THE EFFECT OF COGNITIVE BEHAVIORAL INTERVENTION ON COPING SKILLS, QUALITY OF LIFE AND EMOTIONAL WELLBEING OF UNDERGRADUATES WITH SICKLE CELL DISEASE IN THE UNIVERSITY OF IBADAN

BY

ALERO OLIRE ADEGBOLAGUN

MATRIC NUMBER 188882

A RESEARCH PROJECT SUBMITTED TO THE CENTRE FOR CHILD AND ADOLESCENT MENTAL HEALTH, UNIVERSITY OF IBADAN IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF SCIENCE IN CHILD AND ADOLESCENT MENTAL HEALTH OF THE UNIVERSITY OF IBADAN

JUNE, 2016

CERTIFICATION

This is to certify that both the conduct of this study and the preparation of the thesis were carried out by ADEGBOLAGUN ALERO in the CENTRE FOR CHILD AND ADOLESCENT MENTAL HEALTH, UNIVERSITY OF IBADAN under my supervision.

---------- ----------

Dr. Cornelius Ani Date

Department of Child and Adolescent Psychiatry

Imperial College London

United Kingdom

---------- ----------

Dr Rotimi Adejumo Date

Department of Child and Adolescent Mental Health

University College Hospital

Ibadan

DECLARATION

I hereby declare that this thesis is my original work and that it has not been submitted anywhere else for a diploma, fellowship or degree.

All the sources I have used have been indicated and acknowledged as complete references.

_____

Adegbolagun, Alero Olire

DEDICATION

I dedicate this work to the memory of my late father Mr O. S. James.

You gave me wings.

I celebrate you dad even in death.

ACKNOWLEGDEMENTS

I sincerely appreciate my supervisors Dr. Cornelius Ani and Dr. Rotimi Adejumo, thank you for your all help and support as I carried out this study. I thank sincerely the Principal Investigator of the Centre for Child and Adolescent Mental Health, Professor Olayinka Omigbodun, Ma you are an Icon and I salute you.

To my eldest brother and research support Dr Bawo James, you made statistics look like 'bread and butter,' I am truly grateful.

To the Director of Health University Health Services, Dr O.O. Akingbola, thank you for believing in me, to all the participants, it was a pleasure having you all indeed ''there is a better way to cope''.

To my heartthrob, the one and only 'BABA IJESA' Adedamola Adegbolagun, I love you so much baby. My adorable kids Desina and Desola, thank you for understanding that mummy needed to do her homework love you babies.

To the source of my strength, my stand-by, my help, Heavenly Father I could never have come this far without you, am eternally grateful for you love, thank you most High God.

TABLE OF CONTENTS

LIST OF TABLES

KEY TO ABBREVIATION (ACRONYMS)

CBT	Cognitive Behavioural Therapy
CSQ-SCD	Coping strategy questionnaire for sickle cell disease
HADS	Hospital Anxiety and Depression scale
HBAS	Hemoglobin AS genotype
HBSC	Hemoglobin SC genotype
HBSS	Hemoglobin SS genotype
HRQOL	Health related quality of life
QOL	Quality of Life
RBC	Red blood cells
SCD	Sickle cell disease
WHO	World Health Organisation

ABSTRACT

Introduction

Sickle cell disease (SCD) is now a global health challenge. The disease is prevalent in sub-Saharan Africa with Nigeria having the highest prevalence, with over 150,000 live births yearly. With the improvement in health care services, more individuals living with the SCD now have improved outcomes, growing into adulthood with better chances of survival. However, as a result of the various physical, mental and emotional challenges they face, psychopathologies have been documented extensively amongst them ranging from anxiety, depression, and suicidal ideation among others.

These psychopathologies, in addition to a chronic, sometimes debilitating illness have been documented to impact on their quality of life. Various coping mechanisms have also been employed to enable them deal with these challenges with varying degree of success. This study explored the effect of a cognitive behavioural intervention on coping, quality of life and emotional wellbeing in undergraduates with sickle cell disease in the University of Ibadan.

Methods

It was a quasi-experimental pre and post study, that employed purposive sampling method of all consenting undergraduates with sickle cell disease that had been seen at the university health centre, who scored 8 and above on either the anxiety or depression sub-scale of the Hospital Anxiety and Depression Scale (HADS), outcome measures of anxiety and depression, coping skills and quality of life were collected before and after 6weeks following the intervention. It was a group-based cognitive behavioural intervention and its effect on their quality of life, coping strategies and emotional wellbeing was assessed thereafter.

Data was analysed using the SPSS version 20, Hospital Anxiety and Depression Scale, Coping skills and Quality of life scores were presented using means and standard deviations, association between outcome measures and clinical variables were assessed using independent t-test, differences in mean of the outcome measure scores pre and post intervention was analysed using paired t-test,

Results

All the participants had depressive and anxiety symptoms pre-intervention, however post intervention none of the participants had depressive symptoms and only 11% (2) still had symptoms of anxiety, about 72% had started employing active coping skills in dealing with sickle cell disease above the 50th percentile compared to 44% pre-intervention, a reduction in the number of those using affective-negative skills above the cut-off from 33% to 22% post-intervention and an increase in the number of participants using passive coping skills above the same cut-off from 72% to 89%.

The reduction in both anxiety and depressive symptoms was statistically significant, HADS-A ($t = 7.20$, $p< 0.001$), HADS-D ($t =2.64$, $p< 0.02$), there was also a significant increase in active coping ($t = 2.19$, $p< 0.04$) and passive coping ($t = -2.20$, $p < 0.04$) skills as well as an increase in the social functioning domain of the SF-36 quality of life scores ($t = -5.10$, $p < 0.001$) post-intervention.

Conclusion

This results shows that group based cognitive behavioural intervention appears helpful in reducing anxiety and depressive symptoms, improve adaptive coping skills and improve social functioning in the quality of life of young people living with sickle cell disease in Nigerian universities.

Key Words: Sickle cell disease, Coping skills, Adolescents and Young people, University undergraduates, Cognitive behavioural therapy.

CHAPTER ONE

INTRODUCTION

1.1 Background to the Study

Sickle cell disease (SCD) is an inherited disorder of haemoglobin, the oxygen carrying component of the red blood cell, in blood. It is an autosomal recessive disorder whose manifestation occurs by the inheritance of two abnormal genes from an individual's parents, both of whom must be carriers of the disease or who may even suffer from the disease themselves (Huck 1923). Inheritance of a single gene results in a carrier state (AS) while inheritance of two abnormal genes (SS) confers on the individual the sickle cell disease status with the attendant consequences. Important health consequences include anaemia, hand and foot syndrome in infants, periodic pain, and increased risk of infection, growth delay, leg ulcers and jaundice amongst others (Alexander et al. 2004).

Chronic diseases have long been associated with attendant psychopathologies that may go undetected (Rho et al. 2010, Jenerette et al. 2012, Adeyemo et al. 2015) and psychopathologies in sickle cell disease are receiving attention now because they impact on the quality of life of not only those living with the disease, but those associated with it (Olley et al. 1997, Schnog et al. 2004, Anie et al. 2010).

Mental health problems have been associated with several chronic disorders like juvenile rheumatoid arthritis, juvenile diabetes mellitus and asthma, and sickle cell disorder is not exempted. Several studies within (Iloeje 1991, Bakare et al. 2008) and outside Nigeria (Thomas and Taylor 2002) have reported that the prevalence of detectable psychopathologies among individuals with sickle cell disease could be as high as 38% when compared to healthy controls. Several factors have been attributed to

this, a significant one being the perception of negative attitudes from others towards them because of the disease, including their peers, relatives and health care providers (Anie 2005, Jenerette and Brewer 2010). Others include the severity of the disease, the disability associated with it, type and quality of care received, and also the severity of limitations placed on the individual as a result of the disease. In order to provide holistic care for adolescents and young people living with sickle cell disease, the bio-psychosocial model of health care must be employed, as any impairment in any of the domains would affect the others, and make the care provided ineffective in the long run.

