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FACTORS ASSOCIATED WITH QUALITY OF LIFE AMONG POST STROKE PATIENTS AT THE KORLE-BU TEACHING HOSPITAL STROKE UNIT

BY

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DECLARATION

I, Juliet Opoku, declare that I have independently worked on this dissertation. References of other works have been duly acknowledged and cited. I further declare, that this work has not been submitted for any degree in this or any other university. It has also not been submitted for publication in any other journal.

Juliet Opoku	Prof Moses Aikins
(Student / Author)	(Supervisor)
Date : 24th September 2022	Date : 24th September 2022

DEDICATION

I dedicate this dissertation to my husband, Mr Peter Frimpong-Mansoh for the support he offered me throughout the program. And to my three children, for all the smiles they offered to support me in times of difficulty.

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I would like to express my gratitude to God almighty for seeing me through the MPH program. I thank my supervisor, Prof Moses Aikins profoundly for his guidance and direction in putting together this dissertation. I thank him for his time, patience and encouragement. I am also grateful to my parent, Mr and Mrs Opoku and my sisters, who helped me take care of my children whiles I undertook this program of study. I thank my husband and children for been there for me. May God bless you all.

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ABBREVIATIONS

Table 0. 1: List of abbreviations

Abbreviation	Meaning
ADL	Activities of Daily Living
CI	Confidence interval
CT SCAN	Computerized Tomography scan
DDNS	Deputy Director of Nursing Services
FAI	Frenchay Activities Index
HIV/AIDS	Human immunodeficiency virus/Acquired immunodeficiency syndrome
IRB	Institutional Review Board
KATH	Komfo Anokye Teaching Hospital
KBTH	Korle-Bu Teaching Hospital
NEMESIS	North East Melbourne Stroke Incidence Study
NHP	Nottingham Health Profile
OPD	Out-patient department
QoL	Quality of life
SAGE	Study on global AGEing and adult health
SS-QoL	Stroke specific quality of life
WHO	World Health Organization
WHOQOL-BREF	World Health Organisation Quality of life – Brief Version

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ABSTRACT

Background: Quality of life (QoL) may be affected in individuals with chronic diseases such as stroke. Attention must be paid to the QoL of post stroke patients so as to improve disease outcomes. QoL has not been adequately studied in diverse patient populations in Ghana. This dissertation sought to determine the characteristic features of post stroke patients, determine their QoL and assess the relationship between them.

Methods: A cross-sectional study using simple random sampling was conducted at the Korle-Bu Teaching Hospital, stroke unit in 2021. Post stroke patients reporting for review were included in the study (n= 128). Barthel index was used to assess the severity of stroke and SS-QoL used to assess QoL. Using Stata v.16, the Kruskall Wallis test, Wilcoxon Mann Whitney and quantile regression analysis were used to determine the factors associated with QoL.

Results: The mean age was 58.9 years (*SD*= 13.1) with 53.1% (68) being female. About 85% had hypertension and 18.8% had diabetes. Using the Barthel index, 58.6% had slight dependency whiles 5.5 % total dependency. Quality of life was poor in 6.25% of patients, moderate in 37.50% and normal in 56.25%. Quality of Life domains mostly affected were Energy, family roles, social roles and work/productivity.

Conclusion: QoL is affected in post stroke patients. Age, educational status, employment status before and after the stroke incident, presence of a caregiver, severity of stroke and smoking were significantly related to QoL. Multidisciplinary post stroke management must focus on domains of QoL mostly affected and the features associated with it to improve treatment outcomes.

CHAPTER ONE

INTRODUCTION

1.1 Background to the study

Stroke is the sudden death of brain cells that results from blockage or rupture of a blood vessel that supplies the brain. It results in sudden onset of loss of speech, weakness or paralysis of one side of the body (Sacco et al., 2013). It is a major cause of morbidity and mortality in the world with over 15 million people developing a stroke each year (Sanuade et al., 2019). The increasing global incidence has made it a condition of public health concern. Due to the sudden nature of the symptoms, patients and their relatives are ill prepared for the sequel of the event which in effect, affects the rehabilitation process and the disease outcome (Abubakar & Isezuo, 2012). Stroke survivors loose approximately 44 million disability-adjusted live years each year (Gorelick, 2019). This is related to the poor quality of life lived by these patients.

Quality of life is defined by the WHO as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns". (Harper et al., 1998 & Vahedi, 2010). Studies have identified different quality of life domains to be affected to various degrees in individuals who have chronic diseases (Harper et al., 1998; JW et al., 2004;). Quality of life can be assessed as either general or domain specific. In either case, it is affected differently by various factors that may be socio-demographic, clinical and/or behavioral in origin (Ramos-Lima et al., 2018).

Being a chronic illness with long term complications, the quality of life of stroke patients, like that of most chronic disease patients is negatively affected. Stroke negatively impacts the physical quality of life of individuals as well as their social, emotional, environmental and financial well-

being (Mahesh et al., 2020). If the impact of stroke is left unchecked and therefore not managed, it may lead to adverse rehabilitation outcomes (Chang et al., 2013) . Measurement of quality of life of post stroke patients can be used to assess the effect the illness has on an individual as well as to measure the effectiveness of both acute and long term stroke management. It is therefore a key goal of contemporary stroke care (Megari, 2013).

According to Donkor et al, the physical, psycho-emotional and cognitive domains of the health related quality of life of patients was mainly affected in the Ghanaian population he studied (Donkor et al., 2014). Similar findings were noted in the quality of life and associated factors study in post stroke patients in Nigeria (Oni et al., 2016). Gbiri & Akinpelu (2012), identified age, marital status, occupational status, educational qualification and depression as some of the factors associated with quality of life. Some of these factors had positive effects as some had negative effects. Other studies have also added level of disability, right sided weakness, presence of other co-morbidities and sexual function as other factors associated with post stroke quality of life (Oni et al., 2016 & Ramos-Lima et al., 2018).

Poor quality of life can negatively affect the rehabilitation outcome of post stroke patients (Taştekin, 2015). A clear identification of the factors that may affect a Ghanaian post stroke patient and the specific domains of stroke specific quality of life that may be affected is needed to improve outcomes. This knowledge will help in planning intervention programs aimed at improving quality of stroke care in Ghana. This dissertation will be identifying the factors that are associated with the stroke specific quality of life of post stroke patients in a Ghanaian population.

1.2 Problem statement`

Stroke is the second cause of mortality and the third cause of disability in most countries worldwide (Gorelick, 2019). Globally, approximately 15 million people develop a stroke each year with over 5 million deaths and another 5 million developing permanent disability as a result (Lanas & Seron, 2021; Sanuade et al., 2019). Of the total adult population reporting to Komfo Anokye Teaching hospital (Kumasi-Ghana) for healthcare, 9.1% were stroke patients and stroke mortalities constituted 13.2% of the total mortalities within the hospital (Agyemang et al., 2012). Stroke is increasingly becoming a national burden with the current rate at 2.6% (de-Graft Aikins et al., 2012 & Sanuade et al., 2019). Advances in health care in the form of a multidisciplinary approach to stroke care has resulted in improved stroke outcomes in terms of reduced case fatality and hence an increasing number of post stroke patients (Clarke, 2013)

Post stroke patients have long term medical, musculoskeletal and psychosocial complications that affect their quality of life (Carod-Artal & Egido, 2009). Other studies have identified socio-demographic characteristics, severity of stroke, cognitive impairment and hypertension as some of the factors associated with post stroke quality of life (Gbiri & Akinpelu, 2012 & Ramos-Lima et al., 2018). The need for constant follow-up to manage chronic complications of stroke and other co-morbidities results in physical and financial stress on the patient and their immediate caregivers (Opara & Jaracz, 2010). There is an increased cost of health care on the individual, family, society and the government in an attempt to rehabilitate the individual to be able to fit back into society (Maredza & Chola, 2016).

Several stroke related studies have been undertaken in Ghana: Sanuade et al (2019), using data from Wave 1 of the WHO Survey on Global Ageing and Adult Health (SAGE) identified the prevalence of stroke in the older adult population of Ghana to be 2.6% (Sanuade et al., 2019). De-

Graft Aikins et al, 2012 identified the increasing rise in stroke cases to be a result of the increasing non communicable diseases in Ghana most of which are of cardiovascular origin (de-Graft Aikins et al., 2012). Sarfo et al., (2017) identified that, 4 out of 10 Ghanaian post stroke patients had significant clinical depression and that these patients had a low quality of life.

Despite the increasing number of stroke cases in the country and the importance of quality of life in the management of these patients, minimal work has been done on QoL of post stroke patients. No study has used the stroke specific quality of life tool to assess the QoL of post stroke patients at the KBTH- stroke unit, a multidisciplinary stroke centre in Ghana.

Post stroke quality of life studies aimed at identifying factors that can be determinants for quality of life improvement will aid in the development of new rehabilitation programs for post stroke patients (Carod-Artal & Egido, 2009 & Taştekin, 2015). Targeting patient characteristics that are associated with quality of life in both the short and long-term will help in planning national intervention programs to facilitate the rehabilitation of post stroke patients and the prevention of a poor quality of life (Aprile et al., 2008 & Piravej et al., 2014). This study is aimed at providing information on the stroke specific quality of life of patients in a stroke centre that offers multidisciplinary health care and will add to the diversity of information on the matter.

