnaire is intended to measure), dimensionality (factor structure) and internal consistency. Test-retest reliability and validity should be investigated, and information regarding interpretation of scores must be available. [38, 40]

Validity is the degree to which a questionnaire measures what it sets out to measure. When a new instrument is validated it must be compared to another measure, the gold standard available to measure the construct of interest. This is known as concurrent or construct validity, as both instruments are administered at approximately the same time. [40]

Face validity is a form of content validity -the degree to which all facets of the chosen construct are taken into account. The contents of the questionnaire are reviewed by a team of “experts”, to assess if the items are appropriate for the population being assessed. Face validity is inherently subjective, so is often used in the initial phases of test construction. [40] For this study face validity was assessed by a team of expert clinicians from the appropriate clinical environment. This panel included gynaecologists with an interest in menopausal health, as well as nursing staff who work in reproductive medicine and the principal investigator.

Reliability is the measure to which an instrument is consistent or reproducible. An instrument is thought to be reliable if it produces similar results when it is readministered to the target population.[40, 41] Test-retest reliability is a measure of how stable a questionnaire is over time, and is fundamental when measuring outcomes. This is only appropriate if the measurement remains stable over the time interval.[40] The time interval recommended is usually 1-2 weeks, as this is long enough to prevent recall bias and also short enough so that the parameters being measured do not significantly change.[38]

Test-retest reliability was analysed using the Wilcoxon sign test to calculate if any statistical differences occur between the scores at time 1 and time 2. The results will be taken to be significant if $p < 0.05$.[42]

Factor analysis examines the covariance (the relationship between variables/factors) between items in a questionnaire, which may be expressed via a smaller number of factors. The covariance can be used to determine if any factors need to be removed from the questionnaire, as items/factors that are too closely related can represent the same construct. Factor analysis will be performed by principal component analysis, followed by Varimax rotation with the assistance of a statistician. [28, 41]

Internal consistency is the extent to which items within an instrument relate to one another. Cronbach's alpha is used to determine the internal consistency of a questionnaire. It is expressed as a number between 0 and 1. Acceptable values for alpha are between 0.70 and 0.95. Low scores may indicate poor inter-relatedness between items in a questionnaire, too few questions, or heterogeneous constructs. If alpha is too high, it may be due to redundant items, which should then be removed. [16, 40, 42]

2.8 SELECTION BIAS

In order to avoid selection bias, the participants were recruited not only from the Mature Women's Clinic (MWC) at GSH, but also the general GOPD at GSH and NSH. Most of the women referred to the MWC have symptoms of menopause, so we wished to broaden the patient base to include women of the correct age group who are not necessarily symptomatic or bothered by menopausal symptoms if they are present, and these were not the reason for referral to the gynaecology department.

2.9 ATTRITION BIAS:

We could not predict how many patients would be willing to participate, and how many would respond to readministration of the questionnaires. Our previous experience with QoL questionnaires indicates that most patients are willing to participate, but there is a fall-off of participants for the retest.

2.10 ETHICAL CONSIDERATIONS AND COPYRIGHT PERMISSION

Patient confidentiality was ensured. The data were collected and analysed using study identification numbers. Only the interviewers had access to the patient folders. The folders were assessed at the hospital and no folders were removed from the premises.

Permission to conduct the study was obtained from the Human Research Ethics Committee of the University of Cape Town, HREC REF 828/2014 (Appendix 10). Permission was granted to recruit patients from GSH and NSH by the superintendents of both hospitals (Appendices 11 and 12). The study conforms to Good Clinical Practice Guidelines and the Declaration of Helsinki of 2013.

2.11 DISSEMINATION OF RESULTS

The results of the study will be made available through the Department of Obstetrics and Gynaecology of the University of Cape Town to the Department of Health in the Western Cape and to the broader Obstetrics and Gynaecology community through presentations at meetings and a scientific publication.

CHAPTER 3- RESULTS

3.1 Recruitment:

A total of 52 women were interviewed for the initial questionnaire test, with retesting of 49 participants (94%). As we anticipated there would be a drop-out of participants for the test-retest, we recruited patients until we had completed the test-retest on 46 participants. The final total of patients recruited was 52, with 49 participants retested.

The attrition was due to the inability to contact 3 of the participants within the 2 week retest period (these participants did not answer their telephones despite numerous attempts). The average time to administer the 4 questionnaires for the initial test was 20 minutes, with retesting taking a similar amount of time. We retested all the questionnaires, as the recommendation by the author of the UQOL is to use it in association with a symptom list such as the Greene Climacteric Scale.

Most of the women were recruited from New Somerset Hospital GOPD (55.8% n=29), with the remainder coming from Groote Schuur Hospital (from the Mature Women's Clinic 7.7% [n=4] and 36.5% [n=19] from Gynaecology Out Patients). The participants were recruited from 12 February 2015 to 07 May 2015. The initial tests (52 participants) were named UQOL-1, Greene-1 and WHOQOL-BREF-1. The retests (49 participants) were named UQOL-2, Greene-2 and WHOQOL-BREF-2.

3.2 Demographic data

3.2.1 Background information

The age range of the participants was 45 to 65 years. Fifty percent of the women were between 45 and 51 years, with the remaining 50% between 51 and 65 years.

Table 1: Age distribution of study participants

	Frequency	Percentage
Age (years)		
45-49	20	38.5
50-54	18	34.6
55-59	6	11.5
60-65	8	15.4

The majority of the participants were mixed ancestry (80.8%, n=42), and the remainder black South African (n=10).

The home language and religion of the participants is summarised in Table 2. All the participants stated that they were comfortable being interviewed in English.

Table 2: Distribution of background demographic information

	Frequency	Percentage
Race		
Mixed ancestry	42	80.8
Black South African	10	19.2
Language		
English	25	48.1
Afrikaans	18	34.6
Xhosa	7	13.5
Other African	2	3.8
Religion		
Christian	33	63.5
Muslim	19	36.5

3.2.2 Marital status and support

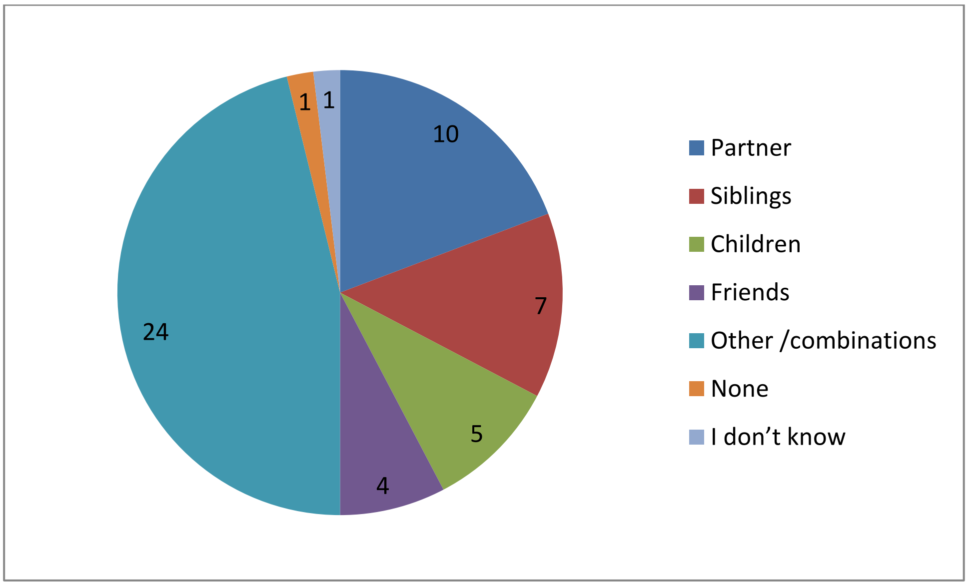
The relationship status of the participants is shown in Table 3. Twenty five (48%) of the women were married and 2 were cohabiting with their stable partners. Ten (19.2%) were divorced, 7 participants were not in a relationship at the time of the interview, 2 were separated, and 6 were widowed.

Table 3: Relationship status distribution of participants

Marital status	Frequency	Percentage
Single	7	13.5
In a relationship/Married	27	51.9
Divorced/Separated	12	23.1
Widowed	6	11.5

Women received emotional support from a number of sources. Most of the emotional support was from family members, with sole support from partners (n=10), siblings (n=7) and children (n=5), or in combinations of these along with other family members or the community. One participant reported that she had no emotional support and another reported that she did not know if she was receiving support.

Fig 2: Sources of emotional support



3.2.3 Socio-economic status

All of the participants had some level of schooling. Forty eight participants had high school education or beyond. Of these, 37 did not complete high school, 6 completed matric but did not have a tertiary education, and 5 had completed tertiary education. Of the remaining 4 participants, 2 completed primary school, but had not attended high school, and 2 did not complete primary school.

Twenty four participants (46.1%) were employed. In this group, 3 were self-employed, 6 had casual jobs, 14 were employed in the formal sector and 1 could not classify her employment. Women were employed as domestic workers, office employees, professionals (e.g. nurses), shopkeeper, driver, child carer, general assistant, household aid in the navy, housekeeper, office manager and a university employee. Of the remaining 28 participants, 13 (25%) stated that they were unemployed, 1 was a student, 4 were pensioners, 6 received a grant (5 received a disability grant, and the other participant did not clarify which type of grant she received) and 4 were housewives. The financial support of the women is shown in Table 4.

Table 4: Financial support of study participants

Source	Frequency	Percentage
Self	17	32.7
Partner	10	19.2
Children	6	11.6
Disability grant only	4	7.7
Self + Partner	4	7.7
Self + Children	3	5.8
Siblings	2	3.8
Self, partner and other	2	3.8
Self, children + siblings	1	1.9
Partner + Parents	1	1.9
Partner + DG	1	1.9
No support	1	1.9

Twenty five (48.1%) women were home owners, and 27 (52%) did not own the dwellings in which they lived. Most of the participants (n=28, 53.8%) lived in free-standing houses, with the remaining 24 (46.2%) living in flats (n=5), semi-detached houses (n=9) or separate entrance rooms (n=4), wendy houses (n=2) and one each of the remaining 4 living in a shack, room, house in the backyard, and in a nurses home.

The socio-economic data of the study participants is summarised in Table 5.

Table 5: Socio-economic data of study population

	Frequency	Percentage
Education		
Primary School	4	7.7
High School	43	82.7
Tertiary	5	9.6
Employment status		
Unemployed	28	53.8
Employed	24	46.2
Home Ownership		
Owner	25	48.1
Renter/ Lodger	27	51.9

3.2.4 Habits

Nineteen participants smoked at the time of the interview. Sixteen smoked less than 10 cigarettes per day, 2 smoked 10-20 cigarettes per day, and only 1 smoked more than 20 cigarettes per day. Of the 33 who did not smoke, 26 had never smoked, 6 had stopped more than 6 months before the interview and 1 had stopped in the 6 months preceding the interview.

Most of the participants did not drink alcohol (n=45), with 3 of these women having stopped more than 6 months prior to the interview. Of the 7 women who consumed alcohol, all reported infrequent consumption of alcohol.