1.2 Statement of the Problem

Nigeria by virtue of her population has the largest number of people living with sickle cell disease (SCD) in the world (WHO 2006). Although it is an international health challenge (Burnes et al. 2008), the prevalence of sickle cell disease in sub-Saharan Africa is the highest with the attendant physical, social and psychological implications. Nigeria has the highest incidence of people with sickle cell disease, with as high as about 150,000 births occurring annually with the disease, while in the United Kingdom about 170 babies are born annually with the disease (Davies et al. 2000). Similarly the incidence of the sickle cell trait in Nigeria is among the highest in the world (WHO 2006), with available statistics showing that over 40 million Nigerians are carriers of the "S" gene, themselves not being ill, but having the potential to transmit the disease to the next generation. The number of people with SCD in Nigeria far exceeds the total population of other affected countries put together (WHO 2006).

The diagnosis of SCD can usually be made in childhood from as early as the age of 6 months, when some symptoms might initially appear and this may set the stage for a

lifetime of pain, anaemia, and fatigue amongst many other symptoms for the patient. In addition emotional, psychological and possibly other mental health implications arise for both the patient (Ohaeri and Shokunbi 2001, Brown et al. 2015) and their caregivers, with recurrent episodes of painful crises sometimes requiring several visits to the emergency department in a year (Jenerette and Brewer 2010, Constantinou et al. 2015).

The time when children with SCD grow into adolescence and transition from paediatric to adult care, usually coincides with the period of undergraduate studies in higher institutions. Difficulties may arise at this stage due to the attendant challenges of adolescents being responsible for managing their experience of a chronic medical condition solely on their own (Jenerette and Brewer 2010). Significant challenges include those that may stem from their physical appearance especially if they have the "sickle cell facie", or have to deal with chronic leg ulcers which might be disfiguring, to worrying about their attractiveness to the opposite gender (DeBaun and Telfair 2012, Casier et al. 2013) and also the stigma of being associated with a medical condition that others may misunderstand (Ani et al. 2012, Ola et al. 2013).

The implications for academic achievements at this developmental stage are also serious because youth with SCD who may have suffered strokes or cerebral infarcts may have poor academic performance, poor cognition in addition to this they often have to miss lectures if they require in-patient admission and catching up on missed activities is often difficult in the absence of special assistance or support (DeBaun and Telfair 2012). The physical challenges of the disease may make it difficult to participate in sports or other rigorous activities as a result of chronic fatigue from baseline anaemia, and the constant fear of future health challenges and unpredictable

nature of the onset of a crisis may be further troubling to the youth with SCD (Ogunfowora et al. 2005)

All these may result in a vicious cycle of anxiety, hopelessness and low self-esteem, most of which goes unnoticed and unattended to, further complicating an already physically stressful chronic health condition (Constantinou et al. 2015).

With an increase in median life expectancy ranging between 40 and 60 years in high income countries, much less though in low income countries (Brousse et al. 2014), there is a need for a well rounded bio-psychosocial approach to their management, but despite the large number of people with sickle cell disorder, the Nigerian society in general still has a negative image of SCD, with reported negative perceptions and attitude (Ani et al. 2012, Ola et al. 2013).

1.3 Justification for the Study

A large portion of the existing literature on children, adolescents and young people with SCD in sub-Saharan Africa has focused on physical challenges (George and Okpara 2011, John-Olabode 2015). Among the relatively few existing studies that had focused on the emotional and psychological health of this vulnerable population, few if any have evaluated the impact of standardized, evidence-based interventions on these health outcomes. Also, majority of the existing research from sub-Saharan Africa has focused on young children, their care givers, and occasionally their peers (Bakare et al. 2008, Ani et al. 2012, Ola et al. 2013). Adolescents and young adults living with SCD have rarely been studied as a unique sub-population with unique needs, and they make up a significant part of the Nigerian population, as high as 20% being between the ages of 15-24 years (Indexmundi 2015).

This study aims to identify the sources of inherent stress youth with SCD have to deal with, the impact on the quality of life (QOL) and emotional well-being of this group of individuals, coping mechanisms they have been employing to deal with the perpetual stress and to teach effective coping mechanism to help improve their QOL and emotional well-being. It aims to bridge this existing gap by focusing on a population of youth living with SCD. It aims to examine the prevalence of emotional distress experienced by these youth, and evaluate the impact of a cognitive-behavioural therapy-based coping skills intervention programme on this experienced distress.

1.4 Relevance of the Study

SCD has major social and economic implications for the affected individual, their family and the society at large. Recurrent sickle-cell crises interfere with the individual's life, especially with regard to education, relationships, work and psychosocial development (WHO 2015). There is an existing dearth of knowledge of the emotional and psychosocial needs of youths living with SCD in this environment, resulting in the lack of evidence-based psychological interventions targeted at improving their quality of life and emotional well-being. According to Kessler et al. (2001), 20 -50% of normal adolescents self-report depressive symptoms. This is expected to be more significant where there are potentials for co-morbidities as is seen in sickle cell disease.

1.5. Research Questions

1. What is the prevalence of anxiety and depressive symptoms amongst undergraduate students (young people) of University of Ibadan living with sickle cell disease?
2. What coping strategies do SCD students employ to deal with anxiety and depressive symptoms?
3. Can a group CBT-based intervention improve the quality of life of young people with SCD at the University of Ibadan?
4. Is there a significant difference between anxiety and depressive symptoms experienced pre and post intervention?
5. Is a group CBT-based intervention appropriate and acceptable to young people with SCD at the University of Ibadan?

1.6. Aim and Objectives of the Study

1.6.1 The overall aim of this study was:

To assess the effect of a group-based Cognitive Behavioural Therapy (CBT) programme on the psychological wellbeing, quality of life and coping of young people (undergraduates) with SCD at the University of Ibadan, Nigeria.

The specific objectives of the study were:

1. To determine the prevalence of anxiety and depressive symptoms among a sample of undergraduates with SCD in the University of Ibadan, Nigeria.
2. To identify coping strategies employed and also their quality of life of this sample of undergraduates with SCD.
3. To evaluate the impact of a CBT-based group intervention on the prevalence of anxiety and depressive symptoms among undergraduates with SCD.
4. To evaluate the effect of a CBT-based group intervention on the quality of life of undergraduates with SCD.
5. To determine the acceptability and appropriateness of a CBT-based intervention among this undergraduates with SCD in the University of Ibadan, Nigeria.

1.7 Hypotheses.

1. There would be no significant difference between the prevalence of anxiety and depressive symptoms before and after the intervention.
2. There would be no significant difference in the coping skills and quality of life of undergraduates with SCD before and after the intervention.

CHAPTER TWO

LITERATURE REVIEW

2.1. Sickle Cell Disease Pathophysiology

Sickle cell disease is an inherited autosomal recessive disorder of the oxygen-carrying components of the red blood cell (RBC) called haemoglobin, which consists of two alpha chains and two beta chains. The disorder occurs as a result of mutations in its beta-globin chains, where the sixth amino acid is changed from glutamic acid to valine, with attendant abnormal physiochemical properties that causes polymerization of the intracellular haemoglobin (Ashley-Koch et al. 2000). This results in loss of deformability of the RBC, a characteristic that is required for the cells to squeeze through tiny blood vessels and capillaries. Normal red blood cells are round and soft and can squeeze through capillaries and small blood vessels, but because of the loss of deformability, sickle red blood cells cannot. Instead, as they assume the shape of a sickle in low oxygen tension, they block the tiny vessels. Organs beyond this blockade do not receive blood supply and nutrients, with repeated episodes then resulting in their damage and sometimes death, with the resulting signs and symptoms seen as manifestation of the disease (Tripette et al. 2009). This blockade of blood vessels and organs results in various forms of acute and chronic symptoms usually called crises or "sickle cell crises" which include vaso-occlusive crises, aplastic crises, splenic sequestration crises, haemolytic crises, acute chest syndrome and dactylitis in very young children as young as six months of age (Kim and Miller 2002).

The diagnosis of sickle cell disease could involve any of the following. Haemoglobin electrophoresis, where electrical currents are used to separate various types of haemoglobin and they move at varying speeds as a result of different electrical charges

they have. A full blood count would reveal low levels of haemoglobin and high reticulocyte count, as a result of the steady state of red blood cell destruction and resulting anaemia and bone marrow compensation. A blood film may show features of reduced spleen function with the presence of target cells and Howell-Jolly bodies. On the blood film also, addition of sodium metabisulfite can also induce sickling of red blood cells.

