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DOCTOR OF PHILOSOPHY

Quality of Life and Health Related Quality of Life in Patients with End Stage Renal Disease
an Omani Context

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Quality of Life and Health Related Quality of Life in Patients with End Stage Renal Disease: an Omani Context

This thesis is presented for the degree of Doctor of Philosophy
(PhD)

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LIST OF ABBREVIATIONS

AQOL- Assessment of Quality of Life
ASSIA: Applied Social Sciences Index and Abstracts
BP: Bodily pain
BUN - blood urea and nitrogen
CASP: Critical Appraisal Skills Program
Cc - Creatinine clearance
CINAHL: Cumulative Index to Nursing and Allied Health Literature
ESRC - Economic and Social Research Council
ESRD: End Stage Renal Disease
et al: et alia: Latin expression means and other
etc.: et cetera: Latin expression means "and other things" or "and so on
GFR - Glomerular Filtration Rate
GH: General health
HD – Haemodialysis
HRQOL: Health-Related Quality of Life
KDOQI - kidney Disease Outcomes Quality Initiation
KDQOL-SF- kidney Disease Outcomes Quality Initiation Short Form
MCS: Mental component summary score
MH: Mental health
NA: Not available
NBS: Norm-Based Score
NHS: National Health Service
PCS: Physical component summary score
PD – peritoneal dialysis
PF: Physical functioning
PGI- Patient Generated Index
PhD: Doctor of Philosophy
PICO- Problem Intervention Comparison Outcomes
PRO: patient reported outcomes
QOL: Quality of Life
QOLI: Quality of Life Index,
RE: Role limitations due to emotional problems
RF- Renal Failure
RP: Role limitations due to physical health problems
RRT – Renal Replacement Therapy
SF: Social functioning
SF36v2: Short Form-36 version 2
SIGN: Scottish Intercollegiate Guidelines Network
UK: United Kingdom
UREC: University Research Ethics Committee
US: United States
USA: United States of America
VAS- Visual Analog Scale
VT: Vitality
WHO: World Health Organisation
WHOQOL-G: World Health Organisation Quality of Life-Group

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Finally, during a time like this, I realised how much our family mean to us. I cannot forget my family who showed me their patience and support during my study time.

Declaration

I, Waleed Khalid Alrajhi, declare that I am the sole author of this dissertation; that all references cited have been consulted; that I have conducted all the work of which this is a record, and that this thesis has not previously been accepted as part of any other degree submission.

Signed:

Date: 15 December 2017

Abstract

Background:

ESRD is a serious and irreversible condition. Understanding the impact of ESRD and its treatment on an individual's QoL is important. There are limited studies found that assess QoL and Health-related QoL in Arab Muslim patients, and Oman in particular.

Method:

A cross-sectional, correlational study was conducted in four phases. Phase One explored the conceptual basis of QoL and how that has been assessed in ESRD patients. Phase Two explored the understanding and acceptability of the concepts within Omani patients using cognitive interviewing and individualised QoL instrument. Phase Three tested the feasibility of the main study design. Phase Four assessed the level and predictors of QoL/HRQoL from 13 haemodialysis units across Oman; and tested psychometric adequacy of key measures using exploratory and confirmatory factor analysis.

Findings:

Phase 1: showed inconsistencies and inappropriate us of the terms QoL and HRQoL in literature. A range of measures used to examine QoL/HRQoL.

Phase 2: revealed some cultural sensitivities in two items of the SF36v2 and QoLI-D measures but generally were accepted. The SEIQoL-DW instrument supported the finding that QoL is a meaningful concept but one significant difference was the importance and universality of religion/spirituality as a key aspect of QoL.

Phase 3: showed that chosen study approach was feasible and acceptable. Six nurses were identified and trained to support in patient recruitment and data collection.

Phase 4: participants were 445 with mean age 46.59. Majority were male (56.3 %), married (62.5%), and employed (37.5%). Significant impairment in HRQoL was found for most of SF36v2 scales: PF 52.24, RP 54.24, BP 56.72, GH 53.18, VT 52.90, SF 60.50, RE 56.25, MH 63.75, respectively. Anxiety and depression symptoms were the most significant predictors and fatigue and pruritus were next. Also Muslims patients with ESRD encounter difficulties in performing their religion obligations due to the disease.

Psychometric testing revealed that SF-36 is a three-factor structure with the inclusion of a separate role functioning component; and HADS one and two factor solutions were supported.

Conclusion: future studies should continue to identify factors that influence quality of life and determine interventions that enhance a person’s sense of well-being.

Chapter 1- Introduction and overview

1. Introduction

This introductory chapter establishes the nature, severity and prevalence of End Stage Renal Disease (ESRD), and its subsequent consequence on patients' lives. The chapter will also critically discuss the rationale for the study focus of Quality of Life (QoL) in this patient group and will finish with a summary of the study aims and research questions.

1.1. Nature and severity of problems in ESRD

End Stage Renal Disease (ESRD) is a serious, irreversible condition that affects a significant number of people worldwide. The Global View Report of ESRD Patients (2011) estimated the prevalence of ESRD to be between 100 to over 2,000 patients per million population (p.m.p), with an annual increase of approximately 6-7% higher than world population growth. The estimated number of patients receiving renal replacement therapy (RRT) is around 2.5 million. In Oman, no studies have been conducted on identifying the prevalence of ESRD, however, Al-Ismaili et al (2017) reported that there were 2386 Omani patients on RRT, of whom 1206 (50.5%) were on haemodialysis, 1080 (45.3%) living with a transplanted kidney, and 100 (4.2%) on peritoneal dialysis. The incidence of ESKD on RRT was 21, 75, and 120 per million population in 1983, 2001, and 2013, respectively. These figures clearly show the incidence of ESRD is increasing substantially which, as a result, means the impact of the condition and its treatment has widespread consequences for healthcare services, individuals, and society.

ESRD occurs when the estimated Glomerular Filtration Rate (eGFR), is <10-15 ml/min/1.73m^2. Renal failure could result from any disease process affecting one or more parts of the kidney including blood vessels, the glomeruli, kidney tubules, and bladder or urethra. The commonest causes of ESRD are: 1) chronic glomerulopathy which is basically an alteration in the immune system in patients in which antibodies damage capillary membranes in the glomerulus; 2) diabetes mellitus could also affect blood vessels of the kidney causing narrowing by arteriosclerosis, 3) ischemic nephropathy which is manifested by ischemia in the kidney caused by hypertension and ageing; 4) hereditary renal disease such polycystic kidney disease and Alport's Syndrome; and 5) obstructive uropathy. Indeed, conditions such as diabetes and hypertension are dominant causes of ESRD in the Middle Eastern countries (Hassanien et al, 2012). Around 40% of patients with diabetes are prone to develop diabetic nephropathy, although it can take around 15 to 20 years between the first sign of renal damage and need for dialysis.

ESRD causes significant biochemical abnormalities leading to symptom groups such as the uremic syndrome (National Kidney Foundation, 2002) that may impact negatively on an individual's quality of life (Trivedi, 2011). Usually the associated symptoms appear late when the renal function is less than 15 % of normal (DOQI Guidelines, 2014). The majority of patients present clinically very late where they require immediate dialysis at time of diagnosis to remove the accumulative waste product in their blood. Consequently, almost all body organs are affected by the accumulative waste product including the gastro-intestinal tract, central nervous system, cardiovascular system, musclo-skeletal system, haematological system, skin, and reproductive organs. Studies that measured the prevalence of symptoms in patients with ESRD reported that fatigue, pruritus, and pain were rated as the most distressing to ESRD patients. Fatigue, for instance, is consistently ranked as the highest debilitating symptom in HD patients (Jablonski, 2007), and pain has been identified as an independent predictor of HRQoL (Davison and Jhangri, 2009). Pruritus was associated with the most intense symptoms and correlated negatively with all HRQoL domains (Yong et al., 2009).

The treatment of ESRD starts virtually when renal function deteriorates to around 80% and kidneys become unable to remove waste products from blood (National Kidney Foundation Guideline, 2005). Although kidney transplantation is considered the gold standard for patients with ESRD, practically it is not easy due to the fact that demand for kidneys exceeds the available supply. Instead, renal replacement therapy is the best option available for ESRD or what is clinically called haemodialysis (HD). Haemodialysis usually commences when the remaining percentage of renal function is insufficient to excrete urea and other toxins from blood which usually leads to the emergence of severe symptoms. HD is the most common renal replacement therapy worldwide. It is performed by filtering patients' blood for three to five hours two to three times every week. Prior to commencing HD, patients are usually required to undergo a surgical procedure to create vascular access so that two needles can be connected to withdraw and return filtered blood. The main advantages of HD are its ability to amend the proportions of body fluids according to dialysis specifications, and efficient removal of body waste. Although HD is a safe procedure which can be performed in out-patients' clinics or patients' homes, complications may occur including hypotension, a sense of fatigue, and hardening of the arteries.

Treating ESRD and its related symptoms has significant costs, not only for the healthcare system but also for the individuals. In the UK, where ESRD represents only 0.05% of the total population, the estimated total cost to the National Health Service (NHS) of managing renal failure patients comprises approximately 2% of its total budget (Kidney Disease Key factors & Figures, 2016, NHS). In countries that do not have a national health system, patients with ESRD may be responsible for the cost of their own treatment and such costs might have a significant and enduring impact on the financial status of patients' families. In Oman, The Ministry of Health (MoH) spends yearly around RO 7,000 (around £ 11,917) on each patient with ESRD who is on regular dialysis (National Renal Statistics Report, 2012, Not Published). The cost of caring for ESRD patients is likely to increase over time, and there are issues around long-term sustainability of these costs.

1.2. Quality of Life, Health, and Health-related Quality of Life

1.2.1. Quality of Life

The notion of quality of life (QoL) in nephrology started appearing in literature in the 1970s. The majority of these studies were conducted in the UK, Canada, USA, and Netherlands. Since then, numerous studies using different designs including quantitative and qualitative approaches have been conducted. Qunatitative studies in particular have used different tools and measures to examine QoL. Similarly, these studies have used several clinical and sociodemographic variables to examine QoL among ESRD patients. Reviewing the published studies that have examined QoL in this group of patients has helped in identifying the gap that exists in current literature and has informed this study design. To the researcher's knowledge, this PhD study is among the few that have used a combination of an individualised QoL instrument, disease-specific measure, HRQoL measure, and symptoms-specific measures. It is also the first known study that examines QoL and health-related quality of life (HRQoL) in patients with ESRD in Oman. Given the characteristics of the Omani population in relation to culture, and religion, it was essential to use different measures including religious and spiritual measures in this population. The measures used in this study were initially developed in western counties and had been translated into different languages including Arabic.

QoL is a complex and scattered concept that makes a significant impact on research exploring patient experience and practice. It is often used to describe different physical and psychosocial variables (Cameron et al., 2010) including health status, functions, behaviours, life satisfaction, perceptions, and symptoms (Fink, 2009). In contemporary health care research, the term QoL has been linked and used interchangeably with different related concepts such as HRQoL and functional ability (Gehrmann et al., 2007). The interchangeable use of the terms 'health', 'functional ability' and 'QoL', far from clarifying and providing exact meaning, might add additional confusion. In spite of inconsistency and the complexity of defining QoL, there is a consistency in literature that QoL is a multidimensional concept (Hass, 2007; Bowling 2005). Due to cultural and religious beliefs that may influence patients' perceptions about QoL, measuring QoL should be considered as an individualised concept.

1.2.2. The relationship between QoL and Health

There is an increased acceptance in the literature of using QoL as a critical endpoint in medical research. Yet, there is little consensus on how it differs from perceived health-status. The term 'health' is usually referred to as the absence of disease and illness, which might indicate a good level of quality of life on an individual level. Most of the measures of health status have considered health as a baseline for QoL (Hall, Krahn et al. 2011). However, a positive conception of health is difficult to measure due to the lack of agreement over its definition

(Kurpas, Mroczek et al. 2013). Also it is difficult to determine if the state of health has been achieved because of the absence of a unified operational definition for the term ‘health’. Clinicians’ judgment might focus on the absence of disease, whereas others professionals, and indeed patients, might see it as the ability to carry out normal everyday tasks, feeling strong and fit to carry out life.

The WHO definition of ‘health’ as a state of complete physical, mental and social well-being provided a new focus to the borders of the meaning of health rather than a narrow (disease-based) focus (Holmes, 2005). This step was followed by the development of measures of positive health. Currently, there is broad agreement that the concept of positive health is more than the absence of disease or even disability, but is about full functioning, efficiency of mind and body and social adjustment (Kaasa and Loge 2003; Krethong et al., 2008). By reflecting on the concept of QoL, it can be realised that ‘health’ is a component of QoL with a kind of tautology and overlap existing between the concepts.

1.2.3. Health-related QoL

Because the majority of life domains are related to health, the term health-related quality of life ‘HRQoL’ is used to differentiate and specify health related issues from the general issues of quality of life. The term HRQoL was developed by psychological and sociological researchers primarily to help measure the health domains that influence an individual’s physical and mental health status (Cella et al., 2005). HRQoL as a concept, therefore, is more appropriate in that it can be measured within distinct components which can be interpreted separately (Kolotkin et al., 2003).

Both QoL and HRQoL concepts represent patients’ own satisfaction with life and can be influenced by how they perceive the physical, mental, and social effects of ESRD on their daily living (Griva et al., 2009). This suggests that QoL and HRQoL are individualised concepts. That is, ESRD may be considered as an irritation for one patient but may be severely frustrating for others (Ferrans, 1996). Studies that examined QoL and HRQoL in ESRD patients with different ethnicities and religious beliefs found significant differences in their perceptions about factors that make up their overall QoL (Guillemin et al., 1993; Hallinen et al., 2009;

Hayashino et al., 2009; Abd Elhfeez et al., 2012). Assessing QoL and HRQoL, therefore, using measures that are able to capture patients' individualised experiences of health becomes a vital and often required part of health outcomes appraisal (Anderson and Burckhardt, 2003).

Measurement of HRQoL has the potential to provide important additional information about the wellbeing of individuals with ESRD which is not readily available from the clinical and laboratory assessments currently used to monitor patients (Soni et al, 2011). Various measures are used with different languages, including Arabic Language, to assess HRQoL and its predictors, such as generic and disease-specific instruments. Generic measures are the ones most commonly used to evaluate different aspects of HRQoL: physical, psychological and social as well as perceived well-being; and disease or condition-specific measures which evaluate the particular symptom or condition that might be associated with level of QoL. Measuring such personal and complex theoretical concepts, therefore, is difficult, and, as a result, individualised QoL tools were developed. These tools allow respondents to nominate the areas of life which are most important, rate their level of functioning or satisfaction with each, and indicate the relative importance of each to their overall quality of life. However, there are very limited studies that have used a combination of generic QoL measures, disease-specific measures, and QoL individualised measures. This study has considered this gap in assessing QoL.

1.3. HRQoL and dialysis patients

The studies that examined HRQoL among ESRD patients revealed that their HRQoL is affected due to major physical, mental, and socioeconomic factors. Patients affected by ESRD have to receive dialysis for survival on a routine basis which creates uncertainty about their future, which may change their perception about their self and self-confidence, and sometimes bring about a reversal in family roles (George, 1998).

Functional status, including physical functioning, role functioning, social functioning, and mental functioning as a result of disease symptoms and treatment regimens, is usually limited in patients with ESRD. Studies that have used physical performance, health, and self-reported measures reported low physical functioning in patients with ESRD (Fidan et al, 2013; Guney et al, 2010; and Morsch et al, 2005). Patients engaged in social activities reported better HRQoL, whereas social isolation and decreased social interactions were associated with worse HRQoL (Kao et al, 2008). This might suggest that patients who develop an appropriate adaptive strategy to manage the stress stemming from the disease and subsequent HD treatment might able to maintain a better QoL (Peruniak, 2008, Skevington, 2009, Welsch, 2009).

Co-morbidities such as malnutrition, anaemia, and congestive heart failure (CHF) are strongly associated with HRQoL in individuals with ESRD. Hypoalbuminemia (albumin <35g/L) influenced physical composite summary negatively by affecting physical functioning and general health and emotional well-being (Laws et al, 2000). Anaemia has also been shown to impact on HRQoL in persons with ESRD. Anaemia severity (haematocrit <33%) is associated with poor physical function, whereas the effect on social function was modest. A pre-existing myocardial infarction was the most common observed predictor of decline in HRQoL influencing physical role-functioning, general health and emotional role-functioning. Similarly, a history of congestive heart failure (CHF) was associated with decline of HRQoL in ESRD patients (Mujais et al, 2009).

Demographic factors, such as gender, age, socioeconomic status, and marital status, correlate with HRQoL in ESRD patients. Female patients on HD consistently reported worse HRQoL when compared to men (Loos, 2003; Mujais et al, 2009; Fidan, 2013). They had lower scores for physical functioning, emotional well-being, social function, and increased fatigue. Elderly patients also reported lower HRQoL in most of the HRQoL measures, particularly on physical functioning. Employment and marital status were associated positively with score of QoL and HRQoL (Oren and Enc, 2013). Patients who were employed and were married or had a marriage-like relationship had higher mental health (Bohlke et al, 2008). Similarly, patients who had a higher level of education associated with better HRQoL (Fagerlind et al., 2010; Mellon et al., 2013).

Healthcare providers including nephrologists and nephrology nurses are encouraged to deal with patients from various ethnicities and cultures and Oman is one of the countries that promotes the teaching of culturally safe practice and meeting an individual’s needs for health care services on an equality basis (Oman Vision 2050 report). Nephrologists and nephrology nurses are the centre of care for ESRD patients, thus they should utilise cross cultural knowledge and culturally sensitive skills in providing and maximising good patient care outcomes. ESRD patients are close to the nephrology healthcare team because they spend around 15 hours each week in dialysis units attending dialysis session. Thus, the healthcare providers need to understand that HRQoL is important in improving renal care services. In Oman as in other countries, nephrology nurses should focus on the development and application of clear concepts that that look into psychosocial aspects of care, like emotional status, and social involvement.

1.4. Overview of Oman and dialysis services

The Sultanate of Oman is located in the south-eastern corner of the Arabian Peninsula. The total area of the Sultanate is around 309.5 thousand square kilometres. According to the census and information centre (2017), the population of the Sultanate was around 3 million by end of March 2017. The Omani population is relatively young of which 12% and 34% of the population are under 5 years and under 15 years, respectively; and only 3.8% are 60 years and above. The sex ratio is 102 males per 100 females; and the singulate mean age at first marriage is 25 years for females and 28 years for males (census and information centre, 2017).

Oman has witnessed significant development over the past thirty years to become one of the wealthy countries in the Arab Gulf area. Health services have improved accordingly, including services for patients with chronic renal failure. However, this dramatic improvement in economic status has been accompanied by changes in the lifestyle of the Omanis which are assumed to contribute to increasing the incidence of ESRD. This dramatic change in lifestyle has challenged the healthcare system in Oman to meet the increase in non-communicable diseases. Although no accurate figures of the prevalence of ESRD in Oman are available, the causes of renal failure are still mostly uncertain but assumed to be due to diabetes, hypertension, and chronic glomerulonephritis, since many cases present at an advanced stage. Diabetes mellitus in itself is responsible for 14.5% of the causes of renal failure in this population (National Health Report, Oman, 2016).

The delivery of treatment for ESRD presents significant costs and ethical challenges in all countries including Oman. The national dialysis services in Oman have expanded between 1985 and 2017 to include an additional private sector dialysis unit to meet the demands for dialysis treatment. Figure 1.1 shows the population of each region in Oman and numbers of patients on dialysis. Since the health services in Oman are provided by the national health system, the services for citizens with renal failure are fully paid for by the government. Despite the expansion of dialysis services of HD and peritoneal dialysis, kidney transplantation is limited within Oman, which could be a factor that may challenge the sustainability of the health services.

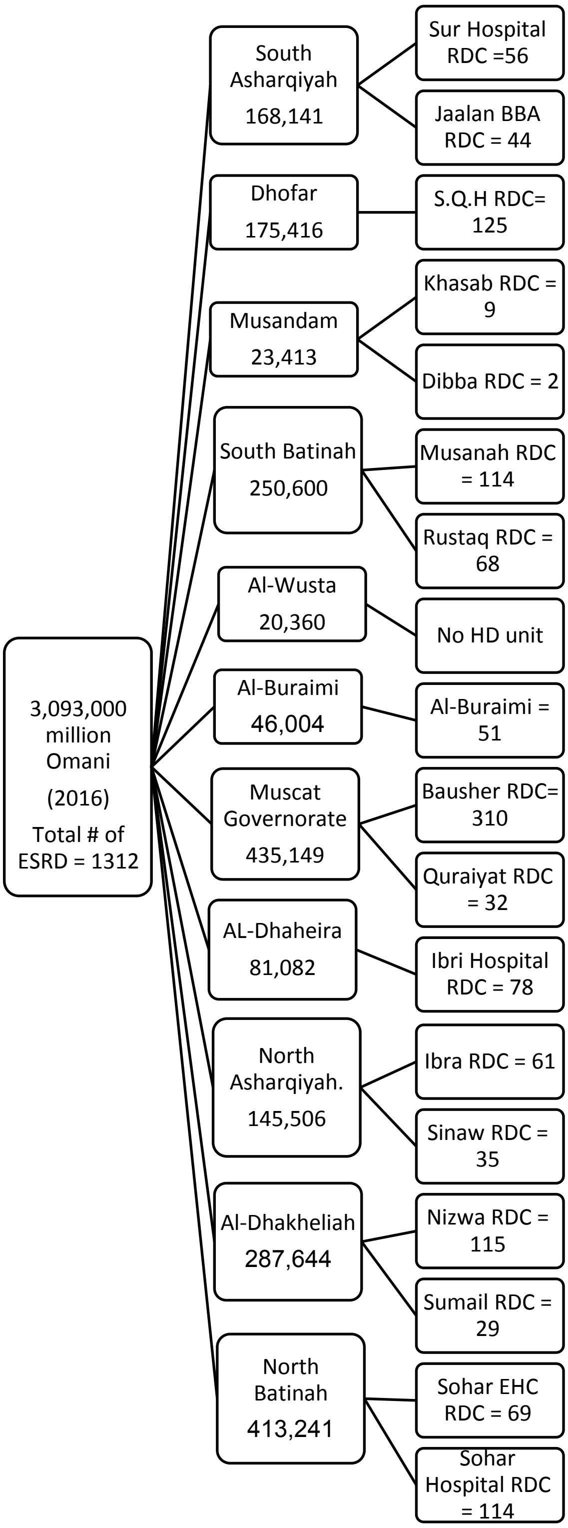


Figure 1. 1 Total population of Omani and number of ESRD patients per regions

1.5. Justification and study relevance to clinical and policy change

The interaction between symptom burden, physical, psychological and socio-demographical factors is important in understanding HRQoL in ESRD. The majority of studies that assessed QoL of patients with ESRD mainly focused on health-related QoL, and no studies were found which comprehensively assessed biological function, symptoms, functional status, general health perceptions, and various characteristics of the individuals and their environment. Even with studies that used more than one measure of QoL, the researchers did not articulate a holistic conceptual framework to guide their study, thus limiting the independent variables used to explain QoL. In addition, most studies were conducted within Western culture, with only two found that examined QoL and HRQoL aspects in ESRD patients in the Arab world. The results of these studies showed a low HRQoL among Arab patients with ESRD, with a significant score variation evident within the different subdomains of HRQoL that were assessed. As in other Arab countries, no studies were found that had been conducted in Oman to assess QoL in this group of patients, or on how these patients perceived their QoL. As a result, this study is needed to fill these gaps in knowledge.

The results of this PhD can create an evidence base upon which future health care services can be developed within the nephrology care services in Oman. Identifying the factors that impact the level of QoL and HRQoL in this group of the population can help to design new strategies to improve their HRQoL in relation to: clinical factors, psychological issues, physical functioning, social support, symptom burden, and spiritual factors. It can, also, promote the use of HRQoL measures in clinical practice to monitor the patients' condition and associated symptoms such as fatigue and pain.

Validating the HRQoL measures in an Omani population will benefit clinical practice as it is likely to provide clinicians with specific validated tools to assess their patients which can greatly improve the integration of HRQoL data into clinical practice. A major benefit to integrating these measures into routine clinical practice is the potential for identifying symptoms and problems that may result in improved patient care and clinical outcomes over time.

This study will significantly contribute to the knowledge of understanding the issues around HRQoL among cultures. It will influence the nephrology services in Oman and help clinicians in developing intervention plans based on a holistic view of physical and psychosocial views. It is also anticipated to facilitate the understanding of the renal failure patients' perceptions about their disease, which can be then tailored into their intervention plans.

Assessing the perceptions of this patient group in Oman, using multi measures including an individualised QoL measure, would help to identify their predictors and measures so that they can be tackled to improve patients' HRQoL; and support the shift of healthcare services from episodic treatment to a treatment that meets their ongoing needs. The intervention model suggested by this study will be presented to those making healthcare decisions, relevant stakeholders, and those providing nephrology services in Oman. This is in line with the aim of the long-term healthcare plan 'Health Vision 2050' developed by the Omani Ministry of Health which emphasises that quality of health is one of its target priorities (Al Mawali et al., 2017).

1.6. Study Purpose, specific aims, and research questions

The purpose of this PhD is to describe the QoL in Omani patients with ESRD and identify factors that predict their QoL and HRQoL.

1.6.1. Study specific aims

The specific aims of this study are:

1. To explore the meaning of 'QoL' to an Omani population
2. To assess the QoL and HRQoL perceptions of Omani patients with ESRD
3. To explore and identify factors that predict QoL/HRQoL in this patient group
4. To test the validity and reliability of common QoL and HRQoL measures within Omani population
5. To test the practicality and feasibility of using the Revised Wilson and Clearly HRQoL model to explore factors associated with HRQOL within Omani patients with ESRD.

1.6.2. Study Questions

1. What does QoL/HRQoL mean to an Omani population?
2. What is the level of QoL/HRQoL for patients with ESRD on HD in Oman?
3. To what extent do the following factors predict QoL/HRQoL in Omani patients with ESRD?
    a) Individual characteristics (age, gender, educational status, income, region, and marital status) measured by demographic.
    b) Treatment characteristics (duration of dialysis, dialysis adequacy, and length of time to get to dialysis) measured by clinical data
    c) Socio-environmental factors (family support, socio-economic, religious and spiritual), measured by disease-specific and generic instruments.
    d) Biological function (anaemia and malnutrition) measured by clinical data such as serum albumin, haematocrit and serum Hb
    e) Symptoms (fatigue, pain, mood, pruritus), measured by symptom-specific instruments.
    f) Functional status and general health perceptions, measured by health status-instruments.
3. What are the psychometric properties of the study measures in an Omani context in relation to its validity and reliability?
4. What intervention model can be recommended for augmenting QoL and HRQoL for Omani patients with ESRD based on the study results?

1.7. List of Definitions

The following terms are defined for the purpose of this study:

- Patient with end stage renal disease (ESRD): the patient who has been diagnosed by a nephrologist to have the last stage of renal diseases and require renal replacement therapy. For this study, only patients with ESRD and on HD were included in the study.
- Haemodialysis: A medical procedure in which the blood is cleaned outside the body using an artificial kidney or filter using a machine named a dialysis machine. Each dialysis session lasts for three to five hours, and sessions are usually needed three times a week.

- Dialysis hours: the amount of time of each HD session in hours.
- Dialysis duration: the amount of time in years that patient has been on dialysis.
- Time to reach dialysis: the amount of time in minutes required by the dialysis patient to reach dialysis unit for routine HD.
- Urea reduction rate (URR): A lab test that compares the amount of blood urea nitrogen before and after haemodialysis to measure the effectiveness of the haemodialysis dose.
- Dialysis adequacy: a measure, commonly expressed as a percentage, of how effectively a dialysis treatment removed urea from blood. According to the Kidney Disease Outcomes Quality Initiative (DOQI), the standard of adequate dialysis is a minimum of URR 65%.
- Spiritual wellbeing: refers to the affirmation of an individual's life in relation to God, self and community (Johnson et al., 2007). It falls very much in line with one's personal values, standards of conduct and the spiritual beliefs that shape one's life. The emphasis of this domain is on the importance of spiritual well-being as a dimension that may help to organise an individual's values to maintain a better QoL.
- Quality of Life (QoL): 'A person's sense of well-being that stems from satisfaction or dissatisfaction with the areas of life that are important to him/ her' (Ferrans et al., 2005).
- Health-related quality of life: refers to the subjective perception of the impact of an illness or its treatment on one's health and QoL.
- Kidney Disease Outcomes Quality Initiation (KDOQI): a recognised evidence-based clinical practice guideline for kidney disease and related complications produced by the National Kidney Foundation, USA.
- University Research Ethics Committee (UREC): the responsible committee at University of Dundee for approving and monitoring research projects.
- Research and Ethical Review & Approve Committee of Ministry of Health, Oman: the central committee at Ministry of Health, Oman, which is responsible for reviewing, approving, and monitoring research proposals and projects.

1.8. Assumptions

A number of assumptions underlie the methods used in this study. First, the concept of QoL is a multidimensional construct. Second, the abstracts and concepts that are unobservable, for instance, symptom burden and health perception, can be assessed by specific-related measures and statistical analysis. This assumption addresses the belief that patients with ESRD will respond to study measures that assess symptom burden, functional status, general health perception, QoL, and individual and environmental characteristics in accurate and honest answers. Lastly, obtained clinical and medical data reflect reality.

1.9. Thesis Outline

Chapter 1- Introduction and overview

Introduces the nature, severity and prevalence of ESRD, and its subsequent consequence on patients' lives. The chapter discusses also the rationale for the study focus of QoL in this patient group, presents a list of definitions of the terms used in this study, and will finish with a summary of the study aims and research questions.

Chapter 2- Definitions and Conceptualisation of QoL and HRQoL (Literature Review One)

It presents the narrative review that was conducted to analyse the conceptual and theoretical issues associated with QoL in general as well as the related concept of HRQoL and its measurement, which, in turn, informed the necessary review that was undertaken in the next stage of this study. The search questions formulated to guide this review, search strategy used to identify the relevant literature, data search results, quality of revealed literature, and characteristics of reviewed literature will be presented, respectively, under a section of 'literature review and selection of relevant articles'. The 'discussion' section of this chapter examines the definitions of QoL and HRQoL, conceptual and theoretical factors associated with QoL and HRQoL, common approaches to measurement of QoL and HRQoL, and critique of the conceptualisation of QoL. Finally, a conclusion and recommendations were drawn to inform the next review (chapter 3).

Chapter 3- QoL and HRQoL in patients undergoing haemodialysis (Literature Review Two)

This chapter contributes to building up the understanding of QoL and HRQoL in ESRD patients. The search questions formulated to guide this review, search strategy used to identify the relevant literature, data search results, quality of revealed literature, and characteristics of reviewed literature were presented, respectively, under the section of literature review and selection of relevant articles. The 'discussion' section examines the factors and predictors of HRQoL in ESRD patients; common measures of QoL and HRQoL in ESRD; and the psychometric properties of the identified measures. Finally, a summary was drawn to inform the chapter of empirical work of this PhD.

Chapter 4- Methodology

The methodology chapter presents justification for the philosophical paradigm, the methodological approach and details of the theoretical framework that are adopted in this study for the three phases to answer the proposed research questions. It also justifies the use of the research design, the population and sampling, and clinical settings; as well as an overview of the three study phases in relation to procedures for data collection, recruitment strategy, ethical approval process and ethical consideration, and data analysis strategies.

Chapter 5– Testing the concept of QoL and measures assessing HRQoL in Omani ESRD patients.

This chapter critically discusses and justifies the approach used to answer the research question-1 (What does QoL/HRQoL mean to an Omani population?). The 'method' section presents the details of the two methods which were used to validate and check the understanding of the concept of QoL and HRQoL in an

Omani context. Ethical approval, sampling and recruiting strategies were implemented for both methods and the results are discussed under this section. Finally, the discussion and recommendations related to this stage were discussed at the end of the chapter to inform the pilot study and the survey phase.

Chapter 6- Health-related QoL of Omani patients with ESRD: a pilot study.

This chapter critically discusses and justifies the pilot study that was conducted to test the feasibility of recruiting research assistants (nephrology nurses) to help in recruiting patients and administering study measures; develop and test the response rate; and 6) develop and test the proposed analytical syntax. The chapter is presented in a format that includes the method utilised, findings, discussion of the findings, and, finally, recommendations that were drawn to inform the main study

Chapter 7- Exploratory and confirmatory factor analysis of the Arabic version SF36v2 and HADS within an Omani context.

This chapter answers the research question–What are the psychometric properties of the study measures in an Omani context in relation to its validity and reliability?–by evaluating the psychometric properties of the Short Form-36v2 (SF36v2) and Hospital Anxiety Depression (HADS) measures within the Omani context. The methods, in details, that were used in conducting the factor analysis were discussed under relevant measure. Likewise, main findings were identified, and discussion of main findings presented under relevant sections. Finally, a conclusion and recommendation were drawn to inform the analysis of the main study

Chapter 8- Main study results.

This chapter presents the results from the cross-sectional survey (main study) analysis. It answers research RQ2 and RQ4 by presenting the details related to the response rate, level of missing data, and description of the characteristics of the participants. It also presents the findings from the scores of study measures and their subscales scores; findings from the comparisons of the independent variables and the total scores. The results of the degree of association and regression analyses were presented according to the study outcomes.

Chapter-9 Discussion and recommendations

This chapter critically discusses the key findings of the PhD according to the research questions. The chapter also discusses the strengths and limitations of the study, the recommendations for future research that might be conducted in this area; and recommendations for practice and future research.

1.10. Summary

The aim of this study was to explore QoL and HRQoL and its predicting factors in patients with ESRD in an Omani context. The revised version of Wilson and Cleary's Model for HRQoL (Ferrans et al., 2005) was used to guide this study. It is anticipated that the results of this study will inform the health care strategies of MoH, the 2050 vision in particular, to allocate necessary resources and future plans related to providing nephrology services. It will also assist nephrologists, nephrology nurses, and researchers in Oman to begin a research trajectory of evaluating QoL and HRQoL and to determine intervention plans to enhance it by targeting influencing factors.

Chapter-2: Conceptual and Theoretical Issues Associated with Quality of Life: Literature review-one

Background: Quality of life (QoL) and health-related quality of life (HRQoL) are multidimensional concepts. Several tools have been developed to measure these concepts. The aim of this narrative review is to gain a general understanding about QoL concepts, track its theoretical development, and identify the theoretical framework underpinning the concept.

Method: SCOPUS, Cochrane Library, ProQuest (ASSIA) and EBSCO (CINAHL and Medline) were the main databases searched. Secondary internet resources (ScienceDirect and PubMed), and non-electronically published relevant articles were also searched. English was the only language used in the search. Joined and separate keywords were used to find the published literature that discussed QoL generally across all disciplines.

Result: A total of 85 articles met the inclusion criteria: 27 empirical studies and 58 discussion articles (7 HRQoL, 18 concept analyses, 21 QoL definitions and 12 papers were related to different factors of QoL and HRQoL). No standard definition was provided for the concepts of QoL and HRQoL. The QoL concept was best described by the WHO definition. Possible factors that might influence QoL definitions are the different use of the term “QoL” at a multidisciplinary level and the ambiguity of which aspects of life are more important in determining QoL. Five substantial areas were identified which related to the concepts of QoL and HRQoL: physical wellbeing, psychological wellbeing, spiritual wellbeing, cognitive wellbeing and social-environmental wellbeing. Three main approaches are being used to assess QoL and HRQoL: generic, disease-specific and individualised measurement measures.

Recommendations: to use the WHO definition of QoL as well as the Revised Wilson and Clarey model of HRQoL by Ferrans et al. (2005) to guide this PhD project. Individualised QoL instrument and cognitive debriefing method can be used to explore the meaning of QoL and test the readability of HRQoL measures within the Omani population.

1. Introduction

Patients affected by the end-stage renal disease (ESRD) might experience deteriorated quality of life due to the imposed limitations in most of life domains. Dialysis procedure may also impose changes in their normal way of living because it requires recurrent dialysis unit visits, usually three times a week. As a result, advancement in medical sciences, for instance, advances in diagnostic procedures, treatments, medications, surgical procedures and primary health care services traditionally have been directed towards improving patients' overall health and increased their life expectancy. However, simply increasing life expectancy without considering a good quality of life might not be sufficient. Considering and assessing quality of life of patients affected by ESRD can be a predictive indicator of the outcome of the disease as well as a valuable research tool in assessing the effectiveness of therapeutic intervention, patients' survival and hospitalisations.

The term 'QoL', however, is a multi-dimensional concept and can have several meanings (Sousa et al., 2006) since several factors related to social and economic aspects must be taken into account when attempting to define the concept of QoL (Kao et al., 2009). Several definitions are available in current literature that define the concept of QoL. Generally, the term "QoL" refers to a wide range of individual experiences related to the individual's overall wellbeing (Revicki et al., 2000). With the existing numerous definitions of QoL, researchers, and clinicians, need to be clear about the conceptual definition of QoL so as not to confuse it with the disease process and complications or with treatment side-effects. As with the definitions of QoL, several tools have been developed to measure QoL. Most of these tools, however, as Fayers et al. (1997) say, are causal indicators of QoL rather than QoL itself.

To narrow and focus on the concept of QoL, the term HRQoL evolved to reflect the value of health states. HRQoL is determined by the manner in which changes in health and treatment-related symptoms affect the dimensions of one's well-being (Huber, Sillick et al. 2010). This description might indicate that HRQoL is entirely constructed by a patient's individual perceptions and that others cannot make judgments about what is best for the patient. Patient perceptions about QoL have been found to have poor correlation with, and wide discrepancies between, practitioners' assessments (Krethong, Jirapaet et al. 2008). Health providers tend to overestimate or underestimate the effects of symptoms on a patient's QoL. Although care providers believe that they know what patients want, patients' feelings, preferences and perceptions cannot be assumed (Painter, Krasnoff et al. 2012).

Despite the extensive research carried out in trying to conceptualise and operationalise QoL and HRQoL, these concepts remain ambiguous. That may be because the concept of HRQoL overlaps with the terms QoL and health concept. It is crucial therefore to have a clear definition of QoL and HRQoL prior to exploring and measuring the factors that could worsen the QoL and HRQoL of patients with ESRD. The aim of this narrative review, therefore, is to analyse the conceptual and theoretical issues associated with QoL in general as well as the related concept of HRQoL and its measurement, which, in turn, informed the focused review related to QoL and HRQoL of patients with ESRD, undertaken in the next chapter of this research.

2. Method

The method section highlights the strategy used to search for relevant literature concerning issues around QoL and HRQoL conceptualisation. It was performed by formulating focused search questions, inclusion and exclusion criteria, keywords, and finally a search in the appropriate databases.

2.1.Search questions

The following are the questions that were formulated prior to conducting the search for relevant articles containing evidence related to the conceptualisation of QoL and HRQoL:

1. What are QoL and HRQoL?
2. How are QoL and HRQoL defined?
3. What concepts are related to QoL and HRQoL?
4. What is the relation between QoL and health?
5. How are QoL and HRQoL assessed?

2.2.Search strategy

The search for articles relevant to this review was initiated by a comprehensive search using four electronic literature databases [SCOPUS, Cochran Library, ProQuest (ASSIA) and EBSCO (CINAHL and Medline)]. The search also covered secondary internet resources (ScienceDirect and PubMed), as well as non-electronically published relevant articles to gain a full view of the relevant information published without specific dates. EBSCO, which consists of CINAHL and Medline, was the initial database accessed as it is known to contain regularly updated evidence-based healthcare literature. For articles not published in an electronic format, the University of Dundee Library Catalogue was consulted to identify this type of article.

The literature search was not limited to any specific date in order to obtain the most applicable and relevant evidence. English was the only language used in the search because of the inability to interpret non-English published articles. All searches were conducted in the second half of December 2013 and updated in April 2017.

Joined and separate keywords were used to find the published literature that discussed quality of life generally across all disciplines: “Quality of life” – “health-related quality of life” – “integrative quality of life” – “QOL” or “QoL” – “QoL” or “HRQoL definition” – “QoL” or “HRQoL concept” or “HRQoL conceptualisation” – “QoL” or “HRQoL theory” – “QoL” or “HRQoL operationalisation” – “well-being”. The inclusion and exclusion criteria are summarised in table 2.1.

Table 2.1. Inclusion and exclusion criteria

Inclusion	Exclusion
1. published in English 2. pertained to QoL and HRQoL concepts and theories 3. included an adult population (>18 years of age) 4. were forms of published evidence **5.** were articles with findings derived from QoL and HRQoL concepts**.**	1. did not pertain to the QoL of humans 2. published in a non-English language 3. published as general information, dissertations, editorials and clinical opinions 4. included a paediatric population

Data were retrieved from empirical studies and discussion articles and were extracted using relevant extraction methods. The results of the “empirical studies articles” were reported based on a modified data-extraction form suggested by the Joanna Briggs Institute (JBI); whereas the results of the “discussion articles” were reported on three different themes (QoL definitions, conceptualisation of QoL and theoretical factors) in a tabular form based on data-extraction tables using criteria suggested by Garrard’s (2007) Matrix Method. The Matrix Method is both a structure and a process for systematically reviewing literature. Consistent with Garrard’s approach, the review matrix table, a place to record notes about papers using columns and rows, provides a standard structure for creating order. Each of the “discussion articles” was evaluated in ascending alphabetical order, using a structured abstracting form with seven columns: author’s name, publication year, country, paper type, paper purpose and context, participants (if any) and study findings (Appendix 2.3). The synthesis method employed in the Matrix Method is a critical-analysis and review process of the literature on a specific topic. Results were then tabulated and presented using the following headings: author and year of publication, country, design, sample size, outcome measures and key results.

3. Result

The inclusive search revealed a total of 4,658 articles. The identified articles were screened against titles in order to match inclusion and exclusion criteria, which then resulted in the exclusion of 4,144 articles. The remaining 514 articles were then checked for duplication using the EndNote X4 reference management software programme in which 148 articles were identified as duplicates and were excluded. Checking the remaining articles against inclusion and exclusion criteria, 193 articles were removed for not meeting inclusion criteria, which left a remaining sum of 173 articles to be screened. No articles were included out of the manual search of the University of Dundee Library Catalogue (this revealed a total of 1,147 different resources: 19 conference papers, two e-books, eight textbooks and one dissertation thesis, with the remaining 1,117 being electronic resources). Of these, 1,054 did not meet the inclusion criteria and 93 were duplicates found in different databases. Figure 2.1 shows the flow of literature identified.

After excluding duplicate articles and those articles fitting the exclusion criteria (Appendix 2.1), two reviewers (the PhD student and the study supervisor) sorted out the list of the potential articles (173 articles) for inclusion independently by reviewing each article’s title and abstract. The aim was to maintain a rigorous selection process and minimise selection bias. A table was created to compare the ratings of both reviewers of articles to be included in the review that met the inclusion and exclusion criteria. Agreement between reviewers was reached in 70 articles. Disagreement occurred in 55 articles and on those occasions, a third reviewer (study supervisor) reviewed.   This resulted in 85 full-text papers to be reviewed.

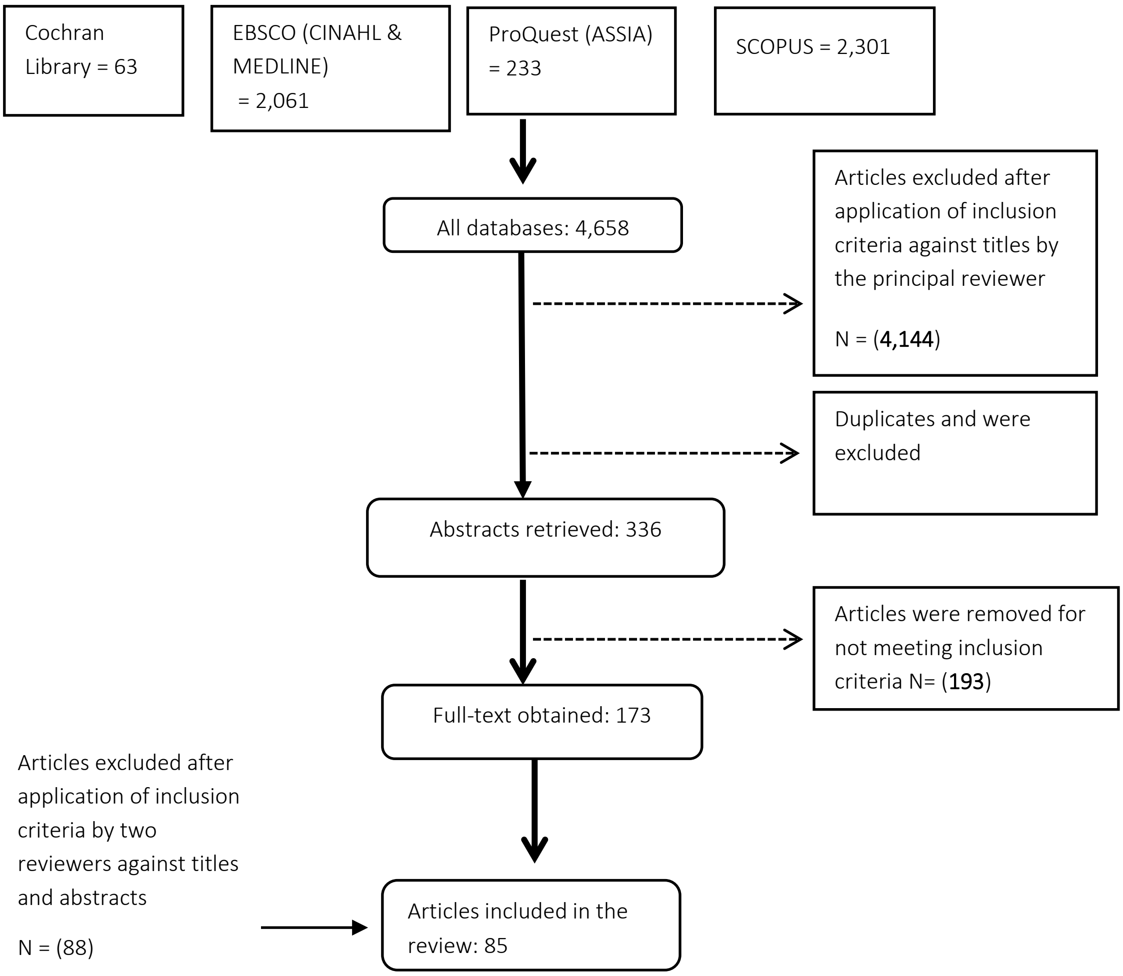


Figure 2. 1   Flow of literature identified through database searching

3.1.Summary of search and quality appraisal of articles

A final total of 85 articles met the inclusion criteria and are included in this narrative review: 27 empirical studies and 58 discussion articles (seven HRQoL; 18 concept analyses; 21 QoL definitions; and 12 papers related to different factors of QoL and HRQoL). The quality of the "empirical study papers" was assessed using the quality appraisal forms of the Critical Appraisal Skills Programme (CASP) criteria; and for "discussion articles", the Joanna Briggs Institute (JBI) critical appraisal checklist was used (Appendix 2.2).

Figure 2. 1 Example of data extraction

Author	**Country**	**Methodology**			**Results**
		Design	**Size and characteristics of sample**	**Measure**	
Abdel-Kader et al (2009)	USA	Cross-sectional design	151 patients undergoing peritoneal or haemo-dialysis.	SEiQoL-DW	Family and health were the most common domain for patients. No significant differences in SEiQoL-DW scores between subgroups. SEiQoL-DW scores correlated mental wellbeing (r= -.22, p <0.010).
Bailey et al (2007)	USA	Cross-sectional	332 psychology and business students from Baylor University.	Trait Hope Scale and Quality of life Inventory (QoLI)	The internal reliabilities of both scales were above 0.70. Alphas for the scales were: Hope scale = 0.79 and QoLI = 0.73.
Fagerlind et al (2009)	Sweden	Phenomenographic qualitative design	Semi structured interviews of 22 patients with rheumatoid arthritis.	Interviews analysed by using QSR NUD*IST VIVO	Two concepts, "being healthy" and "being able to function normally", overlapped with respondents' understanding of QoL.
Garratt et al (1993)	UK	Observational study, postal questionnaire to check if SF36 is a suitable measure for routine use within the NHS.	1,700 patients with one of four conditions (low back pain, menorrhagia, suspected peptic ulcer, varicose veins).	SF36	The SF36 satisfied rigorous psychometric criteria for validity and internal consistency. Internal consistency (0.55-0.78). Validity (factor analysis identified five relevant factors with eigenvalues 12.8 to 1.3)

3.2.Characteristics of reviewed articles

The 85 articles included in this review addressed the both concepts of QoL and HRQoL as the main outcomes. The publishing period was from 1990 (Hoernquist J, 1990) until 2016 (Ravenek et al, 2014). Thirty-two papers were published ≤ 2000, and 53 were published after 2000. Only one study assessed QoL in the Arab world (Abdel-Kader et al, 2009) and the rest were: Europe, 32 papers; USA, 31; Canada, 10; and Asia, six papers. A summary of the empirical studies results are shown in Appendix 2.3.

For discussion articles, the purpose was clearly reported in the introduction section of each article. Two articles (Koller et al, 2005; Carr et al, 2001) did not clearly report the title and field of expertise of the authors, whereas the rest of the articles clearly indicated the author's background and field of expertise, all of which were relevant to the particular areas of studying QoL throughout the various fields. Patients were the central focus of the discussion of these articles. However, Hass et al (1999), Meeberg (1992), George and Bearon (1980), Gladis et al (1999) and Vitterso J (2003) all provided a general discussion around the concept of QoL without any focus on a particular group of individuals. The arguments and discussion around the concepts of QoL and HRQoL and the underpinning factors were developed analytically and supported by relevant references in all the articles included in this review.

The majority of the 27 studies involved common features for quality research including: detailed reporting on study aims; participant demographics and contexts; study design; analytic methods; and a precise description of study procedures. However, only three articles explicitly reported the use of a QoL conceptual framework (Koller et al, 2005; Krethong et al, 2008; Sousa and Kwok, 2006). With regard to study design, one study had a longitudinal design (Rudolf and Priebe, 1999) and the rest used cross-sectional design. As the majority of studies were cross-sectional in design, it is difficult to make causal inference with factors that might contribute to the outcome over time because, in this case, data are collected only at one point in time. Also, when data are collected at one point in time, differing results might have been found if another point in time had been chosen (Bland, 2001). Such methodological limitations in cross-sectional design might affect the generalisability of the results of the studies.

3.3.SQ1: What are QoL and HRQoL?

Tracking the meaning of QoL and HRQoL, it was notable that these two terms are used interchangeably in literature. Despite this, it can be observed that each term has its own meaning. The term ‘QoL’ can be seen as a broader concept that covers all aspects of life; whereas ‘HRQoL’ is a concept that focuses on the effects which disease and its related treatment may have on QoL. QoL is therefore is broader than HRQoL because it includes evaluation of non-health related features of life whereas HRQoL is connected to a patient’s health or disease status. The term “HRQoL”, therefore, is determined by the manner in which changes in health- and treatment-related symptoms affect the dimensions of a patient’s well-being (Huber, Sillick et al, 2010). Hence, it can be argued that QoL and HRQoL are two distinct but related constructs.

The WHO definition of QoL has been found to be consistent with studies that explore the factors comprising QoL, such as physical health, psychological state and socio-environmental factors (Testa et al., 1996; Oort et al., 2005; Brush et al., 2011). Currently, there is broad agreement that the concept of positive health is more than the absence of disease or even disability, but is about having a fully functioning efficiency of mind and body and social adjustment (Kaasa and Loge, 2003; Fleck et al, 2011). Health-related QoL, in turn, is the more appropriate term to be used when describing and assessing the concept of QoL within patients with chronic health issues. That is because it encompasses a broad, multidimensional concept that usually includes self-reported measures of physical and mental health (Debout, 2011). Nonetheless, there is no standard definition available for the term “HRQoL”, the common agreement across the literature being that it is the functional effect of an illness status and/or its consequent therapy on a patient and the encompassing physical and psychological status (Cella, 1995; Guyatt et al., 1993; Fagerlind et al., 2010; Dyess, 2011).

3.4.SQ2: How are QoL and HRQoL defined?

Despite several definitions existing that define both concepts, QoL and HRQoL, no consensus on one standard definition was identified. Different approaches can be found that refer to the meaning of QoL and HRQoL. These approaches are based on an individual’s needs (Huber et al., 2010), subjective wellbeing (Kitayama and Markus, 2000), expectations and phenomenological viewpoints (Johnson et al., 2007).

In the literature, a number of factors can be identified that might contribute towards influencing the definition of QoL. First, the different use of the term “QoL” at a multidisciplinary level has led to a multitude of definitions that reflect the biases of each discipline (Hajiran 2006). For instance, healthcare researchers focus on issues pertaining to quality and healthcare outcomes, while economics researchers interested in measuring QoL focus on issues related to QoL and cost per quantum. Ambient cultural setting is a second factor that might be considered as influencing QoL definition (Bergland and Narum, 2007). The differences in cultural settings may depend on factors such as age, gender, social class and generation. For example, a study that examined racial and ethnic differences in the QoL of cancer patients suggested specific differences in symptomology across cultures (Rao, Debb et al., 2008). Third, a statement of the operational definitions of QoL might also have an influence on understanding the concept of QoL. Operational definitions provide meaning to any concept by describing the operations required to assess that concept (Fink, 2009).

Another possible factor which reflects the difficulty in providing a universal definition of QoL is the decision about which particular aspects of life are more important in determining QoL and how these aspects should be measured (Read, Quinn et al, 1987). Definitions of QoL might provide different meanings with different constructions of that meaning between individuals (Rosenberg, 1995). Regardless of the commonly used aspects of life in measuring QoL, the selection of items to represent aspects identified by any one researcher does not always ensure their relevance to individuals (Antaki and Raply, 1996). The choice of aspects of life raises concerns that might significantly affect the value of data obtained from participants. Thus, whatever instrument is used to assess QoL it should include different aspects of life including health.

Despite these possible factors that might contribute to defining QoL, the common agreement between all the definitions of QoL is that it is a subjective term and depends on one's present and past experiences and on one's dreams and ambitions (Bonner et al., 2013; Camfield and Skevington, 2008). Since QoL depends on a person's perceptions and experiences of life, it should be considered to be dynamic, changing and constantly developing as new knowledge and a range of different experiences are gained (Pastrana, Juenger et al, 2008). That is, the timing of QoL measurement might influence an individual's levels of QoL. Happy moments usually stimulate individuals to express a positive life satisfaction and, in contrast, sad moments might reflect dissatisfaction with life. Patients affected by chronic conditions, such as ESRD, pain and long-life treatment procedures, might not be able to provide one exact meaning of the definition of QoL as their perception may change according to the disease status.

Because the majority of life domains are related to health, the term "HRQoL" is used to specify health-related issues and to differentiate them from general issues of quality of life. Perhaps the World Health Organisation (WHO, 1995) can be seen as providing an inclusive definition of HRQoL. It is about "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns; it is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment" (The WHO QoL Group, 1995). This definition goes beyond the direct measure of health and refers to a multidimensional concept that includes aspects of life related to physical, psychological and social functioning.

Figure 2. 2 Examples of structured definitions of QoL

Examples of QoL and HRQoL definitions

“Quality of life is a feeling of overall life satisfaction, as determined by the mentally alert individual whose life is being evaluated. Other people, preferably those from outside that person’s living situation, must also agree that the individual’s living conditions are not life-threatening and are adequate in meeting that individual’s basic needs”. (Meeberg, 1993, p. 37).

“… the degree of satisfaction or dissatisfaction felt by people with various aspects of their lives”. (Bond et al., 2004, p. 4).

“… a person’s sense of well-being that stems from satisfaction or dissatisfaction with the areas of life that are important to him/her”. (Ferrans, 1990, p. 33).

“'Quality of life' and more specifically, 'health-related quality of life' refer to the physical, psychological, and social domains of health, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations and perceptions (which we refer to here collectively as 'perceptions of health'). Each of these domains can be measured in two dimensions: objective assessments of functioning or health status, and more subjective perceptions of health." (Testa et al., 1996, p. 835).

“QoL is seen, in relation to health, as ‘a positive state, a desirable outcome of healthcare interventions’.” (Holmes, 2005, p 496).

“… an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment.” (The WHO QoL Group, 1995).

“… quality of life should be defined as what the individual determines it to be.” (O'Boyle, 1997, p. 1875)

3.5.SQ3: What concepts are related to QoL and HRQoL?

There is a substantial overlap between the concepts of QoL and HRQoL throughout the literature. Five areas were identified to correlate the concepts of QoL and HRQoL, though mainly related to HRQoL. These areas were grouped under relevant aspects of life and are shown in Table 2.4. For purposes of clarity, the term “aspects of life” refers to the set of factors that combine to determine the related concepts of QoL and HRQoL. These aspects are: physical wellbeing, psychological wellbeing, spiritual wellbeing, cognitive wellbeing and social-environmental wellbeing. The results of the articles analysed QoL concept are shown in Appendix 2.4.

Table 2.2. Reported conceptual and theoretical factors associated with QoL under relevant aspects (n= 85 articles)

QoL aspects and related factors				
Physical well-being	Psychological well-being	Cognitive well-being	Spiritual well-being	Socio-environmental well-being
-Illness and disability -Physical fitness -Accessibility of service	-Emotional/ mental health -Coping abilities -Life acceptance -Achievement of personal goals	-Autonomy/ independence -Thinking process -Management skills -Problem-solving skills/decision-making	-Personal values -Personal beliefs -Sense of life purpose -Sense of wholeness	-Socio-economic factors -Social relationships -Housing conditions -Privacy/ confidentiality -Safety

Physical wellbeing is one of the main determinants of HRQoL (Tsilika et al., 1999; McKevitt et al, 2003; Chang et al, 2005; Brutt et al., 2008). The importance of physical wellbeing as a determinant of HRQoL was highlighted by most of the measures of health status which considered physical health as a predictor of HRQoL (Hall, Krahn et al., 2011). However, physical functioning and functional status are terms that are used interchangeably in studies that also examine QoL. Liedy (1994) provided a basic definition of functional status as “the ability to perform normal daily activities to meet basic needs and maintain health including physical health” (page 66). It might be difficult to determine if the state of health has been achieved solely by a patient’s ability to carry out daily life activities. Understanding the effects of patients’ health conditions on their ability to perform basic tasks and participate in life situations could help in improving their HRQoL.

Psychological well-being is the second concept found to be related to HRQoL. Psychological well-being is a comprehensive term for different personal aspects, including emotional and mental health and general well-being (Peruniak 2008, Skevington 2009, Welsch, 2009). Individuals with a high ability to face and manage life stresses, and a high experience of this, are able to maintain a better HRQoL (Ramirez et al., 2012a). These components of psychological well-being interact with stressful life situations including disease status. Siegrist (2001) argued that individuals depend on their ability to identify and draw upon internal and external resources to face up to their needs, for instance informational and emotional support, which, consequently, might improve their HRQoL.

Despite the high emphasis on psychological factors associated with HRQoL, particularly within a health context (Debout, 2011), there is a need to view each patient as a unique individual and to treat them based on an individualised plan (Mitchell 1990; Lopez, Eng et al, 2005). Certainly, each individual is unique and has unquestionable value. The behavioural changes occurring within the individual who has been diagnosed with a long-term illness, for instance ESRD, might alter that patient's behavioural and cognitive process (Barclay-Goddard, 2012; Oort et al., 2005). This change could be the result of the internal standards, values and conceptualisation of HRQoL which that patient develops to accommodate the new health status.

This view, however, should not overlook the fact that individuals cannot function separately from their socio-environmental interaction, which means that all individuals' lives are interdependent and interconnected. To assess the balance between interpersonal issues and external factors, a comprehensive framework is required which does not exist at present (Chwalisz, 2008; Giordano, Björk et al, 2012; Eckersley, 2013).

Cognitive wellbeing was the third important determinant for HRQoL (Downie, 2000; Hendry and McVittie, 2004; Huber et al., 2010; Kurpas et al., 2013). Self-dependence is linked to patients having control over their own lives and making decisions that they see as the most satisfying and appropriate for them based on their health status. A good level of HRQoL can be determined by a patient's ability to manage life activities such as financial management, performing within a job and learning new skills (Vitterso 2004). Because this is about patients' ability and capacity to make choices and to have control over their lives, patients should therefore have intellectual ability so that they can be self-dependent and can look after their own lives. Cognitive well-being involves the thinking processes and skills needed to manage life situations (Hermann 1995). It includes intellectual capacity and the ability to make decisions that are reasonable and based on rational thought processes (Kaasa and Loge, 2003).

Spiritual wellbeing is the fourth determinant of HRQoL which can also be seen as a determinant of QoL. It refers to the affirmation of an individual’s life in relation to God, self and community (Piderman et al, 2007). It falls very much in line with one’s personal values, standards of conduct and the spiritual beliefs that shape one’s life. The importance of this aspect has often been noted in the literature. Recently, more attention has been given to spiritual well-being as a factor that might improve one’s wellbeing (Fleming and Evans 2008; Dyess 2011; Gall, Malette et al, 2011). The emphasis in this aspect of life might be on the importance of spiritual well-being as a dimension that may help to organise an individual’s values so as to maintain a better QoL and HRQoL. This was highlighted by the literature that examined the influence of religiousness on HRQoL (Ramirez et al., 2012; Gall et al., 2011; Moreira and Koenig, 2006).

Socio-environmental wellbeing was reported in the literature as being an imperative determinant of both QoL and HRQoL. It refers to a person’s ability to interact positively and successfully with the surrounding environment and within the community and its cultural contexts (Carr, Gibson et al, 2001; Camfield and Skevington 2008; Fagerlind, Ring et al., 2010). It is essential for individuals to have a role in their community and to have good links with their social networks in order to maintain a satisfactory level of QoL and HRQoL. The effects of social well-being can, through an interaction between socio-economic factors that might support the individual, bring about an easy life, which ultimately influences their perceptions of their HRQoL. Farsides and Dunlop (2001) argue that relationships of love and friendship, or even of enmity and competition, make life worth living. Community interactions, family and social networks and support, including positive interaction and emotional support, are generally indicators of good levels of social well-being and determinants of social well-being (Huber et al., 2010).This might indicate that the complexity of life dimensions is a multi-faceted element and necessitates the use of a multiple focus-assessment framework when assessing QoL (Flynn, Greenhalgh et al, 2005; Ghylin, Green et al, 2008).

Lastly, the concept of spirituality must also be considered as a possible drive for providing the purpose of life for some individuals (Fleming and Evans, 2008). It is a kind of connectedness and it describes a way of being that is characterised by certain identifiable values in regard to self, others and life (Malette et al., 2011). Religiosity is often understood as an individual's involvement in a set of beliefs and social activities as a means of spiritual expression and this may include adherence to religious practices and traditions, such as Christmas, fasting during Ramadan, or adhering to specific dietary regimens such as avoiding alcohol and being vegetarian. The interplay between the two concepts of spirituality and religiosity may affect how individuals live and may also affect their moral decisions (Malette et al., 2011). These consequently affect their day-to-day choices. In Islam, for instance, being religious is considered an essential element of happiness. Muslims perceive life satisfaction to be connected with (Allah's or God's) satisfaction through the dialogue and performance of worship, which results in the belief of having a pleasant and satisfied life (Al-Zamel et al., 2010).

3.6.SQ4: What is the relation between QoL and HRQoL?

The need to have a measure to rely on to allocate the resources for health care services may have provided the impetus to introduce and relate QoL and HRQoL as a health outcome measure (Brekke et al., 2014). QoL has been discussed in medical literature since 1960s (Karimi and Brazier, 2016). Since development in medical care enabled the prolongation of patients' lives, traditional measures of health, such as death rate, were no longer enough to measure the output of health care systems. The definition of the WHO of HRQoL therefore reflects the relationship between QoL and health (Carr et al. 2001). The term 'HRQoL' was developed by health researchers as a way to measure QoL within health domain (Claes et al., 2012) and to differentiate between QoL as an overall sense of wellbeing and HRQoL as a satisfaction with health status (Debout, 2011). As a result, QoL research has shifted towards considering good HRQoL as a primary goal and outcome of effective health care (Painter, Krasnoff et al. 2012).

However, there are no exhaustive aspects of measurement for HRQoL presented in the literature and therefore its measurement should consider both personal perceptions and socio-environmental conditions alongside health factors. The five aspects that correlate the concepts of QoL and HRQoL discussed earlier might provide a theoretical framework to assessing HRQoL as a health measure, which are: physical well-being, psychological well-being, cognitive well-being, spiritual well-being and socio-environmental well-being. These aspects are similar to the conceptual model of HRQoL by Ferrans et al. (2005) that highlights four main domains: biological functioning, symptoms, functional status, and general health perception. The components of this conceptual model acknowledge that health exists in a continuum from simple to complex outcomes with four determinants, each having multiple variables (Peterson and Bredow, 2009). These determinants, as well as the overall quality of life, are ultimately affected by the characteristics of the individual and by the environment (Ferrans et al., 2005; Kring, 2008).

3.7.RQ5: How are QoL and HRQoL assessed?

Three main approaches are used to assess QoL and HRQoL: generic, disease-specific and individualised measures. Many of the measures that have been developed are currently widely used and have been translated into different languages including Arabic.

Generic instruments, sometimes referred to as health measures, for instance the Short Form-36 (SF36), attempt to measure a broad range of life aspects related to HRQoL. These measures cover a range of areas and can be used across different populations. The perceived strength of these instruments is their ability to allow comparisons of outcomes to be made between the different groups measured (Bowden and Fox-Rushby, 2003). Additionally, they provide the ability to monitor and screen large populations within different age spectrums. However, the use of such measures to assess impairment-specific populations, such as those people with chronic diseases, should be verified in order to ensure their appropriateness (Krahn et al., 2011). The success of these tools is likely to depend on group characteristics and these tools are more susceptible to the influence of general life factors other than illness severity, unlike measurement tools that are disease-specific.

The measures that are condition- or disease-specific are designed to address areas of life that are particularly pertinent for patients with a specific condition or disease in a predefined list of items which must be rated in a particular manner (Bergland and Narum, 2007). The limitations of this method of measurement lie in the difficulty of interpreting the responses and its relevance across different diseases. Despite these tools being criticised for having a narrow focus, they have been credited with being more sensitive to changes in health status compared with generic instruments (Krahn et al., 2011).

Individualised measurement tools were developed as an attempt to explore the aspects of life that the individual perceives to be most important and to assess the level of functioning or satisfaction within each aspect (Totten et al, 2011). A number of such measures have been developed, such as the Schedule for the Evaluation of Individual Quality of Life, based on direct weighting procedure (SEiQoL-DW), by McGee et al (1991) and O'Boyle et al (1992); and the Quality of Life Index (QoLI) by Ferrans and Powers (1985). The main advantage of this type of measure of QoL is the ability to address individuals'own concerns about their lives rather than impose standard questions which might be less relevant (Malette et al., 2011).

There are five main reasons for measuring QoL and HRQoL identified in the literature: (a) it provides an understanding of the causes and consequences of the difference in QoL and HRQoL among individuals and groups (Chang et al., 2005; Gehrmann et al., 2007); (b) it helps in assessing the impact of social and environmental factors on QoL and HRQoL (Bullinger et al., 2008; Krahn et al., 2011); (c) it estimates the needs of a target population; (d) it evaluates the effectiveness of health interventions and the quality of any healthcare system (Anderson and Burckhardt, 1999; Clark 2002; Chwalisz, 2008); and (e) it helps in forming clinical decisions (Greenhalgh et al., 2005). Therefore, measuring overall QoL and HRQoL requires a formal and scientific rigour of assessment in its approach.

3.8.Conceptual model

The use of a conceptual framework of HRQoL in this study could act as a heuristic device to provide a better understanding and clarity of HRQoL. The literature review revealed three conceptual frameworks of HRQoL which are most frequently used, namely, World Health Organisation International Classification of Functioning Disability and Health (WHO ICF), Wilson and Cleary HRQoL Model, and Revised Wilson and Cleary Model of HRQoL by Ferrans et al (2005). Critically reviewing these models, the WHO ICF was more of a mapping and classification framework than a guide for hypothesis generation in the area of HRQoL (Bakas et al., 2012), and for that reason, was not considered in the current study; whereas the Wilson and Cleary model of HRQoL and the revised Wilson and Cleary model of HRQoL by Ferrans et al were more relevant to guide this study.

The original model of Wilson and Cleary, which combines two paradigms of biomedical and social science, was published in 1995. Conceptually, it links four well-defined health concepts on a continuum (biological functioning, symptoms, functional status, and general health perception) with HRQoL as an outcome. The model also considers individuals' interaction with the environment to perceive a level of HRQoL which address the difference between the clinical reported outcomes and the patient reported outcomes (Diagram 2.1).

The definition of the four determinants of health-related outcomes of this model that interlink the different aspects of life with the perception of HRQoL are:

1. Biological functioning: includes the physiological processes that support life, such as cells function and disease severity. It includes body mass index, skin colour, and family history related to genetic disease. It is considered the most fundamental factor of one's health status and focuses on the performance of body cells and organ systems. Biological functioning can be measured through laboratory tests and physical assessment (Wilson and Cleary, 1995). Alterations in biological function can affect all subsequent determinants of QoL, including symptoms, functional status and general health perceptions.
2. Symptoms: refers to the physical and psychological symptoms that the patient may express. The physical symptoms relate to feelings about physical status (body), while psychological symptoms relate to feelings of fear, worry and frustration (mind). According to Wilson and Cleary, a symptom is defined as "a patient's perception of an abnormal physical, emotional or cognitive status" (Wilson and Cleary, 1995: p. 61). Common

to these definitions is that a symptom is a subjective feeling which reflects a change in normal functioning that may be physical, psychological and/or social (Lenz et al, 1997). It is therefore important to measure the influence of symptoms on a patient's overall QoL using symptom-specific measures.

3. Functional health status: this is defined as the patient's ability to perform particular defined tasks or maintain day-to-day activities. The main domains include physical functioning, social functioning, role functioning and cognitive functioning. Many factors may be related directly or indirectly to functional health status, such as physiological factors, symptom status, individual characteristics and environmental factors (Wilson and Cleary, 1995). According to Wilson and Cleary (1995), four areas of functioning are often measured: physical, social, role and psychological can all be assessed by generic types of measures.
4. Perception of general health: this is subjective in nature and allows patients to evaluate and weigh up their past and current overall health status. According to the framework, symptoms can be key predictors of general health perception. It represents all health concepts together and all other concepts that may not be depicted by the model (Wilson and Cleary, 1995). Therefore, assessing the association between symptom status and general health perception is important. A patient's perception of general health is usually measured by one single global question reflecting an overall health rating on a Likert-type scale from poor to excellent.

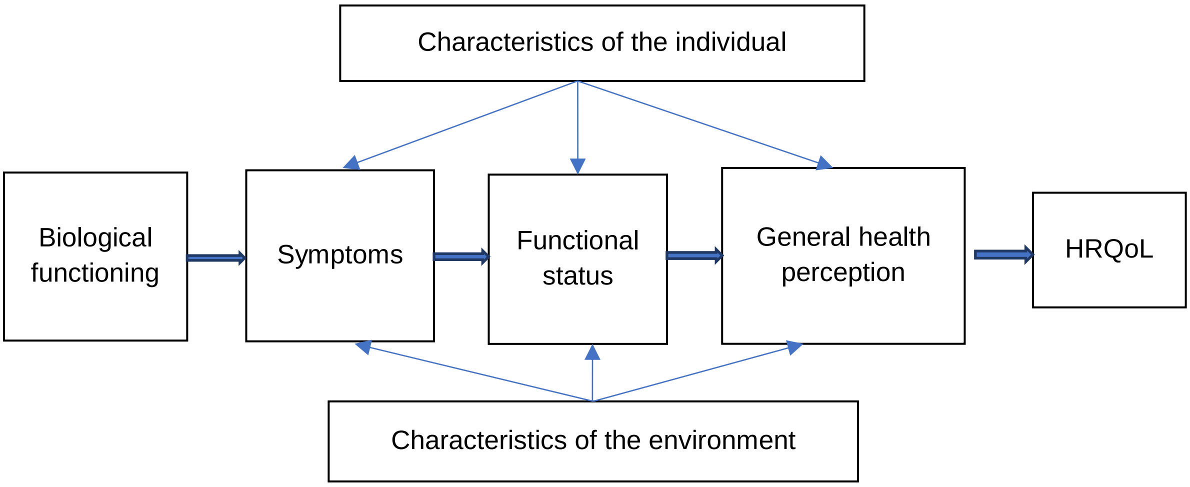


Diagram 2. 1 *Wilson and Cleary Model of HRQoL*

Although Wilson and Cleary provided explicit definitions for the four main domains in the model, the domains of individual and environmental characteristics were not explicit (Bakas et al., 2012). Ferrans and colleague (2005) published a revision of the Wilson and Cleary's HRQoL Model (Diagram 2.2). The revised model of HRQoL retained the four main domains of the original model and, additionally, made, firstly, explicit definitions for the individual and environmental characteristics. They categorised the characteristics of the individual as demographic, developmental, psychological and biological (Ferrans et al., 2005) and for that they added an arrow from characteristics of the individual to biological function, whereas for the characteristics of the environment they categorised it as either social environment, including influence of family, friends, and health providers; or physical environment, including neighbourhood and workplace that influence health outcomes. Secondly, they simplified the description of the model by removing non-medical factors and labels on the arrows depicting the relationships in the figure. They point out that the arrows' directions can be reversed to show shared relationships and that the absence of arrows between framework levels does not suggest that relationships do not exist (Ferrans et al., 2005). This complexity allows for characteristics of the environment to influence characteristics of the individual, which can impact on HRQoL. This pathway is important because it signifies that a completely non-health-related factor, such as a lack of local entertainment, can influence the psychological component of characteristics of the individual, which can in turn affect the perception of overall quality of life.

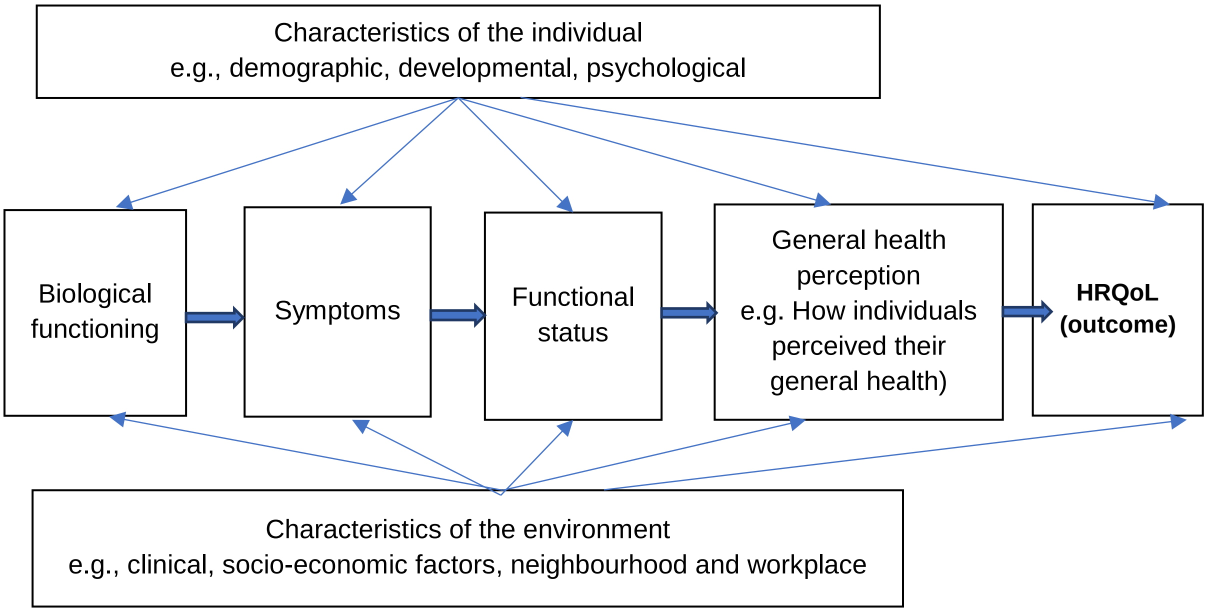


Diagram 2. 2 *Revised Wilson and Cleary Model of HRQoL by Ferans et al (2005)*

The inclusion of the main antecedents of life domains in a clear depiction of relationship to the HRQoL, as an outcome, empowered the model to become a holistic diagram for understanding patients' HRQoL. It may also provide a guidance in selecting the variables of this study which may influence patients' HRQoL. It is believed that using the model to guide this study would provide a rigorous approach to assessing HRQoL in the Omani context.

4. Discussion

This narrative review attempts to gain a general understanding of the QoL concept and to track its theoretical development. It is clear that QoL and HRQoL are multidimensional concepts and the ambiguity of the terms is possibly due to the different ways in which they are defined and the nature of the factors that influence these definitions. The concept of QoL is popularly used in general public life and is very much based on the positive meaning of the general term "quality". Even among the researchers and clinical experts, a wide range of definitions and interpretations of the term "QoL" exists. This has resulted in a trend for some researchers to mix the term with other concepts and employ interchangeable use of these concepts. Life satisfaction, health status and happiness are all examples of this.

Increased application of HRQoL measures to different diseases and populations has encouraged different responses equally from advocates and opponents of patient-based health-outcomes assessment. While the advocates view HRQoL measurement as necessary to make judgements about clinical intervention, opponents have argued that HRQoL lacks conceptual clarity and measurement feasibility (Hunt, 1997). As a result of such debate, developing relevant and accurate HRQoL measurements for use in research has resulted in the development of different measures. However, the utilisation of HRQoL measures has resulted in setting a clear need for a pragmatic priority known as the "construction of measures" (Hacker et al., 2013).

Although this debate has resulted in broad acceptance of HRQoL and has increased the number of studies published, the conceptual and theoretical foundation has put limits on its progress for a number of reasons. First, the normal epistemology order of theory, formulation and testing, with the goal of falsification and its continuing examination against alternative theories, has not been followed (Freestone et al., 2013). Most of the current assessments focus on measuring one perspective on HRQoL, which is group-oriented rather than individualised (Feeny, 2013). These reasons might limit the development of a coherent body of evidence to guide further HRQoL studies and practice.

Likewise, operationalising the concept of HRQoL can be challenging. The questions used to assess HRQoL should be stated within three main levels. These levels are: the instrument of measurement used, the study design and the statistical analysis (Sheetal et al., 2009). Most of the measures available in the literature focus on group-oriented or individual HRQoL assessment. The result of the assessment depends on the instrument of measurement used, the study design and how the results are analysed. It is recommended that the statistical methods used to compare respondents across groups should also be used to analyse individual-specific clusters of QoL statements. These, in addition, can again be compared with an individual's cluster (Feeny, 2013).

However, there are relatively important aspects of patients' lives that can vary over time and with changing circumstances, which may directly affect their level of HRQoL. What a person considers to be important depends on the particular stage of their life cycle and on other related personal factors. For instance, personal incidents and serious illness, such as chronic disease, often force individuals to reassess their lives and therefore the values to which one subscribes can lead to extracting as much meaning and enjoyment from life as possible (Taylor, 1989). Such significant changes in life circumstances may cause or induce temporary changes in life and, as people adapt to these circumstances, these becomes stabilised, reflecting the dynamic nature of QoL (Hagerty, Cummins et al., 2001). The shift from normal health status to chronic health status, as with ESRD, is accompanied by changes in their perceptions about themselves and others (Heiwe et al., 2003).

It is, therefore, crucial to understand the influencing factors that might enhance or hinder patients' HRQoL. Changes in life satisfaction throughout the course of life and across different groups of people need to be understood (Bailey et al., 2007). Unfortunately, there is no clear way to determine the extent to which the level of life satisfaction should be viewed as a stable dimension (Bailey et al., 2007). Individualised instruments, that report patients' satisfaction with their QoL, are supported by many researchers as the most appropriate approach to assessing overall QoL (O'Boyle, 1997; Beckie and Hayduk, 2004; Inglehart et al., 2013; Eckersley, 2013). They argue that satisfaction with QoL is essentially a cognitive assessment of an individual's progress towards desired goals. Hence, this PhD project should perhaps, initially, consider exploring the concept of QoL among Omani patients prior to measuring possible factors that might influence their QoL through using individualised QoL measures. This approach would provide a close insight first into the meaning of QoL among this group of patients.

The individualised QoL instrument could be helpful in examining QoL among rapidly changing societies (Becker et al., 2014). However, the disadvantage of individualised measures might possibly be that they rely on much time and effort. Because the respondents' concerns will be stated within specific aspects and addressed in depth, the researcher should then personally conduct an interview. This necessitates greater resources of time for researchers and participants when compared with self-completed instruments. Although O'Boyle et al (1992) were able to produce some comparative health data with individuals using the SEiQoL instrument, low practical feasibility remains the main potential disadvantage of this method of measurement as it is less easy to produce population-based competitive or normative data (O'Boyle 1994).

Likewise, it has been argued that self-reporting, or using individualised instruments to measure QoL per se, are influenced by participants’ mood, orientation and the timing of the measurement (Diener et al, 1999). Such influences indicate a social-desirability bias that arises from cultural norms. This can be seen in cultures that have traits of humility or self-aggrandisement towards one another. However, these influences were observed to have had a greater effect on overall QoL measurement than did the specific-aspects scores (Cicerchia, 1996; Lee et al., 2005), thereby providing a more detailed view of satisfaction within key life areas. It is not yet understood by cognitive psychologists exactly how the human brain integrates personal factors into an overall judgement of QoL (Kurpas et al., 2013). This is an area which may require more investigation.

Assessing individualised QoL, however, among a group of patients can be challenging due to the variance in thinking processes and the skills required to manage their life situations. Thus, the use of HRQoL measures alongside QoL measures could provide a wide assessment of a patient’s wellbeing. Perhaps a combination of three approaches to measurement (generic, disease-specific and individualised measures) could have the following effects: (a) it could provide an understanding of the causes and consequences of the difference in QoL among individuals and groups (Chang et al., 2005); (b) it could help to assess the impact of social and environmental factors related to QoL and HRQoL (Brutt et al, 2008; Krahn et al., 2011); (c) it could estimate the needs of a target population; and (d) it could help in forming clinical decisions (Greenhalgh et al., 2005). However, an important question that can be raised with regard to measuring QoL is whether the concept can be effectively measured with the same measures across different populations. Despite the availability of several measures designed to assess HRQoL, it has been argued that differences in health conditions and cultures are two important components (Barger et al., 1998; Moreira-Almeida and Koenig, 2006). Using a cognitive-debriefing method, for example, can be a helpful method in testing the readability of HRQoL measures among the target population.

The use of a combination of different measures to assess QoL and HRQoL, however, can be affected by the ability of participants to understand or interpret the questions of the measure. Although this is less of an issue with measures assessing concrete concepts such as alcohol consumption, it can be a significant problem when assessing more abstract concepts such as QoL and HRQoL (O'Connor, 1993). One of the methods presented by the literature that can be used to test the readability of or respondents' understanding of a measure is to use a cognitive debriefing method. Cognitive debriefing is a method used to test the readability of a measure among patients to determine whether participants are able to understand the items of the measure in the same way as the original would be understood (Tavernier et al., 2011). The method can be also used to determine if a translated questionnaire or a measure from original language can be deemed to be appropriate for the target population. Using the cognitive debriefing method in this project to test the readability of HRQoL measures by Omani ESRD patients would help in assessing their acceptance and understanding of the used measures.

To sum up, for the purpose of this PhD project, the definition of QoL by the WHO (1995) and the revised version of the HRQoL conceptual model of Wilson and Cleary by Ferrans et al (1995) can be recommended to guide this PhD project and also to provide a rigorous approach to assessing QoL in the Omani context.

5. Conclusion and recommendations

The majority of authors who conceptualise QoL and HRQoL have introduced the individual factor as a common criterion of QoL and HRQoL. Personal indicators describe individuals' feelings about whether they are satisfied with their well-being and whether they feel good about things in general. It is believed that these indicators exist in the consciousness of an individual and identifying the importance of them to an individual can only be known by asking the person to state them (Abellan-Perpifian and Pinto-Prades, 2005). Measuring personal factors, however, is difficult and is a subject that is always under debate due to its dynamic and individualised nature.

Most QoL researchers suggest that the number of aspects of life is less important when compared with the ability to recognise and represent individual needs. This element should be reflected by QoL frameworks to recognise the need for a multi-element framework and to realise that individuals know what is important to them. The essential characteristics of any set of life aspects is that they represent, in aggregate, the complete QoL construct (Schalock, 2004). Therefore, QoL aspects should be considered as the set of elements to which a variable is limited (Wiesmann et al., 2008), or, in other words, the range over which the concept of QoL extends.

The concepts that researchers depend on when measuring QoL and HRQoL are not theory-based, or at the very minimum are not based on a tested conceptual model. QoL and HRQoL are composed of personal, health, as well as socio-environmental, dimensions and these should be considered equally in any intended measurement of both concepts. Therefore, measurement should consider both personal perceptions and socio-environmental conditions. The Revised HRQoL conceptual model of Wilson and Cleary, by Ferrans et al (1995), can be used to clarify the aspects of HRQoL and the causal relationship between them.

The use of specific measures, including self-evaluation measures, is a helpful way of providing a comprehensive picture of individuals' perception of their lives. Generic QoL instruments assess global QoL, whereas specific measures of HRQoL assess the influence of a particular illness. They appear to be more sensitive to change over time and can be a better discriminator of differences between subgroups. However, this requires a more structured review to assess the related validity and reliability in any tested population. Additionally, the selected measures should be subjected to an acceptable method of psychometric testing.

Future researchers who examine HRQoL should consider that the terms “QoL”, “life satisfaction”, “functional status” and “wellbeing” cannot be used interchangeably because this causes confusion for both the researcher and the participants whose perceptions they intend to measure.

Cultural and language adaptations should also be considered and more cross-cultural research is needed to examine the relationship between QoL and cultural effects. This might include using individualised QoL instruments to explore the meaning of QoL across cultures. Likewise, using cognitive-debriefing methods to test the readability of HRQoL measures to targeted population would help in exploring whether the measures are acceptable and understood by them.

Given the breadth of meaning of QoL and health-related QoL and their underpinning factors, it was therefore recommended that an integrative review be conducted, focusing on QoL and HRQoL among ESRD patients and examining the levels, and predictors, of QoL and HRQoL in this group of patients. This review is presented in chapter three of this study.

Chapter-3: QoL and HRQoL in patients with ESRD Undergoing Haemodialysis (Literature review-two)

Background: The aims of this structured integrative review are to present and critically analyse the nature and significance of the predictors of QoL and HRQoL in patients with ESRD and to evaluate how these concepts are operationalised.

Method: the SCOPUS, Cochran Library, ProQuest (ASSIA) and EBSCO (CINAHL and Medline) were the main databases searched as well as secondary internet resources (ScienceDirect and PubMed. Selected articles were assessed for sample size, design, and methodological limitation. The revised Wilson and Cleary conceptual framework of HRQoL and WHO definition of QoL were used to guide this review.

Results: For this review, 124 articles were screened, out of which 45 articles were selected. Of the 45 studies, 36 were observational, cross-sectional studies and nine were prospective studies. Papers reported a wide range of factors related to QoL and HRQoL of patients with ESRD which were characterised as physical health, mental health, socio-economic, biological, and symptoms. Few studies looked at spiritual beliefs and cultural beliefs. There is a lack of consistency in the use of measures of QoL and HRQoL in ESRD. The most validated measures of HRQoL identified were the Short-Form 36v2 (SF36v2), Quality of life Index-Dialysis (QLI-D), Hospital Anxiety Depression Scale (HADS), Fatigue Severity Scale (FSS), Itch Scale (5-D Itch), Spiritual Wellbeing Scale (SWB), and QoL (The Schedule for the Evaluation of Quality of Life-Direct weighting (SEIQoL-DW)).

The majority of these studies were conducted within Western culture, with only two found that examined QoL and HRQoL aspects in ESRD patients in the Arab world. No studies had been conducted in Oman to assess QoL in this group of patients, or to assess how these patients perceived their QoL.

Conclusions: The possible measures of QoL and HRQoL for this project are health status, disease-specific, symptom-specific, spiritual life and individualised QoL measure. This set of measures is anticipated to capture patients’ own perceptions concerning their QoL and HRQoL.

1. Introduction

This review builds upon results from review-one (Chapter two) that was conducted to analyse the conceptual and theoretical issues associated with QoL in general as well as the related concept of HRQoL. Results indicated that QoL and HRQoL are composed of personal perceptions, health, as well as socio-environmental, dimensions and these should be considered equally in any intended measurement of both concepts. For the purpose of clarity, the term “QoL” refers to individuals’ perceptions of their position of life in relation to culture, goals, and expectations, whereas “HRQoL” is determined by the way in which changes in health- and treatment-related symptoms affect the dimensions of a patient’s well-being. Five aspects of life were identified to correlate the concepts of QoL and HRQoL, though mainly related to HRQoL. These aspects are: physical wellbeing, psychological wellbeing, spiritual wellbeing, cognitive wellbeing and social-environmental wellbeing.

End Stage Renal Disease (ESRD) is a serious, irreversible condition that has a profound impact on patients’ lives. It causes serious implications on different aspects of patients’ lives including physiological, psychological and socioeconomic status (Talas and Bayraktar, 2004; Trivedi, 2011). Although considerable progress has been made in treating ESRD patients and HD procedures, HRQoL remains a significant problem for haemodialysis patients (Cukor et al., 2013). The multiple physiological and psychological complications due to the disease and related treatment that dialysis patients may experience impair their life style which might change and subsequently lower their HRQoL level.

Literature reported several factors that contribute to and influence the level of QoL and HRQoL in patients affected by ESRD. Functional status, for instance, is usually limited in patients with ESRD including physical functioning, role functioning, social functioning, and mental functioning as a result of disease symptoms and treatment regimens (Coons et al., 2000). Studies that have used physical performance, health, and self-reported measures reported low physical functioning in patients with ESRD (Guney et al, 2010; and Morsch et al, 2005). Demographical and clinical factors, such as older age, lower socioeconomic status, malnutrition, are negatively associated with HRQoL in ESRD patients (Fidan et al, 2013).

Assessing health-related QoL and overall QoL, therefore, becomes a vital and often required part of health outcomes appraisal (Anderson and Burckhardt, 2003). Assessment of QoL and HRQoL for patients with ESRD, in particular, could provide a meaningful way to determine the impact of health care when cure is not possible. However, QoL and HRQoL are multi-dimensional and scattered concepts that have a significant impact on research exploring patient experience and practice (Berlim et al., 2006). Both concepts are composed of personal as well as socio-environmental dimensions and these two dimensions should be considered equally in any intended measurement.

The aim of this review, therefore, is to present and analyse the levels of and predictors of QoL and HRQoL in patients with ESRD and to examine how these concepts are operationalised. The approach used to answer the enquiry came through formulating focused search questions. These questions are:

1. What predicts QoL and HRQoL in patients with ESRD?
2. How are QoL and HRQoL operationalised in patients with ESRD?
3. What are the most common validated instruments used to measure QoL and HRQoL in ESRD patients?
4. How effective are the identified QoL and HRQoL instruments?
    a. How accurate are they at measuring the concept of QoL and HRQoL in ESRD patients?
    b. Do they measure what they are supposed to measure?

