HEALTH RELATED QUALITY OF LIFE AND ASSOCIATED FACTORS FOLLOWING MAJOR LOWER LIMB AMPUTATIONS IN PATIENTS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

BY

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A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF REQUIREMENT FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN ORTHOPEDIC SURGERY OF MOI UNIVERSITY.

DECLARATION

Declaration by Student:

This thesis is my original work and has not been presented for a degree in any other university. No part of this thesis may be reproduced without prior written permission of the author and or Moi University.

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DEDICATION

This thesis is dedicated to my lovely parents for their unwavering support, care and love.

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I would like to thank God, family, colleagues and my supervisors for their contribution and support. I would also like to thank MTRH and the study participants for allowing me to conduct this study.

ABBREVIATIONS AND ACRONYMS

HRQOL	Health related quality of life
MESS	Mangled extremity severity score
MTRH	Moi Teaching and Referral Hospital
SF–12	Short form 12
SF-36	Short form 361
EQ – 5D	Euro Quality of Life – 5 dimension
IREC	Institutional Review and Ethics Committee
ANOVA	Analysis of variance
IQR	Interquartile range
WHOQOL-BREF	World Health Organization Quality of Life Brief
DM	Diabetes mellitus

DEFINITION OF TERMS

Health related quality of life - This is broadly defined as the functional effect of a medical condition and or its therapy upon a patient. It is thus subjective and encompasses a physical and occupational function, psychological and social function.

Major lower limb amputation - Surgical removal of all or part of the lower limb through or proximal to the ankle joint

WHOQOL-BREF – This refers to an abbreviated quality of life assessment tool developed by World Health Organization

ABSTRACT

Background: Major lower limb amputations cause physical and psychological disability to both the individual and society. Among the common indications for amputation are peripheral vascular diseases, trauma and tumors. Health related quality of life (HRQOL) following major lower limb amputations in our setting is largely unknown despite it being a principal end point of healthcare.

Objective: To determine the health-related quality of life and associated factors following major lower limb amputations at Moi Teaching and Referral Hospital (MTRH).

Methods: A cross-sectional study of major lower limb amputees at MTRH conducted between 1st January 2017 and 30th June 2018. A census study was done since the average number of major lower limb amputations done annually in 2014 and 2015 was 45. A total of 44 participants were recruited. After informed consent, an interviewer administered questionnaire was used to collect data on socio-demographics, indications for amputation, levels of amputation, prosthesis use, laterality, time interval from amputation, complications and co-morbidities. The World Health Organization Quality of Life instrument (WHOQOL-Bref) was used to assess quality of life. The tool had questions on self-perceived overall quality of life and health and the rest of the 24 questions were domain specific. Continuous variables were summarized using mean ± SD or Median and corresponding IQR in years as appropriate while categorical variables were summarized as frequencies and corresponding percentages. The t - test was used to compare means between two groups while analysis of variance (ANOVA) was used when comparing means among more than two groups. Multivariate linear regression analysis was used to test for association. All data analysis was performed at 95% level of significance.

Results: The median age of the participants was 48(34, 60). The male to female ratio was 2.6:1. Following amputation, 25 (56.8%) of the participants had no occupation as compared to only 2 (4.5%) prior to amputation. The common causes of amputation were trauma and diabetes accounting for 21 (47.7%) and 16 (36.36%) respectively. Twenty-nine (65.9%) were not using prosthesis. Among these, 18 (66.7%) attributed it to high cost of prosthesis while 7 (25.9%) were due to poorly fitting prosthesis. The self-perceived overall HRQOL was poor to fair among 36 (81.8%) participants. A higher overall HRQOL was associated with male gender and having an occupation. The mean physical, psychological and environmental domain specific HRQOL scores were 60.93 ± 15.96, 56.23 ± 13.6 and 60.11 ± 8.73 respectively. The median social domain HRQOL score was 56(50, 69). Higher physical domain HRQOL scores were associated with lower age, male gender and prosthesis use ($p < 0.05$). Higher psychological domain HRQOL scores were associated with having an occupation and prosthesis use ($p < 0.05$). Higher environmental domain HRQOL scores were associated with having an occupation and not having comorbidity ($p < 0.05$).

Conclusion: Majority of major lower limb amputees at MTRH had poor to fair self-perceived HRQOL. The common causes of amputation were trauma and diabetes. A higher HRQOL was associated with male gender, having an occupation, younger age, absence of a comorbidity and using a prosthesis

Recommendation: Adoption of strategies to make well-fitting prostheses available and affordable. Prevention of trauma and adequate treatment of Diabetes to reduce the number of amputations. Emphasis on occupational therapy for amputees in order to reoccupy themselves.

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CHAPTER ONE

1.0 INTRODUCTION

1.1 Background Information

Major lower limb amputation is the surgical removal of all or part of the lower limb through or proximal to the ankle joint. Limb amputation is one of the oldest known surgically performed procedures (Khan *et al.*, 2016). Evidence of this is found back in Neolithic times with the most important steps in its evolution occurring in the 16th, 17th and 18th centuries with discoveries of vessel ligation and the use of tourniquet to control bleeding (Mavroforou *et al.*, 2007). Today with modern advancements the procedure is performed by surgeons armed with surgical principles, post-operative rehabilitation and prosthetic design knowledge. The procedure itself should be seen as a first step in improving the quality of life of a patient. It should be planned and performed with the same care and skill as any reconstructive procedure (Canale, Beaty & Campbell, 2013). The aims of this amputation being rapid primary healing, good mobility and a pain free stump (Campbell *et al.*, 1994). Globally major amputations have an incidence ranging from 5.6 to 600 per 100000 in the diabetic population and 3.6 to 68.4 per 100000 in the total population (Moxey *et al.*, 2011). It is worth noting that more women than men are affected by DM (King *et al.*, 1998). The incidence of amputation rises with age most being done in patients above 60 years (Unwin, 2000).

In the USA, 1.6 million were living with the loss of a limb as of 2005, 38% being due to dysvascular disease with co-morbidity of diabetes. One in one hundred and ninety Americans as of the year 2005 was living with the loss of a limb with this number expected to double by 2050 (Ziegler-Graham *et al.*, 2008). In England a prevalence of 26.3 per 100000 was found in a retrospective cohort study (Ahmad *et al.*, 2014). The

incidence of vascular major lower limb amputations is higher in the developed countries than that reported in the developing ones mainly due to the ageing population (Awori & Atinga, 2007). At MTRH up to 45 major lower limb amputations have been done yearly in 2014 and 2015. There is paucity of local prevalence data on lower limb amputations.

Health related quality of life (HRQOL) includes physical and mental health perceptions and their correlates: health risks and conditions, functional status, social support, and socioeconomic status (Center for Disease Control, 2000). The purpose of its measurement is to be able to quantify the degree to which disease or its treatment has impacted an individual's well-being. HRQOL surveys are of increasing importance as health care providers are challenged to justify treatment approaches and rationale for any intervention (Sajid *et al.*, 2008). It is thus important in informing patient management and policy decisions (Guyatt *et al.*, 1993). In addition, HRQOL has become a principle endpoint in healthcare due to the emergence of patient's rights movements (Pais-Ribero, 2004).

1.1.2 Indications for Amputation

Peripheral vascular disease is the most common cause of amputation occurring in those between 50 and 75 years of age with half of them being done in diabetic patients (Canale, Beaty & Campbell, 2013). A study done in a rehabilitation center in the UK showed vascular and diabetic causes to be the most common indication for lower limb amputation (Davies & Datta, 2003). Lower limb amputation is the most common type of amputation with the leading indications locally being severe vascular disease that maybe of diabetic or non -diabetic causes, severe trauma and tumors (Muyembe & Muhinga, 1999). Trauma is also a leading indication in younger patients with the only absolute indication being

irreparable vascular injury. Several scores have been used the most reliable being Mangled extremity severity score (MESS) to predict need for amputation. At times salvaging a limb though successful results in a chronically painful and/or useless limb (Canale, Beaty & Campbell, 2013).

In a study on major limb amputations in a tertiary hospital in northwestern Tanzania it was found that common indications for amputation were complications of DM, trauma and vascular disease in that order (Chalya *et al.*, 2012). At Kenyatta National Hospital in Nairobi a study done concluded that peripheral vascular disease unrelated to diabetes mellitus was the leading cause with tumors, trauma and diabetes mellitus related gangrene following in that order (Awori & Atinga, 2007). At MTRH, the main indications for lower limb amputations were vascular mainly diabetic vasculopathy and peripheral vascular disease (Kogoss, 2015).

Amputation is indicated in uncontrollable infections. In the acute setting one should be wary of gas forming organisms commonly resulting from farmyard injuries and gun-shot wounds that may result in death. In the chronic setting say a non-healing trophic ulcer, chronic osteomyelitis or an infected non-union then the best outcome might be achieved with amputation (Canale, Beaty & Campbell, 2013). With regards to tumors the advent of radiotherapy and chemotherapy has seen a shift towards limb salvage surgery as compared to amputation the latter being indicated where there is massive necrosis, fungation, infection or vascular compromise (Canale, Beaty & Campbell, 2013).

1.1.2 Levels of Amputation

The following 5 levels of lower limb amputation was included in this study

i) Symes amputation (at ankle joint).

ii) Below knee (transtibial) amputation.

iii) Knee disarticulation (at knee joint).

iv) Above knee (transfemoral) amputation.

v) Hip disarticulation. (at hip joint)

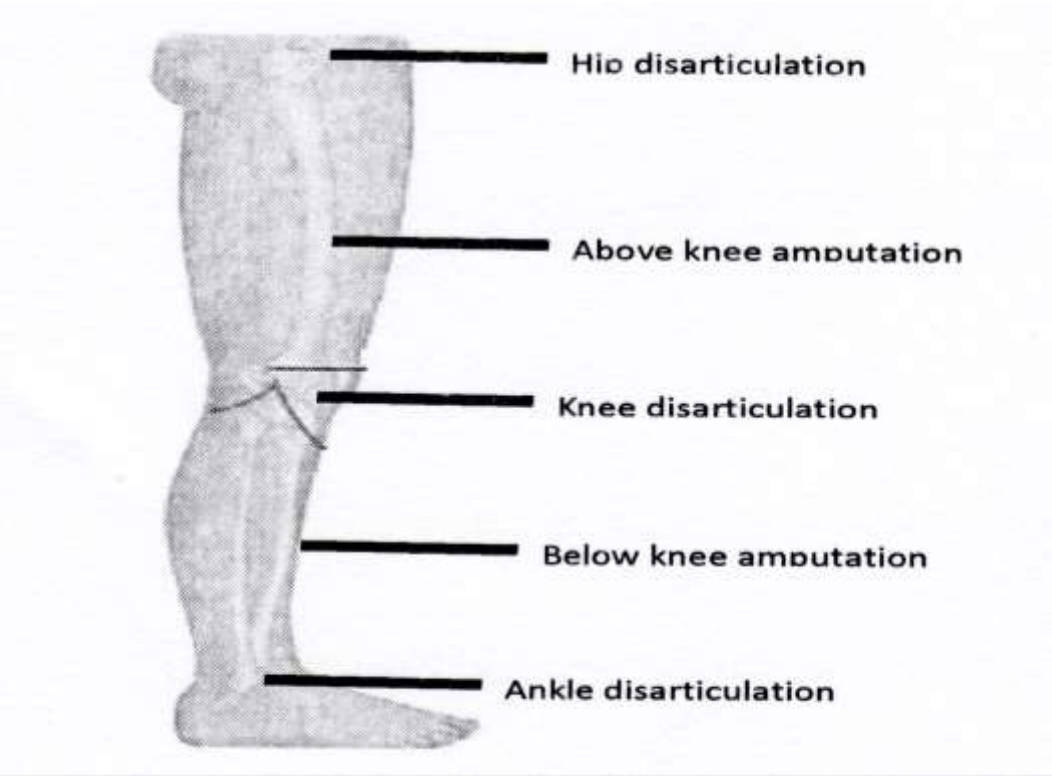

Figure 1: Levels of Amputation. Modified from Canale, Beaty & Campbell, 2013.