2.2. Physical Complications of Sickle Cell Disease

Physical complications of sickle cell disease can be divided broadly into acute and chronic types, with the underlying pathophysiology in both being decreased ability of red blood cells to become deformed (as a result of the polymerization of its haemoglobin content) and the reduced life span these sickle cells have (normal red blood cells have a life span of about 120 days while sickled red blood cells have a life span of between 10-20 days. (Manwani and Frenette 2013)

2.2.1 Acute complications include

Vaso-occlusive crises (VOC): manifesting in pain, resulting from the blockade of micro vessels by sickled cells, thereby occluding blood flow to tissues beyond the obstruction. The resultant ischemia and cell death results in pain, which can range from mild to severe, occurring at any part of the body (Frenette 2004, Manwani and Frenette 2013)

Acute anaemia: which is said to occur when an individual's haemoglobin concentration drops by more than 2g/dl, below the patient's baseline blood level, in patients with sickle cell disease who have a chronic state of anaemia any further loss of blood from the circulation worsens their symptoms. Splenic sequestration or aplastic crises are common causes of acute anaemia (Alexander et al. 2004).

Priapism (ischaemic): described as unwanted, painful and sustained erection, which occurs in males with sickle cell disease. Usually lasting over 4hrs, repeated episodes of priapism can result in impotence (erectile dysfunction) following damage to the penis and is a urologic emergency (Broderick 2012).

Acute chest syndrome (ACS): a life threatening condition for patients with sickle cell disease, usually manifesting with symptoms similar to pneumonia, cough, fever and an abnormal chest X-ray, repeated lung damage may result in pulmonary hypertension (Vichinsky et al. 2000).

Splenic/hepatic sequestration: defined as sudden painful enlargement of either the spleen or liver as a result of pooling of blood in these large organs, leading to severe anaemia, and may also be associated with shock (Alexander et al. 2004).

Acute stroke: a major and sometimes catastrophic complication of sickle cell disease especially among children, that occurs because sickle cells stick to and occlude the tiny blood vessels of the brain with resultant neurological symptoms that might include sudden weakness, speech difficulties or sudden loss of speech, numbness of arms and leg or seizures (Ohene-frempong et al. 1998, Schatz 2004).

Infection proneness: the spleen is very important for protection against certain types of infective micro-organisms. Due to malfunctioning of the spleen, or its absence as a result of auto-splenectomy usually as a result of sickle cell disease, these individuals are at risk for serious bacterial infections, some of which can be life-threatening (Schnog et al. 2004)

Acute renal failure: defined as a sudden reduction in renal function, manifested by a drop in renal glomerular filtration rate and a rise in serum creatinine level. Even in the

presence of normal renal output it can occur as a result of dehydration, damage to the glomerulus or obstruction, all of which are common in sickle cell disease, and can be associated with VOC, ACS, or multi-organ failure (De Santis Feltran et al. 2002, Drawz et al. 2016).

2.2.2 Chronic physical complications of sickle cell disease include some of the following:

Avascular necrosis: the femoral neck being the common site for aseptic necrosis but could occur at the shoulders, ankles or spine, occurring when capillaries at this site are chronically obstructed by sickled cells, resulting in necrosis and increased ease of fracture (Diggs 1967, Almeida and Roberts 2005).

Leg ulcers: an unsightly and sometimes disabling common complication of sickle cell disease, these starts as small sores at the distal aspects of the lower limb. Cause is usually not known, but a combination of several factors that include mechanical obstructions, bacterial infections, anaemia with decreased oxygen carrying capacity, and abnormal autonomic control with excessive vasoconstriction could be responsible, it could persist for many years or recur even after healing (Almeida and Roberts 2005, Minniti et al. 2010).

Eye Disease: SCD has also been known to affect the blood vessels in the eye and lead to long-term damage including blindness (Barbosa de Melo 2014).

Chronic pain: pain may occur as an extension of an acute episode, lasting more than 3 months, or could occur as a result of damage to specific organ like the joints in avascular necrosis, ulcers in the leg. They are also not immune to other causes of

chronic pain like rheumatoid arthritis, with other factors like anxiety and depression colouring its manifestation (Okpala and Tawil 2002, Almeida and Roberts 2005).

Recurrent priapism (stuttering): when multiple self-limiting episodes of unwanted painful penile erection occur. This is quite common with a rate of about 35% of male SCD patients having both simple and recurrent episodes (Olujohungbe et al. 2011, Broderick 2012).

Pulmonary hypertension: a type of high blood pressure affecting the vessels of the lungs and the right side of the heart, and usually begins when the tiny vessels in the lungs become occluded, reduced in size or are destroyed. This is a potentially life threatening condition with a prevalence of about 30% found in a study by Ataga et al. (2004).

Renal complications: renal pathology seen in SCD can affect between 30-50% of adults and includes microalbuminuria, macroalbuminuria, hypersecretion of creatinine. However the most common complication seen in these patients is the inability to concentrate urine, called hyposthenuria (De Santis Feltran et al. 2002, Drawz et al. 2016).

2.3. Mental Health Complications of Sickle Cell Disease

As with physical complications seen in sickle cell disease, several mental health complications have also been documented and they are now receiving attention, because they not only impact on the ability of the affected individual to cope with the disease, they also affect how they relate with others. SCD impacts a youth's psychosocial well-being and can place significant stress on families physically, emotionally and financially (Groove et al. 2013). Several studies now focusing on the

psychological functioning of adolescents with sickle cell disease have shown that they are at risk for psychological dysfunction (Barakat et al. 2007, Kelch-Oliver et al. 2007, Simon et al. 2009).

In his review of common psychiatric problems seen in SCD, Levenson (2008) noted some of the following; anxiety and depression, that result from living with a chronic stigmatizing disease, that is associated with pain, several life threatening complications, unpredictable onset of crises, and poor health related quality of life. He also noted that several other problems associated with the management of the patient also occur including poor pain management, addiction to pain medications, substance misuse and addiction, and defective coping mechanisms. The development of cognitive dysfunction from cerebrovascular accidents that occur usually during childhood was also noted.

In 2001, Key et al. looked at depressive symptoms in adolescents with various chronic illnesses. Using the Beck Depression Inventory, they compared 125 adolescents with various chronic illnesses, including cystic fibrosis, diabetes, spina bifida, sickle cell disease and asthma to 21 healthy adolescents; they found that adolescents with a chronic illness reported symptoms of moderate to severe depression. In addition, the frequency of depression was highest in adolescents with sickle cell disease (Key et al. 2001).

Kavanagh (2012) in her study among sickle cell disease patients, noted that several mental health and learning needs exist among them, many of which are usually overlooked or not noticed when these people present at the hospitals. Usually parents do not recognize these needs and complications of the primary disease over-shadow them. Learning disability amongst this study group of 45 children was as high as 40%,

compared to 15% and 9% amongst those with and without other chronic diseases. Attention deficit hyperactivity disorder (ADHD) and other mental health disorders (anxiety and depression) were found in 9% of them. Children with sickle cell disease have also additional risk factors like poor academic achievements; they usually have many missed school days as a result of frequent hospitalization. It has also been discovered that they may have silent strokes which may further impact on their academic output and self-image (Kavanagh 2012).

Another study comparing siblings with and without SCD found evidence that adolescents with sickle cell disease are at risk for psychosocial adjustment problems and poor academic achievement. The siblings with sickle cell disease reported more internalizing behaviours than their healthy siblings; also they reported less social competence than their healthy siblings. (Thaniel 2013)

2.4. Psychological and Social Problems in Sickle Cell Disease

The psychosocial burden associated with sickle cell disease is enormous with its impact affecting all aspects of the individual's life (Anie and Steptoe 2002, Ani et al. 2012.) Aside from the physical pain from the illness itself, the patient endures emotional and psychological stress. These are associated with the unpredictable nature of the illness, persistent fear of death, social isolation from peers, time lost from school during hospitalization and as a result of poor health (Barrett et al. 1988, Dyson et al. 2010). They also experience stigma and psychological distress spanning across their whole lives, in school from their peers (Dyson et al. 2011), from their teachers (Dyson et al. 2010, Ani et al. 2012), among health care professionals (Jenerette and Brewer 2010, Lin et al. 2015) family members (Ohaeri and Shokunbi 2001) and at work (Pereira et al. 2013).