Only 1 participant had ever used recreational drugs, and she had stopped this use more than 6 months prior to the interview.)

Table 6: Habits of study population

	Frequency			Percentage		
	Yes	Never	Stopped	Yes	Never	Stopped
Cigarettes	19	26	7	36.5	50	13.4
Alcohol	7	42	3	13.5	80.8	5.8
Recreational drugs	0	51	1	0	98.1	1.9

3.2.5 Obstetric history

Forty eight of the participants had been pregnant at least twice. Thirty percent had either 1 or 2 miscarriages, 1 participant had an ectopic pregnancy and 3 women had terminations of pregnancy (TOP). The median gravidity was 4, and median parity was 3. Four of the women were nulligravid and nulliparous.

Table 7: Obstetric history

	Frequency (%), N=52			
	0	**1-2**	**3-5**	**>5**
No of pregnancies	4 (7.6)	8 (15.3)	33 (63.5)	7 (13.5)
No of children	4 (7.6)	12 (23)	30 (57.7)	6 (11.5)

Table 8: Failed pregnancies and termination of pregnancy

	Frequency N=52 (%)		
	0	**1**	**2**
Miscarriages	36 (69.2)	10 (19.2)	6 (11.6)
Ectopic pregnancy	51 (98.1)	1 (1.9)	0
TOP's	49 (94.2)	3 (5.8)	0

3.2.6 Gynaecology history

Thirteen participants (25%) had a hysterectomy, with an age range (of hysterectomy) between 37 and 51 years of age. Two participants had oophorectomy (and one of them only had a bilateral oophorectomy without a hysterectomy). Five women did not know if their ovaries had been removed. Twenty (38%) of the participants were still menstruating at the time of the interview and 30 (57%) were still sexually active.

Forty one women in our study group (79%) experienced some menopausal symptoms, with the age of the onset of symptoms ranging from 35 years to 60 years of age. A third of participants experienced menopausal symptoms for the first time between 48 and 51 years of age. Of the women who experienced menopausal symptoms, 25 participants had consulted a health care practitioner regarding their symptoms, and only 7 participants were receiving treatment for their symptoms. Three of these participants were on hormone therapy, with 1 participant receiving HT along with calcium and/or vitamin D supplementation and another woman on HT with alternative medication.

3.2 Utian Quality of Life Scale

The UQOL has 4 domains: Occupational (7 questions), Health (7 questions), Emotional (6 questions) and Sexual (3 questions). These domains are represented by 23 questions, asked in a random sequence, *i.e.* the questions for each domain are not listed sequentially before moving to a new domain.

The UQOL is scored as a 5 point Likert scale, where 1= not true, 3= moderately true and 5 =very true (2 and 4 were in between 1 and 3, and 3 and 5 respectively). For questions 1-3, 5, 6, 9, 10, 14 and 17-23, the questions and scoring followed the same pattern, *ie* answering 1=1 point, answering 2= 2 points, etc. However, for questions 4, 7, 8, 11-13, 15 and 16, the sequence of the scoring was reversed, *ie* even though the questions were answered 1→5, they were scored 5→1. Therefore for these questions, 1= 5 points, 2= 4 points, 3=3 points, 4= 2 points and 5= 1 point.

The domain scores were then calculated, and converted from a scale of 1-5 to 0-100 in order to allow for comparison between the UQOL and the WHOQOL-BREF. To do this conversion, 1-5 was first converted to 0-4, and then each of 0-4 was multiplied by 25 to give a final scale of 0-100.

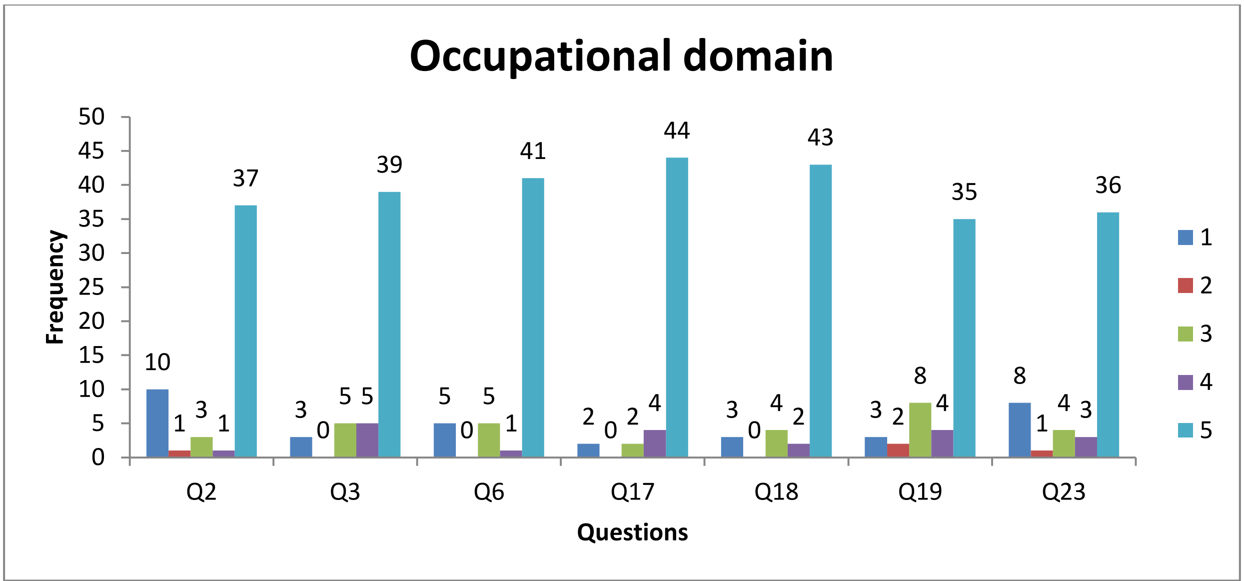
Results from UQOL

a. *Occupational Domain*

The participants scored highly for the occupational domain, with all the questions having a majority score of 5, indicating a high perceived QoL in this domain.

Although only 24 participants were employed, all of the women indicated that they did some form of work, but that they did not necessarily always earn an income from that work. Some of the participants did volunteer work in their communities, which they considered to be their job, and used this experience when answering the questions in this domain. The answers for this domain are shown in Figure 4.

Fig 4: Score distribution for Occupational domain.



For each question a score of 5 indicated highest assessment of QoL, while a score of 1 indicated lowest assessment of QoL.

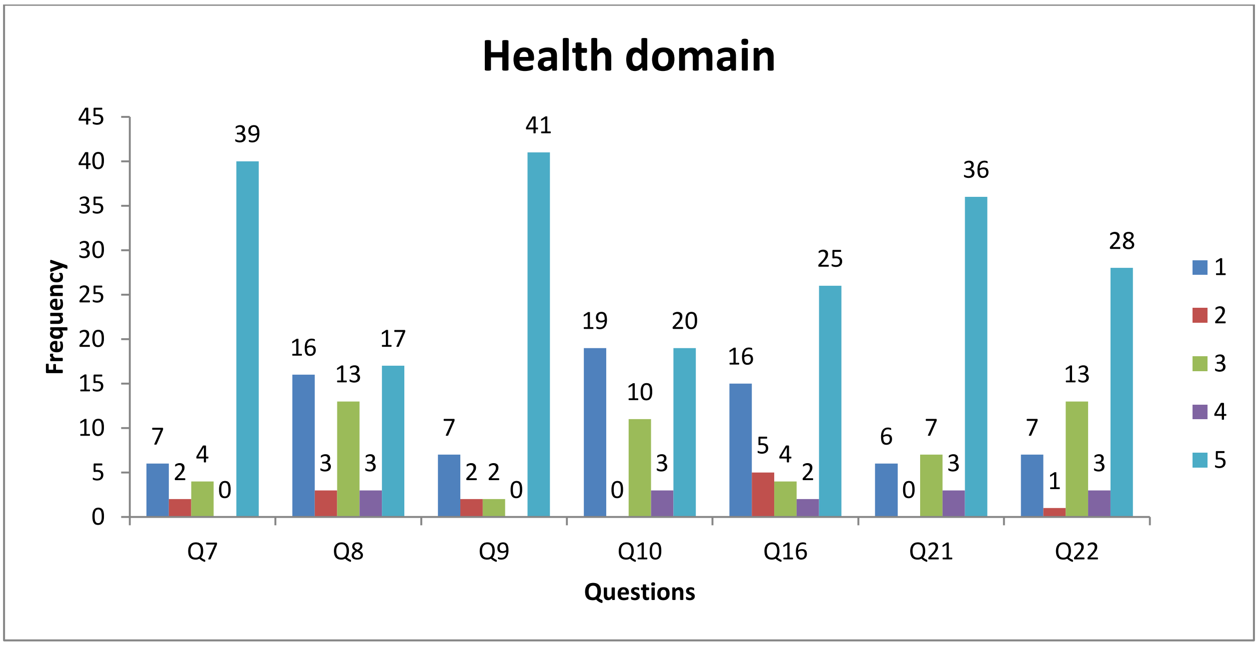
The domain scores for occupational QOL ranged between 15 and 35, with a median score of 33 and a mean of 30.5. The maximum possible domain score is 35, minimum score is 7. This domain had the most positive effect on QoL.

b. Health Domain

The scores were more varied in this domain.

For Q7 (I am unhappy with my appearance) and Q16 (I believe I have no control over my physical health) most of the women scored 5. For both Q8 (My diet is not nutritionally sound) and Q10 (Routinely I engage in active exercise three or more times each week) the scores were almost even for1 and 5 for most of the women, with the rest mainly scoring 3. For Q9 (I feel in control of my eating behaviour), Q21 (I feel physically well) and Q22 (I feel physically fit) the majority of the responses scored 5. The results for this domain are shown in figure 5.

Fig 5: Score distribution for Health domain.



For each question a score of 5 indicated highest assessment of QoL, while a score of 1 indicated lowest assessment of QoL.