1.1.2.1 Ankle Disarticulation (Symes)

This is an amputation done through the ankle joint. Open ankle disarticulation is a quick and simple amputation that can be used to manage a septic foot. Patients younger than 65 years with diabetic vascular disease have better outcomes (Siev-Ner *et al.*, 2006).

It also results in a limb that is near normal in length, provides potential for full end bearing and allows patients to expend less energy when walking. Barring complications most patients can begin ambulating with prosthesis as early as 6 weeks (Philbin *et al.*, 2007).

1.1.2.2 Hip Disarticulation

This is surgical removal of the lower limb through the hip joint capsule with closure of the remaining musculature over the exposed acetabulum.

Indications include tumors, vascular disease and infection. It has been shown that tumors have better outcomes as compared to vascular disease with hip disarticulation (Denes & Till, 1997).

1.1.2.3 Above Knee Amputation

The amputation level routinely used is the junction of the middle and distal third of the femur. Above knee amputation has been found to have an energy expenditure up to 55% more than below knee (Vlassoli *et al.*, 2014) and has also been shown to be a poor predictor for prosthesis use (Taylor *et al.*, 2005). Much of this is explained by the loss of the invaluable knee joint.

1.1.2.4Through Knee Amputation (Knee Disarticulation).

This method remains advantageous in patients who are expected to ambulate with prosthesis due to its end weight bearing capacity as compared to above knee amputation (Penn-Barwell, 2011). The Superior rehabilitation with through knee amputation should prompt us to improve both technique as well as prostheses currently available (Houghton *et al.,* 1989; Moran *et al.,* 1990). The disadvantages of through knee amputation are that prosthetic fitting may prove difficult and cosmetic issues may override functional advantages (Murphy, 2013).

1.1.2.5Below Knee Amputation (Transtibial)

It is the surgical removal of the leg below the knee and has been shown to have better prosthetic outcomes and is known to expend as much energy as in a non-amputated limb (Taylor *et al.*, 2005; Vlassoli *et al.*, 2014). In another study it was found that energy expenditure of transtibial amputees exceeded that of normal control subjects by 0-15% (Genin *et al.*, 2008).

1.1.3 Complications of amputation

1.1.3.1 Stump Hematoma

This is post-operative bleeding in the site of amputation requiring evacuation. It may cause pain, swelling and can also serve as culture medium for infection (Canale, Beaty & Campbell, 2013). Evacuation of the hematoma is indicated in cases of delayed wound healing (Canale, Beaty & Campbell, 2013).

1.1.3.2 Infection

This occurs in up to 13-40% with predisposing factors such as ischemia, pre-existing limb ulceration and gangrene, patient co-morbidities and wound contamination (Sadat *et al.*, 2008). It can either be superficial or deep with management involving release or removal of sutures, antibiotics, cleaning with saline and at times debridement.

At MTRH, surgical site infection was the main compilation seen following lower limb amputation (Kogoss, 2015). Amputation stump infection is common and may necessitate re-amputation, potentially exposing a vulnerable patient to serious complications. It is therefore a standard practice to give prophylactic antibiotics prior to amputation (McIntosh & Earnshaw, 2009).

1.1.3.3 Phantom Pain

This is a sensation of pain located in the amputated limb, which has a high rate of chronicity and is difficult to treat (Foell *et al.*, 2014). Inadequate control of pre and postoperative pain may increase risk of chronic amputation pain. Stump pain of whatever cause is an important factor in predicting HRQOL (Van der Schans *et al.*, 2002).

Risk factors for this pain include female sex, upper extremity amputation, presence of pre-amputation pain, residual pain in remaining limb and time after amputation. Its etiology can be peripheral, central or psychogenic while treatment can be either in form of pharmacotherapy, psychotherapy, surgical or adjuvant therapy (Subedi & Grossberg, 2011). It has also been found that depressive symptoms are related to intensity of pain (Ephraim *et al.*, 2005).

Other common types of amputation related pains are residual stump pain and back pain (Ephraim *et al.,* 2005). Residual stump pain is a painful sensation from the remaining part of the leg and may be caused by stroke.

1.1.3.4 Contractures

Contractures result from fibrosis of the tissues supporting the muscles or joints or from muscle fiber disorders, either of which cause fixed resistance to passive stretch of a muscle with shortening and loss of flexibility of muscles, joints, tendons, or fascia (Herring, 2013).

Gentle passive stretching, proper positioning and muscle strengthening exercises may prevent contractures. Severe fixed contractures may be treated by wedging cast or surgical release (Canale, Beaty & Campbell, 2013).

Other complications of amputations include wound dehiscence, dermatological problems and depression among others.

1.1.4 Quality of Life tools

1.1.4.1 Nottingham Health Profile (NHP)

The NHP has been portrayed as a multipurpose measure of health status, capable of being used in population surveys and evaluation of medical interventions. It has two parts the first focuses on health and comprises 38 items dealing with pain, energy, sleep, mobility, emotional reaction and isolation. The second part focuses on life areas consisting of 7 items which deal with problems regarding occupation, housework, social life, family life, sexual function, hobbies and holidays.

1.1.4.2 Short Form 12 Health Survey

This is a multipurpose short form survey with 12 questions all selected from the SF-36 health survey. The questions were combined, scored and weighted to create two scales that provide glimpses into mental and physical functioning and overall health related quality of life. It has been developed to provide a shorter yet valid alternative to the SF-36.

The physical and mental composite scale scores are computed using the 12 questions and range from 0 to 100 where a zero score indicates the lowest level of health and 100 the highest. The range of Physical Component Summary and Mental Component Summary scores vary over the life span for different age groups hence the essence of using age-specific mean difference scores.

Sub domains used are: general health, physical functioning, role functioning (physical), bodily pain, vitality, role functioning (emotional), mental health and social functioning.

1.1.4.3 World Health Organization Quality of life - BREF

The WHOQOL-BREF is a tool that assesses quality of life and was developed through WHO. It is a genuinely international measure of quality of life tool inspired by the commitment to holistic care. Information pertaining to quality of life was collected from 15 different field centers worldwide including Zimbabwe in the development of the WHOQOL-100.

The WHOQOL-BREF is a subset of 26 items taken from the WHOQOL-100 the original longer version. It was developed through a culturally diverse multicenter project involving a standardized protocol. The initial testing of the psychometric properties of the

WHOQOL-100 involved a pilot study conducted on 4,834 persons in 15 field centers i.e. at least 300 persons, heterogeneous and representative of sick and well people, per center (WHOQOL Group, 1993).

To provide a broad and comprehensive assessment, 24 items (questions) have been included in the WHOQOL-BREF; one item from each of the 24 facets contained in the WHOQOL-100. In addition, two items (questions) from the overall quality of life and general health facets have been included. The WHOQOL-BREF therefore contains a total of 26 items (questions) which make up the facets. These facets are incorporated within a four-domain structure i.e. physical health, psychological, social relationships and environment domains. Higher scores denote higher quality of life and all except 3 items have positive scoring. The domain scores denote an individual's perception of quality of life for that particular domain. The Researcher used the WHOQOL-BREF in this study to assess the quality of life of study participants.

Locally the WHOQOL-BREF has been used in a study looking at the quality of life among people living with epilepsy (Kinyanjui et al., 2013). This was a cross sectional comparative study where they assessed quality of life of people living with epilepsy and accompanying healthy normal controls.

1.2 Problem Statement

Major lower limb amputation is at times the treatment of choice in severe vascular disease, trauma and tumors among other conditions (Khan *et al.*, 2016). At MTRH up to 45 major lower limb amputations have been done yearly in 2014 and 2015. Following amputation, the patients potentially face social, economic, psychological and physical

limitations among others. At MTRH, the quality of life among major lower limb amputees is unknown.

1.3 Justification

The quality of life among amputees is an essential part of their health outcome. Knowledge on the health outcome among amputees and the associated factors would serve to inform clinicians, the society and policy makers on ways to improve their quality of life hence their health outcome.

1.4 Research Question

How is the health-related quality of life and associated factors following major lower limb amputation at MTRH?

1.5 Objectives

1.5.1 Broad Objective

To determine the HRQOL and associated factors following major lower limb amputations at MTRH, Eldoret.

1.5.2 Specific Objectives

i) To assess the health-related quality of life following major lower limb amputations at MTRH.
ii) To determine the association between HRQOL and socio-demographic characteristics among major lower limb amputees at MTRH.
iii) To determine the association between HRQOL and amputation related factors among major lower limb amputees at MTRH.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Health Related Quality of Life among Major Lower Limb Amputees

Health related quality of life (HRQOL) includes physical and mental health perceptions and their correlates, including health risks and conditions, functional status, social support, and socioeconomic status. With the loss of a lower limb there is some expected level of loss of physical, social and even psychological function and therefore at times loss of employment. The importance of paid employment to self-esteem and quality of life among people living with disability cannot be overemphasized (Robinson, 2000).

2.2 Overall health related quality of life outcome

The Quality of life among unilateral lower limb amputations in Nigeria was found to be moderate. In that study 47 individuals with lower limb amputation from rehabilitation centers and clinics were assessed using WHOQOL-BREF (Adegoke *et al.*, 2013). In another pilot study done in Tanzania using the EQ-5D questionnaire lower limb amputees were found to have a poor quality of life (Shaw *et al*., 2018). A study done in Sudan using the medical outcomes study questionnaire found diabetic lower limb amputees to have a poor quality of life (Abdelgadir *et al.*, 2009).

In Asia, a study done in Thailand using the WHOQOL-BREF tool found lower limb amputees to have fair quality of life (Dajpratham *et al.*, 2011). Another study in Malaysia using the WHOQOL-BREF tool found satisfactory quality of life among lower limb amputees (Razak *et al*., 2016).

In Europe, in the Netherlands using the SF-36 questionnaire, a poor quality of life was found among lower limb amputees (Sinha *et al.*, 2011). Another study in Scotland that

was done among lower limb amputees who had peripheral arterial disease also had poor quality of life findings (Pell *et al.,* 1993).

2.3 Socio demographic factors and quality of life

Gender was found to be a significant determinant of quality of life in the physical and social domains with males having better quality of life compared to females (Adegoke *et al.*, 2013). Females were also found to have better quality of life than males in a study done in Jamaica (Cox *et al*., 2011) that focused on diabetic lower limb amputees.

Another significant socio demographic factor was employment status. This was a significant determinant of quality of life among lower limb amputees. Those with employment had better quality of life (Sinha *et al.*, 2011). Paid employment has also been shown to enhance self-esteem (Robinson, 2000).