2. Method

2.1.Search strategy

A comprehensive search was made using several electronic literature databases accessed via the Library and Learning Centre website of the University of Dundee. The search was conducted in three phases: first, by accessing the topic-relevant internet database electronic literature databases [SCOPUS, Cochran Library, ProQuest (ASSIA) and EBSCO (CINAHL and Medline)]; second, secondary internet resources were consulted, such as ScienceDirect and PubMed; and finally, a retrograde search was made through citations from the articles already identified. EBSCO, which consists of CINAHL and Medline, was the initial database accessed as it is known to contain regularly updated evidence-based healthcare literature. All searches were done in the first half of April 2014 and updated by May 2017.

The literature search was not limited to any specific year of publication in order to screen most of the existing relevant evidence. English and translated articles from different languages were used in the search to include different populations in the review, thereby validating the generalisation of the results. The keywords used in the search were: (ESRD AND QoL OR ESRD AND HRQoL); ("QoL AND HRQoL AND predictors"); ("chronic kidney failure OR chronic renal failure AND QoL"); ("HRQoL AND QoL AND measurement"); (QoL AND HRQoL AND conceptualisation OR domains); ("QoL AND HRQoL AND ESRD AND operationalisation") AND haemodialysis.

Inclusion and exclusion criteria were used to produce the final literature to be appraised and discussed (Table 3.1).

Table 3. 1 Inclusion and exclusion criteria

Inclusion	**Exclusion**
Population Adult patients aged >18 years Patients affected by ESRD on HD Patients affected by ESRD on HD with post-renal transplant failure Study selection Articles assessing QoL and HRQoL among HD population Prospective studies measuring patient-reported outcomes Articles published in English	Patients affected by acute renal failure Patients who have had a kidney transplant or who are waiting for kidney transplantation Patients aged < 18 years Patients on peritoneal dialysis Critically ill patients on HD Articles published as general information, abstracts, dissertation, editorials, reports and clinical opinions

3. Results

The database search yielded a total of 4,319 publications with an additional 34 retrieved from secondary resources. The identified articles were screened against titles in order to match inclusion and exclusion criteria, which then resulted in the exclusion of 4,189 articles. Likewise, 164 articles were excluded due to duplication. A further four screening stages took place as follows. (1) the titles of the 4,189 articles were screened; 4,067 articles were excluded because they were irrelevant (22 were non-English language, 283 were discussion articles, 804 related to paediatrics and 2,958 were not related to HD). (2) A retrograde search was made through citations from the articles that were already identified and two articles were identified to provide a total of 124 articles to be reviewed. (3) Abstracts of the remaining articles were screened by three independent reviewers (the PhD student and the study supervisors), of which 79 appeared to be irrelevant (Excluded articles with reasons are shown in Appendix 3.1). The aim was to maintain a rigorous selection process and minimise selection bias. Agreement between reviewers was reached in 45 articles. (4) The full text of the remaining 45 articles was then reviewed, resulting in the inclusion of all these in this review. Figure 3.1 shows the flowchart of articles selection.

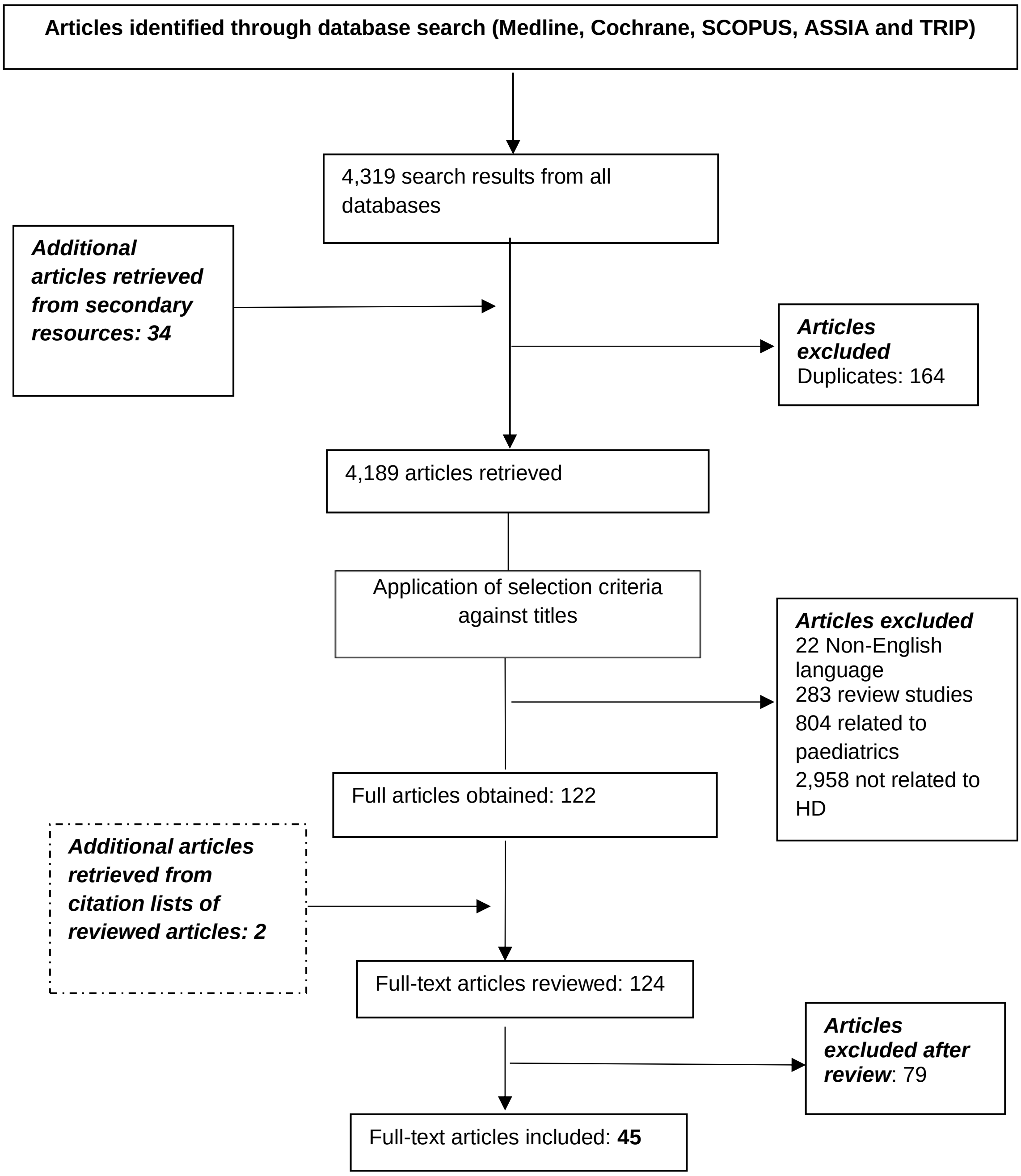


Figure 3. 1 Selection of articles flowchart

3.1.Characteristics of reviewed articles that study HRQoL

Twenty-seven papers studied HRQoL and QoL as the main outcome, 11 papers studied symptoms as the main outcome and seven papers studied validation and comparison of different HRQoL measures in ESRD. The quality of the reviewed studies was assessed using the quality appraisal form (Appendix 3.2) that was developed based on the Critical Appraisal Skills Programme (CASP) criteria. All the studies that met the inclusion criteria were used and no study was excluded because of its quality. The results of all studies are reported in tabular form based on the Joanna Briggs Institute (JBI) Data Extraction Form for Experimental/Observational Studies (Appendix 3.3).

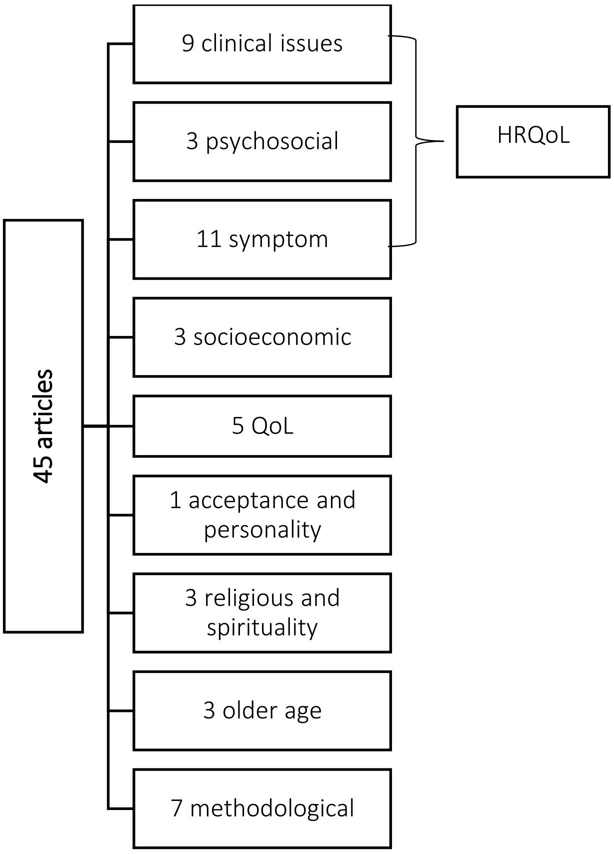


Figure 3. 2 Characteristics of identified studies

All papers were written in English and were published over a 15-year period between 1999 and 2017 (see Appendix 3.2 for the methodological characteristics of the 45 studies). Fourteen of them were conducted in North and South America between 1999 and 2014 (USA 5; Canada 2; and Brazil 7). In Europe, 10 studies were conducted from 2001-2013. In Asia, nine studies were conducted from 2000-2014. The lowest number of published studies was in the Middle East and Africa: Iran, four studies; Turkey, two studies; and Egypt, one study (in 2013). No studies were published that assess QoL or HRQoL in patients with ESRD in Oman. Although the Middle East and Africa recorded a lesser number (two articles) of published studies related to HRQoL compared with North and South

America and Europe, this suggests that there is a growing interest worldwide in assessing HRQoL and QoL in patients affected by ESRD.

3.2.Studied population

A total of 16,234 participants were involved in the observational and prospective studies and were defined as being ESRD patients undergoing maintenance haemodialysis. The study sample sizes varied between 40 and 800 patients in the 45 studies. Twenty-four studies had ≤202 patients (between 22-202 patients) and 21 studies had more than 202 patients (202-1,186 patients). The inclusion and exclusion criteria were clear and provided limitations for a specific group that received mainly haemodialysis (HD). However, in Rao (2000) and Abd El Hafeez's (2012) studies, the main outcome was to develop subscales from previously validated HRQoL instruments to assess their internal consistency reliability.

3.3. Design of studies

Of the 45 studies, 36 were observational, cross-sectional studies and nine were prospective studies. There were no randomised control trial studies identified. Of the nine prospective studies, the longest duration of data collection was three years by Unruh et al (2008) in their study of the influence of age on changes in HRQoL in patients undergoing HD. The shortest duration was one year, from January 2007 to 31 December 2007, by Tsai et al (2009) in their study of the relationship between QoL and the risks of ESRD and mortality in ESRD patients.

The survey, particularly the cross-sectional design, is the most commonly used method in studies that assess HRQoL in ESRD. This limits the ability of studies to identify causal relationships between the studied variables and HRQoL (Naik, N., et al, 2012).

Despite the appropriateness of the methodologies used by literature, there are a number of methodological limitations of studies identified that should be highlighted in this review. First, there is a limitation on methodological basis in ESRD research that can build a bridge between theory and practice, with only three articles using a theoretical framework for the research. Second, there is a lack of consistency in the definitions of QoL and HRQoL, which results in overlapping between the two terms, as well as with other concepts such as functioning health. Third, there is a lack of consistency measuring the aspects of HRQoL throughout the studies. Finally, there is a lack of consistency in the use of measures of QoL and HRQoL in ESRD. Despite these limitations, particularly in the Arab world, no study was excluded because of its quality.

3.4. Predictors of QoL and HRQoL in ESRD patients (answers search question-one)

The 45 studies included in this review reported a wide range of factors related to QoL and HRQoL of patients affected by ESRD. Although these factors may not reflect an individual's priorities, the literature indicates that ESRD patients have several QoL and HRQoL predictors pertaining to this disease (refer to Appendix 3.3). These factors and predictors have been congregated under relevant domains of the selected conceptual model that guides this study, reported in Review One–Chapter two, of The Revised Wilson and Cleary of HRQoL by Ferrans et al (2005), and supported by tables that summarise these factors and predictors, as follows:

3.4.1. Individualised characteristics

Evidence from observational studies found that some socio-demographic factors, such as women, older age, lower employment and marital status correlated with poorer HRQoL in ESRD patients (summarised in Table 3.2). For instance, female patients on HD consistently reported lower HRQoL when compared with men. Mujais et al (2009) reported that women, when compared with men, had lower physical functioning ($p < 0.0001$), role physical ($p < 0.0001$), pain ($p < 0.0001$) and general health ($p < 0.0001$). Similarly, women that had lower scores on role emotional ($p < 0.0001$), social function ($p < 0.0001$) and fatigue ($p < 0.0001$) associated with poorer HRQoL.

Age was reported to correlate with poorer results in most HRQoL measures (Fidan, 2013; Loos, 2003; Unruh, 2008). As the patients' ages increase, their HRQoL scores, particularly those of physical function, usually decrease (Loos et al, 2003). The association of age with HRQoL in ESRD patients is quite complex as age is a main factor linked with deterioration of QoL. Studies conducted cross-culturally have also demonstrated that age is strongly inversely associated with the physical function scores (Rambod, 2010; Weisbord, 2008). Patients on dialysis in southern Brazil reported that a younger age accounted for better physical component summaries within the SF-36 measure (β -0.16; 95% confidence interval, CI: -0.27 to -0.05) (Bohlke et al, 2008). This result was in parallel with Mujais et al's (2009) findings that physical functioning is lower in patients >65 years old (*p* < 0.0001).

Employment and marital status were associated with better HRQoL in patients with ESRD. Patients who are employed (β 8.4; 95% CI: 1.715.1) and are married or have a marriage-like relationship (β 4.56; 95% CI: 0.98.2) were shown to be predictors of higher mental component summary scores (Bohlke et al, 2008). Similarly, there was a statistically significant relationship between higher educational status and better functionality status (*p* < 0.05) (Oren and Enc, 2013).

Table 3. 2 Summary of results of studies of assessed predictors of HRQoL related to the demographic/individualised characteristics

Factor	Predictor	Quality of life parameters					
		PF	RP	P	GH	EWB	Health
Characteristics of the individual	Gender (female)	↓* [1]	↓*** [1,2]	↓*** [1,2]	↓*** [1]	↓*** [1,2]	
	Age (younger)	β -0.16					
	Age (older)					↑*** [2]	
	Marital status (married/partnered)				β= 0.174 [4]		^{a}β=0.161 [3]^{a}
	Educational status	↑ * [3]					

PF – Physical functioning; RP – Role physical; P – Pain; GH – General health; EWB – Emotional well-being.
↓ = Predictor associated with lower scores on the quality of life parameter
↑ = Predictor associated with higher scores on the quality of life parameter
* *p* < 0.05
** *p* < 0.01
*** *p* < 0.001
[1] Saffari et al, 2013; [2] Mujais et al, 2009; [3] Oren and Enc, 2013; [4] Bohlke et al, 2008; Notes: ^{a}β=0.174

3.4.2. Socio- environment and clinical factors

A group of socio-environmental and clinical factors were reported that could lower HRQoL in patients with ESRD (Table 3.4). Four studies (Rambod and Rafi, 2010; Bohlke et al, 2008; Kao et al, 2008; and Oren and Enc, 2013) indicate that the lower socio-environmental status of patients affected by ESRD is considered to be an actual burden (Table 3.3). Chronic dialysis imposes a substantial burden on patients and families and therefore the relationships of the patients with their family members could be affected. Kao et al (2008) report that increased social activities and high monthly income are associated with better HRQoL ($p < 0.05$), whereas social isolation and decreased social interactions are associated with worse HRQoL ($p < 0.01$). Similarly, Bohlke et al (2008) report that a result of the HRQoL was significantly correlated with perceived social support ($r= 0.72$, $p \leq .00$). In a study assessing the perception of social support and HRQoL in Iranian dialysis patients, results showed a statistically positive relationship between perceived social support and health-functioning ($r= .65$, $p \leq .05$), psychological-spiritual ($r= .63$, $p \leq .05$) and family sub-scales of QoL ($r= .51$, $p \leq .05$) (Rambod and Rafi, 2010).

The clinical factors reported that might predict HRQoL in ESRD patients were the length of time over which a patient has had HD sessions and dialysis treatment adequacy. The length of time over which a patient has had HD sessions plays an important role in levels of HRQoL of ESRD patients. The relationship between the duration of dialysis and the SF-36v2 subscales was found to be statistically significant and there was a negative relationship found between the duration of dialysis and the general perception of health ($r = -0.21$; $p < 0.01$). The scores on the general perception of health subscale decreased as the duration of dialysis increased (Oren and Enc, 2013). In parallel to this study, Hsieh and his colleagues (2007) made a similar observation that duration of dialysis treatment had a reverse correlation with HRQoL. It was observed that an increase of dialysis duration was associated with low QoL. As well, the overall score of QoL was observed to be better in HD patients who had experienced dialysis duration of less than eight months compared with patients with a dialysis duration of more than eight months.

Similarly, adequacy of dialysis is another factor linked to the improvement of HRQoL in ESRD patients. It is clinically measured by either the method of urea-reduction ratio (URR) or Kt/v. URR is a laboratory test that refers to the percentage of urea reduction in blood as a result of HD and the range should be around 70% or higher (KDOQI guideline, 2006). Cohen and Kimmel (2013) showed an association between social and emotional well-being domains of SF-36v2 and adequacy of dialysis. In their study specifically assessing doses of HD and QoL, they reported a positive increase in QoL by increasing the HD dose from Kt/V 75 % to 95%.

Table 3. 3 Summary of the results of studies that assessed predictors of HRQoL related to socio-environmental characteristics in ESRD

Factor	Predictor	Quality of life parameters				
		HF	PS	FR	OQoL	GH
Socio-environmental characteristics	Social support	↑ * [1]	↑ * [1]	↑ * [1]		
	Socioeconomic				↑ $^{a}\beta=8.4$ [2]	
	High monthly income				↑ * [1]	
	Duration of haemodialysis					↓ ** [4]
	Social activities				↑ * [3]	

HF – health functioning; PS – psychological-spiritual; FR – family relationship; OQoL – overall quality of life; GH – General health
↓ = Predictor associated with lower scores on the quality of life parameter
↑ = Predictor associated with higher scores on the quality of life parameter
* $p < 0.05$
** $p < 0.01$
*** $p < 0.001$
[1] Rambod and Rafi, 2010; [2] Bohlke et al, 2008; [3] Kao et al, 2008; [4] Oren and Enc, 2013
Notes: $^{a}\beta=0.174$

3.4.3. Biological function

Biological function can be an important determinant of HRQoL and includes the physiological processes that support life. It focuses on the performance of body cells and organ systems which can be measured by laboratory tests, physical assessment and medical diagnosis (Ferrans et al, 2005). Two biological factors retrieved from literature may impact on QoL in ESRD patients (Table 3.4):

a) Malnutrition is common in ESRD and severe malnutrition has been associated with decreased HRQoL (Laws et al, 2000). Laws reported that hypoalbuminemia (albumin <35g/L) influenced physical health negatively by affecting physical functioning (*p*< 0.02) and lowering overall general health (*p*<0.0001). Similarly, it influenced mental health negatively by impacting on emotional well-being (*p*< 0.05) and the emotional role (*p*<0.005). Low albumin has also been identified as a significant predictor of mortality (DeOreo, 1997; Lowrie and Lew, 1990). These findings emphasise the importance of using albumin serum as a measure in HRQoL studies.

b) Anaemia is measured by Hb and haematocrit, which has also been shown to impact on HRQoL in persons with ESRD. It is a condition that is significantly related to low HRQoL and is highly predominant in patients undergoing HD. It is associated with adverse clinical outcomes and diminished HRQoL (Bonner et al, 2013). The most common symptoms associated with anaemia are fatigue, dyspnoea and reduced sense of well-being (Joe et al, 2004; Jablonski et al, 2007). Hansen et al (2009) assessed HRQoL in clinic patients receiving comprehensive anaemia care and reported that anaemia severity (haematocrit <33%) was associated with poor physical role (*p*<0.001).

Table 3. 4 Summary of results of studies assessing predictors of HRQoL related to biological function

Factor	Predictor	Quality of life parameters							
		PF	RP	P	GH	EWB	SF	Fatigue	MH
Biological function	Anaemia	↓ (ES0.23) [2]	↓*** [1]	↓ (ES0.23) [2]	↓*** [1]		↓* [1]		↓ (ES 0.33) [2]
	Hypoalbuminemia	↓** [1]			↓*** [1]	↓*[1]		↓***[1]	

PF – Physical functioning; RP – Role physical; P – Pain; GH – General health; EWB – Emotional well-being; OQoL – overall quality of life; SF – social function; MH – mental health
↓ = Predictor associated with lower scores on the quality of life parameter
↑ = Predictor associated with higher scores on the quality of life parameter
* $p < 0.05$
** $p < 0.01$
*** $p < 0.001$
[1] Mujais et al, 2009
[2] Oren and Enc, 2013
[3] Bohlke et al, 2008

3.4.4. Symptoms

Symptoms including fatigue, pain, pruritus and difficulty with sleep exhibit a particularly high prevalence of depression and substantial impairments in QoL (Table 3.5).

Fatigue can be considered an obvious symptom burden and the most commonly reported symptom by individuals undergoing dialysis at a variation of prevalence of around 84% (Frank et al., 2003), 90% (Curtin, Bultman et al., 2002) 74% (Weisbord et al., 2003) and 86% (Norhayati Ibrahin et al., 2002). Fatigue has been defined as a subjective sense of weakness, lack of energy and tiredness (Stone et al., 1998) in patients with ESRD. Loos et al (2003) predicted that high fatigue might be associated with higher risk of cardiovascular conditions (hazard ratio: 2.17; p <0.01), having controlled for the well-known risk factors, including age, diabetes and cardiovascular diseases, inflammation and malnutrition indicators (Loos et al, 2003). Also, the comparisons of the risks in the main subgroups showed that the risk of high fatigue score for cardiovascular events was more significant in well-nourished patients, including those with an absence of past cardiovascular diseases, higher serum albumin and high non-HDL cholesterol (Koyama et al, 2010).

A correlational analysis showed that high bodily pain associated negatively with lower physical health (r = -0.56, p <0.001; 95% CI = -0.96-0.36) and mental health over time (r = -0.84, p <0.0001; 95% CI = -0.1-0.22) (Bonner et al, 2013). Equally, in a study that measured the prevalence of symptoms and their distress on patients affected by ESRD, fatigue and pain were rated as the most distressing to ESRD patients. Davison and Jhangri (2009) measured the impact of pain and fatigue on the HRQoL of HD patients using KDQoL-SF at baseline and after six months. The results indicated that fatigue was an independent predictor of physical HRQoL at baseline (r = - 1.78, p <0.001; 95% CI = -2.08- 1.48) and similar results were obtained after six months (r = - 1.84, p <0.001; 95% CI = -2.22- 1.47).

Uraemia is known as a predominant condition in ESRD patients and this is because urea is unlikely to be dialysable due to its molecular size and, as a consequence of raised urea levels, it can cause itching (Merkus et al, 2000). It is also augmented by itching which is again another constant problem in patients undergoing HD, resulting in high urea level and fluid imbalance (Mallick and Gokal, 2000). A study conducted in Hong Kong to explore the symptom burden and QoL of ESRD patients on dialysis, in comparison with a palliative care group, indicated that pruritus was associated with the most intense symptoms and correlated negatively with HRQoL domains ($p < 0.001$) (Yong et al, 2009). In this study, the scores of the SF-36 scale correlated negatively with the total number of symptoms in ESRD patients (physical functioning $r = -0.316$; $p < 0.001$, mental health $r = -0.350$; $p < 0.001$).

Patients who experienced pain reported significantly poorer QoL in relation to physical health, psychological health and level of independence when compared with individuals without pain (Soni et al, 2011; Kimmel and Patel, 2005). Davison and Jhangri (2009) measured the impact of the pain and symptom burden on the HRQoL of HD over six months and it was shown to be an independent predictor of physical HRQoL at baseline ($r = -0.74$, $p < 0.001$; 95% CI= -1.02, - 0.46) and after six months ($r = -0.59$, $p < 0.001$; 95% CI= -0.98, -0.19). The impact of the pain and symptom burden on mental HRQoL at baseline was $r = -0.76$, $p < 0.001$; 95% CI= - 1.04, - 0.48 and, after six months, $r = -0.87$, $p < 0.001$; 95% CI= -1.31, - 0.43.

Anxiety and depression were among the significant reported conditions that could reduce the QoL of patients affected by ESRD. Oren (2013) indicated that two-thirds of ESRD patients in Turkey had depression and found an association between depressed mood and HRQoL. In similar studies, Liu et al (2013) and Pakpour et al (2010) showed that ESRD patients suffered from depression in both studies. In a univariate analysis, the scores of depressed patients were significantly lower ($p < .0001$) in all the domains assessed by the Beck Depression Inventory measure (physical health, psychological health, social relationship, environment and overall QoL). However, after performing multiple regression analysis on the data, the QoL profile of depressed patients remained significantly worse (Berlim et al, 2005).

Table 3. 5 Summary of results of studies that assessed predictors of HRQoL related to ESRD symptoms

Factor	Predictor	Quality of life parameters						
		PF	RP	GH	EWB	SF	OQoL	MH
Symptom	Fatigue	↓*** [1,4]	↓*** [1,4]	↓** [2,3,4]				↓*** [1,3,4]
	Pruritus	↓*** [4,5]	↓*** [4,5]				↓*** [5]	↓*** [4,5]
	Pain	↓*** [4]						↓*** [4]
	Depression	↓*** [6]			↓*** [6]	↓*** [6]	↓*** [6]	
	Sleep						↓* [7]	

PF – Physical functioning; RP – Role physical; GH – General health; EWB – Emotional well-being; SF – social function; OQoL – overall quality of life; MH – mental health
↓ = Predictor associated with lower scores on the quality of life parameter
↑ = Predictor associated with higher scores on the quality of life parameter
* p < 0.05
** p < 0.01
*** p < 0.001
[1] Bonner et al, 2013; [2] Koyama et al, 2010; [3] Jablonski A, 2007; [4] Davison & Jhangri, 2009; [5] Young et al, 2009; [6] Berlim et al, 2005; [7] Nejad & Qlich-Khani, 2013

3.4.5. Functional status

Three studies (Fidan et al, 2013; Guney et al, 2010; and Morsch et al, 2005) indicate that physical functioning is usually limited in patients affected by ESRD (Table 3.6). This limitation is a result of disease symptoms and treatment regimen (Cleary et al, 2005; Pai et al, 2009). Fidan et al (2013) reported that physical functioning in ESRD patients may also depends patient's age, as patients aged 65 years or over had poorer functional status scores ($p < 0.05$).

Guney et al (2012) evaluated the mortality status of haemodialysis patients in a prospective study over five years and the association between mortality and HRQoL. Their results showed that surviving patients scored significantly lower than non-surviving patients in domains including functional capacity (p <0.001), physical role functioning (p <0.026), mental health (p <0.033) and total SF-36 score (p <0.001).

Table 3. 6 Summary of results of studies that assessed predictors of HRQoL related to functional status

Predictor	Quality of life parameters			
	PF	RP	OQoL	MH
Functional status	↓ * [1,2,3]	↓ * [1,2]	↓ *** [1,2,3]	↓ ** [1,2,3]

PF – Physical functioning; RP – Role physical; OQoL – overall quality of life; MH – mental health
↓ = Predictor associated with lower scores on the quality of life parameter
↑ = Predictor associated with higher scores on the quality of life parameter
* $p < 0.05$
** $p < 0.01$
*** $p < 0.001$
[1] Fidan et al, 2013; [2] Guney et al, 2010; [3] Morsch et al, 2005

3.4.6. General health perceptions

Perceptions of general health are considered to be central to an individual’s life experience and contain measurable aspects involving an overall assessment of any individual’s life (Schmitt and Jüchtern, 2001; Stanley and Cheek, 2003). In most studies, the cognitive appraisal of life experience, satisfaction and emotional reactions of individuals about their life events are integrated into the overall assessment of QoL. Such a combination of personal well-being, life satisfaction and emotional reactions to life events can all be seen as forms of subjective well-being which might present an “umbrella” term for different evaluations that individuals make about their lives, the events occurring to them and the conditions in which they live (Diener, 2006).

3.4.7. Spiritual wellbeing

Spiritual wellbeing was among the less reported factors that might affect QoL in patients with ESRD (Table 3.7). Ramirez et al (2011) examined the relationship between spiritual/religious factors in Christian patients affected by ESRD. They reported that spiritual/religious struggle is associated with depression ($r = 0.43$; $p < 0.0001$) and anxiety ($r = 0.32$; $p < 0.0001$) symptoms. Despite multivariate adjustment to clinical and socio-demographic variables, these associations remained significant, whereas, in contrast, positive religious coping was associated with a better overall HRQoL (0.17; $p < 0.02$) and better social relations (0.23; $p < 0.01$). Similarly, Saffari et al (2013) examined the relationships between spiritual, demographic and clinical variables and QoL among Iranian Muslims undergoing haemodialysis. Regression analysis revealed that demographics, clinical variables and particularly spiritual factors, explained about 40% of the variance in the results for QoL and approximately 25% of the variance in health status (Saffari et al, 2013).

Table 3. 7 Summary of results of studies that assessed predictors of HRQoL related to health perceptions in ESRD patients

Factor	Predictor	Quality of life parameters					
		PC	SS	DS	AN	OQoL	SR
General health perception	Psychosocial	(r = 65) [1]	(r = 38) [1,2]				
	Religious struggle			↑ *** [2]	↑ *** [2]		
	Positive religious coping					↑ ** [2]	↑ *** [2]

PC – perceived control; SS – social support; DS – depressive symptom; AN – anxiety; OQoL – overall quality of life; SR – social relations
↓ = Predictor associated with lower scores on the quality of life parameter
↑ = Predictor associated with higher scores on the quality of life parameter
* $p < 0.05$
** $p < 0.01$
*** $p < 0.001$
[1] Tovbin et al, 2002; [2] Ramirez et al, 2011; [3] Jablonski A, 2007

In conclusion, the main limitations of this literature are the lack of an explicit theoretical framework as well as the interchangeable use of the terms HRQoL and QoL. The summary of the common predictors of QoL and HRQoL have been identified in the literature and those that may contribute to explaining HRQoL in patients with ESRD are:

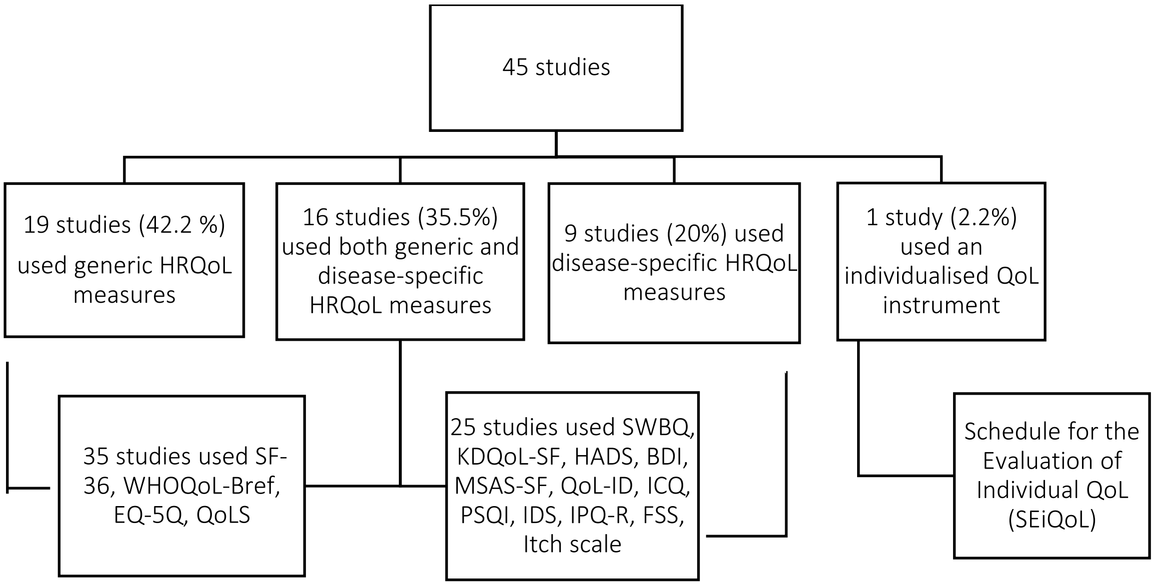
a) Individual characteristics: Age, gender, educational level, marital status, monthly income;
b) Biological factors: anaemia and malnutrition;
c) Clinical factors: length of time on HD, duration of HD session, time to reach HD;
d) Symptoms: fatigue, pruritus, pain, anxiety and depression;
e) Functioning status: ability to maintain-day-to-day activities;
f) Socio-environmental factors: social and family support, income status;

g) General health perception: a representation of the satisfaction level of all health concepts together;
h) Spiritual life: perception about existential need for wholeness and connection with the universe and ability to perform religious rituals.

3.5. How are QoL and HRQoL operationalised in patients with ESRD (answers search question-2)

Numerous measures, accordingly, were developed to examine the relationship between the aforementioned factors of HRQoL and patients' perceptions about their overall QoL as well. The developed measures can be characterised in terms of three continuums: 1) generic measures; 2) disease and symptoms-specific measures; 3) individualised QoL instrument.

Of the 45 studies reviewed, 15 different measures were identified that assess QoL and HRQoL. These measures, as with literature review-one, can be categorised as: 1) generic and health-outcome measures; b) disease-specific measures; and c) individualised QoL measures. Nineteen studies used generic/health measures; 16 studies used both generic and symptom- and condition-specific measures; nine studies used only disease- or condition-specific measures; and one study was found to measure QoL by using an individualised instrument. Figure five illustrates the number of studies using QoL and HRQoL measures and the most common validated instruments.



(SF-36v2): Short Form36 version 2; (WHOQoL-Bref): World Health Organisation Quality of Life-Bref; (EQ)-5D: EuroQol; (QoLS): Quality of Life Scale; (SWBQ): Spiritual Wellbeing Questionnaire; (KDQoL-SF): Kidney Disease Quality of Life-Short Form; (HADS): Anxiety and Depression Scale; (ESRD-SI): End Stage Renal Disease Severity Index; (IPQ): Illness Perceptions Questionnaire; (MSAS-SF): Memorial Symptom Assessment Scale Short Form; (QoL-ID): Ferrans and Powers Quality of Life Index-Dialysis; (ICQ): Illness Cognition Questionnaire; (PSQI): Pittsburgh Sleep Quality Index; (IDS): Fatigue Severity Scale (FSS) Index of Disease Severity; (IPQ-R): Revised Illness Perception Questionnaire.

Figure 3. 3 Number of studies using HRQoL measures

3.6. The most common validated instruments used to measure QoL and HRQoL in ESRD patients and their effectiveness (answer search question-3 and 4)

The accuracy and relevance of the identified measures were explored and evaluated against specific quality criteria of measurement properties. The criteria used for the evaluation of these measures were adopted from the Scientific Advisory Committee (SAC) of the Medical Outcomes Trust. It covers issues of validity, reliability, responsiveness, feasibility and cultural and language adaptation as well as the number of life domains covered. Appendix 3.4 summarises the results of psychometric qualities, feasibility and life domains covered pertaining to the identified measure. However, given the range of measures identified, and for the purpose of this study, the section below will classify and discuss the most common validated and appropriate measures to be used to assess QoL and HRQoL in ESRD patients in this study.

3.6.1. Health status measure

Short Form-36v2 (SF36v2) is a simple and effective health-related quality of life measure. The 36v2 is a 36-item measure assessing eight health concepts: physical functioning, social functioning, physical role limitation, emotional role limitations, bodily pain, mental health, vitality and general heath perceptions. These concepts can also be presented as two summary scores representing physical and mental health. The scoring range of the SF-36v2 is 0-100 for each of the eight domains. Zero indicates poor health status and 100 indicates very good health status. Its internal consistency, based on Cronbach's alpha, was >α 0.80 for most of the domains except social functioning (0.76) (Ware JR, 1992). This finding suggests that all domains are reliable for comparisons between groups of patients. The test-retest reliability showed a correlation coefficient over a two-week period (>.080) across all domains (Green et al, 2001; Morsch et al, 2006; Schell et al, 2013).

The SF-36v2 has been translated into many different international languages and is now considered the most frequently used generic health status instrument across the world (Bowling, 2005): among these languages are French, German, Dutch and Arabic. The method of administration of the SF-36 instrument can be self-completed or interviewer-administered (by face-to-face interview or telephone). The anticipated time to complete the questionnaire is around 10 minutes for most participants and 15-20 minutes for some elderly participants (Pakpour et al, 2010).

3.6.2. Disease-specific measures

The Quality of Life Index-dialysis (QoLI-D) is the version that was primarily developed by Ferrans and Power (1984) for use with dialysis patients. It consists of 68 items that measures four key aspects: health and functioning, social and economic, psychological and spiritual, and family. It consists of two sections assessing participant satisfaction and the relative importance of each aspect, respectively. Six-point ordinal response scales range from "very dissatisfied" or "very unimportant" (1), to "very satisfied" or "very important" (6). Its index scores range from zero to 30, where higher scores indicate a better quality of life (Bowling, 1995, p54).

A high range of internal consistency was reported on the QLI across three studies: Ferrans and Powers (1985) reported α 0.90, Ferrans and Powers (1992) α 0.93 and Tasy and Healsted (2002) reported α 0.88. The QLI concurrent validity was supported for each domain when compared with a life-satisfaction questionnaire with a correlation for the spiritual domain (Song et al, 2009). A computable response rate of 46% of patients through postal administration was reported by Ferrans and Powers (1992) in their later study. This rate was drawn from a large population of 394 HD patients. A higher response rate was reported by Killingworth and Van Der Akker (1996) in their study of measuring QoL of renal-dialysis patients using QLI (86% response rate from PD patients and 48% from HD patients).

The Ferrans and Powers QLI-D instrument has been frequently used to study HRQoL in ESRD patients (Joe et al, 2004; Cheung, 2012; Rambod et al, 2010). The QLI-D was used together with other HRQoL measures, such as SF-36, Index of Well-Being, KDQoL-SF and the Personal Resources Questionnaire (PRQ-85), in a renal-failure population with a positive factor analysis which confirmed the instrument’s construction. The QLI-D covers many dimensions important to an ESRD population, yet there are a few areas that are not covered, such as sleep, cognitive function and areas specific to treatment, such as length of dialysis time.

3.6.3. Symptom-specific measures

Several measures were developed to assess different symptoms related to ESRD. As mentioned earlier, fatigue, pruritus, anxiety and depression are the symptoms most reported by ESRD patients.

The Fatigue Severity Scale (FSS): is a nine-item scale measuring the severity of fatigue and its effect on a patient’s daily life activities and overall QoL. FSS items are scored on a seven-point scale with 1 = strongly disagree and 7 = strongly agree. The minimum score is nine and the maximum possible score is 63. The higher the score, the greater the fatigue severity. It is a self-reported measure and easy to administer. The FSS is reported to be valid as test-retest reliability was found to have an intraclass coefficient (ICC) of 0.91 and an internal consistency of α = 0.94 (Grace et al, 2006). Hagell et al (2006) reported an excellent reliability score of Cronbach's α 0.91. When the FSS test was used in a study with patients affected by Parkinson's disease in the treatment arm ($p < 0.04$), a reduction of 6.5 points in the FSS score was observed from an original score of 43.8 points at baseline (Cohen's $d = 0.79$).

Hospital Anxiety Depression Scale (HADS): HADS was developed by Zigmond and Snaith in 1993 as a quick way to assess symptoms of depression and general anxiety in non-psychiatric patients. It has 21 items in total and assesses anxiety and depression as separate components, each with seven items (Zigmond and Snaith in 1993). The advantage of HADS is that the items exclude somatic symptoms and therefore avoid symptom overlap between mood disorders and somatic illnesses (Harter et al., 2006). HADS is an easily administered questionnaire and takes around 5-10 minutes to complete (Scand and Caring, 2013). The internal consistency for HADS ranges from a Cronbach's alpha of 0.73 to 0.91; likewise, similar reliabilities have been found for the 14 items of the instrument (Martin et al, 2004). HADS shows high internal consistency with alpha coefficients of 0.86 and 0.91 in populations of psychiatric and non-psychiatric patients (Zigmond and Snaith, 1993). However, HADS scores can be easily exaggerated or minimised by the participants, as is the case in other self-reported questionnaires. Similarly, if patients are affected by physical illness, such as fatigue, HADS scores might become inflated and indicate other symptoms rather than those related specifically to depression.

The 5-D Itch**:** The literature revealed limited measures of pruritus in ESRD. The most frequently used quantifying measure is the visual analogue scale (VAS). Although VAS is considered adequate in measuring the severity of pruritus, it is a unidimensional measure and does not take into account the relative impact of pruritus on QoL. The 5-D Itch was developed as a brief and multidimensional measure that can detect different aspects of pruritus as well as changes over time. As its name indicates, it consists of five items that measure five dimensions: the degree of pruritus and its duration, direction, disability and distribution (Elman et al., 2010). The first four items are measured on a five-point Likert scale, while the fifth item has four sub-items that can be scored to provide a sum equal to the other four. The scores of each of the five items are achieved separately and then added together to obtain a total score. The overall scores can potentially range between 5 (no pruritus) and 25 (most severe pruritus). The 5-D Itch scale is reported to be valid as test-retest reliability was found to have an interclass coefficient (ICC) of 0.89 and an internal consistency of $\alpha = 0.73$ (Elman et al., 2010). Khan et al (2013) found that the reliability of the five aspects of the 5-D Itch indicates the practical applicability of the measure with inter-correlation of 0.847 ($p < 0.05$).

3.6.4. Individual QoL instrument

Limited tools were reported that measure individual QoL. SEIQoL-DW can be considered as an innovative measure as it attempts to capture the individual nature of QoL. Unlike many other instruments of QoL and HRQoL, SEIQoL-DW is based on an underlying theory of what makes up QoL from an individual's own perspective and on his/her own perception and understanding of QoL (Kolewaski, 2005).

With regard to the psychometric quality of SEIQoL-DW, the internal consistency cannot be assessed as SEIQoL-DW is a profile measure where each of the listed areas/domains by a patient is considered distinct and related only to that particular patient. For test-retest reliability, Ruta et al (1994) reported a Pearson's correlation of 0.70 over a two-week period. In a more recent evaluation, Loos et al (2003) reported that some elderly patients incorrectly interpret scoring instructions (intraclass correlation coefficient = 0.55), which might reduce the reliability assessment. Content validity is also specified by each individual patient, thus confirming validity for each patient. However, for construct validity, SEIQoL-DW was able to discriminate between patients at different stages of renal failure. The possible limitations of this instrument are that illiterate patients cannot express themselves clearly unless assisted by someone else, while the list of possible affected life domains is limited to five areas.

3.6.5. Religious and Spiritual measure

The review identified a number of measures that that assess some aspects of spirituality in ESRD patients. However, the Spiritual Wellbeing Scale (SWBS) is deemed as an appropriate measure for this study as it assesses spirituality, religiousness, and existential concerns in ESRD patients. It contains 20 items of which 10 assess existential wellbeing and 10 religious wellbeing. Daaleman and Frey (2004) reported significant correlations with other QoL instruments that measure well-being and spirituality: the Zung Depression Scale ($r = 0.42$, $p < .001$), the General Well-Being Scale ($r = 0.64$, $p < .001$) and the Spiritual Index of Well-Being (SIWB) ($r = 0.62$, $p < .001$). Additionally, they reported a total scale of $\alpha = 0.91$ and a test-retest result of $r = 0.79$, showing very good reliability.

In summary, various HRQoL measures, such as generic and disease-specific instruments, were used in ESRD studies. Health measures were the most commonly used to evaluate different aspects of health: physical, psychological and social as well as perceived well-being, with the SF-36v2 being the most commonly used. Similarly, disease- or condition-specific measures evaluate the particular symptom or condition that might be associated with the level of QoL. These measures are available in several languages, such as English, Dutch, Chinese and Arabic. However, demographic and clinical factors have also been shown to have an impact on QoL in ESRD patients. Yet there were fewer research studies found that considered assessing HRQoL and QoL by using a combination of generic, disease-specific and individualised measures. It is believed that using such a tripartite approach (generic, disease- or condition-specific and individualised measures) in assessing the quality of life of patients affected by ESRD would help in understanding the overall sense of well-being of this particular population.

4. Discussion

The heterogeneity of the participants in most of the studies included in this review is problematic regarding the generalisability of its findings to patients affected by ESRD in Oman. There is a concern regarding the composition of the samples in many of the studies as most of the participants were male. Ultimately, this makes the generalisability of these findings to other groups of ESRD patients, and to those from different cultural backgrounds, questionable, as in the case of Omani ESRD patients. Furthermore, the majority of the reviewed studies did not clearly state the encountered confounding factors. Confounding factors could interact and negatively affect measurement of the outcomes. However, some studies indicated that the tackling of confounding factors came through limiting the following covariates: type of dialysis (HD or Peritoneal dialysis); age; patient condition, such as diabetes, depression and hypertension; gender; and common laboratory tests such as albumin and haematocrit (HCT) (Billington et al, 2008; Fidan et al, 2013; Brekke et al, 2014). In contrast, Cleary (2005), Morsch et al (2006) and Hayashino et al (2009) used a statistical matching technique to minimise confounding factors and compromise the factors that estimated the study outcomes. Factors that should be considered when replicating HRQoL studies or generalising the results were found to be: type of dialysis; increased acceptance rate for dialysis of elderly patients; patients affected by serious comorbid diseases; and an increased case mix increasing the difficulties of measuring the QoL of patients on maintenance dialysis.

The review showed that socioeconomic, functional, psychological, clinical and biological factors describe HRQoL in ESRD. Equally, they demonstrate a growing interest in assessing the perceived HRQoL and QoL in this group of patients. All the included studies that have been carried out reached the same conclusion, that ESRD patients have a poorer generic and disease-specific HRQoL. Yet the studies are not clear about which areas of HRQoL are most affected. The lower level of QoL among ESRD patients could be related to the complications associated with disease (Phillips et al., 2001; Patel et al., 2002; Weisbord et al., 2003), clinical factors, socioeconomic factors, and demographic factors.

The term “HRQoL” was more dominant than the overall term “QoL” in literature. Few authors, however, interchanged the use of the QoL and HRQoL terms (Bakewell et al., 2001; Drayer et al., 2006; Morsch et al., 2006). Farquhar (1995), Oort et al (2005), Debout (2011), LA-Placa et al (2003) defined QoL and HRQoL according to self-reported health status and functioning status. These studies, however, did not attempt to define the concept of QoL and HRQoL, or at minimum, clarify the areas associated with QoL and HRQoL. Without clear definitions of QoL and its delineated aspects, conceptual clarity can still be achieved through the use of a conceptual framework or theory (Cortina, 1993). Out of the 45 studies reviewed, only three studies provided a theoretical foundation.

Despite that, the measures used to assess QoL and HRQoL were proven relevant according to the reported psychometric-qualities results. Most of the researchers acknowledged that there were difficulties in determining whether the measures used measured QoL exactly. This is possibly due to the absence of a consensus or gold standard for the meaning of QoL. It is indeed a challenge to determine whether any measures of QoL and HRQoL tap into the intended aspect of any one individual’s experience (Lee et al, 2009). There is also the possibility of variation between the standardised QoL measures and the patient-perceived QoL instrument, which adds a further limitation to the measurement of QoL. Possible reasons for this potential disconnect might be cultural differences, coping mechanisms and patient values. Using a more individualised measure of QoL would perhaps allow and advise patients to select areas of their life that they view as being most relevant to their own well-being (Ferri and Pruchno, 2009).

Likewise, selecting a measure of QoL can be difficult because of the extensiveness of the concept of QoL. The measure should provide an inclusive view of most of the life aspects that might influence QoL in patients affected by ESRD. The disease-specific measures are helpful for researchers as they provide a better focus on functional areas of a particular concern (Glover et al, 2011). Although instruments that measure a specific condition/symptom or disease appear attractive for use in clinical practice and research as a screening instrument to identify a symptom’s severity, they are limited in their scope for measuring broader areas of life aspects (Fryback et al, 2010). Using a generic measure could provide a broader view on the overall aspects associated with QoL. But again, this is unlikely to show the real benefits of specific interventions which demand a use of disease-specific measures. To overcome this, there should be a balance in capturing the aspects, based entirely on the patient’s own perceptions, impacted upon by the disease in a patient’s life and in his or her overall aspects of life.

In spite of the fact that the majority of studies that examine QoL and HRQoL have been conducted within a Western culture, a limited number of studies are available examining QoL and HRQoL aspects in the Arab world. These studies showed a low HRQoL among Arab patients affected by ESRD, with a significant score variation evident within the different subdomains of HRQoL that were assessed (Abd Elhafeez et al, 2012; Al-Jumaih et al, 2011). A possible reason for this variation could be the specificities of each country in terms of social and cultural life, economic status and level of healthcare services. Thus, the determinants and influencing factors of QoL and HRQoL are likely to differ among patients within different countries (Bergland, 2007).

In Oman, there is hardly any evidence of previous assessment of the QoL and HRQoL in ESRD patients. Great consideration is needed when determining the most appropriate measures that will capture the different aspects of QoL within Omani context. It is believed that using the revised Wilson and Cleary model of HRQoL to guide this study would provide a rigorous approach to assessing HRQoL in the Omani context including aspects of biological function, symptoms, functional status, general health perceptions and various characteristics of the individual and the environment. This can be achieved, as one approach, through the use of: 1) a generic measure to capture aspects related to overall quality of life; 2)a kidney disease-specific measure to help in measuring aspects related entirely to ESRD patients which would also gather the clinical-related factors; 3)an individualised QoL measure to help in exploring how Omani ESRD patients perceive the meaning of QoL; and 4)a spiritual and religious measure to assess patient’s relationship with God and sense of their life purpose.

It is believed that assessing the perceptions of this patient group in Oman would increase the general understanding of how to improve their QoL and of how to support the shift of healthcare services from episodic treatment to a treatment that meets their ongoing needs.

5. Conclusion and recommendations

ESRD is a chronic condition that causes a great negative impact on patients' HRQoL mainly due to the accompanied impairment or to the imposed limitations in almost all aspects of their life. Numerous studies have examined QoL and HRQoL in patients with ESRD. The majority of these studies have mainly focused on health-related QoL. Also, no studies have been found that use a comprehensive perspective on analysing aspects of biological function, symptoms, functional status, general health perceptions and various characteristics of the individual and the environment as one approach. This narrow conceptualisation may have left a gap in the understanding of QoL and its influencing factors in patients with ESRD.

Most of these studies were conducted within Western culture, with only two found that examined QoL and HRQoL aspects in ESRD patients in the Arab world (Abd El Hafeez's et al., 2012; Abdel-Kader et al., 2009). The results of these studies showed a low HRQoL among ESRD patients including Arab patients. As with Arab countries, no studies were found that had been conducted in Oman to assess QoL in this group of patients, or to assess how these patients perceive their QoL. As a result, there is a need to explore the concept of QoL within the Omani context prior to describing and measuring the levels of factors of QoL and HRQoL. The individualised QoL (SEIQoL-DW) is a suggested instrument can be employed to explore the perception of Omani ESRD patients. SEIQoL-DW instrument can reveal areas of life not typically included in standardised measures, generic and disease and symptom-specific, but designated as relevant by the patients.

The most frequent measures that were valid and utilised to measure QoL and HRQoL in patients with ESRD were identified and evaluated against specific quality criteria of measurement properties. Therefore, the possible measures of QoL and HRQoL in ESRD patients for this project are related to health status, condition or disease-specific, symptom-specific, and religious/spiritual life. Although suggested measures are available in the Arabic language, they have not been tested and validated within the Omani context. Exploring patients' understanding of the suggested measures is crucial. Hence, cognitive interviewing method can be used to explore patients' interpretations of the measure's items, elaborate on their responses and report any difficulties they might have in answering these items (Beatty & Willis, 2007). It also helps and guides in modification and improvement of the measures.

Chapter 4- Methodology

This chapter presents the theoretical framework that was used to guide this study, study design, sampling, and procedures for data collection including the measurement used as well as clinical setting. The data analysis plan of the three phases of this study is also described. Finally, data management, and the plan of risk assessment that was placed to anticipate potential risks to the project are discussed.

1. Introduction

End-stage renal disease (ESRD) is a serious and chronic disease that negatively impacts patients' HRQoL mainly due to the accompanied impairment or to the imposed limitations in almost all aspects of their lives. Despite the considerable progress which has been made in treating ESRD patients and HD procedures, HRQoL remains a significant problem for haemodialysis patients (Cukor et al., 2013). Numerous studies using different measures have examined both the concepts of HRQoL and overall QoL in patients with ESRD and have revealed that the multiple physiological and psychological factors that patients may experience could impair their life style which in turn might change and subsequently lower their QoL level.

Treating ESRD and its related treatment might consume large amounts from the health budget. The determination of successful health outcome for patients with ESRD has been limited to clinically-focused measures including HD adequacy, acceptable laboratory values and intradialytic management (De Geet and Moons, 2000). Alternative outcome measures of the efficacy of provided treatment and HD are therefore required (Brekke et al., 2014). This seems to be through assessing HRQoL which could be included when health care professionals assess the benefits of different ESRD treatment options. This however might not be sufficient because dialysis patients may not experience satisfaction with their HRQoL despite physiological measures being met. Thus, more subjective, patient-focused, disease-focused measures are needed to enhance the health outcome assessment for patients on HD.

Most of the studies that assess QoL and HRQoL among ESRD patients were conducted within Western culture, with only two studies (Abd Elhafeez et al, 2012; Al-Jumaih et al, 2011) found within Arab countries. The results of these studies showed low scores of HRQoL among Arab patients with ESRD. Similar to Arab countries, no studies were found that had been conducted in Oman to assess QoL in this group of patients, or on how these patients perceive their QoL. Also, no studies were found that have used the approach of assessing the biological function, symptoms, functional status, general health perceptions, and various characteristics of the individual and their environment. Even with studies that used more than one measure of QoL (Saffari et al, 2013; Green et al, 2001; Ramirez et al, 2012; Griva et al, 2009; Kao et al, 2009; Cleary et al, 2005) the researchers did not articulate a holistic conceptual framework to guide their study, providing little justification of the independent variables used to explain QoL. This study is needed to fill these gaps in knowledge.

Accordingly, three different phases were employed to answer the research questions. Phase one (Chapter Five) explored the meaning of QoL to an Omani population, using a cognitive interviewing and a measure of individual QoL. In the second phase (Chapter Six), the practicality of the study measures were piloted and tested within the Omani ESRD population. This phase also assessed the feasibility of the third phase (main study), informed the sampling size, assessed the likely success of the proposed recruitment approaches and identified possible logistical problems. This third phase (Chapter Eight) involved conducting a large cross-sectional study to determine the factors that affect QoL and HRQoL in patients with ESRD, and investigating the associations between symptom burdens and physical, psychological, clinical and socio-demographical factors.

2. Philosophical paradigm, research approach, and theoretical framework

For the purpose of conducting this study objectively and systematically, the Research Onion Diagram by Saunders et al. (2009) was adapted and followed (Diagram 4-1). This diagram illustrates the steps of the research process which was followed to produce valid and replicable data. It consists of philosophical paradigm; selected study method; selected study design; determined time horizon according to the study; and planned data collection procedure and analysis.

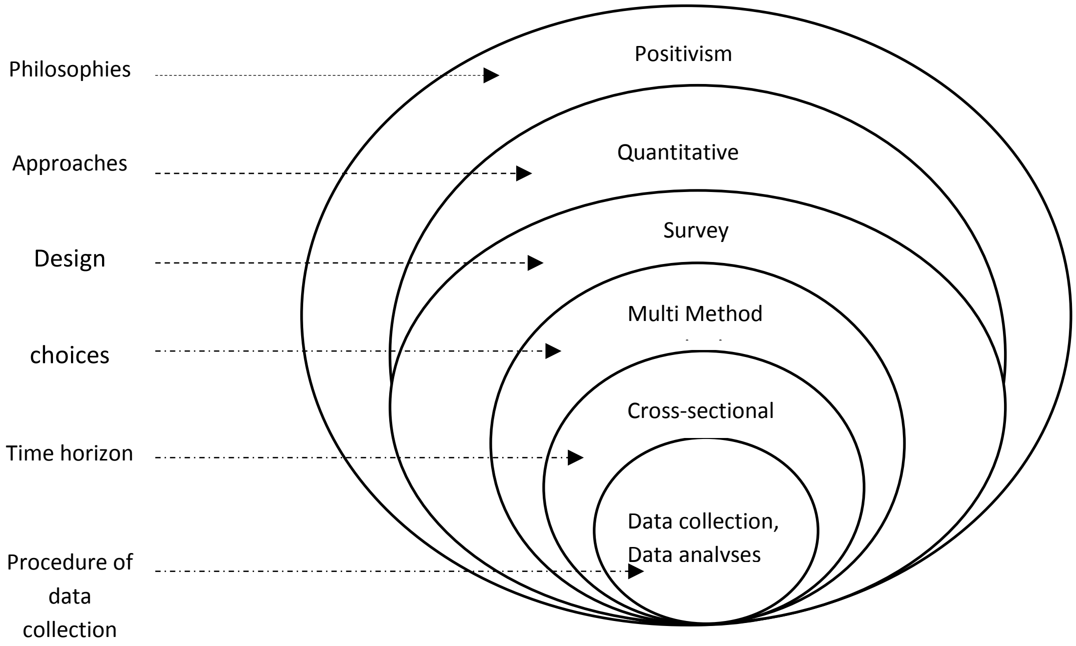


Diagram 4. 1 Research Onion Diagram (adapted from Saunders et al. 2009)

2.1. Philosophical paradigm and research approach

The term paradigm refers to the roadmap that directs a research journey (Black, 1999). Different philosophical paradigms are available that represent different ideas about reality and how knowledge can be gained (Black, 1999), such as positivism, realism and pragmatism. These paradigms include specific methodological strategies which allow researchers to use the research approach and method, and to recognise any limitations that might disrupt the research (Broom and Willis, 2007). For this study, the positivist paradigm was adopted based on the assumption that nature is basically ordered and has antecedent causes (Sapsford, 2007) as is the case with perceived low HRQoL which can be caused by more than one factor.

Quantitative research assumes that phenomena are stable and can be predicted, thus, they can be measured (Matthews and Ross, 2010). The outcomes of this PhD study such as physical health, mental health, symptoms, and even spiritual life, can be measured, therefore, the quantitative approach was considered appropriate for this study to find the frequency and association between factors. In healthcare research, quantitative approach is an essential part and most the common method (Sapsford, 2007). It is a good approach to minimise bias and also to maintain an objective view while studying a phenomenon to develop valid results (Matthews and Ross, 2010).

2.2. Conceptual framework

A conceptual framework could act as a heuristic device to provide a better understanding and clarity of QoL and HRQoL. It also can help in specifying research concepts, and selecting the appropriate measurements for testing these concepts. The revised version of Wilson and Cleary's (1995) model for health-related quality of life (Ferrans et al., 2005) was used to guide this study. This conceptual framework incorporates important health-related factors, as well as individual and environmental characteristics which address the difference between the clinical reported outcomes and the patient reported outcomes. These health-related factors are biological functioning, symptoms, functional status, and general health perception. A summary of all the study variables are combined and shown in Diagram 4.2.

Biological function includes the physiological processes that support life (Ferrans et al, 2005). This describes the patient's biophysical status as a result of the ESRD condition in terms of the status of anaemia and malnutrition. The symptoms experience is the patient's perception of the presence of physical and emotional problems that reflect the severity of their symptoms (Wilson and Cleary, 1995). Although functional status is usually influenced by biological function and symptoms, it is important that it is measured as a separate variable because it may not be completely correlated with biological function or with symptoms. Two aspects of functioning were measured in this study: (1) physical functioning and (2) psychological functioning using the SF36v2 measure. Socio-environmental characteristics were defined as the perceived family, socio-economic and spiritual life, from a patient's perspective, and their influence on the patient's health. For this study, the characteristics of the family and socio-environmental variables were measured by the subscales of QoLI-dialysis.

As the religious and spiritual domain appeared to be important within an Omani context, it was essential that it be tested as a separate variable in this study. It refers to the affirmation of an individual's life in relation to God, self and community (Johnson, Piderman et al, 2007). It falls very much in line with patients' personal values and the spiritual beliefs that shape their lives. Thus, the spiritual wellbeing variable will refer to a patient's sense of wellbeing in relation to God and to a patient's perception of life's purpose and satisfaction.

General health perception is considered to be central to patients' health, a representation of all health concepts together, and contains measurable aspects involving an overall assessment of any individual's life (Schmitt and Jüchtern, (2001); Stanley and Cheek (2003). The cognitive appraisal about health, and emotional reactions of patients about their life events are integrated into the overall assessment of HRQoL. Such a combination of personal well-being, life satisfaction and emotional reactions to life events can all be seen as a subjective well-being which might present an 'umbrella' term of different valuations that patients make regarding their lives, the events happening to them, their bodies and minds, and their circumstances in which they live (Diener, 2006). General health perception is most commonly measured with a single global question, indicating an overall health rating on a Likert-type scale from poor to excellent.

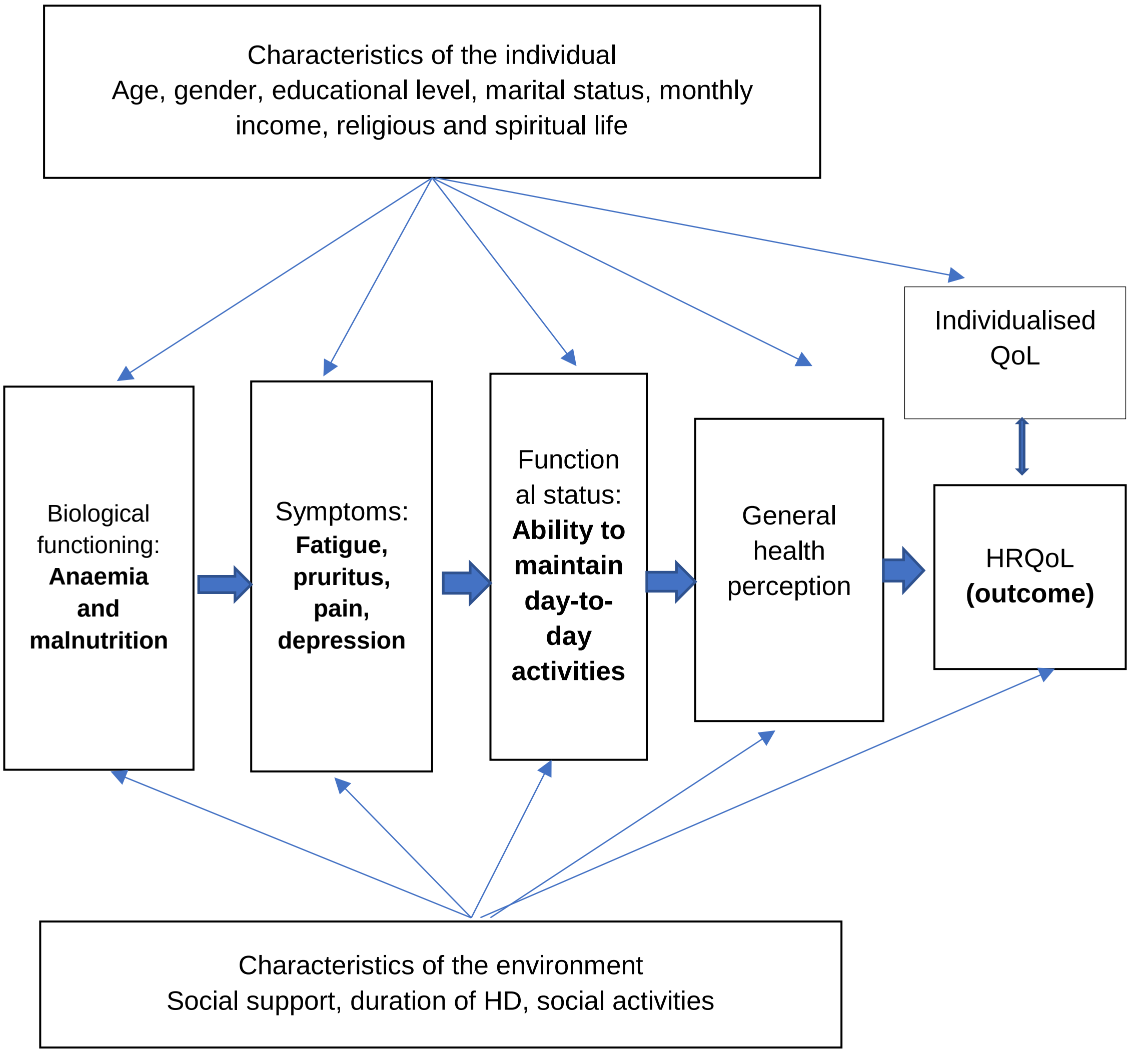


Diagram 4. 2 Summary of factors that may contribute to explain HRQoL in patients affected by ESRD

The components of this conceptual model acknowledge that health exists on a continuum from simple to complex outcomes with four determinants, each having multiple variables (Peterson and Bredow 2009). These determinants, as well as overall quality of life, are ultimately affected by the characteristics of the individual and the environment (Ferrans et al., 2005; Kring, 2008). Further details on the level of the revised version of Wilson and Cleary's (1995) model for HRQoL (Ferrans et al., 2005) are in Chapter Two.

3. Research Methods

3.1. Study Design

This non-experimental study used a cross-sectional, correlational design to explore and assess QoL and HRQoL and to identify its related predictors regarding Omani patients with ESRD. Given that no studies were found that had been conducted in Oman to assess HRQoL in this group of patients or on how these patients perceive their QoL, it was essential to use a design that allowed for, firstly, the identification of the factors and patients' perception that made up their HRQoL/QoL at a specific point in time. The use of cross-sectional design in this study provided data that may reflect the entire Omani population as data were collected across the country. However, the concept of HRQoL is considered dynamic (Pastrana et al., 2008) and cross-sectional design might be limited in capturing dynamic factors. That is, the concepts of and factors influencing HRQoL are dynamic and could change over time depending on one's perception. In the context of this study, and because the study is not examining the changes in QoL and HRQoL over time, a cross-sectional design was deemed appropriate and data were collected at one point in time from patients to examine their level of QoL and HRQoL as well as related factors. It is also believed that the benefit of employing a cross-sectional design is to describe the status of phenomena or the relationship among phenomena (Polit & Beck, 2008).

The correlation design was used to examine the association among study variables.

3.2. Population

3.2.1. Inclusion criteria

The characteristics of patients included in all three phases were: adult patients with ESRD receiving HD; those aged ≥ 18 years; and those who have been on HD for at least three months so that they are adjusted to life on dialysis.

3.2.2. Exclusion criteria

Patients who did not survive on HD longer than three months; patients with acute renal failure; patients aged under 18; patients diagnosed with dementia or any other condition that could impair their ability to answer questions; patients who have recently been diagnosed with cancer; and patients who have recovered their renal function.

3.2.3. Sample size

Phase one sample size was informed by literature that used the cognitive interviewing and individual QoL instruments method in data collection as well as studies using individual QoL measures (Tavernier et al., 2011; McGee et al., 1991; Becker et al., 2014). An average of eight to 15 participants is considered applicable. Accordingly, it was planned for 16 patients to be approached and interviewed during their waiting time before starting their routine HD sessions.

The target sample in **Phase two** was 50 participants in total, during their presence for HD, at a rate of 15 patients from Site 1, 15 patients from Site 2 and 20 from Site 3. Based on the response rate obtained from phase one, 60 patients were approached to avoid any inaccuracy in the list as patients sometimes stop HD for transplants or from personal preference. Participants from phase one were excluded from this phase by excluding their names from the randomisation list.

The statistical analyses in **Phase three** required the calculation of a sample meeting the assumptions of factor statistical analysis and sequential multiple regression analysis. Thus, in order to perform the planned statistical analyses a sample size of 448 is needed.

4. Ethical approval and data management

The study was conducted in accordance with the ethical approval granted by the University Research Ethical Committee (UREC) at the University of Dundee (UoD)-UREC 15060 (Appendix 4.1.a), the Directorate of Research and Ethical Review and Approve Committee, Ministry of Health, Oman, MH/DGP/R&S/PROPOSAL_APPROVAL/16/2015 (Appendix 4.1.b).

It was expected that no potential risks would occur and that any risk of physical or psychological harm was at a minimum level because this study did not involve any clinical interventions. Also, there was no risk of social or economic harm because the participants who took part in this study did not travel to take part, as they were recruited during their regular attendance at HD.

The researcher ensured that patients had complete autonomy to decide whether or not to participate without any pressure being applied. They were informed that their participation was entirely voluntary and they could withdraw from the study at any time without negatively affecting the treatment or care they received. The confidentiality of the participants was preserved throughout the study and participants were reassured that interview content was kept confidential and would be used for study purposes only without identities being mentioned in any documents related to this study.

Participants were informed verbally and in writing, using the information sheet approved by both ethical committees. For patients who could not read, the information sheet and consent form were explained verbally. Participants were required to sign the consent form and for those who could not write, an available witness was required to sign instead. The witness had to be a family member (husband, wife, sister, brother, or close relative such as a cousin).

Confidentiality was maintained on all data-collection forms by using codes to identify patients instead of names or any other personal identifiers. The main list of patients’ names was kept separate from the data-collection forms. This list was used during the data-collection period to ensure that patients were not recruited twice.

Collected data, including digital recordings and transcripts of interviews, are stored in a locked filing cabinet for a period of 10 years as per the University of Dundee data-protection policy, after which they will be destroyed. All the data will be accessed only by the researcher.

The data-management process was ensured in compliance with The Research Council Royal Decree (No. 54/2005) and the Directorate of Research and Studies, Ministry of Health, Oman, and with the Data Protection Act 1998, as required by the University of Dundee, UK. Participants were notified of this in the information sheets.

To empower the ethical part of this study, the researcher has undertaken a master-level research course for one academic year prior to commencing the study. Also, continuous professional development sessions, seminars and conferences were attended, including Good Clinical Practice (GCP) training to gain the necessary skill to carry out this study (GCP is the ethical and practical standard to which all clinical research is conducted in the UK). The study-monitoring supervisors were well qualified researchers who have published extensively.

5. Data Collection Process

5.1. Measurements

Seven measures and an individualised QoL instrument were used to collect the data (appendix 4.2.a – 4.2.h):

1) Background data sheet
2) Short-Form 36v2 (SF36v2)
3) Quality of life Index-Dialysis (QLI-D)
4) Hospital Anxiety Depression Scale (HADS)
5) Fatigue Severity Scale (FSS)
6) Itch Scale (5-D Itch)
7) Spiritual Wellbeing Scale (SWB)
8) The Schedule for the Evaluation of Quality of Life-Direct weighting (SEIQoL-DW).

Further details of these instruments and its psychometric qualities are discussed in Chapter Three of this thesis.

- *Background data sheet*

For this study, the variables that determine the characteristics of the individual are: age, gender, educational level, monthly income, region and marital status that might influence health outcomes. A background data sheet was used to collect the patients' characteristics. This sheet was developed based on the structured reviews (chapters 2 and 3) conducted among ESRD patients. Data relating to marital status, educational level, current employment status and income status were collected from the patients themselves, as this data is not usually recorded on patient file. All socio-demographic data were classified according to the Oman norm, using the National Centre for Statistics and Information, Oman (2016). These data are detailed as follows: the category for marital status (single, married, widowed, divorced); level of education (illiterate, low-intermediate, intermediate, high-intermediate, high); employment status (employed or unemployed); and income, measured in Omani Rials (OMR), One Rial = £2.00 (< OMR 250/month; OMR 250-600/month; OMR 601-1000/month; OMR 1001-1500/month; OMR >1500/month).

The treatment characteristics factors related to HD prescription which might affect patients' HRQoL were collected by the background data sheet. The determinants of treatment characteristics are: time since starting HD in months; time to reach HD in minutes; duration of HD session in hours; and adequacy of HD. The adequacy of HD is measured by the urea-reduction ratio which measures the reduction in blood urea in percentage as a result of HD and the effectiveness of HD treatment in removing waste products from the body.

Biological function (haemoglobin, albumin, haematocrit levels). Biological function can often be measured by the lab tests of Hb, HCT and Albumin. The normal range values of these investigations are adopted from The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (2007).

- *Short-Form 36v2 (SF36v2)*

It consists of 36 items that make up eight health domains: physical functioning, social functioning, physical role limitations, emotional role limitations, bodily pain, mental health, vitality and general heath perceptions. The scoring range of the SF-36 is 0-100 for each of the eight domains, zero indicating poor health status and 100 indicating very good health status. As there is no Omani study that has used the SF-36v2 to establish a norm-based standard of comparison between patients with ESRD and normal individuals, a cut-off score of a mean of 50 and a standard deviation of 10, suggested by Ware et al (2008), was used. That is, any score above or below 50 (standardised score) can be considered above or below the population's average health status for that domain.

Two subscales of the SF36v2 were also used independently to measure:

a) Bodily pain (BP) which refers to the unpleasant sensory and emotional experience associated with ESRD and its related treatment. The BP subscale consists of two items, one of which assesses the rating of the severity of bodily pain during the past four weeks. Its response choices range from "none" to "very severe". The second item assesses the level of bodily pain's effect on/interference in daily life activities including in-house and out-house activities. The total scores of both items are reverse scored, that is, the higher value indicates less bodily pain.

b) General health perception which describes patients' perceptions of their overall health status (Wilson and Cleary 1995). It is a one item subscale asking patients to rate their general health on a five-point scale ranging from 1 = "excellent" to 5 = "poor".

- *Quality of life Index-Dialysis (QLI-D)*

Quality of Life Index **–** Dialysis version (QLI-D) was used as a disease-specific measure of ESRD and consists of 68 items (14 items are disease-specific and four items are related to dialysis treatment). For each pair of items, the first item asks the degree to which patients are satisfied with an aspect of their life and the answer is measured on a six-point Likert-type scale (1 = very dissatisfied, 6 = very satisfied). The second item asks the level of importance of that aspect of their life and this is likewise measured on a six-point Likert-type scale (1 = very unimportant, 6 = very important). The pair of items are finally added together to produce an overall score.

- *Hospital Anxiety Depression Scale (HADS)*

HADS was used to test mood symptoms, anxiety and depression. It consists of 14 items; seven items related to anxiety and seven related to depression, forming two subscales (HADS-A and HADS-D). Responses are measured on a four-point Likert scale, from 0-3, with 0 representing no symptoms and 3 representing the presence of symptoms related to anxiety or depression. Each subscale is summed up separately providing a sum of 21, and the overall score can be obtained by adding up subscales, providing a sum of 42. The possible scores range are 0-6 normal, 7-10 mild, 11-14 moderate, and 15-21 severe (Zigmond and Snaith, 1983).

- *The Fatigue Severity Scale (FSS)*

Fatigue is defined as extreme and persistent tiredness and weakness that patients experience due to ESRD (Pawlikowska et al., 1994). It is measured by the Fatigue Severity Scale (FSS) that measures the severity of fatigue and its effect on patients' daily life activities and overall QoL. These items are scored on a seven-point scale with 1 = strongly disagree and 7= strongly agree. The minimum score is nine and the maximum possible score is 63. The higher the score, the greater the fatigue severity.

- *Itch Scale (5-D Itch)*

The 5-D Itch Scale was used to assess itching in a brief, easy-to-complete, easy-to-score format that is sensitive to the multidimensional nature of pruritus and its effect on HRQoL. The scores of each of these five items are calculated separately and then added together to obtain a total 5-D score. Scores can possibly range between 5 (no pruritus) and 25 (most severe pruritus).

- *The religious and spiritual wellbeing measure (SWB)*

SWB has 20 items, with 10 items to reflect religious wellbeing (RWB) and 10 items for existential wellbeing (EWB). The RWB subscale contains the word “God” – “Allah” in the Arabic version – to assess the patients’ relationship with “God or higher spiritual power” in whatever sense is meaningful to them. The EWB contains no specific religious terms and is instead worded in terms of connection and general satisfaction to assess the patients’ sense of life purpose and life satisfaction. Items are scored on a Likert-scale from 1-6 with a higher number reflecting higher wellbeing. The SWB scale produces three scores: 1) a global SWB score; 2) a score for the religious-wellbeing subscale; and 3) a score for the existential-wellbeing subscale.

The SWB overall scores range from 20 to 120, with 20-40 considered low spiritual wellbeing, 41-99 moderate, and 100-120 high spiritual wellbeing. The scores of religious and existential wellbeing subscales range from 10 to 60, with 10-20 considered as low, 21-49 moderate, and 50-60 high religious and existential wellbeing (Bufford et al., 1991).

- *Individualised QoL instrument*

The Schedule for the Evaluation of Quality of Life-Direct weighting (SEIQoL-DW) was used to assess patients’ own perspective on, and perception and understanding of, QoL (Kolewaski, 2005). It assesses three elements of QoL by asking patients to: a) first nominate five aspects of life they value most; b) rate their functioning/satisfaction level with each aspect of life; and c) rate the importance of each aspect of life in judging overall QoL.

5.2. Overview of clinical settings

In **phase one**, data collection took place in the Nizwa Dialysis Unit. This unit is located in central Oman and is one of the largest dialysis units. There are around 73 patients regularly attending out-patient HD.

In **phase two,** three HD units were involved. These units were located in: a) northern Oman (Sumail Dialysis Unit, Site 1), central Oman (Nizwa Dialysis Unit, Site 2) and western Oman (Ibri Dialysis Unit, Site 3) to provide a representative sample across Omani culture and to test the feasibility of the main study.

In **phase three,** 13 HD units across the Sultanate were involved. These units provide routine HD for out-patients affected by ESRD from a variety of regions and are managed by the Omani Ministry of Health (MOH). The MOH provides HD therapy for a total of 1,381 registered patients with ESRD (Annual Health Report, 2016, Oman). These patients have varied socio-economic, cultural and educational backgrounds and are likely to provide a representative cross-section of the population, thus allowing generalisation of the study results.

5.3. Recruitment process

5.3.1. Data collection assistant

To assist with conducting phases two and three of the study, nurses from all study sites were recruited and trained to administer the study measures and to apply research ethics principles. Initially, the researcher approached dialysis-unit managers to explain the study with the ethical-approval letter and the participants' information sheets, and also to recruit nephrology nurses to assist in the study. The intention here was that the unit managers would circulate the recruitment request to nurses. The nurses who expressed interest in assisting the study were asked to indicate this to their managers who in turn informed the researcher to approach these nurses. To avoid the possible risk of a low recruitment rate for nurses assisting in the study, an advertisement strategy for the study was considered through posters and presentations including an inclusive description and explanation of the study aims, inclusion criteria and methods of data collection.

Training on measures administration was provided to the recruited nurses by the researcher to ensure efficiency in conducting this procedure (Appendix 4.3). It was stressed to nurses that participation in the study was voluntary and that patient care should not be affected in any way. In addition, the participation information sheet contained the number of the “complaints call centre” so that patients could use it in case any coercion occurred during their participation in the study.

They were also trained in correct data-management procedures to maintain confidentiality. The training session took the form of a practical introduction and consisted of a series of short lectures interspersed with practical activities. Topics covered included: the aims and objectives of study, patient recruitment, obtaining a consent form, and method of questionnaire administration. Subsequently, each research assistant was observed in a simulated data-collection session by the researcher and then both researcher and assistant simultaneously collected data from two patients before the research assistant was able to administer the measures independently. The recruited nurses were not directly responsible for the outcome of the study.

5.3.2. Identification of participants and data collection procedure

Patients were identified from the National Renal Registry of patients treated with ESRD in Oman. This registry records registered patients affected by ESRD based on a numerical identifier, contact information, medical history and updated lab results and is organised in a logical and systematic fashion. The authorisation to access the registry was based on the letter from the Directorate of Research and Ethical Review and Approve Committee, Oman.

Phase-one comprised a semi-structured interview process to test the validity of the concept and to explore the understanding of QoL within Omani patients with ESRD. For this phase, patients were approached by the researcher in the allocated waiting area for their regular HD sessions. An explanation about study objectives and an information sheet was provided (Appendix 4.4.a). Patients had

48 hours in which to indicate their interest in participating in the study to the researcher, who was physically available in the dialysis unit when they arrived for their next session, and sign consent form (Appendix 4.4.b). For patients who agreed to participate, an interview venue and time were decided based on the participant's preference. All the interviews were audio-recorded with the patients' permission and the recordings included the administration process of the individualised QoL instrument and the interactions between the patients and the researchers during this process.

Data in this phase were obtained in two ways:

1) A cognitive interviewing method was used to explore the cognitive and sociocultural processes associated with answering the HRQoL measures. Data were collected in a semi-structured interview and transcribed based on the "think-aloud" technique – patients are asked to think out loud while completing the measure – and the "verbal probing" technique in which the researcher searches for potential problems and explores the basis of the participant's answers within the course of the interview (Willis, 1999). The question appraisal system (QAS), a coding form of probed interviews (Willis, 2005) was used to record the process (Appendix 4.5). Patients were asked to complete each measure exactly as normal, but also to "read aloud" each item and to "think aloud" their thoughts as they responded to these items. After each interview, field notes and audio recordings were reviewed to identify any potential problems with the measures so that any issues could be addressed.

2) An individualised QoL instrument (SEiQoL-DW) was administered to identify the aspects of life that Omanis value in relation to their QoL and to measure the current satisfaction with these aspects. SEiQoL-DW was administered in a form of a semi-structured interview, in which the researcher first introduced QoL as an individually defined construct, then asked the patients to nominate their own five most important aspects of QoL. Patients were asked to think about which aspects of life determined their own happiness, or QoL, and then nominated aspects were rated numerically.

Phase-two comprised a pilot study to: a) test the acceptability and practicality of use of the SF36v2 and QoLID within Oman; b) test recruitment, participation and feasibility to ensure that any variations in the research design were effectively managed; and c) identify issues of concern for the main study; for instance, whether the allocated time for field work was enough to recruit a large enough sample for the main study.

Applying inclusion and exclusion criteria, 60 (10% of the sample size for the main study) patients were selected randomly using the “RANDOM” function in the Excel programme (Field and van Belle, 2002; Julious, 2005). A patient-information sheet (Appendix 4.6.a) that explained the purpose of the pilot study, the advantages and disadvantages of participation, the expected duration of participation and the researcher’s contact details was provided to eligible patients who were then approached by nephrology nurses during their attendance for regular HD to obtain consent forms (Appendix 4.6.b) and to respond to study measures.

Patients were asked to complete the study measures before starting their HD session. However, if data were to be collected during the HD session, 60 minutes were allowed before data collection began. This gap in time was designed to prevent any possible errors that might occur, as patients might experience cognitive changes due to fluid and electrolyte shifts.

Using the National Renal Registry, patients in **Phase three** were identified based on an opt-in strategy from 13 dialysis units across Oman. Those who agreed to participate were identified by nurses who were recruited and trained by the researcher to assist in obtaining consent forms, administering the questionnaire package, following up and collecting the completed study questionnaires. These were then stored in a secure box provided by the researcher. As with phases one and two, patients were given 48 hours to decide on their participation so that, when they attended their next HD session, they could indicate their decision to nephrology nurses and sign the consent form (see Appendix 4.6.b).

6. Data Analysis

6.1. Phase One

Data obtained from the cognitive interviewing process were analysed using a matrix-based method of data analysis proposed by Knafl et al., (2007). The matrix illustrated items in a tabular form in which items appeared in a row and patients appeared in a column. The issues identified with were entered into the appropriate intersecting cells, promoting systematic analysis and decision-making regarding item revisions. The matrix-display approach was then used to construct item summaries, linked to all the participating patients, including a coding scheme to reflect problem types specific to each item tested. The findings were then aggregated across all patients, producing a summarised item-by-item analysis of the results associated with the SF-36v2 and QoLI-D.

Data obtained from SEiQoL-DW were presented in a tabular form for each patient including the nominated aspects of life, their levels and weights. The levels of each elicited aspect of life were measured by asking the respondents to draw five bars on the "Levels Record Form". Levels were then scored by measuring the vertical height of each bar in millimetres, using a roller. This produced five scores, which were independent continuous measurements, ranging from 0 to 100, whereas the measuring of the weights of elicited aspects of life was achieved by asking patients to quantify the importance of each aspect, represented by five differently coloured areas of a disc weighing system which was produced by the SEiQoL-DW developers specifically for this purpose. The disc consisted of five interlocking laminated circular discs of different colours on a percentage base which could be rotated independently. Each disc was labelled with one of the cues elicited by the respondent. The weight of each aspect was divided by 100 since the weights, when calculating the SEiQoL-DW Index, range from 0.00-1.00. This was so that the overall SEiQoL-DW Index could be calculated by multiplying the level by weight of each aspect and then adding these products across the five aspects [SEiQoL Index = $\sum$ (levels x weights)].

6.2. Phase Two and Three

6.2.1. Screening and cleaning data

Collected data were entered into the SPSS software and doubled-checked to avoid any possible errors. Initial analysis outputs were checked for missing, invalid and extreme values that might have fallen out of the range of normal possible values. The nominal and categorical data were inspected by running frequency tables, while continuous data were inspected by running descriptive statistics. The frequency and descriptive tests outputs were checked to correct any errors before starting data analysis. Missing data and extreme values of categorical variables were checked visually by observing frequencies in output tables.

Missing data is one of the pervasive problems in data analysis. Tabachnick and Fidell (2014) pointed out that the pattern of missing data is more important than the actual amount missing. The common pattern of missing data can be characterised as either missing completely at random or missing at random (Tabachnick and Fidell, 2014). The missing at random can be considered less serious and almost any procedure for handling missing data produces similar results (Tabachnick and Fidell, 2014). Since the missing data in current study were in random pattern, it was managed by using the individual mean substitution method when missing values were not significant or ≤ 10%. If they were more than 10%, then the affected scale/subscale was excluded in related analyses (Tabachnick and Fidell, 2014). Means were calculated from available data of that particular participant and were used to replace missing values as it is considered the best guess about the value of that variable. The main advantage of this method is that it is conservative in the way that the mean for the distribution as a whole does not change and therefore is not required to guess at missing values.

6.2.2. Computing scales scores

Following data cleaning and missing-data replacement, five measures – Short form 36v2 (SF36v2), Hospital Anxiety Depression Scale (HADS), Fatigue Severity Scale (FSS), Itch-5D and Spiritual Wellbeing Scale (SWB) – were computed and a syntax was created using the SPSSv22 programme. For the Quality of Life Index-Dialysis (QoLI-D), the syntax developed by Ferrans et al

(2005) was used to score the QoLI-D and its four subscales. This was developed specifically to fit the SPSS programme. It should be noted that the scores of the bodily-pain scale are reverse scored: the higher the value, the less the bodily pain.

6.2.3. Checking data normality and outliers

Data normality were checked by running a frequency distribution for each variable and if data-normality assumptions were violated, data were transformed by using square root, logarithm and inverse function, respectively. Outliers were checked by Q-Q Plot. Multivariate outliers were inspected by running standardised residual values, and if greater or less than 3.0, values were categorised as an outlier (Tabachnick and Fidell, 2007). Where presented, outliers were handled by being rescored or deleted or by creating separate regression models. Data linearity was checked using scatter-plots to illustrate differences between each of the independent variables compared with the dependent variable.

6.2.4. Statistical analysis procedures

Descriptive analysis

The SPSS (Statistical Package for the Social Sciences) software (Version 22) was used to compute the frequency for nominal and categorical variables, and mean and standard division for continuous variables. The Pearson product correlation coefficient (r) was conducted to assess the relationship between two parametric variables and the Spearman's rank order correlation (rho) was used to assess the relationship between non-parametric variables.

Reliability

To test the reliability of measures within the Omani context, a Cronbach's alpha was computed to examine the internal consistency of the SF36v2 and HADS measures. Cronbach’s alphas, as indicators of internal consistency, were computed for each item and the whole scale. DeVellis (1991, p.85) and Nunnally and Bernstein (1994) suggest 0.60 and above as an acceptable reliability coefficient since smaller reliability coefficients are seen as inadequate. This value was used since the aim of reliability test is to measure a trait with enough accuracy to establish the existence of a relationship with other traits.

Factor analysis

Exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) tests were performed to explore the factor structure underpinning the mood measure (HADS) and health outcome measure (SF-36v2). The “Mplus” statistical software version 7 (Muthen and Muthen, 1998) was used for these analyses. To perform this test, the ratio of 4-10 cases per item was the rule of thumb employed (Tabachnick and Fidell, 2014). Among the study measures, QoLI-D has the highest number of items (64). Thus, for QoLI-D, around 7 cases x 64 items = 448 participants and this total was deemed sufficient to provide a reliable factor structure.

EFA was done on the 14 items of HADS to explore the best fit among the Omani ESRD patients. Likewise, an EFA series was carried out to explore a range of possible factor structures (from 1-8) on the 35 items of SF36v2. The best structures to come out of EFA were verified by conducting CFA. The approach used to determine and retain the number of extracted factors was eigenvalue (>1) and visual investigation of scree plot (against which the eigenvalues were plotted). The weighted least squares (WLSMV) method, chosen for factor extraction, was selected on the basis that this approach is particularly useful in extracting at least one factor indicator of categorical variables (Muthén et al., 1997). The oblique and orthogonal factor rotation procedures were used to determine the best fit between variables and latent factors. The determination of a significant item-factor loading was set at a coefficient level of ≥.30 (Tabachnick and Fidell, 2007).

The best factor structure identified from HADS and SF36v2 was then verified by CFA. The parameters used to assess the fit of the CFA models were as follows: the chi-square ($\chi 2$); the comparative fit index (CFI); the Tucker-Lewis Index (TLI); and the root mean square error of approximation (RMSEA), plus the Chi-Square Test of Model Fit for the Baseline Model and the Weighted Root Mean Square Residual for the Bi-Factor Model (WRMR). The adequacy of the model fit is considered when: the chi-square is less than 2 or 3 (Kline, 1998; Ullman, 2001); the RMSEA is below 0.08 (MacCallum et al, 1996); the CFI is greater than 0.95 (Hu and Bentler, 1999); the TLI is over .90 (Hu and Bentler, 1999).

Regression analysis

The nature of this study, predictive correlational design, along with the nature of the study questions guided the selection and use of sequential multiple regression. It is a statistical method, sometimes called hierarchical regression, in which independent variables are entered cumulatively according to a prior specified hierarchy which is based on the purpose and logic of the research (Polit and Beck, 2008). The strength of sequential multiple regression is that it adds to the researcher's understanding of the concept being studied since it requires thoughtful input by the researcher in determining the order of entry of independent variables and yields successive tests of the validity of the concept which determine that order (Tabachnick and Fidell (2014).

However, there is no one way recommended for the order of entry of study variables into a sequential regression equation. It can be based on logical or theoretical consideration. For instance, the independent variables that are perceived/presumed by the researcher to be causally prior are given higher priority of entry. For example, in the current study, demographical variables were considered prior to the biological variables in predicting HRQoL and accorded a higher priority of entry (Cohen and Cohen, 1983). On the other hand, important variables can also be entered on later steps, with lesser importance given higher priority for entry in that they were entered first. Finally, after all the variables are entered, summary statistics are provided along with the information available at the last step. Thus, the order of entry of study variables into the sequential regression models was based on the sequence of the study questions, and the literature reviews underpinning this study.