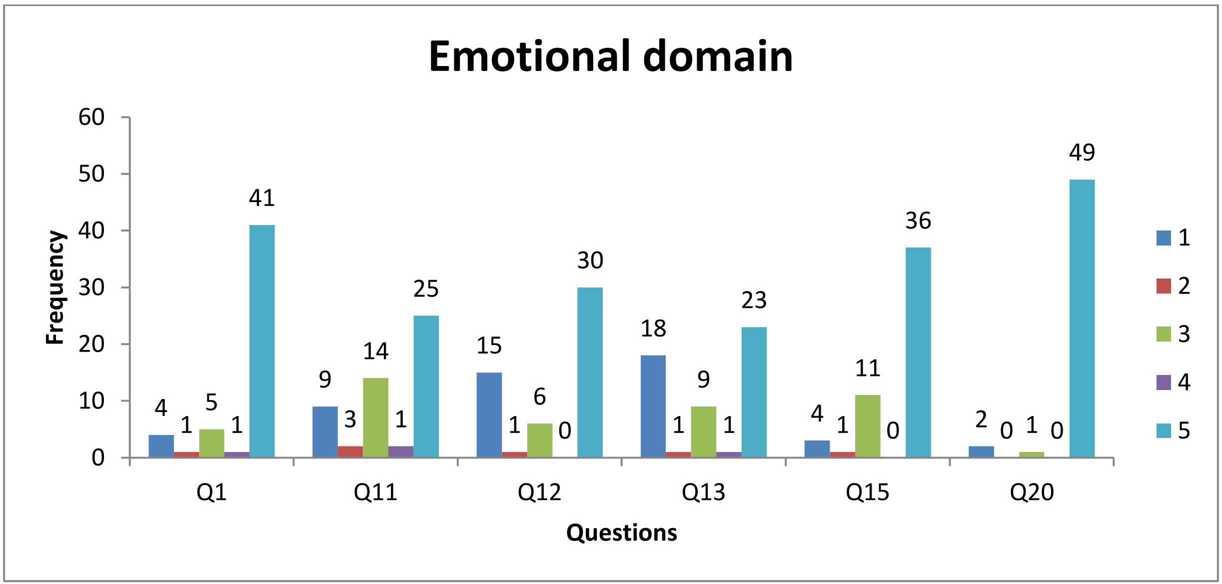
The domain scores for health QOL ranged between 10 and 35, with a median score of 27 and a mean score of 26. The maximum possible domain score 35, and the minimum is 7.

c. Emotional Domain

The replies here were also varied.

For Q1 (I am able to control things in my life that are important to me) and Q20 (I expect that good things will happen in my life) the scores were 5 for the majority of the women. However, for Q11 (My mood is generally depressed), Q12 (I frequently experience anxiety) and Q15 (I currently experience physical discomfort or pain during sexual activity) the scores were mostly 1, with the remainder either 3 or 5. The scores for this domain are summarised in figure 6.

Fig 6: Score distribution for Emotional domain.



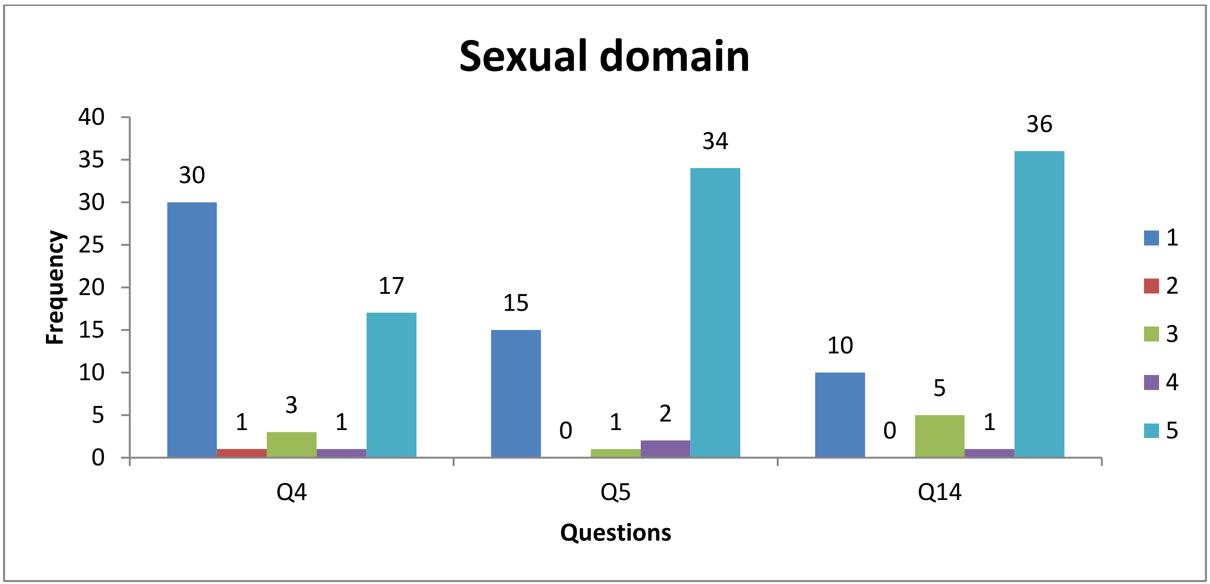
For each question a score of 5 indicated highest assessment of QoL, while a score of 1 indicated lowest assessment of QoL.

The domain score for emotional QOL ranged between 12 and 30, with the median 24 and the mean 23.6. The maximum possible domain score is 30 and the minimum possible score is 6.

d. Sexual Domain

For this domain, the scores for Q4 (I am not content with my sexual life) were low, with most women scoring 1. The remaining two questions Q5 (I am content with my romantic life) and Q14 (I am content with the frequency of my sexual interactions with a partner) scored mainly 5 for the majority of the women. The scores are summarised in figure 7.

Fig 7: Score distribution for Sexual domain.



For each question a score of 5 indicated highest assessment of QoL, while a score of 1 indicated lowest assessment of QoL.

The domain scores for sexual QOL range between 3 and 15, with a median of 11 and a mean of 11.4. The maximum possible domain score is 15 and the minimum possible score is 3. This domain had the lowest score and impacted most negatively on QoL.

The mean domain scores for the UQOL1 are shown in table 9. The sexual domain had the lowest mean score and thus the most negative impact on QoL. The health and emotional domains had a similar effect on QoL and were the next most concerning domains, with the occupational domain the least worrying. Overall the participants assessed their QoL as good.

Table 9: Domain scores for UQOL-1

	Minimum	Percentile 25	Median	Percentile 75	Maximum	**Mean[a]**	Standard Deviation
OCCUPATIONAL QOL	15.0	27.0	33.0	35.0	35.0	**30.6**	5.4
HEALTH QOL	10.0	22.5	27.0	31.0	35.0	**26.0**	6.4
EMOTIONAL QOL	12.0	19.5	24.0	28.0	30.0	**23.6**	5.5
SEXUAL QOL	3.0	8.5	11.0	15.0	15.0	**11.3**	4.0
TOTAL QOL	51.0	82.0	95.0	103.5	114.0	**91.4**	15.5

[a] The values assigned were between 1 and 5. 1 indicating the most impairment and 5 represented the least impairment of the HRQOL.

Table 10 represents the distribution of the individual question scores along with the percentage. The participants answered all the questions.

Table 10: The distribution (and percentage) for the UQOL-1 scores.

Mean scores	**Column1**	**Score N (%)**	**Column2**	**Column3**	**Column4**	**Column5**	**Column6**
Domain	Question	1	2	3	4	5	Total
Occupational	Q2	10 (19.2)	1 (1.9)	3 (5.8)	1 (1.9)	37 (71.2)	52 (100)
	Q3	3 (5.8)	0 (0)	5 (9.6)	5 (9.6)	39 (75)	52 (100)
	Q6	5 (9.6)	0 (0)	5 (9.6)	1 (1.9)	41 (78.9)	52 (100)
	Q17	2 (3.8)	0 (0)	2 (3.8)	4 (7.7)	44 (84.7)	52 (100)
	Q18	3 (5.8)	0 (0)	4 (7.7)	2 (3.8)	43 (82.7)	52 (100)
	Q19	3 (5.8)	2 (3.8)	8 (15.4)	4 (7.7)	35 (67.3)	52 (100)
	Q23	8 (15.4)	1 (1.9)	4 (7.7)	3 (5.8)	36 (69.2)	52 (100)
Health	Q7	40 (77)	0 (0)	4 (7.7)	2 (3.8)	6 (11.6)	52 (100)
	Q8	17 (32.7)	3 (5.8)	13 (25)	3 (5.8)	16 (30.7)	52 (100)
	Q9	7 (13.5)	2 (3.8)	2 (3.8)	0 (0)	41 (78.9)	52 (100)
	Q10	19 (36.5)	0 (0)	11 (21.2)	3 (5.8)	19 (36.5)	52 (100)
	Q16	26 (50)	2 (3.8)	4 (7.7)	5 (9.6)	15 (28.9)	52 (100)
	Q21	6 (11.5)	0 (0)	7 (13.5)	3 (5.8)	36 (69.2)	52 (100)
	Q22	7 (13.5)	1 (1.9)	13 (25)	3 (5.8)	28 (53.8)	52 (100)
Emotional	Q1	4 (7.7)	1 (1.9)	5 (9.6)	1 (1.9)	41 (78.9)	52 (100)
	Q11	25 (48)	2 (3.8)	14 (26.9)	2 (3.8)	9 (17.5)	52 (100)
	Q12	30 (57.7)	0 (0)	6 (11.5)	1 (1.9)	15 (28.9)	52 (100)
	Q13	23 (44.2)	1 (1.9)	9 (17.5)	1 (1.9)	18 (34.6)	52 (100)
	Q15	37 (71.2)	0 (0)	11 (21.1)	1 (1.9)	3 (5.8)	52 (100)
	Q20	2 (3.8)	0 (0)	1 (1.9)	0 (0)	49 (94.3)	52 (100)
Sexual	Q4	31 (59.7)	1 (1.9)	3 (5.8)	1 (1.9)	16 (30.7)	52 (100)
	Q5	15 (29)	0 (0)	1 (1.9)	2 (3.8)	34 (65.3)	52 (100)
	Q14	10 (19.3)	0 (0)	5 (9.6)	1 (1.9)	36 (69.2)	52 (100)

The UQOL is scored as a 5 point likert scale, where 1= not true, 3= mopderately true and 5 =very true (2 and 4 were inbetween 1 and 3, and 3 and 5 respectively). For questions 1-3, 5, 6, 9, 10, 14 and 17-23, the questions and scoring followed the same pattern, ie answering 1=1 point, answering 2= 2 points, etc. However, for questions 4, 7, 8, 11-13, 15 and 16, the sequence of the scoring was reversed, *ie* even though the questions were answered 1→5, they were scored 5→1. Therefore for these questions, 1= 5 points, 2= 4 points, 3=3 points, 4= 2 points and 5= 1 point.
For the table above, for questions 1-3, 5, 6, 9, 10, 14 and 17-23 1= poor QoL and 5 = good QoL. For questions 4, 7, 8, 11-13, 15 and 16 1= good QoL and 5= poor QoL.

3.2.2 World Health Organisation Quality of Life-BREF (WHOQOL-BREF)

The WHOQOL-BREF has 4 domains: Physical QOL, Psychological QOL, Social QOL, and Environment QOL. In addition the first 2 questions do not fall into any of the domains and are assessed separately. They assess the participants' perception of their QOL, and how satisfied they are with their health. All the questions assessed their feelings in the 2 weeks preceding the time of the interviews.

The Likert scale of the WHOQOL-BREF is scored from 1-5, with 1 indicating the worst impairment of HRQOL and 5 the least or no impairment of HRQOL.

The analysis of the WHOQOL-BREF was based on the WHOBREF SPSS Syntax obtained from the WHO. It was used in order to convert the domain scores of the WHOQOL-BREF so that it could be compared to the transformed domain scores of the UQOL.

Results from WHOQOL-BREF

For the first two questions 22(42.8%) of the respondents rated their QoL as good, and 15 (28.8%) as very good. More than half of the women reported they were either satisfied (n=20, 38.5%) or very satisfied (n=12, 23.1%) with their health. These data are shown in table 11.