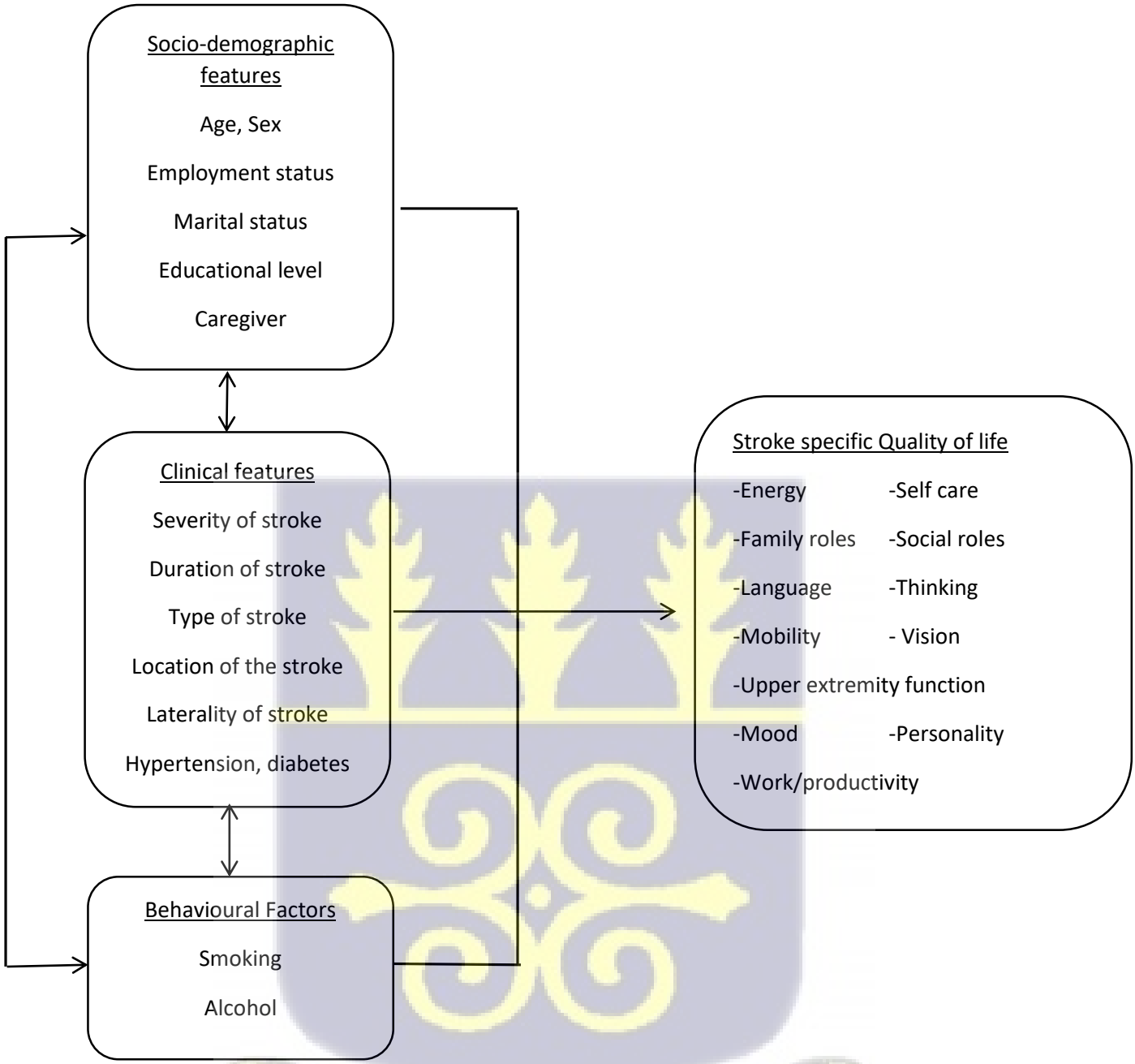
1.3 Conceptual framework of factors associated with quality of life of post stroke patients

Figure 1 shows the conceptual framework of the factors associated with the quality of life of post stroke patients. This framework was constructed by the author using information identified in literature to be associated with the quality of life of post stroke patients. (Gbiri & Akinpelu, 2012; Kim et al., 2005; Ramos-Lima et al., 2018; Roy-O'Reilly & McCullough, 2018; Williams et al., 1999). The Quality of life will be assessed with the stroke specific quality of life which is made

up of the following domains: mobility, personality, mood, language, energy, and family roles. The others are, self-care, social roles, thinking, upper extremities function, vision and work/productivity (Williams et al., 1999). The different domains may be collectively or individually affected by the factors and may be assessed together or as single domains.

Socio-demographic features such as age, sex, occupational status, marital status and educational status have been identified as factors associated with the quality of life of post stroke patients (Gbiri & Akinpelu, 2012 & Ramos-Lima et al., 2018). The location or site of stroke, type of stroke and severity of stroke are clinical features that are associated with the severity of symptoms at onset of stroke and may determine the outcome of stroke. These features may also affect the quality of life of stroke survival patients (Lin et al., 2018 & Ramos-Lima et al., 2018). Longer duration of stroke has been found to be negatively correlated with quality of life. The behavioural factors that have been identified to be related to quality of life in post stroke patients are smoking and alcohol intake (Kim et al., 2005 & Ramos-Lima et al., 2018). Finally, these factors, (i.e. socio-demographic, clinical and behavioural) interact with each other as shown in figure 1 (Roy-O'Reilly & McCullough, 2018 & Shah & Cole, 2010)

Figure 1. 1: Conceptual framework of factors associated with the quality of life of post stroke patient



1.4 Justification of the study

There is a need for this study in order to provide a baseline data of the quality of life of Ghanaian post stroke patients, hence contributing to the data available on the subject. It will assess the specific domains of quality of life that are mainly affected. This will guide clinicians on decision making in terms of provision of stroke specific rehabilitation to manage the various affected domains of quality of life. Intervention programs aimed at improving post stroke QoL may also be planned and implemented based on the factors associated with their QoL. This will lead to improved overall stroke outcome.

1.5 Research questions

1. What are the clinical and behavioural characteristics of post stroke patients at the KBTH stroke unit?
2. What is the quality of life of post stroke patients at the KBTH stroke unit?
3. What is the association between the characteristics (i.e., socio-demographic, clinical and behavioural) of post stroke patients at the KBTH stroke unit and their quality of life?

1.6 Objectives of the study

1.6.1 General objective

The general objective is to determine quality of life and factors associated with it among post stroke patients at the KBTH stroke unit.

1.6.2 Specific objectives

The specific objectives are:

1. To determine the clinical and behavioural characteristics of post stroke patients at the KBTH stroke unit

2. To determine the quality of life of post stroke patients at the KBTH stroke unit.
3. To determine the association between the characteristics (i.e., socio-demographic, clinical and behavioural) of post stroke patients at the KBTH stroke unit and their quality of life.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This literature review was conducted by searching for relevant words on Google Scholar, Google and PubMed. These sites provided assess to reputable journals with published data on the subject matter. The search was conducted for research done in the past 10 years and extended to 15 years on matters without recent publications. To broaden or restrict the search, Boolean operators 'AND' and 'OR' were used. Keywords and phrases such as 'Quality of life', 'stroke specific', 'stroke survivors', 'post stroke patients', etc were used in the search

2.2 Global burden of stroke

Stroke is the sudden loss of speech, weakness or paralysis that results from the blockage or rupture of a blood vessel that supplies the brain (Sacco et al., 2013). It is the second cause of mortality and the third cause of disability in the world. Approximately 15 million people develop a stroke each year with over 5 million deaths and another 5 million developing permanent disability as a result. Ten to fifteen percent of deaths in sub-Saharan Africa are attributed to stroke (Lanas & Seron, 2021; Sanuade et al., 2019).

2.3 The burden of stroke in Ghana

The prevalence of stroke in the older adult population of Ghana is 2.6% with hypertension and diabetes significantly increasing the odds of stroke in this population (Sanuade et al., 2019). About 9.1% of hospital admissions in the adult medical department is associated with stroke (Agyemang et al., 2012) with 4 out of every 10 patients who survive stroke having significant evidence of

clinical depression. Hospital records at the KBTH- internal medicine department shows that stroke is the leading cause of morbidity and mortality, with over 30% of mortality attributed to stroke and related complications. The increasing incident of stroke in Ghana may be attributed to the increasing urbanization that leads to increase in non-communicable diseases, the most common of which are hypertension, diabetes and obesity. These are three very important risk factors for developing stroke. (de-Graft Aikins et al., 2012 & Sanuade et al., 2019). Physical inactivity, smoking and clinical control of hypertension or diabetes may increase the odds of a stroke in this at-risk population (Sarfo et al., 2018). Despite the increasing incidence of stroke in Ghana and the debilitation post stroke complications, most Ghanaians are not aware of the risk factors and complications that are associated with stroke (Donkor et al., 2014).

2.4 Quality of life and quality of life assessment tools

Quality of life is defined by the WHO as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns". (Harper et al., 1998 & Vahedi, 2010). Traditionally, outcome of disease has been measured by the improvement in clinical outcomes, cure, and survival. With improved health care through better knowledge and healthcare financing more patients are having to live with chronic diseases whiles on regular long term treatment plans. A useful way of assessing the impact of disease outcome in these patient groups is to assess their quality of life. Measurement of quality of life has therefore become an important and often required part of health outcome assessment especially in patients with chronic incurable diseases. This trend is useful for individuals with chronic, non-fatal conditions who live for several years after their diagnosis (Litwin, 2007 & Megari, 2013). A scale to measure the quality of life of individuals was first created by American psychologist John Flanagan for this purpose. This originally 15-

item instrument measured five domains of quality of life: material and physical well-being, relationships, social, community and civic activities, personal development and fulfilment, and recreation. Over the next 30 years, this scale has been modified in various ways to assess the quality of life of patients with various chronic illnesses (Burckhardt et al., 2003 & Burckhardt & Anderson, 2003). Other generic and condition or disease specific quality of life tools have also been developed by different researchers. Generic tools can be used across all patient groups and have questions that are not specific to a particular disease condition, whiles disease specific tools are designed with features of a particular disease in mind (Harper et al., 1998; Seow et al., 2019).

Considering improved acute stroke outcomes and the chronic nature of post stroke complications, it is imperative that measurement of post stroke quality of life becomes part of the regular assessment of post stroke patients. Stroke specific quality of life tools may serve a better function where available. Some types of generic quality of life assessment tools that have been used to assess quality of life in post stroke patients include: Nottingham Health Profile (NHP) and the Frenchay Activities Index (FAI) (Indredavik et al., 1998), WHOQOL-BREF (Oni et al., 2016), Health related quality of life (Lin et al., 2018) and 36-Item Short form survey, (Pinedo et al., 2017). Some stroke specific tools that have been used include the Stroke Specific quality of life (Ramos-Lima et al., 2018) and Health related quality of life scale in stroke patients (Owolabi & Ogunniyi, 2009). A review of quality of life studies in Nigeria showed that over 70% of research done in Nigeria had used different stroke specific quality of life tools (Badaru et al., 2015). Two quality of life studies done in Ghana used the health related quality of life scale for stroke patients. (Donkor et al., 2014 & Sarfo et al., 2017).