Age was found to be a determinant of quality of life with younger amputees having better quality of life compared to older ones (Demet *et al.*, 2003). Trauma has been associated with young males as they are generally more adventurous (World Health Organization, 2002).

In one study higher education level was a key determinant of better quality of life among lower limb amputees (Demet *et al.*, 2003).

2.4 Amputation related factors and quality of life

A pilot study in Tanzania (Shaw *et al*., 2018) found prosthesis use to be a definite gap in the quality of life among lower limb amputees. In Nigeria (Adegoke *et al.*, 2013) better quality of life was determined by prosthesis use in the physical, psychological and environmental domains. A study focusing on diabetic amputees also found mobility status to be a determinant of quality of life (Abdelgadir *et al.*, 2009). Similarly, other

studies have found prosthesis use being associated with better quality of life (Razak *et al*., 2016; Sinha *et al.,* 2011). Good prosthetic comfort was associated with better quality of life among lower limb amputees (Dajpratham *et al.*, 2011). The more mobile and independent an amputee can be the better their HRQOL and especially so in those mobile within their homes (Remes *et al.*, 2010). Longer duration of prosthesis use was also associated with better physical domain quality of life (Gallagher & Maclachlan, 2004).

The level of amputation has also been found to have a significant association with quality of life of lower limb amputees (Cox *et al*., 2011; Razak *et al*., 2016). When considering best outcome for a patient after amputation a trade-off between a more distal stump with better functionality and a proximal stump with less complications remains the challenge for the surgeon (Canale, Beaty & Campbell, 2013). Higher levels of amputation come with high energy expenditure thus affecting HRQOL (Vlassoli *et al.*, 2014). The residual stump needs to be as near normal length as possible to provide potential full end bearing thus less energy expenditure (Philbin *et al.,* 2007). In another study however it has been found that there is no difference in HRQOL in consideration of the level of amputation (Mackenzie *et al.,* 2004). In spite of this advantage seen in long residual stumps there is a cost as regards complications especially so with poor wound healing rates (Keagy *et al.*, 1986).

Amputees experiencing pain whether residual or phantom have relatively poor HRQOL in comparison (Van der Schans *et al.*, 2002). Phantom and residual stump pain was of great predictive significance in determining quality of life (Sinha *et al*., 2011). Domains that mattered most in a study on quality of life of vascular amputees were pain, mobility impairment and emotional perturbation while physician-controlled factors like timing of

amputation and post-amputation support and informed decision making play an important role in determining outcomes (Suckow *et al.,* 2015).

Better HRQOL has been reported in those who are amputated as a result of trauma (Demet *et al.,* 2003). The presence of comorbidities was also associated with poorer quality of life (Sinha *et al.,* 2011). Longer duration after amputation was associated with better quality of life (Dajpratham *et al.,* 2011).

In the aforementioned studies the level of amputation, cause of amputation, mobility, Age, pain, prosthesis use, education and employment status are important in determining HRQOL. No published studies seem to have been done in Kenya and therefore the need for this study to be able to inform clinicians and policy makers and thus help improve on the overall care of major lower limb amputees.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Site

The study was conducted at Moi Teaching and Referral Hospital which is the second largest National Teaching and Referral Hospital (level 6 Public Hospital) in the country with a bed capacity of 991 patients, an average number of 1200 patients at any time and about 1500 out patients per day.

Moi Teaching and Referral Hospital is located along Nandi Road in Eldoret Town, Uasin Gishu County (310 Kilometers Northwest of Nairobi). The Hospital serves residents of Western Kenya Region (representing at least 22 Counties), parts of Eastern Uganda and Southern Sudan with a population of approximately 24 Million. ("About Us - Moi Teaching and Referral Hospital", 2020).

The Orthopedics Department attends to over 1300 inpatients per year. In the last 2 years the department has done about 45 major lower limb amputations annually with initial follow up beginning 2 weeks after discharge. Orthopedic clinics are run 5 times a week with an average of 4-5 Major lower limb amputees seen monthly. Most amputees only attend the 1st visit thereafter being lost to follow up. For purposes of prostheses, patients are advised to be seen about 3 months post discharge depending on healing of the stump.

3.2 Study Design

The study employed a cross-sectional descriptive study design.

3.3 Study Population

Patients who had undergone major lower limb amputation at MTRH

3.4 Eligibility Criteria

3.4.1 Inclusion criteria

i. Patients who had either one of the following levels of surgical limb removal:
   - Hip disarticulation.
   - Above knee amputation.
   - Through knee amputation.
   - Below knee amputation.
   - Ankle disarticulation.

ii. Patients above 18 years of age – the study excluded patients under 18 years as these were considered a different population and secondly, the WHOQOL-BREF tool has been validated among adults only.

iii. Amputees who were between 6 months and 5 years post amputation. This was aimed at achieving a homogenous study group as those below 6 months were predisposed to acute complications which would potentially affect their quality of life and those beyond 5 years would likely be subject to multiple confounding factors.

3.4.2 Exclusion criteria

i. Patients who had undergone bilateral amputation. This is because they would be associated with significantly more physical limitation and would potentially introduce a bimodal distribution in the quality of life.

ii. Patients with mental incapacitation

iii. Patients who declined consent

3.4 Recruitment and sample size

To answer the research question, a census study was carried out given the few numbers of major lower limb amputations done annually. Approximately 45 major lower limb amputations among adults were being done annually in 2014 and 2015. A total of 20 participants were recruited from specialty clinics. In addition, recruitment was done through making telephone calls. A total of 96 telephone contacts were sought from the records department. Of this all individuals meeting our inclusion criteria were recruited

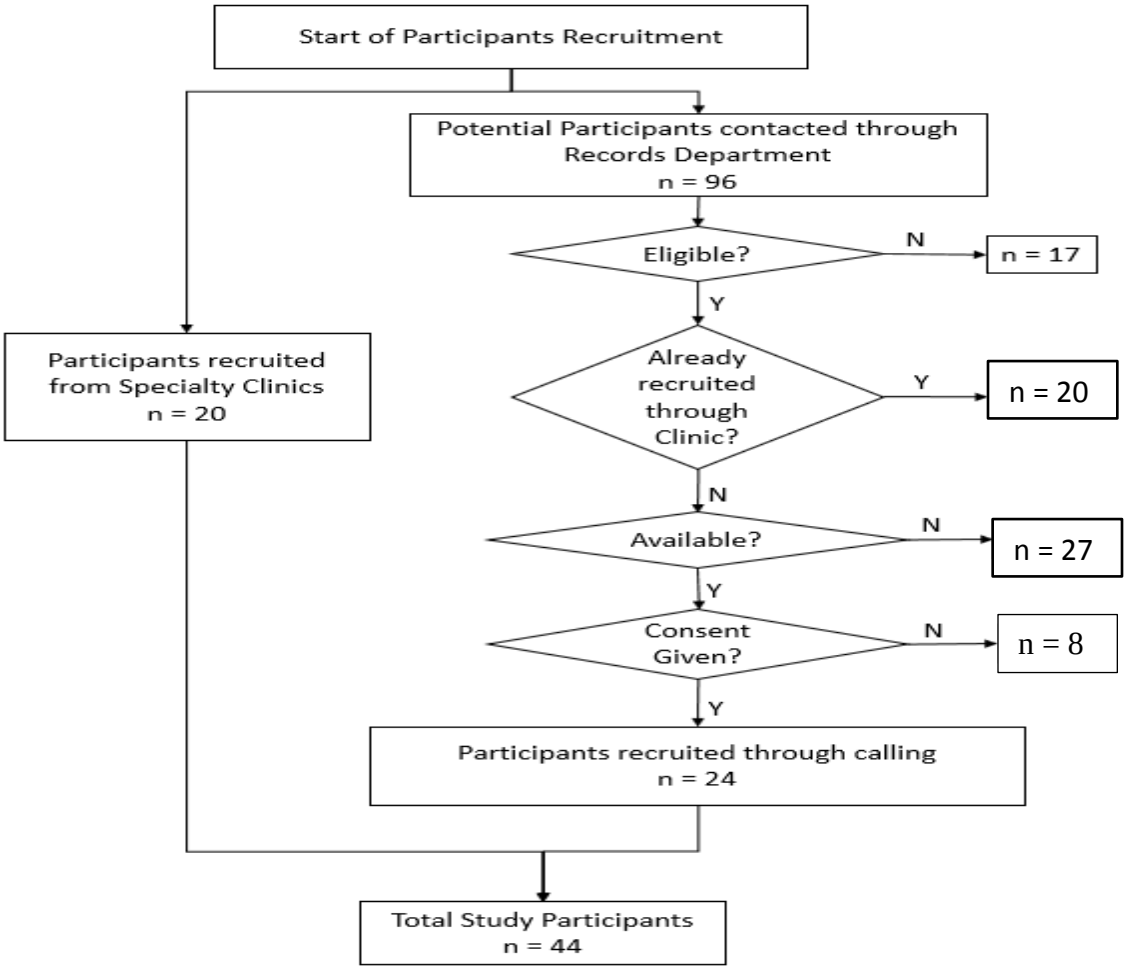

Figure 2: Flowchart of Study Participants Recruitment.

3.5 Procedure

Patients who had undergone major lower limb amputation at MTRH were recruited from follow up clinics and from MTRH records. Where necessary patients were contacted via telephone and subsequent home visits made. For patients who were to be contacted using their telephone numbers, a member of staff from the hospital's records department first contacted the patient. He introduced himself and thereafter informed the patient that a doctor studying at the hospital would like to recruit them into his study. The member of staff stated the title and purpose of the study and thereafter sought verbal consent from the patient. The researcher then contacted those who agreed to take part in the study. Patients who could not be contacted either through the clinics or on phone, were left out of the study. Once contact with participants either at the clinic or in the community was made, an introduction was made disclosing the purpose of the study. Subsequently, informed consent was sought. This was followed by data collection using an interviewer administered questionnaire.

3.6 Data Collection

An interviewer administered questionnaire was used for data collection. This questionnaire (Appendix 6 & 7) comprised on sections on socio demographic characteristic, amputation related factors and the WHOQOL-BREF tool. Data was collected between 1st January 2017 and 30th June 2018.

The socio-demographic parameters included age, sex, occupation, marital status and education level.

The amputation related factors included indication of amputation, level of amputation, time since amputation, laterality i.e. whether dominant or non-dominant limb was

amputated, whether there was informed decision making, specific common complications like pain, post amputation support, prosthesis use and co-morbidities.

The WHOQOL-BREF, a tool that has been validated internationally for assessing quality of life was used to assess the HRQOL. The Researcher used the brief version of the World health organization quality of life scale (WHOQOL-BREF) in this study. This instrument is derived from the WHOQOL-100 a tool with a set of 100 items on the 4 different domains. The WHOQOL-BREF questionnaire contains two items from the overall quality of life and general health and 24 items of satisfaction that are divided into four domains: Physical health with 7 items, psychological health with 6 items, social relationships with 3 items and environmental health with 8 items. Each item was rated on a five-point likert scale. Each item is scored from 1 to 5 on a response scale. Raw domain scores for WHOQOL – BREF was transformed to a 4 to 20 score according to guidelines. Domain scores were scaled in a positive direction (i.e. higher scores denoted higher quality of life). The mean score of items within each domain was used to calculate the domain score. After computation of the scores, they were transformed linearly to a 0-100 scale. The overall quality of life was assessed using question 1 in the WHOQOL-BREF tool on overall quality of life. This was a self-rated overall quality of life assessment. Overall quality of life was either very poor, poor, neither poor nor good, good or very good.