Table 11: The distribution of scores for Q1 and Q2 of the WHOQOL-BREF (N=52)

	Frequency of responses for each score (percentage)				
	1	2	3	4	5
Q1. How would you rate your QOL?[a]	2(3.8)	1 (1.9)	12(23.1)	22 (42.3)	15 (28.8)
Q2. How satisfied are you with your health?[b]	5 (9.6)	3 (5.8)	12 (23.1)	20 (38.5)	12 (23.1)

[a]*: 1= very poor, 2=poor, 3=neither poor nor good, 4= good, 5= very good*

[b]*: 1= very dissatisfied, 2= dissatisfied, 3= neither satisfied nor dissatisfied, 4= satisfied, 5= very satisfied*

Table 12 represents a summary of the raw and transformed WHOQOL-BREF scores. The physical domain demonstrated the highest impairment of QoL, while the psychological domain demonstrated the least impairment of perceived QoL. The environment domain scored slightly better than the physical domain, and the social domain scored slightly lower than the psychological domain.

Table 12: WHOQOL-BREF 1 domain scores (Raw and transformed scores)

	Minimum	Percentile 25	Median	Percentile 75	Maximum	Mean	Standard Deviation
Physical	5.71	12.29	15.43	17.43	20.00	14.85	3.95
Psychological	4.00	15.00	17.33	18.67	20.00	16.28	3.62
Social Relationship	5.33	14.67	16.67	19.33	20.00	15.90	3.90
Environment	6.00	12.50	15.50	17.75	20.00	14.89	3.82
Physical (TRANSFORMED)	10.71	51.79	71.43	83.93	100.00	67.79	24.70
Psychological (TRANSFORMED)	.00	68.75	83.33	91.67	100.00	76.76	22.65
Social Relations (TRANSFORMED)	8.33	66.67	79.17	95.83	100.00	74.36	24.36
Environment (TRANSFORMED)	12.50	53.13	71.88	85.94	100.00	68.09	23.89

The Scores were converted from the original 1-5 to 0-100, where a score of 0 demonstrated the highest impairment of QoL and a score of 100 the least impairment of QoL.

3.2.3 Greene Climacteric Scale

This is a symptom list. We used it in conjunction with the UQOL (as recommended by the author of the UQOL) to determine which, if any, menopausal symptoms were present. We asked patients to report if they had experienced any of the symptoms in the preceding one to two weeks.

Although the participants had symptoms which could be attributed the climacteric to some degree, a large number reported no symptoms, or mild symptoms. Classic symptoms of the climacterium, namely hot flushes, night sweats, irritability, crying spells and decreased libido were experienced to some degree by at least 48% of women.

Table 13 is a summary of the Greene scores obtained at the first interview.

Table 13: Greene Climacteric Scale summary of scores n=52

	Severity n (%)			
Greene Climacteric Scale	**0**	**1**	**2**	**3**
Psychological				
Heart beating strongly or quickly	31 (59.6)	14 (26.9)	5 (9.6)	2 (3.8)
Feeling nervous or tense	26 (50)	14 (26.9	9 (17.3)	3 (5.8)
Difficulty sleeping	16 (30.8)	7 (13.5)	17 (32.7)	12 (23.1)
Excitable	16 (30.8)	19 (36.5)	13 (25)	4 (7.7)
Attacks of panic	36 (69.2)	8 (15.4)	5 (9.6)	3 (5.8)
Difficulty in concentrating	27 (51.9)	9 (17.3	9 (17.3)	7 (13.5)
Feeling tired or lacking in energy	12 (23.1)	11 (21.2)	10 (19.2)	19 (36.5)
Loss of interest in most things	32 (62.5)	6 (11.5)	7 (13.5)	7 (13.5)
Feeling unhappy or distressed	28 (53.8)	10 (19.2)	10 (19.2)	4 (7.7)
Crying spells	27 (51.9)	11 (21.2)	9 (17.3)	5 (9.6)
Irritability	26 (50)	15 (28.8)	7 (13.5)	4 (7.7)
Somatic				
Feeling dizzy or faint	27 (51.9)	16 (30.8)	5 (9.6)	4 (7.7)
Pressure or tightness in head or body	29 (55.8)	10 (19.2)	9 (17.3)	4 (7.7)
Parts of body feel numb or tingling	31 (59.6)	7 (13.5)	7 (13.5)	7 (13.5)
Headaches	22 (42.3)	11 (21.2)	5 (9.6)	14 (26.9)
Muscle and joint pains	18 (34.6)	11 (21.2)	9 (17.3)	14 (26.9)
Loss of feeling in hands or feet	35 (67.3)	5 (9.6)	7 (13.5)	5 (9.6)
Breathing difficulties	37 (71.2)	10 (19.2)	3 (5.8)	2 (3.8)
Vasomotor				
Hot flashes	10 (19.2)	10 (19.2)	7 (13.5)	25 (48.1)
Sweating at night	22 (42.3)	5 (9.6)	8 (15.4)	17 (32.7)
Sexual dysfunction				
Loss of interest in sex	25 (48)	4 (7.7)	11 (21.2)	12 (23.1)

0= Not at all, 1= A little, 2=Quite a bit, 3= extremely

When combining results from the 3 questionnaires, the following interesting results were noted:

- Thirty women (57.7%) were still sexually active, with 11 (21%) reporting loss of interest in sex to some degree in the Greene Scale. Of the women who were sexually active, and reporting some loss of interest in sex, 7 (13.4%) reported some pain and 4 (7.6%) reported no degree of pain.

- More than 50% were unemployed, nearly 80% of the participants reported menopausal symptoms, and all the women indicated that they had some menopausal symptoms when objectively assessed using the Greene Climacteric Scale. When asked about setting new professional and personal goals, 69% and 67% of the women responded that this was very true for them.

3.3 Validation results

3.3.1 Test-retest

The UQOL was administered to the participants on 2 separate occasions in order to calculate the reliability. The first test was done in person by various members of the investigating team, and the retest was done telephonically 3-14 days later. Forty nine women (94.2%) responded in the retest.

Table 14 is a summary of the domain scores of the UQOL1 and UQOL2 test-retest, demonstrating again that the occupational domain scored the highest for perceived QoL and the sexual domain the lowest in the second test.

Table 14: Domain scores for UQOL1[a] and UQOL2[b,c]

Domain	Minimum	Percentile 25	Median	Percentile 75	Maximum	Mean	Standard Deviation
Occupational UQOL1	15.0	27.0	33.0	35.0	35.0	30.5	5.6
Health UQOL1	10.0	22.5	27.0	31.0	35.0	26.0	6.3
Emotional UQOL1	12.0	20.0	25.0	28.0	30.0	23.6	5.6
Sexual UQOL1	3.0	8.5	11.0	15.0	15.0	11.4	3.9
Total UQOL1	51.0	83.0	95.0	103.5	114.0	91.4	15.4
Occupational UQOL2	12.0	28.0	32.0	35.0	35.0	30.6	4.6
Health UQOL2	12.0	22.0	26.0	30.0	35.0	25.8	6.0
Emotional UQOL2	10.0	20.0	25.0	28.0	30.0	23.9	5.5
Sexual UQOL2	3.0	8.0	11.0	15.0	15.0	10.7	4.0
Total UQOL2	51.0	85.0	94.0	100.0	113.0	90.9	14.3

[a] *UQOL1 = Questionnaires from the first interview*

[b] *UQOL2= Questionnaires from the second interview*

[c] *49 participants completed the UQOL on two occasions.*

Lowest possible score achieved= minimum

Highest possible score achieved= maximum

When comparing the results of the Utian Quality of Life Scale initial test to the retest, to test for reliability, the sign test was used because the distribution of the variables was not symmetric. The result was taken to be significant if the p-value was <0.05.[42] There was a statistically significant difference in only 2 questions: no 9- *I feel in control of my eating behaviour*, and no 14- *I am content with the frequency of my sexual interactions with a partner*, with *p-values* of 0.007 and 0.035 respectively. Thus the UQOL demonstrated good reliability in our study population. The test-retest reliability was calculated by deducting the scores for each question in UQOL1 from UQOL2 (ie UQOL2-UQOL1). A negative difference indicates that a higher score in UQOL1, and a positive difference indicates a higher score in UQOL2. The magnitude of the difference between the calculated negative and positive differences determined whether there was a significant difference or not. These data are shown in table 15.

Table 15: Results of the Wilcoxon sign test UQOL1 vs UQOL2

Questions	No of responses	Negative differences	Positive differences	Ties	p-value
Q1	49	9	6	34	0.607
Q2	49	7	11	31	0.332
Q3	49	10	5	34	0.302
Q4	49	13	8	28	0.189
Q5	49	16	8	25	0.152
Q6	49	9	8	32	1.000
Q7	49	7	6	36	0.791
Q8	49	17	11	21	0.345
Q9	49	19	5	25	**0.007**
Q10	49	14	10	25	0.424
Q11	49	11	5	33	0.210
Q12	49	11	10	28	0.832
Q13	49	15	11	23	0.556
Q14	49	17	6	26	**0.035**
Q15	49	8	9	32	1.000
Q16	49	13	10	26	0.541
Q17	49	7	4	38	0.549
Q18	49	7	5	37	0.774
Q19	49	7	13	29	0.263
Q20	49	3	2	44	1.000
Q21	49	8	4	37	0.388
Q22	49	8	11	30	0.648
Q23	49	6	9	34	0.454

The shaded blocks show the 2 questions which demonstrated a statistically significant difference.

3.3.2 Internal consistency of the Utian Quality of Life Scale

Cronbach's alpha was used to calculate the internal consistency of the UQOL as with the WHOQOL-BREF. Acceptable values for alpha are between 0.70 and 0.95. Only the occupational domain of the UQOL had a Cronbach's alpha of >0.7, while the health, emotional and sexual domains had scores of 0.673, 0.691 and 0.655 respectively. Each domain was then assessed separately in a matrix to determine which questions need to be deleted to improve then Cronbach's alpha of each domain.

For the health domain, only if question 8 – *My diet is not nutritionally sound*- was deleted did the Cronbach's alpha for this domain improve to 0.739. If any of the remaining questions were deleted, the Cronbach's alpha decreased.

For the emotional domain if question 8- *I currently experience physical discomfort or pain during sexual activity*- was deleted the Cronbach's alpha improved to 0.707. If any of the other questions were deleted the score decreased.

For the sexual domain the Cronbach's alpha was 0.655. The alpha did not improve if any of the items were deleted from the domain.

Table 16 demonstrates the Cronbach's alpha of the domains of the UQOL.

Table 16: Cronbach's alpha test for reliability of the UQOL1

Cronbach's alpha on the Utian QoL 1 domains				
Domain	**Label**	**No. of cases**	**No. of items**	**Cronbach's Alpha**
1	Occupational	52	7	0.729
2	Health	52	7	0.673
3	Emotional	52	6	0.691
4	Sexual	52	3	0.655

3.3.3 Internal consistency of the WHOQOL-BREF

The internal consistency of the WHOQOL-BREF was determined to see if this questionnaire was a reliable tool in the study population. Cronbach's alpha was used to calculate the internal consistency. A Cronbach's alpha of > 0.7 indicates good correlation between the questions within a domain. The Cronbach's alpha scores are shown in table 17.