Using the BM SPSSv22, three main sequential multiple regression analyses were conducted to test the predictive value of the demographic, treatment, clinical, socio-environmental, symptoms, functional status and general health perception on HRQoL in patients with ESRD: SF36v2 physical component summary–PCS (Two-factor standard model); 2) SF36v2 mental component summary–MCS (Two-factor standard model); 3) QoLI-dialysis; and 4.a) SF36v2–PCS (Three-factor model), SF36v2–MCS (Three-factor model), and SF36v2–Role-functioning component summary–RCS (Three-factor model).

Six of the nominal variables in this analysis (gender, marital status, education status, job, monthly income, and region) required dummy coding prior to being entered into the model. These variables were coded as dichotomous variables (Munro, 2005) according to the most frequent response obtained from respondents. The order of entry of study variables into the sequential regression models was informed by the order of the study questions, the literature reviews underpinning this study and the result of the pilot study conducted in phase-two.

A ratio of cases-to-independent variables is suggested by Tabachnick and Fidell (2007) to test the overall fit of the model (R2): $N \geq 50 + 8m$ (m is the number of IVs) and to test the contribution of each IVs variable to explain dependent factors: $N = 104 + m$. There were 22 IVs in this study and the minimum required sample sizes were 226 to test the overall fit of the model and 126 to test the individual independent variable. These sample-size suggestions were based on detecting a medium effect size β =0.20 with α = or <.05 with a power of 80% (Tabachnick and Fidell 2007). Therefore, a sample size of 451 was considered sufficient for developing four main regression models.

Next, all independent variables were correlated with each other and checked for multi-co-linearity. In the case of two variables correlating at 0.85 or higher, one variable was eliminated from the regression analysis. When all variables were examined together, the tolerance level and variance inflation factor of all IVs were calculated to determine multi-co-linearity. A tolerance value <0.10 and a variance inflation factor >10 was used to identify multi-co-linearity for possible elimination of variables (Mertler & Vannatta, 2002).

A Mahalanobis Distance was computed for each case to detect any extreme multivariate outliers and, once that was done, the Mahalanobis scores were screened in the same manner as the univariate outliers. Hence, frequency distributions were run for each variable and examined for outliers. In addition, multivariate outliers were detected through “standardised residual” values >3.0 or <-3.0. Outliers would either be rescored or deleted, or separate regression models were created (Tabachnick and Fidell, 2007).

All variables were checked for data distribution (multivariate normality, linearity and homo-scedasticity) by visually examining standardised residual scatterplots. Violations of any of the assumptions for multiple regression usually reveal a different scatterplot shape. In case any assumptions were violated, data were transformed in an attempt to stabilise the variance and to achieve linearity and normality (Polit, 1996).

The statistical significance for a variable inclusion into a statistical model was set at $\alpha = .15$ (Tabachnick and Fidell, 2014). This determined liberal probability level was to avoid excluding important variables from the model. Independent variables were entered simultaneously into a sequential multiple regression model to determine how well biological factors, symptoms, functional status, general health perception and socio-demographic and treatment factors predicted a patient’s overall HRQoL.

Variables were entered in sequence in six steps: 1) Patient age, Gender, Education, Job, Income; 2) Time since starting HD, Time to reach HD; 3) Social and Economic, Family; 4) Itch, Fatigue; 5) Anxiety, Depression; 6) Perceived general heath.

The improvement in the regression model at each step was evaluated by the R square (R^2) and Adjusted R^2 values. The process of adding more variables would stop when all the potential variables had been included or when it was not possible to make a statistically significant improvement in R and R_2 (Pallant, 2013). To evaluate which variables included in the model contributed to the prediction of the dependent variables, the unstandardised regression coefficients (B), the standard errors (SE B), the standardised regression coefficients (β), the t-statistic, the significance of the t-statistic, the R, the F statistic (F), R^2 and the change in R^2 (ΔR^2) were reported.

Finally, the accuracy of each regression model was evaluated by conducting a Bootstrapping test. Bootstrapping is considered a sound test which can be performed to obtain robust estimates of the intercept and beta weights (Tabachnick and Fidell, 2014, p 179). It is a process by which regression weights are generated over a very large number of replications (up to 1,000 bootstraps) with samples drawn and replacement from the available data set. Each case may be selected more than once, or not at all, because of replacement (Tabachnick and Fidell, 2014). Conclusions were drawn based on the bootstrapped coefficients' parameter estimates of the overall final model: the unstandardised regression coefficients (B), bias, bootstrapped standard errors (SE B), significance of the regression coefficients, the normal approximated 95% confidence intervals (OLS 95% CI) and the bootstrapped confidence interval (BCa 95% CI).

7. Risk Assessment

As part of the project planning process, a risk analysis took place to anticipate potential risks to the project, with the aim being to formalise actions to prevent or manage these risks. A table outlining each identified risk, and actions to prevent or manage the risk, is presented in Appendix 4.6.

8. Conclusion

A three-phase, cross-sectional, correlational study was conducted to explore the meaning of QoL and to determine factors affecting QoL and HRQoL in Omani patients with ESRD. A targeted sample of around 450 patients undergoing HD at outpatient dialysis units located across Oman was used. The study was approved by the UREC at the University of Dundee, as well as the central research committee at the Ministry of Health, Oman. Eight measures, in total, were administered to patients undergoing regular HD sessions. Data analyses included descriptive statistics and exploratory and confirmatory factor analysis, as well as various sequential multiple-regression models, to determine the influence of study-predictor variables on physical-component summary, mental-component summary, role-functioning component summary and QoL index-dialysis, according to the revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005).

Chapter 5- Testing the concept of Quality of life and measures assessing Health-Related Quality of Life in Omani ESRD patients.

Background: Little is known about how Omani patients with end-stage renal disease (ESRD) view their life quality, yet this is an outcome of increasing importance. Most research in this area has been conducted within a Western context using measures that have not been validated within the Omani context.

Method: Participants were 12 patients randomly selected from a dialysis unit centre in Oman. The understanding of Quality of Life concept was explored using an individualised QoL instrument (SEIQoL-DW). A cognitive interviewing method was used to explore patients' interpretations of the Arabic versions of two standardised measures of HRQoL, SF36v2 and QoLI-Dialysis, measures' items, and report any difficulties they might have in answering these items.

Findings: Mean patient age was 53 years; 8 (78%) were male. All patients completed the SEIQoL-DW, (mean time 16.08 minutes). Omani patients appear to understand the notion of QoL. Fifty-nine cues were identified and categorised. The most important/common aspects of life that determined individual QoL in Omani patients were spiritual life, family, personal health, social life, and leisure activities.

A good completion response rate was obtained (100%) on SF36v2 and QoLI-Dialysis. Patients were able to comprehend most of the items. Two items in QoLI-D measure were identified as sensitive and two items in the SF36v2 also were reported to contain complicated syntax.

Conclusion: SEIQoL-DW was an applicable instrument to explore the meaning of the concept of QoL among this population. Spiritual life aspect should be incorporated in any assessment of QoL and HRQoL in this group of patients. Cognitive interviewing was able to helpfully identify the range and depth of difficulties with items of SF36v2 and QoLI-Dialysis within this context, yet these measures should be tested on a larger group.

1. Introduction

Health-related QoL is an essential part of evaluating dialysis treatment effectiveness and assessing health outcomes of patients with end-stage renal disease. Several measures have been developed to assess HRQoL and can be categorised as generic and condition- or disease-specific measures. Generic instruments attempt to measure a broad range of domains that are related to overall quality of life and HRQoL. These instruments cover a range of areas and can be used across different populations. Disease-specific are designed to address areas of life that are particularly pertinent for patients with a specific condition or disease in a predefined list of items which must be rated in a particular manner (Bergland and Narum 2007). Despite these tools being criticised for having a narrow focus, they have been credited with being more sensitive to changes in health status compared to generic instruments (Hall, Krahn et al. 2011).

However, the current methods of measuring HRQoL impose an external value system on individuals, rather than allowing them to describe their lives in terms of those factors which they consider important. Measuring such personal and complex concepts is, therefore, difficult and may miss aspects of life that are important to the individual. These aspects may be captured by an individualised QoL tool. Individualised measurement tools were developed as an attempt to explore the aspects of life that the individual perceives to be most important and to assess the level of functioning or satisfaction within each aspect (Tavernier, Totten et al. 2011). The Schedule for the Evaluation of Individual Quality of Life-Direct Weighting (SEIQoL-DW) is one of the individualised QoL instruments developed by O’Boyle et al. (1993). The main advantage of such methods of QoL measurement is the ability to address an individual’s own concerns about their life rather than impose standard questions which might be less relevant (Gall, Malette et al. 2011).

There are very few studies that have used a combination of generic HRQoL measures, disease-specific measures and QoL individualised measures. The majority of studies assessing the QoL of patients with ESRD mainly focus on HRQoL. This is perhaps due to the broad agreement that the concept of positive health is more than the absence of disease or even disability, but rather is about full functioning, efficiency of mind and body and social adjustment (Kaasa and Loge 2003, Krethong, Jirapaet et al. 2008, Fang, Fleck et al. 2011). HRQoL is, therefore, a concept that includes aspects related to physical, mental, social and role functioning and can be measured using distinct components that can be interpreted separately (Crosby, Kolotkin et al. 2003).

Even with available studies that assess HRQoL, the majority have been conducted mainly in Western cultures. Limited studies have examined HRQoL aspects in ESRD patients in an Arab population (Abdel-Kader et al., 2009). The results of these studies showed low HRQoL among Arab patients with ESRD, but none were conducted in Oman. This phase of the study therefore considers this gap in assessing QoL through exploring the understanding of the concept QoL among Omani patients using SEIQoL-DW instrument. Besides, a cognitive interviewing method was used to test the readability and relevance of items of HRQoL measures among this group of patients.

Cognitive interviewing is qualitative in nature, with participants asked to explain their interpretations of a measure's items, elaborate on their responses and report any difficulties they might have in answering these items (Beatty & Willis, 2007). It also helps and guides in modification and improvement of the measures, but the major advantage is that the process can be iterative, with further rounds of testing leading to further improvements (Willis, 2005). Tourangeau (1984) presented a structured model of cognitive interviewing which consists of a sequential process of: a) comprehension of the item, b) retrieval from memory of relevant information, c) decision process and d) response processes. The model tests the participants' comprehension of terminology used in the measured items, their sensitivity to answering items (e.g. items related to sexual activities, religious items).

The process of cognitive interviewing includes two techniques, think aloud and verbal probing. Think aloud technique is used to ask participants to vocalise their thought processes while responding to questionnaire items (Willis, 2005). The advantage of this technique is that it does not require highly trained interviewers, and there is less bias imposed by the interviewer. However, it might also have the disadvantage of causing a burden on respondents especially among those whose first language is not English. Verbal probing is a way used to ask respondents to provide additional information related to their answers to questionnaire items either at the time of responding to the question (concurrent probing) or after the completion of the entire questionnaire (retrospective probing). The advantage of this technique is that it maintains a focus and control over the interview, whereas the disadvantage is the potential for interviewer-imposed bias (Willis, 2005).

The overall aim of this phase is to answer RQ1– What does QoL/HRQoL mean to an Omani population using individualised QoL instrument, SEIQoL-DW; and cognitive interviewing to explore their interpretations of the Arabic versions of two standardised measures of HRQoL, SF36v2 and QoLI-D measures' items, and report any difficulties they might have in answering these items.

2. Methods

2.1. Population and sample size

The study population was a subset of the target population from whom a randomised sample was taken over the three-week period of data collection, first three weeks of May 2015, based on study-inclusion criteria. The inclusion criteria were: adult patients with ESRD receiving HD; those aged ≥ 18 years; and those who had been on HD for at least three months so that they were adjusted to life on dialysis. Exclusion criteria were: patients who did not survive on HD longer than three months; patients with acute renal failure; patients aged under 18; patients diagnosed with dementia or any other condition that could impair their ability to answer questions; patients who had recently been diagnosed with cancer; and patients who had recovered their renal function.

This sample size of this phase was informed by literature that used the cognitive interviewing method in data collection as well as studies using individual QoL measures (McGee et al. 1991; Becker et al. 2014; Tavernier et al, 2011). Although the sample size determined at this phase was 12 participants, 16 patients were approached to avoid any inaccuracy of the list as patients sometime quit dialysis for transplant or personal preferences.

Patients were identified from the Dialysis-Unit Registry which records registered patients with ESRD. Using the Dialysis-Unite Registry, eligible patients were approached by the researcher in the allocated waiting area for their regular HD sessions. An explanation about the objectives of this phase and a related information sheet were provided. Patients had 48 hours in which to indicate their interest in participating in the study to the researcher who was physically available in the dialysis unit when they came for their next HD session. For patients who agreed to participate, interview venue and time were decided based on the participant's preference.

2.2. Ethical consideration

Ethics permission was granted by the University Research Ethical Committee (UREC) at the University of Dundee and the Directorate of Research and Ethical Review and Approve Committee, at the Ministry of Health, Oman.

2.3. Setting

Participants were recruited from the Nizwa Dialysis Unit. This unit is located in central Oman and is one of the country's largest dialysis units. There are around 83 patients regularly attending out-patients' HD.

2.4. Data collection process

2.4.1. Measures

Three measures were used in this phase: an individualised QoL instrument (SEIQoL-DW), generic health status measure (Short Form-36v2), and disease-specific measure (QoLI-Dialysis). More details of these measures are presented in Chapter Three including psychometric qualities.

SEIQoL-DW instrument is an individualised QoL instrument. It was administered to test the understanding of the concept of QoL by asking the patients to nominate five areas of life that they value most. SEIQoL-DW is based on an underlying theory of what makes up QoL from an individual's own perspective and on his/her own perception and understanding of QoL (Kolewaski, 2005). The main advantage of such methods of QoL measurement is the ability to address an individual's own concerns about their life rather than impose standard questions which might be less relevant (Gall, Malette et al. 2011).

The SF36v2 measures eight health concepts: physical functioning, social functioning, physical role limitation, emotional role limitations, bodily pain, mental health, vitality and general heath perceptions. These concepts can also be presented as two summary scores representing physical and mental health. The scoring range of the SF-36v2 is 0-100 for each of the eight domains. Zero indicates poor health status and 100 indicates very good health status. The response options for the SF36v2 are rated on a Likert scale.

QoLI-Dialysis was the second HRQoL measure used to explore patients' understanding of items related to QoLI-Dialysis. The QoLI-Dialysis is the version that was primarily developed by Ferrans and Power (1984) for use with dialysis patients. It consists of 68 items and measures four key aspects: health and functioning, social and economic, psychological and spiritual, and family. It consists of two sections assessing participant satisfaction and the relative importance of each aspect, respectively. Six-point ordinal response scales range from "very dissatisfied" or "very unimportant" (1), to "very satisfied" or "very important" (6). Its index scores range from zero to 30, where higher scores indicate a better quality of life (Bowling, 1995, p54).

2.5. Procedure and Data analysis

Participants were informed verbally and in writing, using the information sheet developed specifically for this phase of the study (see Appendix 4.3.a). For patients unable to read, an information sheet and consent form were explained verbally to them. The consent form was required to be signed by participants and, for those who could not write, an available witness signed instead (see Appendix 4.3.b). The witness was a family member (husband, wife, sister, brother, or close relative such as a cousin). Their preferences for time and venue for the cognitive interviewing and for completing the SEIQoL-DW instrument were considered.

All the interviews were digitally audiotaped along with the taking of abbreviated field notes with the patients' permission. The recordings included the administration process of the SEIQoL-DW and the interactions between patients and researchers during this process.

2.5.1. *Individualised Quality of Life instrument (SEIQoL-DW)*

Prior to administration of the SEIQoL-DW, and for the purpose of efficient use of SEIQoL-DW, the researcher translated the SEIQoL-DW instruction manual into Arabic. This process was merely for the purpose of simplifying the use of the manual for the researcher and to avoid any lapses that might occur during the reading of instructions to patients. Initially, the instruction manual was translated by the researcher into Arabic and then sent to two separate reviewers. Reviewer one is a native Arabic speaker who is a doctorate holder and works as a dean for a nursing institute in Oman. Similarly, Reviewer two is a native Arabic speaker and a doctorate holder working as an English-language teacher in a nursing institute in Oman. Both reviewers reviewed and checked the Arabic translation and commented on it independently and neither had any criticisms.

The translated draft was then piloted with three nursing students at their clinical placement at Nizwa Hospital. Students were informed about the aim of this pilot and a consent form was obtained for them to participate willingly. Each interview was audio recorded. The time taken to complete SEIQoL-DW was between 13-18 minutes. The three participants reported no difficulties in understanding the instructions on how to complete the SEIQoL-DW tool, nor did they report fatigue or boredom. The acceptability of the SEIQoL-DW was based on time taken to complete the tool, on the understanding of the method and on the level of fatigue and boredom (O'Boyle et al., 1993).

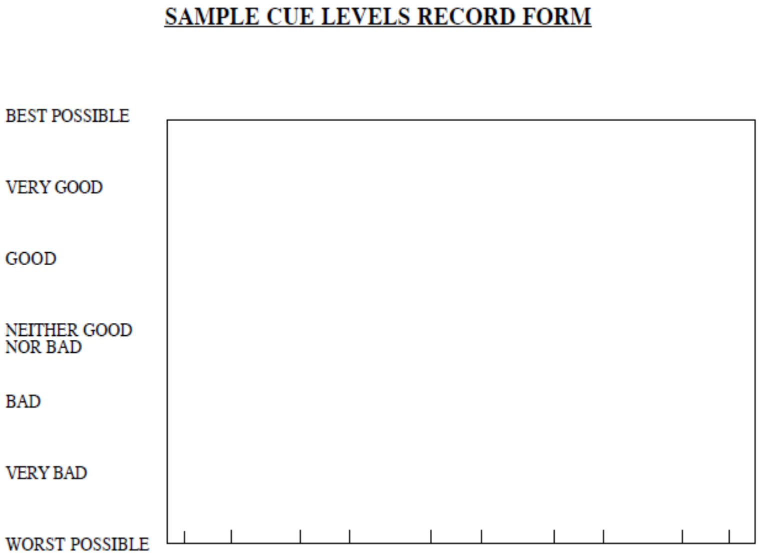
SEIQoL-DW was then administered to patients in three stages. Stage one was the determination of cues, aspects of life. Patients were asked to think of, and nominate, five areas of life (cues) that determine their own happiness, or QoL, without prompts from the researcher (the glossary of terms relevant to SEiQoL-DW in table 5.1). The five cues were elicited by means of a semi-structured interview and are referred to henceforth as “elicited cues”. In stage two, the patients then ‘levelled’ their functioning status on each cue against a vertical visual analogue scale (VAS), labelled at the upper and lower extremes by the terms “As good as could possibly be” and “As bad as could possibly be” respectively (Figure 5.1). These ratings were recorded by the researcher as a bar chart, one bar representing each cue nominated by patients. This produced five scores, independent continuous measurements, ranging from zero to 100. In stage three, for the purpose of weighing the elicited cues, patients were asked to quantify the importance of each aspect, represented by five differently coloured areas of a disc weighing system which was produced by the SEIQoL-DW developers specifically for this purpose. The disc consists of five interlocking laminated circular discs of different colours on a percentage base and can be rotated independently (Figure 5.2).

The weight of each aspect was divided by 100, since the weights, when calculating the SEIQoL-DW Index, range from 0.00-1.00, in order that the overall SEIQoL-DW Index can be calculated by multiplying the level by weight of each aspect and then adding these products across the five aspects [SEIQoL Index = ∑ (levels x weights)].

Table 5. 1 Glossary of terms relevant to SEiQoL-DW

Cue	The elicited aspect of life considered most important by each patient in assessing their overall QoL.
Definitions Record Form	The form used to record the meaning of the elicited aspect of life and to provide definitions by each patient.
Level Record Form	The rate or level of each aspect of life for the patient at that moment.
Cue Levels Record Form	The form used to record the levels and importance of elicited cues.
Weight of cue	The rate of importance of each elicited aspect of life for the patient at that moment.
Disc weighing system	The pi diagram used to rate the importance of each elicited aspect of life.

For grouped data presentation, three reviewers (researcher, reviewers 1 and 2) categorised the elicited aspects of life definitions using a prompt list summarised from the literature. The researcher, initially, independently categorised the nominated “cues” and these were then emailed separately to reviewers. Any discrepancies that occurred were resolved by discussion. This process was entirely anonymous. Where participants' quotes are used to support the results, any personal details will be anonymous.



SAMPLE CUE LEVELS RECORD FORM

BEST POSSIBLE
VERY GOOD
GOOD
NEITHER GOOD NOR BAD
BAD
VERY BAD
WORST POSSIBLE

Figure 5. 1 Cue levels record form of SEIQoL-DW

The time for each interview, for understanding the method of SEIQoL-DW and for possible fatigue/boredom that the patient might experience, and the overall validity of the information obtained (in light of the reported understanding of method and fatigue/boredom) were reported using the Interview Record Form (IRF) suggested by the author of the SEiQoL-DW (Appendix 5.1).

Figure 5. 2 Disc weighing system of SEIQoL-DW

1) Health-related QoL measures (SF36v2 and QoLI-Dialysis)

The Arabic version of the SF36v2 and QoLI-Dialysis were administered using the cognitive interviewing technique to assess whether they were acceptable and understood by Omani ESRD patients. The assumption is that Omani respondents interpret the measures' items in the same way as do the measures' developers (Bowling, 2009) despite cultural differences.

The Tourangeau's model was adopted and employed to test patients' understanding of SF36v2 and QoLI-Dialysis by asking them to complete each measure exactly as normal, but also to read aloud each question and to "think aloud" their thoughts as they respond to these items. After each interview, field notes and audio recordings were reviewed to identify any potential problems with the measures so that issues were addressed prior to piloting the QoL measure in a larger sample.

The Question Appraisal System (QAS) coding form of probed interviews (Willis, 2005) was used to record the process (refer to Appendix 4.4). QAS was developed to guide researchers through a systematic appraisal of questionnaire items and to help to identify potential problems in the wording or structure of the items that may lead to difficulties in questionnaire administration or to other failings (Willis and Lessler, 1999).

Data from the cognitive interviewing process were analysed using a matrix-based method of data analysis proposed by Knafl et al (2007). Problems were identified and systematically analysed to facilitate decisions concerning the measures' use or modification. The matrix illustrates items in a tabular form in which items appear in a row and participants appear in a column. Possible problems to be identified with items are entered into the appropriate intersecting cells, promoting systematic analysis and decision-making regarding item revisions. The matrix-display approach was then used to construct item summaries, linked to all the patients, including a coding scheme to reflect problem types specific to each item that has been tested. The findings were then aggregated across all participants, producing a summarised, measure-by-question analysis of the results associated with QoL measures (SF36, QoLI-Dialysis). Finally, the item summaries examined across the patients informed the reporting and understanding of the measures of

QoL within the Omani context and were used to make decisions about retention, amendment or deletion of individual items.

3. Findings

3.1. Characteristics of participants

Twelve participants were recruited from the Nizwa Dialysis Unit. The mean age was 53 and the SD was 18.90, ranged from 28 to 76 year. Male patients constituted 75% (eight patients) of the total and 25% (four) were female, while 66.7% were married (eight patients), and 33.3% were single (four patients). Their education level was: 33.3% illiterate, 8.3% low-intermediate level, 8.3% intermediate level, 25% high-intermediate level and 25% were college graduates. About one third of the patients were unemployed (33.3%) and housewives (16.7%), whereas the remainder were employed. The range of dialysis hours was 36-48 hrs/month. The dialysis efficiency, based on the test of urea reduction rate (URR), was >70 % (n= 11) and only one was <70%. Table 5.2 presents a summary of the characteristics of the participants.

Table 5. 2 Characteristics of the sample

Characteristics	Participants (*n*= 12)	
	Mean	**SD**
Age [mean (range)]	47.58	18.90
	Frequency	**Percentage**
Gender		
Male	9	75%
Female	3	25%
Marital status	8	66.7%
Married	4	33.3%
Single		
Employment status		
Employed	8	66.7%
Unemployed	4	33.3%
Educational level %		
High	3	25%
High-intermediate	3	25%
Intermediate	1	8.3%
Low-intermediate	1	8.3%
Illiterate	4	33.3%

3.2. Findings of SEIQoL-DW

3.2.1. Completion of the SEIQoL-DW

The Interview Record Form (IRF), the form used to record information about each participant during the interview, was subjectively analysed for understanding, fatigue and overall validity. The IRF data, which was completed by the researcher immediately after interviews, indicated an acceptable time to complete the instrument (*mean*= 16.08 minutes), while the determined time to complete SEIQoL-DW is 10-20 minutes (O'Boyle et al., 1992). The least time taken to complete the tool was 12 minutes and the longest time was 21 minutes. The least time taken was scored by a 28-year-old male patient with a high education level and the longest by a 54-year-old illiterate female patient, suggesting that education level might reflect the level of understanding of SEIQoL-DW. Despite the age variation among the participants, low levels of fatigue were observed.

Three respondents had difficulty with rating negatively worded aspects in the y axis of "worst possible" and "best possible" related to the level of these aspects in the IRF. Similar difficulty was observed when participants were asked to mark the bar chart with a horizontal line to draw a box from baseline to the mark. This problem, however, was dealt with immediately by the researcher at the time of chart completion by reminding the respondent that the task was to rate 'how each of these areas are for you at the moment". The last challenge was encountered during the SEIQoL-DW administration with the interpretation of the "*importance*" of levels of areas of life on the five-weighted coloured disk (pie chart). Out of the 12 participants, six interpreted this step as "level of functioning" on their nominated cues rather than as "importance" of cues to them. Here, respondents were reminded that the task was to indicate "how important each of the five aspects is at present, relative to each other".

3.2.2. Description of frequency of elicited and prompted cues and categories

Fifty-nine cues were reported by patients. These cues were assigned categories by three independent raters (principal researcher, principal supervisor and second supervisor). Sixty per cent of the cues were assigned the same category by the three reviewers, 36% had the agreement of two reviewers and there was no agreement between the reviewers on 5% of the cues (Appendix 5.2 summaries cues definitions and categorisation of cues).

Of the 12 patients, nine patients (75%) nominated five cues without prompting, whereas three required prompting, of which one nominated four cues.

Once reviewers had assigned cues to categories, the percentage of patients nominating each category at least once is shown in Table 5.3. The category of Religion/Spiritual Life was mentioned most frequently, 12 times (100%) by 12 patients, whereas the category of Family was nominated by nine patients (75%), six patients nominated Personal Health, Social Life and Leisure Activities (50%), five patients nominated Work/Occupation and Role Functioning (41.6%), three patients nominated Autonomy/Independence (25%) and 8.3% nominated each of these: Family Health, Sexuality, Finances, Relationships, Enjoying Life and Quality of Care. The content and variety of categories were as expected from reports in the literature. However, it was unique for this study that religious and spirituality issues were the most frequent and dominant among this group of patients.

Table 5. 3 Number of patients nominating category and their percentages

Category	Number of patients nominating categories (%)
Religion/Spiritual Life	12 (100)
Family	9 (75)
Personal Health	6 (50)
Social Life	6 (50)
Leisure Activities	6 (50)
Work/Occupation	5 (41.6)
Role Functioning	5 (41.6)
Autonomy/Independence	3 (25)
Family Health	1 (8.3)
Sexuality	1 (8.3)
Finances	1 (8.3)
Relationships	1 (8.3)
Enjoying Life	1 (8.3)
Quality of Care	1 (8.3)

Having obtained the levels and weights for each of the nominated cues, the SEIQoL-DW index was calculated to provide an overall score (Appendix 5.3). This is a continuous measure ranging from 0 to 100. The minimum score was 33.92 and the maximum score was 79.25 (*M*= 55.60, *SD* = 13.59). Additionally, respondents indicated their current life satisfaction on a visual analogue scale that ranged from 0 = worst life imaginable, to 100 = best life imaginable (Table 5.4). The minimum score was 28 whereas the maximum was 95 (*M*= 66.67, *SD* = 20.61).

Table 5. 4 Scores of SEIQoL-DW overall score and SEIQoL-DW linear analogue score

Instrument	Participants											
	01	02	03	04	05	06	07	08	09	10	11	12
SEIQoL-DW overall score	44.5	52.5	78.4	79.2	57.9	63.3	42.5	54.5	58.5	56.4	33.9	45.4
SEIQoL-DW linear analogue score	28	84	31	85	76	77	53	95	70	74	63	64

In an attempt to examine if there is a possible correlation between the SEIQoL-DW index overall score and the visual analogue scale, a Pearson's (r) test was conducted. The result showed that there was no correlation between the variables [r= 0.117, n= 12, p= 0.358].

3.2.3. Example of cues, levels, direct weightings and overall score of SEIQoL-DW

This section provides an example of SEIQoL-DW result –nominated cues, levels and direct weights– of two patients (Figures 5.3.1 and 5.3.2). The description of illustrated cues was recorded on the Cue Definitions Record Form by the researcher at the time of interview. The descriptions of these cues reflect exclusively the patients' explanations and not the researcher's interpretation.

Patient One: a man of 58 years old and married. He had a low education level and worked in the private sector with a low income. He was able to nominate all the cues without prompting. The time taken for him to complete the SEIQoL-DW was 15 minutes.

Table 5. 5 Example of description of cue, cue label and related category (Patient One)

Cue label	Description of cue	Categorised in
Cue 1: family	"… mixing with people and sitting with them. Sitting with friends, hanging out with them".	Social Life
Cue 2: Body image	"… physical activity, ability to go… shopping and get groceries. Ability to climb up the stairs".	Role Functioning
Cue 3: Mobility	"… transportation. Able to drive to places of interest is highly important to me. Also, ability to bank up the money required to this".	Autonomy/ Independence
Cue 4: Self-development	"I am youth and my future is not clear; the job as well!! I don't know if I will find a job that suits my health condition and how my future will be?"	Role Functioning
Cue 5: Religion	"… going to mosque and praying to Allah 'God', fasting and being able to fast is highly important to me".	Religion/Spiritual Life

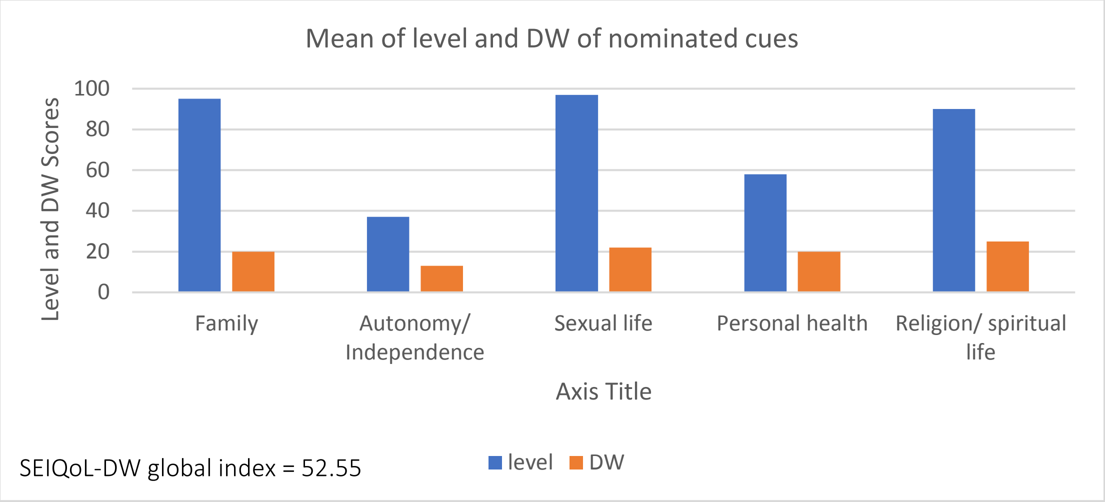


Figure 5.3. 1 Level and direct weights of nominated cues (Patient One)

Patient Two: a man of 53 years old and married. His had a high education level and worked for the government with a long-term contract and a good income level. He was able to nominate the five cues without prompting in a time of 15 minutes.

Table 5. 6 Example of description of cue, cue label and related category (Patient Two)

Cue label	Description of cue	Categorised in
Cue 1: Family	"… my presence at home is very important to care for my wife and children. They are taking most of my time".	Family
Cue 2: Mobility	"… going out from home and coming for dialysis; also getting groceries to home is important. These are all my responsibilities".	Autonomy/ Independence
Cue 3: Sexual relationship	"… it is important to me to care for my wife. Sexual life, for instance, I consider it as an important aspect in my life".	Sexuality
Cue 4: Health	"… diseases; allergies from medications and secondary diseases. Basically, my health".	Personal Health
Cue 5: Worship	"… being on time for prayers, going to mosque; as well as going to Hajj, are important to me".	Religion/Spiritual Life

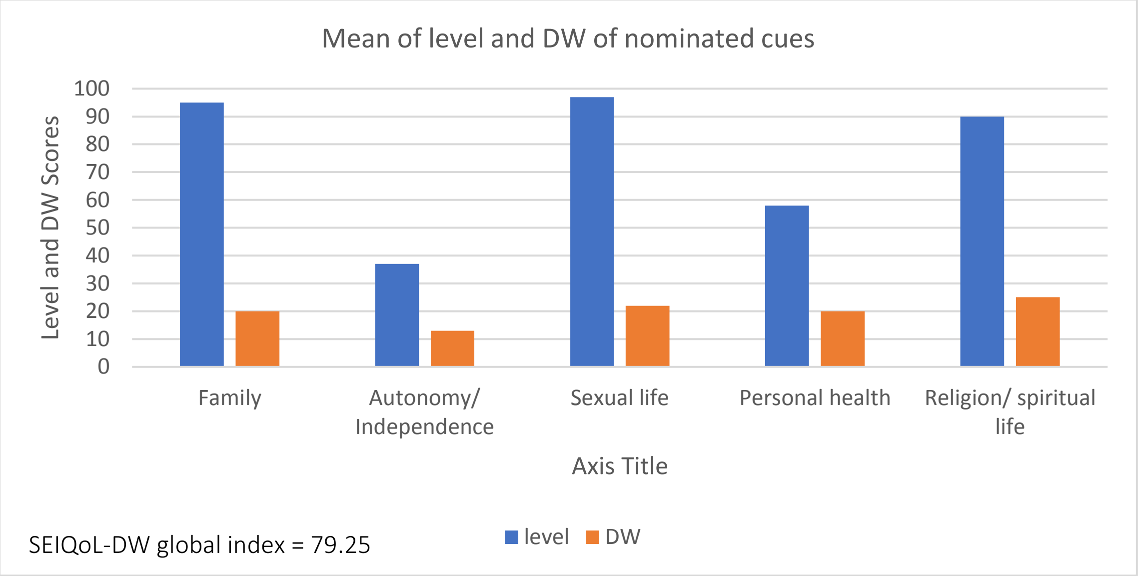


Figure 5.3. 2 Level and direct weights of nominated cues (Patient One)

3.3. Findings of cognitive interviewing of the SF36 and QoLI-Dialysis

3.3.1. SF36v2

The aim for administering SF36v2 using the cognitive interviewing technique was to test the ability of the Omani patients to comprehend and respond to this measure. It was anticipated that, if patients were able to comprehend and respond to the items of the SF36v2, then this would indicate that it is a readable and acceptable HRQoL measure.

All the patients (n=12) completed SF36v2. However, with regard to their response to SF36v2 items, six patients reported some difficulty and a lack of clarity with two items (Item-4b and Item-5b). Patients reported that these items were complex and contained complicated syntax (Table 5.7). For the remaining items, patients were able to supply their answers without any difficulties. A summary of the identified problems across all participants related to SF36 items is presented in Appendix 5.4.

Item 4b asked respondents if they had *“Accomplished less than they would like*” in the past four weeks in relation to problems with their work or other regular daily activities as a result of their physical health. Only one patient expressed a lack of language clarity related to this item. He stated that it was *“unclear”*. However, when the interviewer repeated the question to the respondent, he was then able to comprehend it. Thus, the item appeared to have no problem and was clear to all patients.

Similarly, item 5.b asked respondents if they had *“Accomplished less than they would like”* in the past four weeks in relation to problems with their work or other regular daily activities as a result of their emotional problems (e.g. feeling depressed or anxious). Half of the respondents (50%) expressed issues related to the clarity of the question, such as awkward or complicated syntax.

Table 5. 7 Items 4b and 5b and identified problems related to SF36v2

Items	**Question**	**Summary of problem(s) identified across participants**
Item 4b	4. During the past four weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health: b. Accomplished less than you would have liked	CLARITY: Identify problems related to communicating the intent or meaning of the question to the respondent.
Item 5b	5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? b. Accomplished less than you would like	CLARITY: Identify problems related to communicating the intent or meaning of the question to the respondent.

3.3.2. QoLI-Dialysis

QoLI-Dialysis was also administered to patients for the purpose of assessing their ability to understand and read this measure. A summary of the identified problems across all participants related to QoLI-Dialysis items is presented in Appendix 5.5.

Patients, in general, appeared motivated to complete the QoLI-Dialysis. Of the 64 items of QoLI-Dialysis, three items were left without answer by three patients (one male, two female). These items were numbers eight and 27 from the “satisfaction” part and item 12 from both the “satisfaction” and “importance” parts. When patients were probed regarding their hesitation in answering these items, issues of clarity with item 8 and item 27 and of sensitivity with item 12 were reported. The issues related to clarity were on items that asked patients to indicate their satisfaction on “*chances to live the period of time they wish for*” and chances to “*have a happy future*”. For example, participant M said: “*I don’t know how I will be tomorrow!! So how can I know how I am going to be after one or two years? This disease cannot be predictable in future.”* The item that was reported to be “sensitive” asked participants to indicate the level of satisfaction and importance of their “*sexual life”* (Table 5.8).

Table 5. 8 Identified problems related to QoLI-Dialysis questionnaires

Items	**QOLI-DIALYSIS Items**	**Summary of problem(s) identified across participants**
	Part 1 (satisfaction)	
Item 8	How satisfied are you with: Your chances of living as long as you would like?	CLARITY: Identify problems related to communicating the intent or meaning of the question to the respondent.
Item 12	How satisfied are you with: Your sex life?	SENSITIVE CONTENT (general): The question asks about a topic that is embarrassing, or very private
Item 27	How satisfied are you with: Your chances for a happy future?	CLARITY: Identify problems related to communicating the intent or meaning of the question to the respondent.
	Part 2 (importance)	
Item 12	How important to you is: Your sex life?	SENSITIVE CONTENT (general): The question asks about a topic that is embarrassing, or very private

To examine further the function of items that have issues with clarity and sensitivity and its variance with the total QoLI-Dialysis score, Cronbach’s alpha test was performed. Results showed that QoLI-Dialysis had good level of reliabilities, Cronbach’s α = .870. However, if item 8 is deleted, Cronbach's α will lower to .859. Similarly, for item 12, if deleted, α will lower to .867, whereas for item 27, Cronbach's α remains at a similar level = 0.870. Hence, it was decided to retain these items for use in phase two of this study (Chapter 6).

These findings suggest that Omani patients with ESRD understand the notion of QoL as evidenced by their ability to nominate five main aspects of life that they value most and to comprehend the measures of QoL.

4. Discussion

It can be said that Omani patients with ESRD appear to understand the concept of QoL. That was clear from the result of SEIQoL-DW in which patients nominated “religion/spirituality”, “family”, “personal health”, “social life”, and “leisure activities” as the top five aspects of life that determined their QoL. Interestingly, this result is in keeping with findings in the literature that were conducted within Western context using SEIQoL-DW instrument, except for the “religion/spirituality” aspect. In a study conducted in Western Pennsylvania, USA, patients with ESRD nominated family, health, work, financial, and leisure as aspects of life they valued most (Abed-Kader et al., 2009). Another study conducted in the UK among patients with chronic diseases found that family, health, leisure, home, money were the aspects of life that made up patients’ QoL (Mountain et al., 2004). These comparable findings may suggest that patients with ESRD view the aspects of personal health, socioeconomic, and leisure activities as important determinant of QoL.

Religion and spirituality does not seem to be an important aspect of life for some western patients, unlike Omani patients. That is maybe because Omanis consider religion as the essential reference in dealing with everyday life. It can be said that religion can shape the way Omanis view different aspects of life, including perceptions of health and illness. In Oman, Muslim patients usually understand that illness, suffering and dying are part of their life and a test from Allah, “God”. Their perception is that no one can control how long they are going to live. Thus, their perceptions about QoL may be associated with their religion and spiritual lives.

This perception may be also associated with the aspect of “personal health” as the Islamic religion encourages individuals to live healthily, care for their families and support each other and such support might extend even to financial support. Such insight is instructed by the Holy book of Muslims (Qur’an): *“O mankind we have created you male and female, and have made you into nations and tribes so that you may know each other. Lo! The noblest of you in the sight of Allah is the one with piety or the one who is pious”* (Al-Hujurat 49:13). However, the degree of religiosity in dialysis patients can be affected by the symptoms of ESRD and related treatment requirements. The need to attend dialysis sessions for an average of 12-15 hours per week could interrupt their worship schedules. Similarly, their ability to fast during the holy month of Ramadan (the fasting month in Islam) could be interrupted due to the dialysis sessions, medication and dietary requirements. All these factors may have an impact on their level of functional status and satisfaction with their religious practice and consequently on their level of overall QoL.

Omanis live in large families and are considered an introverted type of community. Family, therefore, is vital from their cultural perspective. "*The family is the nucleus of the society; whenever the nucleus is healthy and strong, so will be the whole structure*" (Shuraida, 2001, p. 10). The main aim of marriage within Omani society is to establish a family and to have children. This creates an equally important role for both wife and husband in forming the family, although the wife will have a different role. Thus, it is not surprising that patients rank “family” as one of the most important aspects of life which contributes towards their QoL. When sickness occurs, patients first get support from their families and it is the family who usually takes the sick person to hospital. They even work closely with healthcare providers to ensure that their family member gets the best care and the necessary psychological support. With such family support, it can be expected that HD patients consider “family” a high priority when assessing their QoL level.

Social life may be one of the most important aspects that determine QoL for Omani patients. In Oman, gender is likely to have an influence on a patient’s QoL, as men and women have different roles to play. Women, for instance, are not encouraged/expected to live alone and men should always be around to assist and give a hand in normal life activities, such as shopping. It is also highly recommended that women do not meet with a non-relative man due to cultural and religious reasons. The social position of women might affect their QoL as this could influence their feeling of self-value. In contrast to women’s social position, the male gender role might also influence men’s QoL as there are fewer restrictions on them socially. However, male patients with ESRD and on HD could be burdened by poor financial status if they are unemployed or if their job is affected by their health condition. Such changes in their normal life activities could affect their functional role and subsequently lower their level of QoL.

Patients with ESRD experience a number of disease- and treatment-related factors that restrict their lifestyle and undermine QoL. In contrast to transplant patients who perceive their condition to be less chronic (Edalat-Nejad and Qlich-Khani, 2013; Bakewell et al, 2001), HD patients reported an uncertain future and limited personal freedom and control (Brekke et al, 2014). Loss of freedom might also cause wider implications in altering marital, family and social relationships (Christensen and Ehlers, 2003). Such instability in feelings caused by physical and psychological alterations in ESRD patients may lead to reluctance in predicting the level of their satisfaction with their future. This gets worse when patients attempt to have balance in their lives when trying to maintain their roles of function, worship practice and care of their family.

Patients were able to understand the SF36v2 measures and comprehend most of its items, but with less clarity on items 4b and 5b. Both questions asked patients if they had *“Accomplished less than they would like*” in the past four weeks in relation to problems with their work or other regular daily activities as a result of their physical and mental health. Although the question statement of both items (Items 4b and 5b) was similar in the English version, the translated question statement to Arabic was slightly different. The item 4b can be understood, in Arabic, as “Accomplished less than you want”, whereas item 5b translated as “Accomplished less than you wish”. This convergence in the meaning of both items has perhaps led to issues of clarity. To the researcher’s knowledge, no studies have been conducted within Oman that tested the validity of SF36v2. The published studies that translated and validated SF36 into Arabic language were in Tunisian (Guermazi et al., 2012), and Saudi populations (Al Abdulmohsin et al., 1997). Both reported acceptable reliability and equivalence of both versions. It should be noted, however, that the Arabic language contains many dialects which significantly differ across Arabic countries. In North Africa, for instance, spoken Arabic may be incomprehensible to an Arabic speaker from the Levant or the Arab Gulf. Hence, existing variations in dialects of the Arabic language may be a factor that affects the clarity of items 4b and 5b. Administering the SF36v2 to a larger group of Omani patients may further explore the clarity issue.

The QoLI-Dialysis was also an acceptable measure to Omani patients. Two items, however, were possibly sensitive. These questions asked about sex lives and partnerships. This conclusion was reached when patients refrained from answering three items specifically related to this area of life. Sensitive items might lower the percentage of respondents who respond to the item truthfully. That is, this aspect affects questionnaires or survey outcomes in relation to: (a) overall response rates, (b) participants declining to respond to that particular sensitive item, and (c) also the accuracy of the respondent's answer (Tourangeau, 2007). From a religious perspective, in Oman, single men and women are forbidden to have any kind of sexual relationship before marriage. Even after marriage, this topic is considered a family secret and it is a taboo to share sexual-activity information outside the confines of the couple. The majority of Omanis may feel offended if they have been asked to share information about their sexual life, whether they are married or not. This perception is manifested in cognitive interviewing when the female participants are reluctant to answer orally to a male interviewer regarding items related to sexual life. A question can be raised here as to whether such reluctance might have been erased by self-reporting as opposed to an interview.

Different modes of administering QoL measures might affect data quality. Chang & Krosnick (2010), in their comparison study between oral interviewing and self-administered measures, reported that self-administration can increase a respondent's willingness to disclose sensitive information, compared with face-to-face or telephone interviews. Greater anonymity offered in surveys has been reported to lead to high item response and more accurate reporting on sensitive topics such as behaviour and relationships. These results, however, contradicted an earlier result, reported by Roberts et al (2004), which showed that item response in face-to-face interviews was higher. The explanation for this was that interviewers motivate people to respond and interviewers have greater control over the situation, for instance, by ensuring that questions are answered and not missed. Such variance in this set of evidence suggests that certain features, and the choice, of the questionnaire-administration format depends on characteristics of the participants and on the study site.

From a cultural perspective, within a Western context, self-administration seems to improve the quality of reports about sexual behaviour in surveys. Bowling (2005) found that self-administration eliminated the gap between the results of men and women, decreasing the average number of sexual partners reported by men and increasing the average number reported by women. Likewise, self-administration increases the reporting of socially undesirable behaviour, such as illegal attitudes or sexual information, usually under-reported in surveys (Newman et al., 2002). This, however, might not be the case in Arabic culture where sensitive items can be seen as socially unacceptable or socially undesirable. It is believed that, if confidentiality can be ensured when administering the questionnaires in the pilot study, the response rate to sensitive items might be improved. Also, it would be useful to explore the effects of different administration formats of QoL and HRQoL questionnaires on a large sample of patients with ESRD in Oman.

A number of limitations can be highlighted in this phase. First, the sample size was relatively small, n= 12, which might affect the reliability of the results. Second, for patients waiting to commence their dialysis session, particularly those who are older, participating in such a study could be overwhelming. It was also observed that using “think aloud” technique could create a false milieu when the researcher was present in the room with participants; and also, that the patients have to talk aloud, which they may not normally do. However, overall, the approach used to answer the RQ1 was shown to be applicable and useful. The cognitive interview method revealed how patients understand the questions of the HRQoL measures. Likewise, SEIQoL-DW appeared to be relevant in exploring the meaning of QoL among this group of patients. In fact, the nominated aspects of life by patients were alike in the domains of the SF36v2 and QoLI-D measures, e.g. psychological and social aspects which may be indicating that the SEIQoL-DW is measuring QoL on a subjective level. This result may represent a small step towards validating the SEIQoL-DW in patients with ESRD.

5. Conclusion

Two methods, the individual QoL instrument and cognitive interviewing, were used to explore the understanding of the concept of QoL in the context of the

Omani population and to address the potential drawbacks of HRQoL instruments that might limit the factors that comprise participants' QoL. The nominated aspects of life – Religion and Spiritual Life, Family, Personal Health, Social Life, and Leisure Activities – contribute significantly to the level of QoL in Omani ESRD patients. Within this group of patients, QoL is a cultural construct that is impacted by social and life events. Findings also show that QoL is an individualised perception and the individual experience is shaped and influenced by Omani society's values and culture. Hence, it is recommended that the level of the effect of these aspects on QoL and HRQoL in this group of patients should be measured. Thus, incorporating and considering these aspects in assessing QoL and HRQoL in phases two and three of this project is recommended in order to enrich its outcomes including a separate measure that assesses spirituality domain.

Results suggest that Omani patients understand the notion of QoL and this is clearly manifested by their ability to nominate the aspects of life that they consider most important. The SEIQoL-DW revealed a reasonable lay definition of QoL in patients with ESRD within Oman. Nominated aspects of life by ESRD patients could be a reliable guide to most important priorities for medical interventions by nephrologist, nephrology nurses, as well as policy makers within healthcare system in Oman.

The association between spirituality domain and health-related QoL should be considered in the main study. The degree of religiosity in dialysis patients can be affected by the symptoms of ESRD and related treatment requirements. This can be manifested by the frequent attendance at HD treatment (12 to 15 hours per week) which can interrupt their religious rituals such worship and fasting during the holy month of Ramadan. These are some possible factors that may have an impact on their satisfaction and level of physical and role functioning status.

The influence of religion and spirituality manifested clearly through the cognitive interviewing method. Although it revealed that Omani patients comprehended the QoL and HRQoL questionnaires (Arabic versions), with a very good response rate to both measures (SF36 and QoLI-Dialysis), they were sensitive to items related to sexual life and partnerships. The low level of response to sensitive items may be attributed to the method of face-to-face interviewing. Cultural and religious factors in Oman could influence patients’ responses to such questions as it is considered taboo to discuss sensitive subjects, such as sexual life, with anyone other than partners. One possible way to overcome this issue is to administer the measures in a larger sample size and to use a different method of administration, such as self-completion.

Chapter 6- Health-Related Quality of Life of Omani Patients with End-Stage Renal Disease: A Pilot Study

Background

Measurement of HRQoL has the potential to provide important additional information about the wellbeing of individuals affected by ESRD. A limited number of studies, however, have been found which address the impairment of HRQoL among Omani patients. It was essential to pilot the selected HRQoL measures, and test the applicability of the selected design among this group of patients.

Method

Six Arabic-version measures that assess health status, mood, physical symptoms and spiritual wellbeing, bound together, were piloted among adult Omani patients who were randomly identified from the National Renal Registry in Oman. Six nurses were recruited and trained to assist in recruitment and data collection. Parametric and non-parametric correlation tested the association between HRQoL variables and study outcomes. Predictors of HRQoL were tested using multiple sequential regression analysis.

Findings

The piloted measure, including socio-demographic questions, has been shown to be reliable in the Omani context. Two measures, however, SF36v2 and HADS, may require further exploration of factor construct using the factor-analysis test.

Forty-four patients participated in the study with a good response rate of 73% over a period of 21 days. The rate of measures completion ranged from 96.7%-100%, indicating a preliminary acceptance and applicability of the measures. The study was guided by the revised Wilson and Cleary model of HRQoL (2005) which seemed to be an applicable conceptual model to guide the main study.

Conclusion

Results indicated the usefulness of the proposed study measures, and design.

1. Introduction and background

The pilot study builds upon a structured review of the conceptual structure of QoL and HRQoL (review one); a review of the measures used to capture HRQoL and its predictors including the symptom burden, physical, psychological and socio-demographical factors and clinical factors (review 2); a small study tested the concept of QoL and HRQoL and the appropriateness of standardised questionnaires in Omani ESRD patients (phase-one).

Measurement of HRQoL has the potential to provide important additional information about the wellbeing of individuals affected by ESRD, which is not readily available from the clinical and laboratory assessments currently used to monitor patients (Soni et al, 2011). Various measures are used targetting different languages, including Arabic, to assess HRQoL and its predictors, such as generic-health outcome and disease-specific measures. Generic-health outcome measures are the ones most commonly used to evaluate different aspects of HRQoL including physical, psychological and social factors, as well as perceived well-being, whereas disease- or condition-specific measures evaluate symptoms or conditions that might be associated with the level of HRQoL. However, in reviews one and two, no studies were found that measured HRQoL among Omani patients with ESRD.

The majority of studies that assess HRQoL in ESRD are limited in the approach used to measure HRQoL. That is, no studies were found which comprehensively assessed biological function, symptoms, functional status, general health perceptions, or various characteristics of the individual and their environment. Even with studies that used more than one measure of HRQoL (Saffari et al., 2013; Kao et al., 2009; Cleary et al., 2005), the researchers did not articulate a comprehensive conceptual framework to guide their study, providing little justification of the independent variables used to explain HRQoL. Even the limited number of studies that have assessed HRQoL among Arab patients with ESRD (Abd Elhafeez et al, 2012; Al-Jumaih et al, 2011) reported low HRQoL scores.

Prior to conducting this pilot study, chapter 5, a cognitive interviewing test and administration of an individualised QoL instrument were used to explore the understanding of the concept of QoL and HRQoL among the Omani patients, which revealed “Religion and spirituality” as the most valued aspect of life, followed by “personal health”, “social life”, “family health” and “leisure activities” respectively. The result also revealed the necessity to determine and test the level of HRQoL in Omani patients affected by ESRD.

This pilot study, therefore, was planned, to: 1) test the practicality **–** and acceptability to respondents **–** of the selected HRQoL measures within an Omani context; 2) inform the study sampling size; 3) assess the likely success of the proposed recruitment approaches if sufficient participants could be generated; 4) test the feasibility of recruiting research assistants (nephrology nurses) to help in recruiting patients and administering study measures; 5) develop and test the response rate; and 6) practice the analysis plan. Likewise, this pilot study highlighted the feasibility to answer RQ2 and RQ3 (presented below in result section).

Conducting a pilot study can be useful in identifying possible problem areas and deficiencies in study measures and protocol prior to the implementation of a larger scale study (Lancaster et al., 2004). However, there are limited benefits for the researchers themselves from a professional perspective including research informed practice, and identification of learning needs pertaining to a specific area of research (Kraemer et al., 2006; Teijlingen and Hundley, 2001). For the researcher of this study, and for the purpose of maintaining a rigorous method of analysis, performing a sequential multiple regression analysis was recognised as an area of a learning need. The analytical protocol of the pilot phase in this study, therefore, consisted of testing the planned sequential multiple regression analysis so that its applicability can be trialled and evaluated prior to conducting the main study. In case of any pitfalls identified, these can be then tackled either by further reading, practice, or statistician consultation.

2. Methods

This section describes the inclusion and exclusion criteria, the methods of recruitment of the research assistants and patients, the data collection and the proposed statistical analyses pertaining to the pilot study.

2.1. Inclusion and exclusion criteria

The inclusion criteria were: adult patients affected by ESRD receiving HD, aged ≥ 18 years and who had been on HD for at least three months so that they were adjusted to life on dialysis.

Exclusion criteria were: patients with acute renal failure; patients aged under 18; patients diagnosed with dementia or any other condition that could impair their ability to answer questions; patients recently been diagnosed with cancer; and patients who had recovered their renal function.

2.2. Ethical aspects

Ethical approval to conduct this pilot study was obtained from the University Research Ethical Committee (UREC) at the University of Dundee (UoD), reference UREC 15060, and the Directorate of Research and Ethical Review and Approve Committee, Oman.

2.3. Setting

Three HD units were involved that function under the Ministry of Health, Oman. These units were located in: a) northern Oman (Sumail Dialysis Unit, Site 1), central Oman (Nizwa Dialysis Unit, Site 2) and western Oman (Ibri Dialysis Unit, Site 3) to provide a representative sample across Omani culture and to test the feasibility of the main study.

2.4. Data collection assistant

Six nurses were recruited and trained to assist in recruiting and administering the study measures. The training session took the form of a practical introduction and consisted of a series of short lectures interspersed with practical activities: the aims and objectives of the study, patient recruitment, obtaining a consent form and the method of measures administration. Subsequently, each research assistant was observed in a simulated data-collection session by the researcher, and then both the researcher and the assistant simultaneously collected data with two participants before the research assistant was able to administer the measures independently. The recruited nurses were not directly responsible for the outcome of the study.

2.5. Recruitment strategy and data collection

Patients were identified from the National Renal Registry of patients treated with ESRD in Oman, which records registered patients affected by ESRD based on a numerical identifier, contact information, medical history and updated laboratory results. Applying inclusion and exclusion criteria, 60 (10% of the sample size for the main study) patients were selected randomly, using the "RANDOM" function in the Excel programme (Field and van Belle, 2002; Julious, 2005).

Nurses approached all eligible patients regarding the study to obtain an initial determination of interest using the study information sheet. The patient information sheet (refer to Appendix 4.5.a), was in Arabic, explaining the purpose of the pilot study, the advantages and disadvantages of participation and the expected duration of participation. Patients who agreed to participate in the study were then approached by a nurse during their attendance for regular HD to obtain a consent form (refer Appendix 4.5.b) and to respond to study questionnaires.

Patients were asked to complete the study measures before starting their dialysis session, or during their dialysis session. If data were collected during the HD session, 60 minutes were allowed before data collection began. This gap in time was designed to prevent any possible errors that might occur, as patients might experience cognitive changes due to fluid and electrolyte shifts.

Six Arabic-version measures, bound together, were piloted and used to collect the data: Short-Form 36v2 (SF36v2); Quality of life Index-Dialysis (QLI-D); Hospital Anxiety Depression Scale (HADS); Fatigue Severity Scale (FSS); Itch Scale (5-D Itch); and Spiritual Wellbeing Scale (SWB). Further details of these instruments and its psychometric qualities were discussed in Chapter Three of this thesis.

Besides these measures, a background data sheet was included within the measures package which consisted of the patients' age, gender, marital status (single, married, widowed, divorced); level of education (illiterate, low-intermediate, intermediate, high-intermediate, high); and employment status (employed – working currently, unemployed – not working currently) and were collected from the patients prior to administering the study measures. All socio-demographic data were classified according to the Omani norm, using data from the National Centre for Statistics and Information, Oman. Clinical data were obtained from each patient's file, in the form of closed questions that asked for up-to-date lab results showing levels of haemoglobin, haematocrit and albumin. The normality level of these tests was considered according to the National Kidney Foundation (2007).

2.6. Statistical analysis

Data entry was double-checked to avoid any possible entry errors. Initial analysis outputs were checked for missing, invalid and extreme values that might have fallen out of the range of normal possible values. The nominal and categorical data were inspected by running frequency tables, while continuous data were inspected by running descriptive statistics. The initial analysis outputs of frequency and descriptive tests were checked to correct any errors before starting data analysis. Likewise, missing data were examined and managed using one of the schemes suggested by Tabachnick & Fidell (2014). Missing data and extreme values of categorical variables were checked visually by observing frequencies in output tables. This was managed by using ipsative individual mean substitution if they were found not to be significant or ≤ 10%, and if > 10%, then the affected measure/subscale was excluded in future analyses (Tabachnick & Fidell, 2014).

The data normality and outliers test was performed by running a frequency distribution for each variable and outliers were checked by Q-Q Plot. Multivariate outliers were detected by running standardised residual values, and if greater or less than 3.0, values were categorised as an outlier (Tabachnick & Fidell, 2014). Outliers were handled either by being rescored, being deleted, or by creating separate regression models. Data linearity was checked using scatter-plots to illustrate the differences between each of the independent variables compared with the dependent variable. In case data normality assumptions were violated, data were transformed by using square root, logarithm and inverse function respectively.

The response rate was calculated by counting the number of participants who answered the questionnaires, divided by the number of individuals in the sample at this phase. Similarly, the percentage of all potentially eligible items that did not have responses was calculated by the frequencies rate of the actual responses compared with the total sample.

To predict the recruitment and participation rate for the main study, the involved study sites in the pilot study were used as a representative of the range of sites in the main study in order to best estimate typical recruitment rates. That is, the patients meeting the study criteria (50 patients) were tracked and recorded per site over a period of one month. Accordingly, the recruitment rate was calculated based on the number of patients who provided written consent divided by the number of eligible patients per site. The recruitment rate over the month was then calculated based on the obtained response rate, divided by the number of piloted sites.

Six measures – SF36v2, QoLI-Dialysis, HADS, FSS, Itch-5D and SWB – were scored and calculated using a syntax developed specifically to fit the SPSS programme. The procedure of scoring and calculating these measures was in accordance with the measure’s scoring guidelines. It should be noted that the scores of the bodily-pain scale are reverse scored: the higher the value, the less the bodily pain.

To explore the association between HRQoL variables and outcomes (SF36: PCS, MCS and QoLI-D), a correlation test was conducted. The Pearson product correlation coefficient (r) was conducted to assess the relationship between two parametric variables and the Spearman's rank order correlation (rho) was used to assess the relationship between non-parametric variables. The statistical significance for a variable inclusion into a statistical model was set at α= .15 (Tabachnick and Fidell, 2014). This determined liberal probability level was to avoid excluding important variables from the model. Independent variables were entered simultaneously into a sequential multiple regression model to determine how well biological factors, symptoms, functional status, general health perception and socio-demographic and treatment factors predicted a patient’s overall HRQoL. The guide from Tabachnick and Fidell (2007) on sample-size estimation for conducting regression analyses was used to determine the main study sample.

3. Results

This section describes the results of the pilot-study statistical analysis. It first describes results from recruitment of research assistants, followed by recruitment of participants and subsequently the statistical analysis pertaining to RQ2 and RQ3.

3.1. Recruitment of research assistants

Six nurses were recruited at a rate of two nurses from each study site. They were all qualified nephrology nurses. Out of the six, five were female nurses and one was male.

The training sessions were delivered in an average of two hours. The majority of participating nurses showed confidence and were able to administer the study measures effectively. The effectiveness of the training session was tested by conducting a simulated data collection and simultaneous administration of the measures to patients.

3.2. Recruitment of Participants

A total of 44 patients participated in the pilot study, with a participation rate of 73% over the period from 13 October 2015 to 24 October 2015. Figure 6.1 shows the flow of participation in the pilot study. At site 1 – Sumail HD Unit – the participation rate was 79.16% (24 patients were approached, 19 gave consent and returned the surveys, four refused to participate and gave no reasons, while one gave verbal consent but did not complete the survey). At site 2 – Nizwa HD Unit – 55.55% was the participation rate (18 patients were approached and, out of those, 10 provided written consent and eight refused to participate, providing no reasons). At site 3 – Ibri HD Unit – 83.33% was the participation rate (18 were approached, 15 gave written consent and three refused).

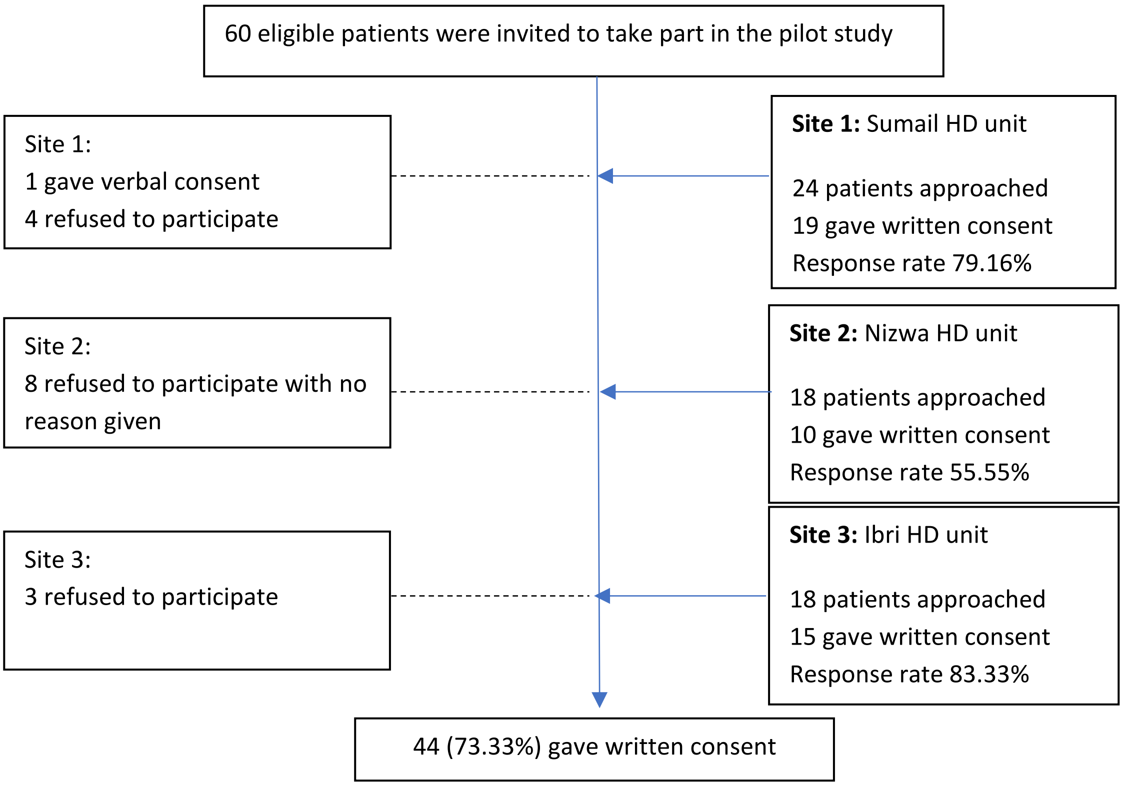


Figure 6. 1 Flow of participants in the pilot study

3.3. Preliminary Examination of Data

The overall completion rate of study measures ranged between 96.76% and 100% (Table 6.1). The highest completion rate was for the HADS and FSS measures (100%) and the lowest was for the QoLI-D (96.76%). These high results for the level of completion might reflect acceptability to patients.

Table 6. 1 Overall completion rate of piloted measures

Measure	# of measure items	Expected total # of items x 44 participants	Number of missing items	Missing items in %	Measure completion rate (%)
SF36	36	1,584	2	0.13 %	99.87
QoLI-D	68	2,992	97	3.24 %	96.76
HADS	14	616	-	-	100
Itch-5D	5	220	3	1.36 %	98.64
SWB	20	880	12	1.36 %	98.64
FSS	9	396	-	-	100

Obtained data were then entered into SPSS version 22.0. Data entry was double-checked and proofread against the original questionnaire. No errors were identified.

No missing data or extreme values were noted in the categorical variables. For continuous variables, descriptive statistics were run to check for missing data and extreme values. Four measures were identified as having missing values (SF36, QoLI-D, Itch-5D and SWB). Missing data were managed by replacing individual means substitution as if they were 10% missing data, except for case numbers 3 (20%) and 19 (40%) in the Itch-5D measures and case numbers 4 (20%) and 23 (25%) in the SWB measure, which were excluded in the inferential analysis pertaining to regression analysis. Subsequently, frequencies and descriptive analyses were repeated to check whether missing data were entirely replaced. No further missing data were shown and this provided the confidence to move to detect outliers and check data distribution.

Following data cleaning, the six measures were computed and a syntax was created using the SPSS programme.

Data were explored to examine distribution, outliers and linearity by observing histogram, Q-Q Plot, scatter-plots and the skewness and kurtosis values. Appendix 6.1 summarises the study variables that have been explored along with outliers, skewness and kurtosis values and tests of normality.

Each continuous variable was examined for normality by calculating skewness and kurtosis statistics. All continuous variables demonstrated acceptable skewness and kurtosis values.

Cronbach's alpha was computed for each measure to check for internal reliability. (Table 6.2). The result indicated that most of the piloted measures were reliable (α= > .70) (DeVellis, 1991; DeVon et al., 2007). The subscales of SF36v2 [Mental Component Summary (α= .500) and Physical Functioning Subscale (α= .508)] and 5D-Itch measure (α= .655), however, were found to be less reliable. By checking the item-total statistics for the 5-D Itch measure, item number -3 seemed to be problematic because, if deleted, alpha would increase to α= .732; whereas for SF36v2, alpha value remained relatively low. Hence, a further investigation may be required to explore the factor structure of SF36v2 using oblique and orthogonal rotation methods.

A further testing might be required to establish construct validity, such as factor analysis and structural equation modelling, to test and confirm the original models of SF36, QoLI-D and HADS against the Omani culture.

Table 6. 2 Internal reliability of total scores and subscales of the piloted measures

Measure	Cronbach's alpha
SF36v2	.875
SF36v2 Physical Component Summary	.799
SF36v2 Mental Component Summary	.500
SF36v2 Physical Functioning Subscale	.508
QoLID	.825
SWB	.829
Itch-5D Scale	.655
FSS	.886
HADS-Anxiety subscale	.845
HADS-Depression subscale	.773

SF36V2: Short Form 36v2; QoLID: Quality of Life Index-Dialysis; SWB: Spiritual Wellbeing Scale; FSS: Fatigue Severity Scale; HADS: Hospital Anxiety Depression Scale.

3.4. Characteristics of participants

Most participants were men (63.3%), married (65.9%), unemployed (63.6%) and illiterate (29.5%). For illiterate participants, the measure was read to them by the nurses without any prompts. Likewise, the majority (70.5%) reported having low incomes of < OMR 250/month (equal to approximately £370). Participants' ages ranged from 22 to 76 years old, with a mean age of 45 (*SD* = 14.23). Demographical data are shown in Table 6.3.

Table 6. 3 Demographical statistics (N = 44)

Variable	Frequency (%)
Gender	
Men	28 (63.6 %)
Women	16 (36.4 %)
Marital status	
Married	29 (65.9 %)
Separated	2 (4.5 %)
Widow	3 (6.8 %)
Single	10 (22.7 %)
Educational status	
Illiterate	13 (29.5 %)
Low-intermediate	6 (13.6 %)
Intermediate	10 (22.7 %)
High-intermediate	11 (25 %)
High	4 (9.1 %)
Job	
Employed	16 (36.4 %)
Unemployed	28 (63.6 %)
Income per month	
OMR <205	31 (70.3 %)
OMR 251-600	3 (6.8 %)
OMR 601-1,000	4 (9.1 %)
OMR 1,001-1,500	3 (6.8 %)
OMR >1,500	3 (6.8 %)

OMR: Omani Rial

Laboratory variables were within therapeutic values (based on KDOQI clinical practice guideline for haemodialysis, 2015) except for Haemoglobin (M= 11.16, SD= 1.42). For clinical variables, time on HD in hours per month ranged from 28 to 63 hours (M = 42.87 SD = 6.78), the adequacy of dialysis, measured by urea reduction rate, was within the normal range (M= 70.20, SD = 7.73). Results are shown in Table 6.4.

Table 6. 4 Clinical data (n 44)

Variable	Mean (SD)	Range	Therapeutic values*
Hb g/L	11.16 (1.42)	8.20-15.5	Male: 13 - 18 g/L Female: 12 - 16 g/L
Haematocrit level	35.68 (5.07)	27.10-49.10	33-36 %
Albumin level	38.51 (3.98)	25.60-44.66	35-48g/L
Dialysis adequacy (urea reduction rate)	70.20 (7.73)	70–90	≥ 65 %
Dialysis hours per month	42.87 (6.78)	28-63	-

* source: KDOQI clinical practice guideline for haemodialysis (2015)

3.5. **Research Question 2:** What is the level of QoL/HRQoL for patients with ESRD on HD in Oman?

This question was answered by descriptive analysis of the generic health measure (SF36v2), the condition-specific measure (QoLI-Dialysis), the emotional-status measure (HADS), the physical symptom-specific measures (Itch-5D, Fatigue Scale) and the spiritual measure (SWB). Means and standard deviation of the scale and subscales were calculated for the entire sample.

3.5.1. SF36v2

Patients reported low health-status scores on PCS (*M* = 40.77, *SD* = 8.61) and MCS (*M* = 43.40, *SD* = 10.82) (Table 6.5). Role limitation due to physical health (RP) and physical functioning (PF) were the lowest rated among the physical-health domain (*M* = 46.73, *SD* =29.57 and 47.39, *SD* = 27.92 respectively). Scores for mental-health domains were better, compared with physical health. The mental-health score was the highest (*M* = 65.68, *SD* = 20.64), followed by social functioning (*M* = 54.26, *SD* = 26.81).

Table 6. 5 Mean scores of SF36 (n = 44)

SF36 domains		Mean (SD)	Possible range
Physical health	PF	47.39 (27.92)	0 - 100
	RP	46.73 (29.57)	0 - 100
	BP	54.86 (24.86)	0 - 100
	General health	53.47 (21.20)	0 - 100
Mental health	Vitality	52.98 (23.13)	0 - 100
	SF	54.26 (26.81)	0 - 100
	RE	50.56 (31.91)	0 - 100
	MH	65.68 (20.64)	0 - 100
Component Summary Scores			
PCS		40.77 (8.61)	0 - 100
MCS		43.40 (10.82)	0 - 100

PF: Phsycial functioning; RP: Role physical; BP: bodily pain; DF; Social functioning; RE: Role emotion; MH: Mental health; PCS: physical component summary; MCS: mental component summary.

3.5.2. General health perception (item one in SF36v2)

A single item (number one in SF36) was used to ask patients to rate their health in general. This item is rated on a five-point Likert scale ranging from one as “excellent” to five as “poor” health status. Patients perceived their health status as fairly good (*M* = 2.93, *SD* = 1.16). The majority, consisting of 16 (36.4%) patients, perceived their health as “fair”, followed by 12 patients (27.3%) who perceived their health as “good”. Very few patients rated their health as “excellent” or “poor”. Table 6.6 shows the rating of perceived general health in numbers and percentages.

Table 6. 6 Perceived general health as rated by ESRD patients (n = 44)

Rating of perceived general health	*n* (%)
Poor	3 (6.8 %)
Fair	16 (36.4 %)
Good	12 (27.3 %)
Very good	7 (15.9 %)
Excellent	6 (13.6 %)

3.5.3. QoLI-Dialysis

The overall QoLI-D was 22.62 (SD = 2.97) out of a possible score of 30 (Table 6.7). The higher score on the QoLI-D indicates a better HRQoL. Each subscale was also measured on a 0-30 scale. The health and functioning subscale was the lowest scored subscale (M = 20.34, SD = 4.45), followed by the socio-economic subscale (M = 21.88, SD = 3.91).

Table 6. 7 Mean scores of QoLI-D (n = 44)

QoLI-D domains	Mean (SD)	Possible range
Health and functioning	20.34 (4.45)	0-30
Socio-economic	21.88 (3.91)	0-30
Psychological/spiritual	24.94 (4.63)	0-30
Family	26.91 (2.21)	0-30
QoLI-Dialysis	22.62 (2.97)	0-30

QoLI-D: Quality of life index-dialysis

3.5.4. HADS

The mean anxiety score was 6.61 (*SD* = 4.08), with scores ranging from 0-15. Forty-three percent of patients (19) obtained a score of ≥8 on the anxiety subscale, which possibly indicates the presence of clinical anxiety. The mean depression score was 6.34 (*SD* = 3.81), with scores ranging from 0 to 13. Thirty-nine percent of patients obtained a score of ≥8 on the depression subscale, indicating possible clinical depression (Table 6.8).

Table 6. 8 HADS scores and possible caseness of anxiety and depression

	N (%)	Mean (SD) (out of scores 0-21)	Minimum	Maximum	Caseness (HADS ≥ 8)
HADS-A Anxiety	44	6.61 (4.08)	0	15	N = 19 (43%)
HADS-D Depression	44	6.34 (3.81)	0	13	N= 17 (39%)

HADS: Hospital anxiety depression scale

3.5.5. Itch-5D

The Itch 5-D scale was used to quantify pruritus in this group of patients. Scores can potentially range between 5 (no pruritus) and 25 (most severe pruritus). The average Itch-5D score was 10.01 (*SD* = 3.41), with scores ranging between 5 and 23. The average was below the mid-range value, which may suggest that Omani ESRD patients had a low level of pruritus symptoms (Table 6.9).

Table 6. 9 Itch 5-D scale scores

	N (%)	Mean (SD)	Minimum	Maximum	Possible range
Itch scale	44	10.01 (3.41)	5	19	5-25

3.5.6. Fatigue Scale

FSS is an unidimensional scale used to measure fatigue severity in ESRD patients. It consists of nine items scored on a seven-point Likert scale with scores <36 suggesting no fatigue and scores ≥36 suggesting possible fatigue that may need future evaluation (Hagell and Hoglund, 2006). The mean FFS score was 44.40 (*SD* = 14.58), with scores ranging from 16-63. Sixty percent (29) of 44 patients obtained a score of ≥36, indicating that a further evaluation of fatigue is required for those patients (Table 6.10).

Table 6. 10 FFS scores possible caseness

	N (%)	Mean (SD)	Minimum	Maximum	Cassenas (FSS ≥ 36)
FSS	44	44.40 (14.58)	16	63	N= 29 (59.90%)

FSS: Fatigue severity scale

3.5.7. Spiritual Wellbeing Scale

The overall SWB score was 97.88 (*SD* =16.77). The mean scores for the EWB and RWB subscales were 46.31 (*SD* = 9.71) and 51.57 (*SD* = 8.55) respectively. This result might suggest that both the existential and religious domains of spirituality were clinically relevant to patients in this study and might have an impact on their HRQoL (Table 6.11). It also emphasises the need to estimate the impact of this domain on patients' physical health, mental health and HRQoL related to the disease.

Table 6. 11 SWB score and subscale scores

	N (%)	Mean (SD)	Minimum	Maximum	Possible range
Existential subscale	44	46.31 (9.71)	20	60	10 - 60
Religious subscale	44	51.57 (8.55)	21	60	10 - 60
SWB	44	97.88 (16.77)	41	120	20 - 120

SWB: Spiritual wellbeing

3.6. Research Question 3: To what extent do the following factors predict QoL/HRQoL in Omani patients with ESRD?

a) Individual characteristics (age, gender, educational status, income, region and marital status), measured by demographics
b) Treatment characteristics (duration of dialysis, dialysis adequacy and length of time to get to dialysis), measured by clinical data
c) Socio-environmental factors (family support, socio-economic, religious and spiritual), measured by disease-specific and generic instruments
d) Biological function (anaemia and malnutrition), measured by clinical data such as serum albumin, haematocrit and serum Hb
e) Symptoms (fatigue, pain, mood, pruritus), measured by symptom-specific instruments
f) Functional status and general health perceptions, measured by health-status instruments

A sequential regression method was used to predict the relationship between study independent variables on the SF36 (PCS and MCS) and QoLI-D scores. Thus, three separate regression models were developed for each of these dependent variables. The sequences for entering predictors into the regression models were determined according to the literature review and the sequence of the research questions.

It should be acknowledged that the assumption of sample size was not met for this pilot study, however, and the test was mainly performed for the purpose of developing and testing the syntax of sequential regression and, if it functioned, it was to be replicated in the main study.

Five of the nominal variables in this analysis (gender, marital status, education status, job and monthly income) required dummy coding prior to being entered into the model. These variables were coded as dichotomous variables (Munro, 2005) according to the most frequent response obtained from respondents (Table 6.12).

Table 6. 12 Dummy coding for nominal variables

Nominal variable	Reference value = 0	Non-reference values = 1
Gender	Male	Female
Marital status	Married	Divorced Widow Single
Education status	Illiterate	Low-intermediate Intermediate High-intermediate High
Job	Unemployed	Employed
Monthly Income (OMR)	<250	251-600 601-1,000 1,001-1,500 >1,501

OMR 1= £2.

3.6.1. Physical component summary (PCS)

Prior to conducing the multiple regression to test the predictors of PCS, the relevant assumptions of this statistical analysis were tested. The assumption of singularity was met as the independent variables (age, marital status, job, income, fatigue, 5-D itch, anxiety, depression and general health perception) were not a combination of other independent variables. An examination of correlations between study IVs (Table 6.13-6.14) revealed that no independent variables were above .85 (Tabachnick & Fidell, 2014). The co-linearity statistics (i.e., tolerance and variance inflation factors) were all above 0.10 and the VIF were all < than 10.0, indicating no concerns with multicollinearity (Tabachnick & Fidell, 2014). The assumption of multicollinearity was deemed to have been met (Coakes, 2005; Hair et al., 1998). No extreme univariate outliers were identified. Also, an examination of the Mahalanobis distance scores indicated no multivariate outliers. Residual and scatter plots indicated that the assumptions of normality, linearity and homoscedasticity were all satisfied in this regression (Hair et al., 1998; Pallant, 2001).

Table 6. 13 Spearman's rho correlations of PCS with independent variables (N = 44)

	Gender	Marital status	Educational status	Job	Income	PCS
Gender	-	-.07	-.46**	.57**	-.18	-.31*
Marital status		-	.31*	.35*	-.20	-.29*
Educational status			-	-.30*	.45**	.09
Job				-	-.41**	-.27$^{\$}$
Income					-	.27$^{\$}$
PCS						-

p ≤ .15$^{\$}$; p ≤ .05*; p < .001**

PCS: Phsyical component summary

Table 6. 14 Pearson's correlations of PCS with independent variables (N = 44)

	PCS	Pt age	Hb	HCT level	Albumin level	HD hours per month	HD adequacy	QoLID socio-eco	QoLID Family	General Health Perception	Anxiety	Depression	5D Itching	SWB	FFS
PCS	-	.20	.17	.21	.01	-.01	-.14	.16	-.06	.52**	-.47**	-.56**	-.30*	.20	-.47**
Pt age		-	-.44**	-.41**	-.01	-.26	-.12	-.08	-.03	.06	-.17	-.12	-.40**	-.01	-.37*
Hb			-	.89**	.10	-.01	-.04	.23$^{\$}$	.14	-.01	-.13	-.19	.19	-.01	-.03
HCT level				-	.17	-.09	.01	.24$^{\$}$	.23	-.10	-.18	-.20	.16	.13	.02
Albumin level					-	-.09	-.01	.06	.41**	-.13	.06	-.02	-.03	-.07	.01
HD hours per month						-	.18	.07	-.11	-.05	-.01	.18	.02	.01	.09
HD							-	-.01	.10	.08	-.36*	-.30*	-.08	.26	-.08
QoLID socio-eco								-	.59**	.12	.07	-.11	-.01	.10	-.08
QoLID Family									-	.01	.04	-.06	.02	.14	-.07
QoLID										.58**	-.60**	-.73**	-.09	.55**	-.58**
General Health Perception										-	-.43**	-.54**	-.17	.34*	-.43**
Anxiety											-	.75**	.19	-.50**	.60**
Depression												-	.18	-.43**	.57**
5D Itching													-	.16	.17
SWB														-	-.34*
FFS															-

p ≤ .15$^{\$}$; p ≤ .05*; p < .001**

PCS: physical component summary; Hb: Haemoglobalin; HD: Heamodialysis; QoLID: Quality of life index-dialysis; SWB: Spiritual wellbeing; FFS: Fatigue severity scale

A four-stage sequential multiple regression was conducted with physical health as the dependent variable. Socio-demographic variables were entered at step one of the regression to control for socio-demographic effects. The physical-symptom variables (fatigue and itch) were entered at step two, mood symptoms (anxiety and depression) at step three and general health perception at stage four. Apart from the sample size, no other violation in assumptions was noted.

At step one, with demographic variables in the equation, F_{inc} (4,37) =.450, p = .78 these accounted for 21% of variance in the PCS score. None of the demographic variables were found to be significant predictors of SF36v2 PCS scores. Introducing the physical-symptom variables in step two explained an additional 22% of variance in the PCS scores and this change in R^2 was significant, F_{inc} (2, 35) =5.472, $p < .01$. Among the two variables added in step two, only high fatigue scores associated with low SF36v2 physical health components cores (p = .008). Adding the mood symptoms to the equation, the regression model explained an additional 13.7% of variance in PCS scores and this change in R^2 was significant, F_{inc} (2,33) =3.832, p = .032. Neither symptom appeared to be significant predictors of SF36v2 PCS. Finally, after the addition of perceived general health at step four, the R^2 was =.476 (adjusted R^2 =.329), F_{inc} (1, 32) =4.054, p= .053. In the final model, no significant predictors were found. Regression statistics are in Table 6.15.

Table 6. 15 Sequential Multiple Regression Analysis predicting SF36v2 PCS (two-factor standardised model) from Treatment Characteristics, Family Support, Symptom Specific Measures, Emotional Measures and Health Status Measures

Variable	***B***	**SE *B***	β	***t*-statistic**	***Significance***	***R***	***F***	R^2	ΔR^2
Step 1						.21	.43	.04	.05
Patient age	.10	.10	.18	1.06	.29				
Marital status	-.06	3.21	-.04	.02	.98				
Job	-1.93	3.32	-.10	.58	.56				
Income	-2.13	3.40	-.11	.62	.53				
Step 2						.52	5.47	.27	.14
Itch	-.60	.39	-.23	1.53	.13				
Fatigue	-.25	.09	-.43	2.79	.01*				
Step 3						.64	3.83	.41	.26
Anxiety	-.17	.46	-.08	.36	.71				
Depression	-.92	.48	-.41	1.89	.06				
Step 4						.69	4.05	.47	.32
Perceived General Health	2.36	1.17	.32	2.01	.05				
Overall Final Model									
Intercept	45.5								
Pt age	.01	.09	.02	.13	.89				
Marital statu	.58	2.62	.03	.22	.82				
Job	-.79	2.72	.04	.29	.77				
Income	-.73	2.75	.03	.26	.79				
Itch	-.46	.35	.18	1.31	.19				
Fatigue	-.05	.10	.09	.53	.59				
Anxiety	-.14	.44	.06	.31	.75				
Depression	-.58	.49	.26	1.18	.24				
Perceived General Health	2.36	1.17	.32	2.01	.05				
F-test for the whole model	4.054								
Significance of *F*-test	.053								
R	.690								
R^2	.476								
Adjusted R^2	.329								

Note: N = 44. CI, confidence interval; NS, not significant; HD, Haemodialysis.
The β weights are the standardised regression coefficients at each step.
**p < .05. **p< .01, *** p< .001*

In summary, none of the tested variables predicted the physical-health scores in this sample of ESRD patients. However, given that the aim of performing this model was to practice the syntax of sequential regression and its functioning, to be replicated in the main study, results evident feasibility of this syntax to the main study.

3.6.2. Mental Component Summary (MCS)

The assumptions relating to this regression model were tested. The assumption of singularity was met as the independent variables (gender, HD adequacy, fatigue, itch, anxiety, depression, physical health and general health perception) were not a combination of other independent variables. An examination of correlations (tables 6.16 and 6.17) revealed no independent variables above .85 (Tabachnick & Fidell, 2014). The co-linearity statistics (i.e., tolerance and variance inflation factors) were all above 0.10 and the VIFs were all < than 10.0, indicating no concerns with multicollinearity (Tabachnick & Fidell, 2014). The assumption of multicollinearity was deemed to have been met (Coakes, 2005; Hair et al., 1998), except for sample size. No extreme univariate outliers were identified. Also, an examination of the Mahalanobis distance scores indicated no multivariate outliers. Residual and scatter plots indicated that the assumptions of normality, linearity and homoscedasticity were all satisfied (Hair et al., 1998; Pallant, 2001).

Table 6. 16 Spearman's rho correlations of MCS with independent variables (N = 44)

	Gender	Marital status	Educational status	Job	Income	MCS
Gender	-	-.04	-.44**	.57**	-.17	-.32*
Marital status		-	.15	.34*	-.25	-.13
Educational status			-	-.28	.20	.21
Job				-	-.44**	-.04
Income					-	.04
MCS						-

$p \leq .15^{\$}$; $p \leq .05^{*}$; $p < .001^{**}$

MCS: Mental component summary

Table 6. 17 Pearson’s correlations of MCS with independent variables (N = 44)

	MCS	Pt age	Hb	HCT	Albumin level	HD hours per month	HD adequa-cy	QoLID socio-eco	QoLID Family	General Health Perception	Anxiety	Depression	5D Itching	SWB	FFS	Bodily pain	PCS
MCS	-	.08	.01	-.01	-.01	-.16	.24$	-.14	-.17	.45**	-.64**	-.71**	-.28$	.35*	-.56**	.76**	.49**
Pt age		-	-.41**	-.41**	.02	-.20	-.09	-.02	.03	.08	-.14	-.10	-.30*	-.02	-.32*	.12	.17
Hb			-	.84**	.06	-.14	-.02	.22$	.10	-.02	-.10	-.16	.08	-.06	-.05	.21	.14
HCT				-	.20	-.18	-.05	.16	.20	-.13	-.17	-.16	.17	.08	.02	.20	.14
Albumin level					-	-.13	-.01	.07	.44**	-.11	.07	-.06	-.04	-.16	-.02	.11	.05
HD hours per month						-	.10	.09	-.16	-.09	-.02	.16	.02	-.01	.06	-.12	.01
HD adequacy							-	-.05	.07	.09	-.36*	-.28	-.10	.28	-.11	-.04	-.14
QoLID socio-eco								-	.64**	.06	.09	-.07	-.05	-.02	-.02	-.02	.13
QoLID Family									-	-.08	.10	.03	.02	.03	-.03	-.17	-.05
General Health Perception										-	-.45**	-.55**	-.15	.34*	-.40**	.38*	.57**
Anxiety											-	.76**	.13	-.38*	.61**	-.53**	-.50**
Depression												-	.14	-.33*	.58**	-.60**	-.57**
5D Itching													-	.20	.17	-.31*	-.30*
SWB														-	-.27	.17	.15
FFS															-	-.46**	-.453*
Bodily pain																-	.74**
PCS																	-
GH perception																	

p ≤ .15$^{\$}$; p ≤ .05*; p < .001**

MCS: Mental component summary; Hb: Haemoglobalin; HD: Heamodialysis; QoLID: Quality of life index-dialysis; SWB: Spiritual wellbeing; FFS: Fatigue severity scale

A five-stage sequential multiple regression was conducted with mental health as the dependent variable. The socio-demographic variable (gender) was entered at step one of the regression to control for socio-demographic effects. The clinical variable (HD adequacy) was entered at step two, physical symptoms at step three, emotional symptoms at step four and perceived general health and physical functioning at step five. The regression-statistics result is in Table 6.18.