Apart from the direct effect of the ailment on the patient, the psychosocial implication on the carers and the family has also been well documented, with the level of support provided for the patient reflecting the family dynamics, relationship and emotional state of the family members (Weatherall and Clegg 2001). A good prognostic index for a patient with SCD is a stable, caring and nurturing family environment, the effect of this life-long disorder on the family would impact their functionality, some of the implications include a huge financial burden, with the cost of caring for the child's illness adversely affecting the family's basic needs, like food and shelter especially in settings where health care cost is still being financed out–of-pocket, or where a lot of caregivers have either lost their jobs, are underemployed or cannot run their businesses because of the time spent taking care of the child (Brown et al. 2010). There is neglect of other family members as a result of demands of the child's illness with resultant sibling rivalry and family dysfunction. Depression amongst caregivers has also been documented (Adegoke and Kuteyi 2012).

Stigmatization was also another issue faced by not only the patient but also their caregivers (Anie et al. 2010). Similarly Jenerette (2010) and colleagues noted that there is significant burden as a result of poor quality of life resulting from stigmatization and psychological distress associated with sickle cell disease.

2.5 Effect of Sickle Cell Disease on Quality of Life and Emotional Well-Being of Adolescents and Young People

The increase in knowledge about sickle cell disease and advances in medical science has been associated with progressive increase in life expectancy among people living with SCD. This is noted to have increased from between 40 to 60 years in recent times (Anie et al. 2002). As a result there is the need to understand their quality of life especially in relation to their health (Schnog et al. 2004, Mostafa et al. 2011).

Quality of life is defined by the WHO (1997), 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, expectation, standards and concerns. A broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment (WHO 1997). It is a concept that encompasses how an individual measures the "goodness" of all the various aspects of their life; it includes their emotional reaction to occurrences in their life, sense of fulfilment, satisfaction with work and personal relationships (Theofilou 2013). This term has also been referred to as "well-being" and while some argue that they essentially mean the same thing, others believe that they are different entities altogether and that if there is any similarity; "well-being" just covers the objective aspect of the "quality of life" (Theofilou 2013).

Constanza (2008) said that while QOL had long been a policy goal, adequate definition and measurement have been elusive, with "objective" and "subjective" indicators across a wide range of discipline. WHO (1997), identified six broad domains of quality of life and they include, physical health, psychological health, level of independence, social relationships, environment and spirituality/religion/personal beliefs.

In the field of healthcare, the concept "Health Related Quality of Life" (HRQOL) is now gaining ground, and it describes how a certain disease or condition affects a patient on an individual level, allowing one achieve their personal, goals, aims and aspirations. Measurement of QOL has now become relevant, allowing for assessment and evaluation of interventions comparing management and therapies and allocation of resources (Anie et al. 2002, Panepinto et al. 2009) Children living with sickle cell disease were noted to have a significant impairment in their health related quality of

life (Panepinto et al. 2009), as with other chronic health conditions, and this varied depending on factors like educational status, income level and occupational status of their caregivers as well as the age and gender of the children, with the disadvantaged group having a lower HRQoL (Mostafa et al. 2011). In various studies amongst adolescents and young adults there were conflicting evidence about what factor affected which domain of HRQoL (Palermo et al. 2002, Panepinto et al. 2009), but there has been consistent evidence of its limitation amongst youth with SCD, with painful episodes decreasing HRQoL across all domains (Mostafa et al. 2011).

2.6. Coping Strategies among Adolescents and Young People with Sickle Cell Disease

Coping is said to be the process of expending conscious effort to solve personal or interpersonal problems, that would help adapt better, or reduce the effect of the problems, Its effectiveness is dependent on the type of coping mechanism adapted for a particular problem and the problem itself. Coping skills can be adaptive (constructive) or maladaptive (non-coping) which result in more problems or produce no change at all (Lazarus and Folkman 1984). They are fairly subconscious and range from being primitive like denial, regression to more matured responses like assertiveness. The more primitive a coping mechanism the less effective it is expected to be for the individual using it over a long period of time. While looking at coping strategies during emergencies, WHO stated that these strategies vary depending on several factors including age, gender, household and social group, and they are deeply influenced by previous experience (WHO 1999). In dealing with chronic illnesses like sickle cell disease, several of these factors also come to bear, including disease severity, onset of symptoms, accessibility of prompt and adequate care, especially in managing pain and reducing chronic complications, attitude of health care professionals towards them and

also adequate family and social support, all these factors may influence the type of coping mechanism employed and its effectiveness. (Brown et al.2010, Jenerette and Brewer 2010, Key et al. 2001 Manwani and Frenette 2013).

Several coping mechanism used by sickle cell disease patients have been described, and they include active coping, affective negative coping and passive coping mechanisms (Anie et al. 2002). Active coping involves utilization of intentional methods of dealing with pain, by employing cognitive and behavioural strategies like ignoring the pain sensations, diverting their attention to other things and re-interpreting the pain sensation. Affective coping involves strategies like isolation and catastrophising and passive coping methods described involved, increasing fluid intake, rest and massaging of places that hurt (Anie et al. 2002).

They found out that those who employed passive adherence coping strategies experienced more intense painful episodes, while those who employed active coping though visiting the hospital more but this was not entirely as a result of more pain, and they suggested that this may be a part of the active coping skills employed, by doing something about their symptoms instead of staying in bed and drinking fluids which are on their own important but may make them feel helpless and unable to control the disease (Anie et al. 2002). On the contrary in another study amongst children and adolescents it was found out that those who employed active coping skills had less visits to the hospitals and emergency services (Gil et al. 1993) . But on the whole psychological coping that has been found to be appropriate would not only impact on the experience of pain in terms of severity and frequency but also improve their quality of life (Anie et al. 2002).

2.7. Psychological Interventions for Improving Outcomes among Adolescents and Young People with Sickle cell disease

Psychosocial treatments are increasingly now being considered as part of the standard management for patients with SCD (Haywood et al. 2005). Treatment methods include cognitive behavioural treatments, self-regulation strategies, behavioural change interventions, psychosocial support treatments, and educational programs.

Cognitive behavioural therapies have been researched for managing SCD pain. The aim is to reduce the frequency and intensity of the pain; help the individuals have a good QOL in spite of the pain, but not to alleviate the pain (Edwards and Edwards 2010). A group conducted a study in which a culturally sensitive cognitive-behavioral pain management treatment was administered to adolescents with SCD, and the participants reported that the intervention was interesting, helpful, and enjoyable and most of them responded well to the intervention (Schwartz et al. 2007)

Another psychosocial intervention is self-regulation strategies which include hypnosis and bio-feedback techniques that are aimed at managing and controlling pain. Vasodilating drugs have been shown to be effective in reversing ischemic injury in the retina, and hypnosis has been related to increased temperature in different parts of the body, such as the hand and foot. Such increases in temperature may provide an estimate of vasodilatation, which indicates that the blood vessels are expanded (Edwards and Edwards 2010).

Cozzi et al. (1987) used biofeedback-assisted relaxation intervention sessions to produce vasodilatation and reduce emotional factors that lead to vaso-occlusion. Although there was no significant change in the number of hospital visits of

participants, there were significant decreases in headaches as a symptom of SCD, medication use, reported pain intensity, and painful episodes.

Self-hypnosis intervention also was related to a reduction in pain unrelated to SCD. The self-hypnosis was more effective against milder vaso-occlusive pain but not as effective for severe SCD pain (Zeltzer et al. 1979).

Behavioural change interventions that involves, modification of behaviour and behavioural contracts has also been employed in the management of SCD pain. An example of a behavioural strategy for managing pain is operant conditioning with focus on behaviours, not sensations of pain. Behaviours such as groans and complaints were ignored, while attempts at more physical activity and other positive behaviours were rewarded (Cohen et al. 2003).

Social support was another important aspect of therapy that was considered in the holistic management of SCD, especially where lay persons were providers of health information rather than health care providers. This social support may be especially important for individuals with SCD because the illness usually results in disruptions in social networks and rejection from peers. Interventions that take into account the importance of culture and social support may prove to result in positive outcomes regarding pain management. Among a support group developed for adults with SCD, the authors found that participants reported an improvement in their ability to manage their pain, and a shorter recovery time from painful episodes (Holmes et al. 1992, Belgrave and Lewis 1994).