2.5 Quality of life domains

Quality of life tools measure quality of life by assessing different domains of life and functions. One such important domains are limitations in physical activities that presents as difficulty in performing activities of daily living. Others are measures of emotional health, happiness and depression. Both generic and condition or disease specific quality of life tools have different domains that are measured with questionnaires. These scales are developed based on research findings (Burckhardt & Anderson, 2003b; Harper et al., 1998). Although they seek to measure quality of life, domains covered and level of comprehensiveness vary widely between generic and stroke-specific measures. Whiles disease specific QoL is generally preferred in tracking the response to treatment, the generic QoL may better assess the overall clinical presentation (Seow et al., 2019 & Wells et al., 2011). For example: the health related quality of life measures domains that are related to physical, mental, emotional, and social functioning. The WHOQOL-BREF consists of six domains which include two general categories of overall health and health satisfaction and four specific domains of physical, psychological, social, and environmental health (Harper et al., 1998).

2.6 Post stroke quality of life and sociodemographic features

Most studies on post stroke quality of life have identified various socio-demographic features as factors that are associated with quality of life. Gbirir and Adekunle (2012) studied the effect of various sociodemographic characteristics on quality of life at different times post stroke. They noticed that marital status, educational qualification and occupational status support had significant positive influence on quality of life in the first 6 months after a stroke. Oni et al (2016), in their quality of life and associated factors among post stroke clinic attendees at a University

Teaching Hospital in Nigeria study, added younger age, female sex, employment status and financial status as factors that influence the post stroke quality of life. Similar studies in well-developed communities also identified similar factors as affecting quality of life (Kim et al., 2005 & Ramos-Lima et al., 2018). Although Oni et al, (2016) identified female sex to be a factor for poorer quality of life, other studies done also in Nigeria did not find any significant difference in quality of life between males and females, (Akosile et al., 2013). This difference in the findings may be as a result of the different quality of life assessment tools used for the research. The former used the generic WHOQOL-BREF whiles the latter used stroke specific quality of life. Quality of life scores were significantly higher in younger patients as compared to older patients. Whiles unemployment, motor impairment, aphasia, dysarthria, dysphagia and severe deficit in performance of activities of daily living were identified to be associated with low quality of life in young patient, the older population also had in addition, stroke laterality, diabetes mellitus co-morbidity and post stroke features (Kim et al, 2005).

2.7 Post stroke quality of life and clinical factors

Various clinical factors have been implicated in the quality of life of stroke patients. The Modified Rankin scale is used to assess the severity of symptoms in post stroke patients whiles the Barthel index measures the ability to perform activities of daily living. These are two common tools used to assess the physical activity of post stroke patients and is usually compared with quality of life (Sulter et al., 1999). Ramos-Lima et al, (2018) identified a positive correlation between the performance of activities of daily living and quality of life. Similar findings were noted by Oni et al (2016) in Nigeria. These point to the fact that patients with severe physical disability tend to have a lower quality of life and this may be as a result of an increased dependency on external source of help for their daily activities. Their caregivers also had a poorer score on quality of life

assessment for similar reasons (Pinedo S et al., 2017 & Quartey et al., 2020). Assessment tools used in some of these studies to measure severity of post stroke symptoms in terms of ability to perform activities of daily living include the Barthel index score, the National Institute of Health Stroke Scale and the modified Rankin scale ((Kim et al., 2005 & Ramos-Lima et al., 2018).

On the other hand, although symptoms of stroke may be determined by the location and laterality of a brain damage, there exists only a weak association between the laterality and the quality of life. Location of the stroke on the other hand, may significantly affect the quality of life in mild ischemic stroke (De Haan et al., 1995 & Lin et al., 2018). Quality of life is poorer during the first few months following a stroke than it is after a longer duration of time. It tends to however improve significantly over the first six months but the improvement between six and twelve months is slow.(Gbiri & Akinpelu, 2012).

2.8 Post stroke quality of life and behavioural factors

Major modifiable risk factors for stroke include hypertension, diabetes, physical inactivity, smoking, excessive alcohol intake and dyslipidemia (de-Graft Aikins et al., 2012; O'Donnell et al., 2010). Only smoking and alcohol intake are considered under behavioural factors because the rest are captured under socio-dermograhic and clinical features. Although smoking and alcohol intake are recognised risk factors for developing stroke, cigarette smoking was associated with a high quality of life in older patients and alcohol intake in both young and old patients(Kim et al., 2005; Ramos-Lima et al., 2018; Shah & Cole, 2010). However, smoking and alcohol intake are risk factors for developing a stroke. They are risk factors for post stroke depression which is known to cause a poor quality of life of post stroke patients (Khedr et al., 2020).

2.9 Quality of life of post stroke patients in Ghana

Very few studies in Ghana have studied quality of life in post stroke patients. Donkor et al (2014) used the health related quality of life in stroke patients tool to study the quality of life of post stroke patients. They identified age, severity of stroke, duration of stroke, recurrence of stroke and frequency of laughter as some of the factors that determine quality of life. These findings are similar to some of the finding in Nigeria, a sub Saharan country with similar socio economic features like Ghana (Gbiri & Akinpelu, 2012; Oni et al., 2016). Post stroke depression which was found in 4 out of 10 stroke survivors also significantly affected their physical, psycho-social, cognitive and eco-social domains of health related quality of life (Sarfo et al., 2017).

Studies of quality of life in Ghana are insufficient in terms of diversity of study population, study design and quality of life assessment tools. The health related QoL tool was used by Donkor et al, (2014) to compare the QoL of post stroke patients and that of non-stroke patients in both a tertiary and secondary health institution. Sarfo et al, (2017) used the Health Related Quality of Life in Stroke Patients' questionnaire in a tertiary institution. The stroke specific quality of life tool has also been used to assess the factors that influence post stroke quality of life in a secondary institution (Odoom, n.d, 2017).

2.10 Conclusion

Stoke is a condition of significant public health importance in throughout the world. This literature review has looked at its global burden as well as the burden in Ghana. It has also looked at the QoL of post stroke patients in different parts of the world including Ghana. Quality of life is an important tool in assessing stroke outcomes and both generic and disease specific tools exist for this assessment. Socio demographic, clinical and behavioural characteristics of post stroke patients

are associated with their QoL. This study aims to determine which of these characteristics are associated with the QoL of post stroke patients at the KBTH stroke unit.

CHAPTER THREE

RESEARCH METHODS

3.1 Study design

A cross-sectional study design using quantitative methods was used for this study. The study was done over six months among post stroke patients reporting to the OPD of KBTH, stroke unit. Participant selection was via a simple random sampling method. This study design allowed for the QoL as well as the clinical, socio-demographic and behavioural characteristics of post stroke patients at the KBTH to be studied. The results of a dynamic change in any of these characteristics on QoL however cannot be ascertained from this type of study design.

3.2 Study Area

The study was conducted in the Outpatient Department (OPD) of the Stroke Unit of the Korle-Bu Teaching Hospital (KBTH), Internal Medicine Department. This Unit is structured to offer a multi-disciplinary approach to stroke management for acute cases of stroke. The department also offers outpatient follow up for patients who are discharged from the Unit as well as other units in the internal medicine department who are discharged after management for acute stroke. Korle-Bu Teaching Hospital is a tertiary institution in Accra, the capital city of Ghana, that receives referral cases from across the country. The Stroke Unit within also receives and manages stroke patients from all over the country. People of different socio economic background will therefore be interacted with during the study. The Unit admits and manages over 200 cases of stroke in a year and their OPD currently has a population of about 300 patients. Approximately 30 people attend the once a week Stroke Outpatient Clinic that the department runs. The department boasts of ten well-trained doctors who are supervised by 3 neurologists, 15 stroke nurses, 3 nutritionists, 3

physiotherapists, an occupational therapist and a clinical psychologist. All these specially trained professionals come together to offer a multidisciplinary care for post stroke patients.

3.3 Study population

The study population was made up of post stroke patients attending the OPD of the Stroke Unit of KBTH. Post stroke patients as used in this study refers to any patient who has ever had a stroke and is currently out of the acute phase of the disease. Such a patient may or may not have any obvious neurological deficit.

3.3.1 Inclusion criteria

All patients who were 18 years and above who had a CT scan confirmed stroke (either infarctive or hemorrhagic) were eligible to be included in the study.

3.3.2 Exclusion criteria

Any patient who fitted into the above inclusion criteria but had any of the following characteristics was excluded from the study.

1. Patients who were severely sick on the day of the their OPD attendance.
2. Deafness, aphasia and other limitations of language such as dysarthria that affected their ability to respond to the questionnaire.
3. Patients with significant co-morbidities such as severe heart failure, chronic kidney disease requiring dialysis, metastatic malignancy etc. and are in a poor state on the day of the interview. These could have a confounding effect on the quality of life

3.4 Sampling strategies

3.4.1 Sample size calculation

The sample size was calculated using the adapted Cochran sample size calculator for cross sectional studies (Pourhoseingholi et al., 2013). Using the rate of poor quality of life of patients in the stroke NEMESIS study of 8% (Sturm et al., 2004), at a confidence interval (CI) of 95% and a significance level of 5%, the minimum sample size was calculated to be 114 people. A total of 126 people were interviewed after adjusting for a non-response rate of 10%

$$n = \frac{Z^2 p(1-p)}{e^2}$$

Z= standard normal deviation at a confidence interval of 95%

p= proportion of post stroke patients with poor quality of life (8% from the NEMESIS trial)

margin of error = 5%

$$n = \frac{(1.96)^2 \times 0.08 \times (1-0.08)}{(0.05)^2}$$

n = 114

Non-response rate = 10% of 114

=12

Total minimum number of respondents needed = 114 + 12

=126

3.4.2 Sampling methods

A simple random sampling method was used for the study. The data collection was done over a fourteen-week period. The Stroke Unit runs the OPD once every week, i.e. every Monday. The weekly attendance is between 15-25 people. In order to reach the required sample size, 5 – 12 people were interviewed weekly for 14 weeks. On each Monday during the data collection period, the inclusion criteria were used to create a sampling frame using the names and hospital records of all the patients who reported in the morning. The names of all these patients were written down and placed into a box. The first name was drawn randomly from the box, and patient identified. The process was repeated without replacing the previously selected names until approximately half of the attendees were selected to be included in the study for the day. These patients where then identified and interviewed. This process was repeated weekly until the fourteenth week by which time the required sample size had been reached. Although the names of the patients were used at the selection level, it was not used for any further analysis to ensure anonymity.

3.5 Study variables

3.5.1 Independent variables

The independent variables for the study are age, sex, marital status, employment status, educational status, presence of a caregiver, type and severity of stroke, location of stroke, duration of stroke, hypertension status, diabetes status, and smoking and/or alcohol intake status.