3.7 Data Analysis

Data were analyzed using STATA version 15. Descriptive statistics such as mean, median, standard deviation and interquartile range were used for continuous variables as appropriate while frequency listings were used for categorical variables. Normality of Gaussian assumptions assessed by Shapiro-Wilk test. The t - test was used to compare means between two groups while analysis of variance (ANOVA) was used when comparing means among more than two groups. Multivariate linear regression analysis was used to test for associations between health-related quality of life and both socio demographic and amputation related factors. Fisher's exact test was used to test for associations between the overall quality of life and both socio demographic and amputation related factors. All data analysis was performed at 95% level of significance.

3.8 Ethical Considerations

Before conducting this study, permission was sought from the Institution Review and Ethics Committee with approval no. IREC/2016/134 (Appendix 1). Subsequently permission was sought from MTRH as well (Appendix 2). Written informed consent was obtained from all participants (Appendix 5). Refusal to participate in the study did not in any way affect patient care at respective clinics. There was no coercion in recruitment of participants and participants were free to withdraw from the study at any time. Confidentiality was maintained during and after the study. Hard copy information obtained was kept under lock and key while any data entered into the computer was password protected. Dissemination will be done through oral defense and publication in scientific journals

3.9 Study Limitation.

In this study, since not all patients attended follow up clinics, participant recruitment at follow up clinics only would potentially pick those with better social support system and therefore better quality of life. To mitigate this limitation, the Researcher visited other participants in the community after contacting them by phone call.

CHAPTER FOUR

4.0 RESULTS

A total of 44 study participants were recruited into the study.

4.1 Socio-Demographic Characteristics

The ages of the study participants ranged from 20 – 93 years with a median of 48 (34, 60).Thirty two (72.7%) of them were male representing a male to female ratio of 2.6:1. Prior to amputation, only two (4.5%) had no occupation whereas this number rose to 25 (56.8%) after undergoing amputation. Thirty-three (75%) of the amputees were married. As regards the level of education, 19 (44.2%) had primary and 12 (27.9%) had secondary school as the highest level of education attained (Table 1 below presents the socio demographic characteristics).

Table 1: Socio Demographic Characteristics

Variable	**N**		**Median (IQR)**	**Frequency**	**%**
Age (years)	44		**48 (34,60)**		
Gender	44	Female		12	27.3
		Male		32	72.7
Occupation Prior to Amputation	44	With Occupation		42	95.5
		Without Occupation		2	4.5
Occupation following Amputation	44	With Occupation		19	43.2
		Without Occupation		25	56.8
Marital	44	Married		33	75
		Divorced/widow/single		13	25
Education level	44	None		6	14.0
		Primary		19	44.2
		Secondary		12	27.9
		Tertiary		7	16.0

4.2 Amputation Related Factors

4.2.1 Levels of Amputation

For the levels of amputations, 20 (45.5%) were above the knee, 21 (47.7%) below the knee, two (4.5%) knee disarticulation and one (2.3%) was a hip disarticulation (Table 2 presents the Amputation Related Factors).

4.2.2 Causes of Amputation

Trauma was the most common cause of amputation at 21 (47.7%) followed by diabetes related amputations at 16 (36.36%), vascular causes at five (11.36%) and tumors at two (4.56%) (Table 2 presents amputation related factors).

4.2.3 Prosthesis Use

Prosthesis use was low with only 15 (34.1%) having and using prosthesis. Among those not using prostheses, 18 (66.7%) attributed it to the high cost of prosthesis acquisition, 7 (25.9%) were due to poorly fitting prosthesis, one (3.7%) had not received information on prosthesis and one (3.7%) had contralateral paralysis (Table 2 presents amputation related factors).

4.2.4 Comorbidities

Among the amputees, 20 (45.5%) had at least one pre-existing comorbidity. The leading comorbidities were diabetes mellitus among 16 (36.4%) and hypertension in four (9.1%) (Table 2 presents amputation related factors).

Table 2: Amputation Related Factors

Variable	N	Frequency	%
Level of Amputation	**44**		
Above knee		20	45.5
Below knee		21	47.7
Hip		1	2.3
Through knee		2	4.5
Indications	**44**		
Trauma		21	47.7
Tumor		2	4.5
DM related		16	36.4
Vascular		5	11.4
Laterality	**43**		
Left		26	60.5
Right		17	39.5
Dominance	**43**		
Dominant		26	60.5
Non-dominant		17	39.5
Informed Consent	**44**		
No		2	4.6
Yes		42	95.4
Phantom Limb Pain	40		
No		21	52.5
Yes		19	47.5
Residual	38		
No		27	71.1
Yes		11	28.9
Prosthesis Use	44		
No		29	65.9
Yes		15	34.1
No		29	65.9
Reason for not Using			
Did not fit well		8	25.9
Expensive		19	66.7
Not informed		1	3.7
Weakness on right side		1	3.7
Comorbidities	**44**		
Yes		20	45.5
No		24	54.5
Comorbidity Types			
Asthma		1	5.0
Diabetes Mellitus		16	80.0
Epilepsy		1	5.0
Hypertension		4	20.0
PUD		1	5.0

4.3 Quality of Life following Amputation

4.3.1 Overall Quality of Life and Health status

Among the major lower limb amputees in this study, 15 (34.1%) recorded poor, 21 (47.7%) fair and 8 (18.2%) good overall quality of life (Table 3 presents Overall Quality of Life).

Table 3: Table of Overall Quality of Life

Quality of Life Rating	Frequency (%)
Poor	15 (34.1)
Fair	21 (47.7)
Good	8 (18.2)

4.3.2 Domain Specific Quality of Life

To enable appropriate data summarization as well as choice of tests for association, the scores from the different domains were tested for normal distribution using the Shapiro Wilk test. The assumption was satisfied for Physical, Psychological and Environmental domains but not the Social domain (Table 4 presents evaluation of normal distribution of domain scores). Therefore physical, psychological and environmental domain scores were summarized as means while social domain score was summarized as median and their corresponding interquartile ranges.

Table 4: Table of Domain Specific Shapiro Wilk Test Results

Variable	N	W	V	Z	*p* value
Physical	44	0.985	0.638	-0.953	0.829
Psychological	44	0.993	0.292	-2.605	0.995
Social	44	0.936	2.725	2.122	**0.017**
Environmental	44	0.985	0.647	-0.921	0.822

Among the major lower limb amputees, the Physical Domain of the HRQOL had a mean score of 60.93 ± 15.96, the Psychological Domain had a mean score of 56.23 ± 13.6 and

the Environmental Domain had a mean score of 60.11 ± 8.73. The Social Domain recorded a median of 56 (50, 69) (Table 5 presents Domain specific Quality of Life).

Table 5: Table of Domain Specific Quality of Life

Variable	N	Mean	SD	Median	First Quartile	Third Quartile
Physical	**44**	**60.93**	**15.96**			
Psychological	**44**	**56.23**	**13.60**			
Social	**44**			**56**	**50**	**69**
Environmental	**44**	**60.11**	**8.73**			

4.4 Association between Quality of Life and Socio-demographic characteristics

4.4.1 Association between Overall Quality of Life and Socio-demographic characteristics

There was a statistically significant association between overall quality of life and gender with females having a larger proportion with poor quality of life compared to males ($p < 0.05$). There was also a statistically significant association between overall quality of life and occupation status with a larger proportion of participants who had a change in their occupation status (lost their primary source of income following amputation) having a poor to neutral overall quality of life ($p < 0.05$) There was no statistically significant association between the overall quality of life and either education level, age or marital status of the study participants ($p > 0.05$) (Table 6 presents the association between overall quality of life and socio demographic factors).

Table 6: Association between Overall Quality of Life and Socio-Demographic Characteristics

Variable	Overall QOL			Fishers' exact *p*-value
	Poor	**Neutral**	**Good**	
	Freq (%)	**Freq (%)**	**Freq (%)**	
Age in years	Freq (%)	Freq (%)	Freq (%)	0.304
20-39	2 (13.3)	9 (60)	4 (26.7)	
40 to 59	5 (33.3)	8 (53.3)	2 (13.3)	
60 to 79	6 (54.5)	3 (27.3)	2 (18.2)	
Above 80	2 (66.7)	1 (33.3)	0 (0)	
Gender				0.012
Female	8 (66.7)	4 (33.3)	0 (0)	
Male	7 (21.9)	17 (53.1)	8 (25)	
Education level				0.144
None	4 (66.7)	2 (33.3)	0 (0)	
Primary	7 (36.8)	8 (42.1)	4 (21.1)	
Secondary	4 (33.3)	7 (58.3)	1 (8.3)	
Tertiary	0 (0)	3 (50)	3 (50)	
Change of occupation				0.038
No	5 (23.8)	9 (42.9)	7 (33.3)	
Yes	10 (43.5)	12 (52.2)	1 (4.3)	
Marital status				0.842
Single/Divorced/Separated	3 (27.3)	6 (54.5)	2 (18.2)	
Married	12 (36.4)	15 (45.5)	6 (18.2)	

4.4.2 Association between Domain Specific Quality of Life and Socio-Demographic Factors

Physical Domain and Socio demographic Factors

There was a significant association between age and physical quality of life ($p < 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

The younger age group that is those between 18 – 37 years had higher scores in the physical domain compared to the older age groups.

There was a significant association between gender and physical quality of life ($p < 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics). Males had higher scores than females in the physical domain.

Those who had to change their occupation status following amputation had lower quality of life in the physical domain and their means were statistically significantly different compared to those who had not changed their occupation ($p < 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

There was no statistically significant association between the physical domain of quality of life and education level ($p > 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

There was no statistically significant association between the physical domain of quality of life and marital status ($p > 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

Psychological Domain and Socio demographic Factors

There was a significant association between gender and psychological quality of life ($p < 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics). Males had higher scores in the psychological domain compared to females.

Those who had to change their occupation status following amputation had lower quality of life in the psychological domain and their means were statistically significantly different compared to those who had not changed their occupation ($p < 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

There was no statistically significant association between psychological domain of quality of life and education level ($p > 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

There was no statistically significant association between the psychological domain of quality of life and marital status ($p > 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

There was no statistically significant association between the psychological domain of quality of life and age ($p > 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

Social Domain and Socio demographic Factors

There was a significant association between gender and social domain of quality of life ($p < 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics). Males had higher scores in the social domain compared to females.

Those who had to change their occupation status following amputation had lower quality of life in the social domain and their means were statistically significantly different compared to those who had not changed their occupation ($p < 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

There was no statistically significant association between the social domain of quality of life and education level ($p > 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

There was no statistically significant association between the social domain of quality of life and marital status ($p > 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

There was no statistically significant association between the social domain of quality of life and age ($p > 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

Environmental Domain and Socio demographic Factors

Those who had to change their occupation status following amputation had lower quality of life in the environmental domain and their means were statistically significantly different compared to those who had not changed their occupation ($p < 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

There was no statistically significant association between the environmental domain of quality of life and education level ($p > 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

There was no statistically significant association between the environmental domain of quality of life and marital status ($p > 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

There was no statistically significant association between the social domain of quality of life and age ($p > 0.05$) (Table 7 presents association between domain specific Quality of Life and socio demographic characteristics).