Table 17: WHOQOL-BREF-1 internal consistency analysis- Cronbach's alpha

Cronbach's alpha on the WHO-BREF domains				
Domain	**Label**	**No. of cases**	**No. of items**	**Cronbach's Alpha**
1	Physical	52	7	0.849
2	Psychological	52	6	0.878
3	Social Relationship	52	3	0.673
4	Environment	52	8	0.856

** For the highlighted cell, Q19 was added to the calculation. It was missing from the calculation in the WHO syntax file and appeared to be left out in error.*

For domains 1, 2 and 4 the Cronbach's alpha was >0.7, illustrating good internal consistency. The Cronbach's alpha for domain 3 was <0.7, indicating poor internal consistency for this domain. For each domain, the inter-item correlation was determined to see which item(s) were not correlating. This was done in a matrix, and the Cronbach's alpha was recalculated once the offending item was removed from the domain.

For domain 2, when question 21 was removed (*How satisfied are you with your sex life?*) the Cronbach's alpha improved to its best value for the domain of 0.679. This was not much above the average Cronbach's alpha for this domain, so the lower internal consistency for this domain is probably due to the low number of items. By deleting each of the other questions in this domain, the Cronbach's alpha was lower than if the average for the domain.

The internal consistency of the WHOQOL-BREF for this study population does not improve by deleting any of the questions in the original questionnaire.

3.3.4 Construct validity

Construct validity is calculated to determine how well the questionnaire being validated is measuring or testing what it is meant to be measuring, in this case QoL. To determine the construct validity the domain scores of the UQOL were compared to the scores of similar domains in the WHOQOL-BREF. For our analysis, we compared the emotional domain of the UQOL to the psychological domain of the WHOQOL-BREF, and the sexual domain of the UQOL to the social relations domain of the WHOQOL-BREF.

The hypothesis was that particular domains from the 2 questionnaires would measure similar concepts and thus have statistically comparable outcomes. The Spearman correlation test was then used to do the comparison. The domain scores of both the UQOL and WHOQOL-BREF were converted to a scale of 0-100 to allow this comparison. Table 18 shows the results of the Spearman correlation test.

Table 18: Spearman's correlation analysis of the UQOL and the WHOQOL-BREF (n=52) p <0.01

UQOL Domain	WHOQOL-BREF Domains	
	Psychological	Social relations
Emotional	0.497	
Sexual		0.573

The emotional domain correlated with the psychological domain with a correlation coefficient of 0.497, and the sexual domain correlated with the social relations domain with a correlation coefficient of 0.573. This comparison demonstrated good construct validity for the UQOL in our study population.

3.3.4 Factor analysis

Factor analysis was tested to determine if the statements would remain in the domains of the original UQOL i.e. to see if the domain structure of the UQOL was stable. The analysis was executed on the initial UQOL test, which had a total of 52 participants. Secondary factor analysis was performed for which we used the principle components method of extraction, followed by the Varimax rotation (which is an orthogonal rotation method). The Varimax rotation assumes that the proposed factors are independent of one another.

Secondary factor analysis

The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was 0.584 and the Bartlett's test of sphericity was statistically significant. The communality (an estimate of a variable's shred variance among the questions) of each question was calculated, and the communality of all the components was >0.3 except for question 17- *I am proud of my occupational accomplishments*- which was 0.220. Since the Bartlett's test is statistically significant we could assume that there was sufficient correlation among the variables to proceed with the factor analysis.

We elected to see what a 4 factor analysis would yield. Four factors explained only 54% of the variation in the data, even after rotation. The factors retained their original names, ie Occupational (component/factor 1), Health (component/factor 2), Emotional (component/factor 3) and Sexual (component/factor 4). The results of the rotated component matrix are shown in table 19, with the larger numbers in the darker shades on the heat map.

Table 19: Rotated component matrix of secondary factor analysis of UQOL

Rotated Component Matrix[a]

	Component/Factor			
	1	2	3	4
NEW PERSONAL GOALS	**0.775[b]**			
NEW PROF GOALS	**0.763[b]**			
GOOD THINGS	**0.713**			
CHALLENGE WORK	**0.655[b]**			
LIFE STIM	**0.570[b]**			
PERSONAL RECOG	**0.529[b]**			
PROUD OCC ACCOMP	0.463[b]			
CONTROL OVER THINGS	0.453			
PHYS FIT		**0.828[b]**		
PHYS WELL		**0.817[b]**		
CONTROL EAT BEH		**0.732[b]**		
ACTIVE EXERCISE		**0.643[b]**		
PAIN WITH SEX		**0.528**		
UNHAPPY APPEARANCE		0.444[b]		
GEN DEPRESSED			**0.751[b]**	
NO CONTROL PHYSICAL HEALTH			**0.734**	
ANXIETY FREQ			**0.683[b]**	
THINGS HAPPEN OUT OF CONTROL			**0.636[b]**	
DIET NOT SOUND			**0.567**	
CONTENT ROM LIFE				**0.706[b]**
CONTENT FREQ SEX				**0.666[b]**
WORK BENEFITS				**0.588**
NOT CONTENT SEX LIFE				0.486[b]

Extraction Method: Principal Component Analysis.
Rotation Method: Varimax with Kaiser Normalization.

a. Rotation converged in 6 iterations.
b. Loaded onto same component as original UQOL

Bold font indicates values >0.5

Extraction method: Principle component analysis

In the secondary factor analysis, the first 6 questions loaded on factor 1 with a value of >0.5 (the value we considered to belong to a particular factor), the next 2 did not load highly onto any factor, the next 5 loaded onto factor 2, the following question did not load strongly onto any factor, the following 5 questions loaded onto factor 3, the next 3 loaded onto factor 4 and the last question did not load onto any factor strongly.

Following factor analysis 5 of the components from the original occupational domain of the UQOL loaded onto factor 1. One question from the original domain, question 3- *I believe my work benefits society*- was lost to the sexual domain and question 17- *I am proud of my occupational accomplishments*- did not load highly onto any domain. Question 17 did load onto factor 1, but with a value of 0.463. Question 20- *I expect that good things will happen in my life*- reloaded from the emotional domain onto this factor.

In factor 2, 4 components were from the health domain of the original UQOL, with the final factor coming from the emotional domain. This was question 15- *I currently experience physical discomfort or pain during sexual activity*.

For factor 3- the emotional domain- 3 questions from the emotional domain of the original UQOL loaded highly, with values of > 0.5. Two questions from the health domain, questions 8 and 16 reloaded onto the emotional domain.

The 3 questions from the sexual domain of the original UQOL all loaded onto factor 4, which we named the sexual domain. Question 4- *I am not content with my sexual life*- had a value of 0.486 for this domain and also loaded poorly onto the emotional domain with a value of 0.385. It could intuitively fit into any one of these domains, as intercourse is an emotional subject for most women. Question 3- *I believe my work benefits society*- also loaded onto this factor from the original occupational domain.

<u>Summary of factor analysis:</u>

In general, questions maintained their domains following factor analysis. Questions 20, 15 and 3 reloaded strongly onto other domains with values >0.5, while questions 17, 1, 7 and 4 did not load strongly onto any factor. Of these, question 17 loaded only onto the occupational domain (factor 1), which was its original domain. Question 7 loaded onto the health domain as well as the sexual domain, but more strongly onto the health domain, also its original UQOL domain. Question 4 has already been reported on. Question 1 reloaded onto both the occupational and health domains from the emotional domain in the original UQOL, but only marginally strongly onto the occupational domain.

3.3.5 Face validity

The UQOL questionnaire was reviewed by a team from the RMU prior to data collection. It was found to be easy to use, with clear instructions for both the participants and interviewers. There were 3 questions that we felt needed to be clarified: Q3 (*I feel challenged by my work*), Q21 *(I feel physically well*) and Q22 (I feel physically fit). For Q3, we took it to have a positive meaning, i.e. the participants found their work stimulating and interesting, and that they enjoyed what they did every day. If they were not formally employed, we enquired about what they did on a daily basis (housework, volunteering, doing informal jobs). For questions 21 and 22, we enquired about general feeling of health, and then ability to perform daily tasks respectively.

For the most part, the participants understood the questions, and were happy to answer all of them. The investigators found the questionnaire easy to use and appropriate for our clinical setting.

SUMMARY OF RESULTS

The validation statistics show that the UQOL is a valid instrument for use in our population, with only 2 questions being statistically significant following test-retest analysis, Cronbach's alpha values between 0.655 and 0.729, good construct validity when compared to the WHOQOL-BREF, and maintenance of most questions in their original domains during factor analysis.

CHAPTER 4- DISCUSSION

The aim of this study was to validate the UQOL in the clinical population we serve. There has been a lack of research dedicated to assessing the QoL in peri- and post-menopausal women in South Africa (the authors only found 3 articles in the literature). This study showed that the UQOL is a valid instrument for use in our study population.

4.1 Demographics

Participants were recruited from 3 hospitals in the Metro West region of Cape Town, in an attempt to get as diverse a study population as possible. The study provided a descriptive analysis of a clinical population accessing health services in our drainage area. The majority of women in the study presented with gynaecological problems not related to the menopause. We did not see this as a limitation because we were assessing quality of life in peri- and post-menopausal women as a whole, and not limited to the menopause.

The population of Cape Town is diverse, with the majority of people being of mixed race or black (42% and 39% respectively) followed by white (16%) and Asian (1.6%) as reported by the National Population Census in 2009.[43] The racial profile of our study population mirrors the population attending our Gynaecology Out Patients Departments, and the population distribution in the Cape Town Metropole. As most of our participants were recruited from the general Gynaecology Out Patients Departments at GSH and NSH, as opposed to the specialist MWC, it is difficult to draw conclusions about different ethnic groups' feelings and health-seeking behaviour regarding menopausal symptoms.

However, the 4 women recruited from the MWC were all of mixed ancestry. There are no formal statistics regarding the racial profile of patients at the MWC or NSH GOPD, but observations by the medical staff working there suggest that most of the patients attending the MWC at GSH are of mixed ancestry.

4.2 Utian Quality of Life Scale

The UQOL was previously used in Cape Town to determine the effect of HT on QoL in a population from a private practice.[21] The original scale was used unchanged. The authors of this study found that HT enhances QoL. The UQOL has not been validated for use in a population such as our study population in South Africa.

UQOL results

The mean scores of the UQOL showed that the sexual domain had the lowest score, with the occupational domain having the highest score. The mean scores for the domains are higher than the mean scores in the original development of the UQOL. [31]

The question with the highest mean score was Q20- *I expect that good things will happen in my life.* This question was in the emotional domain, the same as the Serbian validation study.[37] Those investigators believed that this indicated optimistic beliefs despite bothersome symptoms. [37] This may hold true for our population as well, despite the fact that more than half were unemployed, nearly 80% of the participants reported menopausal symptoms, and all the women indicated that they had some menopausal symptoms when objectively assessed using the Greene Climacteric Scale. When asked about setting new professional and personal goals, 69% and 67% of the women respectively responded that this was very true for them, indicating hopefulness and confidence about their futures. Possible reasons for this were not explored in the interview and would be an interesting area for future research. We can only speculate at this point as to the reasons for this, which may include the fact that these women grew up in the apartheid era where there were not many opportunities for women of colour and in the “New SA” there may be better opportunities for them.