Table 6. 18 Sequential Multiple Regression Analysis predicting MCS From Demographic, Treatment Characteristics, Symptom-Specific Measures, Emotional Measures and Health Status Measures

Variable	***B***	**SE *B***	β	***t-statistic***	***Significance***	***R***	***F***	R^2	ΔR^2
Step1						.35	5.77	.12	.10
Gender	-7.90	3.28	-.35	2.40	.02*				
Step2						.43	3.05	.19	.14
HD Adequacy	.35	.20	.25	1.74	.08				
Step 3						.86	25.45	.74	.70
Itch	-.06	.28	-.01	.21	.83				
Fatigue	-.11	.07	-.15	1.56	.12				
Bodily pain	.28	.04	.66	6.56	.00***				
Step 4						.86	.95	.75	.70
Anxiety	.04	.39	.01	.91	.91				
Depression	-.53	.42	-.19	.21	.21				
Step 5						.88	1.37	.77	.71
Perceived General Health	1.23	1.04	.13	1.18	.24				
Physical health	-.31	.20	-.25	-.154	.13				
Overall Final Model									
Intercept	32.96								
Gender	-2.97	2.22	-.13	-1.33	.19				
HD adequacy	.20	.15	.14	1.32	.19				
Itch	-.18	.29	-.05	-.63	.53				
Fatigue	-.08	.08	-.11	-1.01	.31				
Bodily pain	.29	.06	.68	4.89	.00***				
Anxiety	-.04	.39	-.01	-.12	.90				
Depression	-.57	.44	-.20	-1.27	.21				
Perceived General Health	1.23	1.04	.13	1.18	.24				
Physical functioning	-.31	.206	-.25	-1.54	.13				
F-test for the whole model	1.37								
Significance of *F*-test	.26								
R	.88								
R^2	.77								
Adjusted R^2	.71								

Note: N = 44. CI, confidence interval; NS, not significant; HD, Haemodialysis.
The β weights are the standardised regression coefficients at each step.
**p < .05. **p< .01, *** p< .001*

At step one, with gender variables in the equation F_{inc} (1,40) =5.774, p = .021, these accounted for 35% of the variance in the PCS score. Gender was found to be a significant predictor of MCS scores (p = .021). Introducing the clinical variable (HD adequacy) in step two explained an additional 6% of variance in the MCS scores and this change in R^2 = .774, F_{inc} (1, 39) =3.054, p < .088. The HD adequacy variable was found not to be a significant predictor of MCS. At step three, with physical symptoms in the equation F_{inc} (3,36) =25.451, p < .001, of the three variables added at this step, lower bodily pain associated with better mental health component scores (p< .001). Adding the mood symptoms to the equation in step four, the regression model explained an additional 55% of variance in MCS scores and this change in R^2 was not significant, F_{inc} (2,34) = .955, p = .395. Both symptoms appeared not to be significant predictors of MCS. Finally, the addition of the perceived general health and physical functioning at step five, explained an additional 20% to model, R^2 =.774 (adjusted R^2 =*.710*), F_{inc} (2, 32) =1.371, p= .268. None of the perceived general health and physical functioning factors were significant. In the final model the only significant predictor of MCS scores was bodily pain. Together, all the IVS accounted for 77.4% of the variance in the SF36v2 MCS scores.

In summary, lower bodily pain predicted better mental-health scores in patients with ESRD.

3.6.3. Quality of Life Index-Dialysis (QoLID)

The relevant assumptions of this statistical analysis were tested. The assumption of singularity was met as the independent variables (HD adequacy, haematocrit, itch, fatigue, bodily pain, anxiety, depression, perceived general health and physical functioning) were not a combination of other independent variables. An examination of correlations (tables 6.19 and 6.20) revealed that no independent variables were highly correlated (Tabachnick & Fidell, 2014). The co-linearity statistics (i.e., tolerance and variance inflation factors) were all above 0.10 and the VIF were all < than 10.0, indicating no concerns with multicollinearity (Tabachnick & Fidell, 2014). The assumption of multicollinearity was deemed to have been met (Coakes, 2005; Hair et al., 1998). No extreme univariate outliers were identified. Also, an examination of the Mahalanobis distance scores indicated no multivariate outliers. Residual and scatter plots indicated that the assumptions of normality, linearity and homoscedasticity were all satisfied (Hair et al., 1998; Pallant, 2001).

Table 6. 19 Spearman's rho correlations of QoLID with independent variables (N = 44)

	Gender	Marital status	Educational status	Job	Income	QoLID
Gender	-	-.04	-.44**	.57**	-.17	-.09
Marital status		-	.15	.34*	-.25	.11
Educational status			-	-.28	.20	.16
Job				-	-.44**	.08
Income					-	-.06
QoLID						-

p ≤ .15$; p ≤ .05*; p < .001**

QOLID: Quality of life index dialysis

Table 6. 20 Pearson’s correlations of QoLID with independent variables (N = 44)

	QoLID	Pt age	Hb	HCT	Albumin level	HD hours per month	HD adequacy	General Health Perception	Anxiety	Depression	5D Itching	SWB	FFS	Bodily pain	PCS
QoLID	-	.02	.25	.31*	.04	-.03	.27$^{\$}$	.53**	-.66**	-.70**	-.08	.44**	-.58**	.47**	.57**
Pt age		-	-.41**	-.41**	.02	-.20	-.09	.08	-.14	-.10	-.30*	-.02	-.32*	.12	.17
Hb			-	.84**	.06	-.14	-.02	-.02	-.10	-.16	.08	-.06	-.05	.21	.14
HCT				-	.20	-.18	-.05	-.13	-.17	-.16	.17	.08	.01	.20	.14
Albumin level					-	-.13	-.01	-.11	.07	-.06	-.04	-.16	-.02	.11	.05
HD hours per month						-	.10	-.01	-.02	.16	.01	-.01	.06	-.12	.01
HD adequacy							-	.09	-.36*	-.28	-.10	.28	-.11	-.04	-.14
General Health Perception								-	-.45**	-.55**	-.15	.34*	-.40**	.38*	.57**
Anxiety									-	.76**	.13	-.38*	.61**	-.53**	-.50**
Depression										-	.14	-.33*	.58**	-.60**	-.57**
5D Itching											-	.20	.17	-.31*	-.30*
SWB												-	-.27	.17	.15
FFS													-	-.46**	-.45**
Bodily pain														-	.74**
PCS															-
GH perception															

p ≤ .15$^{\$}$; p ≤ .05*; p < .001**

PCS: physical component summary; Hb: Haemoglobulin; HD: Heamodialysis; QoLID: Quality of life index-dialysis; SWB: Spiritual wellbeing; FFS: Fatigue severity scale

A five-stage sequential multiple regression was conducted with quality of life-index dialysis related as the dependent variable. The treatment characteristic variable was entered at step one of the regression and haematocrit was entered at step two. Physical symptoms were entered at step three, mood symptoms at step four and perceived general health and physical functioning at step five. The regression statistics are in Table 6.21. Apart from the sample size, no violations in assumptions were noted. Thus, these were considered as having been sufficiently met.

Table 6. 21 Sequential Multiple Regression Analysis predicting QoLID Treatment Characteristics, Symptom-Specific Measures, Mood Measures and Health Status Measures

Variable	***B***	**SE *B***	β	***t***	***Significance***	***R***	***F***	R^2	ΔR^2
Step 1						.273	3.22	.07	.05
HD adequacy	.10	.05	.27	1.79	.08				
Step 2						.431	5.33	.18	.14
Haematocrit	.19	.08	.33	2.31	.02*				
Step 3						.730	8.90	.53	.46
Itch	.04	.10	.04	.39	.69				
Fatigue	-.09	.02	-.45	-3.48	.01**				
Bodily pain	.02	.01	.23	1.65	.10				
Step 4						.788	3.91	.62	.54
Anxiety	-.08	.13	-.11	-.59	.55				
Depression	-.30	.14	-.38	-2.124	.04*				
Step 5						.834	3.91	.69	.60
Perceived General Health	.48	.34	.19	1.40	.16				
Physical functioning	.09	.06	.28	1.61	.11				
Overall Final Model									
Intercept	10.01.								
HD adequacy	.07	.04	.19	1.63	.11				
Haematocrit	.16	.06	.28	2.57	.01*				
Itch	.04	.09	.05	.47	.64				
Fatigue	-.05	.02	-.26	-2.02	.05				
Bodily pain	-.01	.01	-.12	-.78	.43				
Anxiety	-.03	.12	-.05	-.29	.77				
Depression	-.17	.13	-.22	-1.26	.21				
Perceived General Health	.48 .09	.34	.19	1.40	.16				
Physical functioning		.06	.28	1.61	.11				
F-test for the whole model	.3.91								
Significance of *F*-test	.03*								
R	.83								
R^2	.69								
Adjusted R^2	.60								

Note: N = 44. CI, confidence interval; NS, not significant; HD, Haemodialysis.
The β weights are the standardised regression coefficients at each step.
**p < .05. **p< .01, *** p< .001*

At step one, with the HD adequacy variable in the equation F_{inc} (1,40) =3.228, $p = .080$, this accounted for 7.5% of the variance in the QoLID score. The HD adequacy variable was found not to be a significant predictor of QoLID scores. Adding the haematocrit variable in step two, F_{inc} (1,39) =5.335, $p = .026$, explained an additional 11% of variance in QoLID scores and this change in R^2, was significant ($p = .026$). That is, higher percentage of haematocrit associated with better QoLI-Dialysis. Introducing the physical-symptom variables in step three explained an additional 34% of variance in the QoLID scores and this change in R^2 was significant, F_{inc} (3, 36) =8.906, $p < .01$. Among the three variables added in step three, only higher fatigue was found to be a significant predictor of low QoLID scores ($p = .001$). Adding the mood symptoms to the equation, the regression model explained an additional 8% of variance in QoLID scores and this change in R^2 was significant, F_{inc} (2,34) =3.832, $p = .029$. Higher depression scores associated with lower QoLI-Dialysis. Finally, after the addition of perceived general health and physical functioning at step five, $R^2 =.695$ (adjusted $R^2 =.609$), F_{inc} (2, 32) =3.914, $p= .030$. In the final model, the only significant predictor of QoLID scores was haematocrit. Together, all the IVS accounted for 67% of variance in the QoLID scores.

In conclusion, haematocrit was found to be a significant factor that positively predicted QoLI related to dialysis. That is, the higher scores of haematocrits predicted high QoLID scores in patients with ESRD. For each unit increase in the haematocrit, the QoLID score is predicted to increase on average by .166 units, with 95% confidence limits from .035 to .298 and this association is statistically significant ($p = .015$).

4. Discussion

The aims of this pilot study were to test the practicality of the selected HRQoL and spiritual-wellbeing measures within an Omani context and their acceptability to patients. Findings reflected the practicality of using the cross-sectional design to test the factors that predict HRQoL among patients with ESRD within Oman. Forty-four patients completed six measures with a completion rate of more than 80%. Likewise, the method employed to recruit research assistants was suitable and can be replicated in the main study.

In preparing the pilot study, the researcher’s concern was based on conducting and ensuring a rigorous sequential regression analysis. As a novice researcher, the pilot study provided the opportunity to gain the necessary experience in conducting the test and identifying practical issues or difficulties in data-analysis and interpretation. Thus, a pilot study can be considered highly useful for novice researchers to safely practice planned statistical analysis and familiarise themselves with any statistical plan prior to conducting the main study. Another advantage for the researcher is that piloting the quantitative approach can be carried out if the researcher lacks confidence particularly when using advance statistical tests such as sequential regression statistics.

Despite the assumption that sample size was not met in this pilot study, results indicate the usefulness of the statistical syntax. To determine the sample size for regression analysis, a rule of thumb suggested by Tabachnick and Fidell (2001) can be used: ($N > 50 + 8m$, where N = number of participants and m = number of independent variables). A sample size of 194 responses would be required to make an overall fit of the model. To test the contribution of each individual independent variable to explain the dependent variable, this rule of thumb was used: $N = 104 + k$. Thus, 122 samples are required to test the individual independent variable. These methods would assume a medium-effect size relationship between independent and dependent variables of $\alpha = 0.05$ and $\beta = 0.20$ when data are normally distributed. Likewise, for factor analysis, the ratio of 4-10 cases per item was the rule of thumb employed (Tabachnick & Fidell, 2014). For instance, SF36v2 has 36 items. Thus, for SF36v2, around 7 cases x 36 items = 252 participants and this total was deemed sufficient to provide a reliable factor structure.

The piloted measure, including socio-demographic questions, has been shown to be reliable in the Omani context. Two measures, however, SF36v2 and HADS, may require further exploration of factor construct using the factor-analysis test. This is to test whether these measures literally reflect the true theoretical meaning of their concepts within the Omani context. The low Cronbach’s alpha of the two subscales of the mental-component summary (α .500) and physical functioning (α .508) of SF36v2 may suggest the existence of a latent variable within the

Omani context that needs to be explored. The HADS result showed a slight variation between the concepts of anxiety and depression among this group of patients. To explore the nature of this variation further and to validate the HADS among Omanis, it would be useful to conduct a factor analysis that explores the factor structure.

In current study, it was observed that the mental-health domain was higher among ESRD patients compared with the physical-health domain. This may indicate that ESRD has a greater impact on physical health and that patients may have developed a mechanism to maintain their mood status throughout their time spent on dialysis. Similarly, Hopman et al (2009) conducted a systematic review and concluded that all chronic health conditions might negatively impact on a patient’s physical-health status, with relatively better mental-health status. The review included 10 studies using SF36 administered to 2,418 patients with different chronic health conditions. This could support the argument that patients with chronic diseases, including ESRD, may develop controllability and coping mechanisms to rebalance their perception of life.

Two measures were used to examine overall health status and HRQoL in Omani patients. The means and standard deviation of the scale and subscales were calculated for both measures for the entire sample. On SF36, patients reported low scores on physical health. Their role limitation, due to physical health and physical functioning, were the lowest rated among the physical-health domain. The scores for mental-health domains were slightly better compared with physical health and the mental-health score was the highest, followed by social functioning, within this aspect. Likewise, for QoLI-D, the overall scores indicated a low level of HRQoL. The health and functioning subscale was the lowest scored subscale, followed by the socio-economic subscale. In addition to SF36 and QoLI-D, a single item (number one in SF36) was used to ask participants to rate their health in general. Overall, the majority of patients perceived their health as “fair” or “good”, with very few rating it as “excellent” or “poor”.

The health and functioning scores were the lowest compared with scores of family support and spiritual-life subscales of QoLI-Dialysis. This result was similar to findings by Ferrans and Powers (1993) in which health and functioning scores were lower than family-support subscale scores. Although it is not clear why patients value family higher in relation to their HRQoL than health and functioning status, it may be that patients place greater importance on non-health factor values as a supportive mechanism for coping with their poor health and functioning. The contribution of non-health factors, such as family and socio-environmental support, was emphasised by the revised Wilson and Cleary model of HRQoL. Family and psychological/spiritual aspects were both rated as high by Omani patients, which may suggest that they use it as a coping mechanism with which to rebalance their life. Additionally, this finding may also explain the focus on the burden of the disease in the majority of studies assessing HRQoL in patients with ESRD.

Albumin variable was a predictor of QoLI-Dialysis and explained 28% of the total variance ($p = .015$). Studies that examined the haematocrit effect on patients with ESRD have used the SF36 health-status measure (Patel et al., 2002; Lopes et al., 2007). Interestingly, these studies did not report any significant correlation between haematocrit and overall health status. It may be that haematocrit is a dialysis-related health factor rather than an overall health-status factor, yet it correlates with overall health status. Clinically, the haematocrit level is usually affected by clinical factors such as malnutrition, blood loss during the dialysis procedure and other medical conditions. Ebben et al. (1998) found, in a comparison study between ESRD patients with ≥30% haematocrit and ≤29% level, that patients with less than 30% haematocrit had a higher risk of mortality. This might indicate that albumin may not directly impact on health stauts unless it is at a severely low level. For this study sample, the mean haematocrit level was 38.42 (SD = 5.13), with therapeutic values around 35-48g/L according to the KDOQI clinical-practice guideline for haemodialysis (2015), which shows the clinically acceptable level of haematocrit. Prior to determining the exact relationship between haematocrit and QoLI-Dialysis, future studies should perhaps be considered which test the haematocrit factor as an outcome.

Higher general health perception was associated with better physical-health status ($r = .527$, $p < .001$), mental-health status ($r = .459$, $p < .001$), and QoLI-Dialysis ($r = .537$, $p < .001$) in patients with ESRD. The contribution of general health perception to better physical health was found by Wu A et al. (2004) in an examination of overall health status in two groups of ESRD patients, on peritoneal and haemodialysis dialysis, in which general health perception was associated with better physical functioning (r = .341, p < .001). Cleary et al. (2005) also found a positive correlation between general health perception and mental-health status. These findings might contribute to formulating a conclusion that general health perception might be associated with a better level of HRQoL in patients with ESRD. It also supports the notion of the importance of using individualised measures when assessing QoL and HRQoL.

Fatigue was a prevalent variable in this study and associated with low HRQoL. Twenty-nine patients (56% of 319) were possible cases which may need further clinical evaluation (≥ 36 may require clinical evaluation; Hagell et al., 2006). Although the fatigue variable was an insignificant factor in study outcomes, it was associated with low physical health, mental health, and QoLI-Dialysis. The finding was similar to that in a study by Williams et al (2007) in which fatigue was high in American patients on haemodialysis (M = 44.6, SD = 33.1). These results furnished evidence that fatigue is associated with poor HRQoL and may be a main symptom that impacts on a patient's overall health, requiring clinical intervention.

Bodily pain was assessed by the bodily-pain (BP) subscale of SF36v2, with reverse scoring meaning that the lower BP scores indicated better health status, and the mean score was 54.86 (*SD* = 24.86). Although there is no published norm for the bodily-pain scale in Oman, this score was comparable with the pain mean of 55.6 (*SD* = 28.8) among Russian ESRD patients (Vasilieva and Irina, 2006). Dudgeon et al (2005) observed that low perceptions of control over pain may lead to decreased motivation to cope with pain and to poorer psychological health. Therefore, the presence of pain, if it is not effectively treated and relieved, might have a detrimental effect on all aspects of HRQoL in patients with ESRD. Thus, future research is required to examine the hidden implication of pain on a patient's HRQoL.

Despite physical symptoms associated with lower HRQoL, the mean itch symptom was 10.01 (SD = 3.41), with a maximum range of 25. The literature did not report a norm or a cut-off value for the 5-D Itch scale. However, scores remain lower compared with scores for fatigue and bodily pain. This score also remains slightly lower compared with international published studies that examine itch among ESRD patients (Lai et al., 2017; Khan et al., 2014). Uraemia (high urea in blood) is often the main cause of itching in ESRD patients and is usually treated by an adequate dialysis regimen. The urea clearance (URR) was within the recommended therapeutic value (≥ 65% based on the KDOQI Guideline, 2007). This reflects the fact that receiving an efficient dialysis regimen helps to reduce uraemia and other toxic consequences. It may also suggest that patients have a good compliance with the recommended dietary intake related to ESRD.

Anxiety was associated with poorer study outcomes. The mean anxiety score was 6.61 with 43% (19 patients) beyond a cut-off score of 8. This indicates that anxiety is a substantial symptom among Omani patients with ESRD. Ramirez et al. (2012) reported similar findings among haemodialysis patients in a study in which 170 patients (25.9%) were anxious.

Six instruments were administered in this pilot to test the practicality of the selected HRQoL measures within an Omani context and their acceptability to patients. The obtained response and completion rate on all administered measures was optimistic (above 80%). It is therefore deemed to be reliable within an Omani context to administer the main study to explore the factors and levels that determine HRQoL in patients with ESRD. However, two measures, SF36v2 and HDAS, may require further construct validation within the Omani context. The low Cronbach's alpha of the two subscales of Mental Component Summary (α .500) and Physical Functioning (α .508) of SF36v2 may suggest the existence of a latent variable within the Omani context that needs to be explored. For this, an exploratory factor analysis may be required, using oblique and orthogonal rotation methods to explore the factor construct of SF36v2 within the given context. The HADS result showed a slight variation between the concepts of anxiety and depression among this group of patients. To explore the nature of this variation further and to validate the HADS among Omanis, it would be useful to conduct a factor analysis to explore the factor structure.

Given that no studies have been conducted assessing HRQoL among ESRD patients within Oman, the nephrology services and literature were lacking in this area of practice. Hence, information on HRQoL is needed to fill this gap and how ESRD patients can be helped. This pilot study may guarantee new knowledge and expanded understanding of HRQoL among dialysis patients. It makes a valuable contribution to the validation of HRQoL among ESRD patients and to the international literature with new knowledge from the piloted measures. The information generated by this study about the cultural relevancy of the HRQoL measures could help researchers aiming to standarised the SF36v2, QoLI-Dialysis, HADS, Itch-D Scale, and FFS measures across cultures.

A number of limitations in this pilot study should be acknowledged. First, the sample was taken from three dialysis units in Oman. This sample therefore may not be representative of the Oman ESRD population. Patients from different regions may perceive their HRQoL differently. Patients from different regions and rural areas may have different backgrounds and value systems. A larger group of patients from different regions in Oman would strengthen the study. Second, although this pilot study used a random group from the ESRD patients in Oman, results might only provide regional norms of the piloted measures which can be used for comparison purposes until establishing normative values for the Omani population. Third, around 30% of the patients in this study were illiterate. Although the measures were read to illiterate patients by the trained nurses without any prompts, the answers provided may not reflect their true perception of helath. Finally, because patients spend around 12-15 hours on dialysis per week, recruitment may be enhanced by asking patients to participate during their regular dialysis schedule. Haemodialysis can cause hypotension and electrolytes imbalance. Patients may not have felt at their best while answering the piloted measures related to their HRQoL.

5. Conclusion

This pilot study tested the acceptability and practicality of the use of study measures within Oman, as well as recruitment procedures, rate of participation and feasibility to ensure that any variations in the research design were effectively managed. Forty-four patients participated in the study with a good response rate of 73% over a period of 21 days. The rate of measures compeletion ranged from 96.7%-100%, indicating a preliminary acceptance and applicability of the measures. The study was guided by the revised Wilson and Cleary model of HRQoL (2005) which seemed to be an applicable conceptual model to guide the main study. It has various domains, including biological function, symptoms, functional status, general health perceptions and various characteristics of the individual and their environment, which provide sufficient justification of the independent variables used to explain HRQoL.

The piloted measure, including socio-demographic questions, has been shown to be reliable in the Omani context. Two measures, however, SF36v2 and HADS, may require further exploration of factor construct using the factor-analysis test. This is to test whether these measures literally reflect the true theoretical meaning of their concepts within the Omani context. The low Cronbach's alpha of the two subscales of the mental-component summary (α .500) and physical functioning (α .508) of SF36v2 may suggest the existence of a latent variable within the Omani context that needs to be explored. The HADS result showed a slight variation between the concepts of anxiety and depression among this group of patients. To explore the nature of this variation further and to validate the HADS among Omanis, it would be useful to conduct a factor analysis that explores the factor structure.

Religion and spirituality is an important factor that may determines a patient's HRQoL and is associated with better mental health and QoLI-Dialysis. Patients, however, may experience religious struggle or be unsettled about their religious activities due to the burden of the disease. Their physical functioning and/or role-functioning status might not help them to perform their obligated religious rituals. This possible negative association between physical functioning and role-functioning needs to be further explored in the main study.

Chapter 7- Exploratory and Confirmatory Factor Analysis of the Arabic Version of SF36v2 and HADS within an Omani Context

Background

Studies that examined factor structure of the Short-Form 36v2 (SF36v2) and Hospital Anxiety Depression Scale (HADS) have yielded inconsistent findings. SF36v2 and HADS have not been validated within the Omani context, and currently their factor structure is not known. This study, therefore, aims to explore the underlying structure of the both measures, using factor analysis and internal-reliability test.

Method

Data from a cross-sectional study conducted across 13 dialysis units in Oman were used in this analysis. Internal consistency, exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) were conducted to test both measures. Factors number were determined by using Eigenvalues and were then explored using oblimin and orthogonal rotation methods. The simplest and clearest identified structures out of EFA were then confirmed using CFA.

Findings

SF36v2 had an acceptable internal consistency. EFA revealed a three-factor structure underpinning the SF36v2 in this population. This was confirmed by CFA which manifested good-fit indices parameters: RMSEA (.06), CFI (.90) and TLI (.90).

HADS did not have an exclusive factor-structure. EFA revealed one-factor structure, and a potential two-factor structure correlated at α .53 Items-6,7,8,10 were problematic and showed inconsistency loading on its hypothesised factor. CFA revealed acceptable fit indices to data for the one-factor (RMSEA: .08, CFI: .92, TLI: .90), original two-factor (RMSEA: .07, CFI: .94, TLI: .92), and emergent two-factor structures (RMSEA: .05, CFI: .96, TLI: .95). Internal-consistency values were better with the original two-factor structure of HADS.

Conclusion

SF36v2 is best described as a three-factor structure and can be used in this study. HADS may require further investigation in relation to improving screening methods to make problematic items more sensitive and specific.

1. Introduction and rationale

Patients affected by end-stage renal disease (ESRD) are confronted with limited choices of treatment, namely dialysis or kidney transplantation. Irrespective of the mode of treatment, patients also encounter numerus difficulties due to the disease and treatment sometimes such as symptom severity, psychosocial distress, biological functioning deterioration, sexual difficulties, and neurocognitive impairment (Agneta et al., 2012; Bonner et al., 2013; Drayer et al., 2006). Consequently, their health-related quality of life (HRQoL) is negatively affected including enormous burden of psychological stress. For that, HRQoL and mood measures were developed and psychometrically tested to evaluate the health outcomes of this group of patients.

The Short-Form 36 version 2 (SF36v2) is well established and a common measure of health-related quality of life in ESRD patients. It is a multi-item type of measure in which the 35 items form eight scales (first-order structure) and the eight scales are aggregated in two-component summary (second-order structure) (Appendix 7.1.). The SF36v2 has proven useful in surveys of general and specific populations, comparing the relative burden of disease, and in differentiating the health benefits produced by a wide range of different treatments. It has been translated in more than 40 countries and normed in 12 countries including Arabic countries (Al Abdulmohsin et al., 1997). It consists of eight scales that can be summarised in two independent aggregate scores: physical component scores (PCS) for physical functioning (PF), physical role (PR), bodily pain (BP) and general health (GH), and the mental component score (MCS) for mental health (MH), vitality (VT), emotional role (ER) and social functioning (SF). Ware et al. (2000) suggest a norm-based score using a cut-off point of mean 50 (SD= 10). SF36v2 can then be interpreted using the norm-based score without the need to use previous studies as a norm. That is, higher mean scores (above 50) indicate better functional health and wellbeing, whereas lower scores (below 50) indicate poorer health functioning and wellbeing (Maruish and DeRosa 2009).

Studies that address the psychological issues in ESRD patients suggest that anxiety and depression should be explored in depth, using valid and reliable measures (Drayer et al., 2006; Fidan et al., 2013; Hofmann et al., 2010). Several instruments were developed to examine and measure emotional disorders, including the Hospital Anxiety Depression Scale. HADS was developed by Zigmond and Snaith (1983) as a two-construct measure to assess anxiety and depression in the non-psychiatric population. It is a 14-item, self-report rating measure with a 0-3 response rating scale. It is an easily administered measure and takes approximately 6-10 minutes to complete. HADS is commonly used among ESRD patients to assess their psychological distress. The internal consistency of HADS ranges from a Cronbach's alpha of adequate to excellent (0.68 to 0.93) (Bjelland et al., 2002; literature review of 747 articles).

However, there is inconsistency among the literature that uses factor analytical techniques, including EFA and CFA, to test the construct validity of the SF36v2 and HADS. De Vet HC et al (2005) reviewed 28 published studies across different populations to examine the structure of SF36v2 that used factor analytical techniques. He found that only six studies explored and confirmed the first-order factor (35 items level), whereas 25 studies explored and confirmed second-order factor (aggregated component summary). This finding is in parallel with Ware et al (1998) in which the factor analysis performed was limited to the second-order structure and was not among the first-order structure (35 items) of the SF36.

Several studies have conducted factor analysis to examine the construct validity of HADS (Dunbar et al., 2000; Friedman et al., 2001; Cosco., 2012). Despite HADS being a valid and widely used measure, several psychometric issues were reported that require further clarification. Razavi et al. (1990) conducted an EFA in a cohort of cancer in-patients and concluded that HADS was a two-structure measure. On the other hand, Friedman et al. (2001) reported three structures to HADS – depression, psychic anxiety and psychomotor agitation – in a group of clinically depressed patients. Identification of an underlying structure of three factors has also occurred in the non-clinical population, as explored by Caci et al. (2003). Cosco et al. (2012) conducted a systematic review on studies examining the latent structure of the HADS and reported different structures of HADS including one-factor structure, two-factor structure, three-factor structure, and even four-factor structure. The heterogeneous results of the review may indicate that the latent structure of HADS is unclear and dependent on the statistical methods invoked and the population studied.

However, to the researcher’s knowledge, the SF36v2 and HADS have not been validated or used to assess the health status or HRQoL within the Omani population with ESRD. This raises a question as to whether these measures are able to measure what they are intended to measure within this population. The aforementioned ambiguity in the factor structure of SF36v2 and HADS measures drives the need for further examination of their underlying dimensional structure, and the need to identify the most consistent factor structure of SF36v2 and HADS across clinical populations. Unfortunately, no attempts were made to evaluate the underlying structure of both measures within the Omani population and specifically in ESRD patients. It was crucial, therefore, to conduct factor analyses, EFA and CFA, on SF36v2 and HADS within the given context to describe the possible variability among patients suffering from ESRD.

Social, cultural and education-system may influence patients’ HRQoL. Results from international studies raised an argument regarding possible cultural influences on the structure factor of SF36v2, in particular, components of mental health among Asian countries (Fukuhara et al., 1998; Suxukamo et al., 2011; Wu CH et al., 2007). In Japan, for instance, Fukuhara found that the scores on the vitality subscale loaded significantly on the physical-health component summary among the general population. Similarly, in Taiwan, the vitality scale was observed as a stronger measure of physical health than of mental health (Wu CH et al., 2007). These findings were in contrast to the work of Ware et al. (1993), the developer of SF36, when reporting the scores on the vitality subscale. It is worth noting that Ware (2004) proposed, at a later date, a three-factor structure model including a “social role” factor in addition to MCS and PCS, suggesting that cultural difference might play a role in how people perceive different health areas.

Factor analysis is a statistical method commonly used to evaluate a measure structure. It is an essential step in validating a multi-item or multi-dimensional measure (Field, 2000). *“The goal of factor analysis is to reduce the dimensionality of the original space and to give an interpretation to the new space, spanned by a reduced number of new dimensions which are supposed to underline the old* *ones"* (Rietveld and Van Hout, 1993, p 254). Subjecting SF36v2 and HADS to a factor analysis would help to explore and confirm the possible underlying latent concepts of these measures within the related collected data. This can be done by using the EFA to explore the underlying structure of SF36v2 and HADS and then using CFA to test whether the study data fit the identified factor structure out of EFA and comparing it against its hypothesised model (Ware et al., 1995).

Given that SF36v2 and HADS were not validated within the Omani context, and that their factor structure is not known, this study, therefore, aims to explore the underlying structure of the both measures, SF36v2 and HADS, within the ESRD population using EFA to establish the factor structure among their items and consequently to validate its use within this context.

2. Method

Data from a cross-sectional study (see chapter eight) conducted across 13 dialysis units in Oman were used in this analysis. Both, SF36v2 and HADS were an Arabic version and self-completed measures. Factor analyses were conducted using the statistical software Mplus version 7. Mplus is a powerful statistical programme that can be used to estimate a wide range of models containing latent variables. The fact that it handles models with both continuous and categorical latent variables, and its capabilities for estimating multi-level models, are considered the strengths of this statistical software (Muthén, L. K., & Muthén, B. O. 1998-2011).

Analyses were conducted using the following steps:

i. The sufficiency of the sample size was determined using the ratio of 7-10 cases per item (Tabachnick and Fidell 2014). For SF36v2, since it has 35 items (one item about self-reported health transition is not included in the scores), around 7 cases x 35 items = 245 participants were required. Whereas for HADS, has 14 items, around 7 cases x 14 items = 98 participants were required. Around 440 patients completed the SF36v2 and HADS and this total was deemed sufficient to provide a reliable factor structure.

ii. Internal-consistency reliability for SF36v2 and HADS subscales was measured in a variety of ways: Cronbach's α for each subscale, Cronbach's α for a subscale if a single item is removed, the range of inter-item correlations and the individual inter-item correlations of the subscale. All correlations are Pearson's r correlations. The criteria used to interpret alphas are shown in Table 7-1.

Table 7. 1 Internal Consistency Criteria for SF36v2 and HADS

Reliability Statistics	**Criteria for a Good Scale**	**Reference**
Cronbach's alpha	Greater than or .60	Nunnally & Bernstein (1994); DeVellis (2003)
Range of inter-item correlations	between .15 and .85	Clark and Watson (1995)
Range of corrected item-scale correlations	Greater than or equal to .50	Clark and Watson (1995)
Range of Cronbach's alpha if item deleted	Deleting any item would decrease the alpha	Tabachnick and Fidell (2014)

iii. Initial data output of the Mplus version-7 was checked for the number of missing data patterns and covariance coverage of data. That is, if a variable has missing values, Mplus would provide information on the number and distribution of those missing values. The proportion of values presented for each variable is illustrated by a covariance coverage matrix (Bruin, 2006).

iv. To obtain factor solutions, polychoric correlations were used. Polychoric correlation is used when variables in the analysis are normally distributed (Muthén and Muthén, 1998), as the case in this data. Polychoric correlations provide a more accurate reproduction of the measurement model to generate the data (Holgado-Tello et al., 2010).

v. EFA was performed on the 35 items of SF36v2 and 14 items of HADS. Since the data were ordinal and the sample size was above 200, the weighted least squares (WLSMV) estimator was used to check the data fitting and suitability for analysis (Muthén et al., 1997; Rhemtulla et al., 2012). The WLSMV is considered a robust estimator which does not assume normally distributed variables and provides the best option for modelling categorical data (Brown, 2006). The criterion used to determine the number of extracted factors accounting for a reasonably large proportion of the total variance was based on eigenvalue above one. Also, the Scree plot of the eigenvalues, plotted against the factor numbers, was observed to inform on the number of factors to be retained (Tabachnick & Fidell, 2007). For factor rotation, the oblique rotation method was used since it is identical to that used by the measure developer, Ware et al. (1998). The determination of a significant-item factor loading was set at a coefficient level of ≥ .30 (Tabachnick and Fidell, 2014). This level was selected to allow a maximum number of items loading on to emerging factors.

vi. The best identified factor structure out of EFA was then verified using CFA. Four fit indices were looked at: the chi-square ($\chi2$); the comparative fit index (CFI); the Tucker-Lewis Index (TLI); and the root mean square error of approximation (RMSEA). The model has good fit when: the chi-square is less than 2 or 3 (Kline 1998 & Ullman 2001) – the chi-square test was likely to be significant because of the large sample size, N>350); RMSEA is below 0.06 (MacCallum et al 1996); CFI is greater than 0.90 (Hu and Bentler 1999); TLI is over .90 (Hu & Bentler 1999).

For HADS, CFA was performed to confirm the best simple structure in EFA along with the other five most published models: 1) Zigmond and Snaith's (1983) original two-factor model; 2) Moorey et al.'s (1991) two-factor model; 3) Razavi et al.'s (1990) single-factor model; 4) Friedman et al.'s (2001) three-factor model; and 5) Caci et al.'s (2003) three-factor model. The characteristics of these tested models are shown in Table 7-B.2. Independence of error terms was determined for all the models. To assess the fit of the models, four fit indices were looked at.

Table 7. 2 Characteristics of the published models of HADS

Model	**Number of factors extracted**	**Sample**	**Items underlying factor structure**		
			Anxiety	Depression	Third factor
Zigmond and Snaith's (1983)	2	Medical	1,3,5,7,9,11,13	2,4,6,8,10,12,14	-
Moorey et al.'s (1991)	2	Cancer patients	1,3,5,9,11,13	2,4,6,7,8,10,12, 14	-
Razavi et al.'s (1990)	1	Cancer patients	Single-factor: 1,2,3,4,5,6,7,8,9,10,11,12,13,14		
Friedman et al.'s (2001)	3	Depressed patients	3,5,9,13	2,4,6,8,10,12,14	1,7,11
Caci et al.'s (2003)	3	Non-clinical	1,3,5,9,13	2,4,6,8,10,12	7,11,14

3. Findings

Four-hundred and forty-nine patients participated in the study. The detailed description of the participants characteristics including clinical data are in Chapter Eight.

3.1. SF36v2

3.1.1. Reliability analysis of the established SF36v2

Prior to conducting EFA and CFA to SF36v2, a reliability analysis of the SF36v2 total all-items and the eight subscales, using Cronbach coefficient alpha, was conducted to ensure that the measures fulfilled the criteria for research purposes (Tables 7.3 to 7.10). The Cronbach's α value for the total SF36v2 was .92, whereas for the eight subscales they were: .82 for PF, .83 for RP, .76 for BP, .65 for GH, .74 for VT, .53 for SF, .84 for RE and .74 for MH. Most of the alphas were above α .65 except for the GH and SF subscales which were .65 and .53, respectively. Thus, the result suggests that majority of the subscales can be considered as reliable (Nunnally & Bernstein, 1994; DeVellis, 2003). However, items that showed a lower correlation might require further examination.

Table 7. 3 Cronbach's alphas of physical functioning (PF) subscale, inter-item, corrected item-scale and alpha if item deleted, n = 443

PF Subscale	Cronbach's α: .82 Range of inter-item correlation: .09 to .58	
	Corrected item-scale correlation	Cronbach's α if item deleted
Vigorous activities (PF01)	.20	.84
Moderate activities (PF02)	.54	.81
Lifting, carrying groceries (PF03)	.56	.80
Climbing several flights (PF04)	.56	.80
Climbing one flight (PF05)	.59	.80
Bending, kneeling (PF06)	.55	.80
Walking one mile (PF07)	.64	.80
Walking several blocks (PF08)	.61	.80
Walking one block (PF09)	.50	.81
Bathing, dressing (PF10)	.39	.82

Table 7. 4 Cronbach's alphas of role physical (RP) subscale, inter-item, corrected item-scale and alpha if item deleted, n = 443

RP Subscale items	Cronbach's α: .83 Range of inter-item correlation: .47 to .62	
	Corrected item-scale correlation	Cronbach's α if item deleted
Cut down time (RP01)	.65	.78
Accomplished less (RP02)	.68	.77
Limited in kind (RP03)	.62	.80
Had difficulty (RP04)	.67	.78

Table 7. 5 Cronbach's alphas of bodily pain (BP) subscale, inter-item, corrected item-scale and alpha if item deleted, n = 439

BP Subscale items	Cronbach's α: .76 Range of inter-item correlation: .63 to .63	
	Corrected item-scale correlation	Cronbach's α if item deleted
Pain-magnitude (BP01)	.63	.39
Pain-interfere (BP02)	.63	.39

Table 7. 6 Cronbach's alphas of general health (GH) subscale, inter-item, corrected item-scale and alpha if item deleted, n = 436

GH Subscale items	Cronbach's α: .65 Range of inter-item correlation: .12 to .43	
	Corrected item-scale correlation	Cronbach's α if item deleted
EVGFP rating (GH1)	.39	.60
Sick easier (GH02)	.32	.64
As healthy (GH03)	.34	.63
Health to get worse (GH04)	.39	.60
Health excellent (GH05)	.58	.50

Table 7. 7 Cronbach's alphas of vitality (VT) subscale, inter-item, corrected item-scale and alpha if item deleted, n = 438

VT Subscale items	Cronbach's α: .74 Range of inter-item correlation: .31 to .63	
	Corrected item-scale correlation	Cronbach's α if item deleted
Pep/Life (VT01)	.58	.66
Energy (VT02)	.53	.69
Worn out (VT03)	.52	.70
Tired (VT04)	.53	.69

Table 7. 8 Cronbach's alphas of social functioning (SF) subscale, inter-item, corrected item-scale and alpha if item deleted, n = 440

SF Subscale items	Cronbach's α: .53 Range of inter-item correlation: .36 to .36	
	Corrected item-scale correlation	Cronbach's α if item deleted
Social-extent (SF01)	.36	.13
Social-time (SF02)	.36	.13

Table 7. 9 Cronbach's alphas of role emotion (RE) subscale, inter-item, corrected item-scale and alpha if item deleted, n = 442

RE Subscale items	Cronbach's α: .84 Range of inter-item correlation: .57 to .72	
	Corrected item-scale correlation	Cronbach's α if item deleted
Cut down time (RE01)	.70	.79
Accomplished less (RE02)	.77	.73
Not careful (RE03)	.66	.83

Table 7. 10 Cronbach’s alphas of mental health (MH) subscale, inter-item, corrected item-scale and alpha if item deleted, n = 437

MH Subscale items	Cronbach’s α: .74 Range of inter-item correlation: .20 to .49	
	Corrected item-scale correlation	Cronbach’s α if item deleted
Nervous (MH01)	.49	.71
Down in dumps (MH02)	.56	.68
Peaceful (MH03)	.48	.71
Blue/sad (MH04)	.57	.68
Happy (MH05)	.44	.72

3.1.2. Exploratory factor analysis of SF36v2

Exploratory factor analysis was performed on the all 35-items of SF36v2. The WLSMV estimator was confirmed that the data distribution satisfied the criteria for factor extraction. Chi-Square Test of Model Fit for the Baseline Model ($\chi 2$ (df) = 6375.178 (561) (Muthén et al., 1997).

Following extraction and oblique rotation, seven factors with eigenvalues greater than one (>1) emerged from analysis of the SF36v2, Figure 7.1, and accumulatively accounted for 62.2% (28%, 11%, 6.2%, 5.8%, 4.3%, 3.6% and 3.3%, respectively). An additional factor, however, Factor-eight, accounting for 2.8% of variance, was included in the test to explore if any factoring might load related to the eight subscales of the SF36v2.

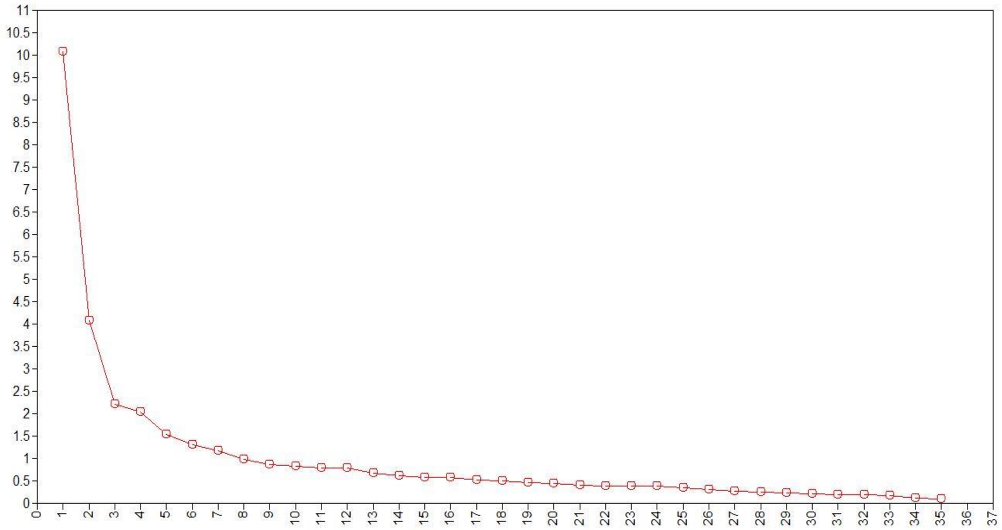


Figure 7. 1 Eigenvalues in SF36 v2 (35-item)

The results of factor loadings of individual SF36v2 items in relation to the three-factor solution are shown in Tables 7.11. This three-factor solution was the only solution which provided simple and clear items structure. It is worth noting that the remaining two and four- to eight-factor structure solutions did not provide a clear item structure among the 35, thus, for the purpose of brevity, full details of the remaining factor solutions are not included and attached with appendices (can be found in Appendix 7.2).

In the three-factor solution, the correlation between Factor 1 and Factor 2 was .25; that of Factor 1 and 3 was .40; and that of Factor 2 and 3 was .42. This solution revealed a clear, simple structure compared with the rest of the identified factor structures, which may suggest three concepts underlying the SF36v2 within the Omani context. These concepts can be labelled as the physical-health component, the role-functioning component and the psychological-functioning component. The PF items loaded on Factor-1 were items related to bodily pain, general health, vitality and social functioning, whereas items related to mental health clustered on Factor 2 and items pertaining to role functioning (physical and emotional) loaded together on Factor 3.

Table 7. 11 Factor structure underlying Factors 1-3 with oblique rotation for the SF36v2 (N = 443)

Item	**Factor 1**	**Factor 2**	**Factor 3**
Vigorous activities (PF01)	**0.36**	0.05	-0.07
Moderate activities (PF02)	**0.66**	0.09	-0.01
Lifting, carrying groceries (PF03)	**0.67**	0.09	-0.02
Climbing several flights (PF04)	**0.71**	0.01	-0.02
Climbing one flight (PF05)	**0.71**	-0.02	0.05
Bending, kneeling (PF06)	**0.67**	0.09	0.06
Walking a mile (PF07)	**0.76**	0.01	0.01
Walking several blocks (PF08)	**0.77**	-0.09	0.02
Walking one block (PF09)	**0.67**	0.05	0.06
Bathing, dressing (PF10)	**0.57**	-0.06	0.08
Cut down time (RF01)	0.06	-0.01	**0.73**
Accomplished less (RF02)	-0.08	0.07	**0.72**
Limited in kind (RF03)	0.12	-0.06	**0.66**
Had difficulty (RF04)	0.15	0.15	**0.64**
Pain-magnitude (BP01)	0.13	**0.70**	-0.03
Pain-interfere (BP02)	0.13	**0.69**	0.01
EVGFP rating (GH1)	0.09	**0.50**	-0.06
Sick easier (GH02)	0.09	**0.33**	0.10
As healthy (GH03)	-0.08	**0.45**	-0.01
Health to get worse (GH04)	0.09	**0.39**	0.02
Health excellent (GH05)	0.07	**0.64**	-0.01
Pep/Life (VT01)	-0.03	**0.74**	-0.14
Energy (VT02)	0.10	**0.66**	-0.22
Worn out (VT03)	-0.02	**0.68**	0.06
Tired (VT04)	-0.08	**0.68**	0.07
Social-extent (SF01)	0.06	**0.63**	0.04
Social-time (SF02)	0.15	**0.37**	0.08
Cut down time (RE01)	-0.01	0.22	**0.72**
Accomplished less (RE02)	-0.07	0.13	**0.79**
Not careful (RE03)	0.04	0.14	**0.62**
Nervous (MH01)	-0.01	**0.47**	0.05
Down in dumps (MH02)	-0.09	**0.65**	0.09
Peaceful (MH03)	-0.08	**0.59**	0.01
Blue/Sad (MH04)	-0.09	**0.56**	0.09
Happy (MH05)	-0.03	**0.63**	-0.04

Bold values indicate that item loading on a factor is ≥ .30
PF: Physical functioning; RF: Role functioning; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: Role emotion; MH: Mental health.

It can be concluded that the EFA results indicated that the hypothesised eight-factor structure was not supported in the ESRD population in Oman. The simple structure was identified for the 35 items of SF36v2 and can be named as the physical-health component, the role-functioning component and the emotional-effect component.

3.1.3. Confirmatory factor analysis

The results of CFA for factor models and accompanying fit indices are shown in Table 7.12. The chi-square estimate of fit was statistically significant (P < .001), demonstrating that a proportion of the total variance was unexplained. The result of the fit indices revealed that the two-correlated factor model had a weak fit, indicated by the RMSEA (0.9), CFI (.78) and TLI (.77). Conversely, the three-correlated factor model offered the best fit for the data (see Figure 3) manifested by the result of the fit-indices parameters: RMSEA (.06), CFI (.90) and TLI (.90).

For the item-level models of both structures, the completely standardised solutions are shown in Figures 7.2 and 7.3.

Table 7. 12 Factor structure of the two- and three-correlated factor SF36v2 determined by CFA

Model	**$\chi 2$**	**RMSEA**	**CFI**	**TLI**
Model 1: based on two-correlated factors (physical functioning, emotional effect)	2882.461 (55)	.09	.78	.77
Model 2: based on three-correlated factors (physical functioning, role functioning, emotional effect)	1582.927 (55)	**.06**	**.90**	**.90**

Bold values indicate good fit indices

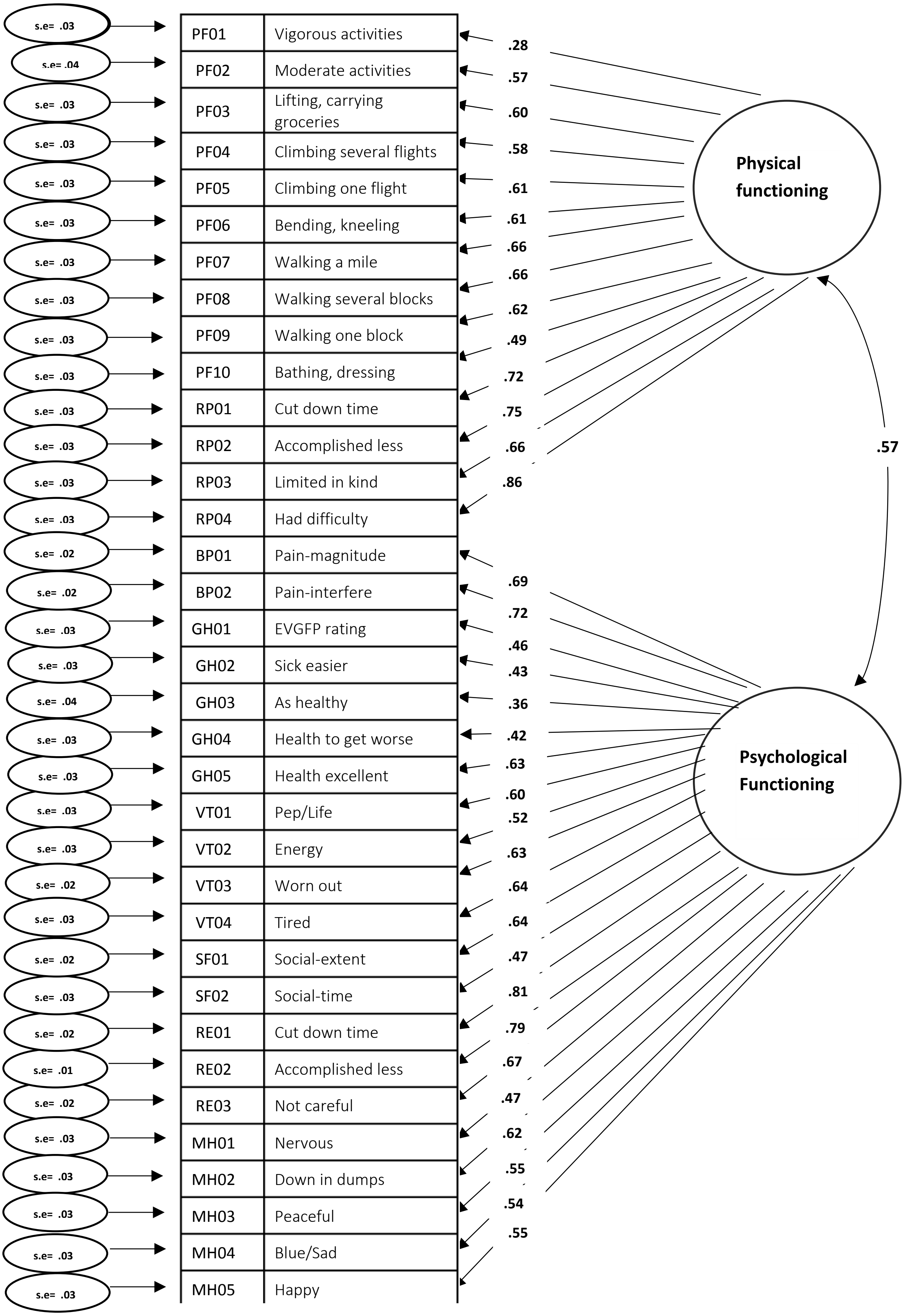


Figure 7. 2 Two-correlated factor model, first-order solution, based on confirmatory factor analysis

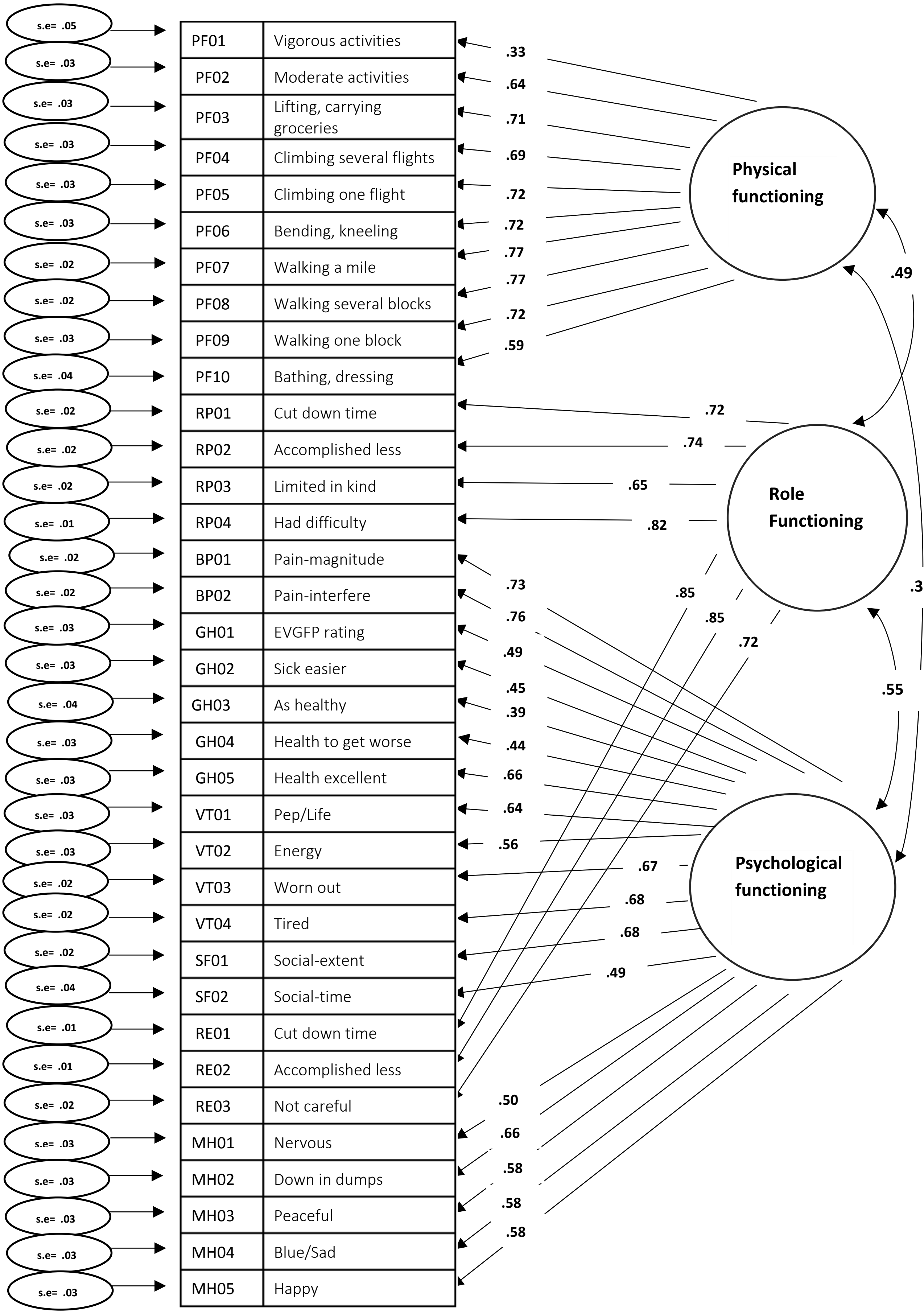


Figure 7. 3 Three-correlated factor model, first-order solution, based on confirmatory factor analysis

3.1.4. Reliability analysis of the emerged three-factor structure of SF36v2

To ensure that the emerged three-factor solution of SF36v2 satisfy the criteria for regression analysis and clinical use, a reliability analysis was conducted. The calculated Cronbach's alpha values for emergent factors (Emergent-Physical functioning subscale, Emergent-Role functioning subscale, and Emergent-pyschological functioning subscale) were .82, .88, .88, respectively, exceeding .06 criterion for acceptable measure internal reliability (Tables 7.13 to 7.15). These result support the application and use of the three-factor structure of SF36v2 as an outcome in regression analysis to predict the level of HRQoL within a given context.

Table 7. 13 Cronbach's alphas of Emergent-Physical functioning (PF) subscale, inter-item, corrected item-scale and alpha if item deleted, n = 443

PF Subscale	Cronbach's α: .82 Range of inter-item correlation: .09 to .58	
	Corrected item-scale correlation	Cronbach's α if item deleted
Vigorous activities (PF01)	.20	.84
Moderate activities (PF02)	.54	.81
Lifting, carrying groceries (PF03)	.56	.80
Climbing several flights (PF04)	.56	.80
Climbing one flight (PF05)	.59	.80
Bending, kneeling (PF06)	.55	.80
Walking one mile (PF07)	.64	.80
Walking several blocks (PF08)	.61	.80
Walking one block (PF09)	.50	.81
Bathing, dressing (PF10)	.39	.82

Table 7. 14 Cronbach's alphas of Emergent-Role (RP) functioning subscale, inter-item, corrected item-scale and alpha if item deleted, n = 441

RP Subscale items	Cronbach's α: .88 Range of inter-item correlation: .39 to .72	
	Corrected item-scale correlation	Cronbach's α if item deleted
Cut down time (RP01)	.64	.86
Accomplished less (RP02)	.66	.86
Limited in kind (RP03)	.58	.87
Had difficulty (RP04)	.71	.85
Cut down time (RE01)	.72	.85
Accomplished less (RE02)	.72	.85
Not careful (RE03)	.60	.87

Table 7. 15 Cronbach’s alphas of Emergent-Emotional effect subscale, inter-item, corrected item-scale and alpha if item deleted, n = 432

BP Subscale items	Cronbach’s α: .88 Range of inter-item correlation: .12 to .63	
	Corrected item-scale correlation	Cronbach’s α if item deleted
Pain-magnitude (BP01)	.64	.87
Pain-interfere (BP02)	.64	.87
EVGFP rating (GH1)	.43	.88
Sick easier (GH02)	.37	.88
As healthy (GH03)	.36	.88
Health to get worse (GH04)	.38	.88
Health excellent (GH05)	.59	.87
Pep/Life (VT01)	.58	.87
Energy (VT02)	.48	.87
Worn out (VT03)	.60	.87
Tired (VT04)	.61	.88
Social-extent (SF01)	.58	.83
Social-time (SF02)	.39	.88
Nervous (MH01)	.42	.87
Down in dumps (MH02)	.56	.87
Peaceful (MH03)	.51	.87
Blue/sad (MH04)	.48	.87
Happy (MH05)	.51	.87

PF: Physical functioning; RF: Role functioning; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: Role emotion; MH: Mental health.

3.2. Hospital Anxiety Depression Scale

3.2.1. Reliability analysis of the established two-factor structure HADS

Primarily, a reliability analysis for the original anxiety subscale was examined prior to conducting factor analysis (Table 7.16). The Cronbach's α value for the total items of the anxiety subscale was .79 (7 items), with inter-item correlation ranging from .18 to .51. Checking the corrected item-scale correlation, three items had lower corrected item-scale correlation below .50 (item-7 “I can sit at ease and feel relaxed”; item-9 “I get a sort of frightened feeling like ‘butterflies’ in the stomach”; and item-11 “I feel restless as if I have to be on the move”).

Table 7. 16 Cronbach's alphas of anxiety subscale, inter-item, corrected item-scale and alpha if item deleted, N = 434

Anxiety Subscale	Cronbach's α: .79 Range of inter-item correlation: .18 to .51	
	Corrected item-scale correlation	Cronbach's α if item deleted
(1) I feel tense or wound up	.53	.76
(3) I get a sort of frightened feeling as if something awful is about to happen	.65	.74
(5) Worrying thoughts go through my mind	.60	.75
(7) I can sit at ease and feel relaxed	.42	.78
(9) I get a sort of frightened feeling like 'butterflies' in the stomach	.43	.78
(11) I feel restless as if I have to be on the move	.43	.78
(13) I get sudden feelings of panic	.58	.75

Likewise, internal reliability test of the original depression subscale of HADS was examined (Table 7.17). The Cronbach's α value for the total items of the depression subscale was .67, lower than the determined value, with inter-item correlation ranging from .10 to .37. Three items had less than .40 corrected item-scale correlation and, in each case, the overall Cronbach's α for the subscale would be higher with the item removed. The lowest Cronbach's α was for item-14 ("I can enjoy a good book or TV programme"), possibly indicating that this item is not sensitive enough to test depressive symptoms.

Table 7. 17 Cronbach's alphas of depression subscale, inter-item, corrected item-scale and alpha if item deleted, N = 433.

HADS items	Cronbach's α: .67 Range of inter-item correlation: .10 to .37	
	Corrected item-scale correlation	Cronbach's α if item deleted
(2) I still enjoy the things I used to enjoy	.39	.62
(4) I can laugh and see the funny side of things	.43	.61
(6) I feel cheerful	.37	.63
(8) I feel as if I am slowed down	.40	.62
(10) I have lost interest in my appearance	.40	.62
(12) I look forward with enjoyment to things	.40	.62
(14) I can enjoy a good book or TV programme	.22	.67

Overall, it is unclear whether the anxiety subscale items (item-7, item-9, item-11) and depression subscale items (item-14) are sensitive enough to assess related symptoms. Further attention is perhaps required to observe the function of these items in EFA and CFA. Overall, given that the Cronbach's α values for the both subscales exceeded .60 criterion for acceptable measure internal reliability (Nunnally & Bernstein, 1994; DeVellis, 2003), the result suggests that these subscales, anxiety and depression, can be considered reliable, despite the low correlation of some items.

3.2.2. EFA of HADS

Exploratory factor analysis was performed on all 14-items of HADS. The data distribution satisfied the criteria for factor extraction, Chi-Square Test of Model Fit for the Baseline Model ($\chi2$ (df)= 3049.898 (91) (Muthén et al., 1997).

Following extraction and oblique rotation, three factors with eigenvalues greater than 1 emerged from analysis of the completed 14-items of HADS, explaining 5.21%, 1.4% and 1.1% of the variance (Figure 7.4).

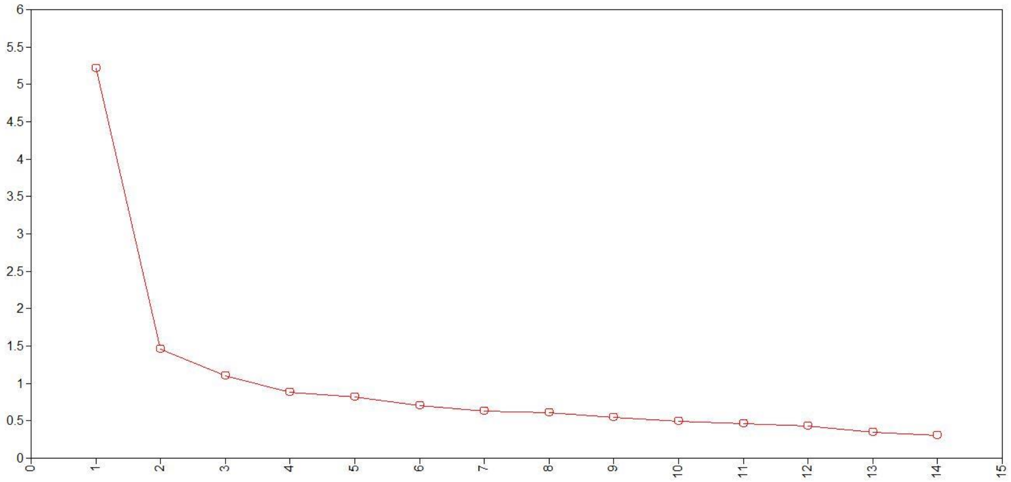


Figure 7. 4 Eigenvalues of the complete HADS

Factor loadings of individual HADS items in relation to the one-factor solution are shown in Table 7.18. Using a coefficient level of 0.3, the HADS items clustered under one factor except for item-14, *r*= .29, suggesting that, overall, HADS is a good measure for identifying psychological distress within this group of patients.

Table 7. 18 One-factor solution of HADS items following with oblique rotation

Items of HADS	Factor 1
Anxiety sub-scale	
(1) I feel tense or wound up	**0.64**
(3) I get a sort of frightened feeling as if something awful is about to happen	**0.74**
(5) Worrying thoughts go through my mind	**0.72**
(7) I can sit at ease and feel relaxed	**0.59**
(9) I get a sort of frightened feeling like ‘butterflies’ in the stomach	**0.51**
(11) I feel restless as if I have to be on the move	**0.53**
(13) I get sudden feelings of panic	**0.74**
Depression sub-scale	
(2) I still enjoy the things I used to enjoy	**0.43**
(4) I can laugh and see the funny side of things	**0.50**
(6) I feel cheerful	**0.55**
(8) I feel as if I am slowed down	**0.54**
(10) I have lost interest in my appearance	**0.60**
(12) I look forward with enjoyment to things	**0.52**
(14) I can enjoy a good book or TV programme	0.29

Bold values indicate that item loading on a factor is ≥ .30

Although the one-factor solution showed a clear factor structure, the two-factor solution clearly shows that HADS is possibly a two-dimensional instrument (anxiety and depression) with significant positive correlation r = .53, p< 0.001, explaining 47% of the common variance between factors. The loadings of individual HADS items in relation to the two-factor solution are shown in Table 7.19. It is observed, however, that item-7 “I can sit at ease and feel relaxed”, item-6 “I feel cheerful”, item-8 “I feel as if I am slowed down” and item-10 “I have lost interest in my appearance” were loading inversely in favour of the opposite factor. In this solution, notably, item-14 was shown to load under Factor-2 with a coefficient level of .38, was insignificant in one-factor solution. It can also be observed that item-7 of the anxiety subscale loaded under factor-2, depression subscale. Using CFA, it would be useful to confirm and compare the fit of this model to the data relating to one-factor structure, Table 7.18, and other published models.

Table 7. 19 Two-factor solution of HADS items following with oblique rotation

Items of HADS	Factor 1	Factor 2
Anxiety sub-scale		
(1) I feel tense or wound up	**0.69**	-0.01
(3) I get a sort of frightened feeling as if something awful is about to happen	**0.86**	-0.08
(5) Worrying thoughts go through my mind	**0.68**	0.1
(7) I can sit at ease and feel relaxed	0.22	**0.49**
(9) I get a sort of frightened feeling like 'butterflies' in the stomach	**0.42**	0.14
(11) I feel restless as if I have to be on the move	**0.57**	0.00
(13) I get sudden feelings of panic	**0.65**	0.15
Depression sub-scale		
(2) I still enjoy the things I used to enjoy	0.04	**0.49**
(4) I can laugh and see the funny side of things	-0.11	**0.77**
(6) I feel cheerful	**0.35**	0.29
(8) I feel as if I am slowed down	**0.34**	0.28
(10) I have lost interest in my appearance	**0.45**	0.23
(12) I look forward with enjoyment to things	0.01	**0.63**
(14) I can enjoy a good book or TV programme	0.00	**0.38**

Bold values indicate that item loading on a factor is ≥ .30

From the preceding factor solutions, it can be suggested that HADS can be regarded as one- dimensional structure and two-dimensional instrument. Yet, to further ensure that the results of the EFA were not confounded by the factor extraction and rotation methods used, an orthogonal rotational (uncorrelated factors) method was performed on this set of data. Table 7.20 shows the two-factor loadings of HADS following orthogonal rotation. This solution seems to support the notion that HADS is a more of a two-dimensional instrument when all the items are loaded on to Factor 1, despite the cross-loading of items 3, 4 and 12. As with the aforementioned one-factor solution, Table 7.18, item-14 again failed to load significantly on both factors, which may suggest that this item has poor performance among this group of patients.

Table 7. 20 Two-factor solution of HADS items following orthogonal rotation (uncorrelated factors)

Items of HADS	Factor 1	Factor 2
Anxiety sub-scale		
(1) I feel tense or wound up	**0.63**	-0.26
(3) I get a sort of frightened feeling as if something awful is about to happen	**0.73**	**-0.36**
(5) Worrying thoughts go through my mind	**0.71**	-0.18
(7) I can sit at ease and feel relaxed	**0.60**	0.21
(9) I get a sort of frightened feeling like 'butterflies' in the stomach	**0.51**	-0.06
(11) I feel restless as if I have to be on the move	**0.53**	-0.20
(13) I get sudden feelings of panic	**0.73**	-0.14
Depression sub-scale		
(2) I still enjoy the things I used to enjoy	**0.43**	0.28
(4) I can laugh and see the funny side of things	**0.50**	**0.51**
(6) I feel cheerful	**0.55**	0.04
(8) I feel as if I am slowed down	**0.54**	0.05
(10) I have lost interest in my appearance	**0.60**	-0.02
(12) I look forward with enjoyment to things	**0.52**	**0.38**
(14) I can enjoy a good book or TV programme	0.29	0.23

Bold values indicate that item loading on a factor is ≥ .30

Overall, EFA findings showed that HADS is good measure of psychological distress among ESRD patients as indicated by one-factor solution, but also can measure distinct constructs of anxiety and depression (r = .34, p< 0.001) as indicated by the two-factor solution.

3.2.3. CFA of HADS

CFA was used to evaluate the fit statistics for the models found in the literature, along with the current one-factor and two-factor models out of EFA. Table 7.21 shows the tested factor models and accompanying fit indices along with the current models. The chi-square estimate of fit for all the models was statistically significant (*P* < 0.001) demonstrating that a proportion of the total variance was unexplained by each of these models. Surprisingly, CFA revealed that all the tested models had good fit indices indicating good fit to data. The emerged models – the one-factor model and the two-correlated factor model – offered the best fit for the data. Despite the one-factor model's good fit with the study data, the emerged two-factor model showed the best fit across all fit indices followed by the Moorey et al. (1991) two-factor structure, identical to original two-factor structure of HADS by Zigmond and Snaith (1983). Overall, this result possibly confirms that HADS is a measure able to distinguish between the concepts of anxiety and depression.

Table 7. 21 Factor structure of the published HADS models and the current model determined by CFA

Model	Sample	Number of factor	Items underlying factor structure			CFA indices			
			Anxiety	**Depression**	**Third factor**	**$\chi2$**	**RMSEA (< .90)**	**CFI (> .90)**	**TLI (> .90)**
Zigmond & Snaith (1983)	Medical	$2^{¥}$	1,3,5,7,9,11,13	2,4,6,8,10,12,14	-	252.413 (76)	.07	.94	.92
Moorey et al. (1991)	Cancer	2	1,3,5,9,11,13	2,4,6,7,8,10,12,14	-	225.927 (76)	.06	.94	.93
Razavi et al. (1990)	Cancer patients	1	1,2,3,4,5,6,7,8,9,10,11,12,13,14			311.367 (77)	.08	.92	.90
Friedman et al. (2001)	Depressed patients	3	3,5,9,13	2,4,6,8,10,12,14	1,7,11	274.052 (74)	.07	.94	.92
Caci et al. (2003)	Non-clinical	3	1,3,5,9,13	2,4,6,8,10,12	7,11,14	243.601 (74)	.07	.94	.93
Emerged 2-factor model (correlated	ESRD	2	1, 3, 5, 6, 8, 9, 10, 11, 13	2, 4, 7, 12, 14	-	186.360 (76)	.05	.96	.95
Emerged 1-factor model	ESRD	1	1,2,3,4,5,6,7,8,9,10,11,12,13,14			304.898 (91)	.08	.92	.90

Bold values indicate best-fit indices. All chi-squared statistics were significant at P < 0.001. $\chi2$ degrees of freedom in parentheses. ¥ original two-factors. Current models: result from current study.

3.2.4. Reliability analysis of emergent two-factor structure of HADS

Since the EFA and CFA revealed some interesting and conflicting findings regarding the structure of HADS, a reliability test was conducted to determine the internal consistency of the emerged two-factor structure, and to compare it with the internal consistency of original two-factor structure (Zigmond and Snaith, 1983; Moorey et al., 1991). Tables 7.22 to 7.23 show the result of internal reliability of emergent two-factor structure of HADS.

The Cronbach's α value for the total items of the emerged anxiety subscale was very good .81 (9 items), with inter-item correlation ranging from .13 to .52. Checking the corrected item-scale correlation, four items had lower corrected item-scale correlation below .50 (item-6, item-8, item-9, item-11). For emerged depression, the Cronbach's α value for the total items was .63, lower than the determined value, with inter-item correlation ranging from .13 to .52.

Notably, the Cronbach's α value of emerged two-factor structure of depression subscale was lower than the original two-factor structure .67. All the items of the emerged two-factor structure had less than .50 corrected item-scale correlation and, in item14, the overall Cronbach's α for the subscale would be higher with the item removed. Also, this item had the lowest Cronbach's α ("I can enjoy a good book or TV programme").

Table 7. 22 Cronbach's alphas of Emergent-Anxiety subscale, inter-item, corrected item-scale and alpha if item deleted, n = 432

Anxiety Subscale	Cronbach's α: **.81** Range of inter-item correlation: .13 to .52	
	Corrected item-scale correlation	Cronbach's α if item deleted
(1) I feel tense or wound up	.53	.79
(3) I get a sort of frightened feeling as if something awful is about to happen	.64	.78
(5) Worrying thoughts go through my mind	.63	.78
(6) I feel cheerful	.43	.80
(8) I feel as if I am slowed down	.42	.81
(9) I get a sort of frightened feeling like 'butterflies' in the stomach	.37	.81
(10) I have lost interest in my appearance	.51	.80
(11) I feel restless as if I have to be on the move	.44	.80
(13) I get sudden feelings of panic	.63	.78

Table 7. 23 Cronbach's alphas of Emergent-Depression subscale, inter-item, corrected item-scale and alpha if item deleted, n = 432

HADS items	Cronbach's α: **.63** Range of inter-item correlation: .13 to .37	
	Corrected item-scale correlation	Cronbach's α if item deleted
(2) I still enjoy the things I used to enjoy	.34	.59
(4) I can laugh and see the funny side of things	.44	.53
(7) I can sit at ease and feel relaxed	.43	.54
(12) I look forward with enjoyment to things	.43	.54
(14) I can enjoy a good book or TV programme	.26	.64

4. Discussion

This section discusses the results of EFA and CFA in relation to the RQ1 and published literature.

4.1. SF36v2

The EFA and CFA revealed a three-factor structure of SF36v2 in patients with ESRD with Oman. However, out of the eight EFAs, only the three-factor structure solution had a simple and clear structure of the SF36v2 within this population. It characterised the first-order structure (35 items) into three main areas: 1) physical functioning; 2) limitation on role functioning due to physical and mental problems; and 3) bodily pain, general health, vitality, social functioning and mental health. This result suggests that the original eight-factor structure of the SF36v2 was not supported within this population.

Notably, the emergent three-factor structure underpinning SF36v2, including the current study, were reported among Asian and Arab populations, an inversion of the result from studies examining the structure of SF36v2 within Western countries (Wagner et al., 1998; Ware et al., 1998; Bullinger et al., 1995). The results of the studies conducted in a Western context revealed a two-factor structure (physical-health and mental-health concepts) underpinning SF36v2. However, the EFA that was carried out in these studies was on the second-order factor structure of SF36v2, contrary to the current study which is on the first-order factor structure. Again, this may support the suggestion that the SF36v2 measure might not be precise across different cultures and populations. Yet this needs to be confirmed in a larger sample and in different populations.

Numerous studies reported possible cultural influences on self-administered HRQoL measures, which can be considered a challenge in generalising the findings of these studies. Researchers attempt to overcome such issues in generalising findings by applying rigorous translation methods and statistical-validation methods to the intended health-status measures. The SF36 measure was translated and validated across 40 countries (Ware, 2000). Translating a measure from one language to another may produce differences in the delivery of the measure, which could appear as differing scale dimensionality (Guermazi et al., 2012). Although SF36 can be considered a well-established HRQoL measure across many different cultures, it does not account for the fact that patients may have different perceptions and expectations for their health that are unrelated to linguistic differences in the phrasing of the measure questions. Despite this seeming to be undeniable, the result of the current study suggests that the SF36v2 measure is generally acceptable to the Omani population. This was evidenced by the good completion rate of the items of SF36v2, 0.9% missing data.

It is anticipated that ESRD could have an influence on the factor structure of a measure. The emerged three-factor structure may suggest that the ESRD condition has an influence on how patients perceive these areas of HRQoL. The items of SF36v2 clustered under three factors: physical functioning; limitation on role functioning due to physical and mental problems; and bodily pain, general health, vitality, social functioning and mental health. Physical functioning is usually limited in patients affected by ESRD (Fidan et al, 2013; Guney et al, 2010; and Morsch et al, 2005). This limitation is a result of disease symptoms and treatment regimen (Cleary et al, 2005; Pai et al, 2009). The same can be said about limitations on role functioning as patients may perceive these as a restraint on different life situations such as family life, partner relationships, social life (including interactions with friends), leisure activities, community involvement and everyday living activities (Anatchkova and Bjorner, 2007). This is clearly manifested in results from the QoL individual instrument (SEiQoL-DW) with around 18% of patients (8/45) reporting “role functioning” as an important aspect of life.

Similarly, the loading of items of bodily pain (BP0) with vitality may reflect the fact that patients who experienced pain reported significantly poorer HRQoL in relation to physical health, psychological health and levels of independence when compared with those without pain (Soni et al, 2011; Kimmel and Patel, 2005). Davison and Jhangri (2009) measured the impact of pain and the symptom burden on the HRQoL of haemodialysis patients over six months and it was shown to be an independent predictor of physical HRQoL at baseline (r = - 0.74, p <0.001; 95 % CI= -1.02, - 0.46) and after six months (r = - 0.59, p <0.001; 95 % CI= -0.98, -0.19). The impact of pain and the symptom burden on mental HRQoL at baseline was (r = - 0.76, p <0.001; 95 % CI= - 1.04, - 0.48) and after six months it was (r = - 0.87, p <0.001; 95 % CI= -1.31, - 0.43).

The response category to items related to role physical (RP01-RP04) and role emotional (RE01-RE03) of SF36v2 may possibly influence a participant's answer, which may affect the scale structure. Although the relationship between the response category and the scale structure here is not clear, it could indirectly result in in common method variance (CMV). That is, it represents a measurement-method issue rather than a construct of the measure. For instance, the response categories to these items are "All of the time", "Most of the time", "Some of the time", "A little of the time" and "None of the time". From a context perspective, this may suggest that it is difficult for ESRD patients to distinguish and understand how much "Some of the time" differs from "A little of the time". Although this misunderstanding did not emerge significantly in the result of the cognitive interviewing phase, Chapter Five, some of the participants suggested that one response category could be overshadowed by neighbouring categories. This, however, did not affect the completion of SF36v2 by participants. Perhaps, in future studies, researchers might need to conduct a study using a large sample at a specific point in time so as to ensure that common method variance is not an issue with SF36v2.

In summary, out of the eight EFAs explored, the three-factor structure can be considered the simplest and clearest structure underpinning the concepts of health measured by SF36v2 among Omani patients. It is recommended that an EFA be conducted to test the second-order factor structure using the SF36v2 subscale scores. Later a CFA might be conducted, based on this result, to investigate the second-order factor structure among the eight-subscale scores. Alternatively, a CFA might be conducted to verify the first- and second-order factor structure of SF36v2.

4.2. HADS

Overall, HADS performed quite well within the given context, yet, in the EFA, all items loaded significantly except for item-14 which had poor correlation (r = .29). The item-loading on the emergent two-factor solution was different from the original two-factor structure to this population with items-1, 3, 5, 6, 8, 9, 10, 11 and 13 tapping on the anxiety scale and items-2, 4, 7, 12 and 14 tapping on the depression scale. The correlation between the factors of anxiety and depression was r = .53. CFA was then performed on both solutions along with other five published models, including original structure. Fit indices indicated that the emergent two-factor solution structure had better fit with the data followed by the two-factor structure model of Moorey et al. (1991), identical to original two-factor structure conducted among cancer patients. The internal consistency for both the original two-factor and emergent two-factor structures of HADS was examined using Cronbach's alpha. The internal consistency test of the original two-factor structure revealed a good α value overall and total HADS (r = .82) for anxiety (r = .79) and for depression (r = .66). No significant increases in alpha for any of the scales could have been achieved by deleting any items; whereas the Cronbach's alpha values of emerged two-factor structure subscales were .81 for anxiety subscale, and slightly lower than original structure for depression subscale, .63. Nevertheless, these diverse results force the researcher to question which analysis has best uncovered the structure of the HADS scale. And for the emergent two-factor structure, can they still be referred to as anxiety and depression scales or are they components of a broader distress scale?

Indeed, it is difficult to determine whether one-factor solution or emergent two-factor solution or original two-factor solution best reflected the structure of HADS within this population. That is because one-factor solution had clear and simple structure, emerged two-factor structure had good fit to data like original two-factor structure of HADS. The only slight difference noted was on the result of internal consistency test between the emergent and original two-factor structure in which original two-factor structure had better internal consistency on depression subscale. For the purpose of this study, it is perhaps advisable to retain and consider using the original two-factor structure of HADS, Zigmond and Snaith

(1983), in this group of patients. Future research then can be carried out to test and explore different factor analysis methodologies than can provide more confidence on determining the structure of HADS within ESRD patients.

Selecting the appropriate technique to be used in exploring the factor structure of a screening tool can be challenging and difficult to an “average second-language” researcher on statistical methodology. Although EFA showed a clear one-factor structure of HADS that measured psychological distress, results also showed that levels of anxiety and depression were not entirely independent in this group of patients, correlated at the level of .53. This may suggest that the use of oblique rotation was efficient in providing the most psychologically meaningful way of analysing the data in this study sample. Similarly, this method of rotation was used by most of the studies that tested the item structure of HADS across clinical and non-clinical subjects. It should be noted, however, that the estimates of model fit for the original two-factor model did not deviate much from those for the emergent two-factor model, that is it offered an acceptable fit for the data and was consistent with some research on HADS across a variety of clinical groups (Dunbar et al., 2000; Friedman et al., 2001; Caci et al., 2003). This can perhaps be confirmed by using CFA method in different groups of patients with different medical conditions and management.

The ability of HADS to distinguish between anxiety and depression is vital as otherwise it might be more appropriately used as an instrument of general distress. Clinically, distinguishing between anxiety and depression in patients with ESRD is important as it may help in determining the right intervention. A prospective study, of four years’ duration, by Preljevic et al. (2013) reported that around 50% of patients experienced depression, 28% anxiety and 33% MADD disorder. Despite many EFAs supporting the two dimensions of HADS, Johnston et al. (2000) suggested that, for an HADS to achieve validity in separating anxiety and depression, a CFA should be performed to demonstrate this separation. Interestingly, in the current study, the findings from the CFA revealed acceptable fit indices for the all tested factor structures of HADS (refer to Table 7.21).

This inconsistency of items loading on supposed factors may be related to sensitivity issues with those items in detecting emotional disorders, as for item-7. It has been reported by previous studies that the original two-factor structure of HADS showed high loading on depression, rather than anxiety as shown in this study (Crawford et al., 2001; Harter et al., 2006). This inconsistency may be caused by the ambiguous wording as it refers to psychomotor agitation and inner tension (Beck et al., 1996). Also, cultural differences may be a factor that influences the understanding of an instrument item. Most of the studies exploring the factor structure were conducted in a Western context and no studies found were found conducting similar tests in Omani. Such an argument, similarly, applies to item-6 “I feel cheerful”, item-8 “I feel as if I am slowed down” and item-10 “I have lost interest in my appearance”. This finding may be specific to the Omani population. Despite the language equivalence of the Arabic version of HADS being well established (Malasi et al., 1991), the response bias might change the basic nature of the depression item to that of an anxiety item (Matsudaira et al., 2009). As a strategy to deal with such conversely loading items, Hulley et al (1996) suggest that such items should be divided into two sentences in future studies and then tested using EFA.

Another query might be raised with regard to the sensitivity of items that detect emotional disorders as to whether they are all valid across different populations with different medical conditions and different forms of management. In the real world, there might be a chance that some items are inappropriate for particular patients. For instance, item-8 “I feel as if I am slowed down” might reflect the effect of a stroke condition, or item-9 “I get a sort of frightened feeling like ‘butterflies’ in the stomach” might interfere with some symptoms of cardiac diseases. Likewise, item-14 “I can enjoy a good book or TV programme” could be a direct result of ESRD symptoms rather than a reflection of a patient’s low mood. That is, the level of bodily pain and low physical functioning that patients with ESRD might have could confound their ability to sit and enjoy reading a book or watching a TV programme. Also, the response to item-14 could be affected by cognitive impairment or the level of reading ability. Twenty-seven percent (27%) of the study sample were illiterate and 22% had a low intermediate level of education. It is anticipated that illiterate patients and patients with cognitive impairment would not be able to enjoy reading a book. Thus, item-14 would not be appropriate for assessing psychological distress among patients with cognitive impairment and a low education level. One way to overcome the issue of possible inappropriateness of some items in some specific patients may be to revise (rewrite) these items (Dunbar et al., 2000).

Although the emerged two-factor structure model shown in Table 7.19 (correlated factors) was comparable to the original anxiety and depression subscales, four items, however, demonstrated a split-loading on to the opposing factor. Anxiety item-7 “I can sit at ease and feel relaxed” was jointly loading on both factors, with split-loading slightly in favour of Factor-2 (depression), and depression item-6 “I feel cheerful”, item-8 “I feel as if I am slowed down” and item-10 “I have lost interest in my appearance” were inversely loading in favour of Factor-1 (anxiety). The inverse loading of these items on to opposite factors may reflect the fact that these items may be problematic, or they may measure something different from other items within this population, or they may measure a similar concept. Going through these items, the first available response option shifts from “not at all”, to “definitely”, to “nearly all the time”, to “definitely”. The “not at all” is for item-6 and item-7. It might it not be clear whether some of these responses refer to actual level of negative affect or to a comparison with ‘usual’. Perhaps adequate revalidation of the Arabic version of HADS among different groups of Arab patients with different medical conditions would elaborate further on the accuracy of HADS response options.

A number of limitations should be acknowledged in this section. First, the primary aim of this chapter was to test and validate HADS among Omani ESRD patients and the full psychometric validation of HADS was beyond this aim. Second, HADS is a self-administered measure and this type of instrument usually tends to inflate the result. Patients with ESRD are also affected by adjustment disorders due to personal and clinical factors and this may influence their response accuracy.

5. Conclusion

This chapter has explored and discussed the process undertaken to validate the SF36v2 and HADS measures among ESRD patients using factor analyses and internal reliability test.

For SF36v2, three-factor structure was identified as underpinning SF36v2 which can be named as physical functioning, emotional effect and role functioning. The result seems to suggest that the role-functioning concept emerged due to cultural differences in item interpretation or possibly because of differences in perception of health. That is, the concept of role functioning may be more dominant and more valued by Omani patients. This result recommends that researchers should take more cautious steps when translating HRQoL standard measures into Arabic. In addition, intensive psychometric testing should be carried out on translated measures.

The three-factor solution was subjected to CFA which proved to fit the data of this study. It can be concluded, then, that the HRQoL status of Omani patients with ESRD is influenced by physical functioning, limitations on role functioning due to physical and mental problems and emotional impact. Hence, SF36v2 needs to be scored according to the emerged three-factor structure. To ensure a rigorous scoring process, a comparison of scoring between the original factor structure of SF36v2 and the emerged three-factor structure can be carried out. These two structures underpinning SF36v2, the standardised two-factor structure and the emerged three-factor structure, can then be regressed with independent variables in the main study.

For HADS, results did not show an exclusive factor-structure of HADS. EFA revealed one-factor structure and a possible two-factor structure correlated at α .53. CFA revealed acceptable fit indices to study data for the one-factor, original two-factor, and emergent two-factor structures, though it was in favour of emergent two-factor structure. Internal reliability test was conducted on original and emergent two-factor structures and results showed better internal consistency of original two-factor structure.

The response rate of HADS in this population reflected the fact that it is an easily administered scale which is not unduly burdensome to ESRD patients who are on continuous dialysis treatment. Despite this, the generalisability of HADS should be well noted since different characteristics of patients, cultures and statistical methods could be sources of spurious results. Clinically, there is a need to develop precise diagnostic criteria for adjustment disorders that can be used in ESRD patients. Despite results indicating that HADS is a valid measure within this population, clearly differentiating between the concepts of anxiety and depression, the sensitivity of items remains an issue. Out of seven items of the depression scale, five items were sensitive in measuring depressive symptoms and the remaining five were loaded on the anxiety scale. Future studies should focus on improving screening methods to make these items more sensitive and more specific. Hence, for the purpose of this study, and on the basis of acceptable internal-consistency values and fit indices of original two-factor structure to data, it is may be advisable to use the original HADS in this study.

Chapter 8- Main Study Results

1. Introduction

This chapter presents the results of the statistical analysis pertaining to phase three of this study. This study is a cross-sectional correlational design.

Since the study is not examining the changes in QoL and HRQoL over time, a cross-sectional design was deemed appropriate and data were collected at one point in time from patients to examine their level of QoL and HRQoL as well as related factors. Patients included in this phase were: adult patients with ESRD receiving HD; those aged ≥ 18 years; and those who had been on HD for more than three months. Patients with acute renal failure; patients aged under 18; patients diagnosed with dementia or any other condition that could impair their ability to answer questions; patients who had recently been diagnosed with cancer; and patients who had recovered their renal function were excluded from study.

Eight instruments were used to collect the data: 1) Background data sheet; 2) Short-Form 36v2 (SF36v2); 3) Quality of life Index-Dialysis (QLI-D); 4) Hospital Anxiety Depression Scale (HADS); 5) Fatigue Severity Scale (FSS); 6) Itch Scale (5-D Itch); 7) Spiritual Wellbeing Scale (SWB); and 8) The Schedule for the Evaluation of Quality of Life-Direct weighting (SEIQoL-DW).

Thirteen dialysis centres across the Sultanate were involved in this phase. These units provide routine HD for out-patients affected by ESRD from a variety of regions and are managed by the Omani Ministry of Health (MOH). Patients were identified from the National Renal Registry of patients treated with ESRD in Oman. Using an opt-in strategy, those who agreed to participate were identified by nurses who were recruited and trained by the researcher to assist in obtaining consent forms, administering the questionnaire package, following up and collecting the completed study questionnaires.

Collected data were analysed using the SPSS software version 22. Initial analysis outputs were checked for missing, invalid and extreme values that might have fallen out of the range of normal possible values. The nominal and categorical data were inspected by running frequency tables, while continuous data were inspected by running descriptive statistics. The frequency and descriptive tests outputs were checked to correct any errors before starting data analysis. Missing data and extreme values of categorical variables were checked visually by observing frequencies in output tables. Missing data were examined and were managed by individual mean substitution if they were found not to be significant or ≤ 10% and if > 10%, then the affected scale/subscale was excluded in related analyses (Tabachnick and Fidell, 2007).

HRQoL, disease-specific, and symptoms-specific measures were computed and a syntax was created. It should be noted that the scores of the bodily-pain scale are reverse scored: the higher the value, the less the bodily pain.

Data normality were tested by running a frequency distribution for each variable and if data-normality assumptions were violated, data were transformed by using square root, logarithm and inverse function, respectively. Outliers were checked by Q-Q Plot. Multivariate outliers were inspected by running standardised residual values, and if greater or less than 3.0, values were categorised as an outlier (Tabachnick and Fidell, 2007). Where presented, outliers were handled by being rescored or deleted or by creating separate regression models. Data linearity was checked using scatter-plots to illustrate differences between each of the independent variables compared with the dependent variable.

Frequency for nominal and categorical variables, and mean and standard division for continuous variables were computed. The Pearson product correlation coefficient (r) was conducted to assess the relationship between two parametric variables and the Spearman's rank order correlation (rho) was used to assess the relationship between non-parametric variables.

Reliability of measures and its subscales was tested using the Cronbach's alpha. DeVellis (1991, p.85) and suggest 0.60 and above as an acceptable reliability coefficient since smaller reliability coefficients are seen as inadequate. This value was used since the aim of reliability test is to measure a trait with enough accuracy to establish the existence of a relationship with other traits.