Table 7: Association between Domain Specific Quality of Life and Socio Demographic Characteristics

Variable	N	Physical		Psychological		Social		Environmental	
		Mean	*p*-value	Mean	*p*-value	Median (IQR)	*p*-value	Mean	*p*-value
Age in Categories									
20-39	15	70.07 ± 11.27	0.000[2]	57.67 ± 18.34	0.571[2]	69 (50,75)	0.964[4]	62.33 ± 6.98	0.065[2]
40-59	15	63.53 ± 15.02		58.40 ± 14.91		56 (44,69)		61.00 ± 8.09	
60-79	11	50.72 ± 14.32		53.54 ± 12.96		56 (50,75)		59.18 ± 9.87	
Above 80	3	39.67 ± 7.51		48.00 ± 6.93		56 (50,69)		48.00 ± 9.16	
Gender									
Male	32	65.75 ± 14.91	0.001[1]	58.72 ± 13.84	0.046[1]	69 (50,75)	0.0122[3]	60.94 ± 9.05	0.312[1]
Female	12	48.08 ± 13.66		49.58 ± 12.00		50 (37,56)		57.92 ± 7.73	
Marital Status									
Married	33	59.73 ± 16.13	0.776[1]	58.18 ± 14.64	0.588[1]	56 (50,69)	0.783[3]	60.39 ± 9.40	0.717[1]
Single/ Divorced/ Separated	11	61.33 ± 16.13		55.58 ± 10.17		56 (31,69)		59.27 ± 6.63	
Education level									
None	6	48.17 ± 12.14	0.167[2]	44.83 ± 11.36	0.158[2]	56 (50,69)	0.280[4]	53.33 ± 11.66	0.124[2]
Primary	19	62.21 ± 17.61		59.32 ± 12.15		56 (50,75)		62.95 ± 7.19	
Secondary	12	62.25 ± 14.24		57.42 ± 15.89		50 (31,69)		59.08 ± 9.46	
Tertiary	6	67.83 ± 14.58		55.5 ± 13.34		69 (50,75)		60.67 ± 6.65	
Changed occupation									
Yes	23	54.65 ± 14.33	0.005[1]	50.65 ± 11.76	0.003[1]	50 (44,69)	0.071[3]	57.48 ± 8.82	0.034[1]
None	21	67.81 ± 15.06		62.33 ± 13.05		69 (44,69)		63.00 ± 7.84	

[1] t-test [2] ANOVA [3] Wilcoxon rank sum test [4] Kruskal wallis test

4.5 Association between HRQOL and Amputation Related Factors

4.5.1 Association between Overall Quality of Life and Amputation related factors

There was no statistically significant association between amputation related factors and overall quality of life ($p > 0.05$) (Table 9 presents association between Overall Quality of Life and amputation related factors)

Table 8: Table of Association between Overall Quality of Life and Amputation Related Factors

Variable	Overall QOL			Fishers' exact *p*-value
	Poor	Neutral	Good	
	Freq (%)	Freq (%)	Freq (%)	
Level of amputation				
Above knee	7 (35)	9 (45)	4 (20)	0.986
Below knee	7 (33.3)	10 (47.6)	4 (19)	
Indications				0.112
Non traumatic	11 (47.8)	8 (34.8)	4 (17.4)	
Traumatic	4 (19)	13 (61.9)	4 (19)	
Laterality				0.186
Left	9 (34.6)	10 (38.5)	7 (26.9)	
Right	6 (35.3)	10 (58.8)	1 (5.9)	
Dominant				0.146
Yes	8 (30.8)	15 (57.7)	3 (11.5)	
No	7 (41.2)	5 (29.4)	5 (29.4)	
Phantom pain				0.384
No	5 (23.8)	12 (57.1)	4 (19)	
Yes	8 (42.1)	7 (36.8)	4 (21.1)	
Residual pain				0.925
No	9 (33.3)	13 (48.1)	5 (18.5)	
Yes	3 (27.3)	6 (54.5)	2 (18.2)	
Prosthesis use				0.145
No	10 (34.5)	16 (55.2)	3 (10.3)	
Yes	5 (33.3)	5 (33.3)	5 (33.3)	
Comorbidity				0.484
No	6 (27.3)	12 (54.5)	4 (18.2)	
Yes	9 (45)	8 (40)	3 (15)	
Duration Time since amputation				0.145
Below 3 years	10 (34.5)	16 (55.2)	3 (10.3)	
Above 3 years	5 (33.3)	5 (33.3)	5 (33.3)	

4.5.2 Association between Domain Specific Quality of Life and Amputation Related Factors

Physical Domain and Amputation Related Factors

Prosthesis use was associated with significant higher quality of life scores in the physical domain ($p < 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

Not having a comorbidity was associated with significant higher quality of life scores in the physical domain ($p < 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

Those who had undergone amputation as a result of trauma had statistically significant higher physical domain quality of life scores as compared to those who had been amputated due to non-trauma causes ($p < 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between level of amputation and physical domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between level of laterality and dominance of amputated lower limb and physical domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between presence of phantom or residual stump pain and physical domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between time since amputation and physical domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

Psychological Domain and Amputation Related Factors

Prosthesis use was associated with significant higher quality of life scores in the psychological domain ($p < 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between level of amputation and psychological domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between presence of comorbidities and psychological domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between time since amputation and psychological domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between laterality and dominance of amputated lower limb and psychological domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between presence of phantom or residual stump pain and psychological domain of quality of life ($p > 0.05$) (Table 10

presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between those who had amputation as a result of trauma and those who had non-trauma related amputations and psychological domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

Social Domain and Amputation Related Factors

There was no statistically significant association between prosthesis use and social domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between level of amputation and social domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between level of amputation and social domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between presence of comorbidities and social domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between time since amputation and social domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between laterality and dominance of amputated lower limb and social domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between presence of phantom or residual stump pain and social domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between those who had amputation as a result of trauma and those who had non-trauma related amputations and social domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

Environmental Domain and Amputation Related Factors

Prosthesis use was associated with significant higher quality of life scores in the environmental domain ($p < 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between level of amputation and environmental domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between level of amputation and environmental domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between presence of comorbidities and environmental domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between time since amputation and environmental domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between laterality and dominance of amputated lower limb and environmental domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between presence of phantom or residual stump pain and environmental domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

There was no statistically significant association between those who had amputation as a result of trauma and those who had non-trauma related amputations and environmental domain of quality of life ($p > 0.05$) (Table 10 presents association between domain specific Quality of Life and amputation related factors).

Table 9: Association between domain specific Quality of Life and Amputation Related Factors

Variable		N	Physical		Psychological		Social		Environmental	
			Mean	*p*-value	Mean	*p*-value	Median (IQR)	*p*-value	Mean	*p*-value
Level of amputation	Above knee	20	60.10 ±14.65	0.748[1]	53.60 ±12.71	0.219[1]	53 (44,72)	0.397[3]	58.60 ±8.28	0.182[1]
	Below knee	21	61.76 ±18.67		59.00 ±14.80		56 (50,69)		62.05 ±7.98	
Laterality	Left	26	61.46 ±16.09	0.838[1]	57.12 ±14.25	0.609[1]	69 (50,75)	0.028[3]	60.73 ±9.03	0.536[1]
	Right	17	60.41 ±16.67		54.88 ±13.27		50 (31,69)		59.00 ±8.66	
Dominant	Yes	26	61.88 ±16.14	0.679[1]	56.08 ±13.75	0.928[1]	56 (44,69)	0.251[3]	59.58 ±9.43	0.671[1]
	No	17	59.76 ±16.52		56.47 ±14.19		69 (50,69)		60.76 ±8.01	
Prosthesis use	Yes	15	71.00 ±13.00	0.002[1]	65.47 ±12.59	0.001[1]	69 (50,75)	0.151[3]	65.20 ±8.44	0.004[1]
	No	29	55.72 ±14.97		51.45 ±11.63		56 (50,75)		57.48 ±7.77	
Comorbidity	Yes	20	53.00 ±16.04	0.016[1]	56.95 ±14.81	0.653[1]	56 (50,69)	0.888[3]	60.70 ±9.16	0.550[1]
	No	22	65.18 ±12.98		55.00 ±13.05		56 (50,69)		59.05 ±8.72	
Phantom pain	Yes	19	63.68 ±16.19	0.567[1]	54.42 ±13.63	0.437[1]	50 (44,69)	0.123[3]	61.11 ±9.76	0.535[1]
	No	21	60.76 ±15.83		57.57 ±11.73		69 (50,69)		59.33 ±8.14	
Residual pain	Yes	11	64.55 ±17.98	0.401[1]	58.82 ±17.67	0.362[1]	69 (50,75)	0.151[3]	61.00 ±8.94	0.579[1]
	No	27	59.59 ±15.66		55.19 ±12.35		56 (44,69)		59.19 ±9.12	
Indication	Non-Trauma	23	54.26 ±16.59	0.003[1]	55.35 ±14.25	0.659[1]	56 (50,69)	0.616[3]	58.83 ±9.76	0.311[1]
	Trauma	21	68.24 ±11.74		57.19 ±13.13		56 (50,75)		61.52 ±7.42	
Time since amputation	Below 3 years	29	59.62 ± 16.22	0.455[1]	56.1 ±12.30	0.934[1]	56 (50,69)	0.660[3]	59.07 ±8.19	0.275[1]
	Above 3 years	15	63.47 ±15.67		56.47 ±16.29		69 (50,75)		62.13 ±9.65	

[1] t-test [2] ANOVA test [3] Wilcoxon rank sum test [4] Kruskal wallis

4.6 Multiple Linear Regression

The socio demographic and amputation related factors that were found to be statistically significantly associated with domain specific quality of life after bivariate analysis were age, gender, occupation status, comorbidities, indication for amputation and prosthesis use. These factors were then subjected to multivariate analysis to check whether they would independently have an effect on quality of life among major lower limb amputees.

When subjected to multiple linear regression, the association between age and physical domain scores retained statistical significance ($p < 0.05$) while the association between age and social, environmental and psychological domain scores was not statistically significant ($p = 0.102$, $p = 0.112$ and $p = 0.787$ respectively) (Table 10 presents multiple linear regression analysis of socio demographic and amputation related factors).

When subjected to multiple linear regression, the association between gender and physical domain scores retained statistical significance ($p < 0.05$) while the association between gender and social, psychological and environmental domain scores was not statistically significant ($p = 0.102$, $p = 0.112$ and $p = 0.787$ respectively) (Table 10 presents multiple linear regression analysis of socio demographic and amputation related factors).

When subjected to multiple linear regression, the association between occupation status and both environmental and psychological domain scores retained statistical significance ($p < 0.05$) while the association between occupation status and both social and physical domain scores was not statistically significant ($p = 0.310$ and $p = 0.1$ respectively) (Table 10 presents multiple linear regression analysis of socio demographic and amputation related factors).

When subjected to multiple linear regression, the association between prosthesis use and both physical and psychological domain scores retained statistical significance ($p < 0.05$) while the association between prosthesis use and both social and environmental domain scores was not statistically significant ($p = 0.343$ and $p = 0.051$ respectively) (Table 10 presents multiple linear regression analysis between domain specific Quality of Life and amputation related factors and socio demographic characteristics).