Sickle cell disease as with other chronic disorders like juvenile diabetes mellitus, asthma, and juvenile rheumatoid arthritis among others, are potentially stress-inducing conditions and aside from management of the disease process itself, the potential

psychological consequences have to be anticipated and managed appropriately. Several studies have shown some effectiveness of adaptive coping skills such as self-talk, avoidance, cognitive behavioural therapy among others to improve the acute and chronic psychopathologies associated with these chronic medical conditions and the need for more interventions in this regard (Sansom-Daly et al. 2012, Anie and Green 2015, Daniels 2015). In a separate study Bakare et al. (2008) also emphasized the need to develop liaison services to deliver holistic care.

2.7.1 Cognitive Behavioural Intervention (Therapy) [CBT] In Sickle Cell Disease

Cognitive behavioural therapy (CBT) as a type of psychological therapy employed in managing sickle cell disease, is a form of intervention that was designed to treat depression, but now has been used for several other mental disorders (Beck 2011), including anxiety, mood disorders, schizophrenia, personality disorder, and alcohol and substance addiction, among many others. It focuses on identifying, and changing thought patterns that are unhealthy and detrimental to the well-being of the individual (Cully and Teten 2008). It combines both behavioural therapies and cognitive therapies to achieve its therapeutic effect, basing its effect on the premise that feelings (emotions) occur as a results of our thoughts (thinking) and that these feelings also determine how we behave (behaviour) in the given situation, this triad of emotions, thoughts and behaviour run as a continuum and a change interjected at any point in the continuum would produce the required change in the others. Since emotions are difficult to change directly, CBT addresses the emotions by changing thoughts and behaviours that are producing them (Cully and Teten 2008). Although recent variations are proposing that the change that occurs are as a result of the individuals change in their relationship to the maladaptive thinking rather than a change in the thought itself,

the aim of CBT is to look at the in dividual as a whole and not in the context of an illness, and to address what needs to be changed (Hayes et al. 2011).

CBT could be therapists or computer-based in its delivery, individualized or group-based, and could also be brief or the regular time-limited form lasting between 12-14 weeks. CBT incorporates a variety of interventions that include motivational self-talk, positive imagery, activity scheduling, distraction, relaxation, graded exposure, development of adaptive coping skills, challenging automatic thoughts and setting of goals (Gatchel et al. 2008). CBT helps to build skills needed to deal with dysfunctional thoughts and behaviour in a collaborative manner between the therapist and the client. This process of skill acquisition and the use of regular homework assignment is what distinguish CBT from talk therapy (Cully and Teten 2008).

In sickle cell disease cognitive behavioural therapy (CBT) has been shown to have an immediate effect in management of pain, improving psychological distress and also improving coping. Over a long period of time its effect however may wane and repeat CBT may be required, but in collaboration with other medical therapies it is a very important resource in the overall management of the disease (Thomas et al. 2010).

CHAPTER THREE

METHODOLOGY

3.1 Study Location

This study took place at the Premier University in Nigeria, the University of Ibadan, Ibadan Oyo state south west Nigeria, a Federal University that provides tertiary education to a total of about 13,000 undergraduates and about 13,500 postgraduate students. Study site was at the University Health Centre, where comprehensive primary health care facilities are provided to all students, staff and their dependants. Mental health services are provided by a specialist team from the department of Psychiatry, University College Hospital in collaboration with the primary health physicians, social workers and nurses in the health centre. Other services provided include, Obstetrics and Gynaecology, Endocrinology, Asthma, Orthopaedics and General surgery clinics. The language of instruction is English, and individuals from diverse culture, religion and ethnic background attend the University.

3.2 Study Design

This is a pre and post quasi-experimental study involving a single group of young adults (undergraduates) with SCD.

3.3 Study Population

Undergraduate students of the University of Ibadan, who had sickle cell disease, were the participants of this study

3.3.1 Inclusion Criteria

- Students aged 16-24 years
- Has had a diagnosis of SCD for at least 1year

- Had visited the health centre at least once for health care services
- Scored 8 or higher on either anxiety or depression on the Hospital Anxiety and Depression Scale (HADS)

3.3.2 Exclusion Criteria

- Students who refused to give their consent for participation
- Students who were acutely unwell (who were having acute physical symptoms) at the time of recruitment for the study

3.4 Sample Size

The sample size was calculated using the formula:

$n = F (\sigma/d)^2$ (Wade 1999, see appendix 3)

Where

n= sample size

$\sigma = 1$ (represents the standard deviation for the Hospital Anxiety and Depression Scale score HADS),

F = 18.37 (based on 99% power and 0.05 level of significance)

d = 1 (hypothesised difference between the pre and post intervention scores)

Assuming the intervention will produce a reduction of one standard deviation in HADS scores, and then the sample size would be 18. This was increased to 20 (based on an attrition rate of 10%) to account for possible attrition that might occur during the study. Previous studies of psychological interventions in Nigeria have demonstrated more than one standard deviation difference is achievable with this type of intervention (Bella-Awusah et al. 2015, unpublished work by Bello-Majeed et al. 2015).

3.5 Sampling Technique

The first stage, the list of all undergraduates who have sickle cell disease and who had been seen at the University Health Center was obtained from the records department and those that met the inclusion criteria were contacted, via text messages and phone calls. All who responded completed the socio-demographic questionnaire and the Hospital Anxiety and Depression Scale (HADS). Those who scored 8 and above in either the anxiety or depression sub scales were then selected for the second stage of the study and were given a packet of the study instrument to fill out, after which the intervention was carried out weekly for five (5) weeks.

3.6 Study Instruments

Six instruments were used for this study, namely a Socio-demographic Questionnaire, Hospital Anxiety and Depression Scale (HADS), Coping Skills Questionnaire modified for sickle cell disease adult version (CSQ-SCD), Short-Form Health Survey (SF-36), Knowledge Questionnaire and a Client Satisfaction Questionnaire. They are described briefly below.

3.6.1 Socio-demographic Questionnaire

Adapted from a questionnaire used in a previous study amongst young people in this environment (Omigbodun et al 2008) It contained items like, age, sex, religion, department, current level in the university, and cumulative grade point average, it also included clinical parameters relevant to the study population like, phenotype of the study participants (HBSS or HBSC), packed cell volume (PCV), number of emergency visit, admission in the clinic, duration of admission, the clinical parameters were collected over twelve months including the period of the study.

3.6.2 The Hospital Anxiety and Depression Scale (HADS)

The HADS is a 14-item self-rated questionnaire validated by Abiodun (1994) in Nigeria, that is commonly used to determine the levels of anxiety and depression an individual may be experiencing. Originally designed by Zigmond and Snaith (1983), 7 of the items relate to anxiety while 7 relate to depression. Each item is scored on a 4 point likert scale from zero to three (0-3) meaning an individual can score between 0 and 21; however a cut-off 8/21 for either anxiety or depression has been used to decide caseness (Bjelland et al. 2002). In this study individuals that scored 8 and above on any of the sub scales were included in the study.

3.6.3 The Short Form Health Survey Questionnaire (SF-36)

A 36 item questionnaire that had been validated in Nigeria (Mbada et al. 2015) to determine the impact of interventions on the quality of life of the recipients, assessing eight domains that include physical functioning, role limitation due to physical health, role limitation due to emotional health, energy and fatigue, emotional health, social functioning, pain and general health. Scoring occurs in two stages first pre-coded numeric values are recorded as given in its scoring table, with a high score denoting a more favorable health state, the lowest score being 0 for any question and the highest 100. Secondly items in the same scale are arranged together and total score obtained for each domain was then gotten the higher the scores obtained the better the quality of life of the participant and vice versa (Ware and Sherbourne 1992), scoring table see appendix 2.

Following the pretest of this instruments some minor modifications were made to aid comprehension, questions 7,8 and 9 under limitation of activity were modified as follows: (7) *walking more than a mile to walking more than 2km*, (8) *walking several*

blocks to walking several streets, and (9) *walking one block to walking one street. Also, questions under energy and emotions 1, 6, 7 were modified slightly: (1) have you felt full of pep to have you felt full of life(cheerful and happy*), (6*) have you felt downhearted and blue* to *have you felt downhearted and sad* and (7) *did you feel worn out* to *did you feel extremely tired and exhausted.* The modifications were necessary because words like ‘‘mile, block, full of pep, downhearted and blue, worn out’’, were not easily understood as they were not words commonly used in Nigeria and had to be explained to the pretest participants

3.6.4 Coping Strategies Questionnaire for Sickle Cell Disease-Adult Version (CSQ-SCD) An 80-Item questionnaire that looks at coping strategies employed by patients with sickle cell disease. Based on previous factor analysis (Anie et al. 2002), the items are grouped into 3 coping skill sets namely, active (e.g. I think of things I enjoy), affective-negative (e.g. I avoid people, if I can't be well no body should), and passive (I go to bed). Each of the 80 questions is scored from 0 meaning "they never use that coping strategy" to 6 meaning "they always used that strategy". The items that make up the three groups of coping strategies (active, affective-negative and passive) were grouped together and the total scores calculated. The Internal Consistency of the CSQ-SCD for the 3 groups of coping strategies in this study ranged from good to excellent [Cronbach Alphas = 0.92 (active coping), 0.90 (affective-negative coping) and 0.68 (passive coping) respectively].