Table 3. 1 Characteristics of independent variables

Independent variable	Type	Measure	Scale
Socio-demographic Characteristics			
Age	Categorical	Polytomous	Ordinal
Sex	Categorical	Dichotomous	Nominal

Educational level	Categorical	Polytomous	Ordinal
Marital status	Categorical	Dichotomous	Nominal
Employment status before	Categorical	Dichotomous	Nominal
Employment status after	Categorical	Dichotomous	Nominal
Presence of a caregiver	Categorical	Dichotomous	Nominal
Clinical characteristics			
Duration of stroke	Categorical	Polytomous	Ordinal
Location of stroke	Categorical	Polytomous	Nominal
Laterality of stroke	Categorical	Polytomous	Nominal
Type of stroke	Categorical	Dichotomous	Nominal
Severity of stroke	Categorical	Polytomous	Ordinal
Hypertension	Categorical	Dichotomous	Nominal
Diabetes	Categorical	Dichotomous	Nominal
Behavioural characteristics			
Smoking	Categorical	Dichotomous	Nominal
Alcohol before stroke	Categorical	Dichotomous	Nominal
Alcohol after stroke	Categorical	Dichotomous	Nominal

3.5.2 Dependent variables

The dependent variable of the study is the stroke specific quality of life which was measured with the stroke specific QoL scale. The raw scores were used as a continuous data to determine the relationship between QoL and the independent variables. A tertile analysis was also used to categorize QoL into poor, moderate and high/normal QoL.

3.6 Data collection techniques and tools

The main data collection tool used was a structured open and close ended questionnaire that included 3 sections. The first section contained the general socio-demographic characteristics of the patient and the second section contained clinical information on the patient regarding the stroke. This included date of stroke, possible risk factors for the stroke, CT scan findings and co-morbidities. This information was taken from the patient's health records which was taken during the admission for the acute onset of stroke. Hypertension and diabetes were defined as a patient who was receiving treatment for either condition at the time of the interview. The Barthel index was used to assess the severity of stroke symptoms in the questionnaire by assessing ability to perform activities of daily living. The third section assessed the behavioural characteristics of the patients. The SS-QoL questions was in the fourth section of the questionnaire and this was used to assess the quality of life of the patients. This is a 49-questions scale that assesses 12 quality of life domains using a Likert scale. The 49 items assess the 12 domains which include five questions for social role, six for mobility, three for energy, five for language, five questions for self-care, five for mood and three for personality. The others are thinking (three questions), upper extremity function (five questions), family role (three questions), vision (three questions) and work/productivity (three questions).

3.7 Quality assurance

The necessary measures were taken to ensure the safety and accuracy of data and to get rid of any biases that may have occurred during data collection and interpretation.

3.7.1 Training of field workers and supervision

The research assistants and field workers were trained by the principal investigator. The principal investigator continued to supervise the work of the assistants throughout the data collection period.

The completed questionnaires were scanned quickly before the patients left the clinic in order to make any necessary corrections.

3.7.2 Data entry, cleaning and editing

Data entry, cleaning and editing were done solely by the principal investigator in order to avoid inaccuracies of data entry. The data collected was screened appropriately, validated and entered on a daily basis into Microsoft Excel 2016.

3.7.3 Pre-testing

The questionnaires were pre-tested on post stroke patients attending the General Outpatient Department of the Internal Medicine Department. Errors were corrected before data collection was started.

3.8 Data Processing

The data was screened or validated before entry into EpiInfo. The entered data was cross checked with the hard copy to ensure accuracy of the data. The data set was then exported to Excel for cleaning and merging. Part of the analyses were done in Excel, whiles the rest were done with STATA v.16.

3.9 Data analysis

3.9.1 Determination of the socio-demographic characteristics of post stroke patients

The socio-demographic characteristics of the respondents was obtained by cross tabulating the following variables - age, sex, educational status, marital and employment status, caregiver- using Stata version 16.

3.9.2 Determination of clinical and behavioural characteristics of post stroke patients

Descriptive statistics was used to describe the clinical and behavioural factors associated with post stroke patients. Data analysis was done with Stata version16.

3.9.3 Determination of QoL of post stroke patients

Responses to the quality of life questions was entered into a spread sheet in Microsoft Excel. This is a 49-question scale that assesses 12 quality of life domains using a Likert scale. Each question is followed by a five-point Likert scale with one meaning total help, couldn't do it at all or strongly agree and two meaning a lot of help, a lot of trouble or moderately agree. Three means some help, some trouble or neither agree nor disagree, four means a little help, a little trouble or moderately disagree and five means no help needed, no trouble at all or strongly disagree. The sum of the scores ranges between 49 and 245 with the lowest indicating poor quality of life. Tertile descriptive statistics was used to describe the QoL of the post stroke patients with 181-245 indicating high/normal QoL, 115-180, moderate and 49-114 indicating poor. A regression analysis using the scores as a continuous data was however used to determine the relationship between QoL scores and the independent variables.

3.9.4 Determination of the relationship between the Post stroke patient characteristics and QoL

The data collected for SS-QoL was used in this part of the analysis as a continuous data. The normality test was violated and so non-parametric analyses were done. For the binomial variables, the relationship with QoL was assessed with the Wilcoxon Mann Whitney test whiles the multinomial variables were analysed with the Kruskall Wallis test. The multivariable analysis was

done with Quantile regression using the 0.5 (median) quantile. The variables that were included in the quantile regression were those variables that had shown some relationship with QoL in the univariable analysis

3.10 Ethical considerations

Ethical approval was obtained from the Korle-Bu Teaching Hospital, Institutional Review Board as a requirement to use Korle-Bu Teaching Hospital as a study site. Permission will also be taken for the Head of Department and the DDNS of the Stroke Unit.

3.10.1 Informed consent

Informed consent was sought from patients and their caregivers before being recruited into the study. An informed consent form was designed and made available to prospective study participants. The participants were asked to read and sign the consent form if they agreed to be part of the study. For those who were unable to read, the interviewer read and explained the information in a language familiar to them. They w then be asked to sign or thumbprint the form if they agree.

3.10.2 Voluntary withdrawal

Patients and their caregivers were made aware that, participation wass voluntary and that they could opt out of the study at any time whiles the study was still ongoing. Their decision to leave the study would not have any negative effect on the provision of healthcare which they received at the OPD.

3.10.3 Potential risks

Participation in this study posed minimal risk to the patient. The nature of the study was explained to patients and they were reassured that this would not cause them any harm.

3.10.4 Benefits

Patients received no benefits for their participation in the study. They did not receive any extra care at the clinic, nor were they to receive any special favours during their OPD attendance either presently or in the future.

3.10.5 Compensation

No monetary compensation was paid to the participants. Their participation however was acknowledged and appreciated.

3.10.6 Confidentiality and anonymity

The participants were assured of complete confidentiality and anonymity of the information they provided. To buttress this point, the questionnaires were numbered and no name was used. They numbers served as codes that aided data entry, cleaning, and validation.

3.10.7 Data storage, security and usage

The collected data in the form of answered questionnaires was kept under lock and key whiles a password was used to save the data collected on the computer. Patients were made aware that this was purely an academic exercise; the collected data would not be used for any other purposes apart from the intended usage.

3.10.8 Conflict of interest

The principal investigator had no conflict of interest in this study.

3.10.9 Protocol funding information

The research was solely funded by the principal investigator

3.10.10 Proposal amendment

No significant amendment was made to the proposal that was submitted for ethical clearance.

CHAPTER FOUR

RESULTS

4.1 Socio-demographic characteristics of post-stroke patients

With regard to the socio-demographic characteristics of the patients, the mean age of the respondents was 58.9 years (*SD*= 13.1). The youngest respondent was 33 years and the oldest was 88 years. A little over 50% of respondents (66) were between the ages of 50 and 69 years whiles 29.7% (38) were less than 49 years and below and 18.8% (24) were 70 years and above. Female respondents were 53.1%. There were 79 married respondents making approximately 62% of the sample size. The rest were not married, i.e. single, widowed, or cohabiting. The highest educational level attained by the majority of respondents was secondary school education (53.1%). About 7.8% had no education, 14.8% (19) had primary education and 24.2% (31) had tertiary education. Most of the patients were employed before the stroke (75.8%), but this dropped to 16.4% after the stroke. More than 80% of respondents needed and had a caregiver at home to assist in their daily activities. Table 1 describes the socio-demographic characteristics of the respondents

Table 4. 1 : Socio-demographic characteristics of Post Stroke patients

Characteristic	Number	Percentage (%)
Age (years)		
<49	38	29.7
50 - 69	66	51.6
70+	24	18.8

Sex		
Male	60	46.9
Females	68	53.1
Marital status		
Married	79	61.7
Not Married	49	38.3
Educational status		
None	10	7.8
Primary	19	14.8
Secondary	68	53.1
Tertiary	31	24.2
Employment status (before stroke)		
Employed	97	75.8
Unemployed	31	24.2
Employment status (after stroke)		
Employed	21	16.4
Unemployed	107	83.6
Caregiver		
Have caregiver	108	84.4
No caregiver	17	13.3
Non-response	3	2.3
Total	128	100.0

4.2 Clinical characteristics of post stroke patients

The study showed that 85.2% of the 128 respondents had hypertension as a risk factor for the stroke whiles a little less than 20% had diabetes. Most of them (59.4%) were interviewed within six months of the stroke incident while 15.6% were within six to twelve months and 12.5% had had the stroke for over one year now. In terms of the type of stroke, 59.4% (76) had an

ischemic/infarctive stroke and 31.3 % (38) had a hemorrhagic stroke. Ninety-three (72.7%) of the stroke cases had lesions located in the supratentorial region of the brain, 13.3 % (17) in the infratentorial region and 1.6 % had lesions in both areas. For laterality, the stroke affected only the left side of the brain in 35.2% (45) of cases whiles it affected only the right side in 38.3% (49 people) of cases. Twenty respondents (15.6%) however had lesions in both the right and left sides of the brain. Information on the type of stroke, location of stroke and laterality of stroke was unavailable in 9.4%, 12.5% and 10.9% of respondents respectively. The severity of stroke as assessed by the Barthel index and classified into 4 levels of dependency showed that, seven (5.5%) of the respondents had total dependency whiles 58.6% (75) had slight dependency. The rest of the scores were severe dependency 16.4%, (21), and moderate dependency 18.0% (23). Table 2 shows the clinical characteristics of the respondents.