When subjected to multiple linear regression, the association between presence of comorbidities and physical domain scores lost statistical significance ($p = 0.37$) while the association between presence of comorbidity and environmental domain scores gained statistical significance ($p < 0.05$) (Table 10 presents multiple linear regression analysis between domain specific Quality of Life and amputation related factors and socio demographic characteristics).

When subjected to multiple linear regression, the association between trauma as an indication for amputation and physical domain scores lost statistical significance ($p > 0.05$) (Table 10 presents multiple linear regression analysis between domain specific Quality of Life and amputation related factors and socio demographic characteristics).

The factors that remained statistically significant after multivariate analysis were age, gender, occupation status, prosthesis use and comorbidities.

Table 10: Multiple Linear Regression

Variable	Physical Domain		Psychological Domain		Social Domain		Environmental Domain	
Age in categories	**Coefficient (CI)**	***p* - value**	**Coefficient (CI)**	***p* – value**	**Coefficient (CI)**	***p* - value**	**Coefficient (CI)**	***p* - value**
40 to 59 vs 20 to 39	-6.31 (-15.61, 3)	0.18	-8.615 (-20.102, 2.873)	0.136	-0.495 (-13.405, 12.415)	0.938	-7.356 (-15.607, 0.895)	0.079
60 to 79 vs 20 to 39	-13.33 (-23.54, -3.12)	**0.01**	-10.274 (-22.874, 2.326)	0.106	1.54 (-11.325, 14.406)	0.808	-9.826 (-18.876, -0.776)	**0.034**
Above 80 vs 20 to 39	-18.04 (-32.34, -3.75)	**0.02**	-1.153 (-18.801, 16.494)	0.895	-3.428 (-27.876, 21.02)	0.776	-12.53 (-25.205, 0.146)	0.053
Male vs Female	8.59 (0.97, 16.22)	**0.03**	7.542 (-1.87, 16.953)	0.112	10.875 (-2.304, 24.053)	0.102	0.9 (-5.86, 7.66)	0.787
Education level								
Primary vs None	0.08 (-9.68, 9.84)	0.99	10.456 (-1.594, 22.507)	0.086	-2.431 (-19.794, 14.933)	0.777	4.573 (-4.082, 13.228)	0.289
Secondary vs None	3.35 (-8.27, 14.97)	0.56	9.761 (-4.59, 24.112)	0.175	-7.3 (-27.265, 12.666)	0.461	0.251 (-10.056, 10.558)	0.961
Tertiary vs None	4.65 (-8.55, 17.85)	0.48	6.692 (-9.606, 22.99)	0.408	-4.031 (-26.288, 18.227)	0.714	2.162 (-9.544, 13.868)	0.708
Change of occupation (Yes vs No)	-5.38 (-11.85, 1.1)	0.1	-10.907 (-18.898, -2.916)	**0.009**	-4.915 (-14.646, 4.816)	0.31	-6.526 (-12.266, -0.787)	**0.027**
Prosthesis use (Yes vs No)	18.79 (12.43, 25.15)	**0**	13.933 (6.081, 21.785)	**0.001**	5.085 (-5.706, 15.876)	0.343	5.624 (-0.016, 11.263)	0.051
Comorbidity (Yes vs No)	-4.2 (-13.58, 5.18)	0.37	11.533 (-0.048, 23.114)	0.051			9.336 (1.018, 17.654)	**0.029**
Indications (Traumatic vs Non traumatic)	-0.12 (-7.43, 7.19)	0.97	-2.14 (-11.16, 6.88)	0.631			0.644 (-5.835, 7.122)	0.84
Laterality Right vs Left)					-7.152 (-24.192, 9.889)	0.398		
Dominant (Yes vs No)					-0.657 (-14.809, 13.495)	0.925		
Phantom pain (Yes vs No)					-7.127 (-17.01, 2.756)	0.151		
Residual pain (Yes vs No)					5.697 (-5.358, 16.752)	0.301		

CHAPTER FIVE

5.0 DISCUSSION

5.1 Overall Quality of Life

Quality of life has become an increasingly important end point in the care of patients with the emergence of patient's rights movement (Pais-Ribero, 2004). The loss of a major lower limb potentially causes a level of limitation whether physical, psychological, social or mental. There is therefore a need to assess the outcomes following major lower limb amputation in a holistic manner.

The overall quality of life of majority of major lower limb amputees in this study was found to be poor to fair. This was in agreement with a study done in Nigeria (Adegoke *et al*., 2013) where they found the quality of life of major lower limb amputees to be moderate. The findings in this study were also in agreement with those in Thailand (Dajpratham *et al*., 2011) where majority of unilateral lower limb amputees were found to have a fair quality of life. Another study done in Sudan (Abdelgadir *et al*., 2009) though focusing on Diabetic amputees found them to have poor quality of life. In Malaysia (Razak *et al*., 2016) quality of life of lower limb amputees was found to be satisfactory. A study done in the Netherlands (Sinha *et al*., 2011) found that lower limb amputees had poor quality of life when compared to the general population. The findings in these studies suggest that the loss of a lower limb has a negative impact on the overall quality of life. This might be explained by the fact that with the loss of a major lower limb there is an associated physical limitation that may result in loss of employment that is essential in providing for the basic needs of daily living. The importance of paid employment to self-esteem and quality of life among people living with disability cannot be overemphasized (Robinson, 2000).

In this study the participants had higher physical domain scores with social domain scores being the lowest. This might be explained by the fact that majority of the participants had lost their lower limb as a result of trauma and were therefore fairly younger meaning their physical ability might be better. This is in contrast to the Malaysian study (Razak *et al*., 2016) which had physical domain scores as the lowest and psychological domain scores as the highest. The low physical domain score in the Malaysian study might have been partly due to the inclusion of bilateral amputees. The Nigerian study (Adegoke *et al*., 2013) had different findings with the highest scores recorded in the social domain and the lowest in the environmental domains.

In this study the socio demographic factors looked at were age, gender, occupation, education level and marital status. The factors that were significantly associated with domain specific quality of life were age, gender and occupation status. The amputation related factors that were looked at were prosthesis use, level of amputation, indication for amputation, comorbidities, phantom or residual pain, time since amputation, laterality of limb, dominance of limb and informed consent. Those that were significantly associated with domain specific quality of life were prosthesis use and presence of comorbidities.

5.2 Factors associated with Overall Quality of Life

The overall quality of life in this study was found to be significantly associated with gender and occupation status. Females had a larger proportion with self-perceived poor quality of life when compared to males while majority of those who had to change their occupation status as a result of amputation had a poor to neutral overall quality of life. Women in the Kenyan society play a fundamental role in the daily activities of their homes as well as income earning activities and the loss of a limb may affect their ability to perform these duties thus having a negative impact on their self-perceived quality of life. Having paid employment has been associated with enhanced self- esteem (Robinson, 2000) and a lack of an occupation may have a negative impact on self-perceived overall quality of life. In contrast the Nigerian study (Adegoke *et al*., 2013) found no significant association between gender or occupation status and overall quality of life. In this study overall quality of life had no significant association with amputation related factors similar to the Nigerian study (Adegoke *et al*., 2013).

5.3 Physical domain

In the physical domain the socio demographic factors that were significant were age and gender. This was in agreement with the Nigerian study (Adegoke *et al*., 2013) where male subjects had higher scores in physical, social and overall health scores. In contrast females were found to have higher scores in the physical domain (Cox *et al*., 2011). It is worth noting that the study by Cox et al done in Jamaica was only for Diabetic amputees and therefore had more females given the higher global prevalence of Diabetes in females (King *et al*., 1998).

In this study age had a significant association with physical domain quality of life scores. The younger you were the better your physical domain quality of life. Similarly, a study in the Netherlands (Sinha *et al.*, 2011) found age to be a significant factor in determining quality of life in the physical component. This observation is expected as with the elderly we have an expected decrease in neuromuscular coordination when compared to the younger population. This in turn affects their physical health and ability. This is in contrast with the Nigerian study (Adegoke *et al*., 2013) where there was no significant association between age and the physical domain. This was attributed to the fact that Nigerians between ages 40 and 80 who comprised 77% of the study participants become less physically active and hence amputation may not affect their quality of life (Adegoke *et al*., 2013).

There was no significant association between occupation status and physical domain of quality of life in this study. This is in contrast to the study done in Netherlands (Sinha *et al*., 2011) where employment was a key determinant of the physical component score.

There was no significant association between marital status and education level and the physical component of quality of life concurring with the Malaysian study (Razak *et al*., 2016).

Prosthesis use was associated with significantly higher quality of life scores in the physical domain in this study. This was in agreement with the Nigerian study (Adegoke *et al*., 2013). Similarly, the use of prosthesis was found to be a predictor of better physical health component (Sinha *et al*., 2011). Longer duration of prosthesis use was also associated with better physical domain quality of life (Gallagher & Maclachlan

2004). Prosthesis use is expected to improve mobility among major lower limb amputees and therefore have a positive impact on the physical domain of quality of life as seen.

In this study the other amputation related factors including indication for amputation, level of amputation, presence of comorbidity, time since amputation, informed consent, laterality and dominance had no significant association with the physical domain of quality of life. The level of amputation was however significant in determining physical domain quality of life with below knee amputees faring better than above knee (Cox *et al.*, 2011). This can be explained by the fact that above knee amputation has been found to have an energy expenditure up to 55% more than below knee (Vlassoli *et al.*, 2014) and has also been shown to be a poor predictor for prosthesis use (Taylor *et al.*, 2005).

Similar to the Nigerian study (Adegoke *et al*., 2013) time since amputation did not have a significant association with domain specific quality of life in this study. The process of learning and adaptation over time would be expected to have an impact on the physical domain of quality of life.

5.4 Psychological domain

Having an occupation was also found to have a positive impact on the psychological domain of quality of life. This is expected as having a paid employment has been shown to enhance self-esteem (Robinson, 2000). In contrast the Nigerian study (Adegoke *et al*., 2013) had no association between occupation status and psychological domain of quality of life. Another study (Razak *et al*., 2016) also found no significant association between occupation status and quality of life in the psychological domain.

There was no significant association between gender and psychological domain of quality of life. This was in contrast to the study done in Jamaica where females had significantly

better mean scores (Cox *et al*., 2011). Women in Jamaica are able to foster social/family relationships and these social networks can give them external motivation to become more functionally independent with better quality of life (Cox *et al*., 2011).

Prosthesis users had significantly better psychological domain quality of life scores compared to those who were not using prosthesis. This was similar to the Nigerian study (Adegoke *et al*., 2013). Prosthesis satisfaction was also strongly related to psychosocial factors (Razak *et al*., 2016). Prosthesis use improves mobility allowing one to interact with society better and at the same time improves self-esteem in terms of physical appearance.

The level of amputation had no significant association with psychological domain of quality of life in this study. The level of amputation was however significant in determining psychological domain quality of life with below knee amputees doing better than above knee (Cox *et al*., 2011). Given that below knee amputees expend less energy than above knee (Vlassoli *et al*., 2014) it can be assumed that they are better able to function and therefore would have a higher level of self-concept and a better self-image.

Concurring with the Nigerian study (Adegoke *et al*., 2013) time since amputation did not have a significant association with domain specific quality of life. One would expect that the longer the duration since amputation the more the time allowed to learn and adapt to the challenges that major lower limb amputees may face and therefore would fare better in the psychological domain compared to those with shorter duration since amputation.