The question with the lowest mean score was Q15- *I currently experience physical discomfort or pain during sexual activity.* It is known that atrophy of the vaginal mucosa is associated with dyspareunia in peri- and postmenopausal women. The physical discomfort could be exacerbated by the loss of interest in sex, or the loss of interest in sex could be due to the physical discomfort. Psychological issues regarding body image could also play a role.[44] Sexual dysfunction is common among menopausal women. This is due a combination of factors and events occurring in the menopause transition, such as changes in her home and/or work environment as well as hormonal changes .[45] Further research is needed to explore the sexual experiences of women of this age group in our drainage area, and the complex relationship between these factors.

Validation results

Test-retest reliability

The reliability of the UQOL was tested using the sign test, as the paired data was not symmetric. There was a significant difference in only 2 questions: no 9- *I feel in control of my eating behaviour*, and no 14- *I am content with the frequency of my sexual interactions with a partner*, with p-values of 0.007 and 0.035 respectively.

There was no significant difference between the 2 tests for the other questions, with p-values ranging between 0.152 and 1.000. Just over 50% of the remaining questions had the same answer (i.e. they tied) for >/= 30 participants.

The reasons for the difference between the 2 significantly different questions could be due to the small sample size, or a problem with communication/difference between the test and the retest, particularly where the two tests were administered by different interviewers.

Despite this difference, we found the UQOL to be a stable, reliable instrument to use in our study population. This is similar to the validation of the UQOL in a Chinese-speaking population, who had similar findings.[34]

Internal consistency

In the development of the UQOL, the internal consistency, measured by Cronbach's alpha, was >0.8 for all the domains, as well as the overall score.[31] In our study, only the occupational domain had a Cronbach's alpha of >0.7. This is comparable to the original UQOL, as well as to the other populations where the questionnaire has been validated.

The other domains had alpha scores of between 0.6 and 0.7. This is still within an acceptable range when measuring the internal consistency of a questionnaire.[46] The original UQOL had 1 domain, the emotional domain with a Cronbach's alpha value of <0.7, but it was not discarded

The Cronbach's alpha for the emotional domain from our study was 0.691. It is slightly better than the alpha in the development of the original UQOL, which was 0.643, the Chinese validation which was 0.66 and the Portuguese validation which was 0.680.[31, 33, 34] It was much better than the Serbian version which was 0.36.[37] When question 15- *I currently experience physical discomfort or pain during sexual activity*- was removed from this domain in our analysis, the alpha value increased to 0.707. When we performed the secondary factor analysis, this question reloaded onto the health domain. As mentioned previously, dyspareunia in the peri- and post-menopausal period is often associated with vaginal dryness and atrophy caused by the oestrogen deficiency during this time.

The Serbian investigators found that question 1- *I am able to control things in my life that are important to me*- formed a new and separate domain, which they called the professional recognition domain.[37] Similarly in our study, this question did not load highly onto any factor in the secondary factor analysis, and had its highest value when it loaded onto the occupational domain. This question is non-specific, in that "things" could be applicable to many things in a woman's life, and not isolated specifically to emotional aspects. In our population it appears that the women's occupations are important to them, even if they were not formally employed, and not earning a formal income. This could imply that this is how they feel they make the most contribution to their families. Most women reported that they continued to set new professional goals for themselves.

Questions related to diet, physical health and the women's work benefiting society from the health domain were reloaded onto other factors following factor analysis. These questions were vague. This could be criticised. Women may have misunderstood the meaning of a "sound diet" in the question relating to the control of diet. It may be perceived to be emotional rather than strictly health-related by the participants. Similarly the question related to appearance deal with how happy or unhappy the woman is with her appearance. For some women this may relate to emotions and feelings rather than health because it may evoke feelings of inferiority or self-worth.

The sexual domain had a Cronbach's alpha of 0.655. This is similar to the validation studies assessing the UQOL in Portuguese, Chinese and Serbian populations, which had alphas of

0.617, 0.61 and 0.66[33, 34, 37]. The original UQOL had an alpha value of 0.876[31]. Twenty two participants stated that they not sexually active at the time of the interview and some of these women did struggle to answer the questions in this domain, which may have contributed to the low score. We did not explore this at the time of the initial interview, as we felt it was a sensitive subject and we had not built up a rapport with the women. The women were attending the OPD's for reasons other than problems with sexuality and relationships, and may not have wanted to delve into this sensitive subject. Also, 60% of the respondents stated that they were not content with their sexual lives, yet 70% stated that they were content with the frequency of their sexual interactions with their partners. They may also have been embarrassed to answer questions relating to their sex lives, especially in a short interview where there was not enough time to ease into speaking about this kind of sensitive information. This is an area which needs further research.

The internal consistency of a scale is influenced by the number of items in that scale. If the number of items is too small, the alpha would be diminished.[42] This could explain the lower alpha in the sexual domain, as well as in the emotional and health domains.

Construct validity

The UQOL was compared to the WHOQOL-BREF to determine construct validity. The hypothesis was that the domains of the 2 questionnaires that measures similar constructs would correlate with each other. For our analysis, we compared the emotional domain in the UQOL to the psychological domain of the WHOQOL-BREF and the sexual domain to the social relations domain. When we looked at the questions in the domains chosen for comparison, we felt that these 2 domains would be the best for this analysis. Both comparisons had statistically significant correlations. The UQOL showed good construct validity.

Factor analysis

Factor analysis was done to confirm the domain structure of the UQOL. We elected to see what a 4-factor analysis would yield. The domain structure of the original UQOL was maintained, i.e. occupational, health, emotional and sexual domains. Most of the questions remained in their original domains following secondary factor analysis. Three questions loading onto different domains, and 4 questions did not load strongly onto any domain.

Question 20- *I expect that good things will happen in my life*- was loaded onto the occupational domain from the emotional domain. This could be related to current employment or future employment opportunities. During the interviews 43 women (82.6%) expressed that they were setting new professional goals for themselves to varying degrees (moderately true to very true). These included both women who were employed as well as those who were unemployed. The women in our study population may place a high degree of importance on their occupations or job prospects, and appear to be optimistic about employment opportunities in the future.

Question 15- *I currently experience physical discomfort or pain during sexual activity*- was loaded onto the health domain from the emotional domain. In menopausal women, dyspareunia is often caused by atrophy of the vaginal mucosa, and may not be an inappropriate question in the health domain. In our population sexual relations are often seen as a physical act as opposed to an emotional act. Some women reported loss of interest in sex, but may have felt that it was their duty as a wife/partner to engage in sexual intercourse. They may also have felt that their partners would have strayed if they did not want to have intercourse due to lack of interest or pain. It would be interesting research to investigate reasons why peri- and post-menopausal women may or may not be partaking in physical relations with their partners, and the knowledge of men involved with these women regarding menopausal changes.

Two questions from the health domain were loaded onto the emotional domain. They were: - *My diet is not nutritionally sound (question 8)*- and - *I believe I have no control over my physical health (question 16)*. These may relate to feelings of helplessness at the perceived lack of control in the women's lives. These issues are often related to finances, and many of the women were not earning money. This can be an emotional issue, related to a feeling of lack of independence and having to rely on others for assistance.

The sexual domain retained the 3 questions from the initial UQOL. In addition question 3 – *I believe my work benefits society*- from the occupational domain loaded onto the sexual domain. The inclusion of question 3 from the occupational domain could not be explained. It should remain in the occupational domain. Although question 4 did not load with a value of >0.5 onto the sexual domain, the nature of the question intuitively puts it into this domain.

The 4 questions with factor loading values of <0.5 (the cut-off we used to determine if a question belonged to a particular domain) were questions 1, 4, 7 and 17, from the emotional and occupational domains respectively. Question 1 - *I am able to control things in my life that are important to me*- loaded onto the "new" occupational domain. This could indicate that "important things" relate to physical health or employment status. Question 17- *I am proud of my occupational accomplishments*- loaded onto the occupational domain, with a loading actor of just below the 0.5 cut-off- 0.463. As previously mentioned, the initial UQOL did not discard any questions even if the factor loading value was <0.4. This question only loaded onto the occupational domain and should not be deleted from the questionnaire. Pride in anything contributes to a feeling of self-worth, which in turn contributes to a person's perceived QoL. Question 7 from the health domain loaded onto both the health and sexual domains, with very similar values. This question could be in either domain as it deals with happiness surrounding physical appearance and perceptions surrounding physical attractiveness are related to sexual functioning.[44] However physical appearance does change in the menopause, and at the same time the woman may be experiencing new health-related issues[45], and our study population may relate the two to each other.

Domain structure was maintained with secondary factor analysis, although the content of each domain did change slightly as described above.

Face Validity

Questions 3, 21 and 22 needed to be clarified. Participants answered all the questions, and very rarely asked for any of the statements to be explained to them. The investigators found the questionnaire easy to administer.

4.3 WHOQOL-BREF

The WHOQOL-BREF is a general QoL questionnaire, which has been widely used to assess HRQoL. The study participants generally perceived their QoL to be good, reflected in the answers to the first question, where 71% of respondents answered good or very good.

For our study, the WHOQOL-BREF demonstrated good internal consistency, with a Cronbach's alpha of >0.8 for all but one domain, the social relationship domain. For this domain the alpha was 0.673, and if any items were deleted, the alpha decreased. For our population, we found the WHOQOL-BREF to be a reliable and valid tool.

Strengths and limitations

A limitation of the study was that we recruited patients whose first language was not English. We did mention in our inclusion criteria that the participants had to understand English and although all of the participants indicated that they were comfortable being interviewed in English, there may have been some misunderstanding of the questions.

A strength of the study was that we recruited from the general gynaecology clinics mostly, so the women were not necessarily seeking assistance for menopause-related issues. This did exclude suitable patients presenting to other disciplines, as well as “healthy” participants (e.g. recruiting members of staff). This is something that should be explored in further studies, and would also produce a larger sample size.

Quality of life questionnaires can be used in future research as an adjunct to gauge if there are other issues that need to be discussed. If they are easy to understand and use as the UQOL is, they would be especially helpful where waiting times are long and patient consultation is often time-pressured (as in a state hospital setting).

CHAPTER 5- CONCLUSION

The UQOL is a valid tool to measure QoL in the peri- and post-menopausal women in our study (and thus clinical) population. It showed good reliability in our study population, as shown by the test-retest analysis. The internal consistency was good for the occupational domain and acceptable for the other domains. Domain structure was maintained following secondary factor analysis. The questionnaire can be used in its original format in the the study population.

The WHOQOL-BREF demonstrated good internal consistency in the study population. It is a general assessment of QoL, unlike the UQOL which is targeted at women in the climacteric.

In our population, women perceive their QoL to be good and that menopause does not have a negative impact on this. This is evidenced by the good scores in both the UQOL and the WHOQOL-BREF.