For regression analysis, three main sequential multiple regression analyses were conducted to test the predictive value of the demographic, treatment, clinical, socio-environmental, symptoms, functional status and general health perception on HRQoL in patients with ESRD: SF36v2 physical component summary–PCS (2-factor standard model); 2) SF36v2 mental component summary–MCS (2-factor standard model); 3) QoLI-dialysis; and 4.a) SF36v2–PCS (emerged 3-factor model), SF36v2–MCS (emerged 3-factor model), and SF36v2–Role-functioning component summary–RCS (emerged 3-factor model).

Independent variables were correlated with each other and checked for multi-co-linearity. In the case of two variables correlating at 0.85 or higher, one variable was eliminated from the regression analysis. When all variables were examined together, the tolerance level and variance inflation factor of all IVs were calculated to determine multi-co-linearity. A tolerance value <0.10 and a variance inflation factor >10 was used to identify multi-co-linearity for possible elimination of variables (Mertler & Vannatta, 2002).

A Mahalanobis Distance was computed for each case to detect any extreme multivariate outliers and, once that was done, the Mahalanobis scores were screened in the same manner as the univariate outliers. Hence, frequency distributions were run for each variable and examined for outliers. In addition, multivariate outliers were detected through “standardised residual” values >3.0 or <-3.0. Outliers would either be rescored or deleted, or separate regression models were created (Tabachnick and Fidell, 2007).

All variables were checked for data distribution (multivariate normality, linearity and homo-scedasticity) by visually examining standardised residual scatterplots. In case any assumptions were violated, data were transformed in an attempt to stabilise the variance and to achieve linearity and normality (Polit, 1996).

The statistical significance for a variable inclusion into a statistical model was set at α= .15 (Tabachnick and Fidell, 2014). This determined liberal probability level was to avoid excluding important variables from the model. Independent variables were entered simultaneously into a sequential multiple regression model to determine how well biological factors, symptoms, functional status, general health perception and socio-demographic and treatment factors predicted a patient's overall HRQoL.

The improvement in the regression model at each step was evaluated by the R square (R^2) and adjusted R^2 values. The process of adding more variables would stop when all the potential variables had been included or when it was not possible to make a statistically significant improvement in R and R_2 (Pallant, 2013). To evaluate which variables included in the model contributed to the prediction of the dependent variables, the unstandardised regression coefficients (*B*), the standard errors (SE *B*), the standardised regression coefficients (β), the *t*-statistic, the significance of the *t*-statistic, the *R,* the *F* statistic (*F*), R^2 and the change in R^2 (ΔR^2) were reported.

Finally, the accuracy of each regression model was evaluated by conducting a Bootstrapping test. Bootstrapping is considered a sound test which can be performed to obtain robust estimates of the intercept and beta weights (Tabachnick and Fidell, 2014, p 179). It is a process by which regression weights are generated over a very large number of replications (up to 1,000 bootstraps) with samples drawn and replacement from the available data set. Conclusions were drawn based on the bootstrapped coefficients' parameter estimates of the overall final model: the unstandardised regression coefficients (B), bias, bootstrapped standard errors (SE B), significance of the regression coefficients, the normal approximated 95% confidence intervals (OLS 95% CI) and the bootstrapped confidence interval (BCa 95% CI).

2. Findings

2.1. Return rates

Eight hundred and two survey packages were distributed to 13 dialysis units across the Sultanate during the months of May and June 2016. Of the 802 respondents who received the survey packages, 451 surveys were returned providing a return rate of 56.23 % (table 8.1), of which one has only socio-demographic and clinical data. One hundred and two (27.01%) illiterate patients required assistance in filling out the surveys by the assigned nephrology nurses.

Table 8. 1 eligible patients and number of returned surveys per unit

Dialysis unit	Eligible patients	Returned questionnaires (%)
Al-Buraimi	36	25 (69.44)
Bausher and Seeb	210	117 (55.71)
Musandam	10	07 (70)
Ibra	44	21 (47.72)
Ibri Hospital	50	15 (30)
Jaalan BBA	44	24 (54.54)
Musanah	114	71 (62.28)
Nizwa	62	10 (16.12)
Rustaq	41	18 (43.90)
Sinaw	25	11 (44)
Sohar EHC	58	54 (93.10)
Sohar Hospital	83	58 (69.87)
Sumail	25	20 (80)
Total	802	451 (56.23)

2.2. Preliminary examination of data

Collected data were analysed using the SPSS version 22.0. Data entry was double-checked and proofread against the original questionnaire. No errors were identified.

The sociodemographic data were checked visually for missing data and extreme values by running frequencies on all related variables. Questions that were related to the demographical variables were all completed except two cases (0.4 %) for gender, six (1.3 %) cases for marital status, three (0.9 %) cases for education level, and seven cases (1.6 %) for income variable (table 8.2). No method was used to replace the missing data on those variables and cases were excluded using pairwise method where necessary. No extreme values were noted.

Table 8. 2 Missing data on sociodemographic data (n= 451)

Variable	**Frequency (%)**
Gender	2 (0.4 %)
Marital status	6 (1.3 %)
Educational level	3 (0.9 %)
Income	7 (1.6 %)

For study continuous data, identified missing data with ≤ 10 % were replaced by the individual mean substitution method; whereas missing data with ≥ 10 % were excluded in the inferential analysis pertaining to regression analysis. Table 8.3 shows the final total number of excluded cases from analysis in relation to each scale and subscales. Subsequently, frequencies and descriptive analyses were repeated to check whether missing data were entirely replaced, which showed no further missing data and thus provided the confidence to move to detect outliers and check data distribution.

Table 8. 3 Total cases were excluded from analysis (n= 451)

Scale and subscales	Missing cases N (%)	Valid cases N (%)
Pt age	12 (2.7)	439 (97.3)
Hb	7 (1.6)	444 (98.4)
Haematocrit level	8 (1.8)	443 (98.2)
Albumin level	8 (1.8)	443 (98.2)
Dialysis adequacy	12 (2.7)	439 (97.3)
dialysis hours per month	8 (1.8)	443 (98.2)
Time since started HD	0 (0)	451 (100)
Time to reach to Dialysis in minutes	9 (2)	442 (98)
HADS Anxiety Subscale	11 (2.4)	440 (97.6)
HADS Depression subscale	10 (2.2)	441 (97.8)
HADS overall Score	10 (2.2)	441 (97.8)
Religious wellbeing	12 (2.7)	439 (97.3)
Existential Wellbeing	14 (3.1)	437 (96.9)
Spiritual Wellbeing	12 (2.7)	439 (97.3)
QoLI-Dialysis Scale	8 (1.8)	443 (98.2)
QoLI-D Health Functioning Subscale	8 (1.8)	443 (98.2)
QoLI-D Socio Economic Subscale	8 (1.8)	443 (98.2)
QoLI-D Psycho Spiritual Subscale	9 (2)	442 (98)
QoLI-D Family Subscale	10 (2.2)	441 (97.8)
Itch Scale	12 (2.7)	439 (97.3)
Fatigue Scale	12 (2.7)	439 (97.3)
SF36v2 Perceived General Health	5 (1.1)	446 (98.9)
SF36v2 Physical Functioning Subscale	6 (1.3)	445 (98.7)
SF36v2 Social Functioning Subscale	11 (2.4)	440 (97.6)
SF36v2 Limitation in role physical Subscale	6 (1.3)	445 (98.7)
SF36v2 Limitation in role emotional Subscale	9 (2)	442 (98)
SF36v2 Mental Health Subscale	13 (2.9)	438 (97.1)
SF36v2 Vitality Subscale	11 (2.4)	440 (97.6)
SF36v2 Bodily Pain Subscale	12 (2.7)	439 (97.3)
SF36v2 General Health Subscale	14 (3.1)	437 (96.9)

HB: Haemoglobulin; QOLI-D: Quality of life index-dialysis; SF36v2: Short form 36 version 2.

Following data cleaning and missing data replacement, five measures–Short form 36v2 (SF36v2), Hospital Anxiety Depression Scale (HADS), Fatigue Severity Scale (FSS), Itc-5D, and Spiritual Wellbeing Scale (SWB)–were computed and a syntax was created using the SPSSv22 programme. For the

Quality of Life Index-Dialysis (QoLI-D), the syntax developed by Ferrans et al (2005) was used to score the QoLI-D and its four subscales. This was developed specifically to fit the SPSS programme. It should be noted that the scores of the bodily-pain scale are reverse scored: the higher the value, the less the bodily pain.

Continuous data were then explored to examine outliers and linearity by visually observing scatter-plots. No outliers were observed.

Each continuous variable was examined for normality by calculating skewness and kurtosis statistics. Single sample z-tests were considered normally distributed if skewness and kurtosis values were between -3.3 and + 3.3 (Tabachnick and Fidell, 2014). Nine variables were found to be skewed: Spiritual wellbeing, Time to reach HD, Time since started HD, Itch, QOLI-D, Fatigue, Psycho-Spiritual subscale of QOLI-D, Family subscale, and HD hours per month. In an attempt to stabilise the variance and achieve normality, these variables were, gradually, transformed using the methods of square root, logarithm, and inverse transformation. These transformations, however, did not significantly mend the skewed variables, except slight improvement on two variables, the Time since started HD and Itch. It was therefore decided to use the variables untransformed and to examine the distribution of the residuals of relevant inferential statistics (Table 8.4).

Table 8. 4 The effect of data transformation on skewness

variable	Pre-transformation			Square root transformation		Logarithm transformation		Inverse transformation	
	skewness	se	z	Skewness	z	skewness	z	skewness	z
Spiritual Wellbeing	1.5	0.11	12.82	0.34	2.93	-3.45	-29.53	19.74	168.76
Time to reach HD	1.09	0.11	9.44	0.45	3.96	-0.26	-2.31	2.03	17.50
Time since started HD	0.96	0.11	8.16	0.23	1.97	-0.58	-4.96	3.39	28.72
Itch	0.79	0.11	6.76	0.16	1.37	0.16	1.36	6.22	53.17
QOLID	-0.41	0.11	-3.59	-0.63	-5.46	-0.89	-7.67	1.68	14.53
Fatigue	-0.59	0.11	-5.04	-1.03	-8.86	-2.27	-19.40	17.75	151.77
Psych-Spiritual Subscale	-0.96	0.11	-8.31	-1.74	-15.0	-1.91	-16.52	4.36	37.62
Dialysis hours per month	-1.05	0.11	-9.06	-1.10	-9.53	-1.16	-10.02	1.29	11.12
Family Subscale	-1.28	0.11	-11.11	-1.69	-14.5	-2.59	-22.36	10.18	87.82

*the values of standard error were same across transformation

Cronbach’s alpha was computed for each measure to check for internal reliability. Scores correlated at range of α= .533 to 0.975 (see Table 8.5) with lowest on Social Functioning subscale of the SF-36v2 and highest on QOLI-D. Exceeding Cronbach’s Alpha value .60, Nunnally and Bernstein (1994) and DeVellis (2003), these findings suggest that study measures are acceptable and reliable within the Omani context.

Table 8. 5 Internal reliability of total scores and subscales of study measures

Measure	Cronbach's alpha
SF-36v2	.668
SF36v2 Physical Functioning Subscale	.829
SF36v2 Role Physical Subscale	.830
SF36v2 Bodily Pain Subscale	.766
SF36v2 General Health Subscale	.656
SF36v2 Vitality Subscale	.748
SF36v2 Social Functioning Subscale	.533
SF36v2 Role Emotion Subscale	.848
SF36v2 Mental Health	.747
QOLID	.975
QOLID-Health and Functioning Subscale	.903
QOLID-Social and Economic Subscale	.807
QOLID-Psychological Spiritual Subscale	.905
QOLID-Family Subscale	.805
SWB	.867
Itch-5D Scale	.678
FSS	.922
HADS	.829
HADS-Anxiety subscale	.795
HADS-Depression subscale	.666

SF36v2: Short form 36v2; QOLID: Quality of life index dialysis; SWB: Spiritual wellbeing; HADS: Hospital anxiety depression scale.

2.3. Participants' characteristics

Four hundred and forty-nine (449) patients completed the study measures. Table 8.6 illustrates the characteristics of the patients. The average age of the patients was 46.59 (SD = 13.6 years) and ranged from 18 to 87 years; of which, 56.3% were men, and 43.2% women. Most of the participants were married (62.5%), employed (37.5%) and illiterate (27.1 %). The majority of the participants were from Al Batina region (44.6%), followed by Muscat governate (25.9%). These two regions consist of seven HD units and accommodate 55% of the Oman population compared to the remaining regions.

Table 8. 6 Patient's characteristics (n 451)

Variable	Mean (SD)	Range
Age	46.59 (13.64)	18-87
Variables	Frequency (%)	
Gender		
male	254 (56.3 %)	
female	195 (43.2 %)	
Marital status		
Married	282 (62.5 %)	
Separated	44 (9.8 %)	
Widow	40 (8.9 %)	
Single	79 (17.5 %)	
Educational status		
illiterate	122 (27.1 %)	
Low-intermediate	98 (21.7 %)	
Intermediate	83 (18.4 %)	
High-intermediate	85 (18.8 %)	
high	60 (13.3 %)	
Job		
Employed	169 (37.5 %)	
Un-employed	278 (61.6 %)	
Income (OMR)		
<250	234 (51.9 %)	
251-600	126 (27.9 %)	
601-1000	25 (5.5 %)	
1001-1500	40 (8.9 %)	
>1500	19 (4.2 %)	
Region		
Muscat	117 (25.9 %)	
Dakhliya	30 (6.7 %)	
Dahira	15 (3.3 %)	
Musandam	7 (1.6 %)	
Buraymi	25 (5.5 %)	
Batina	201 (44.6 %)	

2.4. Clinical characteristics

Table 8.7 summarises results of clinical variables which are Haemoglobin (Hb), Haematocrit (HCT), Albumin level, Dialysis adequacy, Dialysis hours per month, Time since started HD in years, and Time to get to HD in minutes. Time on HD in hours per month ranged from 32 to 48 hours (M = 44.1, SD = 5.5). The length of time that patients had been on dialysis ranged from three months to 24 years (M

= 6.57, SD = 4.6). The average time taken for the patients to travel to dialysis ranged from five minutes to one-and-a-half hours (M = 28.8, SD = 18.0). The adequacy of dialysis, measured by urea reduction rate, was within the normal range (M = 70.50, SD = 11.58).

Table 8. 7 Clinical data (n 451)

Variable	Mean (SD)	Range	Therapeutic values*
Hb g/L	10.98 (1.53)	6-15.5	Male: 113 - 118 g/L Female: 112 - 116 g/L
Haematocrit level	35.71 (5.15)	21.8-49.4	33-36 %
Albumin level	38.42 (5.13)	21.8-52.6	35-48g/L
Dialysis adequacy (urea reduction rate)	70.50 (11.58)	31.1-96.7	≥ 65 %
Dialysis hours per month	44.14 (5.55)	32-48	-
Time since started HD in years	6.57 (4.65)	0.3-24	-
Time to get to HD in minutes	28.87 (18)	5-90	-

* source: KDOQI clinical practice guideline for haemodialysis (2015)

2.5. RQ2: What is the level of QoL/HRQoL for patients with ESRD on HD in Oman?

This question was answered by descriptive analysis of the generic health status measure (SF36v2), condition-specific measure (QOLI-Dialysis), general health perception (item one in the SF-36v2), individualised QoL instrument (SEIQoL-DW), emotional status measure (HADS), and the physical symptom-specific measures (Itch-5D, Fatigue Scale).

2.5.1. Health status (SF-36v2)

The SF36v2 scores ranged from 0 to 100, with 0 indicating lowest health status and 100 being the highest health status. The means and standard deviation (*M* ± *SD*) of the eight subscales of SF-36v2 and the two component summary scores (PCS and MCS) are presented in Table 8.8 The mean scores of the eight domains of the SF-36v2 ranged from 52.24 to 63.75, suggesting that these patients had moderate health status. Physical functioning due to physical health problems (PF) and vitality (VT) due to mental health problems were the lowest rated domains (*M* = 42.24 and 52.90, respectively), while mental health (MH) and social functioning (SF) were the highest rated domains (*M* = 63.75 and 60.51, respectively). Additionally, the PCS score was lower than the MCS score (*M* = 54.09 and 58.35, respectively).

Table 8. 8 Means (SD) and ranges of SF-36v2 domains of patients with ESRD in Oman

SF-36v2 subscales		N	Mean (SD) (out of scores 0-100)	Minimum	maximum
Physical health	PF	446	52.24 (26.31)	0	100
	RP	445	54.24 (24.87)	0	100
	BP	439	56.72 (26.11)	0	100
	GH	447	53.18 (20.06)	0	100
Mental health	VT	440	52.90 (21.23)	0	100
	SF	440	60.51 (25.44)	0	100
	RE	443	56.25 (27.52)	0	100
	MH	440	63.75 (20.31)	5	100
Physical Component Summary (PCS)			54.09 (24.33)	2.5	97.5
Mental Component Summary (PCS)			58.35 (23.62)	10.3	100

2.5.2. Quality of Life Index-Dialysis

The QOLI-D scores ranged from 0 to 30, with 0 indicating poor QoL and 30 good QoL. Findings on the QOLI-D for the patients were all above the midrange value of 15 of the scale and subscales scores (table 8.9). The overall QOLI-D was 21.90 (*SD* = 4.86) out of a score of 30. Health and Functioning was the lowest rated subscale (*M* = 20.36, *SD* = 5.33), followed by the Social and Economic subscale (*M* = 21.24, *SD* = 5.29), the psychological/ spiritual subscale (*M* = 23.43, *SD* = 6.05), and the family subscale (*M* = 25.15, *SD* = 5.50).

Table 8. 9 Mean scores of the quality of life index-dialysis (QOLI-D)

QOLID total and subscales	N	Mean (SD) (out of scores 0-30)	Possible range	Minimum	Maximum
QOLID total	443	21.90 (4.86)	0-30	7.24	29.80
Health and functioning	443	20.36 (5.33)	0-30	5.11	30
Social and economic	443	21.24 (5.29)	0-30	7.88	30
Psychological/ spiritual	442	23.43 (6.05)	0-30	.00	30
Family	441	25.15 (5.50)	0-30	2.40	30

2.5.3. General health perception

Patients' perception of their general health was assessed using a single item (item one in the SF-36v2) that asked patients to rate their health in general. This question is rated on the 5-point ordinal scale ranging from poor = 1 to excellent = 5. Table 8.10 shows that 132 (29.3%) of the patients rated their general health as good followed by 127 (28.2%) patients who perceived their general health as fair. Only 69 (15.3%) of the patients thought their general health was excellent, whereas the remaining 39 (8.6%) patients rated their general health status as poor.

Table 8. 10 Summarises the description of patients' general health perception (n= 446).

Rating scale of perceived general health	N (%)	*Mean (SD)*
Poor	39 (8.6 %)	*M*= 3.02 (1.19)
Fair	127 (28.2%)	
Good	132 (29.3 %)	
Very good	79 (17.5 %)	
Excellent	69 (15.3 %)	

2.5.4. Individualised QoL instrument (SEIQoL-DW)

As described in Methodology Chapter (Chapter six), SEIQoL-DW was used to assess patient's own perspective and on his/her own perception and understanding of QoL. In total, 45 patients completed the SEIQoL-DW. The average length of time required for the patients to complete the SEIQoL-DW was 16.43 (11-25) minutes. The least time taken was scored by a 27 years old male patient with high education level, the longest by a 59 years old illiterate female patient suggesting that education level might reflect level of understanding the SEIQoL-DW instrument. The majority of patients 39 (86.6%) reported that completing the SEIQoL-DW was easy.

Two hundred and twenty cues were reported by the interviewed patients: forty-three patients (95.5%) nominated five cues without prompting whereas two (4.44%) required prompting and nominated four cues. These cues were categorised by three independent raters revealing 19 categories (Table 8.11). Fifty seven percent (127) of the cues were assigned the same category by the three raters, 33.64% (74) had agreement of two raters, and there was no agreement on 19 cues (8.64%). The raters later met to agree and assign a category for the cues that they did not agree.

Table 8. 11 Frequency and percentage of patients nominating each category

Common category	**Frequency (%)**
Religion/spiritual life	36 (80%)
Family	35 (77.7%)
Personal health	31 (68.8%)
Social life	17 (37.7%)
Work/occupation	15 (33.3%)
Leisure activities/hobbies	14 (31.1%)
Autonomy/independence	12 (26.6%)
Role functioning	9 (20%)
Living conditions	9 (20%)
Peace and contentment	7 (15.5%)
Finance	7 (15.5%)
Family health	6 (13.3%)
Quality of care	5 (11.1%)
Sexual life	4 (8.8%)
Enjoying life	4 (8.8%)
Relationships	4 (8.8%)
Coping	3 (6.6%)
Emotional well-being	2 (4.4%)
Exercise/mobility	1 (2.2%)

SEIQoL-DW index was calculated for all patients to provide a global QoL score (Table 8.12). The minimum score was 27.53 and the maximum score was 83.80 (*M*= 60.33, *SD* = 13.99) with the higher rate indicating better QoL. At the same time, and for the purpose of cross validation with SEIQoL-DW scores, patients were asked to indicate their current overall life satisfaction on a visual analogue scale (VAS). The mean score was 66.67 (*SD* = 20.61) with the lowest score of 28 and highest score of 95. The SEIQoL-DW index and the VAS of life satisfaction scores reflect that patients might have moderate levels of QoL and overall life satisfaction.

Table 8. 12 SEIQoL-DW index and AVS life satisfaction scores (n = 45)

Measure	mean (*SD*)
SEIQoL-DW index score	60.33 (13.99)
Life satisfaction AVS score	66.67 20.61)

SEIQoL-DW: The Schedule for the Evaluation of the Individual Quality of Life-Direct Weighting

2.5.5. Hospital Anxiety and Depression Scale (HADS)

The HADS was used to determine the levels of anxiety and depression that Omani ESRD patients might be experiencing. It consists of 14 items of which seven relate to anxiety and seven relate to depression. The possible scores range are 0-6 normal, 7-10 mild, 11-14 moderate, and 15-21 severe (Zigmond and Snaith, 1983; Crawford et al., 2001). Scores of ≥8 are deemed as a possible existence of symptoms of anxiety and depression in this group of patients. The mean anxiety score was 6.91 (*SD*= 4.32), with scores ranging from 0-18. Forty one percent (183) of patients obtained a score of ≥8 on the anxiety subscale which possibly indicates the presence of clinical anxiety. The mean depression score was 6.90 (*SD*= 3.73), with scores ranging from 0 to 17. Forty three percent of patients obtained a score of ≥8 on the depression subscale, indicating possible clinical depression (Table 8.13).

Table 8. 13 HADS scores and possible cassenas of anxiety and depression

	N (%)	Mean (SD) (out of scores 0-21)	Minimum	Maximum	Caseness (HADS ≥ 8)
HADS-A Anxiety	440	6.91 (4.32)	0	18	N= 183 (41.49%)
HADS-D Depression	441	6.90 (3.73)	0	17	N= 189 (42.95%)

HADS: Hospital anxiety depression scale

2.5.6. Fatigue severity scale (FSS)

FSS is a unidimensional scale that is used to measure fatigue severity in ESRD patients. It consists of nine items scored on a seven-point Likert scale with scores <36 suggesting no suffering from fatigue, and scores ≥36 suggesting possible fatigue that may need future evaluation. The mean FFS score was 44.70 (*SD*= 14.91), with scores ranging from 1-63. Seventy three percent (319) of 439 patients obtained a score of ≥36, indicating a further evaluation of fatigue required for those patients (Table 8.14).

Table 8. 14 FFS scores possible cassenas

	N (%)	Mean (SD)	Minimum	Maximum	Cassenas (FSS ≥ 36)
FSS	439	44.70 (14.91)	1	63	N= 319 (72.66%)

FFS: Fatigue severity scale

5.5.7. Itch-5D scale

The itch5-D scale was used to quantify pruritus in this group of patients. Scores can potentially range between 5 (no pruritus) and 25 (most severe pruritus). The average Itch-5D score was 9.33 (*SD* = 3.84), with scores ranging from 1 to 23. The average of the Itch-5D is below the midrange value which may suggest that Omani ESRD patients had low levels of pruritus symptom (Table 8.15).

Table 8. 15 Itch5-D scale scores

	N (%)	Mean (SD)	Minimum	Maximum	Possible range
Itch scale	439	9.33 (3.84)	1	23	5-25

5.5.8. Spiritual Wellbeing Scale (SWB)

SWB scale was used to assess the spiritual life wellbeing of the Omani ESRD patients by two subscales, the existential subscale (as an existential need for wholeness and connection with the universe) and religiosity subscale (religious rituals performance).

The overall SWB score was 55.54 (*SD* =17.86). The mean scores for EWB and RWB subscales were 28.63 (*SD* =8.44) and 27.04 (*SD* =10.10), respectively. Findings on the existential and religious subscale for the Omani patients were just below the midrange value of 30. Likewise, findings on the overall SWB score were under the midrange value of 60. Based on scores range of SWB, this might suggest that both the existential and religious domains of spirituality were clinically relevant to patients in this study and might have an impact on their QoL and HRQoL (Bufford et al., 1991). Table 8.16 shows the overall and subscale scores of SWB.

Table 8. 16 SWB score and subscales scores

	N (%)	Mean (SD)	Minimum	Maximum	Possible range
Existential subscale	437	28.63 (8.44)	3	60	10 - 60
Religious subscale	439	27.04 (10.10)	1	60	10 - 60
SWB	439	55.54 (17.86)	1	120	21 - 120

5.6. **Research question Three:** To what extent do the following factors predict QoL/HRQoL in Omani patients with ESRD?

a) Individual characteristics (age, gender, educational status, income, region, and marital status) measured by demographic.

b) Treatment characteristics (duration of dialysis, dialysis adequacy, and length of time to get to dialysis) measured by clinical data

c) Socio-environmental factors (family support, socio-economic, religious and spiritual), measured by disease-specific and generic-instruments.

d) Biological function (anaemia and malnutrition) measured by clinical data such as serum albumin, haematocrit and serum Hb

e) Symptoms (fatigue, pain, mood, pruritus), measured by symptom-specific instruments
f) Functional status and general health perceptions, measured by health-status instruments

Several sequential multiple regression analyses were performed to test the predictive value of the demographic, treatment characteristics, social-environmental, clinical, physical and emotional symptoms, physical functional status, and general health perception on four main outcomes: 1) SF36v2 physical component summary–PCS (Two-factor standard model); 2) SF36v2 mental component summary–MCS (Two-factor standard model); 3) QoLI-dialysis; and 4.a) SF36v2–PCS (Three-factor model), 4.b) SF36v2–MCS (Three-factor model), and 4.c) SF36v2–Role-functioning component summary–RCS (Three-factor model).

Five of the nominal variables in this analysis (gender, marital status, education status, job, monthly income, and region) required dummy coding prior to entering into the model. These variables were coded as dichotomous variables (Munro, 2005) according to the most frequent response obtained from respondents (Table 8.17).

Table 8. 17 Dummy coding for nominal variables

Nominal variable	Reference value = 0	Non-reference values = 1
Gender	Male	Female
Marital status	Married	Divorced Widow Single
Education status	Illiterate	Low-intermediate Intermediate High-intermediate higher
Job	Unemployed	Employed
Monthly income	<250	251-600 601-1,000 1,001-1,500 >1,501
Region	Interior regions	Muscat

5.6.1. SF36v2 PCS (Two-factor standard model)

Sequential multiple regression was employed to determine if addition of information regarding treatment, then family support, then symptoms, then emotional status and then health status improved prediction of the SF36v2 physical component summary (2-factor standard model), after controlling for the influence of demographics.

Before examining the sequential regression analysis, inspections for assumptions and other potential problems that might affect interpreting the analysis were conducted. Initially, the output was examined for any issues with multicollinearity. Table 18-19 displays the correlation among variables. An examination of the correlations revealed that none of the independent variables were highly correlated except Family and Social and Economic variables (r=.653). However, since the person's correlation was less than .85 (Tabachnick & Fidell, 2014), the assumption of multicollinearity was deemed to have been met. In addition, the tolerance values were all greater than 0.10 and the variance inflation factors were all less than 10.0, revealing no concerns with multicollinearity (Mertler & Vannatta, 2002). Next, the data were checked for multivariate outliers. All standardised residual values fell between -3.0 and 3.0, indicating no issues with outliers (Tabachnick & Fidell, 2001). Using the criterion p < .001 for Mahalanobis distance, no multivariate outliers among the cases were identified.

Table 8. 18 Spearman's rho correlations of SF-36v2 PCS (2-factor standard model)

Variables	SF36v2 PCS (2-factor standard)	Region	Gender	marital status	Educational status	Job	Income
SF36v2 PCS (2-factor standard)	-	.01	-.11*	-.09	.17**	-.07$^{\$}$	.09*
Region		-	.14**	.06	-.21**	.18**	-.13**
Gender			-	.18**	-.14**	.39**	-.12**
marital status				-	.19**	.13**	-.08
Educational status					-	-.21**	.41**
Job						-	-.38**
Income							-

$ p ≤ .15; * p ≤ .05; ** p < .001

PCS: Phsyical component summary

Table 8. 19 Pearson’s correlations SF-36v2 PCS (2-factor standard model)

	PCS (2-factor standard)	Pt age	Hb	**HCT**	**Albumin**	**Dialysis adequacy**	**dialysis hours per month**	**Time since started HD**	**Time to reach HD in minutes**	**Anxiety**	**Depression**	**Spiritual Wellbeing**	**Socio and Econo-mic**	**Family**	Itch	**Fatigue**	**Perceived general health**
PCS (2-factor standard)	-	-.14**	.01	.03	-.01	.06	.06	-.12*	-.15**	-.41**	-.48**	-.04	.32**	.20**	-.24**	-.42**	.46**
Pt age		-	-.01	.01	-.03	-.10*	-.09*	.04	-.07	.03	.11*	-.06	-.07	-.02	.02	.04	-.12**
Hb			-	.63**	.19**	.11*	.05	.04	-.08	-.06	-.10*	.02	.07	.05	.03	-.02	.07
HCT				-	.14**	.03	.04	.01	-.10*	.02	-.01	-.03	-.09	-.06	.02	.03	.07
Albumin					-	.14**	-.05	.01	.08	-.10*	-.08	-.13**	.08	.23**	.05	-.05	.01
Dialysis adequacy						-	.10*	-.01	.03	-.14**	-.16**	.01	.19**	.32**	-.08	-.06	.12*
dialysis hours per month							-	-.08	-.14**	.01	-.04	-.05	.02	-.03	-.06	-.08	.08
Time since started HD								-	-.02	.10*	.11*	.13**	-.12**	-.10*	.05	.06	-.03
Time to reach to HD in minutes									-	.08	.01	.04	.02	.06	.03	.05	-.02
Anxiety										-	.58**	-.01	-.45**	-.40**	.20**	.46**	-.35**
Depression											-	-.06	-.37**	-.34**	.18**	.41**	-.43**
Spiritual Wellbeing												-	-.01	.01	.06	-.03	.02
Social and Economic													-	.64**	-.16**	-.29**	.32**
Family														-	-.07	-.24**	.22**
Itch															-	.12**	-.11*
Fatigue																-	-.39**
Perceived general health																	-

$ $p \le .15$; * $p \le .05$; ** $p < .001$

PCS: physical component summary; Hb: Hemoglobulin; HD: Haemodialysis; FFS: Fatigue severity scale; HCT: Haematocrit

For normality test, the distribution of residuals were found to be nearly normal and centred at 0. Residual and scatter plots indicated the conditions of normality, linearity and homoscedasticity were all satisfied. Thus, all assumptions were sufficiently met.

Variables were entered in sequence in six steps: 1) Patient age, Gender, Education, Job, Income; 2) Time since started HD, Time to reach HD; 3) Social and Economic, Family; 4) Itch, Fatigue; 5) Anxiety, Depression; 6) Perceived general heath.

Table 20 displays the unstandardised regression coefficients (*B*), the standard errors (SE *B*), the standardised regression coefficients (β), the *t*-statistic, the significance of *t*-statistic, the *R,* the *F* statistic (*F*), R^2 and the change in R^2 (ΔR^2). *R* was significantly different from 0 at the end of each step. After Step 6 with all the IVs in the equation, $R^2 = .398$, *F* (14,368) = 17.414, $p <. 001$. The adjusted R^2 value of .376 indicates that more than a third of the variability in the SF36v2 PCS (2-factor standard model) scores is predicted by Treatment Characteristics, Family Support QOLI-D subscales, Symptom Specific Measures, Emotional Measures and Health Status measures.

At Step1, with demographic variables in the equation, F_{inc} (5,377) =2.480, $p < .05$ and these accounted for 3.2% of variance in SF36v2 PCS scores (2-factor standard model) scores. None of the demographic variables were found to be significant predictors of SF36v2 PCS scores (2-factor standard model). Introducing the treatment characteristics variables in Step 2 explained an additional 3.3% of variance in the SF36v2 physical component summary (2-factor standard model) scores and this change in R^2 was significant, F_{inc} (2, 375) =6.581, $p < .01$. Among the two variables added in Step 2, only Time to reach HD was found to be a significant predictor of SF36v2 PCS (2-factor standard model) scores ($p = .002$). Adding the Family and Socioeconomic subscales in Step 3 explained an additional 9.2% of variance in SF36v2 PCS (2-factor standard model) scores and the change in R^2 was significant, F_{inc} (2,373) =20.248, $p < .001$. Among the two subscales added in step 3, only Family was found to be a significant predictor of SF36v2 PCS (2-factor standard model) scores ($p < .001$).

At the end of Step 4, with symptom specific measures in the equation, the regression model explained an additional 13.1 % of variance in SF36v2 PCS (2-factor standard model) scores and this change in R^2 was significant, F_{inc} (2,371) =34.067, $p < .001$. Both the symptom specific measures were significant predictors of SF36v2 PCS (2-factor standard model); Fatigue ($p< .001$) and Itch ($p< .001$). Again, at Step 5 when emotional measures were added, the new model now explained an additional 8.2% of variance in SF36v2 PCS (2-factor standard model) scores and this change in R^2 was also significant, F_{inc} (2, 369) =23.826, $p < .001$. Among the two emotional subscales, Depression was found to be a significant predictor of SF36v2 PCS (2-factor standard model) scores ($p< .001$). Finally, after addition of Perceived general health at Step 6, $R^2 =.398$ (adjusted $R^2 =.376$), F_{inc} (1, 368) =18.224, $p< .001$. When all the IVs were included in Step 6, Family was no longer a significant predictor of SF36v2 PCS (2-factor standard model) scores. In the final model the significant predictors of SF36v2 PCS (2-factor standard model) scores were Time to reach dialysis, Itch, Fatigue, Depression and Perceived general health. The most important predictors of SF36v2 PCS (2-factor standard model) scores were Depression and Perceived general health. Together all the IVS accounted for 39.8% of the variance in the SF36v2 PCS (2-factor standard model) scores

Table 8. 20 Sequential Multiple Regression Analysis predicting SF36v2 PCS (2-factor standard model) From Treatment Characteristics, Family Support, Symptom Specific Measures, Emotional Measures & Health Status Measures

Variable	*B*	SE *B*	β	*t-statistic*	*Significance*	*R*	*F*	R^2	ΔR^2
Step1						.178	2.480*	.032	.032
Patient age	-.147	.076	-.115	-1.92	.056				
Gender	-2.887	1.962	-.082	-1.47	.142				
Education	.566	.847	.045	.668	.505				
Job	-.820	2.145	-.023	-.382	.702				
Income	.025	.955	.002	.026	.979				
Step2						.254	3.704**	.065	.033
Time since started HD	-.369	.189	-.098	-1.95	.052				
Time to reach HD	-.152**	.049	-.157	-3.12	.002				
Step3						.395	7.676***	.156	.092
Social and Economic	1.078***	.210	.326	5.134	.000				
Family	-.089	.207	-.027	-.429	.668				
Step4						.536	13.588***	.287	.131
Itch	-.765***	.201	-.172	-3.81	.000				
Fatigue	-.383***	.055	-.327	-7.00	.000				
Step5						.607	16.578***	.369	.082
Anxiety	-.319	.230	-.079	-1.39	.166				
Depression	-1.397***	.248	-.297	-5.63	.000				
Step6						.631	17.414***	.398	.030
Perceived Gen. Health	3.037***	.711	.208	4.269	.000				
Overall Final Model									
Intercept	79.381***	7.392		10.74	.000				
Pt age	-.119	.062	-.093	-1.92	.055				
Gender	-1.998	1.594	-.057	-1.25	.211				
Education status	.077	.682	.006	.112	.911				
Job	1.248	1.749	.035	.714	.476				
Income	-.582	.768	-.038	-.757	.449				
Time since started HD	-.162	.155	-.043	-1.05	.296				
Time to reach HD	-.122**	.040	-.127	-3.05	.002				
Social and Economic	.348	.190	.105	1.834	.067				
Family	-.270	.179	-.083	-1.50	.133				
Itch	-.573**	.187	-.129	-3.06	.002				
Fatigue	-.199***	.056	-.170	-3.55	.000				
Anxiety	-.272	.225	-.067	-1.21	.228				
Depression	-1.125***	.251	-.240	-4.49	.000				
Perceived Gen. Health	3.037***	.711	.208	4.269	.000				
F-test for the whole model	17.414								
Significance of *F*-test	< .001								
R	.631								
R^2	.398								
Adjusted R^2	.376								

Note: N=383. CI, confidence interval; NS, not significant; HD, Haemodialysis.

The β weights are the standardised regression coefficients at each step. *$p < .05$. **$p < .01$, *** $p < .001$

The higher scores of Perceived general health associated with better SF36v2 PCS (2-factor standard model) whereas longer Time to reach dialysis, high symptoms of Itch, Fatigue and Depression are associated with lower SF36v2 PCS (2-factor standard model). Higher Perceived general health is positively associated with SF36v2 PCS (2-factor standard model) scores, such that adjusting for other variables in the model, for each unit increase in the Perceived general health, the SF36v2 PCS (2-factor standard model) score is predicted to increase on average by 3.037 units, with 95% confidence limits from 1.638 to 4.435, and this association is statistically significant ($p < .001$). High scores of depression are associated with lower SF36v2 PCS (2-factor standard model) scores, such that adjusting for other variables in the model, for each unit increase in Depression the SF36v2 PCS (2-factor standard model) score is predicted to decrease on average by 1.125 units, with 95% confidence limits from -1.619 to -.632, and this association is statistically significant ($p < .001$). High scores of Itch (pruritus) are found to be negatively associated with SF36v2 PCS (2-factor standard model) scores, such that adjusting for other variables in the model, for each unit increase in the itch scores the SF36v2 PCS (2-factor standard model) score is predicted to decrease on average by 0.573 units, with 95% confidence limits from -.942 to -.205 and this association is statistically significant ($p =.002$). High score of Fatigue is also found to be associated with lower SF36v2 PCS (2-factor standard model) scores, such that adjusting for other variables in the model, for each unit increase in the fatigue scores the SF36v2 PCS (2-factor standard model) score is predicted to decrease on average by 0.199 units, with 95% confidence limits from -.309 to -.089 and this association is statistically significant ($p <.001$). The longer Time a patient takes to reach HD centre is associated with lower SF36v2 PCS (2-factor standard model) scores, such that adjusting for other variables in the model, for each unit increase in the time to reach dialysis the SF36v2 PCS (2-factor standard model) score is predicted to decrease on average by 0.122 units, with 95% confidence limits from -.201 to -.043 and this association is statistically significant ($p =.002$).

In summary, it can be concluded that Time to reach Dialysis, Itch, Fatigue, Depression and Perceived general health are the significant predictors of SF36v2 PCS (2-factor standard model) scores. Among these, Depression and Perceived general health are the strongest predictors of PCS (2-factor standard model), whereas Time to reach dialysis, Itch and Fatigue contribute moderately to that prediction. In the final model, Family support subscales have no predictive value.

The trustworthiness of the regression was evaluated by using the Bootstrap technique using the IBM SPSS Bootstrapping method. Table 21 shows the bootstrap parameter estimates of the overall final model; the unstandardised regression coefficients(*B*), the bootstrapped standard errors (SE *B*), the significance of the regression coefficients, the normal approximated 95% confidence intervals (OLS 95% CI) and the bootstrapped confidence interval (BCa 95% CI). From the table, it is observed that the parametric standard errors obtained earlier (see Table 20) are quite comparable to the bootstrapped standard errors. Also, the significance of the bootstrapped coefficients show that Time to reach Dialysis, Itch, Fatigue, Depression and Perceived general health are the significant predictors of SF36v2 PCS (2-factor standard model) score, which are the same as obtained earlier from non-bootstrapped estimates. However, it is noted that Patient age which was not a significant predictor in the non-bootstrapped model, is now a significant predictor of SF36v2 PCS (2-factor standard model) scores (*p= .043*), with BCa 95% confidence limits from -.234 to -.007.

Table 8. 21 Bootstrap Parameter Estimates of the Overall Final Model predicting SF36v2 PCS (2-factor standard model) From Treatment Characteristics, Family Support, Symptom Specific Measures, Emotional Measures & Health Status Measures (N= 383)

Variable	*B*	*bias*	SE *B*	Significance	OLS 95% CI	BCa 95% CI
Intercept	79.381	.510	8.108	.001	[64.845, 93.92]	[63.622, 97.760]
Pt. age	-.119	-1.76	.058	.043	[-.240, .003]	[-.234, -.007]
Gender	-1.998	.045	1.550	.199	[-5.132, 1.136]	[-5.291, 1.112]
Education	.077	.026	.677	.900	[-1.265, 1.148]	[-1.253, 1.556]
Job	1.248	-.053	1.747	.489	[-2.191, 4.687]	[-2.034, 4.556]
Income	-.582	-.016	.739	.441	[-2.092, .929]	[-1.928, .824]
Time since started HD	-.162	-.002	.162	.317	[-.467, .143]	[-.466, .154]
Time to reach HD	-.122	6.88	.038	.004	[-.201, -.043]	[-.192, -.050]
Social and Economic	.348	-.007	.197	.086	[-.025, .721]	[-.073, .727]
Family	-.270	-.010	.201	.177	[-.622, .083]	[-.661, .096]
Itch	-.573	-.002	.209	.008	[-.942, -.205]	[-.986, -.155]
Fatigue	-.199	-.002	.061	.003	[-.309, -.089]	[-.317, -.084]
Anxiety	-.272	-.013	.252	.267	[-.714, .170]	[-.784, .203]
Depression	-1.125	.014	.274	.001	[-1.619, -.632]	[-1.711, -.541]
Perceived Gen health	3.037	.004	.765	.001	[1.638, 4.435]	[1.493, 4.582]

Note: N=383. CI, confidence interval; NS, not significant; HD, Haemodialysis; SF36V2, Short-Form 36 Health Survey; OLS, Ordinary Least Squares; BCa, Bias corrected accelerated.

In conclusion, it can be said that more than a third of the variability in SF36v2 physical component summary (2-factor standard model) scores is predicted by a number of measures. Higher general health perception associated with better physical health; whereas the longer time patients take to reach dialysis and higher symptoms of itch, fatigue, and depression associated with lower physical health. Among these, fatigue, depression and perceived general health are the strongest predictors of SF36v2 physical component summary (2-factor standard model) scores. Treatment measures and symptom specific measures contribute moderately to that prediction; whereas Family support subscales add no further prediction.

5.6.2. SF36v2 Mental Component Summary–MCS (2-factor standard model)

A sequential multiple regression was conducted to determine if addition of information regarding treatment, then socio economic and family support, then symptoms, then emotional status and then health status improved prediction of the SF36v2 MCS (2-factor standard model), after controlling for the influence of demographics.

Before examining the sequential regression analysis, inspections for assumptions and other potential problems that might affect interpreting the analysis were conducted. Primarily, the output was examined for any issues with multicollinearity. Table 22-23 displays the correlation among variables, their means and standard deviations. An examination of the correlations revealed that none of the independent variables were highly correlated. All correlations were less than .85 (Tabachnick & Fidell, 2014), hence the assumption of multicollinearity was deemed to have been met.

Table 8. 22 Spearman's rho correlations SF-36v2 mental component summary (MCS) (2-factor standard model)

	SF36 MCS (2-factor standard)	Region	Gender	marital status	Educational status	Job	Income
SF36 MCS (2-factor standard	-	-.04	-.12**	-.05	.08$^{\$}$	-.07$^{\$}$	.11*
Region		-	.14**	.06	-.21**	.18**	-.13**
Gender			-	.18**	-.14**	.39**	-.12**
marital status				-	.19**	.13**	-.08
Educational status					-	-.21**	.41**
Job						-	-.38**
Income							-

$ p ≤ .15; * p ≤ .05; ** p < .001

In addition, the tolerance values were all greater than 0.10 and the variance inflation factors were all less than 10.0, revealing no concerns with multicollinearity (Mertler & Vannatta, 2002). Next, the data were checked for multivariate outliers. All standardised residual values fell between -3.0 and 3.0, indicating no issues with outliers (Tabachnick & Fidell,2001). Using the criterion $p < .001$ for Mahalanobis distance, no multivariate outliers among the cases were identified. The distribution of residuals were found to be nearly normal and centred at 0. Residual and scatter plots indicated the conditions of normality, linearity and homoscedasticity were all satisfied. Thus, all assumptions were sufficiently met.

Table 8. 23 Pearson’s correlations SF-36v2 MCS (2-factor standard model) standardised

	SF36 MCS (2-factor standard	Pt age	Hb	HCT	Albumin	Dialysis adequacy	dialysis hours per month	Time since started HD	Time to reach HD in minutes	Anxiety	Depression	Spiritual Wellbeing	Social & Economic	Family	Itch	Fatigue	Bodily pain	Perceived general health	Physical functioning
SF36 MCS (2-factor standard	-	-.05	.04	.05	-.03	$.09^{\$}$	.02	$-.11^{*}$	$-.09^{*}$	$-.52^{**}$	$-.54^{**}$	-.01	$.35^{**}$	$.26^{**}$	$-.26^{**}$	$-.42^{**}$	$.66^{**}$	$.32^{**}$	$.343^{**}$
Pt age		-	-.01	.01	-.03	$-.10^{*}$	$-.09^{*}$	.04	-.07	.03	$.11^{*}$	-.06	-.07	-.02	.02	.04	$-.13^{**}$	$-.12^{**}$	$-.12^{**}$
Hb			-	$.63^{**}$	$.19^{**}$	$.11^{*}$	.05	.04	-.08	-.06	$-.10^{*}$	.02	.07	.05	.03	-.02	.06	.07	.02
HCT				-	$.14^{**}$	.03	.04	.01	$-.10^{*}$	.02	-.01	-.03	-.09	-.06	.02	.03	.07	.07	.04
Albumin					-	$.14^{**}$	-.05	.01	.08	$-.10^{*}$	-.08	$-.13^{**}$	.08	$.23^{**}$	.05	-.05	-.06	.00	-.04
Dialysis adequacy						-	$.10^{*}$	-.01	.03	$-.14^{**}$	$-.16^{**}$	.00	$.19^{**}$	$.32^{**}$	-.08	-.06	.08	$.12^{*}$	.00
dialysis hours per month							-	-.08	$-.14^{**}$	.01	-.00	-.05	.02	-.03	-.06	-.08	.04	.08	.05
Time since started HD								-	-.02	$.10^{*}$	$.11^{*}$	$.13^{**}$	$-.12^{**}$	$-.10^{*}$	.05	.06	$-.11^{*}$	-.03	-.02
Time to reach to Dialysis in minutes									-	.08	.01	.04	.02	.06	.03	.05	-.06	-.02	$-.16^{**}$
Anxiety										-	$.58^{**}$	-.01	$-.45^{**}$	$-.40^{**}$	$.20^{**}$	$.46^{**}$	$-.44^{**}$	$-.35^{**}$	$-.12^{*}$
Depression											-	-.06	$-.37^{**}$	$-.34^{**}$	$.18^{**}$	$.41^{**}$	$-.44^{**}$	$-.43^{**}$	$-.16^{**}$
Spiritual Wellbeing												-	-.01	.01	.06	-.03	.01	.02	-.05
Social & Economic													-	$.64^{**}$	$-.16^{**}$	$-.29^{**}$	$.30^{**}$	$.32^{**}$	$.10^{*}$
Family														-	-.07	$-.24^{**}$	$.16^{**}$	$.22^{**}$	.04
Itch															-	$.12^{**}$	$-.23^{**}$	$-.11^{*}$	$-.18^{**}$
Fatigue																-	$-.40^{**}$	$-.39^{**}$	$-.17^{**}$
Bodily pain																	-	$.41^{**}$	$.28^{**}$
Perceived general health																		-	$.15^{**}$
Physical functioning																			-

p ≤ .15$; p ≤ .05*; p < .001**

Variables were entered in sequence in six steps: 1) Gender, Education, Job, Income; 2) Time since started HD, Time to reach HD, HD adequacy; 3) Social and Economic, Family; 4) Itch, Fatigue, Bodily pain; 5) Anxiety, Depression; 6) Perceived general heath, Physical functioning.

Table 24 displays the unstandardised regression coefficients (*B*), the standard errors (SE *B*), the standardised regression coefficients (β), the *t*-statistic, the significance of *t*-statistic, the *R,* the *F* statistic (*F*), R^2 and the change in R^2 (ΔR^2). *R* was significantly different from 0 at the end of each step. After Step 6 with all the IVs in the equation, $R^2 = .602$, *F* (2,364) = 12.260, $p <. 001$. The adjusted R^2 value of .585 indicates that more than half of the variability in the SF36v2 MCS (2-factor standard model) scores is predicted by Treatment Characteristics, Family support QOLI-D subscales, Symptom Specific Measures, Emotional Measures and health status measures.

At Step1, with demographic variables in the equation, F_{inc} (4,376) =1.456, $p < .05$ and these accounted for 1.5% of variance in SF36v2 MCS scores (2-factor standard model) scores. None of the demographic variables were found to be significant predictors. Introducing the treatment characteristics variables in Step 2 explained an additional 3.2% of variance in the SF36v2 MCS (2-factor standard model) scores and this change in R^2 was significant, F_{inc} (3, 373) =4.459, $p < .01$. Among the three variables added in Step 2, the variables Time since started HD ($p= .019$) and HD adequacy ($p= .021$) were found to be significant predictors of SF36v2 MCS (2-factor standard model) scores. Adding the social and economic, and family subscales in Step 3 explained an additional 12.3% of variance in SF36v2 MCS (2-factor standard model) scores and the change in R^2 was significant, F_{inc} (2,371) =27.624, $p < .001$. Among the two variables, only social and economic scores were found to be a significant predictor ($p < .001$). At the end of Step4, with symptom specific measures in the equation, the regression model explained an additional 35.5 % of variance in SF36v2 MCS (2-factor standard model) scores and this change in R^2 was significant, F_{inc} (3,368) =92.259, $p < .001$. All three symptoms measures were significant predictors of SF36v2 MCS (2-factor standard model); Itch ($p< .024$), Fatigue ($p< .001$) and Bodily Pain ($p< .001$). When emotional measures were added in step 5, the model explained an additional 4.8% of variance in SF36v2 MCS (2-factor standard model) scores and this change in R^2 was also significant, F_{inc} (2, 366) =20.659, $p < .001$. The two emotional subscales were found to be a significant predictor of SF36v2 MCS (2-factor standard model) scores, Anxiety ($p< .041$) and Depression ($p< .001$). Finally, after the addition of Perceived general health and Physical functioning scores at step 6, $R^2 =.602$ (adjusted $R^2 =.585$), F_{inc} (2, 364) =12.260, $p< .001$. In the final model, the significant predictors of SF36v2 MCS (2-factor standard model) scores were Education status, Bodily pain, Anxiety, Depression and Physical functioning. The most important predictors in this model were Bodily pain, Depression, and Physical functioning. Together all the IVS accounted for 60.2% of the variance in the SF36v2 MCS (2-factor standard model) scores.

Table 8. 24 Sequential Multiple Regression Analysis predicting SF36v2 MCS (two-factor standard model) From Treatment Characteristics, Family Support, Symptom Specific Measures, Emotional Measures & Health Status Measures (N= 383)

Variable	*B*	SE *B*	β	*t-statistic*	*Significance*	*R*	*F*	R^2	ΔR^2
Step1						.124	1.456*	.015	.015*
Gender	-3.350	2.072	-.091	-1.62	.107				
Education	.028	.760	.002	0.36	.971				
Job	.713	2.268	.019	.314	.753				
Income	1.303	.981	0.82	1.33	.185				
Step2						.222	4.459**	.049	.032**
Time since started HD	-.476**	.201	-.120	-2.365	.019				
Time to reach HD	-.084	.051	-.084	-1.652	.099				
HD Adequacy	.186*	.080	.119	2.323	.021				
Step3						.415	27.624***	.173	.123***
Social and Economic	1.147***	.217	.331	5.288	.000				
Family	.183	.216	.055	.848	.397				
Step4						.726	92.259	.528	.355
Itch	-.395*	.174	-.086	-2.268	.024				
Fatigue	-.160**	.049	-.132	-3.254	.001				
Bodily pain	.379***	.028	.557	13.406	.000				
Step5						.759	20.659	.576	.048
Anxiety	-.414*	.202	-.099	-2.053	.041				
Depression	-1.081***	.220	-.221	-4.913	.000				
Step6						.776	12.260	.602	.027
Perceived Gen. Health	-.917	.623	-.060	-1.471	.142				
Physical functioning	.115	.024	.167	4.732	.000				
Overall Final Model									
Intercept	46.598***	7.061		6.600	.000				
Gender	-.216	1.369	-.006	-1.58	.874				
Education status	-1.660**	.504	-.126	-3.294	.001				
Job	1.402	1.501	.037	.934	.351				
Income	1.212	.646	.076	-1.05	.062				
Time since started HD	-.099	.133	-.025	-.740	.460				
Time to reach HD	-.017	.034	-.017	-.501	.617				
HD adequacy	.014	.056	.009	.259	.796				
Social and Economic	.218	.162	.063	1.347	.179				
Family	.142	.156	.042	.913	.362				
Itch	-.201	.162	-.046	-1.296	.196				
Fatigue	-.080	.049	-.066	-1.648	.100				
Bodily pain	.303***	.029	.445	10.577	.000				
Anxiety	-.465**	.196	-.111	-2.372	.018				
Depression	-1.094***	.219	-.224	-4.994	.000				
Perceived Gen. Health	-.917	.623	-.060	-1.471	.142				
Physical functioning	.115***	.024	.167	4.732	.000				
F-test for the whole model	12.260								
Significance of *F*-test	< .001								
R	.776								
R^2	.602								
Adjusted R^2	.582								

Note: N=383. CI, confidence interval; NS, not significant; Hb, Haemoglobin.
The β weights are the standardised regression coefficients at each step. *$p < .05$. **$p < .01$, *** $p < .001$*

In the final model, the factors that significantly predict SF36v2 MCS (2-factor standard model) scores are Education status, Bodily pain, Anxiety, Depression, and Physical functioning. Among these less Bodily pain and better Physical functioning are associated with better mental health whereas high Education status, Anxiety, and Depression are associated with poorer mental health. Less Bodily pain is associated with higher SF36v2 MCS (2-factor standard model) scores. Higher Physical functioning is associated with better SF36v2 MCS (2-factor standard model) scores, such that adjusting for other variables in the model, for each unit increase in the Physical functioning scores, the SF36v2 MCS (2-factor standard model) score is predicted to increase on average by 0.115 units, with 95% confidence limits from .067 to .163, and this association is statistically significant (p < .001). Higher Education status (low-intermediate and above) associated with lower SF36v2 MCS (2-factor standard model) score, such that adjusting for other variables in the model, for each unit increase in the Education status score is predicted to decrease on average by 1.660 units, with 95% confidence limits from -2.651 to -.669, and this association is statistically significant (p < .001). Higher Anxiety is found to be associated with lower SF36v2 MCS (2-factor standard model) scores, such that adjusting for other variables in the model, for each unit increase in the Anxiety scores the SF36v2 MCS (2-factor standard model) score is predicted to decrease on average by 0.465 units, with 95% confidence limits from -.850 to -.079 and this association is statistically significant (p =.022). Similarly, high Depression is found to be associated with lesser SF36v2 MCS (2-factor standard model) scores, such that adjusting for other variables in the model, for each unit increase in the Depression scores the SF36v2 MCS (2-factor standard model) score is predicted to decrease on average by 1.094 units, with 95% confidence limits from -1.524 to -.663 and this association is statistically significant (p <.001).

The trustworthiness regression model was evaluated using the Bootstrap technique using the IBM SPSS version 22 Bootstrapping method. Table 8.25 shows the bootstrap parameter estimates of the overall final model; the unstandardised regression coefficients(*B*), the bootstrapped standard errors (SE

B), the significance of the regression coefficients, the normal approximated 95% confidence intervals (OLS 95% CI) and the bootstrapped confidence interval (BCa 95% CI). From the table, it can be observed that the parametric standard errors obtained earlier (see Table 18.b) are quite similar to the bootstrapped standard errors. Also, the significance of the bootstrapped coefficients shows that Education status, Bodily pain, Anxiety, Depression, and Physical functioning are the significant predictors of SF36v2 MCS (2-factor standard model) score, which are the same as obtained earlier from non-bootstrapped estimates. This similarity might indicate having a valid sequential multiple regression model.

Table 8. 25 Bootstrap Parameter Estimates of the Overall Final Model predicting MCS (2-factor standard model) From Treatment Characteristics, Family Support, Symptom Specific Measures, Emotional Measures & Health Status Measures (N= 383)

Variable	*B*	*bias*	SE *B*	Significance	OLS 95% CI	BCa 95% CI
Intercept	46.598	.039	7.432	.001	[32.713,60.483]	[32.399,61.762]
Gender	-.216	.068	1.324	.859	[-2.909,2.476]	[-2.852,2.532]
Education status	-1.660	.013	.486	.001	[-2.651, -669]	[-2.632, -.629]
Job	1.402	-.051	1.526	.352	[-1.550,4.353]	[-1.471,4.279]
Income	1.212	.017	.650	.066	[-.059,2.482]	[-.053,2.584]
Time since started HD	-.099	-.003	.143	.486	[-.361,.164]	[-.369,.178]
Time to reach HD	-.017	.000	.032	.598	[-.084,.050]	[-.082,.047]
HD adequacy	.014	.000	.049	.758	[-.095,.124]	[-.078,.108]
Social and Economic	.218	.006	.157	.169	[-.101,.537]	[-.096,.577]
Family	.142	-.006	.157	.369	[-.164,.449]	[-.142,.428]
Itch	-.210	.001	.178	.243	[-.530,.109]	[-.558,.126]
Fatigue	-.080	-.001	.052	.124	[-.175,.015]	[-.190,.024]
Bodily pain	.303	-.363	.031	.001	[.246,.359]	[.245,.361]
Anxiety	-.465	.002	.195	.022	[-.850, -.079]	[-.813, -.081]
Depression	-1.094	.001	.231	.001	[-1.524, -.663]	[-.813, -.081]
Perceived Gen. Health	-.917	-.016	.678	.193	[-2.143,.309]	[-2.181,.275]
Physical functioning	.115	-.001	.023	.001	[.067,.163]	[.070,.158]

Note: N=383. CI, confidence interval; NS, not significant; Hb, Haemoglobin; OLS, Ordinary Least Squares; BCa, Bias corrected accelerated.

In summary, it can be concluded that less Bodily pain and higher Physical functioning are associated with better mental health; whereas high Education status, high symptoms of Anxiety, and Depression are associated with lower mental health in ESRD patients. Among these, low Bodily pain, Depression and Physical functioning are the strongest predictors of SF36v2 mental component summary (2-factor standard model) scores, whereas Education status, and Anxiety contribute moderately to that prediction.

5.6.3. QOLI-Dialysis

Sequential multiple regression was employed to determine if the addition of information regarding treatment, then biological function, then symptoms, then emotional status and then health status improved prediction of the QOLI-D, after controlling for the influence of demographics.

The dependent variable ‘QOLI-D scores’ was negatively skewed. In an attempt to stabilise the variance and achieve normality, this variable was, gradually, transformed using the methods of square root, logarithm, and inverse transformation. These transformations, however, did not significantly mend the skewness; thus, it was decided to use the variable untransformed (Table 8.4 shows the effect of data transformation on skewness result of transformation of the three methods used). The distribution of residuals was found to be nearly normal and centred at 0. Furthermore, residual and scatter plots indicated the conditions of normality, linearity and homoscedasticity were all satisfied. Table 26-27 displays the correlation among variables, their means and standard deviations. An examination of the correlations revealed that none of the independent variables was highly correlated, hence the assumption of multicollinearity was deemed to have been met. Using the criterion p < .001 for Mahalanobis distance, no multivariate outliers among the cases were identified.

Table 8. 26 Spearman's rho correlations of quality of life index-dialysis (QOLI-D)

	QOLI-D	Region	Gender	marital status	Educational status	Job	Income
QOLI-D	-	$-.12^{**}$	$-.07^{\$}$	-.02	$.11^{*}$	$-.16^{**}$	$.11^{*}$
Region		-	$.14^{**}$	.06	$-.21^{**}$	$.18^{**}$	$-.13^{**}$
Gender			-	$.18^{**}$	$-.14^{**}$	$.39^{**}$	$-.12^{**}$
marital status				-	$.19^{**}$	$.13^{**}$	-.08
Educational status					-	$-.20^{**}$	$.41^{**}$
Job						-	$-.38^{**}$
Income							-

$ p ≤ .15; * p ≤ .05; ** p < .001

Table 8. 27 Pearson's correlations QOLI-Dialysis

	QOLI-D	Pt age	Hb	HCT	Albumin	Dialysis adequacy	dialysis hours per month	Time since started HD	Time to reach to Dialysis	Anxiety	Depression	Spiritual Wellbeing	Itch	Fatigue	Bodily pain	Perceived general health	Physical functioning
QOLI-D	-	-.06	.06	-.03	.13**	.24**	.08	-.14**	.01	-.58**	-.55**	-.01	-.21**	-.39**	.42**	.43**	.17**
Pt age		-	-.01	.00	-.03	-.10*	-.09*	.04	-.07	.03	.11*	-.06	.02	.04	-.13**	-.12**	-.13**
Hb			-	.63**	.19**	.11*	.05	.04	-.08	-.06	-.10*	.02	.03	-.02	.06	.07	.00
HCT				-	.14**	.03	.04	.01	-.10*	.00	-.01	-.03	.02	.03	.07	.07	.04
Albumin					-	.14**	-.05	.01	.08	-.10*	-.08	-.13**	.05	-.05	-.06	.00	-.04
Dialysis adequacy						-	.10*	-.01	.03	-.14**	-.16**	.00	-.08	-.06	.08	.12*	.04
dialysis hours per month							-	-.08	-.14**	.01	-.00	-.05	-.06	-.00	.04	.08	.05
Time since started HD								-	-.02	.10*	.11*	.13**	.05	.06	-.11*	-.03	-.02
Time to reach to Dialysis									-	.08	.01	.04	.03	.05	-.06	-.02	-.16**
Anxiety										-	.58**	-.01	.20**	.46**	-.44**	-.35**	-.12*
Depression											-	-.06	.18**	.41**	-.44**	-.43**	-.16**
Spiritual Wellbeing												-	.06	-.03	.01	.02	-.05
Itch Scale													-	.12**	-.23**	-.11*	-.18**
Fatigue														-	-.40**	-.39**	-.17**
Bodily pain															-	.41**	.28**
Perceived general health																-	.15**
Physical functioning																	-

\$ p ≤ .15; * p ≤ .05; ** p < .001

Hb: Hemoglobulin; HD: Haemodialysis; QoLID: Quality of life index-dialysis; HCT: Haematocrit

The steps used to enter the variables into model were: 1) Gender, Education, Job, Income, Region; 2) Time since started HD, Dialysis adequacy; 3) Albumin level; 4) Itch, Fatigue, Bodily pain; 5) Anxiety, Depression; 6) Perceived general health and Physical functioning.

Table 28 displays the unstandardised regression coefficients (B), the standard errors (SE B), the standardised regression coefficients (β), the t-statistic, the significance of t-statistic, the R, the F statistic(F), R^2 and the change in R^2 (ΔR2). R was significantly different from 0 at the end of each step. After Step 6 with all the IVs in the equation, R^2 = .505, F (15,367) = 24.980, p <.001. The adjusted R^2 value of .485 indicates that nearly half of the variability in the QOLI-D scores is predicted by a number of Treatment Characteristics, Clinical Data, Symptom Specific Measures, Emotional Measures and Health Status measures.

At Step1, with demographic variables in the equation, Finc (5,377) =6.186, p < 0.001 and these accounted for 7.6% of variance in QOLI-D scores. Among the five demographic variables only Region was found to be a significant predictor of QOLI-D scores (p<.001). Introducing the treatment characteristics variables in Step 2 explained an additional 5% of variance in QOLI-D scores and this change in R^2 was significant, Finc (2, 375) =10.678, p < .001. Among the two variables added in Step 2, only Dialysis Adequacy was found to be a significant predictor of QOLI-D scores (p< .001). Adding the Clinical Data variable in Step 3 explained an additional 1.2% of variance in QOLI-D scores and the change in R^2 was significant, Finc (1,374) =2.169, p < .05. At the end of Step 4, with symptom-specific measures in the equation, the regression model now explained an additional 20.3 % of variance in QOLI-D scores and this change in R^2 was significant, Finc (3,371) =38.014, p < .001. Among the three symptom specific measures, the significant predictors of QOLI-D scores were Fatigue (p< .001) and Pain (p< .001). Again, at Step 5 when emotional measures were added, the new model now explained an additional 15.7% of variance in QOLI-D scores and this change in R^2 was also significant, Finc (2, 369) =57.492, p < .001. Both emotional subscales were found to be significant predictors of QOLI-D scores, viz., Anxiety (p< .001) and Depression (p< .001). Finally, after addition of health status measures at Step 6, R^2 =.505 (adjusted R2 =.485), Finc (2, 367) =2.931. Addition of health status measures did not significantly increase R^2. Of the two health status measures, Perceived General Health was found to be a significant predictor of QOLI-D scores ($p< 0.01$). When all the IVs were included in Step 6, neither Fatigue nor Bodily pain were found to be significant predictors of QOLI-D scores. The most important predictors of QOLI-D scores were found to be Anxiety and Depression. Together all the IVS accounted for 50.5% of the variance in the QOLI-D scores.

Table 8. 28 Sequential Multiple Regression Analysis predicting quality of Life Index-Dialysis (QOLI-D) From Treatment Characteristics, Clinical Data, Symptom Specific Measures, Emotional Measures & Health Status Measures (N= 383)

Variable	B	SE B	β	t-statistic	Significance	R	F	*R^2*	ΔR2
Step1						.275	6.186***	.076	.076***
Gender	.369	.540	.037	.683	.495				
Education	.129	.199	.037	.647	.518				
Job	-.390	.612	-.039	-.638	.524				
Income	.316	.253	.074	1.251	.212				
Region	-.422***	.102	-.224	-4.134	.000				
Step2						.354	7.696***	.126	.050***
Time since started HD	-.100	.053	-.095	-1.896	.059				
Dialysis Adequacy	.090***	.021	.214	4.295	.000				
Step3						.371	7.482***	.138	.012*
Albumin Level	.112*	.048	.113	2.314	.021				
Step4						.584	17.424***	.341	.203***
Itch	-.107	.055	-.087	-1.953	.052				
Fatigue	-.081***	.015	-.249	-5.333	.000				
Bodily Pain	.049***	.009	.271	5.593	.000				
Step5						.705	28.078***	.497	.157***
Anxiety	-.322***	.056	-.289	-5.771	.000				
Depression	-.367***	.063	-.281	-5.798	.000				
Step6						.711	24.980***	.505	.008
Perceived Gen. Health	.435*	.183	.106	2.377	.018				
Physical Functioning	.003	.007	.017	.436	.663				
Overall Final Model									
Intercept	19.816***	2.355		8.415	.000				
Gender	.758	.408	.077	1.858	.064				
Education status	-.096	.151	-.027	-.635	.526				
Job	-.091	.463	-.009	-.197	.844				
Income	.287	.191	.067	1.500	.135				
Region	-.230**	.080	-.122	-2.870	.004				
Time since started HD	-.046	.041	-.044	-1.139	.255				
Dialysis Adequacy	.045**	.016	.107	2.765	.006				
Albumin Level	.088*	.038	.089	2.349	.019				
Itch	-.053	.048	-.043	-1.094	.274				
Fatigue	-.022	.014	-.069	-1.549	.122				
Bodily Pain	.012	.009	.065	1.379	.169				
Anxiety	-.317***	.056	-.284	-5.700	.000				
Depression	-.331***	.065	-.254	-5.129	.000				
Perceived Gen. Health	.435*	.183	.106	2.377	.018				
Physical Functioning	.003	.007	.017	.436	.663				
F-test for the whole model	24.980								
Significance of F-test	< .001								
R	.711								
R^2	.505								
Adjusted R2	.485								

Note: N=383. CI, confidence interval; NS, not significant; Hb, Haemoglobin.
The β weights are the standardised regression coefficients at each step.
*p < .05. **p< .01, *** p< .001

In the final model, the factors that significantly predict QOLI-D scores are Region, Dialysis adequacy, Albumin level, Anxiety, Depression and Perceived general health. Among these, high Dialysis adequacy, high Albumin Level and better

Perceived general health are associated with high QOLI-D scores whereas Region (living outwith the capital), high Anxiety and Depression are associated with lower QOLI-D scores. Living outwith the capital (Muscat) is associated with lower QOLI-D scores (p= .004). The model predicts that when all else held constant, living outside Muscat is associated on average with a decrease of 0.23 units in QOLI-D scores. Better Dialysis adequacy is associated with higher QOLI-D scores, such that adjusting for other variables in the model, for each unit increase in the Dialysis adequacy scores, the QOLI-D score is predicted to increase on average by 0.045 units, with 95% confidence limits from .013 to .077, and this association is statistically significant (p = 0.006). Likewise, higher Albumin level is associated with better QOLI-D such that adjusting for other variables in the model, for each unit increase in the Albumin level, the QOLI-D scores is predicted to increase on average by 0.088 units, with 95% confidence limits from 0.014 to 0.162, and this association is statistically significant (p =.019). Looking at the adjusted regression coefficients (β), we see that Anxiety & Depression are the strongest predictors of QOLI-D scores. High level of Anxiety is associated with lower QOLI-D scores, such that adjusting for other variables in the model, for each unit increase in the Anxiety the QOLI-D score is predicted to decrease on average by 0.317 units, with 95% confidence limits from -.426 to -.207, and this association is statistically significant (p < .001). Similarly, higher level of Depression is found to be associated with low QOLI-D scores, such that adjusting for other variables in the model, for each unit increase in the depression scores the QOLI-D score is predicted to decrease on average by 0.331 units, with 95% confidence limits from -.459 to -.204 and this association is statistically significant (p < .001). Finally, better Perception of general health is associated with better QOLI-D such that adjusting for other variables in the model, for each unit increase in the Perceived General Health scores, the QOLI-D score is predicted to increase on average by 0.435 units, with 95% confidence limits from 0.075 to 0.795, and this association is statistically significant (p =.018). In summary we conclude that living outwith the capital, better Dialysis adequacy, high Albumin level, high level of Anxiety and Depression, and better perception of general health are the significant predictors of QOLI-D scores. Among these, the emotional measures, Anxiety & Depression are the strongest predictors of

QOLI-D scores, whereas Region, Dialysis adequacy, Albumin level and Perceived general health contribute moderately to that prediction. In the final model, symptom-specific measures such as Pruritus, Fatigue and Pain have no predictive value.

The trustworthiness of this regression model was evaluated using the Bootstrap technique using the IBM SPSS Bootstrapping method. Table 29 shows the bootstrap parameter estimates of the overall final model; the unstandardised regression coefficients(B), the bootstrapped standard errors (SE B), the significance of the regression coefficients, the normal approximated 95% confidence intervals (OLS 95% CI) and the bootstrapped confidence interval (BCa 95% CI). From the table, it be seen that the parametric standard errors obtained earlier (see Table 19.c) are quite comparable to the bootstrapped standard errors. Also, the significance of the bootstrapped coefficients show that Region, Dialysis adequacy, Albumin level, Anxiety, Depression and Perceived general health are all significant predictors of QOLI-D scores, which are the same as obtained earlier from non-bootstrapped estimates. However, the BCa 95% confidence interval for Albumin level, [-.001, .171] suggests that the clinical variable, Albumin level, just misses statistical significance. Perhaps a further investigation is required before concluding this variable as a reliable predictor of QOLI-D scores.

Table 8. 29 Bootstrap Parameter Estimates of the Final Model predicting quality of Life Index-Dialysis (QOLI-D) From Treatment Characteristics, Clinical Data, Symptom Specific Measures, Emotional Measures & Health Status Measures (N= 383)

Variable	B	Bias	SE B	Significance	OLS 95% CI	BCa 95% CI
Intercept	19.816	-.035	2.504	.001	[15.185, 24.446]	[14.804, 24.619]
Gender	.758	.002	.403	.069	[-.044, 1.561]	[-.101, 1.555]
Education	-.096	.006	.145	.507	[-.392, .201]	[-.391, .223]
Job	-.091	-.017	.488	.850	[-1.002, .819]	[-1.027, .808]
Income	.287	-.001	.193	.144	[-.089, .663]	[-.088, .672]
Region	-.230	-.002	.077	.002	[-.388, -.073]	[-.382, -.084]
Time since started HD	-.046	.001	.040	.254	[-.126, .034]	[-.123, .033]
Dialysis adequacy	.045	.001	.017	.013	[.013, .077]	[.011, .080]
Albumin level	.088	-.001	.041	.034	[.014, .162]	[-.001,.171]
Itch	-.053	.004	.051	.315	[-.148, .042]	[-.154, .061]
Fatigue	-.022	.000	.015	.142	[-.051, .006]	[-.049, .008]
Bodily pain	.012	.001	.008	.180	[-.005, .028]	[-.006, .031]
Anxiety	-.317	.001	.067	.001	[-.426, -.207]	[-.449, -.178]
Depression	-.331	-.003	.065	.001	[-.459, -.204]	[-.456, .215]
Perceived general health	.435	-.006	.185	.025	[.075, .795]	[.084, .783]
Physical functioning	.003	.000	.007	.658	[-.011, .017]	[-.011, .016]

Note: N=383. CI, confidence interval; NS, not significant; Hb, Haemoglobin; SF36V2, Short-Form 36 Health Survey; OLS, Ordinary Least Squares; BCa, Bias corrected accelerated.

In conclusion, nearly half of the variability in QOLI-D scores is predicted by a number of measures such as demographics, treatment measures, clinical, symptom-specific, and emotional measures. Over a third of variability in QOLI-D scores is explained by symptom- specific measures and emotional measures. Demographics & Treatment measures contribute moderately to that prediction and Clinical measures contribute least; health status measures add no further prediction.

5.6.4. SF36v2 PCS (Emerged Three-factor model)

A sequential multiple regression was performed to determine if addition of information regarding treatment characteristics, then socio-economic and family support, then symptoms, then emotional status and then health status improved prediction of the SF36v2 PCS (3-factor model), after controlling for the influence of demographics.

Prior to examining the sequential regression analysis, inspections for assumptions and other potential issues that might affect interpreting the analysis were conducted. Initially, the output was examined for any issues with multicollinearity. Tables 30-31 display the correlation among variables, their means and standard deviations. An inspection of the correlations revealed that all the independent variables correlated less than .85 (Tabachnick & Fidell, 2014), hence the assumption of multicollinearity was thought to have been met. All of the tolerance values were also greater than 0.10 and the variance inflation factors were all less than 10.0, revealing no concerns with multicollinearity (Mertler & Vannatta, 2002). The data were also checked for multivariate outliers. All standardised residual values fell between -3.0 and 3.0, indicating no issues with outliers (Tabachnick & Fidell,2001). Using the criterion *p* < .001 for Mahalanobis distance, no multivariate outliers among the cases were identified.

Table 8. 30 Spearman's rho correlations SF-36v2 physical component summary (PCS) (3-factor model)

	SF36v2 PCS (3-factor)	Region	Gender	marital status	Educational status	Job	Income
SF36v2 PCS (3-factor)	-	.03	-.12**	.09$^{\$}$	.20**	-.10*	.11*
Region		-	.14**	.06	-.21**	.18**	-.13**
Gender			-	.18**	-.14**	.39**	-.12**
marital status				-	.19**	.13**	-.08
Educational status					-	-.21**	.41**
Job						-	-.38**
Income							-

$\$\ p \le .15$; * $p \le .05$; ** $p < .001$

Normality was examined and the distribution of residuals was found to be nearly normal and centred at 0. Residual and scatter plots indicated the conditions of normality, linearity and homoscedasticity were all satisfied. All the assumptions, therefore, were sufficiently met.

Table 8. 31 Pearson’s correlations SF-36v2 PCS (3-factor three-factor model)

Variables	SF36v2 PCS (3-factor)	Pt age	Hb	HCT	Albumin	Dialysis adequacy	dialysis hours per month	Time since started HD	Time to reach to Dialysis in minutes	Anxiety	Depression	Spiritual Wellbeing	Social & Economic	Family	Itch	Fatigue	Perceived general health
SF36v2 PCS (3-factor)	-	-.18**	.04	.05	-.06	.07$^{\$}$	.05	-.09*	-.14**	-.42**	-.45**	-.01	.29**	.17**	-.24**	-.43**	.49**
Pt age		-	-.01	.00	-.03	-.10*	-.09*	.04	-.07	.03	.11*	-.06	-.00	-.02	.02	.04	-.12**
Hb			-	.63**	.19**	.11*	.05	.04	-.08	-.06	-.10*	.02	.00	.05	.03	-.02	.07
HCT				-	.14**	.03	.04	.01	-.10*	.00	-.01	-.03	-.09	-.06	.02	.03	.07
Albumin					-	.14**	-.05	.01	.08	-.10*	-.08	-.13**	.08	.23**	.05	-.05	.00
Dialysis adequacy						-	.10*	-.01	.03	-.14**	-.16**	.00	.19**	.32**	-.08	-.06	.12*
dialysis hours per month							-	-.08	-.14**	.01	-.00	-.05	.00	-.03	-.06	-.00	.08
Time since started HD								-	-.02	.10*	.11*	.13**	-.12**	-.10*	.05	.06	-.03
Time to reach to Dialysis in minutes									-	.08	.01	.04	.02	.06	.03	.05	-.02
Anxiety										-	.58**	-.01	-.45**	-.40**	.20**	.46**	-.35**
Depression											-	-.06	-.37**	-.34**	.18**	.41**	-.43**
Spiritual Wellbeing												-	-.01	.01	.06	-.03	.02
Social & Economic													-	.64**	-.16**	-.29**	.32**
QOLID Family														-	-.07	-.24**	.22**
Itch Scale															-	.12**	-.11*
Fatigue																-	-.39**
Perceived general health																	-

$ p ≤ .15; * p ≤ .05; ** p < .001

PCS: physical component summary; Hb: Hemoglobulin; HD: Haemodialysis; QoLID: Quality of life index-dialysis; FFS: Fatigue severity scale; HCT: Haematocrit

The variables in this model were entered in sequence as the following steps: 1) Patient age, Gender, Marital status, Education, Job, Income; 2) HD adequacy, Time since started HD, Time to reach HD; 3) Social and Economic, Family; 4) Itch, Fatigue; 5) Anxiety, Depression; 6) Perceived general heath.

Table 32 shows the unstandardised regression coefficients (*B*), the standard errors (SE *B*), the standardised regression coefficients (β), the *t*-statistic, the significance of *t*-statistic, the *R,* the *F* statistic (*F*), R^2 and the change in R^2 (ΔR^2). *R* was significantly different from 0 at the end of each step. After Step 6 with all the IVs in the equation, $R^2 = .428$, *F* (1,360) = 32.148, $p <. 001$. The adjusted R^2 value of .402 indicates that more than a third of the variability of the SF36v2 PCS (3-factor model) scores is predicted by Treatment Characteristics, Family support QOLI-D subscales, Symptom-Specific Measures, Emotional Measures and Health Status measures.

At Step1, with demographic variables in the equation, F_{inc} (6,370) =3.711, $p =$ .001 and these accounted for 5.1% of variance in SF36v2 PCS scores (3-factor model) scores. Of the six variables entered in Step 1, Patient Age (*p*= .011) was the only significant variable. Introducing the treatment characteristics variables in Step 2 explained an additional 3.2% of variance in the SF36v2 PCS (2-factor model) scores and this change in R^2 was significant, F_{inc} (3, 367) =4.323, $p =$ .005. Among the three variables added in Step 2, the variable Time to reach HD (*p*= .002) was found to be the only significant predictor of SF36v2 PCS (2-factor model) scores. Adding the social and economic, and family subscales in Step 3 explained an additional 7.0% of variance in SF36v2 PCS (3-factor model) scores and the change in R^2 was significant, F_{inc} (2,365) =15.084, $p < .001$. Among the two QOLI-D subscales, only the Social and economic scores were found to be a significant predictor of SF36v2 PCS (3-factor model) scores ($p < .001$). At the end of Step 4, with symptom-specific measures in the equation, the regression model explained an additional 14.4 % of variance in the model scores and this change in R^2 was significant, F_{inc} (2,363) =37.524, $p < .001$. The symptoms that were significant predictors of SF36v2 PCS (3-factor model)were: Itch (*p*< .001), and Fatigue (*p*< .001). At Step 5, when emotional measures were added, the model explained an additional 7.4% of variance in SF36v2 PCS (3-factor model) scores and this change in R^2 was also significant, F_{inc} (2, 361) =21.401, $p < .001$. The two emotional subscales were found to be significant predictors of SF36v2 PCS (3-factor model) scores, Anxiety ($p = .019$) and Depression ($p < .001$). Finally, after addition of Perceived general health scores at Step 6, $R^2 = .428$ (adjusted $R^2 = .402$), F_{inc} (1, 360) =32.148, $p < .001$. In the final model, the significant predictors of SF36v2 PCS (3-factor model) scores were Patient age, Time to reach HD, Itch, Fatigue, Anxiety, Depression, and Perceived general health. The most significant predictor of SF36v2 PCS (3-factor model) scores was Perceived general health. Together all the IVs accounted for 42.8% of the variance in the SF36v2 PCS (3-factor model) scores.

Table 8. 32 Sequential Multiple Regression Analysis predicting SF36v2 PCS (3-factor model) From Treatment Characteristics, Family Support, Symptom Specific Measures, Emotional Measures & Health Status Measures (N= 383)

Variable	*B*	SE *B*	β	*t*-statistic	*Significance*	*R*	*F*	R^2	ΔP^2
Step1						.238	3.711	.057	.057
Pt age	-.212**	.083	-.160	-2.546	.011				
Gender	-3.093	2.060	-.084	-1.501	.134				
Marital status	-.568	.874	-.037	-.650	.516				
Education status	1.128	.885	.086	1.274	.203				
Job	-.834	2.248	-.022	-.371	.711				
Income	.061	1.002	.004	.061	.951				
Step2						.298	4.323	.089	.032
HD adequacy	.108	.079	.069	1.371	.171				
Time since started HD	-.263	.197	-.067	-1.334	.183				
Time to reach HD	-.157**	.050	-.156	-3.114	.002				
Step3						.398	15.084	.159	.070
Social and Economic	1.060***	.221	.307	4.796	.000				
Family	-.198	.228	-.058	-.870	.385				
Step4						.55	37.524	.303	.144
Itch	-.848***	.210	-.183	-4.028	.000				
Fatigue	-.415***	.057	-.341	-7.292	.000				
Step5						.614	21.401	.377	.074
Anxiety	-.568**	.242	-.134	-2.350	.019				
Depression	-1.216***	.261	-.249	-4.654	.000				
Step6						.654	32.148	.428	.051
Perceived Gen. Health	4.181***	.737	.274	5.670	.000				
Overall Final Model									
Intercept	82.682***	8.467		9.765	.000				
Pt age	-.166**	.067	-.125	-2.490	.013				
Gender	-2.003	1.656	-.054	-1.210	.227				
marital status	-.404	.697	-.026	-.580	.562				
Educational status	.768	.706	.058	1.087	.278				
Job	1.557	1.814	.041	.858	.391				
Income	-.679	.802	-.043	-.847	.398				
Dialysis adequacy	-.021	.067	-.013	-.311	.756				
Time since started HD per month	-.082	.159	-.021	-.518	.605				
Time to reach to HD	-.116**	.041	-.116	-2.836	.005				
Social & Economic	.227	.196	.066	1.161	.246				
Family	-.334	.192	-.098	-1.742	.082				
Itch	-.676**	.193	-.145	-3.496	.001				
Fatigue	-.197**	.058	-.162	-3.398	.001				
Anxiety	-.515*	.232	-.121	-2.218	.027				
Depression	-.830**	.260	-.170	-3.196	.002				
Perceived general health	4.181***	.737	.274	5.670	.000				
F-test for the whole model	32.148								
Significance of *F*-test	< .001								
R	0.654								
R^2	0.428								
Adjusted R^2	0.402								

Note: N=383. CI, confidence interval; NS, not significant; Hb, Haemoglobin.
*The □ weights are the standardised regression coefficients at each step. *p < .05; **p< .01; *** p< .001*

Of the factors that were significant in the final model, better perception of general health is associated with higher SF36v2 PCS (3-factor model) scores whereas older age, longer Time to reach HD, Itch, high level of Fatigue, Anxiety, and Depression are associated with lower SF36v2 PCS (3-factor model) scores. Patients who perceived better general health seem to have better physical health (3-factor model), such that adjusting for other variables in the model, for each unit increase in the Perceived general health scores, the SF36v2 PCS (3-factor model) score is predicted to increase on average by 4.181 units, with 95% confidence limits from 2.731 to 5.631, and this association is statistically significant (*p* = .001). Older age associated with lower SF36v2 PCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in the Patient age, score is predicted to decrease on average by 0.166 units, with 95% confidence limits from -.297 to -.035, and this association is statistically significant (*p* = .007). The longer time the patients take to reach HD is found to be associated with lower SF36v2 PCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in the Time to reach HD the SF36v2 PCS (3-factor model) score is predicted to decrease on average by 0.116 units, with 95% confidence limits from -.197 to -.036 and this association is statistically significant (p =.003). With regards to physical symptoms, high level of Itch is found to be associated with lower SF36v2 PCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in the Itch scores the SF36v2 PCS (3-factor model) score is predicted to decrease on average by .676 units, with 95% confidence limits from -1.055 to -.296 and this association is statistically significant (p = .002). Similarly, higher Fatigue level is found to be associated with lower SF36v2 PCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in the Fatigue the SF36v2 PCS (3-factor model) score is predicted to decrease on average by 0.197 units, with 95% confidence limits from -.311 to -.083 and this association is statistically significant (p =.003). For mood symptoms, high level of Anxiety is found to be associated with lower SF36v2 PCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in the Anxiety the SF36v2 PCS (3-factor model) score is predicted to decrease on average by 0.515 units, with 95% confidence limits from -.971 to -.058 and this association is statistically significant (p =.040). Also, high level of

Depression is found to be associated with lower SF36v2 PCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in Depression the SF36v2 PCS (3-factor model) score is predicted to decrease on average by 0.830 units, with 95% confidence limits from -1.341 to -.319 and this association is statistically significant (p =.003).

The trustworthiness of this regression model was evaluated using the Bootstrap technique using the IBM SPSS version 22 Bootstrapping method. Table 33 shows the bootstrap parameter estimates of the overall final model; the unstandardised regression coefficients(*B*), the bootstrapped standard errors (SE *B*), the significance of the regression coefficients, the normal approximated 95% confidence intervals (OLS 95% CI) and the bootstrapped confidence interval (BCa 95% CI). From the table, it can be observed that the parametric standard errors obtained earlier (see Table 32) are relatively comparable to the bootstrapped standard errors. The significance of the bootstrapped coefficients show that Patient age, Time to reach HD, Pruritus, Fatigue, Anxiety, Depression, and Perceived general health are the significant predictors of SF36v2 PCS (3-factor model) score, which are the same as obtained from our non-bootstrapped estimates.

Table 8. 33 Bootstrap Parameter Estimates of the Overall Final Model predicting SF36V2 physical component summary (3-factorl model) From Treatment Characteristics, Family Support, Symptom Specific Measures, Emotional Measures & Health Status Measures (N= 383)

Variable	*B*	Bias	SE *B*	Significance	OLS 95% CI	BCa 95% CI
Intercept	82.682	.448	9.522	.001	[66.030,99.333]	[65.502,103.469]
Pt age	-.166	.002	.059	.007	[-.297, -.035]	[-0.281, -.042]
Gender	-2.003	.025	1.666	.236	[-5.260,1.253]	[-5.226,1.675]
marital status	-.404	.009	0.651	.545	[-1.775,.966]	[-1.616,.912]
Educational status	.768	.024	0.691	.280	[-.621,2.157]	[-0.527,2.210]
Job	1.557	-.008	1.785	.386	[-2.010,5.125]	[-1.956,4.957]
Income	-.679	-.001	.830	.409	[-2.257,.899]	[-2.278,.986]
Dialysis adequacy	-.021	-.001	.076	.783	[-.154,.112]	[-0.172,.126]
Time since started HD	-.082	-.001	.170	.615	[-.396,.231]	[-0.391,.260]
Time to reach to HD	-.116	.000	.038	.003	[-.197, -.036]	[-0.194, -.039]
Social and Economic	.227	.005	.194	.254	[-.158, .612]	[-0.167,.639]
Family	-.334	-.012	.209	.106	[-.712, .043]	[-0.771,.044]
Itch	-.676	.002	.211	.002	[-1.055, -.296]	[-1.071, -.265]
Fatigue	-.197	-.004	.058	.003	[-.311, -.083]	[-0.313, -.091]
Anxiety	-.515	-.006	.252	.040	[-.971, -.058]	[-1.014, -.052]
Depression	-.830	-.009	.283	.003	[-1.341, -.319]	[-1.373, -.300]
Perceived general health	4.181	-.023	.813	.001	[2.731,5.631]	[2.613,5.779]

Note: N=383. CI, confidence interval; NS, not significant; OLS; Ordinary Least Squares; BCa, Bias corrected accelerated.

In conclusion, older age, longer Time to reach HD, high level of Itch, Fatigue, Anxiety, Depression, and better Perception of general health are the significant predictors of SF36v2 physical component summary (3-factor model) scores. Of these variables, Perceived general health is the highest/best predictor of outcome scores, whereas Patient age, Time to reach HD, Itch, Fatigue, Anxiety, Depression contribute least.

5.6.5. SF36v2 MCS (Emergent Three-factor model)

Sequential multiple regression was conducted to examine if addition of information regarding treatment, then family support, then symptoms, then emotional status and then health status improved prediction of the SF36v2 MCS (3-factor model), after controlling for the influence of demographics.

Before examining the sequential regression analysis, inspections for assumptions and other potential problems that might affect interpreting the analysis were conducted. The output was initially examined for any issues with multicollinearity. Table 34-35 displays the correlation among variables, their means and standard deviations. An examination of the correlations revealed that none of the independent variables were correlated above person's correlation .85 (Tabachnick & Fidell, 2014), thus the assumption of multicollinearity was deemed to have been met. In addition, the tolerance values were all greater than 0.10 and the variance inflation factors were all less than 10.0, revealing no concerns with multicollinearity (Mertler & Vannatta, 2002). Next, the data were checked for multivariate outliers. All standardised residual values fell between -3.0 and 3.0, indicating no issues with outliers (Tabachnick & Fidell, 2014). Using the criterion p < .001 for Mahalanobis distance, no multivariate outliers among the cases were identified. The distribution of residuals was found to be nearly normal and centred at 0.