5.5 Social domain

There was no significant association between the social domain of quality of life and either the socio demographic or the amputation related factors. This was in contrast to the Malaysian study (Razak *et al*., 2016) where there was a significant association with the level of amputation with those who had below knee amputations having better social domain quality of life than those who had above knee amputations. Similarly, the level of amputation was significant in determining social domain of quality of life with below knee amputees doing better than above knee (Cox *et al*., 2011).

In contrast the Nigerian study (Adegoke *et al*., 2013) found an association between the social domain of quality of life and gender with male participants having better scores for quality of life. This was in agreement with the study done in Jamaica (Cox *et al*., 2011) where gender had a significant association with the social domain of quality of life with females having better mean scores. In the Jamaican study the females had almost twice the mean scores of males in the social domain and this was attributed to their ability to foster social/family relationships. This is because women in Jamaica are heads of their households, they are more active in church and were younger at the time of amputation allowing them to reintegrate into the society with employment (Cox *et al*., 2011). In this MTRH study though the women were not necessarily younger at the time of amputation given the predominant role of trauma as an indication of amputation. Trauma has been associated with young males as they are generally more adventurous (World Health Organization, 2002).

Concurring with the Nigerian study (Adegoke *et al*., 2013) time since amputation did not have a significant association with the social domain of quality of life. The process of

learning and adaptation over time would have been expected to have a positive impact on the social domain of quality of life.

5.6 Environmental domain

In the environmental domain the socio demographic factor that was significant was the occupation status. This is expected as with an occupation comes financial security that would help to improve the environmental domain of quality of life. This is in contrast to the Nigerian study (Adegoke *et al*., 2013) and the Malaysian study (Razak *et al*., 2016) where there was no association between occupation status and environmental domain of quality of life.

There was no significant association between gender and environmental domain of quality of life. This was in contrast to the study done in Jamaica where female gender had better mean scores (Cox *et al*., 2011). This study was conducted in a rehabilitation center and had more female than male participants reflecting the better response of females to rehabilitation. The women in Jamaican society are more able to foster social/family values and hence are more comfortable in their physical environment (Cox *et al*., 2011).

The presence of a comorbidity which is an amputation related factor was also significantly associated with environmental domain quality of life with higher mean scores in those who had no comorbidity. Comorbidities would impact on the overall health, the need for access to health care and financial resources thus affecting environmental domain of quality of life.

There was no significant association between environmental domain and prosthesis use. In contrast the Nigerian study (Adegoke *et al*., 2013) had a significant association

between prosthesis use and the environmental domain of quality of life. Prosthesis use would increase mobility hence enhance interaction with the physical environment.

The level of amputation had no significant association with environmental domain of quality of life in this study. The level of amputation was however significant in determining environmental domain of quality of life with below knee amputees doing better than above knee (Cox *et al*., 2011). This might be because below knee amputees functioned better as a result of less energy expenditure compared to above knee amputees (Vlassoli *et al*., 2014) hence would better function in his or her environment.

Concurring with the Nigerian study (Adegoke *et al*., 2013) time since amputation did not have a significant association with environmental domain quality of life. The process of learning and adaptation over time would have been expected to have a positive impact on the environmental domain of quality of life.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

Majority of Major lower limb amputees at MTRH had a poor to fair overall self-perceived Quality of Life.

The highest mean scores were in the physical domain and lowest in the psychological domain.

Female gender and lacking an occupation was associated with significantly poor self-perceived overall quality of life.

Lower physical domain quality of life scores was associated with being older, female gender and not using prosthesis.

Lower psychological domain quality of life scores was associated with lacking an occupation and not using prosthesis.

Lower environmental domain quality of life scores was associated with lacking an occupation and having a comorbidity.

6.2 Recommendation

1. The involvement of occupational therapists in the rehabilitation of major lower limb amputees in order to enhance their independence and reintegration in to society
2. To address the challenges of prosthesis use by;
    a. Planning for prosthesis even before amputation with involvement of all cadres including psychological counsellors, physiotherapists and prosthesis officers
    b. Advocating for prosthesis inclusion in the health care packages as an important part in the care of Major lower limb amputees
3. The involvement of physicians in the management of leading comorbidities like diabetes and hypertension in a multidisciplinary approach.

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APPENDICES

APPENDIX 1: IREC APPROVAL

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2016/134
Approval Number: 0001712

1st September, 2016

Dr. Collins Chirchir,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
01 SEP 2016
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Chirchir,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Health Related Quality of Life and Associated Factors Following Major Lower Limb Amputation at Moi Teaching and Referral Hospital, Eldoret, Kenya".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1712*** on 1st September, 2016. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 31st August, 2017. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2016/134
Approval Number: 0001712

1st September, 2018

Dr. Collins Chirchir,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
01 SEP 2018
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Chirchir,

RE: CONTINUING APPROVAL

The Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

"Health Related Quality of Life and Associated Factors Following Major Lower Limb Amputation at Moi Teaching and Referral Hospital, Eldoret, Kenya".

Your proposal has been granted a Continuing Approval with effect from 1st September, 2018. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 31st August, 2019. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

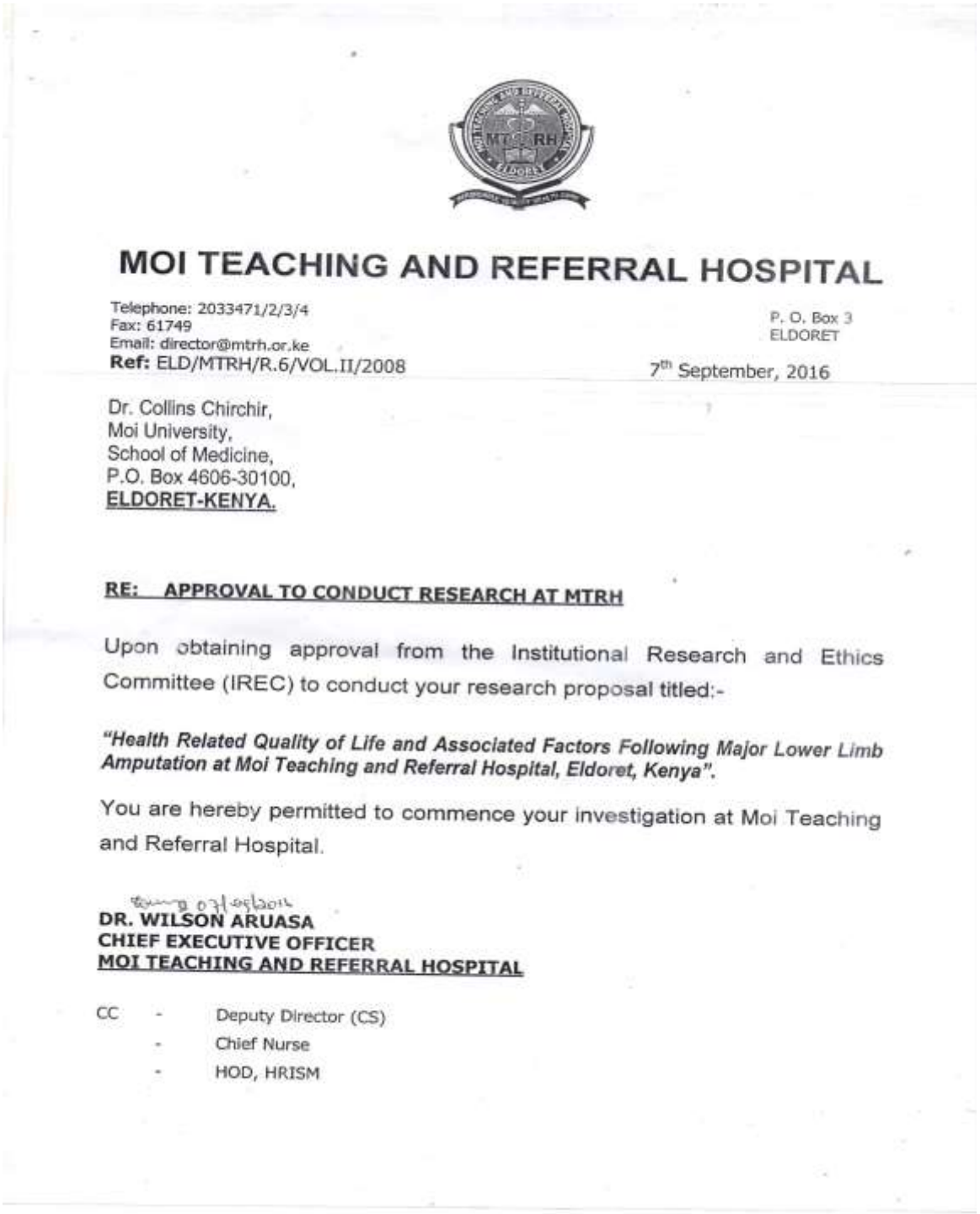
You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc:	CEO	-	MTRH	Dean	-	SOD
	Principal	-	CHS	Dean	-	SPH
	Dean	-	SOM	Dean	-	SON

APPENDIX 2: MTRH APPROVAL



MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke
P. O. Box 3
ELDORET

Ref: ELD/MTRH/R.6/VOL.II/2008

7th September, 2016

Dr. Collins Chirchir,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"Health Related Quality of Life and Associated Factors Following Major Lower Limb Amputation at Moi Teaching and Referral Hospital, Eldoret, Kenya".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

07/09/2016

DR. WILSON ARUASA
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
- Chief Nurse
- HOD, HRISM

APPENDIX 3: INTRODUCTORY LETTER

INTRODUCTORY LETTER

I am Dr. Chirchir Collins, a medical doctor currently pursuing Master of medicine degree in Orthopedic Surgery in the department of Orthopedic Surgery and Rehabilitation at Moi University, College of Health Sciences. I am conducting a study on the Health-related Quality of life following lower limb amputation**.**

You are being asked to take part in the research study. Information on the study and your participation is detailed below. Please read this form carefully. You are free to ask any question during any time of the study. If you decide to participate in the study, you will be given a copy of this introductory letter and the consent form for your records.

Taking part in the study is voluntary. Choosing not to participate in the study will not, in any way, affect the care you receive at MTRH. If you accept to enroll in the study, you will be free to terminate your participation at any time. Any new information concerning the risks and benefits of the study will be communicated to you promptly after which you will be free to opt out or continue with the study.

The purpose of this study is to assess the Health related quality of life in major lower limb amputees. The process of your participation will involve filling the WHOQOL-BREF questionnaire as well as questions related to amputation and bio-data. Your involvement in the study will be for one sitting. There will be no follow-up required for the purpose of the study.

The information you provide will be kept confidential at all times and there will be no use of identifiers that may trace back to you.

For more information concerning your rights as a research participant, you may contact the Moi University/MTRH Institutional Research Ethics Committee (IREC) on telephone number 053 – 33471 ext 3008.

Yours faithful,

_____

Dr. Collins Chirchir

P.O.Box 1124

Kericho.

Barua ya Utangulizi

Mimi ni Daktari Chirchir Collins. Nimehitimu kama daktari na nimesajiliwa na Bodi ya Madaktari ya Kenya. Kwa sasa, ninasomea shahada ya juu (masters) ya udaktari wa upasuaji wa magonjwa ya mifupa katika Chuo Kikuu cha Moi. Ninafanya utafiti kuhusu ubora wa maisha kufuatia upasuaji wa kukata mguu.