The domain which had the worst impact on QoL was the sexual domain. The sexual experiences of peri- and post-menopausal women should also be explored in further studies to adequately assess this.

The UQOL is a satisfactory instrument to assess QoL in peri- and post-menopausal women in the Metro West region of Cape Town.

Future research should focus on validating this questionnaire into Afrikaans as well as local Black African languages.

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APPENDICES **PAGE**

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Title: Executive summary of the Stages of Reproductive Aging Workshop + 10: addressing the unfinished agenda of staging reproductive aging

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Utian Quality of Life Scale (UQOL)

Please rate the degree to which you agree with the following statements, as they apply to you *within the past month*. Be sure to *answer every question!* Please circle your answer using the following 5-point scale:

1	2	3	4	5
Not true of me		Moderately true of me		Very true of me

1. I am able to control things in my life that are important to me.	1	2	3	4	5
2. I feel challenged by my work.	1	2	3	4	5
3. I believe my work benefits society.	1	2	3	4	5
4. I am not content with my sexual life.	1	2	3	4	5
5. I am content with my romantic life.	1	2	3	4	5
6. I have gotten a lot of personal recognition in my community or at my job.	1	2	3	4	5
7. I am unhappy with my appearance.	1	2	3	4	5
8. My diet is not nutritionally sound.	1	2	3	4	5
9. I feel in control of my eating behavior.	1	2	3	4	5
10. Routinely, I engage in active exercise three or more times each week.	1	2	3	4	5
11. My mood is generally depressed.	1	2	3	4	5
12. I frequently experience anxiety.	1	2	3	4	5
13. Most things that happen to me are out of my control.	1	2	3	4	5
14. I am content with the frequency of my sexual interactions with a partner.	1	2	3	4	5
15. I currently experience physical discomfort or pain during sexual activity.	1	2	3	4	5
16. I believe I have no control over my physical health.	1	2	3	4	5
17. I am proud of my occupational accomplishments.	1	2	3	4	5
18. I consider my life stimulating.	1	2	3	4	5
19. I continue to set new personal goals for myself.	1	2	3	4	5
20. I expect that good things will happen in my life.	1	2	3	4	5
21. I feel physically well.	1	2	3	4	5
22. I feel physically fit.	1	2	3	4	5
23. I continue to set new professional goals for myself.	1	2	3	4	5

Utian Quality of Life Scale (UQOL) Scoring Summary

Instructions: Each of the four subscales of the UQOL is represented by a unique color, as shown below. Sum the circled responses by color and enter the sum in the scoring summary section at the bottom of the page.

1. I am able to control things in my life that are important to me.	1	2	3	4	5
2. I feel challenged by my work.	1	2	3	4	5
3. I believe my work benefits society.	1	2	3	4	5
4. I am not content with my sexual life.	5	4	3	2	1
5. I am content with my romantic life.	1	2	3	4	5
6. I have gotten a lot of personal recognition in my community or at my job.	1	2	3	4	5
7. I am unhappy with my appearance.	5	4	3	2	1
8. My diet is not nutritionally sound.	5	4	3	2	1
9. I feel in control of my eating behavior.	1	2	3	4	5
10. Routinely, I engage in active exercise three or more times each week.	1	2	3	4	5
11. My mood is generally depressed.	5	4	3	2	1
12. I frequently experience anxiety.	5	4	3	2	1
13. Most things that happen to me are out of my control.	5	4	3	2	1
14. I am content with the frequency of my sexual interactions with a partner.	1	2	3	4	5
15. I currently experience physical discomfort or pain during sexual activity.	5	4	3	2	1
16. I believe I have no control over my physical health.	5	4	3	2	1
17. I am proud of my occupational accomplishments.	1	2	3	4	5
18. I consider my life stimulating.	1	2	3	4	5
19. I continue to set new personal goals for myself.	1	2	3	4	5
20. I expect that good things will happen in my life.	1	2	3	4	5
21. I feel physically well.	1	2	3	4	5
22. I feel physically fit.	1	2	3	4	5
23. I continue to set new professional goals for myself.	1	2	3	4	5

Scoring Summary

	Lower QoL -2SD	-1SD	Mean	+1SD	Higher QoL +2SD
Occupational QoL	13	19	25	31	35
Health QoL	11	16	21	26	31
Emotional QoL	12	16	20	24	28
Sexual QoL	0	4	8	12	15
Total QoL	48	61	74	87	100

Instructions: Means for each factor, along with standard deviations above and below the mean, are shown above. After summing each factor, mark with an "X" roughly where the patient's score falls along each continuum. These marks will provide a graphic summary of the patient's QOL score on each factor and for the scale as a whole

The World Health Organization Quality of Life (WHOQOL) -BREF

The World Health Organization Quality of Life (WHOQOL)-BREF

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WHOQOL-BREF

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2.	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last four weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
4.	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
5.	How much do you enjoy life?	1	2	3	4	5
6.	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15.	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5

20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last four weeks.

		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	5	4	3	2	1

Do you have any comments about the assessment?

____

____

[The following table should be completed after the interview is finished]

		Equations for computing domain scores	Raw score	Transformed scores*	
				4-20	0-100
27.	**Domain 1**	(6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
28.	**Domain 2**	Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26) ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
29.	**Domain 3**	Q20 + Q21 + Q22 ☐ + ☐ + ☐	a. =	b:	c:
30.	**Domain 4**	Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:

* See Procedures Manual, pages 13-15

GREENE CLIMACTERIC SCALE

Instructions: Please indicate the extent to which you are bothered at the moment by any of these symptoms by placing a tick mark in the appropriate box.

SYMPTOMS	Not at all	A little	Quite a bit	Extremely
1. Heart beating quickly or strongly				
2. Feeling tense or nervous				
3. Difficulty sleeping				
4. Excitable				
5. Attacks of panic				
6. Difficulty concentrating				
7. Feeling tired or lacking in energy				
8. Loss of interest in most things				
9. Feeling unhappy or depressed				
10. Crying spells				
11. Irritability				
12. Feeling dizzy or faint				
13. Pressure or tightness in head or body				
14. Parts of body feel numb or tingling				
15. Headaches				
16. Muscle and joint pains				
17. Loss of feeling in hands or feet				
18. Breathing difficulties				
19. Hot flushes				
20. Sweating at night				
21. Loss of interest in sex				

Greene Climacteric Scale© 1991 - All rights reserved.

English for South Africa

Participant Information Sheet

Study title: Validation of the Utian Quality of Life Scale in The Metro West Region of Cape Town

Locality: Groote Schuur Hospital, New Somerset Hospital, Mitchells Plain District Hospital

Ethics committee ref.: 828/2014

Lead investigator: Dr Trevi Spence — Contact phone number: 021 404 6020/ 77452

Email: trevispence@gmail.com

Supervisors: Dr Malika Patel — 021 404 6020/ malikahassan@wol.co.za

Prof Petrus Steyn — steynp@who.int

Prof Zephne Van Der Spuy — 021 404 6020/ Zephne.VanDerSpuy@uct.ac.za

You are invited to take part in the above-mentioned study. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

(This study has been approved by the Ethics Committee of the University of Cape Town). The study adheres to the SA Good Clinical Practice Guidelines and Declaration of Helsinki of 2013.

WHAT IS THE PURPOSE OF THE STUDY?

There is very little information about the menopause and the quality of life of women going through the menopause in South Africa. The purpose of this study is to see if the Utian Quality of Life Scale can be used to assess quality of life in menopausal women in Cape Town.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been chosen as you fit the profile of the women we would like to use the questionnaire on.

You will have to fill in 3 questionnaires, each one will take about 5 minutes to complete. We will then contact you in 1-2 weeks by telephone to repeat the questionnaires. The questionnaires are a tick list format. There will be staff available at the first interview to assist if you have any questions.

The questionnaires will be anonymous, with only a study number and your telephone number assigned to the questionnaires. Once the study is completed, your telephone number will be deleted from all the data bases.

Some of the questions may seem to be embarrassing, but we ask that you complete all the questions, as this information is important for the purpose of the study.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

The benefit of this study is that we would be able to evaluate quality of life in all our menopausal patients, which impacts their potential benefits regarding treatment choices. We do not expect any risks to you during this study. Whether you decide to participate or not will not affect your management.

WHO PAYS FOR THE STUDY?

You will not be charged to participate in this study, and there is no payment to you to participate in the study either. There is no financial incentive for the investigators.

WHAT ARE MY RIGHTS?

Participation in this study is voluntary, and you are free to decline to participate or withdraw from the study at any time. This will not affect your management. All questionnaires remain anonymous, with only a study number and your telephone number in order for us to contact you to do the repeat questionnaire. Once the second set of questionnaires has been completed, we will remove your telephone numbers from the data bases and questionnaires.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Name: Dr Trevi Spence		Dr Malika Patel
Telephone number: 021 404 6020	**OR**	021 404 6020
Email: trevispence@gmail.com		malikahassan@wol.co.za

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

University of Cape Town Human Research Ethics Committee: 021 406 6338/6492

Consent Form

Please tick to indicate you consent to the following (Add or delete as appropriate)

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet. Yes ☐ No ☐

I have been given sufficient time to consider whether or not to participate in this study.

Yes ☐ No ☐

I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. Yes ☐ No ☐

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. Yes ☐ No ☐

I consent to the research staff collecting and processing my information, including information about my health. Yes ☐ No ☐

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. Yes ☐ No ☐

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. Yes ☐ No ☐

I know who to contact if I have any questions about the study in general. Yes ☐ No ☐

I understand my responsibilities as a study participant. Yes ☐ No ☐

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date:

VALIDATION OF UTIAN QUALITY OF LIFE SCALE IN PERIMENOPAUSAL WOMEN IN THE METRO WEST REGION OF CAPE TOWN

Patient Name & No: ________________________

Study Number: ________________________

Date of Interview: ________________________

Place of Interview: ________________________

Interviewer: ________________________

2013-02-25

BACKGROUND INFORMATION

1. Date of Birth (DD/MM/YYYY) ____/____/________	
2. Age (in years and months) ____y____m	
3. Population Group (1) Black South African (2) Coloured (3) White (4) Asian (5) Foreign African (please specify) ____________________ (6) Foreign Non African (please specify)____________________ (7) Other (please specify) ____________________	
4. Home Language (1) English (2) Afrikaans (3) Xhosa (4) French (5) Other (please specify) ____________________	
5. Religion (1) Muslim (2) Protestant (3) Roman Catholic (4) Christian Other (please specify) ____________________ (5) Hindu (6) Jewish (7) Other (please specify) ____________________	

RELATIONSHIP STATUS AND SUPPORT

6. Marital Status (1) Single, not in a relationship (2) Single in a stable relationship but not cohabiting (3) Single and cohabiting (4) Married (5) Divorced (6) Separated (7) Widowed	
7. From whom do you receive **financial support**? (Mark all that apply) (1) Self (2) Partner/ Husband (3) Parent/s (4) Children (5) Sibling/s (6) Other Relative/s (please specify) ________________________________ (7) Friend/s (8) Disability Grant (9) No Financial Support (10) I don't know	
8. From whom do you receive **emotional support**? (Mark all that apply) (1) Partner/Husband (2) Parent/s (3) Sibling/s (4) Children (5) Other relatives (please specify) ________________________________ (6) Friend/s (7) Other (please specify) ____ (8) No Emotional Support (9) I don't know	