Table 8. 34 Spearman's rho correlations SF-36v2 mental component summary (MCS) (3-factor model)

	SF36v2 MCS (3-factor)	Region	Gender	marital status	Educational status	Job	Income
SF36v2 MCS (3-factor)	-	-.05	-.13**	-.04	.10*	-.09*	.12*
Region		-	.14**	.06	-.21**	.18**	-.13**
Gender			-	.18**	-.14**	.39**	-.12**
marital status				-	.19**	.13**	-.08
Educational status					-	-.21**	.41**
Job						-	-.38**
Income							-

$ p ≤ .15; * p ≤ .05; ** p < .001

Residual and scatter plots indicated the conditions of normality, linearity and homoscedasticity were all satisfied. Thus, all assumptions were sufficiently met.

Table 8. 35 Pearson's correlations SF-36v2 MCS (3-factor model)

	MCS (3-factor)	Pt age	Hb	HCT	Albumin	Dialysis adequacy	dialysis hours per month	Time since started HD	Time to reach HD in minutes	Anxiety	Depression	Spiritual Wellbeing	Social & Economic	Family	Itch	Fatigue	Bodily pain	Perceived general health	Physical functioning
MCS (3-factor)	-	-.05	.03	.09$^{\$}$	-.00	.10*	.03	-.12*	-.07$^{\$}$	-.51**	-.53**	.00	.36**	.27**	-.25**	-.41**	.66**	.34**	.26**
Pt age		-	-.01	.00	-.03	-.10*	-.09*	.04	-.07	.03	.11*	-.06	-.00	-.02	.02	.04	-.13**	-.12**	-.13**
Hb			-	.63**	.19**	.11*	.05	.04	-.08	-.06	-.10*	.02	.00	.05	.03	-.02	.06	.07	.00
HCT				-	.14**	.03	.04	.01	-.10*	.00	-.01	-.00	-.09	-.06	.02	.03	.07	.07	.00
Albumin					-	.14**	-.05	.01	.08	-.10*	-.08	-.13**	.08	.23**	.05	-.05	-.06	.00	-.04
Dialysis adequacy						-	.10*	-.01	.03	-.14**	-.16**	.00	.19**	.32**	-.08	-.06	.08	.12*	.00
dialysis hours per month							-	-.08	-.14**	.01	-.00	-.05	.02	-.03	-.06	-.00	.04	.08	.05
Time since started HD								-	-.02	.10*	.11*	.13**	-.12**	-.10*	.05	.06	-.11*	-.03	-.02
Time to HD in minutes									-	.08	.01	.04	.02	.06	.03	.05	-.06	-.02	-.16**
Anxiety										-	.58**	-.01	-.45**	-.40**	.20**	.46**	-.44**	-.35**	-.12*
Depression											-	-.06	-.37**	-.34**	.18**	.41**	-.44**	-.43**	-.16**
Spiritual Wellbeing												-	-.01	.01	.06	-.03	.01	.02	-.05
Social & Economic													-	.64**	-.16**	-.29**	.30**	.32**	.10*
Family														-	-.07	-.24**	.16**	.22**	.04
Itch															-	.12**	-.23**	-.11*	-.18**
Fatigue																-	-.40**	-.39**	-.17**
Bodily pain																	-	.41**	.28**
Perceived general health																		-	.15**
Physical functioning																			-

$ p ≤ .15; * p ≤ .05; ** p < .001; Hb: Hemoglobulin; HD: Haemodialysis; QoLID: Quality of life index-dialysis; HCT: Haematocrit

The variables in this regression model were entered in sequence in six steps: 1) Gender, Education, Job, Income; 2) HCT; 3) Social and Economic, Family; 4) Itch, Fatigue; Bodily pain; 5) Anxiety, Depression; 6) Perceived general health and Physical functioning.

Table 36 displays the unstandardised regression coefficients (*B*), the standard errors (SE *B*), the standardised regression coefficients (β), the *t*-statistic, the significance of *t*-statistic, the *R,* the *F* statistic (*F*), R^2 and the change in R^2 (ΔR^2). *R* was significantly different from 0 at the end of each step. After Step 6 with all the IVs in the equation, $R^2 = .557$, $F\ (2,381) = 3.646$, $p=.\ 027$. The adjusted R^2 value of .541 indicates that more than half of the variability in the SF36v2 MCS (3-factor model) scores is predicted by Treatment Characteristics, Social & Economic and Family QOLI-D subscales, Symptom-Specific Measures, Emotional Measures and Physical and Health Status measures.

At Step1, with demographic variables in the equation, $F_{\text{inc}}\ (4,391) = 2.159$, $p = .07$ and these accounted for 2.2% of variance in SF36v2 MCS scores (3-factor model) scores. None of the demographic variables was found to be a significant predictor of SF36v2 MCS (3-factor model). Introducing the clinical variable Haematocrit in Step 2 explained an additional 1.0% of variance in the SF36v2 MCS (3-factor model) scores and this change in R^2 was significant, $F_{\text{inc}}\ (1, 390) = 3.995$, $p = .046$. Adding the Socio-Economic, and Family subscales in Step 3 explained an additional 12.4% of variance in SF36v2 MCS (3-factor model) scores and the change in R^2 was significant, $F_{\text{inc}}\ (2,388) = 28.389$, $p < .001$. Among the two subscales, only the variable Social and Economic scores were found to be a significant predictor ($p < .001$). At the end of Step 4, with symptom-specific measures in the equation, the regression model explained an additional 35.5 % of variance in SF36v2 MCS (3-factor model) scores and this change in R^2 was significant, $F_{\text{inc}}\ (3,385) = 92.811$, $p < .001$. All three symptoms measures were significant predictors of SF36v2 MCS (3-factor model); Itch ($p = .031$), Fatigue ($p < .001$) and Bodily Pain ($p < .001$). Again, at Step 5 when emotional measures were added, the model explained an additional 3.9% of variance in SF36v2 MCS (3-factor model) scores and this change in R^2 was also significant, $F_{\text{inc}}\ (2, 383) = 16.488$, $p < .001$. The two emotional subscales were found to be a significant predictor of SF36v2 MCS (3-factor model) scores, Anxiety ($p = .033$) and

Depression ($p < .001$). Finally, after addition of Perceived general health and Physical functioning scores at Step 6, R^2 =.557 (adjusted R^2 =*.541*), F_{inc} (2, 381) =3.646, p= .027. In the final model, the significant predictors of SF36v2 MCS (3-factor model) scores were Education status, Haematocrit, Fatigue, Bodily pain (reverse scoring), Anxiety, Depression and Physical functioning. The most significant predictors of SF36v2 MCS (3-factor model) scores were Bodily pain and Depression. Together all the IVS accounted for 55.7% of the variance in the SF36v2 MCS (3-factor model) scores.

Table 8. 36 Sequential Multiple Regression Analysis predicting SF36v2 MCS (3-factor model) From Treatment Characteristics, Family Support, Symptom Specific Measures, Emotional Measures & Health Status Measures (N= 383)

Variable	*B*	SE *B*	β	*t-statistic*	*Significance*	*R*	*F*	*R*^{2}	*Δ*□^{2}
Step1						.147		.022	.022
Gender	-3.349	2.051	-.089	-1.633	.103				
Education	-.026	.756	-.002	-.034	.973				
Job	-.437	2.254	-.011	-.194	.846				
Income	1.561	.963	.098	1.622	.106				
Step2						.178	3.995	.032	.010
HCT	.361*	.181	.10	1.999	.046				
Step3						.394	28.389	.155	.124
Social & Economic	1.101***	.219	.312	5.039	.000				
Family	.232	.210	.068	1.106	.269				
Step4						.714	92.811***	.510	.355
Itch	-.383*	.178	-.081	-2.159	.031				
Fatigue	-.177***	.050	-.143	-3.540	.000				
Bodily pain	.383***	.029	.550	13.236	.000				
Step5						.741	16.488***	.549	.039
Anxiety	-.434*	.203	-.103	-2.138	.033				
Depression	-.928***	.222	-.187	-4.173	.000				
Step6						.746	3.646**	.557	.008
Perceived Gen. Health	-.844	.662	-.054	-1.276	.203				
Physical functioning	.060**	.025	.086	2.377	.018				
Overall Final Model									
Intercept	40.891***	7.811		5.235	.000				
Gender	-.446	1.426	-.012	-.313	.754				
Educational status	-1.405**	.525	-.105	-2.676	.008				
Job	.479	1.562	.012	.306	.759				
Income	1.224	.663	.077	1.848	.065				
HCT	.253*	.127	.070	1.992	.047				
Social & Economic	.142	.171	.040	.834	.405				
Family	.188	.158	.055	1.194	.233				
Itch	-.245	.171	-.052	-1.431	.153				
Fatigue	-.108*	.051	-.087	-2.111	.035				
Bodily pain	.320***	.030	.459	10.555	.000				
Anxiety	-.456*	.202	-.108	-2.261	.024				
Depression	-.968***	.226	-.195	-4.280	.000				
Perceived general health	-.844	.662	-.054	-1.276	.203				
Physical functioning	.060**	.025	.086	2.377	.018				
F-test for the whole model	3.646								
Significance of F-test	.027								
R	.746								
R2	.557								
Adjusted R2	.541								

Note: N=383. CI, confidence interval; NS, not significant; Hb, Haemoglobin.
The □ weights are the standardised regression coefficients at each step.
**p < .05. **p< .01, *** p< .001*

In the final model, lower Bodily pain is associated with higher SF36v2 MCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in the Bodily pain scores (reverse scoring), the SF36v2 MCS (3-factor model) score is predicted to increase on average by .320 units, with 95% confidence limits from .260 to .380, and this association is statistically significant (*p* = .001). Better Physical functioning is associated with higher SF36v2 MCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in the Physical functioning scores, the SF36v2 MCS (3-factor model) score is predicted to increase on average by .060 units, with 95% confidence limits from .010 to .110, and this association is statistically significant (*p* = .022). On the other hand, higher Education status associated with lower SF36v2 MCS (3-factor model) score, such that adjusting for other variables in the model, for each unit increase in the Education status score is predicted to decrease on average by 1.405 units, with 95% confidence limits from -2.437 to -.373, and this association is statistically significant (*p* = .007). High level of Fatigue is found to be associated with low SF36v2 MCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in the Fatigue scores the SF36v2 MCS (3-factor model) score is predicted to decrease on average by 0.108 units, with 95% confidence limits from -.209 to -.007 and this association is statistically significant (*p* =.048). For mood symptoms, high level of Anxiety is found to be associated with low SF36v2 MCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in the Anxiety scores the SF36v2 MCS (3-factor model) score is predicted to decrease on average by .456 units, with 95% confidence limits from -.853 to -.060 and this association is statistically significant (*p* =.026). Likewise, high level of Depression is found to be negatively associated with low SF36v2 MCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in the Depression scores the SF36v2 MCS (3-factor model) score is predicted to decrease on average by .968 units, with 95% confidence limits from -1.412 to -.523 and this association is statistically significant (*p* = .001).

The trustworthiness of the regression model was evaluated using the Bootstrap technique using the IBM SPSS version 22 Bootstrapping method. Table 37 shows the bootstrap parameter estimates of the overall final model; the unstandardised regression coefficients(*B*), the bootstrapped standard errors (SE *B*), the significance of the regression coefficients, the normal approximated 95% confidence intervals (OLS 95% CI) and the bootstrapped confidence interval

(BCa 95% CI). From the table, it can be observed that the parametric standard errors obtained earlier (see Table 36) are quite similar to the bootstrapped standard errors. Also, the significance of the bootstrapped coefficients show that Education status, Fatigue, Bodily pain, Anxiety, Depression, and Physical functioning are the significant predictors of SF36v2 MCS (3-factor model) score, which are the same as obtained from the non-bootstrapped estimates. However, it was also noted that Income which was not a significant predictor in the non-bootstrapped model, is now a significant predictor of SF36 MCS (3-factor model) scores (*p*= .045), with BCa 95% confidence limits from -.078 to -.2.527.

Table 8. 37 Sequential Multiple Regression Analysis predicting SF36v2 MCS (3-factor model) From Treatment Characteristics, Family Support, Symptom Specific Measures, Emotional Measures & Health Status Measures (N= 383)

Variable	*B*	Bias	SE *B*	Significance	OLS 95% CI	BCa 95% CI
(Constant)	40.891	-.653	9.101	.001	[25.53,56.249]	[23.167,56.131]
Gender	-.446	.014	1.433	.756	[-3.250,2.357]	[-3.317,2.309]
Educational status	-1.405	.007	.519	.007*	[-2.437, -.373]	[-2.468, -.377]
Job	.479	-.014	1.547	.754	[-2.593,3.550]	[-2.335,3.654]
Income	1.224	-.016	.615	.045*	[-.078,2.527]	[-.037,2.370]
HCT	.253	.004	.139	.068	[.003,.502]	[-.024,.559]
Social & Economic	.142	.013	.156	.383	[-.193,.478]	[-.154,.483]
Family	.188	-1.660	.161	.245	[-.122,.498]	[-.134,.505]
Itch	-.245	.013	.185	.192	[-.582,.092]	[-.607,.181]
Fatigue	-.108	-.001	.054	.048*	[-.209, -.007]	[-.212,.003]
Bodily pain	.320	.000	.033	.001*	[.260,.380]	[.252,.385]
Anxiety	-.456	.000	.202	.026*	[-.853, -.060]	[-.851, -.049]
Depression	-.968	.019	.235	.001*	[-1.412, -.523]	[-1.467, -.439]
Perceived general health	-.844	.005	.697	.226	[-2.146,.457]	[-2.256,.594]
Physical functioning	.060	.001	.026	.022*	[.010,.110]	[.007,.115]

Note: N=383. CI, co-.009nfidence interval; NS, not significant; Hb, Haemoglobin; OLS, Ordinary Least Squares; BCa, Bias corrected accelerated.

It can be concluded that better Physical functioning is associated with better mental health; whereas high Education status, high Fatigue, Bodily pain, Anxiety, and Depression are associated with low mental health.

5.6.6. SF36v2 Role Component Summary-RCS (Emergent three-factor model)

To determine the prediction relationship between the predictors of demographics, treatment characteristics, socio-economic and family support, symptoms, emotional status, health status on SF36v2 RCS (3-factor model) a sequential multiple regression was conducted.

Prior to examining the sequential regression analysis, inspections for assumptions and other potential issues that might affect interpreting the analysis were conducted. Firstly, the output was examined for any issues with multicollinearity. Table 38-39 displays the correlation among variables, their means and standard deviations. An inspection of the correlations revealed that all the independent variables correlated less than .85 (Tabachnick & Fidell, 2014), hence the assumption of multicollinearity was thought to have been met. All of the tolerance values were also greater than 0.10 and the variance inflation factors were all less than 10.0, revealing no concerns with multicollinearity (Mertler & Vannatta, 2002). The data were also checked for multivariate outliers. All standardised residual values fell between -3.0 and 3.0, indicating no issues with outliers (Tabachnick & Fidell,2001). Using the criterion *p* < .001 for Mahalanobis distance, no multivariate outliers among the cases were identified. For normality check, the distribution of residuals found to be nearly normal and centred at 0. Residual and scatter plots indicated the conditions of normality, linearity and homoscedasticity were all satisfied. All the assumptions, therefore, were sufficiently met.

Table 8. 38 Spearman's rho correlations SF-36v2 role component summary (RCS) (3-factor model)

Variables	SF36v2 RCS (3-factor)	Region	Gender	marital status	Educational status	Job	Income
SF36v2 RCS (3-factor)	-	-.02	-.06	-.06$^{\$}$	.09	.02	.02
Region		-	.14**	.06	-.21**	.18**	-.13**
Gender			-	.18**	-.14**	.39**	-.12**
marital status				-	.19**	.13**	-.08
Educational status					-	-.21**	.41**
Job						-	-.38**
Income							-

$ p ≤ .15; * p ≤ .05; ** p < .001

Table 8. 39 Pearson correlations SF-36v2 RCS (3-factor model)

	SF36v2 RCS (3-factor)	Pt age	Hb	HCT	Albumin	Dialysis adequacy	dialysis hours per month	Time since started HD	Time to reach HD in minute	Anxiety	Depression	Spiritual Wellbeing	Social & Economic	Family	Itch	Fatigue	Bodily pain	Perceived general health	Physical functioning
SF36v2 RCS (3-factor)	-	-.02	-.04	-.05	.03	.06	.05	-.15*	-.11*	-.34**	-.42**	-.09$^{\$}$	.29**	.20**	-.19**	-.29**	.43**	.27**	.42**
Pt age		-	-.01	.00	-.03	-.10*	-.09*	.04	-.07	.03	.11*	-.06	-.07	-.02	.02	.04	-.13**	-.12**	-.13**
Hb			-	.63**	.19**	.11*	.05	.04	-.08	-.06	-.10*	.02	.07	.05	.03	-.02	.06	.07	.00
HCT				-	.14**	.03	.04	.01	-.10*	.00	-.01	-.00	-.09	-.06	.02	.03	.07	.07	.00
Albumin					-	.14**	-.05	.01	.08	-.10*	-.08	-.13**	.08	.23**	.05	-.05	-.06	.00	-.04
Dialysis adequacy						-	.10*	-.01	.03	-.14**	-.16**	.00	.19**	.32**	-.08	-.06	.08	.12*	.00
dialysis hours per month							-	-.08	-.14**	.01	-.00	-.05	.00	-.03	-.06	-.08	.04	.08	.05
Time since started HD								-	-.02	.10*	.11*	.13**	-.12**	-.10*	.05	.06	-.11*	-.03	-.02
Time to reach HD in minutes									-	.08	.01	.04	.02	.06	.03	.05	-.06	-.02	-.16**
Anxiety										-	.58**	-.01	-.45**	-.40**	.20**	.46**	-.44**	-.35**	-.12*
Depression											-	-.06	-.37**	-.34**	.18**	.41**	-.44**	-.43**	-.16**
Spiritual Wellbeing												-	-.01	.01	.06	-.03	.01	.02	-.05
Social & Economic													-	.64**	-.16**	-.29**	.30**	.32**	.10*
Family														-	-.07	-.24**	.16**	.22**	.04
Itch															-	.12**	-.23**	-.11*	-.18**
Fatigue																-	-.40**	-.39**	-.17**
Bodily pain																	-	.41**	-.28**
Perceived general health																		-	.15**
Physical functioning																			-

$ p ≤ .15; * p ≤ .05; ** p < .001

Hb: Hemoglobulin; HD: Haemodialysis; QoLID: Quality of life index-dialysis; HCT: Haematocrit

As with other models, variables were entered in sequence in six steps: 1) Marital status; 2) Time since started HD, Time to reach HD; 3) Social and Economic, Family, Spiritual wellbeing; 4) Itch, Fatigue, Bodily pain; 5) Anxiety, Depression; 6) Perceived general health and Physical functioning.

Table 8.40 shows the unstandardised regression coefficients (*B*), the standard errors (SE *B*), the standardised regression coefficients (β), the *t*-statistic, the significance of *t*-statistic, the *R,* the *F* statistic (*F*), R^2 and the change in R^2 (ΔR^2). *R* was significantly different from 0 at the end of each step. After Step 6 with all the IVs in the equation, $R^2 = .389$, *F* (2,374) = 21.256, $p <. 001$. The adjusted R^2 value of .368 indicates that more than a third of the variability of the SF36v2 RCS (3-factor model) scores is predicted by Treatment Characteristics, Social and Economic subscales, Symptom-Specific Measures, Emotional Measures and Health Status measures.

At Step1, with demographic variable of Marital status in the equation, F_{inc} (1,386) =2.080, $p = .150$ and these accounted for 0.5% of variance in SF36v2 RCS (3-factor model) scores. This predictor, however, was not significant of SF36v2 RCS (3-factor model) scores. Introducing the treatment characteristics variables in Step 2 explained an additional 2.3% of variance in the SF36v2 RCS (2-factor model) scores and this change in R^2 was significant, F_{inc} (2, 384) =4.449, $p = .012$. Among the two variables added in Step 2, the variable Time since started HD ($p= .015$) was found to be the only significant predictor of SF36v2 RCS (2-factor model) scores. Adding the Social and Economic, Family, and Spiritual Wellbeing scores in Step 3 explained an additional 10.1% of variance in SF36v2 RCS (3-factor model) scores and the change in R^2 was significant, F_{inc} (3,381) =14.671, $p < .001$. Among the three predictors, Social and Economic scores was found to be a significant predictor of SF36v2 RCS (3-factor model) scores ($p < .001$) with the Spiritual Wellbeing scores ($p = .037$). At Step 4, with symptom-specific measures in the equation, the regression model explained an additional 14.5 % of variance in SF36v2 RCS (3-factor model) scores and this change in R^2 was significant, F_{inc} (3,378) =25.186, $p < .001$. Of these symptom-specific measures, Fatigue ($p= .040$) and Bodily pain ($p< .001$) were significant predictors of SF36v2 RCS (3-factor model). Again, at Step 5 when emotional measures were added, the model explained an additional 4.6% of variance in SF36v2 RCS (3-factor model) scores and this change in R^2 was also significant, F_{inc} (2, 376) =21.771, $p < .001$. Among the two emotional subscales, Depression ($p< .001$) was found to be the only significant predictor of SF36v2 RCS (3-factor model) scores. At Step 6, with the addition of Perceived general health and Physical functioning scores, R^2 =.389 (adjusted R^2 =*.368*), F_{inc} (2, 374) =21.256, $p< .001$. In the final model, the significant predictors of SF36v2 RCS (3-factor model) scores were Spiritual Wellbeing, Bodily pain, Depression, and Physical functioning. The most significant predictors of SF36v2 RCS (3-factor model) scores were Bodily pain, Depression, and Physical functioning. Together all the IVS accounted for 38.9% of the variance in the SF36v2 RCS (3-factor model) scores.

Table 8. 40 Sequential Multiple Regression Analysis predicting SF36V2 RCS (3-factor model) From Treatment Characteristics, Family Support, Symptom Specific Measures, Emotional Measures & Health Status Measures (N= 383)

Variable	*B*	SE *B*	β	*t-statistic*	*Significance*	*R*	*F*	R^2	ΔR^2
Step1						.073	2.080	.005	.005
Marital status	-1.507	1.045	-.073	-1.442	.190				
Step2						.167	4.449**	.028	.023
Time since started HD	-.637*	.261	-.123	-2.441	.015				
Time to reach to HD	-.121	.067	-.090	-1.792	.074				
Step3						.359	14.671***	.129	.101
Social & Economic	1.272***	.287	.281	4.426	.000				
Family	.158	.279	.036	.564	.573				
Spiritual Wellbeing	-.136*	.065	-.102	-2.098	.037				
Step4						.523	25.186***	.274	.145
Itch	-.412	.283	-.067	-1.460	.145				
Fatigue	-.164*	.079	-.102	-2.061	.040				
Bodily pain	.296***	.045	.332	6.584	.000				
Step5						.566	12.771***	.320	.046
Anxiety	-.076	.330	-.014	-.232	.817				
Depression	-1.668***	.360	-.258	-4.638	.000				
Step6						.624	21.256***	.389	.069
Perceived Gen. Health	-1.273	.995	-.062	-1.279	.202				
Physical functioning	.250***	.039	.275	6.393	.000				
Overall Final Model									
Intercept	51.417***	10.428		4.931	.000				
marital status	-.837	.841	-.041	-.996	.320				
Time since started HD	-.150	.215	-.029	-.701	.484				
Time to reach to HD	-.051	.056	-.038	-.911	.363				
Social & Economic	.505	.258	.112	1.954	.051				
Family	.036	.243	.008	.149	.881				
Spiritual Wellbeing	-.147**	.055	-.110	-2.662	.008				
Itch	-.089	.264	-.014	-.338	.735				
Fatigue	-.071	.079	-.045	-.904	.367				
Bodily pain	.185***	.045	.208	4.084	.000				
Anxiety	-.200	.314	-.036	-.636	.525				
Depression	-1.590***	.349	-.246	-4.555	.000				
Perceived Gen health	-1.273	.995	-.062	-1.279	.202				
Physical functioning	.250***	.039	.275	6.393	.000				
F-test for the whole model	21.256								
Significance of F-test	<.001								
R	.624								
R2	.389								
Adjusted R2	.368								

Note: N=383. CI, confidence interval; NS, not significant; Hb, Haemoglobin; SF36V2, Short-Form 36 Health Survey. *The weights are the standardised regression coefficients at each step. *p < .05; **p< .01; *** p< .001.*

In this final model, two of the factors, low Bodily pain and high Physical functioning, associated with better Role-functioning. On other hand, Spiritual wellbeing and Depression associated with limited Role-functioning in this group of patients.

Low Bodily pain is associated with high SF36v2 RCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in the Bodily pain scores, the SF36v2 RCS (3-factor model) score is predicted to increase on average by 0.185 units, with 95% confidence limits from .096 to .275, and this association is statistically significant (*p* = .001). Ability to perform Physical functioning also associated with high SF36v2 RCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in the Physical functioning scores, the SF36v2 RCS (3-factor model) score is predicted to increase on average by 0.250 units, with 95% confidence limits from .173 to .327, and this association is statistically significant (*p* = .001). In contrast, high Spiritual wellbeing score associated with low SF36v2 RCS (3-factor model) score, such that adjusting for other variables in the model, for each unit increase in the Spiritual wellbeing score is predicted to decrease on average by 0.147 units, with 95% confidence limits from -.256 to -.038, and this association is statistically significant (*p* = .027). High level of Depression is found to be associated with low SF36v2 RCS (3-factor model) scores, such that adjusting for other variables in the model, for each unit increase in the Depression the SF36v2 RCS (3-factor model) score is predicted to decrease on average by 1.590 units, with 95% confidence limits from -2.276 to -.904 and this association is statistically significant (*p* = .001).

The trustworthiness of regression model was evaluated using the Bootstrap technique as with other models using the IBM SPSS version 22 Bootstrapping method. Table 8.41 shows the bootstrap parameter estimates of the overall final model; the unstandardised regression coefficients(*B*), the bootstrapped standard errors (SE *B*), the significance of the regression coefficients, the normal approximated 95% confidence intervals (OLS 95% CI) and the bootstrapped confidence interval (BCa 95% CI). From the table, it can be seen that the parametric standard errors obtained earlier (see Table 8.40) are quite comparable to the bootstrapped standard errors. The significance of the bootstrapped coefficients show that Spiritual Wellbeing, Bodily pain, Depression, and Physical functioning are the significant predictors of SF36v2 RCS (3-factor model) score, which are the same as obtained from our non-bootstrapped estimates.

Table 8. 41 Bootstrap Parameter Estimates of the Overall Final Model predicting SF36V2 RCS (3-factor model) From Treatment Characteristics, Family Support, Symptom Specific Measures, Emotional Measures & Health Status Measures (N= 383)

Variable	*B*	Bias	SE *B*	Significance	OLS 95% CI	BCa 95% CI
Intercept	51.417	-.653	11.400	.001	[30.912,71.922]	[29.632,72.814]
marital status	-.837	.007	.853	.331	[-2.490,.816]	[-2.565,.810]
Time since started HD	-.150	-.014	.203	.451	[-.572,.271]	[-.551,.291]
Time to reach to HD	-.051	-.016	.055	.357	[-.160,.059]	[-. 166,048]
Social & Economic	.505	.004	.264	.060	[-.003,1.013]	[-.063,1.116]
Family	.036	.013	.254	.892	[-.442,.515]	[-.454,.526]
Spiritual Wellbeing	-.147	1.660	.063	.027	[-.256, -.038]	[-.272, -.021]
Itch	-.089	.013	.276	.757	[-.608,.429]	[-.598,.435]
Fatigue	-.071	-.001	.077	.355	[-. 226,084]	[-.235,.093]
Bodily pain	.185	.000	.050	.001	[.096.275]	[.093,.281]
Anxiety	-.200	.000	.321	.529	[-.818,.418]	[-.808,.453]
Depression	-1.590	.019	.345	.001	[-2.276-.904]	[-2.246, -.858]
Perceived general health	-1.273	.005	1.028	.225	[-3.231,.684]	[-3.101,.817]
Physical functioning	.250	.001	.046	.001	[.173,.327]	[.147,.338]

3. CI, confidence interval; NS, not significant; Hb, Haemoglobin; OLS, Ordinary Least Squares; BCa, Bias ccelerated.

In conclusion, more than a third of the variability in SF36v2 Role Component Summary (3-factor model) scores is predicted by a number of measures such as Spiritual Wellbeing, Bodily pain (reverse coding), Depression, and Physical functioning. Among these, low Bodily pain, high Depression, and better Physical functioning are the strongest predictors of SF36v2 Role Component Summary (3-factor model) scores, whereas Spiritual wellbeing contributed moderately to this prediction.

3. Summary

Four hundred and fifty-one patients with ESRD on HD were surveyed to determine the level of HRQoL, and 45 were interviewed to explore their level of QoL. The majority of patients were male, married, illiterate, living on low income, with a relatively young mean age of 47, and a mean time on haemodialysis of over six years. The mean time required for them to get to dialysis centre was 29 minutes. The clinical parameters such as Hb, HCT, and Albumin were within acceptable range.

Patients had moderate physical and mental health status ranged from 52.24 to 63.75, respectively. The mean scores of the eight domains of the SF-36v2 ranged from 52.24 to 63.75. The highest mean scores were in mental health (MH) subscale (63.75) and the lowest scores were in physical health subscale (42.24).

For the QoLI-Dialysis, the highest mean scores were in family subscale (25.15) and the lowest scores were in the health and functioning subscale (20.36).

One-hundred and thirty-two (29.3%) patients perceived their general health as good followed by 127 (28.2%) patients who perceived their general health as fair.

The individualised QoL instrument (SEIQoL-DW) was completed by 45 patients on an interview basis. The average length of time required for them to complete the SEIQoL-DW was 16.43 (11-25) minutes. The majority of patients, 39, (86.6%) reported that completing the SEIQoL-DW was easy. All patients, except two, were able to nominate five areas of life that they valued most. Religion/spiritual life was the most frequent domain, 36 (80%), nominated by patients, followed by Family 35 (77%), Personal health 31 (68.8), Social life 17 (37.7), Work/occupation 15 (33.3). The mean score of the global index of SEIQoL-DW was 60.33, with a minimum score of 27.53 and a maximum score of 83.80. This finding, supported by the mean of spiritual wellbeing scores 55.54 (range from 20 to 120), suggests that the existential and religious aspects of spirituality are clinically relevant to patients in this study and possibly could have an impact on their HRQoL.

For the mood measure, HADS, the mean anxiety score was 6.91 (*SD*= 4.32) and the mean depression score was 6.90 (*SD*= 3.73). Using the cut-off score of ≥8, 183 (41%) patients obtained a score of ≥8 on the anxiety subscale which possibly indicates presence of clinical anxiety. Similarly, around 43% of patients obtained a score of ≥8 on the depression subscale, indicating possible clinical depression. This cut-off score, however, is debateable since the scores of self-completed measures tend to be inflated. It is recommended that this value be compared with a higher cut-off score, e.g. ≥11, to provide an accurate conclusion with regard to possible cases of anxiety and depression.

For the symptoms measures, the mean fatigue severity score was 44.70 (*SD*= 14.91) indicating a further evaluation of fatigue required for those patients. 73% (319) patients obtained a score of ≥36. The average Itch-5D score was 9.33 (*SD* = 3.84), with scores ranging from 1 to 23 which may suggest that patients had low level of pruritus symptom.

Several sequential multiple regression models were used to examine which factors best explained physical health, mental health, quality of life index-dialysis, and role functioning. A summary of results of the performed models is in table 42 and as follows:

- *SF36v2 physical health component (2-factor standard model):* higher perception of general health associated with better physical health; whereas the longer time patients take to get to dialysis centre and higher symptoms of itch, fatigue, and depression associated with lower physical health.
- *SF36v2 mental health component (2-factor standard model):* less bodily pain and higher physical functioning are associated with better mental health; whereas high education status, high symptoms of anxiety, and depression are associated with lower mental health in ESRD patients.
- *Quality of life Index-Dialysis:* living outwith the capital, higher dialysis adequacy, high level of albumin, and better perception of general health associated with better QoLI-Dialysis. High level of anxiety and depression associated with lower level of QoLI-Dialysis.
- *SF36v2 physical health component (Emergent 3-factor model):* older age, longer time to get to dialysis centre, high level of itch, fatigue, anxiety,

depression are associated with lower physical health. High perception of general health is associated with better physical health component.

- *SF36v2 mental health component (Emergent 3-factor model):* better physical functioning is associated with better mental health; whereas high education status, high level of fatigue, bodily pain, anxiety, and depression are associated with low mental health.
- *SF36v2 role-functioning component (Emergent 3-factor model):* low bodily pain and better physical functioning associated with higher role-functioning; whereas high level of depression and spiritual/religious life associated with limited role-functioning.

Table 8. 42 A summary of outcome variables, predictors, R2 of significant predictors and overall models

Regression models	SF36v2 Physical Component Summary (2-factor traditional model)	SF36v2 Mental Component Summary (2-factor traditional model)	Quality of life Index-Dialysis	SF36v2 Physical Component Summary (3-factor model)	SF36v2 Mental Component Summary (3-factor model)	SF36v2 Role Component Summary (3-factor model)
Predictors (p value)	Patient age (β= -0.9, *p* < .05) Time to reach HD (β= -.12, p < .01) Itch (β= -.12, p < .01) Fatigue (β= -.17, p < .01) Depression (β= -.24, p < .01) Perceived Gen health (β= .20, p < .01)	Education status (β= -.12, *p* = .01) Pain (reverse scoring) (β= .44, *p* = <.001) Anxiety (β= -.11, *p* = <.02) Depression (β= -.22, *p* = <.001) Phys functioning (β= .16, p < .001)	Region (β= -.12, p < .01) Adequacy (β= .10, p < .01) Albumin (β= .08, p < .05) Anxiety (β= -.28, p < .01) Depression (β= -.25, p < .01) Perce Gen health (β= .10, p < .05)	Patient age (β= -.12, p < .01) Time to HD (β= -.11, p < .01) Itch (β= -.14, p < .01) Fatigue (β= -.16, p < .01) Anxiety (β= -.12, p < .05) Depression (β= -.17, p < .01) Perce Gen health (β= .27, p < .001)	Educational status (β= -.10, p < .01) Income (β= .07, p < .05) Fatigue (β= -.08, p < .05) Pain (reverse scoring) (β= p < .01) Anxiety (β= -.10, p < .05) Pain (β= .45, p < .001) Depression (β= -.19, p < .001) Physical functioning (β= .08, p < .05)	Physical functioning (β= .27, p< .001) Pain (reverse scoring) (β= .20, p < .001) SWB (β= -.11, p < .05) Depression (β= -.24, p= <.001)
R	63.1	77.6	71.1	65.4	74.60%	62.40%
R^2 of the regression model	39.8	60.2	50.5	42.8	55.70%	38.90%
adjusted R^2	37.6	58.2	48.5	40.2	54.1	36.8

Chapter 9- Discussion and Recommendations

1. Introduction and summary of results

This chapter critically evaluates the key findings of the study and the implications for improving nephrology healthcare practice in the Arab Islamic world and in Oman in particular. Recommendations for future research are explained, followed by a critical analysis on the strengths and limitations of the study. Finally, a summary is provided.

This study was carried out in four combined phases. The first phase consisted of two integrative reviews that explored the conceptual basis of QoL and how that was assessed in this patient group. It also explored the differences between the meaning of QoL for individuals and how health status might impact on an individual's life reflecting the notion of HRQoL. A sensitive search was performed by accessing five main relevant databases (SCOPUS, Cochran Library, ProQuest (ASSIA) and EBSCO (CINAHL and Medline)). Secondary internet resources (ScienceDirect and PubMed), and non-electronically published relevant articles were also search.

Main findings showed: 1) a considerable overlap between the terms QoL and HRQoL, in which QoL can be defined as the *'individuals' 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, expectations, values and concerns'* (WHO report, 1998, p. 551); whereas HRQoL refers to patients' subjective satisfaction with their health status, including domains related to physical, mental, emotional, and social functioning (Debout, 2011). Although these two terms share some communality, they are not equivalent; therefore any assessment of QoL/HRQoL should recognise and differentiate on the use between them. 2) Three main approaches are used to assess HRQoL: i.e. those using generic, disease-specific and individualised measures. However, none of them combined the use of generic, disease-specific and individualised measures as an integrated approach to comprehensively assess HRQoL. Finally, and most importantly, most of the studies were conducted within Western culture and no studies were found that had been conducted in Oman to assess QoL or HRQoL in this group of patients, or to assess how these patients perceived their QoL/HRQoL. As a result, there was a necessity to explore the concept of QoL within the Omani context prior to describing and measuring the levels of factors of QoL and HRQoL.

Phase two tested the understanding and acceptability of QoL/HRQoL within a small (n=12) subset of Omani ESRD patients. A cognitive interviewing method was used to test a generalised standardised measure of HRQoL (Short Form 36v2) and a disease-specific measure (Quality of Life Index-Dialysis) (QoLID). In addition, an individualised measure (Schedule for the Evaluation of Individual Quality of Life-Direct Weighting [SEIQoL-DW]) was used to establish whether the concept of QoL could be identified and defined within the Omani culture. The cognitive testing of the SF36v2 and QoLI-Dialysis identified few cultural sensitivities but was generally well accepted and questionnaire items appeared to have meaning to patients. The SEIQoL-DW supported the finding that QoL was generally understood and it is a meaningful concept and includes health considerations. By establishing the meaning of QoL and suitability of HRQoL measures to this group of patients it was necessary to pilot the remaining study measures in a larger group.

Phase three was a small pilot study (n=45) testing the feasibility and acceptability of a larger cross-sectional survey. Six Arabic-version questionnaires that assessed HRQoL, mood, physical symptoms and spiritual wellbeing, bound together, were piloted among the patients who were randomly identified from the National Renal Registry in Oman. The piloted measure, including socio-demographic questions, has been shown to be reliable in the Omani context. This phase informed the data collection strategy and guided the development of statistical analysis syntax for the main study phase.

Phase four (main study) was a large scale cross-sectional design. Random sampling was used to capture a representative national sample from 13 haemodialysis units across Oman. A subsample of these participants also completed the SEIQoL-DW to further explore the concept of QoL. In this phase, planned analytic techniques included testing the psychometric adequacy of key measures using exploratory and confirmatory factor analysis. Despite the questionnaires being translated according to WHO guidelines on translation and back translation, further validation is required in this population. This has not been done previously within the Arab Peninsula.

This doctoral research is highly important, given the number of patients in Oman with ESRD, the severity of their condition and the cost to the health service in providing ongoing support. This study shows that HRQoL was largely not predicted by the biomedical markers regularly measured by the ESRD service, and that symptoms were key drivers of both disease specific and generic HRQoL.

2. Discussion

The following sections discuss the study findings in relation to the research questions.

a. Meaning of QoL/HRQoL among Omani population

The first RQ1 in this study was: What does QoL mean to an Omani population? The meaning of QoL to this group of patients was explored by using the SEIQoL-DW instrument.

This is the first study to assess the potential utility of a formal assessment of QoL among Omani patients with ESRD. The use of SEIQoL-DW showed the potential usefulness of the information in the assessment of individualised QoL instrument along with standardised HRQoL. All the participants were able to comprehend and complete the SEIQoL-DW in an acceptable time (*mean*= 16.25 minutes), while the determined time to complete SEIQoL-DW is 10-20 minutes (O’Boyle et al., 1992). The successful completion of the SEIQoL may reflect patients’ insight into the factors that determine their QoL and ability to make judgments. This is manifested by their ability to identify the aspects of life that they consider important in making up their QoL and then by rating the level and importance of these aspects (Appendix 9.1). This is perhaps what distinguishes the individual QoL measures from the standardised HRQoL measures in that it is much more relevant to patients with incurable diseases such as ESRD.

With regard to the patients’ views about very important aspects in their QoL, the analysis of responses to the SEIQoL-DW indicated that 19 domains characterised their self-reports. These were religion/spiritual life, family, personal health, social life, work/occupation, leisure activities/hobbies, autonomy/independence, role functioning, living conditions, peace and contentment, finance, family health, quality of care, sexual life, enjoying life, relationships, coping, emotional well-being, and exercise/mobility. However, the most nominated categories were religion and spirituality (80%), family (78%), personal health (69%), social life (38%) and work/occupation (33%). These categories were in line with the literature that examined QoL in patients with ESRD (Tobin et al. 2002), multiple myeloma (Durner et al., 2013), diabetes (Walker & Bradely, 2002), and amyotrophic lateral sclerosis (Clark et al., 2001). Notably, although not in the same percent, the constant aspects of life nominated by these different groups of patients were health, family, work, social life and leisure activities.

Although there is no specific explanation for the emergence of these common aspects of life among different groups of patients, it may illustrate a mechanism for a disease management (DiMatteo, 2004). Family and social support could help patients with chronic conditions to buffer stress, increase self-efficacy, and influence change in negative health behaviours (DiMatteo, 2004). The emotional support that patients with ESRD might receive from family and friends could create a positive influence on global measures of disease management. Similarly, this study found that patients with higher scores of family support reported better disease-specific HRQoL. Patients were also able to cope better with ESRD if they were involved in leisure activities. Increase in confidence and self-esteem, and personal achievements are often observed when patients are involved in a leisure activity (Misener et al. 2010). A further discussion on common nominated aspects of life can be found in Chapter 5.

It was observed that the inclusion of a religion/spirituality category was different and unique for this study group. Within a Western context, religion may be mentioned by certain groups but it would be unlikely to be as consistently identified as a domain of QoL. Religion and spirituality does not seem to be an important aspect of life for some western patients, unlike Omani patients. That is perhaps because Omanis consider religion as the essential reference in dealing with everyday life. It can be said that religion can shape the way Omanis view different aspects of life, including perceptions of health and illness. In Oman, Muslim patients usually understand that illness, suffering and dying are part of their life and a test from Allah, “God”. Their perception is that no one can control how long they are going to live. Thus, their perceptions about QoL may be closely entwined with their religion and spiritual lives.

The cognitive interviewing method was used to test the readability and relevance of items of SF36v2 HRQoL measure and disease-specific measure (QoLI-Dialysis) among this group of patients. The preliminary result in phase two showed that two items of SF36v2 measure were less clear and two items related to QoLI-Dialysis measure were possibly sensitive. This however was not the issue when these measures were administered to a larger group of participants in the main study. Although these measures were relevant to this group of patients, there is a danger that validated and widely used measures of HRQoL do not address the entirety of what patients perceive as important in determining their HRQoL (Carr and Higginson, 2001). Indeed, measures that are irrelevant and do not cover aspects of life that are important to Omanis might not be valid. Basically, using standarised measures without checking their relevance to any targeted population might assess something distinct from what it is supposed to measure, or may fail to measure what is important to the individual. Such limitation can be evident in studies that used some standard measures of QoL and HRQoL in different groups of patients (Bowling, 1995; Carr, 1996). In this study, the tested HRQoL and disease-specific measures were clear and readable to this group of patients.

2.1.Level of QoL/HRQoL for patients with ESRD on HD in Oman

The second RQ2 was: What is the level of QoL/HRQoL for patients with ESRD on HD in Oman? A variety of measures was used to answer this question including individualised QoL instrument, HRQoL measures including disease-specific measure, symptoms-specific measures, and spiritual measures.

Using the SEIQoL-DW to assess the level of QoL, patients perceived their overall level of QoL to be lower than ESRD patients from Iran (Matlabi & Ahmadzadeh, 2016), USA (Abdel-Kader et al., 2009), and patients with cancer on radiation therapy (Becker et al., 2014). The variances in how these patients perceived their levels of QoL differently adds further support to the notion that QoL is an individual concept. SEIQoL-DW is an individualised QoL instrument that allows individuals to select domains that they view as important to their own wellbeing (O'Boyle et al., 1993). Obviously, SEIQoL-DW was able to capture patients' individual values which determined their QoL domains. The findings also contribute to the argument that individualised measures are essential to address the potential drawbacks of HRQoL instruments that might limit the factors that comprise participants' QoL.

Likewise, patients reported low levels of HRQoL particularly on the physical health component and mental health components. These findings were consistent with results from three observational studies in ESRD patients (Bohlke et al., 2008; Poppe et al., 2012; Hopman et al., 2009) and patients with other chronic conditions such as osteoporosis (Hopman et al., 2009). However, in current study, patients rated their mental health components better when compared to physical health components. Familes in Oman are more of an introverted type of families .and looking after family memebers is considered as an obligation. It was not surprising that patients scored higher in social function subscale compared to the other subscales of SF36v2. Social support has been reported to be an important factor in ESRD patients' perceived HRQoL (Giordano et al., 2012). Supportive social environment, friends, and family can improve patients' mental health and role functioning (Wilson and Cleary, 1995). Given that no previous study has assessed the association between family and social support and HRQoL in ESRD patients within Oman, exploring the mechanisms at work could be an important area for future research.

Remarkably, the level of disease-specific HRQoL was better compared to their overall HRQoL. Although this result seems curious, as patients on dialysis usually experience a burden of symptoms and complications associated with dialysis and ESRD, recent studies show that the life expectancy and bearing of the burden of disease and treatment among ESRD patients have increased (Bieber et al., 2014; Brekke et al., 2014; Griva et al., 2009). This seems encouraging because it perhaps reflects that the current standards of, and complex medical care provided to, ESRD patients are effective and could be an influencing factor for better HRQoL. In fact, it may lend support to nephrology services within and outwith Oman to further improve the care of patients with ESRD. Furthermore, results may suggest that QOLI-Dialysis measure is a good tool in HRQoL which is able to discriminate between different clinical groups.

Fatigue and pain were significant in this group and this is consistent with the results of previous studies in ESRD patients (Drayer et al, 2006; Jablonski, 2007). Fatigue and pain were the most significant burdensome symptoms that patients reported in this study. Kimmel et al (2003) found that around 50% of patients with ESRD experienced pain, using the McGill QoL Scale. Although this study did not investigate the severity of these symptoms, presence of symptom burden can be considered substantial and might impact on patients' HRQoL. It is not surprising that these findings are important for a number of reasons: first, ESRD patients have numerous symptoms, many of which can be severe (Davison & Jhangri, 2010). Second, symptoms that are common in dialysis patients such as muscles cramps, drowsiness or restless legs usually are not included in symptoms measures, which raises the possibility that symptom burden might be even higher than that observed in this study. A prior study conducted in 226 Dutch ESRD patients found that physical symptoms accounted for one-third of the impairment in HRQoL (Merkus et al., 1999).

Mood symptoms are commonly experienced by ESRD patients. Forty-one per cent of patients reported symptoms of anxiety and 43% reported depressive symptoms. These figures are higher than reported results by Ramirez et al. (2012) in which 25.9% patients had anxiety and 28% of patients had depressed symptoms, using the HADS instrument. However, the diagnosis of mood symptom in ESRD patients could be highly variable, from patients showing no symptom of the disease to patients who show severe symptoms (CHILCOT et al., 2008; FIDAN et al., 2016). This is perhaps due to different concepts of depression and anxiety, which may vary from isolated symptoms to major depressive and anxiety disorder (FRIEDMAN et al., 2001). Anxiety and depression may affect the patient with ESRD in many ways. Overall, patients with ESRD have higher morbidity and mortality caused by the chronicity of the disease (BERLIM et al., 2006). For this reason, early recognition of mood changes and establishment of specific intervention to this group of patients are necessary.

Despite religious/spirituality variable being unique in this group of patients, surprisingly patients reported low scores (mean 55.54 (possible range 20-120)). There is no clear explanation for this; however, Ramirez et al (2012) found that religious struggle was independently associated with greater psychological distress, impairing HRQoL and increasing anxiety among ESRD patients. Muslim patients might encounter difficulties in carrying out some religious rituals, as certain rituals require physical endurance. They are obliged to perform acts of worship five times a day, consisting of kneeling and prostration. They are also obliged not to eat or drink (not even water) over the period of the sun shining during the fasting month (Ramadhan). Perhaps failing to honour their religious commitment might lower their satisfaction with religious practice. Despite the difficulty that patients might face in performing Islamic obligations, they may perceive their faith as a coping mechanism with what would otherwise be a poorer HRQoL. Family and faith are more controllable factors than health and money (Hofmann et al., 2010). Leaning on family and deepening one's faith may be strategies employed by people with ESRD to improve their HRQoL. Accordingly, psycho-social interventions can be planned to help them to overcome their religious struggles.

2.2.Predictors of HRQoL

This section discusses the findings related to RQ3: To what extent do the following factors predict QoL/HRQoL in Omani patients with ESRD individual characteristics, treatment characteristics, socio-environmental factors, biological function, symptoms, and functional status and general health perceptions? The sequence of discussion in accordance to the Revised Wilson and Clearly HRQoL Modle by Ferrans et al., (2005).

2.2.1. Practicality of the Revised Wilson and Clearly HRQoL model

The revised model of Wilson and Cleary by Ferrans et al (2005) was used as a conceptual framework to guide this study. It can be concluded that the model provides a theoretical basis for the selection of study variables according to the series of health concepts which can be then translated to clinical intervention based on these findings.

This is evident by the result in which an understanding of associations among objective clinical outcomes and subjective patients' experiences in ESRD, including biological function, emotional and physical symptoms, functional status, and general health perceptions is clear. That is, the domains of characteristics of the individual (age), characteristics of the environmental (family support), biological function (albumin), emotional symptoms (anxiety and depression), physical symptom (fatigue), functional status (physical health), and positive health perceptions predicted the HRQoL in this group of patients with ESRD. Hhealthcare providers, therefore, should focus on caring for the ESRD patient as a holistic being who faces challenges arising from living with ESRD and challenges arising from the entire life context which reflect the philosophy of integration both of biomedical and social science paradigms in healthcare of the revised Wilson and Clearly Model of HRQoL.

2.2.2. Characteristics of the individual

There were a number of individual characteristics that predicted HRQoL. These included age, educational status, and income status.

Age was a significant predictor for low physical health. This result was in line with the findings of studies that examined HRQoL in ESRD patients using SF36v2 in which higher age predicted lower physical functioning (Walters et al., 2002; Lopes et al., 2007; Frank et al., 2003). As age increases, particularly in the elderly, the physical function of their body decreases (Loos et al., 2003). Thus, age might become a confounding factor in studies that evaluate and measure HRQoL. For that, future studies perhaps should consider measuring HRQoL of elder individuals separately from young populations or maybe control age variable in a sequential regression. The findings of this study are of value to healthcare workers, in Oman particularly, in order that they can devise an advance plan to address the issues that might reduce or worsen the level of HRQoL in this group of patients, particularly now that Oman has an increasingly older population.

Educational status variable showed an interesting, as well as a conflicting, interpretation. Low education status variable associated with better HRQoL on the mental-health domain by 12% of the total model of MCS (*p* = .004). This is difficult to explain because this finding is contrary to studies that examined educational level as a determinant of HRQoL in which higher education level associated with better mental HRQoL (Cukor et al., 2013; Finkelstein et al., 2009; Kimmel et al., 2003). That is, those with higher educational status are differentially, negatively affected. These findings force us to question whether there is anything specific about Omani culture. Is ESRD a greater threat to HRQoL for the better educated? Does religion have anything .to do with this? Does educational status relate as you would expect to income? Does higher educational status relate to lower HRQoL if you control for income? Indeed, this is an area that requires further exploration.

Patients with a higher monthly income also reported better mental HRQoL. International studies that assessed socio-economic status in patients with ESRD reported a positive association between a higher monthly income and better emotional and mental HQoL (Kao et al., 2009; Welsch, 2009). Similarly, a Brazilian study showed that lower socio-economic status was related to poorer HRQoL and to increasing functional decline over time (Santos et al., 2010). However, socio-economic status is a multi-dimensional factor and could vary among different national populations depending on types of cultures and healthcare services and on countries' overall economic status. In Oman, citizens with low income (earning less that OMR 264 (< GBP 500)) are entitled to financial support (PASI annual report, 2015). In addition, the healthcare services under the national health scheme are currently provided at no charge for all citizens. This kind of support may not reflect patients' exact socio-economic status and therefore require further investigation.

2.2.3. Charactaristics of the environemnt

The variable of 'time spent travelling to dialysis' was associated with lower physical-health scores in this group of patients. Unfortunately, none of the reviewed literature particularly examined the relationship between time taken to reach the dialysis unit and HRQoL. However, given the fact that these patients have lower physical health than mental health, it might have been expected that the longer time spent travelling to dialysis would be a source for physical health burden.

Despite the limited literature that examined the relationship between time spent to reach dialysis and HRQoL, this result indeed is important in that it provides valuable information regarding the effect of time taken to reach the dialysis unit and HRQoL in patients with ESRD.

Better dialysis adequacy predicted better disease-specific HRQoL. The result was comparable to a study by Cohen and Kimmel (2013) in which a better dialysis adequacy was associated with increased scores in social and emotional health-related QoL. It was also observed that higher patients' overall health status was associated with a better adequacy of dialysis. Another study reported that a higher rate of dialysis adequacy was associated with better physical-health status and lesser bodily pain (Unruh et al., 2008). Despite the positive association between higher dialysis adequacy and better health outcome, several clinical and biological factors should be considered that could interrelate with dialysis adequacy. Lambie et al (2004) found that dialysis adequacy could be strongly influenced by factors related to dialysis procedure, such as blood-pump speed, vascular access and sodium-removal degree. It is likely that these factors confound with the dialysis-adequacy measure and therefore should be noted and controlled prior to testing the correlation between dialysis adequacy and HRQoL.

2.2.4. **Biological function**

Higher albumin score predicted a better disease-specific HRQoL. The majority of studies that examined the albumin effect on patients with ESRD used the SF36 health-status measure (Patel et al., 2002; Lopes et al., 2007). Interestingly, these studies did not report any significant correlation between albumin and overall health status. It may be that albumin is a dialysis-related health factor rather than an overall health-status factor. Laws et al (2000) tested the association between albumin and QoLI-dialysis as an outcome in ESRD patients with severe malnutrition and found that a low albumin level associated with poorer HRQoL. This possibly indicates that albumin may not lower HRQoL unless the latter is at a severely low level. For this population, the mean albumin level was 38.42 (SD = 5.13), with therapeutic values around 35-48g/L according to KDOQI clinical-practice guidelines for haemodialysis (2015), and this may reflect the clinically acceptable level of albumin. Hence, further exploration of the albumin relationship with QoLI-dialysis is required before concluding that this variable is a reliable predictor of disease-specific HRQoL scores.

2.2.5. Symptoms

The presence of physical symptoms, as manifested by high level of fatigue, itch, and bodily pain, predicted poorer physical and mental health scores. This finding is in keeping with similar findings reported by Williams et al. (2007), Hagell et al. (2006), and Pakpour et al. (2010). From a behavioural perspective, physical symptoms could limit physical and functional activities, consequently leading to decreased positive reinforcement and eventual depressive symptomatology (Ibrahim, 2011). Dudgeon et al (2005) observed that low perceptions of control over physical symptoms may lead to poorer psychological health. These results furnish evidence that physical symptoms are associated with poor HRQoL and are predominant symptoms among ESRD patients, requiring clinical intervention. Thus, if an existing physical symptom is not effectively relieved, it may have detrimental effects on most aspects of HRQoL. To avoid this unpleasant cycle, the nephrology care practitioner should perhaps consider a comprehensive symptom-management programme that helps to reduce fatigue, itch and bodily-pain impact on physical and emotional health status.

Mood symptom, anxiety and depression, predicted low physical and mental health components, disease-specific HRQoL, and role-functioning scores. This finding is comparable to findings of studies which used HADS to measure mood symptom in ESRD patients (Berlim et al., 2006; Bornivelli et al., 2012; Fidan et al., 2013). It can be argued that the anxiety and depression symptom are the most important health-related variable found in this sample due to its consistent significance in predicting the scores of the study outcomes. Given the seriousness of mood symptom on HRQoL, notably, none of the studies reviewed used mood symptom as dependent variables. Its relative absence in the literature may be due to its ubiquitous nature, or to possible convergences of anxiety stigma with psychological disorders which hinder reporting it as a distinct symptom (Johnston et al., 2000). Such pitfalls in addressing anxiety as an important determinant of HRQoL may underestimate its prevalence. Findings, therefore, reveal a possible gap regarding the importance of assessing mood symptom as a vital determinant of HRQoL in patients with ESRD. Future research, therefore, should consider and assess anxiety and depression as a dependent variable.

Gender difference in the depression mean was observed in this study. Female patients exhibited higher depressive symptoms compared with men. This finding was comparable to studies which reported a similar result (Bornivelli et al, 2012; Fidan et al 2013). Although no explicit reason for gender variation has been identified, it may be that women are just more likely to express their feelings (SIMON & NATH, 2004). HADS is shown to have contested factor-structure. Also, studies that used HADS in patients with ESRD argue about the appropriateness of the predetermined cut-off score (Berlim et al., 2006; Bornivelli et al., 2012; Fidan et al., 2013). It is anticipated that patients' poorer physical- and mental-health status may reflect their responses in HADS and consequently inflate the scores. To overcome this, a higher cut-off score may perhaps be more appropriate for HADS, as well as further psychometric evaluations.

2.2.6. Physical functional status and general health perceptions variables

Physical functional status predicted better mental health and role-functioning. This finding was comparable to findings of former studies (Cleary et al., 2005; Rebollo et al., 1998; Santos et al., 2010). Patients with ESRD are prone to face higher level of debilitation and deconditioning and most of them cannot perform more than their daily living activities (Bonner et al., 2013). Physical functioning, however, is potentially modifiable. Bayoumi et al. (2010) found that patients who are able to maintain independent functioning might have better HRQoL. Home dialysis, independent home-exercise programmes and in-centre exercise programmes, for instance, can maintain physical functioning (Glover et al., 2011; Meers et al., 1996). Although functional status seems to be an important dimension of HRQoL, it is a multi-dimensional domain as it may include mental-component aspects. For that reason, when assessing functional status, it should be considered as a multidimensional domain. Also, studies that attempt to measure physical functioning status may need to consider using a multi-dimensional functioning scales.

In keeping with the literature findings (Wu A et al. (2004) Cleary et al. (2005)), positive general health perceptions predicted better physical health, mental health, QoLI-dialysis and role functioning. Younger patients, for instance, in phase one of this study, reported uncertainty about their future, which may reflect a grievance caused by their health-status deterioration. It was observed, while collecting study data, that some patients with considerable physical weakness perceived their health status as better compared with some younger patients on haemodialysis, who seemed to be more active. Although this seems odd, it may be that patients evaluate their own health status by comparing it with individuals of a similar age (Mangione, 2002; Tovbin et al., 2001). Older patients on haemodialysis may perceive that individuals of the same age, who are not on dialysis, have different health problems; whereas younger patients on dialysis observe fewer health-related issues in non-dialysis individuals of a similar age. Patients with chronic diseases usually adjust their aims and aspirations in life to the demands of their new health status so that they can maintain subjective wellbeing (Ferrans and Powers, 1995). Such behavioural change in patients with long-term illness was highlighted by the Response-Shift Model (Barclay-Goddard, 2012; Oort et al., 2005). The principle of the response-shift concept refers to a change in the meaning of an individual’s self-evaluation and the reconceptualisation that may occur due to changes in health status over time.

2.3.Validity and reliability of the HRQoL measures

RQ5: What are the psychometric properties of the study measures in an Omani context in relation to its validity and reliability? This is discussed under this section. A more detailed discussion can also be found in chapter seven.

Because no studies were found that validated or explored the measures of HRQoL in Oman, this study explored the underlying structure of the SF36v2 and HADS measures using exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). EFA was used to establish the factor structure among measures’ items and CFA to validate its use within this context. Surprisingly, for SF36v2, the original factor structure (eight-factor) was not supported within this population. Instead, the EFA and CFA revealed a three-factor structure for SF36v2. Likewise, for HADS, results did not show an exclusive factor-structure. EFA revealed a one-factor structure and a possible correlated two-factor structure. CFA revealed acceptable fit indices to study data for the one-factor, original two-factor, and emergent two-factor structures, though it was in favour of emergent two-factor structure.

Another important observation with regard to the three-factor model of the SF36v2 is the combination of physical functioning, role functioning, and psychological functioning. The EFA result of the three-structure factor was similar to the findings in studies conducted in Asia such as Singapore (Thumboo et al., 2001), Japan (Fukuhara et al., 1998) and Taiwan (Fuh JL et al., 2000). Their results showed that half of the items related to the vitality scale and some items related to bodily pain and social functioning merged into the mental-health factor (psychological functioning). These results are identical to the result in the current study, which may suggest that the standardised, original factor structure of SF36v2 is not reliable across different populations due to possible cultural influences on the structure factor of HRQoL measures. A potential explanation is that social, cultural and education factors play a role in how participants perceive different health areas. Also, the translation process of HRQoL measures from its origin language to Arabic or other intended languages may cause response bias. Despite the language equivalence of the Arabic version of HRQoL being well established, the response bias might change the basic nature of some of its items. Thus, researchers should take more cautious steps when translating HRQoL standard measures into Arabic. In addition, intensive psychometric testing should be carried out on translated measures.

Another possible factor that influced the structure of the SF36v2 is that one or more of the subscales of SF36v2 have poor measurement properties in patients with ESRD. There are a number of indications of this. First, the internal consistency was relatively low in two subscales of SF36v2 (general health subscales α= .65, and social functioning α= .53). Second, around 220 (48.8 %) participants who completed the SF36v2 measure were illiterate and with low-education level were assisted by the research assistant which may have affected the response to the measure items. Finally, the World Health Organization (WHO) defines health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. This definition affirms the concept of body-mind connection. Thus, participants may perceive the answer to the items of BP, Vitality, and GH subscales from a psychological perspective.

It is worth noting that no correlation was observed between the individualised QoL instrument (SEiQoL-DW) and health-related QoL measures (SF36v2 and QoLI-dialysis). This may suggest that individualised QoL measures are distinct from HRQoL measures and that they assess something different. HRQoL determinates are very much individualised and the importance of these determinates is influenced by several factors (Roback et al., 2011). These factors can be seen as patients' expectations and ambitions, religious beliefs, culture and socio-demographic characteristics (Chisholm et al., 2007). Thus, more attention should be paid to further develop the patient-generated index so that assessing HRQoL can be achieved.

Although individualised measures have their limitations, a compromise can be used to include common factors of life that are important to renal-failure patients from the recently developed standardised measures that use direct weighting systems (Flokstra-De Blok et al., 2009). It is anticipated that identical trends might result in an individualised approach towards assessing patients' quality of life. Nevertheless, the extent of such measures, and how sensitively they reflect the individualised QoL, would require further evaluation. The clinical effectiveness and interpretability of these measures also will also need to be evaluated and established (Johnson et al., 2006).

3. Implications for Practice

This section answers RQ5 by providing recommendations to clinicians and policy makers regarding concerns for augmenting QoL and HRQoL in patients with ESRD based on the study results.

This study is highly important, given the number of patients in Oman with ESRD, the severity of their condition and the cost to the health service in providing ongoing support. Its findings therefore could benefit and contribute positively in improving patient care at different levels including clinical practice, policy development, and Muslim patients worldwide.

Nephrologists and nephrology nurses in clinical practice could benefit from the current study findings by the potential influence on patients' HRQoL directly through facilitating supportive and educative programmes that could assist ESRD patients in rebalancing their lives. This can be achieved through the use of an integrated approach therapy that incorporates support groups and religious and spiritual counselling. The use of such complementary approaches may expose useful interventions that might influence patients' overall QoL.

The results of the current study can create an evidence base upon which current clinical policy and future healthcare services can be developed within the nephrology care services in Oman. For instance, currently, the psychological services available for patients with ESRD in Oman are limited. Only diagnosed patients with significant psychological issues are referred to psychiatry therapy. Patients with ESRD experience significant emotional and psychological problems, which untreated can have considerable negative impact on their HRQoL. Similarly, patients' perceptions about their ESRD condition are extremely important in determining their response to management of ESRD. That is because patients are active participants in their own care/treatment plan and for that care providers are required to understand and respect the dynamic role that patients have in the management of their own disease. This process can be enhanced by the application of the Nichol's Psychological Care Scheme (Figure one). It suggests that the key to a better psychological care for this group of patients is the monitoring of their psychological state, ensuring provision of information, emotional care, basic counselling and advocacy (Nichols, 1993). Given the significant proportion of patients with ESRD who could potentially benefit from improved support, the most feasible interventions are likely to be low-cost and easy to incorporate into current policies and everyday clinical practice.

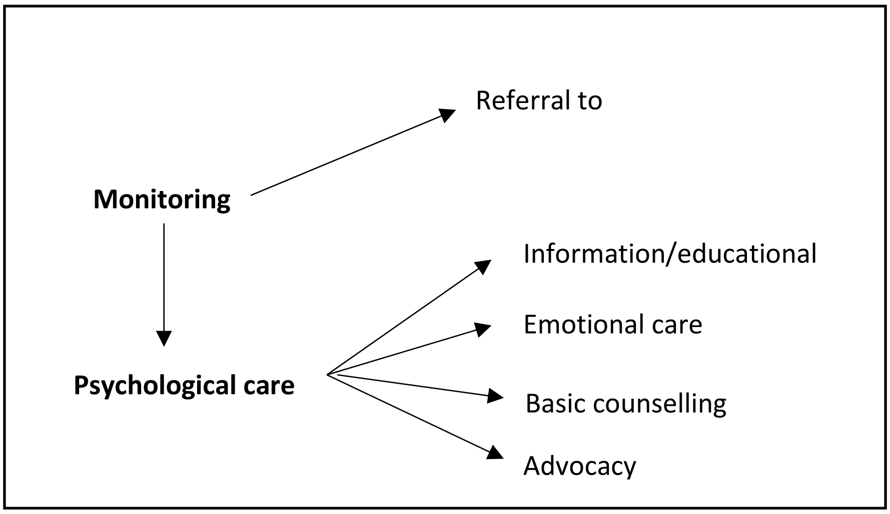


Figure 1: Nichol’s Psychological Care Scheme.

This research used highly original, patient-centred methods, testing both the understanding and the meaning of the concepts of QoL and HRQoL in a representative Islamic, Omani sample. Participants’ reports confirmed that health status was an important element and that spirituality was a universal component of QoL and HRQoL. The result therefore has the potential to contribute to the care of Muslim patients within the UK health service through understanding the possible influence of their religious perceptions on their treatment. It also can inform developing a culturally and religiously competent education toolkit tailored to their religious beliefs.

Validating the HRQoL measures in an Omani population will benefit clinical practice as it is likely to provide clinicians with specific validated tools to assess their patients, which can greatly improve the integration of HRQoL data into clinical practice. A major benefit of integrating these measures into routine clinical practice is the potential for identifying symptoms and problems that may result in improved patient care and clinical outcomes over time.

Assessing QoL is an important outcome measure for patients with ESRD to ensure that their care provides a sense of wellbeing and satisfaction with life. This cannot be achieved, however, without patients’ input as it is an individualised concept and thus their judgment on this is justifiable. This is clearly revealed by the individualised QoL instrument (SEiQoL-DW) in which patients nominated more than 14 areas that they perceived as important to their life. Besides the health-status measure, symptom-specific, disease-specific and spiritual-wellbeing measures were used to assist in quantifying the assessment of HRQoL factors. Although these measures were developed for research purposes, they could be employed in monitoring individual changes in HRQoL over time in dialysis centres and clinical settings.

This study shows that HRQoL was largely not predicted by the biomedical markers regularly measured by the ESRD service, and that symptoms were key drivers of both disease specific and generic HRQoL. Symptoms, particularly anxiety and depression, appeared to place a burden on dialysis patients with ESRD. A recommended intervention is that patients be assessed for symptoms prior to initiating the dialysis session. Patients should also be encouraged to discuss their symptoms with healthcare providers and not to consider them merely as routine, disease-related symptoms. The immediate tackling and managing of symptoms, including physical and mental symptoms, is expected to reduce their burden and to help in improving patients' overall QoL (Berlim et al., 2006).

The result of this study showed that anxiety and depression were highly dominant in ESRD patients including those in the Omani context. Special vigilance is therefore required for these two symptoms and for depression in particular. Depression was more prevalent, at around 43%, and assessing for symptoms related to depression could help in providing early interventions (Colin et al., 204). Some possible interventions that can be suggested to reduce the depressive symptoms in this group of paitnets are to use cognitive behavioural therapy (CBT) and exercise programmes. CBT uses well-structured techniques to support patients' logical thinking and ability to recognize negative thoughts, and consequently mood status (Hedayati et al., 2012). Studies that used CBT as therapy among depressive ESRD patients reported a significant amelioration of depressive symptoms (Duarte et al., 2009; Weiner et al., 2010). Likewise, the use of physical exercise programmes associated with an improvement in self-reported physical functioning on the PF scale of the SF-36 and also a reduction in fatigue in the groups that were assigned to exercise (KOLEWASKI et al., 2005; Painter, 2009).

Patients with ESRD are usually at risk of being underdiagnosed for mood disorders. This is due to unremarkable symptoms such as feeling tired, sometimes interchanged with physical symptoms such as fatigue, which can be understood as normal consequences of dialysis treatment. For some patients, women in particular, expressing these feelings with a male healthcare worker might be embarrassing or unimportant in relation to other existing physical symptoms. Emotional health, however, seems to have a large influence on HRQoL. Hence, consistent support and a comfortable environment should be developed with each patient to allow them to express their feelings. Also, a multidiscipline team should be involved in the patient-care plan, including a psychologist, providing social support as well as pharmacological interventions. Omani patients reported that family relationships were an important source of support, evidenced by the high scores on the Family subscale of QoLI-dialysis. Thus, involving family members, to an acceptable level, in determining care plans may enhance QoL outcomes. Family involvement may also help in detecting changes in behaviour that are not reported by the patient so as to ensure continuity of care (Bieber et al, 2014).

Fatigue was also a significant problem in patients with ESRD on dialysis. It has a physical impact on patients as well as an emotional toll. Assessing fatigue levels in this group of patients should be carried out on a frequent basis. The challenge, however, may be that there is no predetermined norm level of fatigue among Omani patients and a further study is required to determine this. Until then, screening the factors that may contribute to the intensity and type of fatigue may help in developing interventions for minimising post-dialysis fatigue. When fatigue cannot be adequately controlled, it may be that emotional support would help via active listening which can provide some empathetic relief.

Assessing patients' general health perception could be a significant way for nurses, as well as other healthcare providers, to gain an insight into that perception. General health perception is a subjective concept and might include functional status and physical and mental symptoms (Ferrans et al., 2005). The revised Wilson and Cleary model of HRQoL by Ferrans et al is comprehensive and patient-centred and might guide healthcare providers when assessing HRQoL. According to the result of this study, patients' perception of general health has a significant association with overall QoL and thus can be considered a unique indicator of wellbeing. A high level of health perception may also provide validation that overall QoL is an acceptable concept.

Of all the variables tested in this study, religion and spirituality, depression, anxiety, fatigue and health perception were the most important in explaining patients' QoL and HRQoL. This finding shows the powerful connection between mind-body-spirit. This conclusion corroborates a randomised control study that examined the effectiveness of body-mind-spirit intervention in improving well-being, HRQoL and functional impairment among patients with depression. This study found that the intervention group had a significant improvement in wellbeing and HRQoL scores over a six-month period (Rentala et al., 2015). Despite the Rentala study being conducted exclusively among depressive patients, not ESRD patients, it is coupled with the findings of this study in terms of importance to provide a holistic approach to HRQoL. That is, HRQoL cannot be determined merely by health status.

4. Recommendations for future research

The majority of studies that examined HRQoL in patients with ESRD have likened the term to "health status", "wellbeing" and "QoL". This interchangeability in the use of this term in the literature has had mixed results. Future studies should clearly define the term "HRQoL" and distinguish it from other related terms. Future studies examining HRQoL should also consider incorporating different approaches of assessment, including the use of different measures to describe HRQoL in patients with ESRD. The factors that might possibly affect HRQoL from a holistic perspective need to be searched for in future studies.

Most importantly, given that the concepts of and factors influencing the HRQoL are dynamic and could change over time depending on one's perception, the use of an observational longitudinal design would be more useful. Longitudinal study would offer a better understanding of the subjective and objective factors that may influence one's HRQoL, including the degree of change, over the life span (Bonner et al., 2013). Special attention however should be paid to the possible limitations that this design may include. Repeated measures over time on the same patients with same chronic conditions are not independent and might cause issue of withdrawals and loss of follow-up (Curran et al., 2002). HRQoL studies also may involve sources of bias including selection bias, heterogeneity issue, and confounding (Mangione, 2002).

This study has used 23 variables representing several antecedents of QoL and HRQoL with the guidance of the revised Wilson and Cleary model of HRQoL (Ferrans et al., 2005). Five variables were important determinants of Omani patients' overall wellbeing: religion and spirituality, anxiety, depression, fatigue and general health perception. Because only these variables were the most important across the regression models, other independent variables need to be further identified and tested, such as characteristics of the individual and clinical factors. Thus, the effect of these variables remains unclear. Future studies examining correlation or differences between the variables of the characteristics of the individual and HRQoL may provide additional understanding.

Despite the clear influence of family and social support in Omani patients, marital status was shown to be insignificant in explaining patients' HRQoL. Possible future studies looking at the broader concept of family and social support may provide further exploration of this aspect. Currently, in Oman, there are no specific centres, including dialysis settings, providing social support to ESRD patients. Establishing social support and rehabilitation centres within dialysis settings may foster patients' perception of social support. It may also help patients to develop skills and strategies that help them to cope with the disease's chronic nature and its related complications and then to apply specific mechanisms of disease management to adapt and maintain their lives.

The sample in this study consisted of Omani Muslim patients affected by ESRD and this may limit the results' generalisability in terms of non-Muslim populations. Regional and religious differences may play a role in influencing individuals' perceptions of their health and overall QoL. Further comparative studies need to be conducted among ESRD patients to assess perceptions of health and HRQoL across different religions and cultures.

Physical and mood symptoms associated negatively with HRQoL level. Further exploration of symptoms related to ESRD is required. While some symptoms may be tolerable, there may be a level where patients cannot manage disease-associated symptoms over a long period. Hence, longitudinal studies need to be conducted to track the full load of symptoms and their possible implications for patients' HRQoL. Categorising patients on dialysis into groups based on length of time on dialysis would perhaps assist in exploring the threshold of symptoms and explaining strategies of adaptation to symptoms over time.

Functional status was measured by the subscale of physical functioning of SF36v2. The findings revealed that a higher functional status variable was associated with better mental health and role-functioning components. Using a single subscale, however, to measure the relationship between functional status and HRQoL may not be sufficient because of the need to examine this relationship by stratifying dialysis patients into different functional categories to explore differences in HRQoL. Accordingly, intervention plans should be set and tailored for the patients with last stage of renal failure as the level of physical function differs through the disease trajectory.

The revised Wilson and Cleary conceptual model of HRQoL (Ferrans et al., 2005) was used to guide this study in the selection of variables and data analyses. While this conceptual model provided clear conceptual and operational definitions, it requires further testing in ESRD patients as well as in different populations. Future studies using this model may assist in testing the relationship among HRQoL concepts using structural equation modelling (SEM). This type of formal testing could clarify the strength of the concepts of this conceptual model. The SEM type of statistical analysis allows for a non-recursive pathway (Munro, 2005) which might help in understanding how patients adjust to ESRD. As formerly discussed, patients with ESRD may readjust their general health perception as a way to cope with the chronic nature of the disease. The new adjustment may positively influence patients' symptom experience, which in turn may reverse the dominant causal flow of the model (Ferrans et al., 2005). Also, the use of SEM can be useful to test whether the revised Wilson and Cleary model performs equally in different populations. Weak correlation between the concepts of the model, if this becomes apparent, can then be identified for amendment.

General health perception was shown to be an important factor determining patients' HRQoL. This association, however, requires further examination by future studies. An area of research in this aspect could be a comparison of the differences between how ESRD patients rate their health status and how healthcare providers rate patients’ health status. Determining the causes that may influence patients’ and healthcare providers’ perceptions of rating health status could provide an insight into the unknown factors. These factors could be psycho-social, spiritual, coping strategies, personal traits, or patients’ disease perceptions. It is recommended that future research should look for these factors and then examine their effects on HRQoL. Interventional programmes could then be identified to manage these factors to enhance patients’ HRQoL.

5. Strengths and limitations of this study

Several strengths can be seen in this study. First, because no studies had been conducted to assess QoL and HRQoL among ESRD patients in Oman, this study will fill this gap in the existing knowledge and help in planning appropriate interventions to improve patients’ HRQoL. Second, the study may guarantee new knowledge and expanded understanding of HRQoL among dialysis patients in Oman. Third, it makes a valuable contribution to the validation of HRQoL among ESRD patients and to international literature by adding new knowledge in this setting. Finally, the information generated by this study about the cultural relevance of HRQoL measures could help researchers aiming to standardise SF36v2, QoLI-dialysis, HADS, Itch-D Scale and FFS measures across cultures.

This thesis used highly original, patient-centred methods, testing both the understanding and the meaning of the concepts of QoL and HRQoL in a representative Islamic, Omani sample. Participants’ reports confirmed that health status was an important element and that spirituality was a universal component of QoL and HRQoL. This study has high levels of rigour, and has, using state of the art psychometric approaches for the first time, validated and confirmed the factor structure of these key HRQoL measures, adding to our knowledge and understanding regarding the measurement of HRQoL in an Islamic context.

This PhD study has many implications for clinical practice. It has identified the critical importance of QoL and HRQoL as key outcomes in the care of Omani ESRD patients which may improve HRQoL in this patient group. This research specifies the identity and importance of key symptoms that are related to physical health status, mental health status and role functioning. This study has the potential to contribute to Omani health policy and to the care of Muslim patients within the UK health service.

Future developments include the exploration and validation of QoLID, knowledge mobilisation to patient, practitioner and policy maker groups. Development, piloting and evaluation of a patient-centred intervention to support and improve HRQoL in ESRD patients in Oman can build on this.

A number of limitations in this pilot study should be acknowledged. First, although the sample was taken from 13 dialysis units across Oman, it may not be representative of the entire ESRD population within Oman as patients from different regions may perceive their HRQoL differently. Patients from different regions and rural areas may have different backgrounds and value systems. A larger group of patients from different regions in Oman would strengthen the study. Second, although this study used different methods of sampling, including random and opt-in sampling techniques, the results might only provide regional norms of the study measures, which can be used for comparison purposes until establishing normative values for the Omani population. Third, data are required on “time since patients started their dialysis” and “time needed to get to the dialysis unit”. Results revealed a low HRQoL level among the patients and such information would help in assessing the effects of these variables. Fourth, about 30% of the patients in this study were illiterate. Although the measures were read to illiterate patients by trained nurses without any prompts, the answers provided may not reflect the true situation. Finally, because patients spend around 12-15 hours on dialysis each week, recruitment may be enhanced by asking patients to participate during their regular dialysis schedule. Haemodialysis can cause hypotension and electrolyte imbalance and patients may not have felt at their best while answering the piloted measures related to their HRQoL.

6. Summary

The aims of this study were to explore the meaning of “QoL” to an Omani population, to identify factors that predicted their QoL and HRQoL and to test the validity and reliability of HRQoL measures within this setting. Patients nominated religion and spirituality, family, personal health, social life and work/occupation as their most valued aspects of life. These nominated aspects of ESRD patients’ lives could be a reliable guide to the most important priorities for medical interventions by neurologists and nephrology nurses, as well as policymakers within the healthcare system in Oman.

Patients reported relatively moderate levels of HRQoL, considering that they were suffering from the burden of disease symptoms, lower functional status and reasonable general health perceptions. Emotional symptoms, including anxiety and depression, had the greatest impact on reducing their HRQoL. This may suggest that psychological factors may be better predictors of HRQoL than physiological factors. Thus, consistent clinical assessment of anxiety and depression symptoms is essential for these patients. Introducing interventions to rebalance patients’ moods and incorporate psycho-social support into routine care may help them to experience a higher HRQoL (Rentala et al., 2015).

Future studies should continue to identify and examine factors that may influence HRQoL and determine interventions to enhance patients’ overall wellbeing.