Ninaomba ujiunge na utafiti huu. Maelezo yafuatayo yanahusu utafiti wangu. Ningependa usome na iwapo una maswali yoyote kwa sasa au baadae kuwa huru kuuliza.

Kujiunga kwako ni kwa hiari. Kutojiunga hakutaathiri matibabu yako ya baadae. Una huru wakujiondoa kutoka kwa utafiti huu wakati wowote. Iwapo kutatokea maelezo zaidi kuhusu utafiti huu tutakueleza na utapata fursa ya kuamua iwapo ungependa kuendelea na kujihusisha na utafiti huu.

Utafiti huu unachunguza ubora wa maisha ya wale waliofanyiwa upasuaji wa kukata mguu. Kuhusishwa kwako, utakuwa kwa kuyajibu maswali kutoka kwa WHOQOL-BREF yanayohusu ubora wa maisha yako pamoja na upasuaji uliofanyiwa.

Hakutakuwa na wakati wa kufuatiliwa kwa minajili ya utafiti kwani tutamaliza shughuli ya utafiti kwa siku moja.

Maelezo yote utakayotoa yatahifadhiwa vyema na kwa njia ya siri. Pia, hatutatumia maelezo yoyote ambayo yanawezesha kukufahamisha.

Iwapo utahitaji maelezo zaidi, waweza kuwasiliana na kikundi kinachoangazia utafiti na usawa wake wa IREC katika nambari ya rununu 053 – 33471 (ext 3008)

Mimi wako mwaminifu,

_____

Daktari Collins Chirchir

SLP 1124, Kericho.

NambariyaRununu 0728502211

APPENDIX 4: PHONE CONTACT STUDY INTRODUCTION SHEET

Phone Contact Introductory Sheet (English)

I am (Name of Caller) calling you from MTRH. Am I speaking to (Name of patient)?

One of the doctors, Dr. Chirchir Collins, who is currently studying Masters of Medicine in Orthopedic Surgery would like to make contact with you with regard to his research study. The study is entitled '**Health Related Quality of Life and Associated Factors Following Major Lower Limb Amputation at Moi Teaching and Referral Hospital, Eldoret, Kenya'** The purpose of his study is to assess the quality of life in major lower limb amputees.

The purpose of this call is to seek your permission to allow the hospital to give him access to your mobile number.

Do you have any questions?

Do you give your verbal consent for your mobile contact to be shared with Dr. Chirchir?

Yes _____ No _____

Thank you for your time.

Maelezo YaUtangulizi kwa Simu (Kiswahili)

Jina langu ni (jina la mpiga simu) Ninapiga kutoka Hospitali ya Rufaa la Moi. Je naongea na (jina la mgonjwa)?

Mmoja wa madaktari kwa jina Daktari Chirchir Collins anayesomea Upasuaji wa mifupa angependa kuwasiliana na wewe kwa minajili ya utafiti wake. Utafiti wake kwa jina ni **'Ubora wa maisha kufuatia upasuaji wa kutoa sehemu ya mguu katika Hospitali ya Rufaa ya Moi, Eldoret, Kenya.'** Lengo la utafiti wake ni kuangazia ubora wa maisha baada ya upasuaji huu.

Madhumuni ya kupiga simu ni kuomba ruhusa ya kumpa Daktari Chirchir nambari zako za rununu.

Je una swali lolote?

Je Daktari Chirchir anaweza pewa nambari zako?

Ndio _____ La _____

Asante kwa muda wako.

APPENDIX 5: CONSENT FORM

Research Title: Health Related Quality of Life and associated factors following major lower limb amputation at Moi Teaching and Referral Hospital, Eldoret, Kenya.

Investigator: Dr. Collins K. Chirchir

P.O Box 1124 Kericho, Kenya, Mobile No: 0728502211

I……. of P.O Box……

Tel……..hereby give informed consent to participate in this study at MTRH. The study has been explained to me clearly by Dr. Collins Chirchir (or his appointed assistant) of P.O. Box 1124 Kericho.

I have understood that by participating in this study, I shall volunteer information regarding my health related quality of life following lower limb amputation. I am aware that I can withdraw from this study at any time without prejudice. I have also been assured that all information shall be treated and managed in confidence. I have not been induced or coerced by the investigator (or his appointed assistant) to cause my signature to be appended in this form and by extension participate in this study.

Initials of participant……

Signature…… Date……

Name of witness……

Signature…… Date……

FOMU YA KIBALI

MADA YA UTAFITI: Health Related Quality of Life and associated factors following major lower limb amputation at Moi Teaching and Referral Hospital, Eldoret, Kenya.

MTAFITI - Dr. Collins Chirchir

P.O Box 1124 Kericho,

Simu ya Rununu: 0728502211

Mimi _____wa Sanduku la Posta _____, Nambari ya Simu_____najitolea kwa hiari yangu mwenyewe kutoa kibali cha kujihusisha katika utafiti uliotajwa hapo juu unaoendelezwa katika MTRH. Nimepokea maelezo ya tafsili kuhusu utafiti huu kutoka kwa DaktariChirchir Collins (au Mtafiti msaidizi wake) katika lugha, kanuni na masharti ninayoelewa vyema. Nimehakikishiwa kuwa, sitadhurika kamwe kutokana na kujihusisha kwangu katika utafiti huu. Ilibainishwa kuwa kujihusisha katika utafiti huu ni kwa hiari na nina uhuru wa kujiondoa wakati wowote ule bila ya kuhujumiwa hasa kuhusu haki yangu ya kupokea matibabu katika MTRH. Zaidi ya hayo, nilihakikishiwa kuwa, kanuni zote za maadili ya utabibu, uhuru, haki, na manufaa zitazingatiwa katika utafiti huu.

Jina la Mhojiwa_____

Sahihi _____

Tarehe _____

Jina la shahidi _____

Sahihi _____

Tarehe _____

APPENDIX 6: QUESTIONNAIRE

Socio-demographic Characteristics

i. Subject code: _____

ii. Age: _____

iii. Gender: Male: ☐ Female: ☐

iv. Occupation Before: _____

v. Occupation After: _____

vi. Marital Status: _____

vii. Education Level:

- None ☐
- Primary ☐
- Secondary ☐
- Tertiary ☐

Amputation related factors

i. Level of amputation;

- Hip ☐
- Above knee ☐
- Through knee ☐
- Below knee ☐
- Ankle ☐

ii. Indication of Amputation_____

iii. Laterality:

☐ ☐

- Laterality left; Dominant Non-dominant
- Laterality Right; Dominant ☐ Non-dominant ☐

iv. Informed decision making; ☐ Yes ☐ No

v. Complications:

- Phantom pain Yes ☐ No ☐
- Residual Sharp pain Yes ☐ No ☐
- Other complications

……...

……

vi. Prosthesis use; Yes ☐ No ☐

If no, why?

……

……

……. ☐ ☐

vii. Co-morbidities; Yes No

If yes, specify

……...

……

……

Viii.Time since amputation…….

APPENDIX 7: WHO QOL-BREF

WHO QOL-BREF

Instructions

This questionnaire asks how you feel about quality of life. Health, or other areas of your life. Please answer all the questions. If you are unsure about which response to give to a question, please choose the one that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasure and concerns. We ask that you think about your life in the last two weeks. For example, thinking about the last two weeks, a question might ask:

Please read each question, assess your feelings, and circle the number on the scale that gives the best answer for you for each question.

		(Please circle the number)				
		Very poor	**Poor**	**Neither poor nor good**	**Good**	**Very good**
1	How would you rate your quality of life?	**1**	**2**	**3**	**4**	**5**

		(Please circle the number)				
		Very poor	**Poor**	**Neither poor nor good**	**Good**	**Very good**
2	How satisfied are you with your health?	**1**	**2**	**3**	**4**	**5**

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

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

		(Please circle the number)				
		Not at all	**Slightly**	**A moderate amount**	**Very much**	**Extremely**
7	How well are you able to concentrate?	**1**	**2**	**3**	**4**	**5**
8	How safe do you feel in your daily life?	**1**	**2**	**3**	**4**	**5**
9	How healthy is your physical environment?	**1**	**2**	**3**	**4**	**5**

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

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

		(Please circle the number)				
		Very poor	**Poor**	**Neither poor nor good**	**Good**	**Very good**
15	How well are you able to get around?	**1**	**2**	**3**	**4**	**5**

The following questions ask you to say how good or satisfied you have felt about various aspects of your life over the last two weeks.

		(Please circle the number)				
		Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
16	How satisfied are you with your sleep?	**1**	**2**	**3**	**4**	**5**
17	How satisfied are you with your ability to perform your daily living activities?	**1**	**2**	**3**	**4**	**5**
18	How satisfied are you with your capacity for work?	**1**	**2**	**3**	**4**	**5**
19	How satisfied are you with yourself?	**1**	**2**	**3**	**4**	**5**
20	How satisfied are you with your personal relationships?	**1**	**2**	**3**	**4**	**5**
21	How satisfied are you with your sex life?	**1**	**2**	**3**	**4**	**5**
22	How satisfied are you with the	**1**	**2**	**3**	**4**	**5**

	support you get from your friends?					
23	How satisfied are you with the conditions of your living place?	**1**	**2**	**3**	**4**	**5**
24	How satisfied are you with your access to health services?	**1**	**2**	**3**	**4**	**5**
25	How satisfied are you with your mode of transportation?	**1**	**2**	**3**	**4**	**5**

The following questions refers to **how often you** have felt or experienced certain things in the last two weeks.

		(Please circle the number)				
		Never	**Seldom**	**Quite often**	**Very often**	**Always**
26	How often do you have negative feelings, such as blue mood, despair, anxiety, depression?	**1**	**2**	**3**	**4**	**5**

Did someone help you to fill out this form? (*Please circle Yes or No)* Yes No

THANK YOU FOR YOUR HELP

APPENDIX 8: WORK PLAN

Date	**Activity**	**Duration**	**Responsible persons**
Sept- Nov, 2015	Selection of topic	3 months	Researcher
Nov,2015- Jan, 2016	Literature review	3 months	Researcher
Feb, 2016	Writing proposal	1 month	Researcher and Supervisors
April 2016	Submission to IREC	1 month	Researcher
May 2016	Approval by IREC	1 month	IREC
Jan 2017 – May 2018	Data collection	18 months	Researcher
JUNE 2018-DEC 2018	Writing the thesis report	6 months	Researcher and Supervisors
NOV 2019	Submission of thesis for marking	1 month	Researcher
SEPT 2020	Submission of final corrected thesis	1 month	Researcher

APPENDIX 9: BUDGET

Code	Item	Cost (Kshs)
1	10 reams of plain and ruled paper @ 500	5,000.00
2	Pens, pencils, folder and other stationery	2,000.00
3	Two Computer Flash discs	3,000.00
4	Printing research proposals	10,000.00
5	Printing thesis, four copies	5,000.00
6	Binding thesis	6,200.00
7	Research assistant	20,000.00
8	I.R.E.C. fee	1,000.00
9	Data handling	20,000.00
10	Cost for Telephone Communication	10,000.00
11	Add 10% contingency	7, 000.00
	TOTAL	**89,200.00**