Table 4. 2 : Clinical characteristics of Post Stroke patients

Characteristic	**Number**	**Percentage (%)**
Hypertension		
Hypertensives	109	85.2
Non- hypertensives	18	14.1
Non- response	1	0.8
Diabetes		
Diabetics	24	18.8
Non- diabetics	103	80.5
Non- response	1	0.8
Duration of stroke		
< 6months	76	59.4
Between 6 months and 12 months	20	15.6

>1 year	16	12.5
Non- response	16	12.5
Type of stroke		
Ischemic/ Infarctive	76	59.4
Hemorrhagic	38	31.3
Non- response	14	9.4
Location of stroke		
Supratentorial	93	72.7
Infratentorial	17	13.3
Both (Supratentorial and infratentorial)	2	1.6
Non- response	16	12.5
Laterality of stroke		
Left sided stroke	45	35.2
Right sided stroke	49	38.3
Bilateral lesion	20	15.6
Non-response	14	10.9
Severity of stroke (assessment of ADL with Barthel's Index)		
Total dependency (0-20)	7	5.5
Severe dependency (21-60)	21	16.4
Moderate dependency (61-90)	23	18.0
Slight dependency (91-100)	75	58.6
Non-response	2	1.6
Total	128	100.0

4.3 Behavioural characteristics of post stroke patients

Two main behavioural characteristics were assessed, i.e. smoking and alcohol intake. 6.2 % (8) had ever smoked cigarette whiles 93.8% (120) people had never smoked a cigarette. Eighty-four respondents (65.6%) did not have any history of alcohol intake either before or after the stroke.

Prior to the stroke, however, 34.4% (44) were taking alcohol. This number however dropped to 2.3% (3) after they developed the stroke. Table 3 shows the behavioural characteristics of the respondents.

Table 4. 3 : Behavioural characteristics of Post Stroke patients

Characteristic	Number	Percentage (%)
Smoking		
Smoker	8	6.2
Non-smoker	120	93.8
Alcohol intake before stroke		
Drinker	44	34.4
Non- drinker	84	65.6
Alcohol intake after stroke		
Drinker	3	2.3
Non- drinker	125	97.7
Total	128	100.0

4.4 Stroke specific quality of life of post stroke patients

Both the total and domain specific quality of life of the respondents were assessed with the stroke specific quality of life scale. The mean total SS-QoL score for respondents was 182 (SD= 43.12). The highest score was 245 (2 respondents) whiles the lowest was 83 (2 respondents). None of the participants scored total help needed in terms of their total SS-QoL scores. Only 5 (4%) scored a lot of help needed, 27 (21%) scored some help needed, 42 (33%) scored a little help needed and 54 (42%) scored no help needed. From the tertile descriptive statistics of the total SS-QoL scores,

6.25% of respondents had a poor quality of life score (49-114), 37.5% had a moderate quality of life (115-180) and 56.25% had a normal quality of life (181-245).

In terms of the Energy domain of the SS-QoL, 20% scored strongly agree, 25 % moderately agree whiles 27% scored strongly disagree. The rest of the respondents neither agreed nor disagreed (7%) or moderately disagreed (20%). For family roles the scores were 25%, 8% 10% 21% and 36% for strongly agree, moderately agree, neither agree or disagree moderately disagree and strongly disagree respectively. Only one person scored strongly agree for the language domain and 102 (80%) scored strongly disagree. In terms of mobility, 17 persons (13%) needed total help, 13 (10%) needed a lot of help, 22 (17%) needed some help, 18 (14%) needed a little help and 73 (57%) needed no help. For mood most of the respondents scored strongly disagree (57%), whiles 14% scored moderately disagree, 16% had neither agree nor disagree and the rest had had strongly agree (3%) and moderately agree (9%). In the personality domain, most of the participants scored strongly disagree (63%), whiles 14% scored moderately disagree, 8% had neither agree nor disagree and 16% had strongly and moderately agree. For self-care a few of the participants needed total help whiles more than 50 % needed no help. The rest of them scored in-between these scores. In terms of social roles, 22% strongly agreed, 20% moderately agreed, 8 % neither agreed nor disagreed, 10% moderately disagreed and 30% strongly disagreed. For the thinking domain, 63% scored strongly disagree and 10% scored moderately disagree. A little less than 30% scored neither agree nor disagree and below. More than 90% scored strongly disagree for vision. For work/productivity 32 participants (25%) scored total help needed and 10 (8%) scored a lot of help needed. Fourteen (11%) scored some help needed, 9 (7%) scored a little help and 63 (49%) scored no help needed. For upper extremity function, 15 participants (12) scored total help needed and 13 (10%) scored a lot of help. Four (3%) scored some help, 8 (6%) scored a little help and 88 (69%) scored no help needed. The analysis showed that The domains that were mostly affected are

Energy, Family roles, social roles and work/productivity. Those that were moderately affected were mood, self-care, mobility and upper extremity function. The domains that were least affected were language, vision, personality, and thinking. Table 4 shows the total and domain-specific scores of the patients.

Table 4. 4 : Stroke specific quality of life of post stroke patients (Domain-specific and total score)

Domain	**Total help/ Strongly agree N (%)**	**A lot of help/ Moderately agree N (%)**	**Some help/ Neither agree or disagree N (%)**	**A little help/ Moderately disagree N (%)**	**No help needed/ strongly disagree N (%)**	**Total N (%)**
Energy	26 (20)	32 (25)	9 (7)	26 (20)	35 (27)	128 (100)
Family roles	32 (25)	10 (8)	13 (10)	27 (21)	46 (36)	128 (100)
Language	1 (1)	5 (4)	7 (5)	13 (10)	102 (80)	128 (100)
Mobility	17 (13)	13 (10)	22 (17)	14 (11)	62 (48)	128 (100)
Mood	4 (3)	12 (9)	21 (16)	18 (14)	73 (57)	128 (100)
Personality	5 (4)	15 (12)	10 (8)	18 (14)	80 (63)	128 (100)
Self-care	7 (5)	19 (15)	14 (11)	15 (12)	73 (57)	128 (100)
Social roles	28 (22)	25 (20)	23 (18)	14 (11)	38 (30)	128 (100)
Thinking	5 (4)	20 (16)	10 (8)	13 (10)	80 (63)	128 (100)
Upper extremity function	15 (12)	13 (10)	4 (3)	8 (6)	88 (69)	128 (100)
Vision	2 (2)	2 (2)	2 (2)	20 (16)	102 (80)	128 (100)
Work/ Productivity	32 (25)	10 (8)	14 (11)	9 (7)	63 (49)	128 (100)

Total SS-Qol scores	0 (0)	5 (4)	27 (21)	42 (33)	54 (42)	128 (100)

Figure 4. 1:Overall SS-QoL of patients

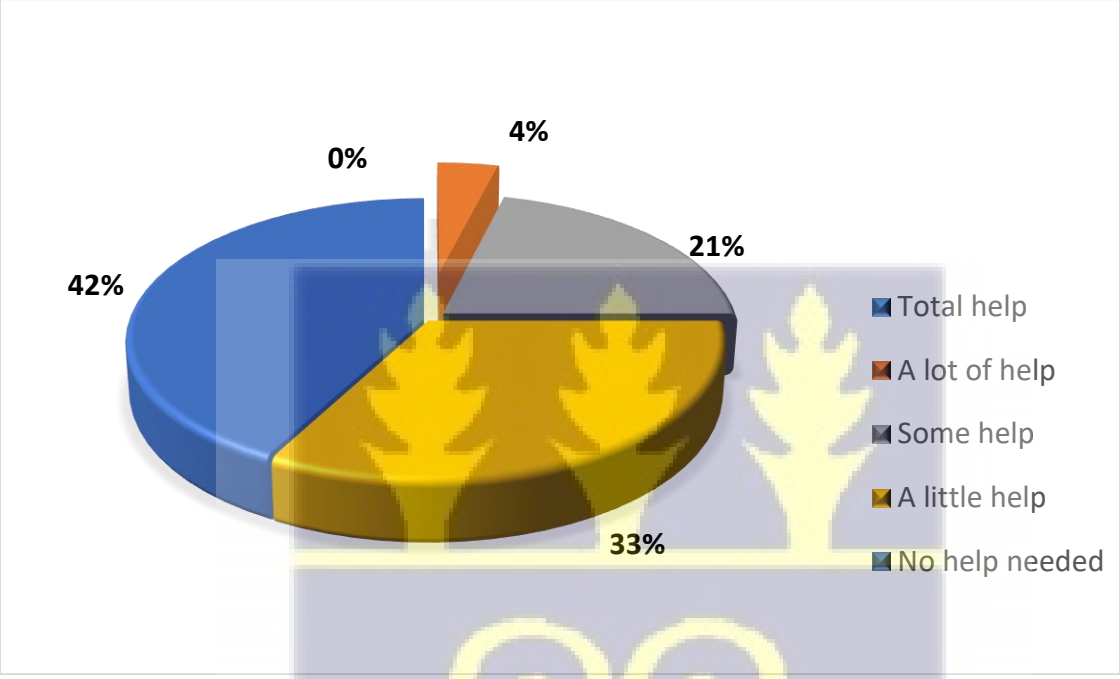
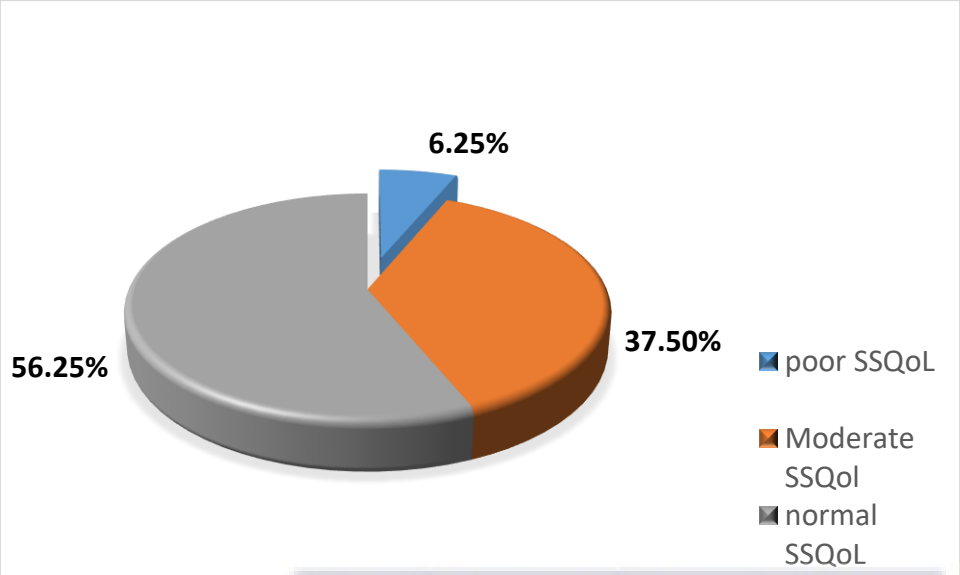