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Appendices

Appendix 2.1. Excluded articles from review-1 with reasons

Study title	Reasons for exclusion
Abellan-Perpifian, J.-M. and J.-L. Pinto-Prades (2005). "Measuring the health of populations: the veil of ignorance approach." Health Economics 14(1): 69-82.	Economical paper
Acton, G. J. and P. Malathum (2000). "Basic Need Status and Health-Promoting Self-Care Behavior in Adults." Western Journal of Nursing Research 22(7): 796-811.	Not related to QoL
Ashby, M., et al. (2005). "Renal dialysis abatement: lessons from a social study." Palliative Medicine 19(5): 389-396.	A summary article
Bennett, K., et al. (1991) Methodologic challenges in the development of utility measures of health-related quality of life in rheumatoid arthritis. Controlled Clinical Trials 12, 118s-128s	Methodology paper
Berger-Schmitt, R. (2002). "Considering social cohesion in quality of life assessments: concept and measurement." Social Indicators Research 58(1-3): 403-428.	Focus on social cohesion
Bonner, A. and J. Greenwood (2006). "The acquisition and exercise of nephrology nursing expertise: A grounded theory study." Journal of Clinical Nursing 15(4): 480-489.	Focus on exercise
Bournes, D. A. (2000). "Concept inventing: a process for creating a unitary definition of having courage." Nursing Science Quarterly 13(2): 143-149.	Focus on courage concept
Brander, P., et al. (2004). "Living with a terminal illness: patients' priorities." Journal of Advanced Nursing 45(6): 611-620.	Not related to QoL
Brazier, J. and M. Deverill (1999). "A checklist for judging preference-based measures of health related quality of life: learning from psychometrics." Health Economics 8(1): 41-51.	Methodological study
Brooks, N. (2000). "Quality of life and the high-dependency unit." Intensive and Critical Care Nursing 16(1): 18-32.	Focus on high-dependency unit
Brush, B. L., et al. (2011). "Overcoming: A Concept Analysis." Nursing Forum 46(3): 160-168.	Methodological paper
Bullinger, M., et al. (2008). "Psychometric properties of the KINDL-R questionnaire: results of the BELLA study." European Child & Adolescent Psychiatry 17(1): 125-132.	Methodological study
Burnes, B. and B. Cooke (2012). "Kurt Lewin's Field Theory: A Review and Re-evaluation." International Journal of Management Reviews.	No abstracts
Calvin, A. O. and L. R. Eriksen (2006). "Assessing advance care planning readiness in individuals with kidney failure." Nephrology Nursing Journal: Journal Of The American Nephrology Nurses' Association 33(2): 165-170.	Not related to QoL
Candow, D. G. (2011). "Sarcopenia: Current theories and the potential beneficial effect of creatine application strategies." Biogerontology 12(4): 273-281.	No abstract
Carlesso, L. C., et al. (2012). "Reflecting on whiplash associated disorder through a QoL lens: An option to advance practice and	No abstract

	research." Disability and Rehabilitation 34(13): 1131-1139.	
	Carvalho, A. F., et al. (2013). "The psychological defensive profile of hemodialysis patients and its relationship to health-related quality of life." The Journal Of Nervous And Mental Disease 201(7): 621-628.	Focus on psychological defensive profile
	Cella, D., et al. (2005). "Defining higher order dimensions of self-reported health: further evidence for a two-dimensional structure." Evaluation & the Health Professions 28(2): 122-141.	General review
	Chwalisz, K. (2008). "The Future of Counseling Psychology: Improving Quality of Life for Persons With Chronic Health Issues." The Counseling Psychologist 36(1): 98-107.	Focus on counselling
	Cicerchia, A. (1996). "Indicators for the measurement of the quality of urban life. What is the appropriate territorial dimension?" Social Indicators Research 39(3): 321-358.	Related to environment
	Claes, C., et al. (2012). "The influence of supports strategies, environmental factors, and client characteristics on quality of life-related personal outcomes." Research in Developmental Disabilities 33(1): 96-103.	Focus on intellectual disability
	Clark, E. H. (2002). Quality of life: psychiatric nurses hearing the voices of individuals with severe mental illness, University of Maine. Ph.D.: 194 p.	Focus on mental illness
	Corcoran, M. A. (2007). "Defining and Measuring Constructs." The American Journal of Occupational Therapy 61(1).	Relevant to inclusion criteria
	Cote, I., et al. (2000) Health-related quality-of-life measurement in hypertension. A review of randomised controlled drug trials. Pharmacoeconomics 18, 435-450	Describes the instruments of HRQoL
	Crosby, R. D., et al. (2003) Defining clinically meaningful change in health-related quality of life. Journal of Clinical Epidemiology 56, 395-407	Clinical relevance
	Cudney, S., et al. (2003). "Management of chronic illness: voices of rural women." Journal of Advanced Nursing 44(6): 566-574.	Focus on chronic illness management
	Curran, D., et al. (2002). "Analysing longitudinal continuous quality of life data with dropout." Statistical Methods in Medical Research 11(1): 5-23.	Focus on statistical issues
	Debout, C. (2011). "The concept of quality of life in healthcare, a complex definition]." Soins: La Revue de Reference Infirmiere(759): 32-34.	Relevant to inclusion criteria (article in French Language)
	Diener, E., et al. (2013). "Theory and Validity of Life Satisfaction Scales." Social Indicators Research 112(3): 497-527.	Focus on satisfaction scale
	Dyess, S. M. (2011). "Faith: a concept analysis." Journal of Advanced Nursing 67(12): 2723-2731.	Relevant to inclusion criteria
	Ebrahim, S. H., et al. (2007) Reporting on health-related quality of life in Cochrane reviews - a challenge for authors? [abstract]. XV Cochrane Colloquium; 2007 Oct 23-27; Sao Paulo, Brazil 116-117	Relevant to inclusion criteria (still under review)
	Eckersley, R. (2013). "Subjective Wellbeing: Telling Only Half the Story: A Commentary on Diener et al. (2012). Theory and Validity of Life Satisfaction Scales. Social Indicators Research." Social Indicators Research 112(3): 529-534.	Commentary paper
	Fang, J., et al. (2011). "The response scale for the intellectual disability module of the WHOQOL: 5-point or 3-point." Journal of Intellectual Disability Research 55(6): 537-549.	Focus on disability module
	Farsides, B. and R. J. Dunlop (2001). "Is there such a thing as a life not worth living? Measuring quality of life." British Medical Journal 322(7300): 1481-1483.	Focus on termination of pregnancy
	Ferrin, J. M., et al. (2011). "Psychometric validation of the Multidimensional Acceptance of Loss Scale." Clinical Rehabilitation 25(2): 166-174.	Focus on loss scale

	Fetherman, D. L., et al. (2011). "A pilot study of the application of the transtheoretical framework during strength training in older women." Journal of Women and Aging 23(1): 58-76.	Focus on strength training
	Fink, A. M. (2009). "Toward a new definition of health disparity: a concept analysis." Journal of Transcultural Nursing 20(4): 349-357.	Focus on health disparity
	Fleming, S. and D. S. Evans (2008). "The concept of spirituality: its role within health promotion practice in the Republic of Ireland." Spirituality & Health International 9(2): 79-89.	Relevant to inclusion criteria
	Flynn, R., et al. (2005). "The use of patient reported outcome measures in routine clinical practice: lack of impact or lack of theory?" Social Science & Medicine 60(4): 833-843.	Focus on clinical decision making
	Frankel, A. (2009). "Nurses' learning styles: promoting better integration of theory into practice." Nursing times 105(2): 24-27.	Relevant to inclusion criteria
	Frisch, M. B. (2013). "Evidence-Based Well-Being/Positive Psychology Assessment and Intervention with Quality of Life Therapy and Coaching and the Quality of Life Inventory (QOLI)." Social Indicators Research 114(2): 193-227.	No sufficient data provided
	Gall, T. L., et al. (2011). "Spirituality and Religiousness: A Diversity of Definitions." Journal of Spirituality in Mental Health 13(3): 158-181.	Relevant to inclusion criteria
	Ghylin, K. M., et al. (2008). "Clarifying the dimensions of four concepts of quality." Theoretical Issues in Ergonomics Science 9(1): 73-94.	Focus on industry quality
	Gibson, B., et al. (2005). "Variation and change in the meaning of oral health related quality of life: a "grounded" systems approach." Social Science & Medicine 60(8): 1859-1868.	Focus on oral health quality of life
	Gill, L., et al. (2010). "Transitional aged care and the patient's view of quality." Quality in Ageing & Older Adults 11(2): 5-18.	Focus on health service quality
	Gillison, F. B., et al. (2006). "Relationships among adolescents' weight perceptions, exercise goals, exercise motivation, quality of life and leisure-time exercise behaviour: A self-determination theory approach." Health Education Research 21(6): 836-847.	Focus on adolescent’s weight
	Giordano, G. N., et al. (2012). "Social capital and self-rated health – A study of temporal (causal) relationships." Social Science & Medicine 75(2): 340-348.	Focus on social capital role
	González, A., et al. (2012). "Motivational and emotional profiles in university undergraduates: A self-determination theory perspective." Spanish Journal of Psychology 15(3): 1069-1080.	No abstract
	Hagerty, M. R., et al. (2001). "Quality of life indexes for national policy: review for research." Social Indicators Research 55(1): 1-96.	Focus on life indexes
	Hallinen, T., et al. (2009). "Costs and quality of life effects of the first year of renal replacement therapy in one Finnish treatment centre." Journal Of Medical Economics 12(2): 136-140.	Focus on renal transplant
	Halvari, A. E. M., et al. (2013). "Oral health and dental well-being: Testing a self-determination theory framework." Journal of Applied Social Psychology 43(2): 275-292.	Focus on oral heath
	Hanestad, B. R. (1996). "Nurses' perceptions of the content, relevance and usefulness of the quality of life concept in relation to nursing practice." Vard i Norden 16(1): 17-21.	Not relevant to inclusion criteria
	Hawthorne, G. (2009). "Assessing utility where short measures are required: development of the short Assessment of Quality of Life-8 (AQoL-8) instrument." Value In Health: The Journal Of The International Society For Pharmacoeconomics And Outcomes Research 12(6): 948-957.	Methodological paper
	Herbert, R. J., et al. (2009). "A systematic review of questionnaires measuring health-related empowerment." Research & Theory for Nursing Practice 23(2): 107-132.	focus on health related empowerments
	Hiemstra, M., et al. (2012). "Smoking-specific communication and children's smoking onset: An extension of the theory of planned	Focus on children population

	behaviour." Psychology and Health 27(9): 1100-1117.	
	Holt, J. (2000). "Exploration of the concept of hope in the Dominican Republic." Journal of Advanced Nursing 32(5): 1116-1125.	Focus on Dominican republic
	Ismael, S. T. (2002). "A PAR approach to quality of life: frameworking health through participation." Social Indicators Research 60(1-3): 41-54.	Focus on Canadian government health vision
	Jalowiec, A., et al. (2007). "Predictors of Perceived Coping Effectiveness in Patients Awaiting a Heart Transplant." Nursing Research 56(4): 260-268.	Focus on predictors
	Johnson, M., et al. (2012). "Professional identity and nursing: Contemporary theoretical developments and future research challenges." International Nursing Review 59(4): 562-569.	Focus on professional identity
	Johnson, M. E., et al. (2007). "Measuring spiritual quality of life in patients with cancer." Journal of Supportive Oncology 5(9): 437-442.	Focus on spiritual domain
	Julkunen, J. and R. Ahlstrom (2006). "Hostility, Anger, and Sense of Coherence As Predictors of Heath-Related Quality of Life. Results of an ASCOT Substudy." Journal of Psychosomatic Research 61(1): 33-39.	Focus on predictors
	Kaasa, S. and J. H. Loge (2003). "Quality of life in palliative care: principles and practice." Palliative Medicine 17(1): 11-20.	Focus on principles and practice
	Kemmler, G., et al. (2010) A new approach to combining clinical relevance and statistical significance for evaluation of quality of life changes in the individual patient. Journal of Clinical Epidemiology 63, 171-179	Clinical relevance
	kritsonis, a. (2005). "comparison of change theories." International journal of scholarly academic intellectual diversity 8(1): 3-7.	Focus on change theory
	Krueger, J. I., et al. (2013). "Comparisons in research and reasoning: Toward an integrative theory of social induction." New Ideas in Psychology 31(2): 73-86.	No abstracts
	Lach, L. M., et al. (2006). "Health-related quality of life in youth with epilepsy: Theoretical framework for clinicians and researchers. Part I: The role of epilepsy and co-morbidity." Quality of Life Research 15(7): 1161-1171.	Focus on youth population
	Lambiri, D., et al. (2007). "Quality of Life in the Economic and Urban Economic Literature." Social Indicators Research 84(1): 1-25.	Focus on economic literature
	Lang, H.-C., et al. (2012). "Quality Of Life, Treatments, and Patients' Willingness to Pay for a Complete Remission of Cervical Cancer in Taiwan." Health Economics 21(10): 1217-1233.	Focus on payment preferences
	La-Placa, V., et al. (2003). "Defining and using quality of life: a survey of health care professionals." Clinical Rehabilitation 17(8): 865-870.	Focus on health care professionals
	Lasseter, J. A. (2009). "Chronic Fatigue: Tired of Being Tired." Home Health Care Management & Practice 22(1): 10-15.	Focus on chronic fatigue
	Lemmens, K. M. M., et al. (2008). "Designing patient-related interventions in COPD care: Empirical test of a theoretical framework." Patient Education and Counseling 72(2): 223-231.	Focus on interventions
	Leung, K.-f., et al. (2005). "Development and validation of the Chinese Quality of Life Instrument." Health And Quality Of Life Outcomes 3: 26-26.	Methodological study
	Lindelöf, N., et al. (2012). "Experiences of a high-intensity functional exercise programme among older people dependent in activities of daily living." Physiotherapy Theory and Practice 28(4): 307-316.	Focus on exercise programme
	Lopez, E. D. S., et al. (2005). "Quality-of-Life Concerns of African American Breast Cancer Survivors Within Rural North Carolina: Blending the Techniques of Photovoice and Grounded Theory." Qualitative Health Research 15(1): 99-115.	Describe the blended photo voice method
	Mandhouj, O., et al. (2012). "French-language version of the World Health Organization quality of life spirituality, religiousness and personal beliefs instrument." Health And Quality Of Life Outcomes 10: 39-39.	Non-English language

	Mann, M., et al. (1986). "OASIS: a new concept for promoting the quality of life for older adults." American Journal of Occupational Therapy 40(Nov 86): 784-786.	Describes a programme located in stores for older people
	Mary, D.-W. (2011). "Using framework-based synthesis for conducting reviews of qualitative studies." BMC Medicine: 39.	Focus on conducting reviews
	Mehrez, A. and A. Gafni (1990). "Evaluating health related quality of life: an indifference curve interpretation for the time trade-off technique." Social Science and Medicine 31(1990): 1281-1283.	Focus on trade-off technique
	Mellon, L., et al. (2013). "Factors influencing adherence among Irish haemodialysis patients." Patient Education and Counseling 92(1): 88-93.	Focus on HD influencing technique
	Mitchell, G. J. (1990). "The lived experience of taking life day-by-day in later life: research guided by Parse's emergent method." Nursing Science Quarterly 3(1): 29-36.	Focus on lived experience in later life
	Montpetit, M. A., et al. (2006). "Adaptive change in self-concept and well-being during conjugal loss in later life." International Journal of Aging & Human Development 63(3): 217-239.	Focus on self-concept on conjugal loss
	Moreira-Almeida, A. and H. G. Koenig (2006). "Retaining the Meaning of the Words Religiousness and Spirituality: A Commentary on the WHOQOL SRPB Group's "A Cross-Cultural Study of Spirituality, Religion, and Personal Beliefs As Components of Quality of Life" (62: 6, 2005, 1486-1497)." Social Science & Medicine 63(4): 843-845.	A commentary paper
	Mullaney, A. and G. Pinfield (1996). "No indication of quality or equity." Town and Country Planning 65(5): 132-133.	Focus on equity
	Mystakidou, K., et al. (1999). "Quality of life as a parameter determining therapeutic choices in cancer care in a Greek sample." Palliative Medicine 13(5): 385-392.	Focus on therapeutic choices
	Noll, H. H. (2002). "Towards a European system of social indicators: theoretical framework and system architecture." Social Indicators Research 58(1-3): 47-87.	Focus on European system of social indicators
	O'Connell, K. A. and S. M. Skevington (2010). "Spiritual, religious, and personal beliefs are important and distinctive to assessing quality of life in health: A comparison of theoretical frameworks." British Journal of Health Psychology 15(4): 729-748.	Theoretical comparison
	Painter, P., et al. (2012). "Effects of modality change on health-related quality of life." Hemodialysis International. International Symposium On Home Hemodialysis 16(3): 377-386.	Focus on dialysis modality change on HRQOl
	Pastrana, T., et al. (2008). "A matter of definition - key elements identified in a discourse analysis of definitions of palliative care." Palliative Medicine 22(3): 222-232.	Focus on palliative care
	Paterson, B. L., et al. (2001). "Critical analysis of self-care decision making in chronic illness." Journal of Advanced Nursing 35(3): 335-341.	Focus on self-care decision making
	Patrick, D., et al. (2005) Meta-analyses and systematic reviews of quality of life outcomes: preliminary results and work in progress [abstract]. XIII Cochrane Colloquium; 2005 Oct 22-26; Melbourne, Australia 127	On-going study
	Perlman, R. L., et al. (2005). "Quality of life in chronic kidney disease (CKD): a cross-sectional analysis in the Renal Research Institute-CKD study." American Journal Of Kidney Diseases: The Official Journal Of The National Kidney Foundation 45(4): 658-666.	Comparison study between dialysis treatment
	Peruniak, G. S. (2008). "The Promise of Quality of Life." Journal of Employment Counseling 45(2): 50-60.	General paper
	Portillo, M. C. (2009). "Understanding the practical and theoretical development of social rehabilitation through action research." Journal of Clinical Nursing 18(2): 234-245.	No sufficient information
	Read, J. L., et al. (1987) Measuring overall health: an evaluation of three important approaches. Journal of Chronic Diseases 40, 7s-26s	General review paper

	Reininghaus, U. and S. Priebe (2012). "Measuring patient-reported outcomes in psychosis: conceptual and methodological review." The British Journal of Psychiatry 201(4): 262-267.	Focus on outcome in psychosis
	Roberts, J. A. and A. Clement (2007). "Materialism And Satisfaction With Over-All Quality Of Life And Eight Life Domains." Social Indicators Research 82(1): 79-92.	Focus on materialism and satisfaction
	Royuela, V. and J. Surinach (2005). "Constituents of Quality of Life and Urban Size." Social Indicators Research 74(3): 549-572.	Focus on urban size
	Sartorius, N. (1995). "Rehabilitation and quality of life." International Journal of Mental Health 24(1): 7-13.	Focus on rehabilitation
	Schunemann, H. J., et al. (2006) Interpreting the results of patient reported outcome measures in clinical trials: the clinician's perspective. Health And Quality Of Life Outcomes 4, 62	Focus on interpreting patient’s report
	Senzon, S. A. (1999). "Causation related to self-organization and health related quality of life expression based on the vertebral subluxation framework, the philosophy of chiropractic, and the new biology." Journal of Vertebral Subluxation Research (JVSR) 3(3): 1-9.	Focus on causation related to self-organisation
	Shaw, C., et al. (2008). "How people decide to seek health care: A qualitative study." International Journal of Nursing Studies 45(10): 1516-524.	Focus on service use
	Siegrist, J. (2001). "Stress, ageing and quality of life." European Review 9(4): 487-499.	Focus on stress and aging
	Sirgy, M. J. (1998). "Materialism and quality of life." Social Indicators Research 43(3): 227-260.	Focus on materialism
	Stuifbergen, A. K., et al. (1990). "Perceptions of health among adults with disabilities." Health Values: The Journal of Health Behavior, Education & Promotion 14(2): 18-26.	Focus on health perception among disabilities
	Suh, E. E. (2004). "The framework of cultural competence through an evolutionary concept analysis." Journal of Transcultural Nursing 15(2): 93-102.	Discussion paper
	Tayeb, M. A., et al. (2010). "A "good death": perspectives of Muslim patients health care providers." Annals of Saudi Medicine 30(3): 215-221.	Focus on good death
	Taylor, C. L. C., et al. (2007). "A social comparison theory analysis of group composition and efficacy of cancer support group programs." Social Science & Medicine 65(2): 262-273.	Focus on support group programme
	Thomé, B., et al. (2003). "Home care with regard to definition, care recipients, content and outcome: systematic literature review." Journal of Clinical Nursing 12(6): 860-872.	Focus on definition of home care
	Twycross, R. G. (1987). "Quality before quantity - a note of caution." Palliative Medicine 1(1): 65-72.	Focus on the aim of medicine from the cradle to grave
	Walker, H., et al. (2012). "Are they worth it? A systematic review of QOL instruments for use with mentally disordered offenders who have a diagnosis of psychosis." British Journal of Forensic Practice 14(4): 252-268.	Focus on instrument specific to mental disorders
	Wan, C., et al. (2011). "Development and Validation of the General Module of the System of Quality of Life Instruments for Chronic Diseases and Its Comparison with SF-36." Journal of Pain and Symptom Management 42(1): 93-104.	Methodological study/review two
	Wasserman, L. I., et al. (2002). "Concepts of rehabilitation and quality of life: their continuity and differences in modern approaches." International Journal of Mental Health 31(1): 24-37.	Focus on rehabilitation concept in modern approach
	Weinert, C., et al. (2008). "Evolution of a Conceptual Framework for Adaptation to Chronic Illness." Journal of Nursing Scholarship 40(4): 364-372.	Focus on evaluation of conceptual framework
	Wiesmann, U., et al. (2008). "Dimensions and profiles of the generalized health-related self-concept." British Journal of Health	Focused on self-concept

	Psychology 13(Pt 4): 755-771.	
	Wood, A. M., et al. (2010). "Gratitude and well-being: A review and theoretical integration." Clinical Psychology Review 30(7): 890-905.	Focus on gratitude.
	Yin, M. S. (2013). "Fifteen years of grey system theory research: A historical review and bibliometric analysis." Expert Systems with Applications 40(7): 2767-2775.	Discussion paper
	Young, Y., et al. (2009). "Can successful aging and chronic illness coexist in the same individual? A multidimensional concept of successful aging." Journal of the American Medical Directors Association 10(2): 87-92.	Focus on aging concept

Appendix 2.2 Critical Appraisal Checklist for Discussion Papers of Review-1: Discussion articles. (adopted from JBI)

Author	**Criteria**						
	Yes = ✓ No = × Unclear = UN	Yes = ✓ No = × Unclear = UN	Yes = ✓ No = × Unclear = UN	Yes = ✓ No = × Unclear = UN	Yes = ✓ No = × Unclear = UN	Yes = ✓ No = × Unclear = UN	Yes = ✓ No = × Unclear = U
	Is the source of opinion/discussion clearly identified?	Does the source of the discussion/ opinion have standing in the field of expertise?	Are the interests of patients/clients the central focus of the opinion?	Is the discussion/ opinion's basis in logic/experience clearly argued?	Is the argument developed analytical?	Is there reference to the extant literature/ evidence and any incongruence with it logically defended?	Is the discussion/ opinion supported b peers?
Anderson & Burckhardt (1998)	✓	✓	✓	✓	✓	✓	✓
Camfield & Skevington (2013)	✓	✓	✓	✓	✓	✓	✓
Carr & Higginson (2001)	✓	✓	✓	✓	✓	✓	✓
Carr et al (2001)	✓	UN	✓	✓	✓	✓	UN
Chung et al (1997)	✓	✓	✓	✓	✓	✓	×
Cohen & Kimmet (2013)	✓	✓	✓	✓	✓	✓	✓
Dijkers M (2006)	✓	✓	✓	✓	✓	✓	✓
Downie R (2000)	✓	✓	✓	✓	✓	✓	✓
Farquhar M (1994)	✓	✓	✓	✓	✓	✓	✓
Felce (1997)	✓	✓	✓	✓	✓	✓	UN

George & Bearon (1980)	✓	✓	UN	✓	✓	✓	✓
Gill T (1995)	✓	✓	✓	✓	✓	✓	×
Gladis et al (1999)	✓	✓	UN	✓	✓	✓	✓
Gokal et al (1999)	✓	✓	✓	✓	✓	✓	✓
Hagerty M (1998)	✓	✓	✓	✓	✓	✓	✓
Hass B (1999)	✓	✓	✓	✓	✓	✓	UN
Hass et al (1999)	✓	✓	UN	✓	✓	✓	×
Hendry & McVittie (2004)	✓	✓	✓	✓	✓	✓	✓
Holmes S (2005)	✓	✓	✓	✓	✓	✓	✓
Koller et al (2005)	✓	UN	✓	✓	✓	✓	×
Meeberg (1992)	✓	✓	UN	✓	✓	✓	UN
Moons et al (2006)	✓	✓	✓	✓	✓	✓	✓
Muldoon et al (1998)	✓	✓	✓	✓	✓	✓	×
Ravenek et al (2013)	✓	✓	✓	✓	✓	✓	✓
Rebollo & Ortega (2002)	✓	✓	✓	✓	✓	✓	✓
Schalok R (2004)	✓	✓	✓	✓	✓	✓	UN
Smith A (2000)	✓	✓	✓	✓	✓	✓	UN
Tienery et al (2007)	✓	✓	✓	✓	✓	✓	✓
Ventegot et al (2003)	✓	✓	✓	✓	✓	✓	✓
Vitterso J (2003)	✓	✓	UN	✓	✓	✓	UN
Zhan L (1991)	✓	✓	✓	✓	✓	✓	✓

Appendix 2.3. A summary of the empirical studies results of Review-1.

Author	**country**	**Methodology**			**Results**
		Design/sampling method	**Size and characteristics of sample**	**Measure**	
Abdel-Kader et al (2009)	USA	Cross-sectional design	151 patients undergoing peritoneal or haemodialysis.	SEiQOL-DW	Family and health were the most common domain for patients. No significant differences in SEiQOL-DW scores between subgroups. SEiQOL-DW scores correlated mental wellbeing (r= -.22, p <0.010).
Bailey et al (2007)	USA	Cross-sectional	332 psychology and business students from Baylor University	Trait Hope Scale, and Quality of life Inventory (QOLI)	The internal reliabilities of both scales were above 0.70. Alphas for the scales were: Hope scale= 0.79 and QOLI= 0.73.
Fagerlind et al (2009)	Sweden	A phenomenograpic Qualitative design	Semi structured interviews of 22 patients with rheumatoid arthritis	Interviews analysed by using QSR NUD*IST VIVO	Two concepts ‘being health’ and ‘being able to function normally’ overlapped with respondents understanding of QoL.
Garratt et al (1993)	UK	Observational study, postal questionnaire to check if SF-36 is a	1700 patients with one of four conditions (low back pain,	SF-36	The SF-36 satisfied rigorous psychometric

		suitable measure for routine use within the NHS.	menorrhagia, suspected peptic ulcer, varicose veins)		criteria for validity and internal consistency. Internal consistency (0.55-0.78) Validity (factor analysis identified 5 relevant factors with eigenvalues 12.8 to 1.3
Huber et al (2010)	USA	Cross-sectional design	278 women with HIV disease	Chronic Illness Quality of Life Ladder (CIQOLL)	All internal consistency alpha coefficients were (0.91-0.95). Inter-item correlations (r=0.30-0.70).
Kerthong et al (2008)	Thailand	Cross-sectional design	A stratified four-stage random sampling of 422 heart-failure patients	Enhancing Recovery in Coronary Heart Disease Social Support Instrument; Cardiac Symptom Survey; the New York Heart Association functional classification system; and a 100-mm horizontal visual	Wilson and Cleary's HRQoL fit well with the empirical data (X2=19.87, df=13, p=0.10, GFI=0.99, and RMSEA=0.04). Symptom status was the most influential factor affecting HRQoL and social support was the least influential factor affecting HRQoL.

				analogue scale of GHP.	
Kurpas et al (2012)	Poland	Cross-sectional design	131 advanced age patients with chronically ill primary care	WHOQoL-bref	Highest score was on social relationship (M= 12.38 ± 2.75) and lowest was in the psychological domain (M= 12.38 ± 2.66)
Murphy H & Murphy E (2006)	UK	Comparative observational study	104 participants 52 mental health service users 20 general population	WHOQOL-100	Significant differences between the two groups in 4 domains of the WHOQoL (independence and social relationships $t=12.150$, $p<0.001$ and $t=7.252$, $p<0.001$)
O’Boyle et al (1992)	Ireland	Prospective study (6 months)	20 patients undergoing unilateral hip-replacement	SEiQOL	Health status significantly improved by hip replacement ($p<0.001$)
Prince P & Gerber G (2001)	Canada	Qualitative study	Convenience sample of 36 patients serious mental illness	SEiQOL-DW	The SEiQOL-DW well accepted measure. The SEiQOL-DW global index (69.04, SD=24.58) was correlated with the satisfaction with life scale (SWLS) (20.97, SD= 8.33).
Rao et al (2008)	USA	Cross-sectional design	898	Functional assessment of cancer therapy-general (FACT-G)	Subscale scores: Physical wellbeing: $p<0.001$ Social wellbeing: $p<0.001$

					Emotional wellbeing: p<0.001
Rudolf & Priebe (1999)	German	Longitudinal study. Interview within the first three weeks of admission	185 women (42 women with depression, 70 women with alcoholism, 73 women with Schizophrenia)	SQOL	Depressive women after admission express low SQOL ((sub-scale: anxiety/depression [r:-.40, p<0.05], activation [r:-.40, p<0.05], thought disorder [r: -.46, p<0.01]
Saban et al (2007)	USA	Longitudinal one-group Pilot study	57 patients undergoing elective lumber spinal surgery	SF-36	HRQoL significantly improved postoperatively (t[56] = 6.45, p<.01).
Seongkum et al (2008)	Canada	Qualitative design	Convenience sample of 20 patients	Interviews guided by a set of questions to standardise the content of interview	Patient's definition of QoL their active pursuit of happiness and relationships with others. Patient's self-evaluation of QoL reflected their adopted perception to their changed clinical condition and their positive outlook.
Soaban et al (2008)	USA	Prospective observational study	322 veterans receiving HD	SF-6D KDCS	The SF-6D correlated .911 (p<.05), indicating 83% of the variance in the 7-subscales of KDCS measure.
Souse K & Kwok O (2006)	USA	Cross-sectional	917 HIV patients	AIDS-specific symptoms scale	The range of correlations (n=917) for the composites of each

					domain were: symptom status, 0.27-0.56; functional health, 0.77-0.97; general health perception, 0.81; and overall QoL, 0.70.
Souse K & Williamson A (2003)	USA	Longitudinal design (3 years)	99 patients were presenting to the emergency department	SF-36	Symptom status is a key predictor of HRQoL. The baseline symptom status contributed 20.2% (p=0.001) of the variance explained the baseline physical score, and symptom status at follow-up 23.2% (p= 0.001). symptom status explained the variance in baseline and follow-up mental scores (9.8%, p= 0.001 and 29.2%, p= 0.001)
Soyupek et al (2010)	Turkey	Cross-sectional design	40 patients	Quality of Life Inventory (QOLI)	Self-concept and QoL of these patients were lower (p<0.001).
Sprangers et al (2002)	Netherland	Cross-sectional design	217 consecutive cancer patients in the acute phase of their illness vs 192 disease free cancer patients	Activities of Daily Living Scale	Patient with cancer reported poorer QoL (p<0.001).

Staniszewska et al (1999)	UK	Qualitative study	25 ethnic group (15 Indian patients and 10 white patients)	SF-36	No differences identified between the two groups.
Staniszewska S (1999)	UK	Qualitative study	Semi-structured interviews for 33 cardiac patients to explore the possibility of extending the evaluation of health by patient's expectation concept.	SF-36	Comparison of the content of patient expectations with the SF-36 found some overlap but indicated that patients seemed to adopt a broader approach to their health (internal consistency (0.82 and 0.88)
Tavernier et al (2011)	USA	Qualitative design	Cognitive interviewing to explore patients with cancer understanding of PGI (7 men and 8 women)	PGI	Interview data supported the content validity of the PGI in comprehensively defining and adequately sampling participant HRQoL as an individualised construct.
Tokuda et al (2009)	Japan	Cohort study design	3344 participants (53% women; median ager 35 years)	SF- 36	One factor was retained (eigenvalue, 4.65; variance proportion f0.58). All item response category characteristic curves satisfied the monotonicity assumption in accurate order with corresponding ordinal responses.

Unruh et al (2003)	USA	Comparative study : self-administered vs interviewer-administered surveys in HD patients	978 HD patients: N= 427 interview survey N= 551 self-administered	KDQOL-SF	The interviewer group: had higher scores on sales that measured role-physical, role-emotional and effects of kidney disease (p<0.001).
Verdugo et al (2012)	Spain	Analyses of the relationship between eight core QoL domains and 34 articles contained in the Convection. (The concept of QoL and its role in enhancing human rights of persons with intellectual disability)	-	-	There is a close relationship between the core QoL domains (independence, social interaction, and wellbeing) and the 34 articles contained in the Convection. Three strategies can be used to enhance human rights of persons with intellectual disability: employ person-centred planning, publish provider profiles and implement as system of support.
Wu. A et al (2004)	USA	Prospective cohort study	Baseline: 698 HD 230 PD I year: 452 HD 133 PD	SF-36	Better HRQoL for PD patients (bodily pain, travel, diet restriction, and dialysis access [p<0.05]). At 1 year, SF-36 scores improved. HD patients had greater improvement in domains (physical

					functioning and general health perception).
Zadeh K & Unruh M (2005)	USA	Cohort study	10,030 dialysis patients	KDQOL-SF	Patients in the lowest quintile of physical score, the adjusted relative risk (RR) of death was 93% higher (RR= 1.93, p<0.001) and the risk of hospitalisation was 56% higher (RR= 1056, p<0.001).

Appendix 2.4. Results of the articles analysed QoL concept (Review-1)

Author (year)	Category	Purpose and Context	Participant Characteristics (if any)	Main Findings and Limitations
(Meeberg 1993)	A concept analysis paper	**Purpose:** to clarify the concept of QoL for further use. **Context:** Health care **Setting: -** **Country:** Canada	-	○ A clarified definition of QoL is proposed, as "QoL is a feeling of overall life satisfaction, as determined by the mentally alert individual whose life is being evaluated". ○ Individual's living conditions should meet their basic life needs. ○ QoL both subjective and objective components
(Man Cheung, Killingworth et al. 1997)	A concept analysis paper	**Purpose:** to examine briefly the concept of QoL by using some philosophical thoughts, particularly those from Ludwig Wittgenstein (1889-1951). **Context:** Health care **Setting: -** **Country:** UK	-	○ Authors believe that QoL concept is humanly-made arbitrary products. ○ Health care researchers should remain critical about the usage of QoL concepts and keep re-examining them. This study look at such topic with new perspectives which generate new insights. ○ Philosophy has a role to play in understanding some issues in health care research.
(Haas 1999)	A concept analysis paper	**Purpose:** to analyse how the concept of QoL is currently being defined and used within health care. **Context:** health care **Setting: -** **Country:** USA	-	○ The analysis supports the theorists who advocate QoL's comprising subjective and objective indicators. ○ Future efforts are required in developing an understanding of QoL to be directed towards two major areas: (a) the concepts of QoL must be further refined and opposing conceptual perspectives must be resolved; (b) the differentiation of QoL from closely related concepts such as well-being, life satisfaction, functional status and health status.

(Dupuis, Le May et al. 2003)	Systematic review paper	**Purpose:** (a) to identify the most frequently used HRQoL models and (b) critique those models **Context:** health care **Setting: -** **Country:** USA	-	○ The most frequently used HRQoL models were: Wilson and Cleary (16%), Ferrans and Colleagues (4%), or WHO (5%). Ferrans and colleague's model was a revision of Wilson and Cleary's model and appeared to have the greatest potential to guide future HRQoL research and practice. ○ Search strategy were limited to selected databases (PubMed, MEDLINE, CINAHL and PsychINFO) and limited time of 10 years. ○ Most of analysed articles were descriptive, correlational or literature reviews.
(Schalock 2004)	A discussion paper	**Purpose:** to summarise the current understanding of the construct of individual QoL (as spate from family or health related) as it pertains to persons with intellectual disabilities. **Context:** health care **Setting: -** **Country:** USA	-	○ Currently, QoL is an important concept in service delivery principle, along with its current use and multidimensional nature. QoL researchers beginning to understand the importance of methodological pluralism in the assessment of QoL, the multiple uses of quality indicators, the predictors of assessed QoL, the effects of different data collection strategies and the etic (universal) and Emic (culture-bound) properties of the construct. Yet to understand fully the use of QoL-related outcomes in programme change, how to best evaluate the outcomes of QoL-related services.
(Moons, Budts et al. 2006)	A discussion paper	**Purpose:** to present an overview and critique of different conceptualisation of QoL, with the ultimate goal of making QoL a less ambiguous concept. **Context:** health care **Setting: -** **Country:** Belgium	-	○ Defining QoL in terms of life satisfaction is most appropriate because this definition successfully deals with all the conceptual problems discussed within this paper. ○ It is recommended that researchers and theorists can initiate conceptual debates with the aim of making QoL a less ambiguous concept.

(Camfield and Skevington 2008)	Literature review paper	**Purpose:** to review literatures that could improve understanding about the relationship between conceptualisations of QoL and subjective well-being. **Context:** health psychology **Setting: -** **Country:** UK	-	○ The definition of subjective well-being derived by an expert panel displays high convergence with an international definition of QoL. ○ Cross-cultural evidence showed that subjective well-being and QoL contained a substantial component of life satisfaction. ○ Increased material resources (objective factors) do not directly lead to improvements in subjective well-being, however might influence some of subjective factors. ○ Social capital acts as a buffer to poor QoL and subjective well-being in poorer communities.
(Murphy and Murphy 2006)		**Purpose:** to compare QoL in individuals with server mental illness against a sample of the general population and to investigate the role of self-esteem, self-efficacy and social functioning. **Context:** mental health		○ Significant differences found between clinical and non-clinical groups in four domains of the QHOQOL-100 and in a majority of the aspects within domains. ○ Participants with mental illness have similar need to a normal population in terms of social support and social networks. ○ Some key variance exist between the samples in terms of age, employment, marital status and education.

Appendix 3.1. Excluded articles with reasons (Review 2)

Study title	Reasons for exclusion
1. Auslander, G. K., et al. (2003). "Quality of life of patients with end-stage renal disease at various stages of the illness." Social Work in Health Care 38(2): 1-27.	Not related to ESRD
1. Auzac, C. D., et al. (2004). "Do health causal attributions and coping strategies act as moderators of quality of life in peritoneal dialysis patients?" Journal of Psychosomatic Research 55(3): 317-322.	Focuses on HD
2. Avramovic, M. and V. Stefanovic (2012). "Health-Related Quality of Life in Different Stages of Renal Failure." Artificial Organs 36(7): 581-589.	Discussion paper
3. Bayoumi, M. R. N. P. and Y. El-Fouly (2010). "EFFECTS OF TEACHING PROGRAMME ON QUALITY OF LIFE FOR PATIENTS WITH END-STAGE RENAL DISEASE." Journal of Renal Care 36(2): 96-101.	Not related to HD
4. Bilgic, A., et al. (2011). "Daytime Sleepiness and Quality of Life in Peritoneal Dialysis Patients." Therapeutic Apheresis and Dialysis 15(6): 565-571.	Focuses on PD
5. Boateng, E. A. R. G. N. B. M. and L. R. N. B. M. P. East (2011). "THE IMPACT OF DIALYSIS MODALITY ON QUALITY OF LIFE: A SYSTEMATIC REVIEW." Journal of Renal Care 37(4): 190-200.	Systematic review
6. Callahan, M. B., et al. (1999). "A model for patient participation in quality of life measurement to improve rehabilitation outcomes." Nephrology news & issues 13(1): 33-37.	Discussion paper
7. Chan, R., et al. (2011). "Studying psychosocial adaptation to end-stage renal disease: The proximaladistal model of health-related outcomes as a base model." Journal of Psychosomatic Research 70(5): 455-464.	Focuses on PD
8. Chilcot, J. (2012). "The Importance of Illness Perception in End-Stage Renal Disease: Associations with Psychosocial and Clinical Outcomes." Seminars in Dialysis 25(1): 59-64.	Seminar paper
9. Cohen, S. D. (2013). "Social Support Interventions will improve the Quality of Life of ESRD Patients." Seminars in Dialysis 26(3): 262-265.	Seminar paper
10. Cohen, S. D. and P. L. Kimmel (2013). "Quality of Life and Mental Health Related to Timing, Frequency and Dose of Hemodialysis." Seminars in Dialysis 26(6): 697-701.	Seminar paper
11. Cukor, D., et al. (2013). "Anxiety and Quality of Life in ESRD." Seminars in Dialysis 26(3): 265-268.	Seminar paper
12. Danquah, F. V. N. P. R. N., et al. (2010). "Quality of Life Measures for Patients On Hemodialysis: A Review of Psychometric Properties." Nephrology Nursing Journal May/June 37(3): 255-269.	Review paper

13. de Jonge, P., et al. (2003). "A simple risk score predicts poor quality of life and non-survival at 1 year follow-up in dialysis patients." Nephrology Dialysis Transplantation 18(12): 2622-2628. 14.	No abstract
15. Devine, E. B. P. M. B. A., et al. (2003). "Health-related quality of life assessment in chronic kidney disease." Expert Review of Pharmacoeconomics & Outcomes Research 3(1): 89-100.	No abstract
16. Diaz-Buxo, J. A., et al. (2000). "Quality-of-life evaluation using Short Form 36: comparison in hemodialysis and peritoneal dialysis patients." American Journal Of Kidney Diseases: The Official Journal Of The National Kidney Foundation 35(2): 293-300.	No abstract
17. Finkelstein, F. O., et al. (2002). "The treatment of depression in patients maintained on dialysis." Journal of Psychosomatic Research 53(4): 957-960.	Discussion paper
18. Fryback, D. G., et al. (2010). "Comparison of 5 health-related quality-of-life indexes using item response theory analysis." Medical Decision Making: An International Journal Of The Society For Medical Decision Making 30(1): 5-15.	Not related to HD
19. Fu, A. Z. and M. W. Kattan (2006). "Racial and ethnic differences in preference-based health status measure." Current Medical Research And Opinion 22(12): 2439-2448.	Not related to HD
20. Glover, C., et al. (2011). "Understanding and assessing the impact of end-stage renal disease on quality of life: A systematic review of the content validity of self-administered instruments used to assess health-related quality of life in end-stage renal disease." The Patient: Patient-Centered Outcomes Research 4(1): 19-30.	Systematic review
21. Gokal, R., et al. (1999). "Outcomes in peritoneal dialysis and haemodialysis-a comparative assessment of survival and quality of life." Nephrology Dialysis Transplantation Healthcare Systems: An International Review 14 Supplement(6): 24-30.	No abstract
22. Griva, K., et al. (2012). "The impact of treatment transitions between dialysis and transplantation on illness cognitions and quality of life -- A prospective study." British Journal of Health Psychology 17(4): 812-827.	Focuses on transplantation
23. Gudex, C. M. (1995). "Health-related quality of life in endstage renal failure." Quality Of Life Research: An International Journal Of Quality Of Life Aspects Of Treatment, Care And Rehabilitation 4(4): 359-366.	Focuses on PD
24. Hansen, R. A. P. D. a., et al. (2009). "Predialysis chronic kidney disease: Evaluation of quality of life in clinic patients receiving comprehensive anemia care." Research In Social & Administrative Pharmacy 5(2): 143-153.	Not related to HD
25. Hawthorne, G., et al. (1999). "The Assessment of Quality of Life (AQoL) instrument: a psychometric measure of health-related quality of life." Quality Of Life Research: An International Journal Of Quality Of Life Aspects Of Treatment, Care And Rehabilitation 8(3): 209-224.	Discussion paper
26. Hays, R. D., et al. (2005). "Evaluating the statistical significance of health-related quality-of-life change in individual patients." Evaluation & The Health Professions 28(2): 160-171.	Not related to HD

27. Hsieh, R.-L., et al. (2007). "Quality of life and its correlates in ambulatory hemodialysis patients." Journal of Nephrology 20(6): 731-738.	No abstract
28. Hutchinson, T. A. (2005). "Transitions in the lives of patients with End Stage Renal Disease: a cause of suffering and an opportunity for healing." Palliative Medicine 19(4): 270-277.	Discussion paper
29. Jablonski, A. (2007). "The Multidimensional Characteristics of Symptoms Reported by Patients on Hemodialysis." Nephrology Nursing Journal January/February 34(1): 29-37.	Not related to QoL
30. Kalantar-Zadeh, K. and M. Unruh (2005). "Health related quality of life in patients with chronic kidney disease." International Urology and Nephrology 37(2): 367-378.	Not related to HD
31. Kinchen, K. S. and N. R. Powe (2001). "Measuring and Managing Health Outcomes and Quality of Care in End-Stage Renal Disease." Disease Management & Health Outcomes 9(9): 483-493.	No abstract
32. Kolewaski, C. D. M. B. O. T. O. T. R. M. C., et al. (2005). "Quality of life and exercise rehabilitation in end stage renal disease." CANNT Journal October/November/December 15(4): 22-29.	No abstract
33. Kring, D. L. and P. B. Crane (2009). "Factors Affecting Quality of Life In Persons on Haemodialysis." Nephrology Nursing Journal January/February 36(1): 15-24.	No abstract
34. Kusztal, M., et al. (2003). "[Evaluation of health-related quality of life in dialysis patients. Personal experience using questionnaire SF-36]." Polski Merkuriusz Lekarski 14(80): 113-117.	Non-English language
35. Kutner, N. G. and S. V. Jassal (2002). "Quality of Life and Rehabilitation of Elderly Dialysis Patients." Seminars in Dialysis 15(2): 107-112.	No abstract
36. Lausevic, M., et al. (2007). "Health-related Quality of Life in Patients on Peritoneal Dialysis in Serbia: Comparison with Hemodialysis." Artificial Organs 31(12): 901-910.	Focuses on PD
37. Leao, R., et al. (2010). "Sexual dysfunction in uraemic patients undergoing haemodialysis: predisposing and related conditions." Andrologia 42(3): 166-175. 38.	Not related to QoL
39. Lee, C. P., et al. (2009). "An Empiric Estimate of the Value of Life: Updating the Renal Dialysis Cost-Effectiveness Standard." Value in Health 12(1): 80-87.	Focuses on cost effectiveness
40. Li, I. C. and S.-F. Niu (2005). "Quality of life of patients having renal replacement therapy." Journal of Advanced Nursing 51(1): 15-21.	Not related to HD
41. Liem, Y. S. M. D. M., et al. (2008). "Preference-Based Quality of Life of Patients on Renal Replacement Therapy: A Systematic Review and Meta-Analysis." Value in Health July/August 11(4): 733-741	Systematic review
42. Lin, P.-F., et al. (2003). "Acupoints massage in improving the quality of sleep and quality of life in patients with end-stage renal disease." Journal of Advanced Nursing 42(2): 134-142	Not related to HD
43. Lindqvist, R. R. N. and P.-O. P. Sjoden (1998). "Coping strategies and quality of life among patients on continuous ambulatory peritoneal dialysis (CAPD)." Journal of Advanced Nursing 27(2): 312-319.	Focuses on PD

44. Lindqvist, R., et al. (2000). "Coping strategies and health-related quality of life among spouses of continuous ambulatory peritoneal dialysis, haemodialysis, and transplant patients." Journal of Advanced Nursing 31(6): 1398-1408.	Focuses on PD
45. Martin, C. R. and D. R. Thompson (2000). "Prediction of quality of life in patients with end-stage renal disease." British Journal of Health Psychology 5(1): 41-55	No abstract
46. Meers, C., et al. (1996). "Self-delivery of hemodialysis care: a therapy in itself." American Journal Of Kidney Diseases: The Official Journal Of The National Kidney Foundation 27(6): 844-847.	Review paper
47. Mozes, B. and E. Shabtai (1996). "The contribution of personal rating to the clinimetric functioning of a generic quality of life instrument." Journal of Clinical Epidemiology 49(12): 1419-1422.	Not related to HD
48. Murray, M. A., et al. (2009). "Review: A systematic review of factors influencing decision-making in adults living with chronic kidney disease." Patient Education and Counseling 76(2): 149-158.	Review paper
49. Naik, N., et al. (2012). "Measurement of Health-Related Quality of Life in the Care of Patients with ESRD: Isn’t This the Metric That Matters?" Seminars in Dialysis 25(4): 439-444.	Seminar paper
50. Pai, A. B., et al. (2009). "Health-related quality of life is maintained in hemodialysis patients receiving pharmaceutical care: A 2-year randomized, controlled study." Hemodialysis International 13(1): 72-79.	Related to pharmaceutical care
51. Painter, P., et al. (2012). "Effects of modality change on health-related quality of life." Hemodialysis International 16(3): 377-386	Focuses on modality changes
52. Patel, S. S. (2013). "Treating Pain to Improve Quality of Life in End-Stage Renal Disease." Seminars in Dialysis 26(3): 268-273.	No abstract
53. Rebollo, P., et al. (2000). "[Factors associated with health related quality of life in patients undergoing renal replacement therapy]." Nefrología: Publicación Oficial De La Sociedad Española Nefrologia 20(2): 171-181	Non-English language
54. Romney, D. M. and D. R. Evans (1996). "Toward a general model of health-related quality of life." Quality Of Life Research: An International Journal Of Quality Of Life Aspects Of Treatment, Care And Rehabilitation 5(2): 235-241.	Not related to HD
55. Santos, P. R. and L. R. Pontes (2007). "[Change in the level of quality of life in end-stage kidney patients during a 12 months follow-up]." Revista Da Associacao Medica Brasileira 53(4): 329-334.	Non-English language
56. Schell, J. O. a. b., et al. (2013). "Recent insights into life expectancy with and without dialysis." Current Opinion in Nephrology & Hypertension 22(2): 185-192.	No abstract

57. Schneider, R. A. (2004). "Chronic renal failure: assessing the fatigue severity scale for use among caregivers." Journal of Clinical Nursing 13(2): 219-225.	Focuses on caregivers
58. Shayamsunder, A. K., et al. (2005). "PSYCHOSOCIAL FACTORS IN PATIENTS WITH CHRONIC KIDNEY DISEASE: Sleepiness, Sleeplessness, and Pain in End-Stage Renal Disease: Distressing Symptoms for Patients." Seminars in Dialysis 18(2): 109-118.	Seminar paper
59. Son, Y.-J., et al. (2012). "Influence of Type D personality on health-related quality of life among Korean patients with end-stage renal disease." International Journal of Nursing Practice 18(3): 260-267.	Not related to HD
60. Symister, P. (2011). "Beyond social support: Using family expectations to predict psychological adjustment in end-stage renal disease patients." Journal of Health Psychology 16(7): 1015-1026.	Patients is not the focus
61. Tayeb, M. A., et al. (2010). "A "good death": perspectives of Muslim patients and health care providers." Annals of Saudi Medicine 30(3): 215-221.	Not related to HD
62. Taylor, C. L. C., et al. (2007). "A social comparison theory analysis of group composition and efficacy of cancer support group programs." Social Science & Medicine 65(2): 262-273.	Related to cancer
63. Terada, I. and C. Hyde (2002). "The SF-36: an instrument for measuring quality of life in ESRD patients." Edtna-Erca Journal 28(2): 73-76, 83.	Review paper
64. Tierney, D. K., et al. (2007). "Response shift: A theoretical exploration of quality of life following hematopoietic cell transplantation." Cancer Nursing 30(2): 125-138	Not related to HD
65. Tobita, I. and C. Hyde (2007). "QUALITY OF LIFE RESEARCH: A VALUABLE TOOL FOR NEPHROLOGY NURSES." Journal of Renal Care 33(1): 25-29.	No abstract
66. Tokuda, Y., et al. (2009). "Assessing Items on the SF-8 Japanese Version for Health-Related Quality of Life: A Psychometric Analysis Based on the Nominal Categories Model of Item Response Theory." Value in Health 12(4): 568-573.	Not related to HD
67. Twycross, R. G. (1987). "Quality before quantity - a note of caution." Palliative Medicine 1(1): 65-72.	Not related to HD

68. Verdugo, M. A., et al. (2012). "The concept of quality of life and its role in enhancing human rights in the field of intellectual disability." Journal of Intellectual Disability Research 56(11): 1036-1045.	Not related to HD
69. Vitterso, J. (2004). "Subjective well-being VERSUS self-actualization: using the flow-simplex to promote a conceptual clarification of subjective quality of life." Social Indicators Research 65(3): 299-331.	Not related to HD
70. Walker, H., et al. (2012). "Are they worth it? A systematic review of QOL instruments for use with mentally disordered offenders who have a diagnosis of psychosis." British Journal of Forensic Practice 14(4): 252-268.	Systematic review
71. Wan, C., et al. (2011). "Development and Validation of the General Module of the System of Quality of Life Instruments for Chronic Diseases and Its Comparison with SF-36." Journal of Pain and Symptom Management 42(1): 93-104.	Not related to HD
72. Wasserman, L. I., et al. (2002). "Concepts of rehabilitation and quality of life: their continuity and differences in modern approaches." International Journal of Mental Health 31(1): 24-37.	Not related to HD
73. Weinert, C., et al. (2008). "Evolution of a Conceptual Model for Adaptation to Chronic Illness." Journal of Nursing Scholarship 40(4): 364-372.	Not related to HD
74. White, C. and H. McDonnell (2014). "PSYCHOSOCIAL DISTRESS IN PATIENTS WITH END-STAGE KIDNEY DISEASE." Journal of Renal Care 40(1): 74-81.	Continuing Education (CE) series
75. Wiesmann, U., et al. (2008). "Dimensions and profiles of the generalized health-related self-concept." British Journal of Health Psychology 13(Pt 4): 755-771.	Not related to HD
76. Wood, A. M., et al. (2010). "Gratitude and well-being: A review and theoretical integration." Clinical Psychology Review 30(7): 890-905.	Not related to HD
77. Yamamoto-Mitani, N., et al. (2002). "Development of a Japanese quality of life instrument for older adults experiencing dementia (QLDJ)." International Journal of Aging and Human Development 55(1): 71-95.	Not related to HD

Appendix 3.2. Critical Appraisal Criteria Form (Review-2)

Study	Reporting				External validity (Generalisability)		Internal validity					
	Yes = ✓ No = × Unclear = UN				Yes = ✓ No = × Unclear = UN		Yes = ✓ No = × Unclear = UN					
	Clearly described the study aim, hypotheses or research questions	Clearly described the main outcome	Clearly described participants characteristics	Clearly described the key findings	Participants are representative of the entire population	Healthcare resources in setting or data collection representative of intervention that majority of patients receive	Used valid and reliable measurement	Used appropriate statistical data analysis	Recruited study and control from the same population	Used appropriate sampling method	Reported number and characteristics who lost during study	Reporter method of sample calculation
Abd Elhafeez et al (2012)	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓
Berlim et al (2006)	✓	UN	✓	✓	✓	✓	✓	✓	✓	UN	✓	UN
Bohlke et al (2008)	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓	✓
Bonner et al (2013)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Brekke et al (2014)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cheung et al (2012)	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	UN	✓

Cleary & Drennan (2004)	✓	✓	UN	✓	✓	✓	✓	✓	✓	UN	✓	✓
Davison et al (2010)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ferri & Pruchno et al (2009)	✓	UN	✓	✓	✓	✓	✓	✓	✓	✓	×	×
Fidan et al (2013)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×
Green et al(2001)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Griva et al (2009)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓
Hayashino et al (2009)	✓	✓	✓	✓	✓	UN	✓	✓	✓	✓	×	✓
Ibrahim et al (2011)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Jablonski A (2007)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Kao et al (2009)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Kovacs et al (2010)	✓	✓	✓	✓	UN	✓	✓	✓	✓	✓	UN	UN
Lee et al (2004)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓
Liu et al (2014)	✓	✓	UN	✓	✓	✓	✓	✓	✓	UN	UN	✓
Loos et al (2003)	✓	✓	✓	✓	✓	✓	✓	✓	✓	UN	✓	✓

Loos-Ayav et al (2007)	✓	✓	UN	✓	✓	✓	✓	✓	✓	✓	×	✓
Merkus et al (1999)	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓	✓
Morsch et al (2005	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	×
Morsch et al (2005)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	×
Mujais et al (2009)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	UN	UN
Nejad & Khani (2013)	✓	✓	UN	UN	✓	✓	✓	✓	✓	✓	UN	✓
Neto et al (2000)	✓	✓	UN	✓	✓	✓	✓	✓	✓	✓	×	✓
Oren & Enc (2012)	✓	✓	UN	✓	✓	✓	✓	✓	✓	✓	✓	×
Pakpour et al (2010)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	UN	✓
Poppe et al (2012)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	×
Rambod & Rafii (2001)	✓	✓	UN	✓	✓	✓	✓	✓	✓	✓	×	×
Ramirez et al (2012)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Rebollo et al (1998)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Saban et al (2008)	✓	✓	✓	✓	✓	UN	✓	✓	✓	✓	✓	✓
saffari et al (2013)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	UN	UN
Saini et al (2006)	✓	✓	×	✓	✓	✓	✓	✓	✓	UN	UN	✓
Santos S (2010)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	UN
Tovbin et al (2003)	✓	✓	✓	✓	✓	✓	✓	✓	UN	UN	✓	×
Tsai et al (2010)	✓	✓	✓	✓	✓	UN	✓	✓	✓	✓	✓	UN
Unruh et al (2002)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Unruh et al (2008)	✓	✓	✓	✓	✓	UN	✓	✓	✓	✓	✓	UN
Vasilieva I (2006)	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓	✓
Vazquez et al (2005)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	UN	✓
Yong et al (2009)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Appendix 3.3. Summary of Data Extraction of Review 2 (Adopted From JBI)

Author	**Country**	**Study aim**	**Methodology**			**Results**	**QoL & HRQoL Model used**	**Strength and Limitations**
			Study design/ population	**Sample size**	**Instrument**			
Abd ElHafeez et al (2012)	Egypt	Present an Arabic translation, adaptation and the subsequent validation of the Kidney Disease Quality of Life Questionnaire in Egyptian ESRD patients.	Cross-sectional design	100 patients with ESRD	KDQOL-SF	All items of the questionnaire met the criterion for internal consistency of α≥ 0.7. Three dimensions were < α0.7 (Social interaction [0.23], work status [0.23], and cognitive function [0.60].	-	Rigors translation process followed by validation stage with adequate sample size.
Neto et al (2000)	Brazil	Evaluate the construct validity of the SF-36 and to assess the QoL of patients with ESRD at the initiation of maintenance dialysis treatment	Cross-sectional design	80 ESRD patients at the initiation of dialysis treatment	SF-36	SF-36 dimensions correlated significantly with those of the kidney disease questionnaire (correlation coefficients ranging from 0.23 to 0.68.	-	Health status of ESRD patients changes rapidly at the stage of initiating dialysis. This could confound with the results.
Brekke et al (2014)	Norway	Examine the association between sleep quality, daytime sleepiness and mortality in dialysis patients.	Cross-sectional design	160 HD patients.	KDQOL-SF Pittsburgh Sleep Quality Index	Daytime sleepiness was not related to mortality (HR 1.01. CI 0.95-1.08, p= 0.751). Higher consumption of antidepressants reduce HRQoL (mental component summary: 45.4±11.0 vs 50.0± 10.4, p< 0.001. physical component	-	Principal study which attempted to examine the association between sleep quality and morality in HD patients. A chance for selection bias might exist because of the exclusion of fragile and hospitalised patients. Data on urea removal rate were scarce which might masked a

						summary score: 35.0±9.9 vs 38.5± 10.5, p= 0.004)		possible association between dialysis efficiency and QoL.
Cheung et al (2012)	Singapore	Examine the measurement properties of the Chines version of the KDQoL-SF in ethnic Chinese ESRD patients who live in Singapore.	Cross-sectional design.	78 Chines-speaking patients HD	KDQOL-SF	Majority of the scales in the Chinese version of the KDQOL-SF were valid and have achieved internal consistency reliability (alpha= 0.97), except for the ‘work status scale’ (alpha= 0.32).	-	Low sample size.
Cleary et al (2005)	Ireland	Measure the overall QoL of people receiving HD and compare their QoL with that of the general population and identify any differences between the QoL in relation to adequately dialysed and those inadequately dialysed.	Cross-sectional design	Non-probability sample of 97 patients	SF-36	Patients with HD have number of factors affecting their QoL: vitality score was the lowest (mean= 44.97, SD= 27.24). General health scale (mean= 50.87, SD= 26.96), physical functioning (mean= 53.40, SD= 27.23), role functioning-physical (mean= 54.19, SD= 32.15), role functioning-emotional (mean= 69.85, SD= 31.61).	-	Examined QoL among two sub-groups (adequately dialysed and inadequately dialysed) as dialysis might contribute significantly on improving patients QoL. The use of only one clinical site. Small sample size
Jamaiyah et al (2010)	Malaysia	Investigate the reliability and validity of EQ-5D in the Malaysian dialysis population	Cross-sectional, survey	686 dialysis patients	EQ-5D	Majority of patients reported no problems with their health in terms of mobility (82.42%), pain (64.53%), and anxiety (77.22%). EQ-5D was able to demonstrate moderate convergent validity between study population of 0.45 (p<0.05). Age groups vs mobility was	-	Large sample size. This study reported opposite effect in terms of the influence of age compared to other studies used EQ-5D, e.g. similar study in the UK found differences in anxiety among males vs females.

						found to be statistically significant at the p<0.05. Statistically significant difference was found comparing modality vs usual activity (p<0.05).		
Fidan et al (2013)	Turkey	Assess the HRQoL in patients with HD using KDQOL and determine its relationship with conventional clinical measures, musculoskeletal problems, hand disability and depression	Cross-sectional design	50 HD patients	KDQOL-SF Beck Depression Inventory (BDI)	Patients aged ≥ 65 had poorer KDQoL subgroups scores for physical component scale (p= 0.000), and for symptom list (p= 0.007). they also had poorer BDI scores (p< 0.05).	-	A primary study on physical functioning specific to hand disability and pain in HD patients Use of four relevant measures. Relatively small sample size .
Ferri & Pruchno (2009)	USA	Examine similarities and differences in spouse and patient ratings of the QoL of patients with ESRD	Prospective study design	315 couples	Quality of Life Index	HD patients and their spouses perceive QoL and predictors of patients QoL differently as spouses rated all patients QoL characteristics wore than patients did. The mean rating of QoL by the patients is significantly higher than mean rating by the spouse (baseline: *M* paitnet= 3.35, *M* spouse= 2.90, t (313)= 6.29, p<0.000; Follow-up: *M* paitnet= 3.30, *M* spouse= 2.98, t (202)= 3.37, p<0.001.	-	Provide a rational of why proxy ratings are consistently lower than patient rating. Use of signal-item to assess QoL.
Rebollo et al (1998)	Asturias	Assess HRQoL of elderly patients on renal replacement therapy and to identify socio-	Cross-sectional design	124 dialysis patients	SF-36	PF (47.8±25.6) RP (63.8±45.6) BP (66.6±31.6) GH (36.3±19.8) SF (80±25)	-	This study would be better if designed in longitudinal design especially if assessing clinical variables with ESRD patients, such anaemia.

		demographic and clinical variables that influence HRQoL				MH (76.4±88.6) HCT (30.1±5) g/dl (9.9±5)) Albumin (3.7±0.4)		
Green et al (2001)	Japan	Translation, cultural adaptation and initial reliability and multi-trait testing of the Kidney Disease Quality of Life Instrument (KDQOL)	Cross-sectional design into stage: focus-group and survey.	930 HD patients.	SF-36	SF-36 scales are internally consist and their scores are reproducible (Cronbach's α ranged from 0.73 to 0.92). Interclass correlation between test and retest scores ranged from 0.60 to 0.82.	-	A comparison of two QoL instruments used. The KDQOL instrument initially subjected to a focus group validation before field test. Focus-group: patients were asked only to state whether the items were difficult to understand. It would be more useful if they were asked to describe it by their own words what the questions meant.
Griva et al (2009)	UK	Assess the illness representation and treatment disruption beliefs of patients with ESRD and to determine whether beliefs about illness and treatment differ between different renal therapy; and whether these beliefs are associated with HRQoL.	Cross-sectional design.	262 ESRD patients.	ESRD-SI Illness perceptions questionnaire (IPQ) 36-SF	HD patients, in comparison with other renal replacement therapy, reported lower control beliefs and more illness and treatment disruptiveness which inversely associated with HRQoL. HRQOL scores was higher in transplant patients (p< .001), stronger chronic timeline beliefs (p< .001), lower control beliefs (p <.05)	-	It is the first empirical study that attempt to investigate the extended common sense model (CSM) in ESRD patients. The tight inclusion criteria that was applied to rule out potential confounders has affected results in terms of recruiting patients who are young and free of comorbid conditions.
Hayashino et al (2009)	Japan	Investigate the impact of HRQoL on mortality risk in patients with diabetes on HD.	Cross-sectional design	527 diabetic patients on HD.	SF-36	The mortality age-adjusted hazard ratio of having a physical component score greater than or equal to the median was 0.27 [95% confidence interval (CI) 0.08-0.96]. The multivariable-adjusted mortality hazard ratio of having mental component	-	Large sample of diabetes patients on HD.

						score greater than or equal to the median was 1.21 (95% CI 0.44-3.35).		
Poppe et al (2012)	Belgium	Investigate whether acceptance of the disease contributes in a better physical and mental HRQoL.	Cross-sectional design	155 dialysis patients	SF-36	Disease acceptance was positively correlated with MH QoL (r= 0.56, p< 0.01) and positively correlated with PH QoL (r= 0.45, p< 0.01). Neuroticism showed negative correlation with acceptance (r= -0.49, p< 0.01) and with MH QoL (r= -0.52, p< 0.01)	-	The sample size is relatively small and consisted nearly completely of Caucasians patients from a single region which might limit its results generalisability.
Kao et al (2009)	Taiwan	Examine the associations between economic, social, psychological factors, and HRQoL of HD patients.	Cross-sectional design	861 HD patients	Short Forum-36 Beck Depression Inventory (BDI)	High monthly income was positively associated with role emotional and mental health (p <0.05). Increased frequency of social activities with social functioning (p <0.05). Higher depression scores were associated with lower scores of all SF-36 dimensions (p <0.01)	Revised Wilson and Cleary HRQoL model	The presentation of the statistical parameters is comprehensive and clear. Patients who were too sick were excluded from study which might miss valuable information about this subgroup. Cross-sectional design which cannot differentiate the exact causal relationship between various factors and HRQoL.
Mujais et al (2009)	USA	Investigate the determinants of HRQoL in chronic kidney disease (CKD) patients.	A prospective design study	1189 patients with CKD	KDQoL-SF	Baseline measures of HRQoL were reduces in these patients. Physical functioning score declined progressively with more advance stage of CKD. Female gender and a history of cardiovascular co-morbidities were also associated with reduced HRQoL (PCS score: male: 41.0±10.2; female: 37.7±10.8; p< .001; diabetic: 41.6±10.2, p< .001; history of	-	Factors affecting completion of the questionnaire were not explored prospectively.

						congestive heart failure, yes: 35.4±9.7; no: 40.3±10.6; p< 0.0001; history of myocardial infraction, yes: 36.12±10.0; no: 40.2±10.6; p<0.0001). Albumin lower than 35g/l was associated with a significant decline in sexual function (albumin≤35 g/l= -8.48, albumin >35g/l= -0.8, p<0.05)		
Lee et al (2004)	Republic of Korea	Examined the putative association between the levels of HCT and improvement of cognitive function and QoL in ESRD patients	Comparative study	56 patients (group A-28) (group B-28)	SF-36 HCT level	Patients with higher HCT level scores better in the neurocognitive function test (p= .034). QoL was not any better than those with lower HCT level.	-	Underlying disease was not completely excluded. Medication could confound the result of the study particularly Iron supplements.
Bohlke et al (2008)	Brazil	Examine the predictors of HRQoL in a sample of patients undergoing dialysis in southern brazil.	Cross-sectional design	140 patients: 94 HD 46 PD	SF-36	The predictors of better physical component summary were; younger age (β-0.16; 95% confidence interval, CI: -0.27 to -0.05), shorter time on dialysis (β-0.06; 95% CI: -0.09 to -0.02). the predictors of higher mental component summery were: being married of having a marriage-like relationship (β4.56; 95% CI:0.9-8.2), being on PD (β4.9; 95% CI: 0.9-8.8) and not having BP (β3.9; 95% CI:0.3-7.6)	-	This study shows that most of the associations detected have also been described in pervious studies involving similar populations.
Liu et al (2013)	Malaysia	Evaluate the QoL among dialysis patients using WHOQOL-BREEF	Cross-sectional design	1332 ESRD patients	WHOQOL-BREEF (English-	PD patients achieve higher combined overall QoL that HD patients (63.0 vs 60.0, p< 0.001).	-	Sample size had adequate number of both HD & PD from various dialysis institutions.

		and examine significant factors that affect QoL scores.			Malay-Chinese)	Mean (SD) transformed QoL scores were 56.2 (physical 15.8), psychological 59.8 (16.8), social relations 58.2 (18.5), environmental domains 59.5 (14.6), and combined overall QoL 61.0 (18.5).		The use of three translations of WHOQOL-BREEF facilitated inclusion of ethnic origin. Participants from big urban dialysis centres with experienced staff and patients from rural areas usually have different socioeconomic-cultural profile. The WHOQOL-BREEF version does not explore issues related to spirituality or religiosity compared with the full version.
Loos et al (2003)	French	Assess the effect of ESRD on QoL of older patients	Cross-sectional design	169 (mean age 76.2) with ESRD	SF-36	Older patients undergoing HD have lower QoL scores. Physical functioning dimension had fewer points (p= .014).	-	Co-morbid diseases in older patient might affect overall QoL. The use of one measurement tool of QoL could be considered as limit in this study.
Loos-Ayav et al (2008)	French	Assess the changes of HRQoL during the first year of dialysis by comparing independent dialysis patient with patients on in-centre dialysis.	Cross-sectional design	In-centre dialysis patients: 195 pts in HD 147 Autonomous patients.	KDQOL-SF	Independent patients showed improved HRQoL when compared with in-centre dialysis patients. Several dimensions of HRQoL were significantly higher in autonomous pats (physical functioning [60.4 vs 50.7], work status [30.9 vs 18.4].	-	The age of independent patients were younger compared to the age of in-centre dialysis patients.
Morsch et al (2006)	Brazil	Examine the association between QoL and morbidity, mortality and clinical indicators in HD patients	Descriptive cohort design	40 HD patients followed for 12 months	SF-36	Men patients presented higher HRQoL scores in the energy and fatigue component (p=0.04). Patients treated for over one year (p<0.05). Patients with diabetes perceived their physical functioning more negatively (p= 0.045). a	-	Prospective design (40 patients followed for 12 months). Age factor was not measured as independent variable as it might associate with different diseases.

						correlation were found between physical functioning and serum albumin (r= 0.341, p<0.05) and physical functioning and haematocrit (r= 0.317, p<0.05).		
Oren (2013)	Turkey	Quality of life in chronic haemodialysis and peritoneal dialysis patients in Turkey and related factors	Cross-sectional deign	175 HD patients 125 PD patients	SF-36	The QoL values in PD is higher than those of HD (P< 0.05). Both groups affected by varies factors: significant relationship between age and functionality (p<0.01); wellbeing (p<0.05) and overall QoL (p<0.05). There was statistically significant relationship between educational status and functionality (P<0.05). No QoL subscale scores difference between both groups due to employment status (<0.05).	-	Inclusion of samples from two different health sectors (private and university hospital)
Nejad and Khani (2013)	Iran	Examine the QoL and sleep in HD patients	Cross-sectional deign	115 HD patients	SF-36 Pittsburgh Sleep Quality Index (PSQI)	There was a negative relationship between the quality of sleep and MCS scores (r= -0.222; p<0.01), and the global SF-36 (r= -0.227; p>0.05) show that as the quality of sleep worsened, the QoL decreased. There was no correlation between PCS and the global PSQI (r= -0.159; p= 0.090).	-	Because of the absence of polysomnographic data it was not possible to determine the exact cause of insomnia and sleep disturbance.

<table>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>The correlation between total SF-36 score and global PSQI was statistically significant (r= -0.227, p<0.05).</td><td></td><td></td></tr>
<tr><td>Pakpour et al (2010)</td><td>Iran</td><td>Compare HRQoL in Iranian patients with ESRD on HD with healthy population and compare study data with data from similar studies that were conducted in Asia, West, and East European.</td><td>Cross-sectional.</td><td>250 patients with ESRD on HD were recruited based on convenience sampling method.</td><td>SF-36</td><td>Iranian HD patients reported lower HRQoL compared to other five nations.
<table>
<tr><th>Subscale</th><th>Iranian sample</th><th>General population</th></tr>
<tr><td>PF</td><td>41.6±30.2</td><td>85.3±20.8</td></tr>
<tr><td>RP</td><td>30.8±32.5</td><td>70.0±38.0</td></tr>
<tr><td>BP</td><td>43.9±28.0</td><td>79.4±25.1</td></tr>
<tr><td>Vitality</td><td>46.3±23.9</td><td>65.8±17.3</td></tr>
<tr><td>SF</td><td>44.1±25.7</td><td>76.0±24.4</td></tr>
<tr><td>MH</td><td>56.7±22.4</td><td>67.0±18.0</td></tr>
</table></td><td>-</td><td>Variation in sample size (Iranian n=250 vs general cohort n=1997). Cultural and socio-environmental variation.</td></tr>
<tr><td>Rambod et al (2010)</td><td>Iran</td><td>Examine the relationship between perceived social support and the QoL in HD patients from an Islamic cultural background</td><td>Cross-sectional design</td><td>202 HD patients</td><td>Ferrans and Powers Quality of Life Index-Dialysis</td><td>Significant relationship were found between perceived social support and health-functioning (r= .65, p≤.05) socioeconomic (r= .67, ≤.05), psychological-spiritual (r= .63, p≤ .05) and family subscales of QoL (r=.51, p≤ .05). Total QoL also found to be significant correlated with perceived social support (r= 0.27, p= .00).</td><td>-</td><td>Patients usually defined Social support based on the context of the demands of their illness and study design could be a limitation in this context.</td></tr>
</table>

Ramirez et al (2012)	Brazil	Assessed whether positive religious coping or religious struggle was independently associated with psychological distress and HRQoL in HD patients.	Cross-sectional design. 170 HD patients		Anxiety and Depression Scale (HADS) Current Psychometric Status of a Short Measure of Religious Coping World Health Organisation Quality of Life Instrument-Abbreviated Version (WHOQOL-BEEF)	Religious struggle was independently associated with greater psychological distress and impaired HRQoL (r=0.43; p< .0001) and anxiety (r= 0.32; P< .0001).	-	Was able to demonstrate the independent association of religious coping strategies with HRQoL and psychological distress in HD patients. The sample of the study was only limited to participants with Christian which limits the generalizability of the results. The design of the study (cross-sectional) could not establish a causal relationship between religious coping, psychological distress and HRQoL in HD patients.
Saban et al (2008)	USA	Examine the measurement invariance of the KDQOL-SF across veterans and non-veterans with ESRD.	Prospective observational design	Veterans: 314 patients Non-veterans: 3300	KDQOL-SF KDCS	The SF-6D correlated .911 (p<.05), indicating 83% of the variance in the 7-subscales of KDCS measure.	-	First study to examine QoL in Veterans group. Large variation in the number of participants groups Demographic data were not control which could interfere with the results
Saffari et al (2013)	Iran	Examine the relationship between spiritual/religious, demographic and	Cross-sectional.	362 patients on HD.	Spiritual coping strategy (SCS)	Religious/ spirituality is an important factor in the QoL in patients with ESRD on HD. Correlations between spiritual coping score with	-	Large sample size. Face to face data collection conducted to collect more completed data. Convenience sampling method which can reduce findings generalizability. Use of

		clinical variables and QoL among Iranian Muslims.			EQ-5D	EQ-5D index score was (r=0.182, p< 0.001) and EQ-VAS scores (r= 0.131, p= 0.012). There is a significant difference of QoL between male and female (p= 0.005), but not health status. Married patients reported better health status than unmarried (p= 0.005)		Self-report which might present reporting and recall biases.
Santos et al (2010)	Brazil	Analysed the correlation between coping style and QoL in HD patients.	Cross-sectional	166 HD patients	SF-36	QoL dimensions: Physical functioning (55.4±25.5) General health (46.1±21.3) Social functioning (69.2± 30.3) Mental health (64.2 ± 22.0) Problem-oriented coping (51.4± 8.4) Emotion-oriented coping (68.1± 9.6)	-	Use of appropriate tools for comparison between problem-oriented coping and emotional-oriented coping. Considering the nature of coping behaviour, longitudinal design would fit more the aim of this study. Results can be compared with a transversal study to identify if the low QoL makes patients coping low. Sample was limited to one area which increase homogeneity rate and therefore might affects study results.
Tasi et al (2010)	Taiwan	Examine the relationship between QoL and risk of ESRD and mortality in CKD patients	Prospective design (12 months)	423 patients	WHOQOL - bref Beck Depression Inventory	Physical, psychological and overall QoL correlate with increased risks of ESRD and death. The total scores and scores of both physical and psychological domains predicted dialysis and mortality (every 1 point decrease hazard ratio (HR): 1.050, 95% CI: 1.008-1.095, p= 0.020; HR: 1.179, CI: 1.033-	WHO QoL model	One of the first study to evaluate the association between all components of QoL and the adverse outcome in ESRD patients with WHOQOL-BREEF tool. Comorbidity histories was not considered as a confounder which can confound with the study results

						1.346, p= 0.014; HR: 1.167, CI: 1.016-1.339, p= 0.028)		
Tovbin et al (2002)	USA	Examine the interrelation between psychosocial factors and individualised QoL of HD patients	Cross-sectional	48 HD patients	SEiQOL Scale	Perceived-control is mediated by clinical variable such as albumin, hostility and moderated by social-support. QoL was significantly correlated with physical component (r= 0.65) and social support (r= 0.38), and inversely correlated with hostility (r= -0.31), diabetes and hypoalbuminemia (p<0.05).	-	The use of SEiQOL as a self-rating scale allowed to include patients with relatively ill and cognitively limitations. Small sample size Use of cross-sectional design doesn't permit to interpret compensating effects of causal relationship.
Unruh et al (2003)	USA	Examine the relationship of patient-reported HRQoL to the mode of survey administration in HD patients.	Cross-sectional design 975 patients Interview: 427 Self-administered: 551	978 HD patients: N= 427 interview survey N= 551 self-administered	KDQOL-LF	Patients in the interviewer-administered group reported higher scores on scales that measured Role-Physical, Role-Emotional and Effects of Kidney Disease.	-	The interviewer group: had higher scores on sales that measured role-physical, role-emotional and effects of kidney disease (p<0.001).
Unruh et al (2008)	USA	Assess the extent to which persons aged 70 and older undergoing HD had greater changes in HRQoL over 3 years than younger patients undergoing HD	Longitudinal study design over 3 years	Secondary analysis of the HEMO study (1,813 HD patients)	KDQOL-LF	HRQoL scores at baseline reflected a better-preserved multidimensional QoL in patients with age 70 and older: physical component summary (34.4 ±9.8) and mental component summary (50.2±10.9). No substantial relationship reported between age and average decline in HRQoL	-	Study population was large Multicentre HD Instruments measured multidimensional aspects of life. Patients who had been in HD for less than 3 months were excluded from study.

<table>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>score over 3 years in participants.</td><td></td><td></td></tr>
<tr><td>Vasilieva and Irina (2006)</td><td>Russia</td><td>Compare HRQoL of Russian HD patients with the general population and international data.</td><td>Cross-sectional design</td><td>1047 HD patients</td><td>SF-36</td><td>Russian HD patients had significantly lower scores on the majority of SF-36 measure:
<table>
<tr><th>scale</th><th>HD patients</th><th>General pop</th></tr>
<tr><td>PF</td><td>61.2±25.8</td><td>79.6±22.0</td></tr>
<tr><td>BP</td><td>55.6±28.8</td><td>66.4±25.0</td></tr>
<tr><td>Vitality</td><td>49.3±19.8</td><td>56.2±18.2</td></tr>
<tr><td>MH</td><td>61.3±17.9</td><td>58.0±16.4</td></tr>
</table></td><td>-</td><td>Results were compared with an international data.
Large sample size. Study design limit determining the causality relationship between different QoL factors..</td></tr>
<tr><td>Vázquez et al (2005)</td><td>Spain</td><td>Examine the relationship between psychosocial status and KDQOL-SF by controlling sociodemographic and clinical variables.</td><td>Cross-sectional design</td><td>194 HD patients</td><td>KDQOL-SF</td><td>Trait anxiety and depressive symptoms found to increase the proportion of explained variability with highest standardised regression coefficients observed for most KDQOL scales (emotional wellbeing R^2=0.556; mental component summary R^2=0.505; physical functioning R^2=0.456)</td><td>-</td><td>Use of different measures. Study participants were relatively young (mean age= 48.5±16.06 years)</td></tr>
</table>

Appendix 3.4. Psychometric Properties of the instruments of QoL and HRQoL in ESRD

Instrument	Test-retest reliability	Internal consistency	Content validity	Construct validity	Responsiveness	Interpretability	Precision	Acceptability	Feasibility	Cultural and language adaptation
Health and Generic measures										
SF-36v2	ID	Physical summary (alpha = 0.88) and mental summary (alpha = 0.82)	✓	Physical summary (F-ratio = 6.09, p < 0.001) Mental summary (F-ratio = 2.37, p < 0.001)	80%	ID	ID	✓	Easy to administer and can be used by patients with different conditions.	Translated into different international languages including Arabic.
Quality of Life Scale	*r* = 0.78 to 0.84)	α = .82 to .92	✓	Correlates with The Life Satisfaction Index (r= 0.67 to 0.75)	60%	ID	ID	✓	Easy to administer and can be used by patients with different conditions.	Used across different cultures and translated into different languages including Arabic.
EQ-5D	(*r* = 0.69 to 0.94)	ID	✓	✓	Small treatment effect: 0.10	ID	ID	✓	Easy to administer (self-administration, through a proxy, or can be administered	Translated into different languages including Arabic.

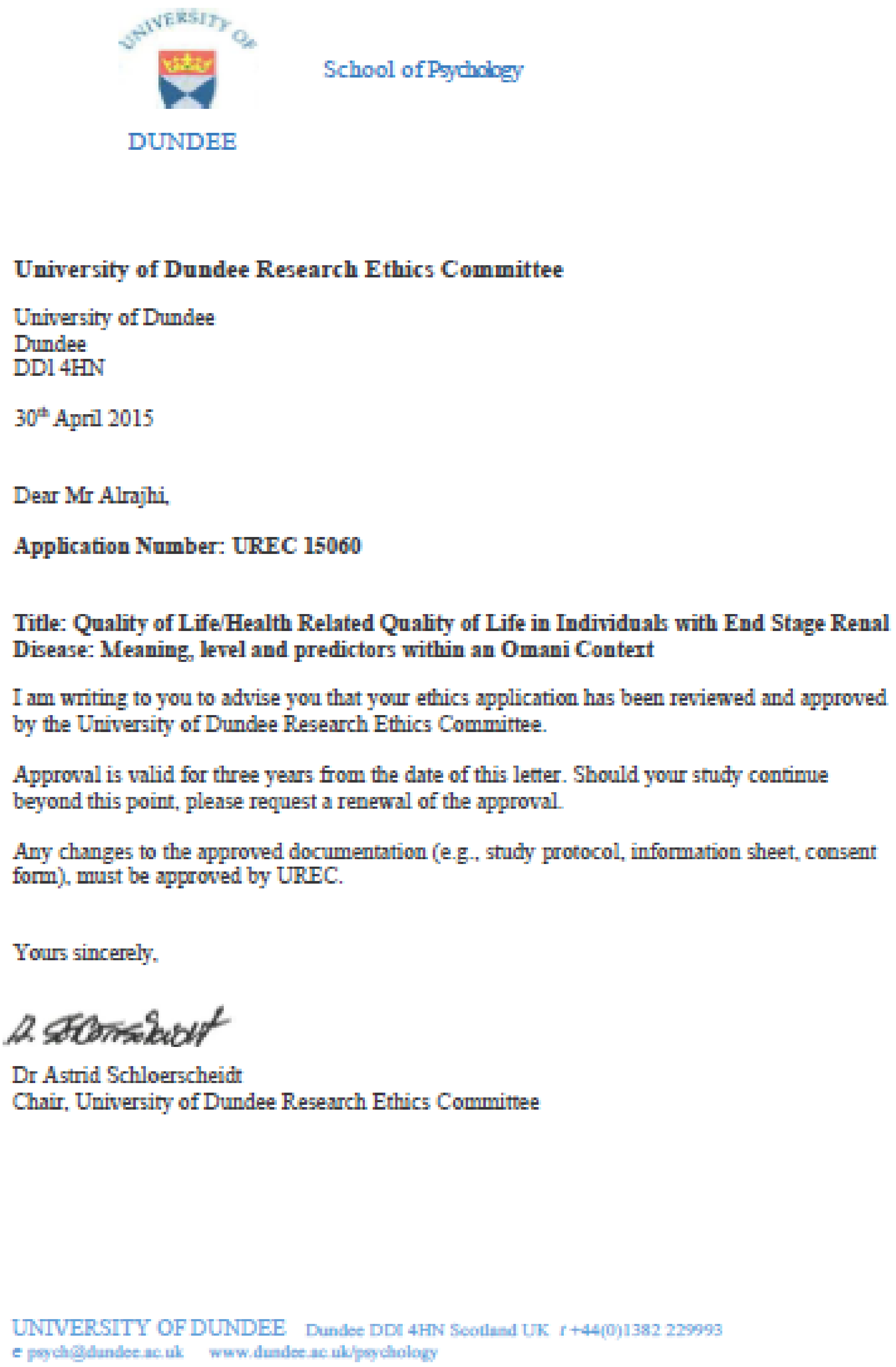
									in a postal survey form).	
WHOQoL-Bref	ID	α 0.66 α 0.97	✓	✓	ID	ID	ID	✓	Easy to administer. A valuable tool for clinical practice and international studies.	Used cross-culturally and translated into 40 different languages.
Disease-specific measures										
KDQoL-SF	ID	α 0.80	✓	✓	✓	ID	ID	✓	Self-reported. Consists of SF-36 items and kidney disease-specific items.	Used on a worldwide basis and has been translated into many different languages including Arabic.
ESRD-SI	ID	α 0.92	✓	✓	ID	ID	ID	✓	Easy to administer.	ID
QoLI-Dialysis	ID	α 0.91	✓	✓	46 % (394 HD patients)	ID	ID	✓	Can be administered via post and by interview.	ID
Symptom measures										
Memorial Symptom Assessment Scale Short Form (MSAS-SF)	ID	α 0.80	✓	Correlate with FACT measure (r=-.035 to -0.54)	(t-test, *P* <0.05) 60%	ID	ID	✓	Easy to administer and can be used by patients with different conditions.	Used across different cultures and translated into different languages

										including Arabic
Revised Illness Perception Questionnaire (IPQ)	ID	ID	ID	(r= .47, P < .001)	ID	ID	ID	✓	Easy to administer and can be used by patients with different conditions.	Used across different cultures and translated into different languages including Arabic.
5-D Itch Scale	Correlation at baseline r= .727 to r= .892 at 6-week	r= .734, p< .001	✓	Correlated strongly with the VAS (r= .862)	50% HIV Pts 48% ESRD Pts 50% Liver disease Pts	ID	ID	✓	Easy to administer (5-8 minutes). Used by patients with different conditions e.g. HIV, ESRD, Burn.	Used across different cultures and translated into different languages including Arabic.
The fatigue severity scale	(ICC= 0.91)	α 0.86 – 0.94	ID	Correlates with functional assessment (r=-0.77). Correlates with the Nottingham Health Profile (r= 0.62)	*P* <0.04	ID	ID	✓	Easy to administer and can be used by patients with different conditions.	Used across different cultures and translated into different languages including Arabic.

				Correlates with Parkinson's Fatigue Scale (r= 0.84)						
Individualised measures										
(SEiQoL-DW) Scale	0.70	ID	✓	✓	✓	ID	ID	✓	Easy to administer and can be used by patients with different conditions.	Used across different cultures and translated into different languages including Arabic.
Patient-generated index (PGI)	ID	ID	✓	✓	✓	ID	ID	✓	Easy to administer and can be used by patients with different conditions.	Used across different cultures and translated into different languages including Arabic.

Note: *r* = test-retest; internal consistency: Cronbach's alpha (α);✓ = qualitative evidence exists; ID = indeterminate.

Appendix 4.1. a University Research Ethical Committee (UREC)



School of Psychology

University of Dundee Research Ethics Committee

University of Dundee
Dundee
DD1 4HN

30th April 2015

Dear Mr Alrajhi,

Application Number: UREC 15060

Title: Quality of Life/Health Related Quality of Life in Individuals with End Stage Renal Disease: Meaning, level and predictors within an Omani Context

I am writing to you to advise you that your ethics application has been reviewed and approved by the University of Dundee Research Ethics Committee.

Approval is valid for three years from the date of this letter. Should your study continue beyond this point, please request a renewal of the approval.

Any changes to the approved documentation (e.g., study protocol, information sheet, consent form), must be approved by UREC.

Yours sincerely,

Dr Astrid Schloerscheidt
Chair, University of Dundee Research Ethics Committee

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ZURICH MUNICIPAL

To Whom It May Concern

Our ref: AB/IND 17 June, 2014

Zurich Municipal Customer: University of Dundee

This is to confirm that University of Dundee have in force with this Company until the policy expiry on 31 July 2015 Insurance incorporating the following essential features:

Policy Number: NHE-14CB07-0013

Limit of Indemnity:

Public Liability:	£ 25,000,000	any one event
Products Liability:	£ 25,000,000	for all claims in the aggregate during any one period of insurance
Pollution:		
Employers' Liability:	£ 35,000,000	any one event inclusive of costs

Excess:

Public Liability/Products Liability/Pollution:	Nil any one event
Employers' Liability:	Nil any one claim

Indemnity to Principals:
Covers include a standard Indemnity to Principals Clause in respect of contractual obligations.

Full Policy:
The policy documents should be referred to for details of full cover.

Yours faithfully

Underwriting Services
Zurich Municipal
Farnborough

Zurich Municipal
Zurich House
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Appendix 4.1.b. Directorate of Research and Ethical Review and Approve Committee, Oman

Sultanate of Oman
Ministry of Health
Directorate General of Planning and Studies

سلطنة عمان
وزارة الصحة
المديرية العامة للتخطيط والدراسات

Ref. : MH/DGP/R&S/PROPOSAL_ APPROVED/16/2015 الرقم :

Date. : 20.04.2015 التاريخ :

الموافق :

Waleed Khalid Al-Rajhi
Principal Investigator

Study Title: " **Quality of Life and Health Related Quality of Life in Individuals with End Stage Renal Disease: meaning, level and predictors within an Omani Context**"

After compliments

We are pleased to inform you that your research proposal **"Quality of Life and Health Related Quality of Life in Individuals with End Stage Renal Disease: meaning, level and predictors within an Omani Context"** has been approved by Research and Ethical Review and Approve Committee, Ministry of Health.

Regards,

٢٠١٥/٤/٢٢

Dr. Ahmed Mohamed Al Qasmi
Director General of Planning and Studies
Chairman, Research and Ethical Review and Approve Committee
Ministry of Health, Sultanate of Oman.

Cc
Day file

P.O. Box : 393, Postal Code : 100, Muscat, Tel. : 24601161, Fax : 24696533 ص.ب : ٣٩٣ ، الرمز البريدي : ١٠٠ ، مسقط ، هاتف : ٢٤٦٠١١٦١ ، فاكس : ٢٤٦٩٦٥٣٣

Appendix 4.2.a (Demographical questions)

استبيان البيانات الديموجرافية و الطبية

البيانات الديموجرافية

العمر (✓): ....

الجنس (✓):

ذكر ☐ أنثى ☐

الحالة الاجتماعية والاقتصادية:

الحالة الاجتماعية:

متزوج ☐ مطلق ☐ أرمل ☐ أعزب ☐

مستوى التعليم :

غير متعلم (لم ألتحق بمدرسة) ☐ أكملت الدراسة اللإبتدائية ☐

أكملت الدراسة الإعدادية (المتوسطة) ☐ أكملت الدراسة الثانوية ☐ جامعي ☐

العمل:

حكومي ☐ حكومي خاص ☐ قطاع خاص ☐ عمل حر ☐ ربة منزل ☐ باحث/ة عن عمل ☐

مستوى الدخل:

أقل من 250 ريالا عمانيا ☐ بين 250-600 ريالا عمانيا ☐ بين 1000-1500 ريالا عمانيا ☐

بين 600-1000 ريالا عمانيا ☐ أكثر من 1500 ريالا عمانيا ☐

البيانات الطبية (تعبأ من قبل الطاقم الطبي)

معدل الهيموغلوبين (Hb): .... معدل الهيموكريت (Hematocrit): .... %

معدل الزلال (Albumin): .... معدل الكلسترول (cholesterol): ....

التخليص/كفاية الغسيل الدموي: .... Kt/V

عدد ساعات الغسيل فى الشهر: .... ساعة

المدة على الغسيل الدموى بالسنوات: .... سنة

الوقت المستغرق للوصول إلى وحدة الغسيل: .... ساعة

Appendix 4.2.b (SF36v2)

إستبيان صحتك ورفاهيتك

يسأل هذا الاستبيان عن وجهة نظرك حول صحتك. ستساعد هذه المعلومات في تتبع شعورك وكيف كنت قادرا على القيام بنشاطاتك الاعتيادية بشكل جيد. *شكرا لإكمالك هذا الاستبيان!*

في كل واحد من الأسئلة التالية، الرجاء وضع إشارة ☒ في المربع الذي يصف بأفضل شكل إجابتك.

1. بشكل عام، تود أن تقول أن صحتك...

ممتازة	جيّدة جدا	جيّدة	معتدلة	ضعيفة
▼	▼	▼	▼	▼
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

2. بالمقارنة مع السنة الماضية، كيف تقيّم صحتك الآن بشكل عام؟

أفضل بكثير الآن بالمقارنة مع العام الماضي	أفضل نوعا ما الآن بالمقارنة مع العام الماضي	تقريبا نفس العام الماضي	أسوأ نوعا ما الآن بالمقارنة مع العام الماضي	أسوأ بكثير الآن بالمقارنة مع العام الماضي
▼	▼	▼	▼	▼
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

3. الأسئلة التالية تدور حول نشاطات من الممكن أن تقوم بها خلال يوم عادي. هل تقيدك صحتك الآن في النشاطات التالية؟ إذا كانت كذلك، فإلى أي مدى؟

نعم، تقيّدني كثيرا	نعم، تقيّدني قليلا	لا، لا تقيّدني على الإطلاق
▼	▼	▼

ا. النشاطات القوية، مثل الركض، رفع أشياء ثقيلة، المشاركة في رياضة شاقة .... ☐1 .... ☐2 .... ☐3

ب. النشاطات معتدلة الشدة، مثل تحريك طاولة، دفع مكنسة كهربائية، السباحة أو ركوب الدراجة .... ☐1 .... ☐2 .... ☐3

ج. رفع أو حمل مواد البقالة.. ☐1 .... ☐2 .... ☐3

د. صعود الدرج عدة طوابق .... ☐1 .... ☐2 .... ☐3

ه. صعود الدرج طابق واحد .... ☐1 .... ☐2 .... ☐3

و. الانحناء، الرّكوع، أو طأطأة الرأس والكتفين........................... ☐1 .... ☐2 .... ☐3

ز. المشي أكثر من كيلومتر واحد.. ☐1 .... ☐2 .... ☐3

ح. المشي عدة مئات من الأمتار .... ☐1 .... ☐2 .... ☐3

ط. المشي مئة متر... ☐1 .... ☐2 .... ☐3

ي. الاستحمام أو ارتداء الملابس .... ☐1 .... ☐2 .... ☐3

4. خلال الأسابيع الأربعة الماضية، كم من الوقت واجهت أيا من المشاكل التالية في عملك أو نشاطاتك اليومية الاعتيادية الأخرى نتيجة لصحتك الجسدية؟

كلّ الوقت	معظم الوقت	بعض الوقت	قليل من الوقت	ولا في أي وقت
▼	▼	▼	▼	▼

ا. انخفاض في كمية الوقت الذي قضيته في العمل أو النشاطات الأخرى...................... ☐1 .... ☐2 .... ☐3 .... ☐4 .... ☐5

ب. أنجزت أقل مما تريد................................ ☐1 .... ☐2 .... ☐3 .... ☐4 .... ☐5

ج. كنت مقيّدا/ة في نوع العمل أو النشاطات الأخرى.. ☐1 .... ☐2 .... ☐3 .... ☐4 .... ☐5

د. واجهت صعوبة في أداء عملك أو النشاطات الأخرى (مثلا، أخذت منك جهدا إضافيا). ...... ☐1 .... ☐2 .... ☐3 .... ☐4 .... ☐5

5. خلال أسابيع الأربعة الماضية، كم من الوقت واجهت أيا من الصعوبات التالية أثناء قيامك بعملك أو بأنشطتك العادية اليومية الأخرى بسبب أي مشاكل متعلقة بالعاطفة (مثل الإحساس بالإكتئاب أو القلق)؟

	كلّ الوقت ▼	معظم الوقت ▼	بعض الوقت ▼	قليل من الوقت ▼	ولا في أي وقت ▼
ا. انخفاض في كمية الوقت الذي قضيته في العمل أو النشاطات الأخرى........................	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
ب. أنجزت أقل مما كنت ترغب........................	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
ج. قمت بعمل أو نشاطات أخرى بحذر أقل من المعتاد	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

6. خلال الأسابيع الأربعة الماضية، إلى أي مدى تدخلت مشاكلك الجسدية أو العاطفية في نشاطاتك الاجتماعية الاعتيادية مع العائلة، الأصدقاء، الجيران، أو المجموعات؟

لا على الإطلاق	قليلا	بشكل معتدل	كثيرا	بشدة
▼	▼	▼	▼	▼
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

7. كم من الألم الجسدي عانيت خلال الأسابيع الأربعة الماضية؟

لا شيء	خفيف جدا	خفيف	متوسط	شديد	شديد جدا
▼	▼	▼	▼	▼	▼
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

8. خلال <u>الأسابيع الأربعة الماضية</u>، إلى أي مدى تدخل <u>الألم</u> بعملك الاعتيادي (بما فيه العمل خارج البيت أو العمل البيتي)؟

لا على الإطلاق	قليلا	بشكل معتدل	كثيرا	بشدة
▼	▼	▼	▼	▼
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

7 هذه الأسئلة تستفسر عن شعورك وكيف سارت الأمور معك خلال <u>الأسابيع الأربعة الماضية</u>. لكل سؤال، الرجاء إعطاء الجواب الأقرب إلى الطريقة التي شعرت بها. كم من الوقت خلال <u>الأسابيع الأربعة الماضية</u>...

	كلّ الوقت	معظم الوقت	بعض الوقت	قليل من الوقت	ولا في أي وقت
	▼	▼	▼	▼	▼
ا. شعرت بالحيوية ؟................................	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
ب. شعرت بأنك عصبيّ/ة جداً؟	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
ج. شعرت بأنك محبط/ة جدا بحيث انه لا شيء يمكنه إسعادك؟...............	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
د. شعرت بالهدوء والطمأنينة؟	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
ه. كانت لديك طاقة كبيرة؟	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
و. شعرت بأنك حزين/ة ومكتئب/ة؟	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
ز. شعرت بأنك منهك/ة؟............................	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
ح. شعرت بالسعادة؟...................................	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
ط. شعرت بالتعب؟....................................	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

8 خلال <u>الأسابيع الأربعة الماضية</u>، كم من الوقت تدخلت <u>صحّتك الجسديّة أو مشاكلك العاطفية</u> في نشاطاتك الاجتماعية (مثل القيام بزيارات للأصدقاء، الأقارب، الخ.)؟

كلّ الوقت	معظم الوقت	بعض الوقت	قليل من الوقت	ولا في أي وقت
▼	▼	▼	▼	▼

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

9 ما مدى صحة أو خطأ كلٍ من العبارات الآتية بالنسبة لك؟

	بشكل مطلق صحيحة	على الأغلب صحيحة	لا أعرف	على الأغلب خاطئة	بشكل مطلق خاطئة
	▼	▼	▼	▼	▼
ا. يبدو أنّي أكثر سهولة في التعرّض للمرض من أشخاص آخرين.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
ب. أنا سليم/ة بنفس قدر السلامة التي يتمتّع بها أي شخص أعرفه	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
ج. أتوقع أن تزداد صحتي سوءا.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
د. صحّتي ممتازة.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Appendix 4.**2. c**

مقياس نوعية الحياة

(نموذج غسيل الكلى

(Quality of Life Inde

Dialysis Version III

ة حول الإجابة الملائمة لكل مما يلي وفقا لما تراه مناسبا لوصف **مدى رضاك**

الرجاء وضع دائرة حول الرقم الذي يمثل رأيك علما بأنه لا توجد إجابة

	غير راضي جدا	غير راضي بشكل متوسط	غير راضي قليلا	راضي قليلا	راضي بشكل متوسط	راضي جدا
	1	2	3	4	5	6
2. الرعاية الصحية التي تتلقاها؟	1	2	3	4	5	6
3. مدى طاقتك على القيام بالنشاطات اليومية؟	1	2	3	4	5	6
4. قدرتك على رعاية نفسك بنفسك؟	1	2	3	4	5	6
5. احتمالية حصولك على زرع الكلى؟	1	2	3	4	5	6
6. التغيرات التي طرأت على حياتك بسبب الفشل الكلوي (مثل الحمية و الحاجة إلي الغسيل الكلوي)؟ 7. مدى سيطرتك على حياتك؟	1	2	3	4	5	6
8. فرصك لعيش الفترة الزمنية التي تتمناها؟	1	2	3	4	5	6
	1	2	3	4	5	6
	1	2	3	4	5	6
	1	2	3	4	5	6
	1	2	3	4	5	6
12. حياتك الجنسية؟						
	1	2	3	4	5	6
14. أصدقاؤك؟	1	2	3	4	5	6
15. الدعم المعنوي الذي تتلقاه من عائلتك؟	1	2	3	4	5	6

(يرجى الذهاب إلى الصفحة التالية)

	غير راض جدا	غير راض بشكل متوسط	غير راض قليلا	راض قليلا	راض بشكل متوسط	راض جدا
16. الدعم المعنوي الذي تتلقاه من الآخرين خارج عائلتك؟	1	2	3	4	5	6
17. قدرتك على القيام بالواجبات العائلية؟	1	2	3	4	5	6
18. مدى فلئدتك للآخرين؟	1	2	3	4	5	6
19. مقدار الضغط النفسي أو القلق الذي تعانيه في حياتك؟	1	2	3	4	5	6
20. جيرانك؟	1	2	3	4	5	6
21. بيتك أو منزلك أو مسكنك؟	1	2	3	4	5	6
22. عملك (إذا كنت تعمل)؟	1	2	3	4	5	6
23. عدم حصولك على عمل (إذا كنت لا تعمل، أو متقاعد،						
24. تحصيلك العلمي؟	1	2	3	4	5	6
25. قدرتك على تدبير أمورك المالية؟	1	2	3	4	5	6
26. الأنشطة التي تسلي بها نفسا	1	2	3	4	5	6
27. فرصك لتحقيق مستقبل سعيد؟	1	2	3	4	5	6
28. راحة بالك أو استقرارك النفسي؟	1	2	3	4	5	6
29. إيمانك بالله عز وجل؟	1	2	3	4	5	6
30. تحقيقك للأهداف الشخصية؟	1	2	3	4	5	6
31. سعادتك بشكل عام؟	1	2	3	4	5	6
33. مظهرك الشخصي؟	1	2	3	4	5	6
32. حياتك بشكل عام؟ 34. نفسك بشكل عام؟	1	2	3	4	5	6

ى الصفحة التالية)

الجزء الثاني: يرجى وضع دائرة حول الإجابة الملائمة لكل مما يلي وفقا لما تراه مناسبا لوصف **مدى أهمية** كل من النواحي التالية من حياتك. الرجاء وضع دائرة حول الرقم الذي يمثل رأيك علما بأنه لا توجد إجابة صحيحة أو خاطئة.