3.6.5 Knowledge Questionnaire

This is a self-rated questionnaire with two segments. The first segment contains 8 questions about the intervention content, with each question rated on a scale of 1-3, 1

for incorrect answer, 2 for not sure and 3 for the correct answer, both the incorrect and not sure answers were grouped together as false while the correct answer was coded as true. The total score obtainable is 8-24. The second segment that assessed the knowledge of coping skills and confidence of its use before and after the intervention consists of 9 questions rated from Zero (0) meaning the participant had no knowledge to Ten (10) the participant had a good knowledge or was very confident. The total score obtainable here is 0-90.

3.6.6 Client Satisfaction Questionnaire

A 10 item questionnaire adapted from the Client Satisfaction Questionnaire (Attkisson and Greenfield, 2004). Seven (7) of the items were scored on a scale of 1-4 giving a total score obtainable of 7-28, and the other three (3) questions were open ended questions, that included what the participants liked, disliked and would love to improve about the intervention.

3.7 Ethical Considerations

This study was carried out in accordance with the ethical principles enshrined in the Helsinki Declaration and the National Human Research Ethical code (World Medical Association 2013). Ethical approval was obtained from University of Ibadan/University College Hospital Ethical Review Committee (Appendix 4). The study aim and procedure was explained to each participant and afterwards those that were interested in participating were asked to fill a written informed consent form (Appendix 1).

Participants were assured that all information obtained would be kept in strict confidence, no names were required to be written on the questionnaires, as all

questionnaires had been pre-coded (numbers were given and the participants were given a small card containing the same number, this number was to ensure that post intervention they filled the corresponding questionnaire), the questionnaires were kept in a locked drawer and after data was entered into the computer it was accessible to only the researcher and the data analyst. No links or identifiers were used that could be associated with them.

English language was the mode of delivery of this intervention, being the language of instruction in the University so there was no need to translate the intervention manual or outcome measure to any local language. The manual and outcome measures were pretested among 5 students with sickle cell disease at the University of Benin to check understanding.

There were no monetary benefits for participating in the study. However, the study provided an avenue for participants to access more information about their health status. Participation provided psychological support for the participants through interaction with peers with similar health challenges, refreshments were provided during each session of the intervention.

Aside from their time and effort during the period of this study, the study was not injurious to the participants in anyway. There was no invasive procedure except for checking their stable packed cell volume (PCV) during a session of the intervention, which was part of their routine care.

Participants had a right to decline participation in the study or withdraw from the study at any time, they still had full access to care for any medical needs they might have during or after the study period.

3.8 Study Procedure

All undergraduates with SCD who had attended the University clinic between the specified age brackets were approached in the first stage of the study; those who consented were asked to fill the socio-demographic questionnaire and the Hospital Anxiety and Depression Scale (HADS). Pre-assigned identification numbers were used for each of them and the investigator had a list containing both their names and the corresponding identification number to ensure confidentiality, those who scored 8 and above on either the anxiety or depression subscales of the HADS were then included in the second stage of the study. In this second stage they were asked to complete the Coping Strategy Questionnaire for Sickle Cell Disease (CSQ-SCD) and the SF-36 questionnaire after which they were divided into 2 groups of 10, and the intervention was done in these groups for ease of its administration.

After 6 weeks all the participants were asked to complete the HADS, CSQ-SCD, SF-36, Knowledge of the intervention content questionnaire and a Client Satisfaction questionnaire. The questionnaire used for the coping skills had not been validated in Nigeria but was reviewed by 3 separate consultant psychiatrists for face and content validity. The outcome measures used was pretested among five students of the University of Benin, for ease of understanding and comprehension; average completion time was forty-five minutes (45mins).

3.9 Intervention

The intervention was a cognitive behavioural therapy programme, which was delivered weekly over 5 weeks. The sessions took place on Saturday and Sunday afternoons as this was preferred by the students. Each session was structured to include an interactive lecture, group discussion, and a question and answer segment. Intervention lasted between 60-90 minutes and held in the doctor's common room of the clinic. Post-

intervention measures were administered at the 6th week. Light refreshments were provided for the participants during each session.

Session one involved introductions; opportunity for participants to know each other and the investigator and also setting the ground rules. This session also covered Psycho-education about SCD, the mode of its inheritance, prevalence and types of haemoglobinopathies, abnormalities in the haemoglobin and its consequence on the oxygen carrying component of the red blood cells, the pathogenesis of sickle cell crises and pain.

The second session provided the participants the overview about understanding the pain experience including the ‘‘gates’’ systems in the neuro-muscular pathways that are involved in the perception of pain and can manipulated in the management of pain, covered during this session also was the management of negative thoughts and feelings, because your thoughts and feelings and behaviour work in a triad, with thoughts and feelings determining life experiences and behaviour, they were taught how to deal with automatic thoughts or self statements about sickle cell disease, identify negative self statements and help them replace such with more helpful positive self statements that made them feel better and do things that were helpful feelings like fear and anger were also addressed. Homework activity was to keep a ‘thought diary’ with the aim of monitoring thoughts and feelings about sickle cell disease.

The third session involved activity and relaxation intervention- including simple muscle relaxation, positive imagery and breathing techniques. The fourth session involved attention diversion intervention and effective communication skills such as assertiveness. The fifth session covered general self management, all the previous sessions, the techniques and the skills learnt throughout were recapped. At the sixth week the post intervention measures were administered.

The intervention manual used had been utilized among sickle cell disease patients with significant improvement by Anie et al. (2002) in the United Kingdom. Two sessions were randomly audio-recorded and were assessed to determine adherence to the content of the intervention and efficient delivery. Participants who attended 3 or more sessions were offered outcome measures, having attended at least three sessions of all five was adjudged to be the minimum requirement as before patient could be said to have benefitted from the intervention.

3.10 Data Management

Data was cleaned and coded where this was appropriate, it was entered and analysed using the Statistical Package for Social Sciences, version 20 (SPSS 20). Socio-demographic and clinical variables were presented by frequency tables and percentages. Hospital Anxiety and Depression Scale, Coping skills and Quality of life scores were presented using means and standard deviations, association between outcome measures and clinical variables were assessed using independent t-test. Differences in mean of the outcome measure scores pre and post intervention were analysed using paired t-test, knowledge of the intervention content and client satisfaction and evaluation of the intervention was also analysed using frequencies and percentages.

CHAPTER FOUR

RESULTS

4.1 Socio-demographic characteristics of participants

A total of 44 students were contacted and screened for anxiety or depressive symptoms using the HADS, 24 of them met the inclusion criteria of scoring 8 and above on either the anxiety or depression sub scale, 21 eventually were present for the first day of the intervention, but one student had to be exempted as a result of increasing physical health challenge that required in-patient admission away from the university. Of the twenty (20) undergraduate students that were finally involved in this intervention study, 18 students attended all intervention sessions. The mean age of the students was 19.8 (SD 2.18) years, their ages ranged between 16 and 24 years, with the modal age being 20 years.

Participants were evenly distributed by gender male 9 (50.0%) and female 9 (50.0%) with a majority being Christian 13 (72.2%), and about a quarter were Muslims 5 (27.8%). Yoruba was the predominant ethnicity 17 (94.4%), while Igbo was 1 (5.6%). A third was in their 400 levels 7 (38.9%) and they represented the highest number of participants from any level. See Table 1.