Figure 4. 2 : Percentage distribution of SS-QoL of patients



4.5 Relationship between socio-demographic, clinical and behavioural characteristics and stroke specific quality of life

The relationship between the SS-QoL in respondents and their socio-demographic, clinical and behavioural characteristics are summarised in the tables 5, 6, 7 and 8. A Kruskal Wallis test was performed to identify any relationship between SS-QoL and age and educational status. A Wilcoxon Mann-Whitney test was also performed to identify a relationship between SS-QoL and sex, employment before and after stroke, presence of a caregiver and marital status. These univariable analyses showed that SS-QoL was significantly related to age (X^2 =6.366, p=0.0415), educational status (X^2 =8.861, p=0.0312), employment status before stroke (z= 1.966, p=0.0492), employment status after stroke (z=3.797, p=0.0001) and presence of a caregiver (z=-4.120, p<0.001). Similar analysis done on the clinical characteristics showed that only severity of stroke was significantly related to the quality of life (X^2 =62.077, p=0.0001). There was no significant

relationship between the presence or absence of hypertension and diabetes and the type, location, or laterality of the stroke. The duration of the stroke also did not significantly affect the SS-QoL. Again, the Wilcoxon Mann Whitney test indicated that there was a significant relationship between smoking and SS-QoL, (z=-3.087 p=0.0020). It however did not indicate any significant relationship with alcohol intake either before or after the stroke.

Table 4. 5: Relationship between socio-demographic characteristics and stroke-specific quality of life

Characteristic	**Median(IQR)**	**Mann Whitney test** ***z –score*** ***(p-* value*)***	**Kruskal-Wallis test** X^2 ***(p-* value*)***
Age (years)		-	6.366
<49	199.5 (40)		(0.0415)
50 - 69	179 (83)		
70+	164 (56)		
Sex		-0.731	-
Male	188.5 (53)	(0.4650)	
Females	183 (83.5)		
Marital status		-1.343	-
Married	189 (59)	(0.1791)	
Non Married	175 (82)		
Educational status		-	8.861
None	164 (44)		(0.0312)
Primary	143 (87)		
Secondary	197.5 (65)		
Tertiary	183 (72)		

Employment status (before stroke)		1.966 (0.0492)	-
Employed	187 (74)		
Unsssemployed	167 (75)		
Employment status (after stroke)		3.797 (0.0001)	-
Employed	225 (47)		
Unemployed	179 (71)		
Caregiver		-4.120 (<0.001)	-
Have caregiver	180 (73)		
No caregiver	226 (26)		
Non-response	-		

Table 4. 6 Relationship between clinical characteristics and stroke specific quality of life

Characteristic	**Median (IQR)**	**Mann Whitney test** ***z –score*** **(*p*- value)**	**Kruskal-Wallis test** X^2 **(*p*- value)**
Hypertension		-1.331 (0.1832)	-
Hypertensives	183 (75)		
Non- hypertensives	210 (40)		
Non- response	-		
Diabetes		-0.394 (0.6934)	-
Diabetics	180 (90)		
Non- diabetics	185 (69)		
Non- response	-		
Duration of stroke		-	1.894 (0.3879)
< 6months	175 (74.5)		

Between 6 months and 12 months	207.5 (66)		
>1 year	184.5 (51.5)		
Non- response	-		
Type of stroke		-1.151	-
Ischemic/ Infarctive	181.5 (74)	(0.2496)	
Hemorrhagic	203 (85)		
Non- response	-		
Location of stroke		-	0.168
Supratentorial	184 (68)		(0.9196)
Infratentorial	175 (106)		
Both (Supratentorial and infratentorial)	177 (54)		
Non- response	-		
Laterality of stroke		-	0.422
Left sided stroke	184 (95)		(0.8097)
Right sided stroke	183 (70)		
Bilateral lesion	187.5 (69)		
Non-response	-		
Severity of stroke (assessment of ADL with Barthel's Index)		-	62.077 (0.0001)
Total dependency (0-20)	132 (76)		
Severe dependency (21-60)	142 (29)		
Mod. dependency (61-90)	161 (61)		
Slight dependency (91-100)	219 (46)		
Non-response	-		

Table 4. 7: Relationship between behavioural characteristics and stroke specific quality of life

Characteristic	**Median (IQR)**	**Mann Whitney test** ***z –score*** ***(p-* value*)***	**Kruskal-Wallis test** X^2 ***(p-* value*)***
Smoking		-3.087	-
Smoker	126 (32.5)	(0.0020)	
Non-smoker	187 (69)		
Alcohol intake before stroke		0.118	-
Drinker	189 (82.5)	(0.9061)	
Non- drinker	183.5 (69)		
Alcohol intake after stroke		1.638	-
Drinker	233 (47)	(0.1014)	
Non- drinker	97.7 (73)		

The quantile regression analysis was done on the variables that showed a significant relationship in the univariable analysis above. They were age, employment status before, employment status after, educational status, smoking, severity of stroke and presence of a caregiver. Only the severity of stroke was significantly related to the SS-QoL in this analysis. The SS-QoL of patients who scored moderate dependency on the Barthel index was 45 units higher than that of those who scored total dependency (t=2.97, P=0.004) so far as the other variables were kept constant. Similarly, those who scored slight dependency had a SS-QoL of 91 units higher than those who scored total dependency (t= 7.06, P<0.001) when the other variables were kept constant.

Table 8: Quantile regression of Stroke Specific quality of life with variables that showed significant relationship in the univariable analysis

Variable	Quantile = 0.5		
	B	95% CI	*p*- value
Age			
<49	ref		
50 - 69	-3	(-18.44, 12.44)	0.701
70+	3	(-21.03, 27.03)	0.805
Educational level			
None	ref		
Primary	-5	(-41.00, 31.00)	0.784
Secondary	9	(-26.20, 44.20)	0.613
Tertiary	-2	(-38.30, 34.30)	0.913
Employment before			
Employed	ref		
Unemployed	1	(-19.44, 21.44)	0.923
Employment after			
Employed	ref		
Unemployed	-7	(-27.15, 13.15)	0.493
Caregiver			
Have caregiver	ref		
No caregiver	10	(-10.41, 30.41)	0.334
Severity of stroke (assessment of ADL with Barthel's Index)			
Total dependency (0-20)	ref		
Severe dependency (21-60)	20	(-8.51, 48.51)	0.167
Mod. dependency (61-90)	45	(14.96, 75.04)	0.004
Slight dependency (91-100)	91	(65.44, 116.56)	0.000
Smoking			

Smoker	ref		
Non-smoker	31	(-12.62, 74.62)	0.162
Constant	96	(35.57, 156.43)	0.002

4.6 Summary

The mean age of the respondents was 58.9 years, there were more females than males and most of the respondents were married. Most of the stroke cases were ischemic/infarctive and the commonest risk factor was hypertension. The SS-QoL domains that were most affected are Energy, Family roles, social roles and work/productivity. Mobility, mood, self-care and upper extremity function were moderately affected and language, vision, personality, and thinking were least affected. The characteristics that significantly affected SS-Qol were age, educational status, employment status before and after stroke, presence of a caregiver, severity of stroke and smoking. The quantile regression however showed only severity of stroke to significantly affect SS-QoL when age, educational status, employment status before and after stroke, presence of a caregiver and smoking where considered as possible confounders.

CHAPTER FIVE

DISCUSSION

This study has characterized the socio-demographic, clinical and behavioural features of post stroke patients and has determined any relationship that exists between these and their QoL. The major finding is that QoL is affected by the occurrence of a stroke in an individual. The severity of this effect may be determined by the age, educational status, employment status, presence of a caregiver, severity of stroke and smoking. However, the severity of stroke was the only post stroke characteristic that was significantly related to QoL, after adjusting for these other characteristics.

5.1 Socio-demographic characteristics of post stroke patients

The mean age of post stroke patients (58.9 years) is similar to what was reported by Donkor et al in 2014. The highest number of cases fell between the ages of 50-69 years (51.6%). This number is slightly lower than the findings of Sanuade et al (2019), in the SAGE evidence research where they studied the prevalence and correlates of stroke among older Ghanaian adults. Their prevalence rate of over 70% for age range 50-69 years may be higher than this research because they only considered the older population whiles this study added respondents as young as 33 years. Other international research have a higher age of onset of stroke (65 years and above) than the Ghanaian population (Ramos-Lima et al., 2018). This shows that stroke affects people who are economically active in the Ghanaian population. This may be as a result of incidence of stroke risk factors in the younger population (de-Graft Aikins et al., 2012). This renders them inactive and dependent on caregivers for both physical and financial support. Stroke prevention campaigns must therefore be directed at people in their prime ages of life. The female respondents formed more than half of the study population (53.1%) which is a similar finding by Sanuade et al, 2019, (52.3%) in Ghana.

Sex distribution of stroke incidence have yielded conflicting results. Whiles some have identified a higher incidence in males, others have noted otherwise (Vyas et al., 2021). Sex may also affect the severity and mortality of stroke at the acute stage. In Ghana however, the higher incidence of women at the post stroke clinic may be due to a higher health seeking behaviour among women than men resulting in a higher post stroke clinic attendance. Most of the respondents were married which was an important correlate also identified in the SAGE evidence study in Ghana (Sanuade et al., 2019). In terms of employment, over 75% of the respondents were employed before the stroke incident. Most of those who were unemployed were retired before the onset of stroke. This number however reduced to 17% after the stroke. This may be because most of the respondents could not work because of the consequences of the stroke. They may not be physically fit to engage in their original activities or felt the need to rest after the stroke. Moreover, most of the respondents had a need for a caregiver. The presence of such an individual may serve as a physical, social or mental support for the patient. (Quartey et al., 2020b).