SOCIO-ECONOMIC STATUS

9. Highest Level of Education (1) No formal schooling (2) Primary School- incomplete (3) Primary School- complete (4) High School- incomplete (5) High School – complete (6) Tertiary – incomplete (7) Tertiary- complete	
10. Employment Status (1) Unemployed (2) Self Employed (3) Employed (Casual) (4) Employed (Formal) (5) Student (6) Housewife (7) Disability or Other Grant (8) Other (please specify) ______________________________	
11. What is your job? (1) N/A – unemployed (2) N/A- Disability or Other Grant (3) Housewife (4) Domestic Worker (5) Factory Worker (6) Office Worker (7) Professional (8) Other (please specify) ______________________________ (9) Student/Scholar	
12. Type of Dwelling (1) Formal house on separate stand (2) Flat (3) Semi-detached house (4) Separate entrance (room in main dwelling) (5) Wendy house (room in backyard) (6) Informal Dwelling/Shack (7) Room in main dwelling (8) Homeless (9) Other (please specify) ______________________________	
13. Do you own your own home? (1) YES (2) NO (3) N/A (4) unknown	

HABITS

14. Do you smoke cigarettes? (1) YES (2) NO, never (3) STOPPED less than 6 months ago (4) STOPPED more than 6 months ago	
15. If ***YES,*** how many cigarettes a day? (1) 0-10 (2) 10-20 (3) >20 (4) >30 (5) Other (please specify)______________________ (6) N/A	
16. Do you consume alcohol? (1) YES (2) NO, never (3) STOPPED less than 6 months ago (4) STOPPED more than 6months ago (5) N/A	
17. If ***YES,*** how many units per week? 1 unit of alcohol = 1 glass of wine, a nip or 1 shot of spirit, 1 glass of beer (1) <1 = infrequent use 99 if no alcohol	
18. Do you use any recreational drugs? (1) YES (2) NO, never (3) STOPPED less than 6 months ago (4) STOPPED more than 6 months ago	
19. If ***YES***, what drug do you use? (please list all) (1) TIK (2) Dagga (3) Opiates (4) Ecstasy (5) Mandrax (6) Other (please specify) ____ (7) Not Applicable	

OBSTERIC HISTORY

20. Have you ever been pregnant? (1) Yes (2) No	
21. Gravidity (Number of pregnancies) __________	
22. Parity (Number of children) __________	
23. Miscarriages __________	
24. Ectopics __________	
25. TOPs __________	

GYNAECOLOGY HISTORY

26. Have you had a hysterectomy? (1) Yes (2) No	
27. At what age did you have the hysterectomy? (1) _________ (2) N/A	
28. Do you know if your ovaries were removed? (1) Yes (2) No (3) I don't know	
29. Do you still menstruate? (1) Yes (2) No	
30. At what age did you have your last menstrual period? (1) _________ (2) N/A	
31. Are you sexually active? (1) Yes (2) No (3) Never	
32. Do you experience any menopausal symptoms? (1) Yes (2) No	
33. At what age did you start you experience menopausal symptoms? (1)_________ (2) N/A	
34. Have you ever consulted a health care professional about your menopausal symptoms? (1) Yes (2) No (3) N/A	
35. Have you ever received any treatment for your menopausal symptoms? (1) Yes (2) No (3) N/A	
36. What type of treatment have you received? (1) Hormone therapy (2) Calcium +/- Vitamin D (3) Clonidine (4) Bisphosphonates (5) Alternative medication (Evening Primrose Oil, Phyto-oestrogen, etc) (6) N/A	

User Agreement for "WHOQOL-100" and/or WHOQOL-BREF and related materials

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The approved study for this User Agreement is:

Study Title	VALIDATION OF UTIAN QUALITY OF LIFE SCALE IN METRO WEST REGION OF CAPE TOWN
Principal Investigator	DR TREVI SPENCE
Sample characteristics	WOMEN, 45-65 YEARS OLD, SYMPTOMATIC OR ↑ FSH ENGLISH SPEAKING
Sample size	MINIMUM OF 46
Treatment Intervention	N/A
Total number of assessments	MINIMUM OF 46
Assessment time points	01.02.15 – 01.08.15
"WHOQOL-100" or WHOQOL-BREF version – *Please specify language version(s) you would like to receive.*	WHOQOL-BREF
Other measures	UTIAN QUALITY OF LIFE SCALE

This User Agreement is based upon the following conditions:

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www.corptransinc.com

Greene Climacteric Scale
LICENSE AGREEMENT
(To be completed for all non-commercial studies)

Name of Institution where Study is Being Conducted	UNIVERSITY OF CAPE TOWN/ GROOTE SCHUUR HOSPITAL
Contact Name	TREVI SPENCE
Address	ROOM 63, H45, OLD MAIN BUILDING, GROOTE SCHUUR HOSPITAL, MAIN RD, OBSERVATORY CAPE TOWN, 7925
Phone Number	(021) 404 6020 072 409 4318
Email Address	trevispence@gmail.com
Official Name of Study	VALIDATION OF UTIAN QUALITY OF LIFE SCALE IN OUR CLINICAL SETTING
Purpose of Study	REQUIREMENT FOR FCOG
Names of any colleagues working with you on the study	DR MALIKA PATEL, PROF ZEPHNE VAN DER SPUY PROF PETRUS STEYN
Name of person/entity sponsoring the study	N/A
Method of administering the Greene Climacteric Scale	IN PERSON FOR FIRST INTERVIEW, THEN TELEPHONICALLY FOR RETEST
Number of Patients to be Enrolled	MIN OF 46
License Fee ($10 USD x No. Patients to be enrolled	Waived

Driven by Definition

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

11 December 2014

HREC REF: 828/2014

Dr M Patel
Obstetrics & Gynaecology
H45
OMB

Dear Dr Patel

PROJECT TITLE: VALIDATION OF UTIAN QUALITY OF LIFE SCALE IN THE METRO WEST REGION OF CAPE TOWN (student- Dr T Spence)

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

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 December 2015.

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.

We acknowledge that the student, Dr Trevi Spence will also be involved in this study.

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

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 Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

HREC 828/2014

Western Cape Government
Health

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

Dr M. Patel
Obstetrics & Gynaecology
H45 – Old Main Building

E-mail: trevispence@gmail.com / M.Patel@uct.ac.za

Dear Dr Patel

RESEARCH PROJECT: Validation of Utian Quality of Life Scale in the Metro West Region of Cape Town (Student Dr. T. Spence)

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 Head of Department 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

DR AGATA KRAJEWSKI
***(Acting)* CHIEF OPERATIONAL OFFICER**
Date: 19th January 2015

C.C. Mr. L. Naidoo
Professor L. Denny
Dr H. Aziz

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Western Cape Government
Health

NEW SOMERSET HOSPITAL

Enquiries: Dr. J Hendricks
Contact number: 021 402 6400
Email: Jacques.Hendricks@westerncape.gov.za

Dear Dr Spence

PERMISSION TO CONDUCT AN AUDIT AT NEW SOMERSET HOSPITAL

Project Tittle: Validation of Utian Quality of Life scale in the Metro West Region of Cape Town

HREC Ref: **828/2014**

Thank you for submitting your proposal to undertake the above-mentioned study.

I am pleased to inform you that your request to conduct the above-mentioned research at New Somerset Hospital has been approved.

Wishing you all the best in your research.

Yours Sincerely

Dr. Donna Stokes
Chief Executive Officer
New Somerset Hospital

Date: 19 January 2015

Beach Road, Green Point, Cape Town, 8001   Private Bag, Green point, 8051
tel: +27 21 402 6408 fax: +27 21 402 6409   www.capegateway.gov.za

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES

DECLARATION FORM – MASTERS DEGREE CANDIDATES

Title:	Dr	*Student No:*	SPNTRE001
Name, Surname:	Trevi Alison Olga Spence		
Tel No's:	021 404 6020		
Email add:	trevispence@gmail.com		
Dissertation Title:	Validation of the Utian Quality of Life Scale in peri- and post-menopausal women in the Metro West region of cape Town		

Supervisor	Dr Malika Patel	**Word count**	18103	**No. of pages**	116

1. **IMPORTANT NOTES:**

1.1 Candidates for graduation in June and December may expect to receive notification of the outcome of the examination of the dissertation not later than 1st week in June and last week in November, respectively, provided the dissertation was submitted by the due date. Where a dissertation has been submitted well in advance of the due date, earlier notification will be given, if possible. However, the University does not undertake to reach a decision by any specific date.

1.2 Candidates who are required to revise and re-submit for re-examination are required to register during the revision phase. Fees will be calculated according to the date of the notification of the "revise and re-submit" result and the date of re-submission. [Faculty will advise Fees by sending copy of R&R result to Fees.]

1.3 Candidates are asked to note that the University will not permit degree/diploma qualifiers to graduate if they have any outstanding fees, fines, interest or dues. **The final date for payment of outstanding amounts is 30 April in the case of qualifiers for June graduation and 31 October in the case of qualifiers for December graduation.**

1.4 Please note that should your examination process run into the following year, you will have to re-register in order to be considered for graduation.

2 **DECLARATIONS:**

2.1 I am presenting this dissertation in **FULL/PARTIAL** fulfilment of the requirements for my degree.

2.2 I know the meaning of plagiarism and declare that all of the work in the dissertation, save for that which is properly acknowledged, is my own.

2.3 I hereby grant the University of Cape Town free licence to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever of the above dissertation.

Signature		*Date:*	11.03.2016

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page 1 of 2

3 FUNDING AND FEES:

Candidates submitting have a choice in regard to fees and funding options:

3.1 To claim a fee rebate* and discontinue funding through the PGFO, if applicable (the student remains registered until graduation or the start of the next academic year (see University Rule G5.2). *(Only applicable in second or subsequent year in which the dissertation is being completed - Fee Rule 8)

3.2 To remain registered and engaged in the department while **writing up a paper for publication**, with full student rights and full access to facilities, full liability for fees for the year and continued eligibility for funding already awarded for that academic year. Access will extend only until such time as you graduate. Should you need access beyond this, you will need to arrange for 3rd party access within your department.

Please indicate your preference

I wish to claim the rebate and discontinue funding (if applicable) and physical and library access**	
I wish to continue fee liability, funding eligibility (if applicable) and access to all facilities	X

****Students asking for a fee rebate acknowledge**

a) the implications of the fee rebate on their access to facilities and eligibility for funding, and

b) that if they were to stay on in the department and receive payment through the payroll, such payment is taxable.

Signature		*Date:*	11-03.2016

FOR COMPLETION BY FACULTY OFFICE

I acknowledge receipt of two bound copies of the Masters dissertation of the above candidate plus compact disc containing PDF file of the dissertation being submitted for examination:

Signature		*Date:*	
Abstract submitted	Yes		No

cc **Fees**
IAPO
PGFO
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E:\DECLARATION.doc page 2 of 2