Table 1: Socio-demographic characteristics of participants

Variable	Frequency (%)
Age group (years)	
16-18	5 (27.8)
19-21	9 (50.0)
22-24	4 (22.2)
Religion	
Christianity	13 (72.2)
Islam	5 (27.8)
Ethnic group	
Yoruba	17 (94.4)
Igbo	1 (5.6)
Undergraduate Level	
100	4 (22.2)
200	2 (11.1)
300	4 (22.2)
400	7 (38.9)
500	1(5.6)

4.2 Clinical characteristics of participants

Clinical characteristics of the participants revealed that 14 (78%) of the participants had the HBSS phenotype and 4(22%) the HBSC phenotype, visits to the emergency room over the last 12months including the period of the study ranged between 1-10, with a majority (78%) visiting the clinic between 1-5 times in the past one year, hospital admissions in the same time period ranged between none at all to six (0-6), with a majority (56%) having between 1-3 hospital admissions over the 12 month period. Mean packed cell volume for each participant ranged between 15%-35% over the 12 month period, 61% of the participants had packed cell volume between 21%-25%, however those with the HBSC phenotype were noted to have the higher PCV and lower frequencies of hospital visits and admissions compared to the HBSS phenotype. See Table 2.

Table 2: Clinical characteristics of participants over twelve months

Variable	Frequency (%)
Phenotype	
HBSS	14 (78%)
HBSC	4 (22%)
Emergency visits (days)	
1-5	14 (78%)
6-10	4 (22%)
Admission (days)	
None	3(17%)
1-3	10(56%)
4-6	5(28%)
Packed cell volume (PCV) (%)	
15-20	3(17%)
21-25	11(61%)
26-30	2(11%)
30-35	2(11%)
Mean PCV by genotype	
HBSS	15- 28 (22.4%)
HBSC	26-35 (30.5%)

4.3: Anxiety and depressive symptoms among participants' pre and post-intervention

All the participants involved in the study (N=18) pre-intervention had symptoms of either anxiety or depression, using the cut-off required for screening with the hospital anxiety and depression score scale (HADS), however post intervention none of the participants had depressive symptoms and only 11% (2) still had symptoms of anxiety.

4.4: Coping strategies used by participants' pre -intervention

Assuming the 100th percentile as the total score obtainable for each coping skill set (Active, Affective-negative, Passive) the values were dichotomized with the 50th percentile used as the cut-off point, with a higher score indicating a better coping strategy for both active and passive coping skills and the reverse for affective negative coping skills.

Pre-intervention 10 (56%) of the participants scored below 50% in the use of active coping skills, while 5 (28%) scored below the cut-off in the use of passive coping skills and 6 (33%) of them scored above the cut off in the use of affective coping skills. See Table 3.

Table 3: Frequency distribution of the coping strategies used by participants' pre –intervention (N = 18)

	Frequency	%
Active coping		
<132	10	55.6
>=132 (50th percentile)	8	44.4
Affective coping		
<66	12	66.7
>=66 (50th percentile)	6	33.3
Passive coping		
<33	5	27.8
>=33 (50th percentile)	13	72.2

4.5: Quality of life scores across domains pre-intervention

Assuming the 100th percentile as the total score obtainable for each domain, the values were dichotomized, with the 50th percentile used as the cut-off point.

Pre-intervention below the 50th percentile the proportion for each domain were, physical functioning 4(22%), role limitation due to physical health 10(56%), role limitation due to emotional health 8(44%), energy and fatigue 6 (33%), emotional wellbeing 2(11%), social functioning 1(6%), pain 2(11%) while general health was 4(22%). Above the cut-off point the following frequencies were seen across each domain pre-intervention, physical functioning 14(78%), role limitation due to physical health and emotional health 8(44%) and 10(56%) respectively, 12(67%) for energy and fatigue, 16(89%) for emotional well being, social functioning, pain and general health had 17(94%), 16(89%) and 14(78%) respectively See Table 4.

Table 4: Frequency distribution of participants' quality of life scores across domains pre intervention (N = 18)

	Frequency	%
Physical functioning		
<50th percentile	4	22.2
>=50th percentile	14	77.8
Role limit physical		
<50th percentile	10	55.6
>=50th percentile	8	44.4
Role limit emotional		
<50th percentile	8	44.4
>=50th percentile	10	55.6
Energy/ fatigue		
<50th percentile	6	33.3
>=50th percentile	12	66.7
Emotional wellbeing		
<50th percentile	2	11.1
>=50th percentile	16	88.9
Social function		
<50th percentile	1	5.6
>=50th percentile	17	94.4
Pain		
<50th percentile	2	11.1
>=50th percentile	16	88.9
General health		
<50th percentile	4	22.2
>=50th percentile	14	77.8

4.6: Relationship between haemoglobin phenotype and coping skills used pre intervention

There was no significant association between phenotype and type of coping skills used before the intervention (see Table 5).

Table 5: Relationship between haemoglobin phenotype and use of coping skills pre intervention (N – 18)

	Phenotype	N	Mean	SD	t	P
Active Coping	SS	14	128.0	34.4	-0.5	0.6
	SC	4	137.5	25.7		
Affective Coping	SS	14	56.8	20.1	0.1	0.9
	SC	4	55.0	41.6		
Passive Coping	SS	14	39.4	8.3	-0.9	0.9
	SC	4	40.0	11.9		

4.7: Coping strategies used by participants post intervention

Post intervention about 72% had however started employing active coping skills in dealing with sickle cell disease above the 50th percentile, the was a reduction in the number of those using affective-negative skills above the cut-off from 33% to 22% and an increase in the number of participants using passive coping skills above the same cut-off from 72% to 89%.See Table 6.

Table 6: Frequency distribution of coping strategies used by participants post intervention (N = 18)

	Frequency	%
Active coping		
<132	5	27.8
>=132 (50th percentile)	13	72.2
Affective coping		
<66	14	77.8
>=66 (50th percentile)	4	22.2
Passive coping		
<33	2	11.1
>=33 (50th percentile)	16	88.9

4.8: Quality of life scores across domains post intervention

Post-intervention, the proportion of participants below the cut-off point was 1(6%) for physical functioning, 9(50%) and 7(39%) for role limitation due to physical and emotional health respectively, while for energy and fatigue, emotional wellbeing, social functioning, pain and general health the frequencies were 2(11%), 1(6%), 1(6%), 2(11%) and 2(11%) respectively. Above the 50th percentile for each domain, the proportions were 17(94%), 9(50%), 11(61%) and 16(89%) for physical functioning, role limitation due to physical health, role limitation due to emotional health and energy and fatigue. Emotional well being, social functioning, pain and general health had following percentages respectively 17(94%), 17(94%), 16(89%) and 16(89%). See Table 7.

Table 7: Frequency distribution of participants' quality of life scores across domains post intervention (N = 18)

	Frequency	%
Physical functioning		
<50th percentile	1	5.6
>=50th percentile	17	94.4
Role limit physical		
<50th percentile	9	50
>=50th percentile	9	50
Role limit emotional		
<50th percentile	7	38.9
>=50th percentile	11	61.1
Energy/ fatigue		
<50th percentile	2	11.1
>=50th percentile	16	88.9
Emotional wellbeing		
<50th percentile	1	5.6
>=50th percentile	17	94.4
Social function		
<50th percentile	1	5.6
>=50th percentile	17	94.4
Pain		
<50th percentile	2	11.1
>=50th percentile	16	88.9
General health		
<50th percentile	2	11.1
>=50th percentile	16	88.9

4.9: Relationship between haemoglobin phenotype and use of coping skills post intervention

Post intervention there was significant association between the participant's phenotype and the use of passive coping skills, scores were significantly higher for HBSS phenotype (M =46.9, SD =7.0) than the HBSC (M =37.5, SD =7.2), t =2.4, p =0.03 in the use of passive coping skills. See Table 8.

Table 8: Showing relationship between haemoglobin phenotype and use of coping skills post intervention

	Phenotype	N	Mean	SD	t	p
Post Active Coping	SS	14	156.7	35.4	2.1	0.06
	SC	4	116.3	30.6		
Post Affective Coping	SS	14	57.9	24.5	1.7	0.1
	SC	4	35.0	17.0		
Post Passive Coping	SS	14	46.9	7.0	2.4	**0.03***
	SC	4	37.5	7.2		

* Shows significant value

4.10 Effect of CBT intervention on depression and anxiety symptoms

All outcome variables were normally distributed using Kolmogorov-Smirnov tests and pre and post intervention scores were analysed using paired t-tests. There was a significant reduction in anxiety symptoms post-intervention ($t=7.20$, $p<0.001$). There was also a statistically significant reduction in depressive symptoms post-intervention ($t=2.64$, $p<0.02$). See Table 9.