5.2 Clinical and behavioural characteristics of post stroke patients

Major modifiable risk factors for stroke include hypertension, diabetes, physical inactivity, smoking, excessive alcohol intake and dyslipidemia (de-Graft Aikins et al., 2012; O'Donnell et al., 2010). Stroke patients may have either one or more of these risk factors. The most prevalent stroke risk factor is hypertension with literature reporting about 64% of hypertension in stroke patients across the world (Wajngarten & Sampaio Silva, 2019). In Ghana, Donkor et al, (2014) realised that 89% of their stroke patients had hypertension. These findings are in keeping with the finding of 85.2% of hypertensives in the present study. Sarfo et al had a hypertension prevalence of 56.7%, diabetes of 12.8% and both hypertension and diabetes of 12.8%. in terms of diabetes as a risk factor, a meta-analysis done by Lau et al., (2019) showed a prevalence of 25% of diabetes

in acute stroke cases (Lau et al., 2019; Fred S. Sarfo et al., 2018). This study identified a prevalence of 18.8% of diabetes in post stroke patient which is a slightly lower value than what has been reported in both international and local literature. The reason for this low value is not obvious from the study. The gradual increase in stroke incidence in the Ghanaian population has been linked to the increasing trend of hypertension and diabetes coupled with poor information and non-compliance to therapy (de-Graft Aikins et al., 2012; Donkor, et al., 2014). Primary prevention of stroke must be geared towards increasing awareness on these diseases in the communities and improving compliance to treatment. Other less common risk factors are alcohol and smoking. About 35% of respondents had an alcohol consumption history whiles only 8 % had a smoking history.

The commonest type of stroke in the study population was ischemic/infarctive stroke (67%). This is slightly lower than the findings of Feigin et al., (2015) in their analysis of stroke cases that occurred from 1990-2013. This study showed that 71% of stroke survivors had had an ischemic stroke. They however acknowledged a gradual increase in the percentage of hemorrhagic stroke cases over the years which may explain why Shiber et al., (2010) had an ischemic stroke incidence of 58.1% in their study done in Florida (USA). Other research done in Ghana have however yielded findings similar to the study by Feigin et al., 2015 i.e. 73% to 78% of ischemic stroke. (Donkor et al., 2014; Edzie et al., 2021). Although the data on type of stroke favours ischemic stroke as the commoner type of stroke, data on laterality is conflicting. This study noted a slightly higher incidence of right hemispheric, lesions as compared to left sided lesions. Whiles Hedna et al., (2013) had a slightly higher incidence of left hemispheric ischemic stroke, Rastogi et al., (2015) had a higher incidence of left sided strokes. These conflicting findings may be as a result of difference in aetiology of the stroke cases studied in both studies.

5.3 Quality of life of post stroke patients

Almost all domains of the SS-QoL were affected negatively by the stroke. The domains mostly affected were Energy, family roles, social roles and work or productivity. This is in keeping with other research done using the SS-QoL.(Kim et al., 2005; Ramos-Lima et al., 2018). This may be as result of the effect that stroke has on the functional ability of post stroke patients which in turn may affect their family and social roles and responsibilities. Donkor et al, (2014), also noted a significant decrease in the physical, psycho-emotional and cognitive domains indicating a multi domain involvement of quality of life of post stroke patients. There is minimal information in the Ghanaian population of Stroke specific quality of life. The affected domains in this study are however similar to those affected in the Nigerian communities were the stroke specific quality of life tool has been used (Akosile et al., 2013; Gbiri & Akinpelu, 2012).

5.4 Relationship between stroke characteristics and QoL

The current study showed quality of life was significantly related to age, employment status, educational status and presence of a caregiver. The other associated features were severity of the stroke and smoking. Some of these characteristics are in keeping with what is reported in literature. Whiles others have had conflicting results. In terms of the sociodemographic features, age and sex have been noted to have a complex impact on quality of life (Roy-O'Reilly & McCullough, 2018). This may be due to the functional limitation associated with aging as well as the cultural expectations of different ages and sexes in a community. Although our study had a similar finding for increasing age being associated with a poorer quality of life, there was no significant relationship with sex. Akosile et al, (2013), also did not find any sex relationship in their study. Employment status before and after stroke and educational status are other sociodemographic

characteristics that have been noted in different studies to have significant relationship with QoL (Gbiri & Akinpelu, 2012; Oni et al., 2016). Another significant factor is presence of a caregiver. This may be because most post stroke patients become reliant on a second party in order to achieve their daily basic needs as a result of the disability associated with stroke. Other studies have gone ahead to assess the QoL of caregivers of stroke survivors and this has also been noted to be affected negatively. Although this research did not confirm an association with marital status, others have noted such relationship and have implicated dependence on a spouse as a major caregiver as an advantage for stroke recovery (Quartey et al., 2020). Severity of stroke has been recognized in literature to have an inverse relationship with QoL (Kim et al., 2005; Ramos-Lima et al., 2018). Stroke severity is related to ability to perform activities of daily living, dependence on a caregiver and ability to return to a previous form of employment. It therefore affects QoL either directly or indirectly by affecting other sociodemographic features of post stroke patients. Although several research papers have identified duration of stroke to affect QoL (Gbiri & Akinpelu, 2012), the findings in this paper does not support this feature. Smoking cigarette and alcohol intake have also had varying results in literature. Whiles smoking cigarette was significantly related to QoL, alcohol intake had effect. Similarly, Kim et al, (2005), noted a higher QoL score in older respondents who had a history of smoking.

5.5 Limitations

This study had some limitation. Being a cross-sectional study, the relationship between duration of stroke and quality of life could not be objectively assessed over a time period. Again, since the aim of the study was to investigate the QoL of patients in a stroke centre that provides multidisciplinary care, the findings cannot be generalized to other populations were stroke care is not multidisciplinary and does not involve other cadres of health care providers. Thirdly, since

aphasia was one of the exclusion criteria, the findings of this study may not be generalized in stroke patients who have aphasia or other speech impairment. Although a later sample size would have improved its generalizability, the calculated minimum sample size for this study was reached and this is a strength. The use of the SS-QoL tool in this study is an added strength since this tool is specifically designed for stroke cases.

CHAPTER SIX

CONCLUSION AND RECOMMENDATION

6.1 Conclusion

The mean age of post-stroke patients at the KBTH stroke unit was 58.9 years. Hypertension, diabetes, smoking and alcohol intake are common risk factors in stroke and were also identified in this population. Stroke affected both the total and domain specific QoL of patients. Approximately 6.25% of post stroke patients had a poor QoL. The SS-QoL domains mostly affected were energy, family roles, social roles and work/productivity. Post stroke quality of life was significantly affected by age, educational status, employment status, presence of a caregiver, smoking and severity of stroke. Paying attention to which domains of QoL are affected and the characteristic features that affect QoL of post stroke patients will help direct a patient-centred treatment that improves outcomes.

6.2 Recommendations

The following recommendations are being made,

1. Patients must be screened for early identification of characteristics that are associated with QoL such as age, educational status, employment status, presence of a caregiver, smoking and severity of stroke and therapy directed at modifying these risk factors to improve health outcomes.
2. Post-stroke patients must have their quality of life assessed and management tailored at the domains that are most affected such as energy, family roles, social roles and work/productivity.using a multidisciplinary approach to stroke management.
3. Further studies need to be done in other institutions that offer diverse forms of acute and long term stroke care to further improve the knowledge on the subject matter.

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APPENDIX

Appendix I: Questionnaire

FACTORS ASSOCIATED WITH QUALITY OF LIFE AMONG POST STROKE PATIENTS AT THE KBTH STROKE UNIT

RESEARCHER: JULIET OPOKU (WEEKEND MPH PROGRAM)

THIS RESEARCH IS IN PARTIAL FULFILLMENT OF A DEGREE IN MASTERS IN PUBLIC HEALTH AT THE UNIVERSITY OF GHANA SCHOOL OF PUBLIC HEALTH

QUESTIONNAIRE

Questionnaire No.	
Name of interviewer	
Date of interview	

SECTION ONE: SOCIO DEMOGRAPHIC CHARACTERISTICS OF THE PATIENT

No	Questions	Responses
1	Age (in years)	_____
2	Sex 1. Male 2. Female	
3	Marital status 1. Single 2. Married	

	3. Cohabiting 4. Divorced 5. Widowed	
4	Educational level 1. Primary 2. Secondary 3. Tertiary 4. Post–Tertiary	
5	Were you employed before the stroke 1. Yes 2. No	
6	If yes, describe the nature of your work	_____
7	Are you still employed? 1. Yes 2. No	
8	If yes, describe the nature of your work	_____
9	If no, why 1. Do not want to work 2. Cannot work because of the stroke 3. Has been sacked from work because of the stroke	
Comorbidities		
10	Hypertension	

	1. Yes 2. No	
11	If yes was it present before stroke diagnosis 1. Yes 2. No	
12	If yes, where you on treatment 1. Yes 2. No	
13	Diabetes 1. Yes 2. No	
14	If yes was it present before stroke diagnosis 1. Yes 2. No	
15	If yes, where you on treatment 1. Yes 2. No	
16	Dyslipidemia (determined by Statin use before stroke onset) 1. Yes 2. No	
17	Do you have a care-giver 1. Yes	

	2. No	
18	Who is your most permanent care-giver 1. Spouse 2. Child (daughter or son older than 18 years) 3. Paid help 4. Other long distance relative	
19	Number of medications currently taken a day (tablets)	_____

SECTION TWO: CLINICAL CHARACTERISTICS

No	Questions	Responses
20	Date of stroke	
21	Duration of stroke (calculate from date of stroke in months)	
22	Date of admission	
23	Was patient referred from a facility other than KBTH? 1. Yes 2. No	
24	If yes indicate the facility	
25	Was the patient admitted to the stroke unit? 1. Yes	

	2. No	
26	Total hospital stay (in days)	
27	Duration of stay at the stroke unit (in days)	
28	Type of stroke 1. Ischemic 2. Hemorrhagic	
29	Location of stroke 1. Infratentorial 2. Supratentorial 3. Cerebellar	
30	Laterality of stroke (site of lesion in the brain) 1. Left sided stroke 2. Sided stroke stroke 3. Bilateral lesions	
31	Severity of stroke (Barthel Index)	
31a	FEEDING 1. Unable 2. Needs help cutting, spreading butter, etc., or requires modified diet 3. Independent	
31b	BATHING 1. Dependent 2. Independent	

31c	GROOMING 1. Needs to help with personal care 2. Independent face/hair/teeth/shaving (implements provided)	
31d	DRESSING 1. Dependent 2. Needs help but can do about half unaided 3. Independent (including buttons, zips, laces, etc.)	
31e	BOWELS 1. Incontinent (or needs to be given enemas 2. Occasional accident 3. Continent	
31f	BLADDER 1. Incontinent or catheterized and unable to manage alone 2. Occasional accident 3. Continent	
31g	TOILET 1. Dependent 2. Needs some help, but can do something alone	