كم هو مهم بالنسبة لك:	غير مهم جداً	غير مهم بشكل متوسط	غير مهم قليلا	مهم قليلا	مهم بشكل متوسط	مهم جداً
1. صحتك؟	1	2	3	4	5	6
2. الرعاية الصحية التي تتلقاها؟	1	2	3	4	5	6
3. توفر طاقة كافية لديك للقيام بالنشاطات اليومية؟	1	2	3	4	5	6
4. رعاية نفسك بنفسك؟						
5. الحصول على زراعة الكلى؟	1	2	3	4	5	6
6. التغيرات التي طرأت على حياتك بسبب الفشل الكلوي (مثل الحمية والحاجة لغسيل الكلى)؟						
7. القدرة على ضبط أمورحياتك؟	1	2	3	4	5	6
8. العيش للفترة الزمنية التي تتمناها؟						
9. صحة عائلتك؟	1	2	3	4	5	6
10. أطفالك؟	1	2	3	4	5	6
11. سعادة عائلتك؟						
12. حياتك الجنسية؟	1	2	3	4	5	6
13. زوجك أو شريك حياتك؟	1	2	3	4	5	6
14. أصدقاؤك؟	1	2	3	4	5	6
15. الدعم المعنوي الذي تتلقاه من عائلتك؟						
16. الدعم المعنوي الذي تتلقاه من الآخرين خارج عائلتك؟	1	2	3	4	5	6

(يرجى الذهاب إلى الصفحة التالية)

	غير مهم جداً	غير مهم بشكل متوسط	غير مهم قليلاً	مهم قليلاً	مهم بشكل متوسط	مهم جداً
17. القيام بالواجبات العائلية	1	2	3	4	5	6
18. أن تكون مفيداً للآخرين؟	1	2	3	4	5	6
19. خلو حياتك من الضغوطات النفسية؟	1	2	3	4	5	6
20. جيرانك؟	1	2	3	4	5	6
21. بيتك أو منزلك أو مسكنك؟	1	2	3	4	5	6
22. عملك (إذا كنت تعمل)؟	1	2	3	4	5	6
23. حصولك على عمل (إذا كنت لا تعمل، أو متقاعد، أو غير قادر على العمل)؟	1	2	3	4	5	6
24. تحصيلك العلمي؟	1	2	3	4	5	6
25. القدرة على تدبير أمورك المالية؟	1	2	3	4	5	6
26. القيام بأنشطة ترفيهية؟	1	2	3	4	5	6
27. حصولك على مستقبل سعيد؟	1	2	3	4	5	6
28. راحة بالك أو استقرارك النفسي؟	1	2	3	4	5	6
29. إيمانك بالله عز وجل؟	1	2	3	4	5	6
30. تحقيق أهدافك الشخصية؟	1	2	3	4	5	6
31. سعادتك بشكل عام؟	1	2	3	4	5	6
32. أن تكون راضيا عن حياتك؟						
33. مظهرك الشخصي؟	1	2	3	4	5	6
34. نفسك بالنسبة إليك؟	1	2	3	4	5	6

(يرجى الذهاب إلى الصفحة التالية)

Appendix 4.2.d (HADS)

مقياس القلق والاكتئاب الخاص بالمستشفيات والمرا كز الصحية (HADS)

الاسم: ____ التاريخ: ___________

اطوي هنا

طوي هنا

يعرف الأطباء أن المشاعر تلعب دوراً هاماً في مُعظم الأمراض. فإذا عرف طبيبك عن هذه المشاعر، سيستطيع أن يساعدك أكثر.

هذا الاستبيان مُصمم لمساعدة طبيبك في معرفة ما تشعر به. إقرأ كل بند في المقطع التالي ***وضع خطاً أسفل*** *الإجابة الأقرب إلى ما كنت تشعر به خلال الايام السبعة الماضية. تجاهل الأرقام المطبوعة علي أطراف الاستبيان. لا تفكر طويلاً في الإجابات، إذ أن رد فعلك الفوري لكل بند سيكون غالباً أدق مما لو فكرت طويلاً.*

A	D	
		أشعر بأني متوتر أو"مشدود"
٣		معظم الوقت
٢		كثيراً من الوقت
١		أحياناًً
٠		مطلقاً
		ما زلت أستمتع بالأمور التي كنت أستمتع بها من قبل
	٠	بالتأكيد بنفس القدر
	١	ليس بنفس القدر
	٢	قليلاً فقط
	٣	يكاد يكون مطلقاً
		ينتابنى نوع من الشعور بالخوف وكأن شيئاً فظيعاً على وشك الحدوث
٣		بالتأكيد وبدرجة سيئة
٢		نعم، ولكن ليس بدرجة سيئة
١		قليلاً، ولكن لا يقلقنى
٠		مطلقاً
		أستطيع أن أضحك وأن أرى الجانب الفكاهي في الأمور
	٠	بنفس القدر كما كنت دائماً
	١	ليس بنفس القدر الآن
	٢	بالتأكيد ليس بنفس القدر الآن
	٣	مطلقاً
		تمر بذهني أفكار مُقلقة
٣		كثيراً جداً من الوقت
٢		كثيراً من الوقت
١		ليس كثيراً
٠		قليلاً جداً
		أشعر بالمرح
	٣	مطلقاً
	٢	ليس كثيراً
	١	أحياناً
	٠	مُعظم الوقت
		أستطيع أن أجلس بأمان وأن أشعر بالاسترخاء
٠		بالتأكيد
١		عادةً
٢		ليس كثيراً
٣		مطلقاً

	A	D
أشعر كأني بطيء		
تقريباً طول الوقت		٣
كثيراً جداً		٢
أحياناً		١
مطلقاً		٠
ينتابني نوع من الشعور بالخوف مثل شعور غريب فى المعدة		
مطلقاً	٠	
أحياناً	١	
كثيراً إلى حد ما	٢	
كثيراً جداً	٣	
لقد فقدت الاهتمام بمظهري		
بالتأكيد		٣
لم أعد أهتم بالقدر الذى ينبغي		٢
ربما لا أهتم بنفس القدر		١
أهتم بنفس القدر كما كنت دائماً		٠
أشعر بعدم الإستقرار وكأني يجب أن أتحرك طول الوقت		
كثيراً جداً	٣	
كثيراً	٢	
ليس كثيراً	١	
مطلقاً	٠	
أتطلع إلى الأمور باستمتاع		
بنفس القدر كما كنت دائماً		٠
أقل نوعا ما مما كنت من قبل		١
بالتأكيد أقل مما كنت من قبل		٢
يكاد يكون مطلقاً		٣
تنتابني مشاعر مفاجئة بالذعر		
في أحيان كثيرة جداً	٣	
في أحيان كثيرة	٢	
ليس كثيراً	١	
مطلقاً	٠	
أستطيع أن أستمتع بكتاب جيد أو الراديو أو برنامج تليفزيوني		
كثيراً		٠
أحياناً		١
ليس كثيراً		٢
نادراً جداً		٣

الآن تحقق من أنك قد قمت بالإجابة على كل الاسئلة

	A	D
المجموع	☐	☐

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Appendix 4.2.f (FATIGUE SEVERITY SCALE)

مقياس شدة التعب

خلال الإسبوع الماضي وجدت أن:	لا أوافق تماما			لا أوافق ولا أرفض			أوافق تماما
1. دافعيتى لعمل الأشياء تكون أقل حينما أشعر بالإعياء	1	2	3	4	5	6	7
2. حينما أمارس الرياضة أو أقوم بنشاط، يسبب ذلك شعورا بالإعياء	1	2	3	4	5	6	7
3. أصاب بالإعياء بسهولة	1	2	3	4	5	6	7
4. الإعياء يقف في طريق ممارستي لوظائفي الجسدية	1	2	3	4	5	6	7
5. الإعياء يسبب لي مشاكل عديدة ومتكررة	1	2	3	4	5	6	7
6. الإعياء يمنعني من الاستمرار في عمل وظائفي الجسدية	1	2	3	4	5	6	7
7. الإعياء يقف في طريق تأديتي لواجباتي ومهامى	1	2	3	4	5	6	7
8. الإعياء من أهم ثلاثة أعراض تتسبب في إعاقتي	1	2	3	4	5	6	7
9. الإعياء يضايقني ويؤثر سلبا حياتي العملية، العائلية أو الاجتماعية	1	2	3	4	5	6	7

(يرجى الذهاب إلى الصفحة التالية)

Appendix 4.2.g (5D Itching Scale)

مقياس الحكة

1. في أخر اسبوعين, كم عدد الساعات التي شعرت خلالها بالحكة؟

5	4	3	2	1
طول اليوم	23-18 ساعة	18-12 ساعة	12-6 ساعة	أقل من 6 ساعات

2. كيف تقيم شدة الحكة في أخر أسبوعين؟

5	4	3	2	1
لايحتمل	قوي	متوسط	خفيف	لايوجد

3. خلال الأسبوعين الماضيين, هل تحسنت الحكة أم ساءت مقارنتاً بالشهر الماضي؟

5	4	3	2	1
ساءت	لم تتغير	تحسنت قليلاً مع وجود	تحسنت كثيراً لكن	انتهت الحكة

4. قيم تأثير الحكة على النشاطات التالية خلال أخر أسبوعين؟

a. تأثير الحكة على النوم

5	4	3	2	1
تؤخر النوم وتسبب اليقظة كثيراً	تؤخر النوم وتسبب اليقظة	تؤخر النوم كثيرا	تؤخر النوم نادرا	لا تؤثر على النوم

b. ماهو مدى تأثر الحكة على نشاطات التواصل الاجتماعي لديك؟

5	4	3	2	1
دائماً	كثيراً	أحيانا	قليلاً	لا تؤثر

c. ماهو مدى تأثير الحكة على نشاطك اليومي؟

5	4	3	2	1
دائماً	كثيراً	أحيانا	قليلاً	لا تؤثر

d. ما مدى تأثير الحكة على عملك؟

5	4	3	2	1
دائماً	كثيراً	أحيانا	قليلاً	لا تؤثر

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5. أي من أعضاء الجسم التالية الأكثر تأثرا بالحكة خلال الأسبوعين الماضين (إذا لم يكن العضو المتأثر من ضمن القائمة فبالإمكان وضع علامة بالعضو الأقرب للموضع)؟

العضو الجسدي	لا توجد حكة	توجد حكة
a. فروة الرأس		
b. الوجه		
c. منطقة الصدر		
d. منطقة البطن		
e. منطقة الظهر		
f. المؤخرة		
g. الفخذين		
h. الأرجل		
i. بطن القدم		
j. بطن الكف		
k. اليدين والأصابع		
l. الكتفين		
m. أعلى اليدين		
n. الأماكن الملامسة للملابس		
o. بين الفخذين		
p. أعلى أصابع القدمين		

(يرجى الذهاب إلى الصفحة التالية)

Appendix 4.2.h (Spritual Wellbeing Scale)

مقيياسس االصحة االرووحانيية

(ضع إإشاررة ة ،للاختييارر االداالل بصوررة مـ ثـ لى عـ لى ددررجهه موواافقتك أأوو مخـ ا لـ فـ تك لمضموونن كل عباررة ة,)
وواالمعبر عن خـ بر تك االشخصي

أأوواافق بشدده لا أأوواافق باعتداالل لاأأوواافق أأوواافق أأوواافق اعتداالل أأوواافق بشدده

لا إإ لىالله وو توسـلي في مـ نـ لجـ ا تي أأكـثر بـ ارر تـ يـ يـ احح أأشعر						
أأوو،من أأ يين من أأ نـ ا, أأوو، أأ تـ يـ يت, مـ اسـ يـ يكوونن صـ يـ يري ي لا االعلم						
الله يـ يحـ بـ ني أأؤمن بر عـ ا يـ يـ تـ هه وو يـ يحـ فظـ ني أأنن						
أأررىى االحـ يـ يـ اة ة أأنن تدعو لـ لـ تفـ اؤولل						
الله يـ يرعـ ى االعتقدحـ يـ يـ اتي أأنن االـ يـ يومـ يـ ية . أأموورر						
مسـ تـ قـ بـ لي بـ ا لـ قـ لق عـ لى أأشعر						
)علاقة عميـ يقة . تـ ر بطـ ني بـ ا						
وو االرضـ ا أأشعر بـ الاكـ تـ فـ اء في االحـ يـ يـ اة ة						
االصـ بر وو تعـ ا لى)الله (سـ بحـ ا نـ هه االـ كـ افـ يـ يـ يين من وو لا أأسـ تمد االعوونن						
بـ الاتجـ اهه تـ شـ يير االـ تـ اامم بـ هه حـ يـ يـ اتي االـ نـ يي أأشعر بـ الارر تـ يـ يـ احح						
في ههههوو مي الله يـ يرعـ ا ني االعـ تـ قد أأنن						
أأحب االحيياة ة						
مرضـ يـ ية. بـ ا(علاقة لا ضـ دلـ ني						
بمسـ تـ قـ بـ لي االستبشر						
تـ د فع عـ نيصـ د لـ تي بـ ا2 االشعوررر بـ ا لوحـ د ة ة						
أأنن مـ ثـ قـ لـ هه أأررىى االحـ يـ يـ اة ة وو االمـ لـ ي بـ ا لـ تـ نـ اقضـ تت						
أأشعر االطـ مـ أأ نـ يـ ينة ددررجـ تت عـ لى صـ لـ هه عـ نـ د مـ ا أأكوونن بـ أعـ لى !مـ تـ يـ ينة بـ ا						
لا من االمعـ نى االكـ ثـ يير تحـ مل االحـ يـ يـ اة ة						
بـ الارر تـ يـ يـ احح بـ اـ تشعر نيصـ د لـ تي						

Note: The original English Spiritual Well-Being Scale (SWBS) is in the *Journal of Psychology and Theology*, 1983, 11(4), p. 340. English SWBS © 1982 & Arabic SWBS © 2010 by C. W. Ellison & R. F. Paloutzian. All rights reserved. Translation courtesy of Ahmad S. Musa. Layout by John Thibdeau. Not to be duplicated unless expressed written permission is granted by copyright holder or Life Advance: www.lifeadvance.com.

Appendix 4.3. Lesson Plan for Questionnaire Administration Procedure

Lesson Title: Principles of self-administered questionnaire related to a pilot study

Date: 2nd week of October 2015

Presenter: Waleed Al Rajhi

Rationale:

This is a 2-3 hours session is designed for the key individuals (nephrology nurses) from haemodialysis units, Oman, whom agreed to assist in conducting the pilot study which is a part of main study of Quality of Life and Health Related Quality of Life in Individuals with End Stage Renal Disease: meaning, level and predictors within an Omani Context. It is presented very much as a practical introduction to the assistants and consists of a mixture of a series of short lectures interspersed with practical activities. The areas of discussion will include: aims and objectives of study, consent form, and principles and procedure of administering the questionnaire.

Prescribed Learning Outcome(s):

Attendants will be able to:

1. Administer effectively the study questionnaire pertaining to phase 2 of Quality of Life and Health Related Quality of Life in Individuals with End Stage Renal Disease: meaning, level and predictors within an Omani Context.
2. Maintain confidentiality and sounds ethical principles throughout the process of administering, following-up, and collecting back the questionnaires.
3. Respond to participant’s enquiries that might arise related to study questionnaire.

Instructional Objective(s):

At the end of this session, attendants will be able to:

1. Gain an insight into the aims and objectives of the pilot study
2. Understand and practice the method for obtaining consent form related to the pilot study
3. Understand and practice the method of self-administered questionnaire
4. Understand and practice the method of following-up and handling questionnaire after completion by participants
5. Recognise and discuss the special issues that might arise in self-administered questionnaire.

(التالية الصفحة إلى الذهاب يرجى)

Prerequisite Concepts and Skills:

It is essential for nurses who will assist in administering the study questionnaire that have/are: self-interest to assist; qualified nephrology nurses registered at Ministry of Health, Oman; permitted by authorities of HD unit; and their participation would not negatively affect their clinical role and tasks.

Materials and Resources:

Presenter	Attendant
Sample of the study questionnaire Flip chart Laptop Overhead projector	Note book and pencil

Lesson Activities:

Presenter Activities	Attendant Activities	Time	Venue
1. Introduction to the study aims and objectives 2. Discussion on ethical principles applied to the study 3. Demonstration for obtaining consent form 4. Demonstration of questionnaire administration 5. Discussion and distribution of the key instructions to administer a questionnaire 6. Wrap-up	1. In all the activities, attendants are expected to engage in discussion and enquire about aspects that are not clear.	09-12 am	Dialysis unit: Seminar room, meeting room.

(التالية الصفحة إلى الذهاب يرجى)

Key Instructions to Administering Pilot Study Questionnaire

1. Participant should complete the questionnaire independently without assistance from health professionals or family members. If the patient is unable to complete/read the questionnaire themselves, the questions can be read out for them and/or their responses recorded. The questionnaire is designed to assess the patient's perception so their answers should not be influenced in any way.
2. Ensure that consent form has been signed and handed over along the questionnaire.
3. Express the importance of the research that they are contributing to, and that the answers they give on the questionnaires may be an important contribution to the health of others.
4. Emphasise that the questionnaire's scientific value is contingent on carefully and thoughtfully given answers.
5. The questionnaire must be completed with a dark blue or black pen.
6. Tell the participant that if they have any uncertainty about how to answer a question, they should select what they think is the most appropriate answer.
7. Remind the participant to answer all of the questions.
8. Instruct the participant on how to correct mistakes, if necessary, by crossing out the wrong answer, filling in the correct answer, and circling the correct answer.
9. Thank the participant for completing the questionnaires.
10. REMEMBER: confidentiality is vital throughout the process.

Quality assurance of the self-administered questionnaires

Before participant leaves the HD unit, a quality assurance check of the questionnaire must be done. Remind the participant with the following items:

1. Completeness: that all questions have been answered.
2. Accurate identification: make sure that the questionnaire has a printed code on the cover page.
3. Coherence: that only one answer is given for each question. If the participant has made any corrections on the questionnaire, to sure that the intended answer is clearly marked.

Resources for additional information

If you have questions related to this or during the questionnaire administration, please contact Waleed Khalid Alrajhi, Researcher, in any of the following ways: Telephone: 00968 99636344 OR Email: wkalrajhi@dundee.ac.uk. Alternatively, you can contact Dr Abdullah Al Battashi on 00968 99885711 (Study supervisor).

Appendix 4.3.a. **Participant information sheet– Phase 1**

UNIVERSITY OF DUNDEE

Ministry of Health
Sultanate of Oman

PARTICIPANT INFORMATION SHEET – PHASE 1

Quality of Life and Health Related Quality of Life in Individuals with End Stage Renal Disease: Meaning, level and predictors within an Omani Context.

You are being invited to take part in a research study that will assess quality of life (QoL) and health related quality of life (HRQoL) in patients with end stage renal disease (ESRD) in an Omani context. Before you decide to take part, it is important that you understand firstly why the research is being done and what it will involve. Please take time to read the following information, and carefully consider whether you want to take part. Please ask the researcher or nurse involved in this study if there is anything that is not clear or if you would like more information.

Aim

The aims of this phase are to explore your thoughts about quality of life, and to identify the areas of life which are most important to you and rate your level of satisfaction with each of them. This phase of the study will help the researcher to explore the understanding of the meaning of quality of life in an Omani context. This will then inform the next phase of the study in terms of ensuring that we use the appropriate study questionnaires suitable to Omani patients.

Why have I been invited?

You are being asked to participate as you are an adult with ESRD and on haemodialysis therapy on a regular basis. Your dialysis nurse has identified that you are eligible to participate in this study. I hope that 12 patients will agree to take part in this study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your medical or nursing care.

What will happen if I agree to help?

If you agree to take part in this study, it will involve you completing two questionnaires related to quality of life during an interview while your presence in dialysis unit for your regular haemodialysis sessions. You are required to think out loud while completing the questionnaires, and following the completion of items/questions, I will explore the basis of your answers. I might also ask you to nominate the areas of life which are most important, rate your level of satisfaction with each, and indicate the relative importance of each to your overall quality of life.

The time is expected to finish the interview around one hour. The interview will take place in the dialysis unit, pre-dialysis waiting room, or a place you prefer. There will be a private room for conducting the interview to maintain privacy. If you like, you can ask a relative or friend to be present during the interview but not contribute.

With your permission, I would like to audio record this interview so that I have an accurate account of what was said. You can ask me to stop to take a rest at any point during the interview.

We do not anticipate that there will be any disadvantages or risks if you choose to participate in the study. The information will be gathered may not benefit you directly, but I hope that it will help individuals with the same condition in the future.

What if there is a problem?

If you have a concern about any aspects of the study, you should speak to the researcher who will do his best to answer your questions. The contact details are listed below. If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint to the Dialysis Unit In-charge or to the Call Centre, Ministry of Health. To do so, you can phone the Ministry of Health Call Centre on number 24441999. Working hours: 7:30am to 9.30pm, and during public holidays: 9:30am until 4:30pm.

Who will disclose, use and/or receive my health information?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you (name, address, phone number, direct quotes and locations) that is obtained from you either during the interview or through the questionnaires will be anonymised for publication purposes (e.g. trial report, research paper, conference presentation) so that you cannot be recognised from it. All study data will be kept separately from the consent forms and personal contact information so that

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no connection can be made between the data and your identify. Personal contact information (e.g. name, phone number, etc.) will be stored as a hard copy separately in a secure location for at least 5 years after the study has ended. All study data will be stored safely and securely either on a password protected file, on a secure, password protected PC within the university or in a locked filing cabinet in a locked room at the University of Dundee, Scotland, UK. If you decide to withdraw from the study, all identifiable data will be withdrawn; however, any unidentifiable data already collected prior to your withdrawal will be retained and used in the study.

The Ethical Committee on Medical Research at Ministry of Health, Oman, which has responsibility for scrutinizing all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from Ethical Committee, Ministry of Health, Oman, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected. Once the results are ready I hope to publish them in a medical journal so that other healthcare professionals can benefit from the results. At the end of the study, results will be disseminated to the key stakeholders.

The study has been organised and supervised by the School of Nursing and Midwifery, University of Dundee, Scotland, UK.

Contact

Thank you for taking time to consider taking part in this study. If you would like to find out more about it, please contact:

Waleed Khalid Alrajhi, Researcher, Department of Nursing and Midwifery, University of Dundee – Scotland. I can be contacted in any of the following ways: Telephone: 00968 99636344 OR Email: wkalrajhi@dundee.ac.uk

Alternatively,

Dr. Abdullah Al Battashi on 00968 99885711 (Dean of Nursing Institute, Ibri) who will be happy to discuss it with you.

Thank you for taking the time to consider taking part in this study.

(يرجى الذهاب إلى الصفحة التالية)

Appendix 4.3.b. PARTICIPANT INFORMED CONSENT FORM-PHASE 1

PARTICIPANT INFORMED CONSENT FORM-PHASE 1

Please take some time to read the following statements. If you agree with the statements, please put your initials in each box, thus indicating your consent to take part in the study. Thank you.

STUDY TITLE

Quality of Life and Health Related Quality of Life in Individuals with End Stage Renal Disease: meaning, level and predictors within an Omani Context.

	Statement	**Initial each box**
1.	I confirm that I have read and understood the patient information sheet dated 15 March 2015 (final version 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without any medical care or legal rights being affected.	
3.	I understand that data collected during the study may be looked at by the study supervisors, where it is relevant to my taking part in this research. I give permission for them to have access to these data.	
4.	I give permission that personal information (e.g. telephone number) will be used by the researcher only to contact me during this study.	
5.	I understand that if I choose to withdraw from the study, any information provided till this moment will be included in the study, with my personal data remaining confidential.	

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6.	I give permission for all the information I provide during the study to be used for research purposes (including reports, publications and presentation), with strict preservation of anonymity.	
7.	I understand that any information I provide will be treated in strict confidence. The information will be held securely for at least 5 years and will only be available to the research team. The information will be destroyed thereafter.	
8.	I agree that personal contact information (e.g. name, phone number) will be stored as hard copy separately in a secure location for at least 5 years after the study has ended.	
9.	I give permission for the researcher to audio record the interview for the purpose of study only.	
10	I agree to take part in this study.	

_______________________ _______________________ _________________

Name of participant Date Signature

_______________________ ____________________ _________________

Name of person taking consent Date Signature

When complete, 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes

(يرجى الذهاب إلى الصفحة التالية)

Appendix 4.4 Coding Form for Cognitive Interviews (adopted from Willis, 2005)

QUESTION APPRAISAL SYSTEM: CODING FORM

INSTRUCTIONS. Use one form for EACH question to be reviewed. In reviewing each question:

1. WRITE OR TYPE IN QUESTION NUMBER. ATTACH QUESTION.

Question number or question here:

2. Proceed through the form - Circle or highlight YES or NO for each Problem Type.
3. Whenever a YES is circled, write detailed notes on this form that describe the problem.

STEP 1 - READING: Determine if it is difficult for the interviewers to read the question uniformly to all respondents.		
1a. WHAT TO READ: Interviewer may have difficulty determining what parts of the question should be read.	YES	NO
1b. MISSING INFORMATION: Information the interviewer needs to administer the question is not contained in the question.	YES	NO
1c. HOW TO READ: Question is not fully scripted and therefore difficult to read.	YES	NO
STEP 2 - INSTRUCTIONS: Look for problems with any introductions, instructions, or explanations from the respondent’s point of view.		
2a. CONFLICTING OR INACCURATE INSTRUCTIONS, introductions, or explanations.	YES	NO
2b. COMPLICATED INSTRUCTIONS, introductions, or explanations.	YES	NO
STEP 3 - CLARITY: Identify problems related to communicating the intent or meaning of the question to the respondent.		
3a. WORDING: Question is lengthy, awkward, ungrammatical, or contains complicated syntax.	YES	NO
3b. TECHNICAL TERM(S) are undefined, unclear, or complex.	YES	NO
3c. VAGUE: There are multiple ways to interpret the question or to decide what is to be included or excluded.	YES	NO
3d. REFERENCE PERIODS are missing, not well specified, or in conflict.	YES	NO
STEP 4 - ASSUMPTIONS: Determine if there are problems with assumptions made or the underlying logic.		
4a. INAPPROPRIATE ASSUMPTIONS are made about the respondent or about his/her living situation.	YES	NO
4b. ASSUMES CONSTANT BEHAVIOR or experience for situations that vary.	YES	NO
4c. DOUBLE-BARRELED: Contains more than one implicit question.	YES	NO
STEP 5 - KNOWLEDGE/MEMORY: Check whether respondents are likely to not know or have trouble remembering information.		
5a. KNOWLEDGE may not exist: Respondent is unlikely to know the answer to a factual question.	YES	NO
5b. ATTITUDE may not exist: Respondent is unlikely to have formed the attitude being asked about.	YES	NO
5c. RECALL failure: Respondent may not remember the information asked for.	YES	NO
5d. COMPUTATION problem: The question requires a difficult mental calculation.	YES	NO
STEP 6 - SENSITIVITY/BIAS: Assess questions for sensitive nature or wording, and for bias.		

6a. SENSITIVE CONTENT (general): The question asks about a topic that is embarrassing, very private, or that involves illegal behaviour.	YES	NO
6b. SENSITIVE WORDING (specific): Given that the general topic is sensitive, the wording should be improved to minimize sensitivity.	YES	NO
6c. SOCIALLY ACCEPTABLE response is implied by the question.	YES	NO
STEP 7 - RESPONSE CATEGORIES: Assess the adequacy of the range of responses to be recorded.		
7a. OPEN-ENDED QUESTION that is inappropriate or difficult.	YES	NO
7b. MISMATCH between question and response categories.	YES	NO
7c. TECHNICAL TERM(S) are undefined, unclear, or complex.	YES	NO
7d. VAGUE response categories are subject to multiple interpretations.	YES	NO
7e. OVERLAPPING response categories.	YES	NO
7f. MISSING eligible responses in response categories.	YES	NO
7g. ILLOGICAL ORDER of response categories.	YES	NO
STEP 8 - OTHER PROBLEMS: Look for problems not identified in Steps 1 - 7.		
8. Other problems not previously identified.	YES	NO

(يرجى الذهاب إلى الصفحة التالية)

Appendix 4.5.a. Participants information sheet-phase 2 & 3

UNIVERSITY OF
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Ministry of Health
Sultanate of Oman

Quality of Life and Health Related Quality of Life in Individuals with End Stage Renal Disease: an Omani Context.

You are being invited to take part in a research study that will assess quality of life (QoL) and health related quality of life (HRQoL) in patients with end stage renal disease (ESRD) in an Omani context. Before you decide to take part, it is important that you understand firstly why the research is being done and what it will involve. Please take time to read the following information, and carefully consider whether you want to take part. Please ask the researcher or nurse involved in this study if there is anything that is not clear or if you would like more information.

Aim

The aims of this study are to identify the level of quality of life for patients with end stage renal disease on dialysis by using a number of questionnaires. These will tell us how well these questionnaires are accepted by Omanis; and to what extant disease symptoms, social spiritual factors affect quality of life in Omani patients. The findings from the present study will improve our understanding of the ESRD patients' perceptions about their disease, which can be then incorporated into their future medical and nursing care.

Why have I been invited?

You are being asked to participate as you are an adult who has been diagnosed with ESRD and on haemodialysis therapy on a regular basis. Your dialysis nurse has identified that you are eligible to participate in this study. I hope that 400 patients will agree to take part in this study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your medical or nursing care.

What will happen if I agree to help?

If you agree to take part in this study, it will involve you completing 6 questionnaires during your presence in dialysis unit for your regular haemodialysis sessions. The estimated time to complete these questionnaires will be around 30-40 minutes, but it may take less or more time for some individuals.

The questionnaires to fill out are:

a) Three questionnaires to assess your experience with three symptoms associated with your ESRD disease and how these may affect your everyday activities.
b) A questionnaire to assess what you think about your health status.
c) A questionnaire to assess the impact of ESRD on your socio-economic activates.
d) A questionnaire to assess the impact of ESRD on your spiritual aspects.

You will also be asked some background questions related to your age, gender, education level, marital status, monthly income.

A clinical data will be collected from your medical record (e.g. total hours of haemodialysis per week; malnutrition status, anaemia status) to examine its impact and association with your level of QoL.

Once you have finished completing the questionnaires, you will hand it over to your nurse who in turn will seal it and hand it over to the researcher.

We do not anticipate that there will be any disadvantages or risks if you choose to participate in the study. The information will be gathered may not benefit you directly, but I hope that it will help individuals with the same condition in the future.

What if there is a problem?

If you have a concern about any aspects of the study, you should speak to the researcher who will do his best to answer your questions. The contact details are listed below. If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint to the Dialysis Unit In-charge or to the Call Centre, Ministry of Health. To do so, you can phone the Ministry of Health Call Centre on number 24441999. Working hours: 7:30am to 9.30pm, and during public holidays: 9:30am until 4:30pm.

Who will disclose, use and/or receive my health information?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you (name, address, phone number, direct quotes and locations) that is obtained from you either during the interview or through the questionnaires will be anonymised for publication purposes (e.g. trial report, research paper, conference presentation) so that you cannot be recognised from it. All study data will be kept separately from (the consent forms) and personal contact information so that no connection can be made between the data and your identify. Personal contact information (e.g. name, phone number, etc.) will be stored as a hard copy separately in a secure location for at least 5 years after the study has ended. All study data will be stored safely and securely either on a password protected file, on a secure, password protected PC within the university or in a locked filing cabinet in a locked room at the University of Dundee, Scotland, UK. If you decide to withdraw from the study, all identifiable data will be withdrawn; however, any unidentifiable data already collected prior to your withdrawal will be retained and used in the study.

The Ethical Committee on Medical Research at Ministry of Health, Oman, which has responsibility for scrutinizing all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from Ethical Committee, Ministry of Health, Oman, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected. Once the results are ready I hope to publish them in a medical journal so that other healthcare professionals can benefit from the results. At the end of the study, results will be disseminated to the key stakeholders.

The study has been organised and supervised by the School of Nursing and Midwifery, University of Dundee, Scotland, UK.

Contact

Thank you for taking time to consider taking part in this study. If you would like to find out more about it, please contact:

Waleed Khalid Alrajhi, Researcher, Department of Nursing and Midwifery, University of Dundee – Scotland. I can be contacted in any of the following ways: Telephone: 00968 99636344 OR Email: wkalrajhi@dundee.ac.uk

Alternatively,

Dr. Abdullah Al Battashi on 00968 99885711 (Dean of Nursing Institute, Ibri) who will be happy to discuss it with you.

Thank you for taking the time to consider taking part in this study.

(التالية الصفحة إلى الذهاب يرجى)

Appendix 4.5.b. participant information consent form-phase 2 & 3

UNIVERSITY OF DUNDEE

Ministry of Health
Sultanate of Oman

PARTICIPANT INFORMED CONSENT FORM-PHASE 2 and 3

Please take some time to read the following statements. If you agree with the statements, please put your initials **in each box**, thus indicating your consent to take part in the study. Thank you.

STUDY TITLE

Quality of Life and Health Related Quality of Life in Individuals with End Stage Renal Disease: an Omani Context.

	Statement	**Initial each box**
1.	I confirm that I have read and understood the patient information sheet dated 15 March 2015 (final version 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without any medical care or legal rights being affected.	
3.	I understand that data collected during the study may be looked at by the study supervisors, where it is relevant to my taking part in this research. I give permission for them to have access to these data.	

4.	I give permission that personal information (e.g. telephone number) will be used by the researcher only to contact me during this study.	
5.	I understand that if I choose to withdraw from the study, any information provided till this moment will be included in the study, with my personal data remaining confidential.	
6.	I give permission for all the information I provide during the study to be used for research purposes (including reports, publications and presentation), with strict preservation of anonymity.	
7.	I understand that any information I provide will be treated in strict confidence. The information will be held securely for at least 5 years and will only be available to the research team. The information will be destroyed thereafter.	
8.	I agree that personal contact information (e.g. name, phone number) will be stored as hard copy separately in a secure location for at least 5 years after the study has ended.	
9.	I agree to take part in this study.	

Name of participant Date Signature

Name of person taking consent Date Signature

When complete, 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes

(يرجى الذهاب إلى الصفحة التالية)

Appendix 4.6. Risk assessment plan

Risk	Action to prevent	Action to manage
University and Ministry of Health, Oman, ethics approval takes longer than anticipated	Study documentation is prepared as early as possible. Check slots for ethics review as early as possible.	Engage in discussion with Research office and Directorate of Research, Oman.
Recruitment to cognitive interviews proves challenging	Patients are invited to take part when next in clinic. Flexibility in dates is allowed.	A minimum of 3 interviews is allowed. An extra month of recruitment is allowed.
Attendance of patient to cognitive interview proves challenging and creates delay	Patients are invited to take part when next in clinic. Patients are given the option to participate at different times and dates.	An extra month of recruitment is considered.
Responses to pilot study survey are fewer than required	Oversampling technique is pursued. Two weekly reminders are sent by the researcher.	Additional 2 reminders will be sent if required. Additional invitations are sent by the researcher.
Responses to main study survey are fewer than required	Oversampling technique is pursued. Two weekly reminders are sent.	Additional reminders are sent if required. Additional invitations are sent.
Nephrology nurses or clinical site is not engaging as planned	Ensure involvement of clinicians in planning discussions. Identify clinicians who show interest in research. Regular contact and updates sent to clinicians.	Engage in discussion and negotiation with clinicians. Identify source of sub-optimal engagement. Examine alternatives to increase engagement.
Nephrology nurses or clinical site withdraws early	Ensure involvement of clinicians in planning discussions. Identify clinicians who show interest in research. Regular contact and updates sent to clinicians.	Start negotiations with another clinical site. Inform other clinical sites about development and request support with recruitment until a new clinical site comes on board.
Recruitment to main study survey proves challenging	Ensure involvement of clinicians in planning discussions. Identify clinicians who show interest in research. Regular contact and updates sent to clinicians.	Offer to support clinicians during recruitment. Consider adding a new clinical site.
Patient withdraws early	Ensure patient fully understands the purpose and procedures of the study.	Replace patients who withdraw. Intensify recruitment. Set minimum number of patients required.

Risk	Action to prevent	Action to manage
Recruiting clinicians for the study proves challenging	Set intense recruitment strategy, ensuring study advertisements are widely available.	Relax requirements set in the job description. An additional month of recruitment is allowed. Explore possible availability within research group.
Data collection rates are lower than expected	Ensure that questionnaires have been adequately prepared. Ensure that participants fully understand procedures.	Administering questionnaires as an interview base.

(التالية الصفحة إلى الذهاب يرجى)

Appendix 5.1. SEIQoL-DW interview record form (IRF)

Respondent	**Interview Record Form (IRF)**									
	Time taken to complete (minutes: seconds)	**Understanding of method**			**Fatigue/Boredom**			**Overall validity of information**		
		Not understood	Poor/Uncertain Understanding	understood	None	Some	A lot	Definitely Invalid	Uncertain	Valid
01	21	-	-	✓	-	-	-	-	-	✓
02	15	-	-	✓	-	-	-	-	-	✓
03	12	-	-	✓	-	-	-	-	-	✓
04	15	-	-	✓	-	-	-	-	-	✓
05	15	-	-	✓	-	-	-	-	-	✓
06	16	-	-	✓	-	-	-	-	-	✓
07	14	-	-	✓	-	-	-	-	-	✓
08	13	-	-	✓	-	-	-	-	-	✓
09	18	-	-	✓	-	-	-	-	-	✓
10	21	-	-	✓	-	-	-	-	-	✓
11	14	-	-	✓	-	-	-	-	-	✓
12	19	-	-	✓	-	-	-	-	-	✓

Appendix 5.2. Summary of cues definitions and categorisation of cues

Participants	**Description of Cue**	**Cue Label**	**Categorisation of QoL cues**			
			Researcher	**Reviewer 1**	**Reviewer 2**	**Agreed category**
Participant 001	“…mixing up with people and sitting with them. Sitting with friends, hanging out with them..”.	Socialisation	Social life	Social life	Social life/ enjoying life	*Social life*
	“physical activity, ability to go to shopping and get groceries. Ability to climb up the stairs”.	Physical activity	Living conditions	Independence	Role functioning	*Role functioning*
	“transportation. Able to drive to places of interest is highly important to me. Also ability to bank up the money required to this”.	Mobility/money	Finances	Enjoying life	Autonomy/ Independence	Autonomy/ Independence
	“I am youth and my future is not clear; the job as well!! I don’t know if I will find a job that suits my health condition and how my future will be?”	Future	Role functioning	Work	Autonomy/ Independence	*Role functioning*
	“going to mosque and praying to Allah ‘God’, fasting and being able to fast is highly important to me”.	Religion	Religion/spiritual life	Religion	Religion/spiritual life	*Religion/ spiritual life*
Participant 002	“family life and specifically children are important to me. They make up my life”.	Family	Family	Family	Family	*Family*
	“diabetic was a cause to amputate my leg. I wish to have it back so that I can walk and looks normal; having good health extremity is what I want”.	Body image	Health	Not sure	Health	*Personal and family health*

	“mobility, walking and meeting my needs”.	Mobility	Living conditions	Autonomy/ Independence	Role functioning	*Role functioning*
	“I wish to study; learning is important”.	Self-development	Autonomy/ independence	Attitudes to life	Autonomy/ Independence	*Autonomy/ independence*
	“religion is very important; in fact it is on top of this list”.	Religion	Religion/spiritual life	Religion	Religion/spiritual life	*Religion/ spiritual life*
Participant 003	“praying five time a day; and being fasting is crucial to me. I don’t want to feel delinquent at this part”	Religion	Religion/spiritual life	Religion	Religion/spiritual life	*Religion/ spiritual life*
	“health and being able to move and live in normal life”.	Health	Health	Personal health	Health	*Personal and family health*
	“work. I work in army and such type of job demands you to be active most of time”.	Job	Work/occupation	Work	Work/occupation	*Work/ occupation*
	“sport and mobility. As being in army, sport become part of my life”.	Sport	Leisure activities/hobbies	Leisure activities	Leisure activities/ Hobbies	*Leisure activities*
	“my family and close relatives are important to me. I am the only one who looks after them”.	Family	Family	Family	Family	*Family*
Participant 004	“my presence at home is very important to care for my wife and children. They are taking most of my time”.	Family	Family	Family	Family	*Family*
	“going out from home and coming for dialysis; also getting groceries to home is important. These are all my responsibilities”.	Mobility	Role functioning	Autonomy/Independence	Autonomy/ Independence	*Autonomy/ Independence*
	“it is important to me to care for my wife. Sexual life, for	Wife/sexual ability	Sexuality	Relationships	Sexuality	*Sexuality*

	instance, I consider it as an important aspect in my life”.					
	“diseases; allergies from medications and secondary diseases. Basically, my health”.	Health	Health	Personal health	Health	*Personal and family health*
	“being on time for prayers, going to mosque; as well as going to Hajj are important to me”.	Religion/worship	Religion/spiritual life	Religion	Religion/spiritual life	*Religion/spiritual life*
Participant 005	“reading Quran (holy book), prying and going to Hajj. These on top of the important list in my life”	Worship	Religion/spiritual life	Religion	Religion/spiritual life	*Religion/spiritual life*
	“looking after my family and caring for my children comes after worship”.	Family	Family	Family	Family	*Family*
	“practical life, living in good condition and with sufficient money are also important to me”.	Wealth	Finances	Finances	Living conditions	*Finances*
	“herbal remedy, using ‘Quran recitation’ in treating myself can improves my health condition”	Health	Health	Personal Health	Religion/spiritual life	*Personal and family health*
	“neighbourhood and neighbours, sitting with my friend and going out with me makes me feel good”.	Social life	Social life	Social Life	Relationships	*Social life*
Participant 006	“I am from Al-Jabal Al-Akhdar (called the ‘Green Mountain’ in Arabic. Located at 2,000 metres above sea level). Driving up and down is important to me so that I can come for dialysis”.	Health	Health	Personal Health	Living conditions	*Personal and family health*

	“raising children is a huge responsibility and I devote it a lot of time”.	Children	Family	Family	Family	*Family*
	“overall responsibilities that I have and the provision of food to my family are important”.	Responsibility	Role functioning	Family	Role functioning	*Role functioning*
	“worship and praying. It is obligatory to perform prayers in congregation”.	Prayer	Religion/spiritual life	Religion	Religion/spiritual life	*Religion/spiritual life*
	“visiting relatives and friends and sitting with them. I would say family gathering is important to me”.	Family gathering	Social life	Social life	Family	*Social life*
Participant 007	“I am 31 years old; not yet married. Marriage and engagement something important to me”.	Marriage	Partnership	Relationships	Relationships	*Relationships*
	“I usually spend most of time doing sport. Sport and physical activity are dominating most of my time”.	Sport	Leisure activities/ hobbies	Leisure activities	Leisure activities/ Hobbies	*Leisure activities/ Hobbies*
	“travelling and sightseeing is my favourite. I have been to different places.. I like seeing new places”.	Entertainment	Leisure activities/ hobbies	Attitudes to life	Leisure activities/ Hobbies	*Leisure activities/ Hobbies*
	“the relationship with people and specifically with my colleagues at work, and neighbours are important”.	Social life	Social life	Social life	Relationships	*Social life*
	“spirituality; praying and going to places of worship are also important to me”.	Spirituality	Religion/spiritual life	Religion	Religion/spiritual life	*Religion/spiritual life*
Participant 008	“looking and caring after my young children something I would rank it as very	Family	Family	Family	Family	*Family*

	important. Their study as well is very important” .					
	“religious issues, like prayer and fasting something obligatory in this life. I am delinquent in this aspect”.	Religion	Religion/spiritual life	Religion	Religion/spiritual life	*Religion/spiritual life*
	“connecting with people and friends something that I like. Especially when I site with them I feel the joy”.	Social interaction	Social life	Social Life	Social life	*Social life*
	“my job. I have my own small business and I devote it much of my time”.	Job	Work/occupation	Work	Work/occupation	*Work/occupation*
	“tourism was my profession. Till today, sightseeing and tourism are very important to me”.	Tourism	Leisure activities/ hobbies	Enjoying life	Work/occupation	*Enjoying life*
Participant 009	“family. my family is my main responsibility. I have to keep them happy and provide them with whatever required to live happily”.	Family	Family	Family	Family	*Family*
	“worship, going to mosque and Hajj (Makha). I have never been there and it is my dream. It is something important to me”.	Worship	Religion/spiritual life	Religion	Religion/spiritual life	*Religion/spiritual life*
	“work, active, earning money and settling a business”.	Job	Finances	Autonomy/Independence	Work/occupation	*Work/occupation*
	“can’t believe that I am away from agriculture. It is my hoppy and it is important to me”.	Agriculture	Leisure activities/ hobbies	Leisure activities	Leisure activities/ Hobbies	*Leisure activities/ Hobbies*
Participant 010	“I would say my children, my children and my children. The greatest	Children	Family	Family	Family	*Family*

	interest in my life is my children”.					
	“the trip to dialysis unit is very important to me. It is what it keeps me alive”.	Health	Health	Personal health	Quality of life	*Personal and family health*
	“my prayers and fasting. Although my health deteriorated, but these are of something that I have to do”.	Worship	Religion/spiritual life	Religion	Social life	*Religion/spiritual life*
	“”I work on trading. It keeps me busy and gives me a secured wealth”.	Business	Finances	Work	Work/occupation	*Work/ occupation*
	“I have had kidney transplantation. Unfortunately it failed and to have another one is crucial to me”.	Kidney transplant	Kidney transplant/ health	Personal Health	Quality of care	*Personal and family health*
Participant 011	“socialisation and staying connected with people. This what I would say”.	Social life	Social life	Social Life	Social life	*Social life*
	“my job. I would say my job is something very important in my life”.	Job	Work/occupation	Work	Work/occupation	*Work/ occupation*
	“you might not believe this!, kitchen and cooking. It is always of my interest.. maybe it is a matter of self-esteem.. I don’t know”.	Cooking	Leisure activities/ hobbies	Autonomy/Independence	Leisure activities/ Hobbies	*Leisure activities/ Hobbies*
	“the difficulties that I face in praying, fasting and going to ‘Makah’ is bothering me. Worship is important”.	Worship	Religion/spiritual life	Religion	Religion/spiritual life	*Religion/spiritual life*
	“I am a young girl, and my future is vague to me. I wish to marry and have children”.	Future	Role functioning	Other – not sure	Role functioning	*Role functioning*
Participant 012	“my health is the most important aspect in my life.	Health	Health	Personal Health	Health	*Personal and family health*

	How can I mobilise when I am ill?”					
	“the healthcare that I receive from the medical team at dialysis unit is very important to me”.	Healthcare	Quality of care	Quality of care	Quality of care	*Quality of care*
	“fasting. I can’t fast and my health condition doesn’t really support me to fast. Another ‘Ramadan-fasting month- will be coming and I didn’t fast. I wish to do this”.	Fasting	Religion/spiritual life	Religion	Religion/spiritual life	*Religion/spiritual life*
	“currently, I look after my grandchildren. My children have a busy life, and I enjoy looking after my grandchildren”.	Grandchildren	Family	Family	Family	*Family*
	“I have a small garden; I like agriculture. I spend free time there. It also keeps me busy and active”.	Garden/agriculture	Leisure activities/ hobbies	Leisure activities	Work/occupation	*Leisure activities/ hobbies*

Appendix 5.3. Cues, the levels and weights reported per participants

Respondent 1	Deriving SEiQOL outcome data	Cues category				
		Social life	Physical movement	Future	Money	Religion
	Cues levels	54	48	10	12	63
	Cues weights	15	10	15	15	45
	SEiQOL index	8.1	4.8	1.5	1.8	28.35
Overall SEiQOL-DW score		44.55				

Respondent 2	Deriving SEiQOL outcome data	Cues category				
		Family	Body image	Mobility	Self-development	Religion
	Cues levels	98	28	20	53	32
	Cues weights	30	15	15	15	25
	SEiQOL index	29.4	4.2	3	7.95	8
Overall SEiQOL-DW score		52.55				

Respondent 3	Deriving SEiQOL outcome data	Cues category				
		Religion	Health	Job	Sport	Family
	Cues levels	88	52	87	60	97
	Cues weights	30	30	05	05	30
	SEiQOL index	26.4	15.6	4.35	3	29.1
Overall SEiQOL-DW score		78.45				

Respondent 4	Deriving SEiQOL outcome data	Cues category				
		Family	Mobility	Sexual relationship	Health	Religion & worship
	Cues levels	95	37	97	58	90
	Cues weights	20	13	22	20	25
	SEiQOL index	19	4.81	21.34	11.6	22.5

Overall SEiQOL-DW score	79.25

Respondent 5	Deriving SEiQOL outcome data	Cues category				
		Worship	Family	Wealth	Health	Social life
	Cues levels	71	69	36	40	71
	Cues weights	26	20	15	24	15
	SEiQOL index	18.46	13.8	5.4	9.6	10.65
Overall SEiQOL-DW score		57.91				

Respondent 6	Deriving SEiQOL outcome data	Cues category				
		Health	Family	Responsibility	Prayer	Social gathering
	Cues levels	42	75	65	59	86
	Cues weights	20	26	14	30	10
	SEiQOL index	8.4	19.5	9.1	17.7	8.6
Overall SEiQOL-DW score		63.3				

Respondent 7	Deriving SEiQOL outcome data	Cues category				
		Marriage	Sport	Entrainment	Social life	Religion
	Cues levels	07	62	58	38	60
	Cues weights	27	22	15	15	21
	SEiQOL index	1.89	13.64	8.7	5.7	12.6
Overall SEiQOL-DW score		42.53				

Re		Cues category

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	Deriving SEiQOL outcome data	Family	Worship	Social interaction	Job	Tourism
	Cues levels	77	39	50	40	62
	Cues weights	33	30	5	23	9
	SEiQOL index	25.41	11.7	2.5	9.2	5.58
Overall SEiQOL-DW score		54.39				

Respondent 9	**Deriving SEiQOL outcome data**	**Cues category**			
		Family	Worship	Job	Agriculture
	Cues levels	60	70	40	33
	Cues weights	39	38	14	9
	SEiQOL index	23.4	26.6	5.6	2.97
Overall SEiQOL-DW score		58.57			

Respondent 10	**Deriving SEiQOL outcome data**	**Cues category**				
		Children	Health	Worship	Business	Kidney transplant
	Cues levels	77	57	52	43	19
	Cues weights	31	28	21	08	12
	SEiQOL index	23.87	15.96	10.92	3.44	2.28
Overall SEiQOL-DW score		56.47				

Respondent 11	**Deriving SEiQOL outcome data**	**Cues category**				
		Social life	Job	Cooking	Worship	Future
	Cues levels	26	6	13	38	74
	Cues weights	28	19	16	11	26

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	SEiQOL index	7.28	1.14	2.08	4.18	19.24
Overall SEiQOL-DW score		33.92				

	Deriving SEiQOL outcome data	**Cues category**				
Respondent 12		Health	Health care	Fasting (spiritual)	Grandchildren	Agriculture
	Cues levels	34	68	25	68	30
	Cues weights	20	18	27	24	11
	SEiQOL index	6.8	12.24	6.75	16.32	3.3
Overall SEiQOL-DW score		45.41				

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Appendix 5.4 Findings of the Cognitive interviewing of SF-36 across participants

SF-36 items	Participants											
	01	02	03	04	05	06	07	08	09	10	11	12
1.General health	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2.Health compared to 1 year ago	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3(a) Limitations of activities (Vigorous activities)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3 (b) Moderate activities	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3 (c) Lifting or carrying groceries	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3(d) Climbing several flights of stairs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3(e) Climbing one flight of stairs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3(f) Bending, kneeling, or stooping	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3(g) Walking more than a mile	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3(h) Walking several blocks	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3(i) Walking one block	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3(j) Bathing or dressing yourself	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4(a) Physical health problems (time you spent on work)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4(b) Accomplished less than you would like	✓	✓	✓	✓	✓	Question is undefined, unclear, or complex.	✓	✓	✓	✓	✓	✓
4(c) limited in the kind of work	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4(d) limited in the kind of work	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

5(a) emotional health (cut down amount of work)	✓	Question is contains complicated syntax.	✓	Question is lengthy and contains complicated syntax.	✓	✓	✓	✓	Question is awkward, or contains complicated syntax.	✓	Question is lengthy.	Question is lengthy, awkward.
5(b) Accomplished less than you would like	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
5(c) Didn't do work or other activities as carefully as usual	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
6 (social activities)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
7. bodily pain during the past 4 weeks	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
8. pain interference with normal work	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9(a) energy and emotions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9(b) Have you been nervous person	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9(c) Have you felt so down	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9(d) Have you felt calm and peaceful	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9(e) Did you have a lot of energy	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9(f) Have you felt downhearted	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9(g) Did you feel worn out	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9(h) Have you been a happy person	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9(i) Did you feel tired	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10.Social activities	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
11(a) General health	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
11(b) I am as healthy as anybody I know	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
11(c) I expect my health to get worse	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
11(d) My health is excellent	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

✓ = item probed what was intended and participant was able to find his/her answer

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Appendix 5.5 Findings of the Cognitive interviewing of QOLI-D across participants

QOLI-D items	Participants											
	01	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**	**11**	**12**
Part 1 (how satisfied are you with)												
1- Health	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2-Health care	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3-Energy for everyday activities	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4-Self-care	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓
5-Chance to get Kidney transplant	✓		✓		✓	✓	✓	✓		✓		
6-Changes due ESRD	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
7-Control on life	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
8-Chance to live long	✓	Clarity: not clear	✓	✓	✓	✓	✓	✓	✓	Clarity: not clear	✓	Clarity: not clear
9-Family health	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10-Children	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
11-Family happiness	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
12-Your sexual life	✓	✓	✓	✓	✓	Sensitivity: The question asks about a topic that is embarrassing and very private	✓	✓	✓	Sensitivity: The question asks about a topic that is embarrassing and very private	Sensitivity: The question asks about a topic that is embarrassing and very private	Sensitivity: The question asks about a topic that is embarrassing and very private
13-partnership	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
14-Friendship	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

15-Emotional support from family	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
16-Emotional support from others	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
17-Ability to look after family	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
18-Usefulness to others	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
19-Worries in life	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
20-Neighbourhood	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
21-Place where you live	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
22-Job (if employee)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
23-Not having a job (if unemployed)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
24-Education	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
25-Financial needs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
26-Entertainment	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
27-Chances for Happy future	✓	✓	✓	Clarity: not clear	✓	✓	✓	✓	Clarity: not clear	✓	✓	✓
28-Peace of mind	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
29-Faith in God	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
30-Achievement of personal goals	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
31-Happiness in general	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
32-Life in general	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

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33-Personal appearance	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
34Yourself in general	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Part 2 (how important to you is)												
1- Health	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2-Health care	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3-Energy for everyday activities	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4-Self-care	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓
5-Chance to get Kidney transplant	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
6-Changes due ESRD	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
7-Control on life	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
8-Chance to live long	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9-Family health	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10-Children	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
11-Family happiness	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
12-Your sexual life	✓	✓	✓	✓	✓	Sensitivity: The question asks about a topic that is embarrassing and very private	✓	✓	✓	Sensitivity: The question asks about a topic that is embarrassing and very private	Sensitivity: The question asks about a topic that is embarrassing and very private	Sensitivity: The question asks about a topic that is embarrassing and very private
13-partnership	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
14-Friendship	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
15-Emotional support from family	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

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16-Emotional support from others	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
17-Ability to look after family	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
18-Usefulness to others	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
19-Worries in life	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
20-Neighbourhood	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
21-Place where you live	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
22-Job (if employee)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
23-Not having a job (if unemployed)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
24-Education	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
25-Financial needs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
26-Entertainment	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
27-Chances for Happy future	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
28-Peace of mind	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
29-Faith in God	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
30-Achievement of personal goals	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
31-Happiness in general	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
32-Life in general	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
33-Personal appearance	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

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34- Yourself in general	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

✓ = item probed what was intended and participant was able to find his/her answer

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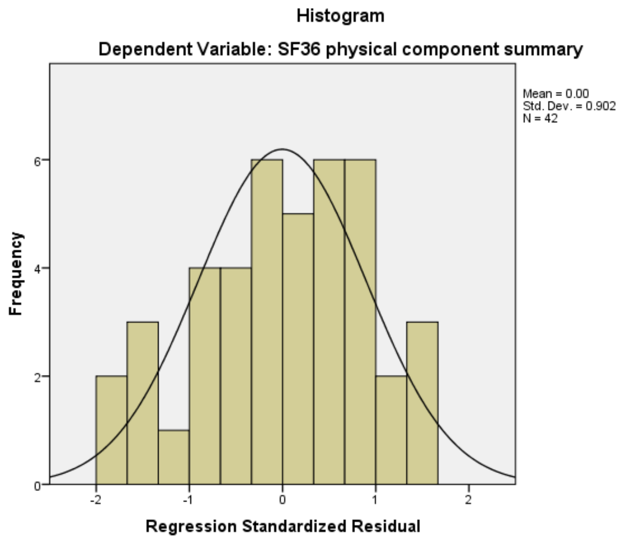
Appendix 6.1 Summary of the variables against outliers, skewness and kurtosis values, distribution, and tests of normality

Variable	Outlier		skewness	Z score	kurtosis	Z score	Tests of normality (*p* value)	
	Upper end	Lower end					Kolmogorov-Smirnov	Shapiro-Wilk
Pt age	-	-	.497	1.392	.133	0.189	.001	.002
Hb level	2	2	.546	0.194	1.225	1.745	.200*	.340
HCT	2	-	.730	2.044	.651	0.927	.200*	.112
Albumin	-	2	-.987	-2.764	1.578	2.247	.200*	.026
HD hours	-	-	.106	0.296	.322	0.458	.000	.000
HD adequacy	-	-	-.142	-0.397	.002	0.002	.200*	.267
SF36- PF	-	-	.029	0.08	-.923	-1.31	.200*	.193
SF36-RP	-	-	.154	0.43	-.769	-1.09	.200*	.094
SF36-BP	-	-	.211	0.59	-.613	-0.87	.060	.081
SF36-GH	-	-	.049	0.13	-.917	-1.30	.200*	.340
SF36-vitality	-	-	.100	0.28	0.49	0.698	.124	.340
SF36-SF	-	-	0.096	0.26	-.752	-1.07	.010	.048
SF36-RE	-	-	-.021	-0.05	-1.060	-1.51	.062	.017
SF36-MH	-	-	-.056	-0.15	-.537	-0.76	.200*	.274
SF36-PCS	-	-	-.012	-0.03	-.947	-1.34	.120	.353
SF36-MCS	-	-	.081	0.22	-.460	-0.65	.200*	.908
QOLI-D-total	-	-	-.342	-0.957	-.841	-0.00	.200*	.530
QOLI-D-health & functioning	-	-	-.394	-1.10	-.264	-0.37	.200*	.607
QOLI-D-social & economic	-	1	-.407	-1.14	-.193	-0.27	.200*	.240

QOLI-D-psychological/ spiritual	-	-	-.809	-2.26	-.013	-0.01	.036	.001
QOLI-D-family		3	-1.489	-4.17	3.656	5.65	.002	.000
HADS-anxiety	-	-	.300	0.84	-.592	-0.84	.200*	.189
HADS-depression	-	-	.067	0.18	-.963	-1.37	.200*	.151
HADS- total	-	-	.119	0.33	-.664	-0.94	.200*	.510
Itch-5D	-	-	.432	1.21	-.140	-0.19	.200*	.216
FSS	-	-	-.317	-0.88	-1.171	-1.66	.019	.007
SWB-religious	-	-	-1.547	-4.33	3.38	4.82	.041	.002
SWB-existential		2	-.567	-1.58	.344	0.49	.200*	.107
SWB- total	-	1	-1.273	-3.56	2.44	3.48	.075	.129

Multivariate normality, linearity, and homoscedasticity

SF-36 (PCS)


Histogram

Dependent Variable: SF36 physical component summary

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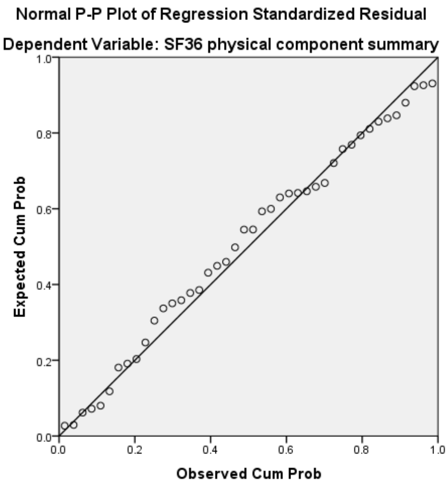
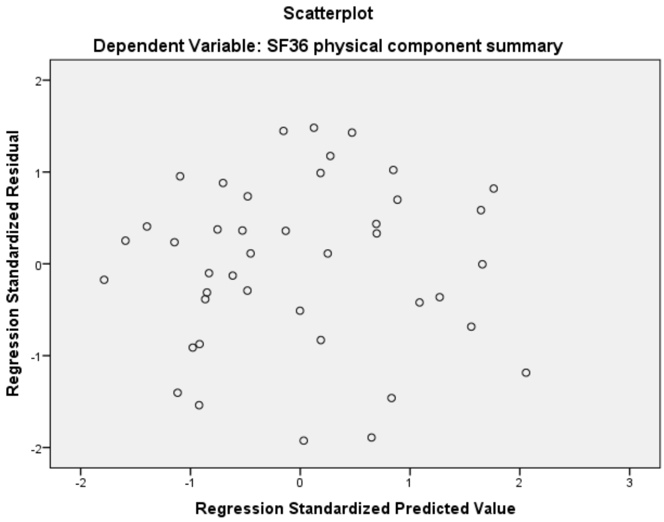
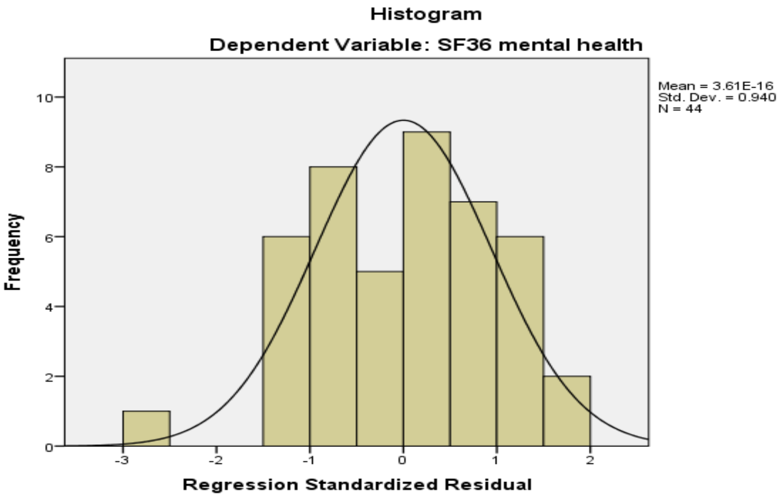
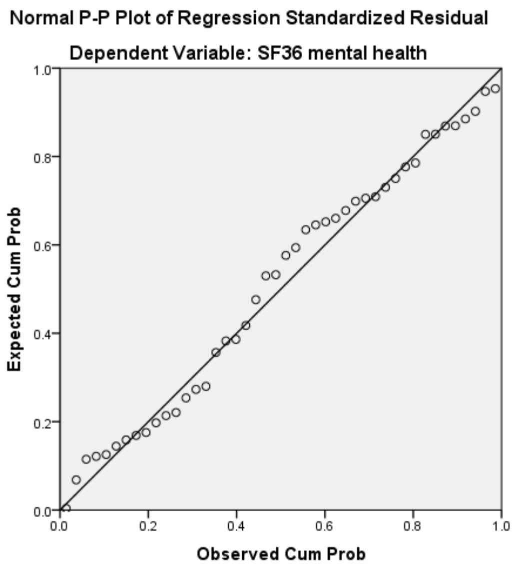


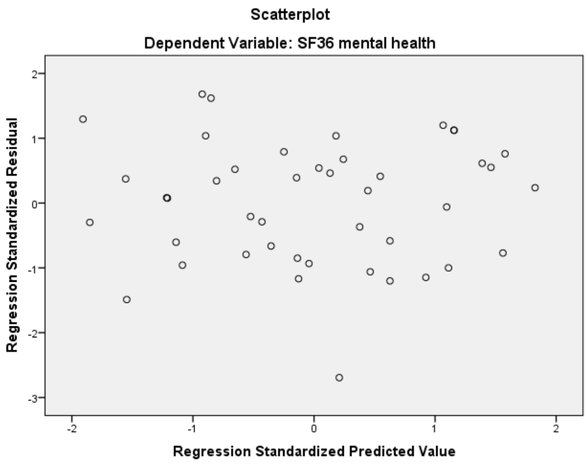


SF-36 (MCS)

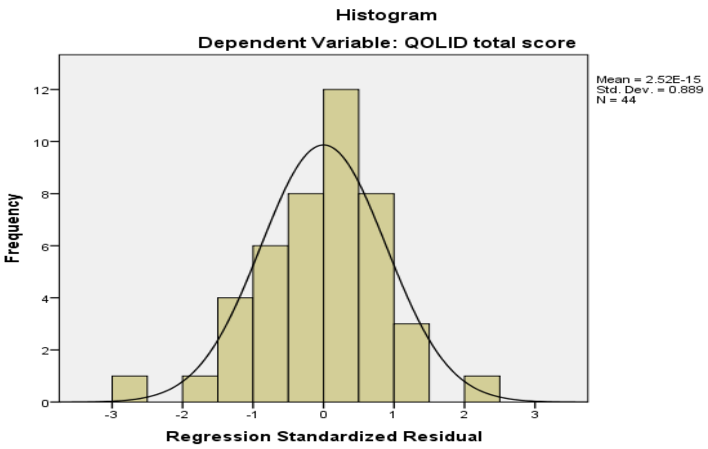


(التالية الصفحة إلى الذهاب يرجى)

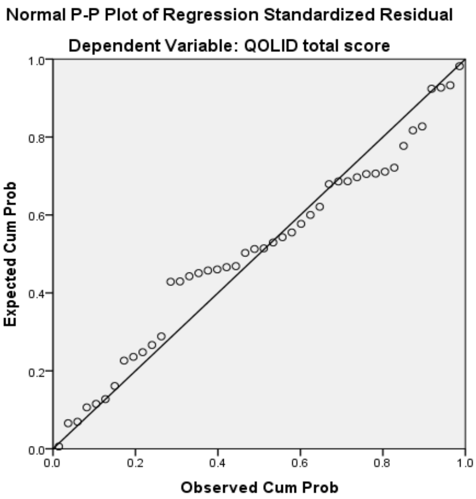




QOLI-D



(التالية الصفحة إلى الذهاب يرجى)



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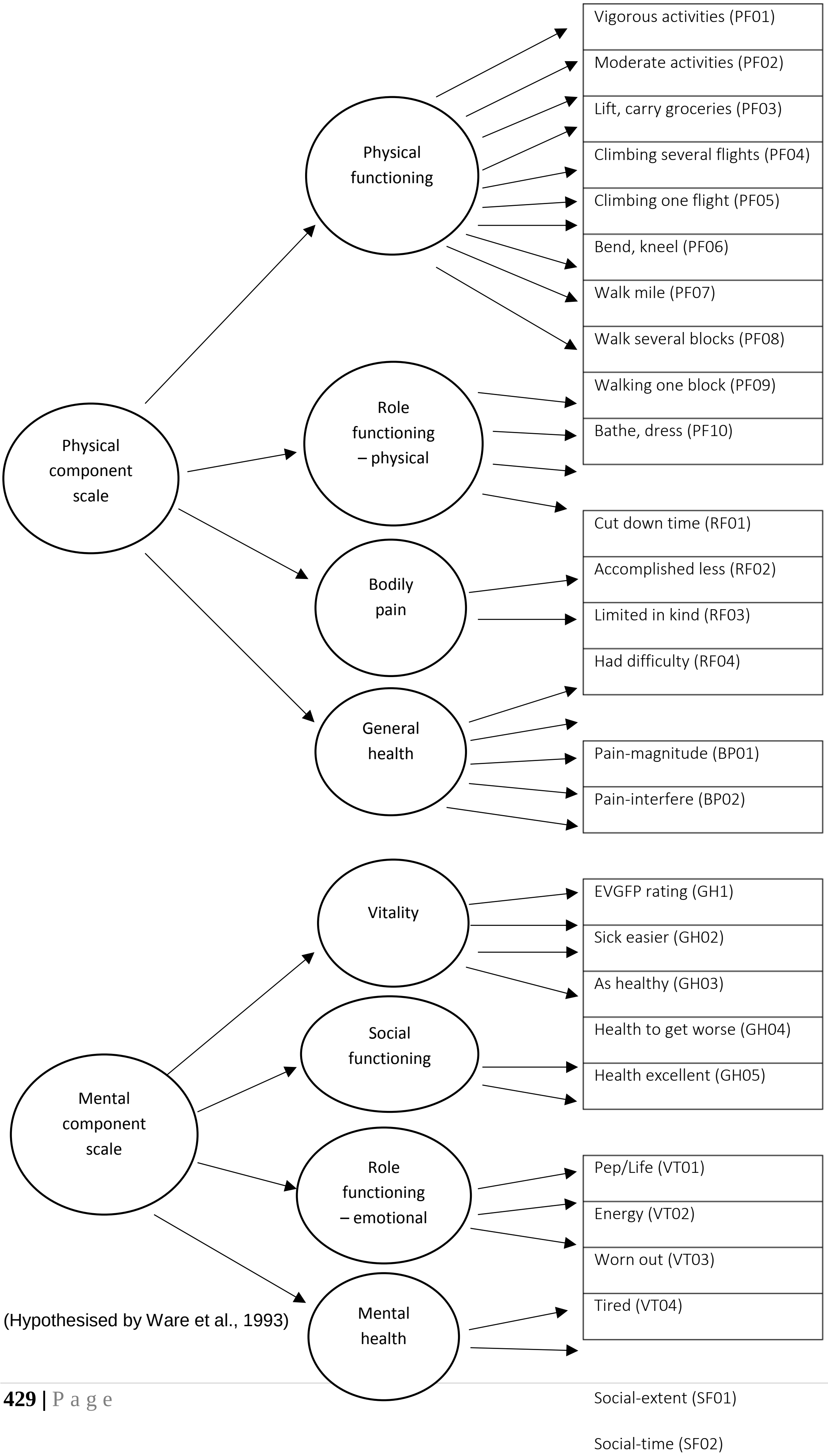
Appendix 7.1 standarised factor structure of the SF36 V2



(Hypothesised by Ware et al., 1993)

Appendix 7.2 SF36v2 underlying factor structures 4-8

SF36v2 4-Factor structure

Item	Factor 1	Factor 2	Factor 3	Factor 4
Vigorous activities (PF01)	**0.56**	0.26	0.01	0.03
Moderate activities (PF02)	0.27	**0.62**	-0.08	0.01
Lift, carry groceries (PF03)	0.18	**0.65**	0.09	-0.00
Climbing several flights (PF04)	**0.35**	**0.67**	-0.08	0.02
Climbing one flight (PF05)	-0.04	**0.73**	-0.01	0.01
Bend, kneel (PF06)	-0.14	**0.70**	0.03	0.01
Walk mile (PF07)	0.12	**0.76**	0.01	0.08
Walk several blocks (PF08)	-0.01	**0.78**	0.03	-0.00
Walking one block (PF09)	-0.16	**0.70**	0.02	0.01
Bathe, dress (PF10)	-0.33	**0.63**	-0.03	0.09
Cut down time (RF01)	0.03	0.02	-0.10	**0.79**
Accomplished less (RF02)	0.07	-0.05	-0.01	**0.80**
Limited in kind (RF03)	0.05	0.09	-0.14	**0.71**
Had difficulty (RF04)	0.04	0.11	0.07	**0.70**
Pain-magnitude (BP01)	0.09	0.11	**0.69**	0.01
Pain-interfere (BP02)	0.04	0.12	**0.68**	0.04
EVGFP rating (GH1)	0.24	0.04	**0.47**	0.01
Sick easier (GH02)	-0.07	0.11	**0.33**	0.09
As healthy (GH03)	0.17	-0.13	**0.42**	0.05
Health to get worse (GH04)	-0.01	0.09	**0.39**	0.02
Health excellent (GH05)	0.22	0.02	**0.61**	0.07
Pep/Life (VT01)	**0.36**	-0.11	**0.70**	-0.00
Energy (VT02)	**0.38**	0.01	**0.63**	-0.10
Worn out (VT03)	-0.16	0.02	**0.70**	-0.04
Tired (VT04)	-0.15	-0.05	**0.68**	0.04
Social-extent (SF01)	-0.09	0.08	**0.63**	0.03
Social-time (SF02)	-0.07	0.16	**0.36**	0.07
Cut down time (RE01)	-0.12	-0.02	0.13	**0.77**
Accomplished less (RE02)	-0.14	-0.01	0.04	**0.84**
Not careful (RE03)	-0.05	0.02	0.06	**0.67**
Nervous (MH01)	**-0.39**	0.08	**0.49**	-0.03
Down in dumps (MH02)	**-0.30**	-0.03	**0.65**	0.03
Peaceful (MH03)	-0.05	-0.01	**0.58**	0.02
Blue/sad (MH04)	**-0.38**	-0.02	**0.58**	0.06
Happy (MH05)	0.12	-0.07	**0.61**	0.01

Bold values indicate that item loading on a factor is ≥ .30

(يرجى الذهاب إلى الصفحة التالية)

SF36v2 5-Factor structure

Item	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
Vigorous activities (PF01)	**0.77**	0.05	0.05	0.10	-0.08
Moderate activities (PF02)	**0.43**	**0.52**	0.02	0.01	-0.01
Lift, carry groceries (PF03)	0.28	**0.59**	0.01	0.12	-0.01
Climbing several flights (PF04)	**0.49**	**0.54**	0.03	0.05	-0.06
Climbing one flight (PF05)	0.09	**0.72**	0.01	-0.04	0.02
Bend, kneel (PF06)	-0.07	**0.74**	0.01	0.03	0.01
Walk mile (PF07)	**0.33**	**0.69**	0.01	-0.02	0.05
Walk several blocks (PF08)	0.16	**0.76**	-0.01	-0.04	0.06
Walking one block (PF09)	-0.07	**0.73**	0.01	-0.01	0.04
Bathe, dress (PF10)	**-0.38**	**0.75**	0.01	-0.01	-0.04
Cut down time (RF01)	0.03	-0.03	**0.83**	-0.15	0.01
Accomplished less (RF02)	0.07	-0.13	**0.84**	-0.01	0.04
Limited in kind (RF03)	0.10	0.01	**0.75**	-0.20	0.01
Had difficulty (RF04)	0.04	0.06	**0.73**	0.01	0.07
Pain-magnitude (BP01)	-0.02	0.13	-0.01	**0.57**	0.24
Pain-interfere (BP02)	-0.07	0.15	0.03	**0.53**	0.26
EVGFP rating (GH1)	0.02	0.04	0.01	**0.56**	-0.03
Sick easier (GH02)	-0.03	0.12	0.09	0.16	0.23
As healthy (GH03)	-0.04	-0.12	0.06	**0.47**	0.01
Health to get worse (GH04)	0.03	0.08	0.02	0.23	0.23
Health excellent (GH05)	0.04	0.01	0.07	**0.59**	0.10
Pep/Life (VT01)	0.05	-0.12	0.01	**0.79**	0.01
Energy (VT02)	0.13	-0.01	-0.10	**0.75**	-0.02
Worn out (VT03)	0.15	-0.01	-0.04	0.20	**0.64**
Tired (VT04)	0.04	-0.06	0.05	0.26	**0.56**
Social-extent (SF01)	-0.04	0.10	0.03	**0.33**	**0.42**
Social-time (SF02)	-0.06	0.19	0.06	0.22	0.21
Cut down time (RE01)	-0.23	0.01	**0.79**	0.07	0.07
Accomplished less (RE02)	**-0.34**	0.02	**0.87**	0.07	-0.06
Not careful (RE03)	-0.23	0.06	**0.68**	0.13	-0.08
Nervous (MH01)	-0.03	0.09	-0.04	-0.07	**0.68**
Down in dumps (MH02)	-0.06	-0.01	0.04	0.15	**0.64**
Peaceful (MH03)	-0.01	-0.01	0.01	**0.38**	**0.31**
Blue/sad (MH04)	0.01	-0.01	0.01	-0.04	**0.76**
Happy (MH05)	0.12	-0.11	0.02	**0.44**	0.28

Bold values indicate that item loading on a factor is ≥ .30

SF36v2 6-Factor structure

Item	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6
Vigorous activities (PF01)	**0.83**	**-0.66**	0.03	0.04	-0.02	-0.01
Moderate activities (PF02)	**0.70**	0.01	0.01	-0.01	-0.01	0.01
Lift, carry groceries (PF03)	**0.60**	0.17	-0.01	0.08	-0.01	0.05
Climbing several flights (PF04)	**0.79**	-0.05	0.01	0.01	-0.03	-0.01
Climbing one flight (PF05)	**0.49**	**0.41**	0.01	-0.06	0.01	0.01
Bend, kneel (PF06)	**0.33**	**0.55**	0.01	0.01	-0.01	0.04
Walk mile (PF07)	**0.72**	0.17	-0.01	-0.08	0.08	0.02
Walk several blocks (PF08)	**0.55**	**0.41**	0.01	-0.01	0.05	0.07
Walking one block (PF09)	0.26	**0.65**	0.04	0.07	-0.01	-0.01
Bathe, dress (PF10)	0.01	**0.86**	0.01	0.04	-0.11	-0.26
Cut down time (RF01)	0.02	0.03	**0.77**	-0.01	-0.04	-0.28
Accomplished less (RF02)	-0.01	-0.04	**0.80**	0.07	-0.01	0.01
Limited in kind (RF03)	0.13	0.01	**0.71**	-0.07	-0.03	-0.03
Had difficulty (RF04)	0.11	0.04	**0.69**	0.08	0.04	-0.07
Pain-magnitude (BP01)	0.05	0.08	-0.03	**0.50**	0.25	-0.06
Pain-interfere (BP02)	-0.01	0.18	0.02	**0.49**	0.27	0.03
EVGFP rating (GH1)	0.03	0.04	0.01	**0.57**	-0.04	0.20
Sick easier (GH02)	0.08	0.03	0.05	0.07	0.26	0.11
As healthy (GH03)	-0.12	-0.01	0.05	**0.49**	-0.01	0.04
Health to get worse (GH04)	0.09	-0.01	0.01	0.16	0.26	0.26
Health excellent (GH05)	0.01	0.03	0.07	0.61	0.09	0.03
Pep/Life (VT01)	-0.03	-0.08	-0.01	**0.79**	0.02	0.14
Energy (VT02)	0.10	-0.06	-0.10	**0.74**	-0.01	-0.02
Worn out (VT03)	0.14	-0.17	-0.05	0.07	**0.72**	-0.03
Tired (VT04)	0.02	-0.13	0.03	0.14	**0.62**	-0.05
Social-extent (SF01)	-0.01	0.11	0.03	0.27	**0.45**	0.04
Social-time (SF02)	0.07	0.12	0.04	0.14	0.24	0.09
Cut down time (RE01)	-0.01	-0.01	**0.71**	-0.01	0.14	0.01
Accomplished less (RE02)	-0.04	0.02	**0.77**	-0.02	0.02	0.20
Not careful (RE03)	0.03	-0.01	**0.59**	0.03	-0.01	**0.38**
Nervous (MH01)	-0.01	0.08	-0.03	-0.18	**0.73**	**0.48**
Down in dumps (MH02)	-0.06	0.01	0.03	0.03	**0.71**	**0.47**
Peaceful (MH03)	-0.07	0.09	0.03	**0.37**	**0.33**	-0.05
Blue/sad (MH04)	-0.01	-0.01	0.02	-0.16	**0.83**	0.01
Happy (MH05)	-0.01	-0.06	0.04	**0.46**	**0.30**	-0.19

Bold values indicate that item loading on a factor is ≥ .30

SF36v2 7-Factor structure

Item	Factor 1	Factor 2	Factor3	Factor 4	Factor 5	Factor 6	Factor 7
Vigorous activities (PF01)	**0.83**	**-0.67**	0.03	0.05	-0.04	-0.03	-0.03
Moderate activities (PF02)	**0.71**	-0.01	0.02	-0.01	0.01	-0.02	-0.01
Lift, carry groceries (PF03)	**0.60**	0.18	-0.05	0.11	0.04	-0.14	-0.01
Climbing several flights (PF04)	**0.79**	-0.09	0.08	-0.06	-0.06	0.04	0.10
Climbing one flight (PF05)	**0.49**	**0.39**	0.01	-0.05	0.04	0.01	0.02
Bend, kneel (PF06)	**0.33**	**0.56**	0.01	0.03	0.03	-0.08	0.04
Walk mile (PF07)	**0.72**	0.12	-0.05	-0.10	0.05	0.11	0.09
Walk several blocks (PF08)	**0.56**	**0.31**	0.05	-0.04	0.01	**0.34**	-0.02
Walking one block (PF09)	0.27	**0.55**	0.03	0.03	-0.05	**0.44**	-0.01
Bathe, dress (PF10)	0.01	**0.89**	0.02	0.07	-0.06	-0.07	0.01
Cut down time (RF01)	0.04	0.01	**0.73**	0.01	-0.02	0.14	0.01
Accomplished less (RF02)	0.01	-0.04	**0.76**	0.11	0.02	0.09	-0.06
Limited in kind (RF03)	0.14	0.01	**0.68**	-0.01	0.03	-0.02	-0.11
Had difficulty (RF04)	0.11	0.04	**0.66**	0.11	0.06	0.03	0.04
Pain-magnitude (BP01)	0.06	-0.03	-0.039	**0.37**	0.129	0.22	**0.43**
Pain-interfere (BP02)	0.01	0.03	0.01	**0.36**	0.12	**0.39**	**0.41**
EVGFP rating (GH1)	0.02	0.04	0.04	**0.55**	-0.06	0.01	0.12
Sick easier (GH02)	0.06	0.06	0.05	0.05	0.26	-0.19	0.24
As healthy (GH03)	-0.10	0.01	0.05	**0.48**	-0.02	-0.05	0.05
Health to get worse (GH04)	0.08	0.09	0.01	0.19	**0.34**	**-0.36**	0.02
Health excellent (GH05)	0.03	0.08	0.07	**0.63**	0.12	-0.09	-0.02
Pep/Life (VT01)	-0.04	-0.06	-0.03	**0.77**	-0.01	0.04	0.07
Energy (VT02)	0.08	-0.01	-0.09	**0.76**	-0.06	-0.07	-0.02
Worn out (VT03)	0.13	-0.16	-0.05	0.05	**0.70**	-0.05	0.09
Tired (VT04)	0.01	-0.15	0.03	0.09	**0.57**	0.04	0.20
Social-extent (SF01)	0.01	0.06	0.02	0.16	**0.36**	**0.32**	0.24
Social-time (SF02)	0.07	0.06	0.02	0.06	0.15	0.12	**0.35**
Cut down time (RE01)	-0.02	-0.03	**0.66**	-0.04	0.07	0.08	**0.44**
Accomplished less (RE02)	-0.06	0.03	**0.72**	-0.03	-0.03	-0.07	**0.49**
Not careful (RE03)	0.01	-0.01	**0.55**	0.01	-0.08	-0.09	**0.49**
Nervous (MH01)	-0.05	0.07	-0.02	-0.19	**0.73**	0.03	0.01
Down in dumps (MH02)	-0.08	0.02	0.03	0.02	**0.70**	-0.03	0.06
Peaceful (MH03)	-0.07	0.05	0.03	**0.34**	**0.31**	0.21	-0.04
Blue/sad (MH04)	-0.02	-0.03	0.02	-0.16	**0.85**	-0.09	-0.08
Happy (MH05)	-0.03	-0.05	0.05	**0.48**	**0.34**	0.07	-0.23

Bold values indicate that item loading on a factor is ≥ .30

SF36v2 8-Factor structure

Item	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7	Factor 8
Vigorous activities (PF01)	**0.84**	0.03	0.05	-0.02	-0.05	0.15	-0.05	-0.02
Moderate activities (PF02)	**0.36**	**0.50**	0.02	0.09	-0.01	-0.01	-0.03	-0.03
Lift, carry groceries (PF03)	0.19	**0.58**	-0.01	0.25	0.01	0.01	-0.12	-0.03
Climbing several flights (PF04)	**0.46**	**0.50**	0.01	0.12	-0.08	-0.03	0.07	0.03
Climbing one flight (PF05)	-0.07	**0.71**	0.01	0.08	0.02	-0.09	0.01	0.01
Bend, kneel (PF06)	-0.20	**0.76**	0.01	0.04	0.04	0.03	-0.08	0.08
Walk mile (PF07)	0.27	**0.70**	0.01	-0.13	0.08	0.02	0.08	0.10
Walk several blocks (PF08)	0.06	**0.75**	0.01	-0.10	0.03	0.01	0.26	-0.13
Walking one block (PF09)	-0.23	**0.75**	0.03	-0.04	-0.04	0.01	**0.38**	-0.17
Bathe, dress (PF10)	**-0.57**	**0.79**	0.01	0.04	-0.05	0.01	-0.01	0.03
Cut down time (RF01)	0.01	0.01	**0.78**	0.02	-0.04	-0.07	0.07	-0.01
Accomplished less (RF02)	0.02	-0.06	**0.81**	0.01	0.01	0.04	0.01	-0.05
Limited in kind (RF03)	0.05	0.08	**0.72**	-0.02	0.01	-0.04	-0.10	-0.05
Had difficulty (RF04)	0.02	0.10	**0.70**	0.08	0.05	0.03	-0.01	0.04
Pain-magnitude (BP01)	0.08	-0.01	-0.03	**0.60**	0.06	0.01	**0.40**	0.09
Pain-interfere (BP02)	-0.01	0.02	0.01	**0.51**	0.06	0.01	**0.57**	0.02
EVGFP rating (GH1)	0.01	0.02	0.01	**0.42**	-0.10	0.29	0.10	-0.03
Sick easier (GH02)	0.01	0.05	0.05	**0.36**	0.21	-0.12	-0.07	0.18
As healthy (GH03)	-0.05	-0.14	0.05	**0.44**	-0.05	0.20	0.04	-0.09
Health to get worse (GH04)	0.01	0.07	0.01	**0.34**	0.29	0.04	-0.29	0.03
Health excellent (GH05)	-0.03	0.01	0.06	**0.61**	0.05	0.28	-0.02	-0.21
Pep/Life (VT01)	0.01	-0.03	0.01	0.08	0.01	**0.72**	0.13	0.07
Energy (VT02)	0.03	0.13	-0.10	-0.01	0.04	**0.80**	-0.05	0.06
Worn out (VT03)	0.16	-0.02	-0.05	0.07	**0.67**	0.07	0.01	0.06
Tired (VT04)	0.10	-0.09	0.03	0.04	**0.55**	0.10	0.13	0.14
Social-extent (SF01)	-0.01	0.04	0.02	0.17	**0.33**	0.04	**0.41**	0.02
Social-time (SF02)	-0.01	0.13	0.02	0.12	0.14	0.01	0.24	0.25
Cut down time (RE01)	0.01	-0.03	**0.71**	0.02	0.08	-0.03	0.07	**0.42**
Accomplished less (RE02)	-0.07	0.01	**0.77**	-0.06	0.01	0.04	-0.01	**0.52**
Not careful (RE03)	0.01	0.03	**0.59**	0.02	-0.05	0.04	-0.01	0.50
Nervous (MH01)	-0.05	0.06	-0.03	0.03	**0.70**	-0.19	0.04	-0.06
Down in dumps (MH02)	-0.06	-0.01	0.03	0.01	**0.69**	0.06	0.01	0.05
Peaceful (MH03)	-0.08	0.04	0.03	-0.01	**0.32**	**0.31**	0.22	-0.13
Blue/sad (MH04)	-0.01	0.01	0.03	-0.09	**0.84**	-0.07	-0.03	-0.08
Happy (MH05)	0.02	-0.02	0.06	0.03	**0.34**	**0.44**	0.02	-0.27

Bold values indicate that item loading on a factor is ≥ .30

Appendix 9.1. Number of patients nominating category and their percentages

Phase Two n= 12		Phase Four n= 45	
Category	# of patients nominating categories (%)	Category	# of patients nominating categories (%)
Religion/Spiritual Life	12 (100)	Religion/spiritual life	36 (80%)
Family	9 (75)	Family	35 (77.7%)
Personal Health	6 (50)	Personal health	31 (68.8%)
Social Life	6 (50)	Social life	17 (37.7%)
Leisure Activities	6 (50)	Work/occupation	15 (33.3%)
Work/Occupation	5 (41.6)	Leisure activities/hobbies	14 (31.1%)
Role Functioning	5 (41.6)	Autonomy/independence	12 (26.6%)
Autonomy/Independence	3 (25)	Role functioning	9 (20%)
Family Health	1 (8.3)	Living conditions	9 (20%)
Sexuality	1 (8.3)	Peace and contentment	7 (15.5%)
Finances	1 (8.3)	Finance	7 (15.5%)
Relationships	1 (8.3)	Family health	6 (13.3%)
Enjoying Life	1 (8.3)	Quality of care	5 (11.1%)
Quality of Care	1 (8.3)	Sexual life	4 (8.8%)
		Enjoying life	4 (8.8%)
		Relationships	4 (8.8%)
		Coping	3 (6.6%)
		Emotional well-being	2 (4.4%)
		Exercise/mobility	1 (2.2%)

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