	3. Independent (on and off, dressing, wiping)	
31h	TRANSFERS (BED TO CHAIR AND BACK) 1. Unable, no sitting balance 2. Major help (one or two people, physical), can sit 3. Minor help (verbal or physical) 4. Independent	
31i	MOBILITY (ON LEVEL SURFACES) 1. Immobile or < 50 yards 2. Wheelchair independent, including corners, > 50 yards 3. Walks with help of one person (verbal or physical) > 50 yards 4. Independent (but may use any aid; for example, stick) > 50 yards	
31j	STAIRS 1. Unable 2. Needs help (verbal, physical, carrying aid) 3. Independent	

Score 0 points for 1, 5 points for 2, 10 points for 3 and were applicable, 15 points for 4

SECTION THREE: BEHAVIOURAL CHARATERISTICS

No	Questions	Responses
32	Smoking (before stroke) 1. Yes 2. No	
33	If yes, Pack years	_____
34	Smoking after stroke 1. Yes 2. No	
35	Alcohol (before stroke) 1. Yes 2. No	
36	Units per week	
37	Alcohol (after stroke) 1. Yes 2. No	
38	Units per week	

SECTION FOUR: STROKE SEPCIFIC QUALTIY OF LIFE SCALE

Scoring: Each item shall be scored with the following key *(cross [X] the appropriate box)*

Total help – Couldn't do it at all – Strongly agree- 1

A lot of help – A lot of trouble – Moderately agree- 2

Some help – Some trouble – Neither agree nor disagree- 3

A little help – A little trouble – Moderately disagree- 4

No help needed – No trouble at all – Strongly disagree- 5

		1	2	3	4	5
Energy						
1	I felt tired most of the time					
2	I had to stop and rest during the day					
3	I was too tired to do what I wanted to do					
Family roles						
1	I didn't join in activities just for fun with my family					
2	I felt I was a burden to my family					
3	My physical condition interfered with my personal life					
Language						
1	Did you have trouble speaking? For example, get stuck, stutter, stammer, or slur your words?					
2	Did you have trouble speaking clearly enough to use the telephone?					

3	Did other people have trouble in understanding what your said?					
4	Did you have trouble finding the word you wanted to say?					
5	Did you have to repeat yourself so others could understand					
Mobility						
1	Did you have trouble walking? (If patient can't walk, go to question 4 and score questions 2-3 as 1					
2	Did you lose your balance when bending over to reaching for something?					
3	Did you have trouble climbing stairs?					
4	Did you have to stop and rest more than you would like when walking or using a wheelchair?					
5	Did you have trouble with standing?					
6	Did you have trouble getting out of a chair					
Mood						
1	I was discouraged about my future activities					

2	I wasn't interested in other people or activity					
3	I felt withdrawn from other people					
4	I had little confidence in myself					
5	I was not interested in food					
Personality						
1	I was irritable					
2	I was inpatient with others					
3	My personality has changed					
Self-care						
1	Did you need help preparing food ?					
2	Did you need help eating? For example, cutting food or preparing food?					
3	Did you need help getting dressed? For example, putting on socks or shoes, buttoning buttons, or zipping?					
4	Did you need help taking a bath or a shower?					
5	Did you need help to use the toilet?					
Social roles						
1	I didn't go out as often as I would like					
2	I did my hobbies and recreation for shorter periods of time than I would like					

3	I didn't see as many of my friends as I would like					
4	I had sex less often than I would like					
5	My physical condition interfered with my social life					
Thinking						
1	I was hard for me to concentrate					
2	I had trouble remembering things					
3	I had to write things down to remember them					
Upper extremity function						
1	Did you have trouble writing or typing?					
2	Did you have trouble putting on socks?					
3	Did you have trouble buttoning buttons?					
4	Did you have trouble zipping a zipper?					
5	Did you have trouble opening a jar?					
Vision						
1	Did you have trouble seeing the television well enough to enjoy a show?					
2	Did you have trouble reaching things because of poor eyesight?					
3	Did you have trouble seeing things off to one side?					

Work/ productivity						
1	Did you have trouble doing daily work around the house?					
2	Did you have trouble finishing jobs that you started?					
3	Did you have trouble doing the work you used to do?					

Appendix II: Participant Information Sheet

FACTORS ASSOCIATED WITH QUALITY OF LIFE AMONG POST STROKE PATIENTS AT THE KBTH STROKE UNIT

PARTICIPANT INFORMATION SHEET

My name is Juliet Opoku, a masters' student at the School of Public Health, University of Ghana. I am conducting this research on the factors associated with quality of life among stroke patients reporting to the KBTH stroke unit as part of my study requirements. I wish to invite you to participate in this study. The aim is to determine the quality of life of post stroke patients and the factors that are associated with it. Your participation is entirely voluntary and refusal to participate will not be held against you or affect the health care you receive at this hospital. You will be interviewed at the stroke unit deuring your regular day for OPD attendance. The interview will last approximately 45 minutes. You are free to withdraw from the study at any time and you may also refuse to answer any question that you feel uncomfortable answering. With your permission, your clinical data will be collected from your hospital record notes. The data collected for this research will be used solely for the purpose intended and the findings submitted to the University of Ghana as part of the MPH program requirement in the form of a dissertation. The results will not be made known to your clinician. Please feel free to ask any questions regarding the study. I shall answer them to the best of my ability. I may be contacted on my cell phone with questions regarding the study (Tel no. 0208198225). Should you wish to receive a summary of the results of the study, an abstract will be made available on request.

Thank you.

Appendix III**:** Participant Consent Form

FACTORS ASSOCIATED WITH QUALITY OF LIFE AMONG POST STROKE PATIENTS AT THE KBTH STROKE UNIT

CONSENT FORM

Dear Patient and caregiver

My name is Juliet Opoku, currently a Masters student at the University of Ghana, School of Public Health. I am conducting research on the factors associated with the quality of life of patients who have had a stroke. I will ask questions on your clinical characteristics as well as the physical emotional and social wellbeing which you experience after the stroke.

The purpose of the study is to determine the factors that are associated with the quality of life of post stroke patients. This study is a partial requirement for the award of master of Public Health in the University of Ghana. The data collected for this research will be used solely for the purpose intended and the findings submitted to the University of Ghana as part of the MPH program requirement in the form of a thesis. Confidentiality will be maintained and the information will not be disclosed to anyone including your clinician. Participants' names will not be used in the study. You are free to withdraw from the study at any point. Your decision to withdraw from the study will not have any negative effect on the provision of healthcare which you receive at the hospital. Your participation in the study will not gain you any added benefit from the health care provider. You are assured that participation in this study will not pose any harm to you. There will be no monetary compensation for your participation and there shall be no direct benefits for you or your relatives

I am therefore asking your permission to allow me to interview you. If you agree to participate in this study kindly sign the attached slip confirming your consent. For further information about the study, please feel free to contact me on 0208198225 or my supervisor, Prof Moses Aikins (SPH, UG)

Thank you

PATIENT CONSENT FORM

I, Mr/Mrs/Miss/Dr/Prof _____, have read (or has been read and explained to me in a language I understand) and understood the consent form. I agree to participate in this study.

_____

Signature

OR

_____

Thumbprint

_____

Date

Appendix IV: Ethical Clearance Letter

In case of reply the number
And the date of this
Letter should be quoted

My Ref. No. KBTH/MD/C3/121

Your Ref. No......

KORLE BU TEACHING HOSPITAL
P. O. BOX KB 77,
KORLE BU, ACCRA.

Tel: +233 302 667759/673034-6
Fax: +233 302 667759
Email: Info@kbth.gov.gh
pr@kbth.gov.gh
Website: www.kbth.gov.gh

23rd September, 2021

JULIET OPOKU
DEPT. OF INTERNAL MEDICINE AND THERAPEUTICS
KORLE BU

"FACTORS ASSOCIATED WITH QUALITY OF LIFE AMONG POST STROKE PATIENTS AT THE KORLE BU TEACHING HOSPITAL STROKE UNIT"

KBTH-IRB /000131/2021

INVESTIGATOR: JULIET OPOKU

The Korle Bu Teaching Hospital Institutional Review Board (KBTH IRB) reviewed and granted approval to the study entitled: "**Factors Associated with quality of life among Post Stroke Patients at the Korle Bu Teaching Hospital Stroke Unit**"

Please note that the Board requires you to submit a final review report on completion of this study to the KBTH-IRB.

Kindly, note that, any modification/amendment to the approved study protocol without approval from KBTH-IRB renders this certificate invalid.

Please report all serious adverse events related to this study to KBTH-IRB within seven days verbally and fourteen days in writing.

This IRB approval is valid till 31st October, 2022. You are to submit annual report for continuing review.

Sincere regards,

DR. DANIEL ANKRAH
VICE CHAIR (KBTH-IRB)
FOR: CHAIR (KBTH-IRB

Cc: The Chief Executive Officer, KBTH
The Director of Medical Affairs, KBTH

Appendix V: Institutional (KBTH) Approval Letter

In case of reply the number
And the date of this
Letter should be quoted
My Ref. No. KBTH/MS/G3/21
Your Ref. No.....

KORLE BU TEACHING HOSPITAL
P. O. BOX KB 77,
KORLE BU, ACCRA.

Tel: +233 302 667759/673034-6
Fax: +233 302 667759
Email: Info@kbth.gov.gh
pr@kbth.gov.gh
Website: www.kbth.gov.gh

28th September, 2021

JULIET OPOKU
DEPT. OF MEDICINE
P.O. BOX KB 77
KORLE BU TEACHING HOSPITAL

INSTITUTIONAL APPROVAL: KORLE BU TEACHING HOSPITAL-SCIENTIFIC AND TECHNICAL COMMITTEE/INSTITUTIONAL REVIEW BOARD (KBTH-STC/IRB/000131/2021

Following approval of your study entitled "Factors associated with qualify of life among post stroke patients at the Korle Bu Teaching Hospital" by the Korle Bu Teaching Hospital-Scientific and Technical Committee/Institutional Review Board.

I am pleased to inform you that institutional approval has been granted for the conduct of your study in Korle Bu Teaching Hospital.

Please contact the Heads of Departments to discuss the commencement date of the study.

Please note that, this institutional approval is rendered invalid if the terms of the Institutional Reviewed Board/Scientific and Technical Committee approval are violated.

Sincere regards,

Dr. Harry Akoto
Ag. Director of Medical Affairs
For: Chief Executive