Table 9: Pre and post intervention mean scores on the HADS

Variable	Pre-intervention: mean (SD)	Post-intervention: mean (SD)	t	P
Anxiety	9.22 (1.67)	5.00 (3.03)	7.20	**0.001***
Depression	4.50 (2.81)	2.83 (1.92)	2.64	**0.02***

*Shows value that are significant

4.11 Effect of intervention on participants coping skills

The intervention resulted in a statistically significant improvement in active coping skills (t=-2.19, p<0.04) as well as passive coping (t=-2.20, p<0.04). No significant difference was observed in the affective-negative coping skills (p=0.58). See Table 10.

Table 10: Effect of intervention on participants coping skills

Variable	Pre-intervention mean (SD)	Post-intervention mean (SD)	t	p
Active coping	130.11 (32.23)	140.72 (37.70)	2.19	**0.04***
Affective coping	56.39 (24.79)	52.78 (24.65)	0.57	0.58
Passive coping	39.56 (8.83)	44.83 (7.96)	-2.20	**0.04***

*Shows values that are significant

4.12 Effect of intervention on quality of life

No significant differences were observed in several domains (physical functioning, limitation in physical and emotional role, emotional wellbeing, energy fatigue, pain and general health) of the SF36. There was however an improvement in social functioning post intervention ($p<0.001$). See Table 11.

Table 11: Quality of life scores of participants' pre and post intervention

Variable	Pre-intervention: mean (SD)	Post-intervention: mean (SD)	t	p
Physical functioning	666.67 (194.03)	691.67 (159.27)	-0.71	0.48
Physical role limitation	166.67 (137.19)	161.11 (124.33)	0.13	0.89
Emotional role limitation	172.22 (101.78)	188.89 (118.27)	-0.47	0.64
Energy fatigue	234.44 (68.88)	267.78 (62.93)	-1.91	0.07
Emotional wellbeing	334.44 (79.06)	345.56 (57.32)	-0.56	0.58
Social functioning	118.06 (26.85)	156.94 (36.19)	-5.10	**0.001***
Pain	149.72 (41.57)	146.39 (49.34)	0.21	0.83
General health	287.50 (90.04)	318.06 (55.43)	-1.67	0.11

4.13: Effect of intervention on the knowledge and practice of coping skills among participants

Following the intervention, there was a significant improvement in self-rated knowledge about coping skills (t=-6.73, p<0.001), knowledge about change in thinking patterns (t=-8.29, p<0.001), as well as an increase in confidence in using coping skills (t=-7.94, p<0.001). See Table 12.

Table 12: Effect of intervention on knowledge and confidence regarding coping skills

Variable	Pre-intervention: mean (SD)	Post-intervention: mean (SD)	t	p
Knowledge about coping skills	4.72 (2.29)	7.78 (1.48)	-6.73	**0.001***
Knowledge about changing thinking patterns	4.56 (2.61)	8.28 (1.32)	-8.29	**0.001***
Confidence using coping skills	6.06 (2.09)	7.83 (1.75)	-7.94	**0.001***

*Shows values that are statistically significant

4.14: Knowledge of intervention content and sickle cell disease

Participants showed good knowledge about the content of the intervention, with the majority knowing about the means of acquiring the disease, ways of managing pain aside from taking medications, including breathing and relaxation exercises and the uses of effective communication skills like assertiveness in ensuring they get adequate care. The entire participants had correct knowledge of the usefulness of psychological therapies for managing sickle cell disease in addition to other therapies, including changing their thought patterns about SCD pain and engaging in pleasurable activities. Knowledge about predictability of the onset of sickle cell crises was poor with only 16.7% having correct knowledge. See Table13.

Table 13: Frequency distribution showing knowledge of the intervention content and sickle cell disease

Variable	Frequency	%
SCD is acquired by other means apart from inheritance of the genes from our parents	3	16.7
False	15	83.3
True		
Onset of SCD crises can be predicted		
False	15	83.3
True	3	16.7
No treatment can make pain better except medication		
False	3	16.7
True	15	83.3
Pain from SCD should stop one from enjoying other pleasurable activities	3	16.7
False	15	83.3
True		
Doing enjoyable activities like swimming, playing games can help cope with SCD	18	100
True		
Thoughts about our situation when in crises affect our feelings (positively or negatively)	18	100
True		
Slow breathing exercises can help us relax when having pain		
False	2	11.1
True	16	88.9
Assertiveness help us get optimum care		
False	1	5.6
True	17	94.4

4.15 Satisfaction with intervention by participants

A majority (n=11; 61.1%) rated the intervention as excellent. Most (n=12, 66.7%) generally agreed that they got what they expected from the intervention (awareness of other means of dealing with sickle cell disease pain aside from taking medications, forum for interacting with people with the same condition and learning how they from each other). Similarly, a majority would definitely recommend the intervention (n=17; 94.4%) and would take the intervention again if help was needed (n=14; 77.8%). See Table 14.

Table 14: Frequency distribution of participant responses to satisfaction with intervention

Variable	Frequency	%
How would you rate the intervention		
Good	7	38.9
Excellent	11	61.1
Did you get the help you wanted?		
Yes, generally	12	66.7
Yes, definitely	6	33.3
Would you recommend this intervention		
	1	5.6
Yes, probably	17	94.4
Yes, definitely		
Satisfied with help received?		
Mostly satisfied	13	72.2
Very satisfied **better?**	5	27.8
Yes, a little		
Intervention helped you cope		
Yes, a little	8	44.4
Yes, a lot	10	55.6
Overall satisfaction with intervention?		
Mostly satisfied	11	61.1
Very satisfied	7	38.9
Take intervention again if help needed?		
Yes, probably	4	22.2
Yes, definitely	14	77.8

4.16 Emerging themes from intervention

4.16.1 Satisfaction with the intervention

Unstructured questions regarding satisfaction with the intervention with various multiple responses were organised into themes. Thirteen participants were satisfied because of the knowledge that was transferred during the intervention e.g. *'I gained total exposure and understanding', 'I learnt practical tips', 'I learnt how to cope with stress and pain'.* Four participants were satisfied because of the interactive nature of the intervention e.g. *'I found it to be simple and interactive'; 'I enjoyed the interactive nature of the intervention as well as the discussions'.* One participant was satisfied because of the characteristic of the trainer; *'The trainer was so accommodating'*. See Table 15.

Table 15: Themes that emerged from satisfaction with the intervention

Themes	frequency	%
Interactive nature of the intervention	**5**	**27.8**
'The interactive nature of the intervention'		
'The interactive discussion about the disease'		
'Being interactive'		
'Being interactive'		
'Simple and interactive'		
Practical and informative	**8**	**44.44**
'The total exposure and in-depth understanding'		
'I liked the fact that it was brief explanatory and very practical, it was of great help'		
'Learnt many new things I didn't know before'		
'It's simple and confidential'		
'Knowing our stable PCV'		
'Learnt practical tips'		
'Interesting and practical'		
'The trainer was so very accommodating'		
Improved coping skills learnt	**5**	**27.8**
'How to cope with pain'		
'About coping with stress, how to ameliorate the co-existence of pain'		
'It taught me about having a positive outlook, knowing i would come out of it, it also taught me relaxation techniques'		
'Learnt new skills on how to cope before, during and after crises'		
'Dealing with stress'		
Total	**18**	**100**

4.16.2 Dissatisfaction with intervention

Thirteen participants had no reason to be dissatisfied with the intervention. One complained of the attitude of other participants; *'the attendees were lackadaisical as to attending frequently'*. Two complained about the short duration of the intervention; *'It was too short and theoretical'.* One complained about the lack of adequate illustrations and another complained that the intervention was coming too late in the course of their illness. See table 16.

What participants did not like about the intervention

Table 16: Themes that emerged from what participants did not like about the intervention

Themes	frequency	%
There was nothing we did not like	**13**	**72.2**
Too theoretical and short	**3**	**16.7**
'It was short and theoretical'		
'Not much of the aids discussed were seen'		
I had this intervention too late	**1**	**5.55**
Poor attitudes among some attendees	**1**	**5.55**
Total	**18**	**100**

4.16.3 Suggestions for improvement

Eight participants recommended regularity of the intervention and follow-up sessions; *'there should be regular seminars and follow-up', 'a social media platform for participants e.g. WhatsApp', 'the intervention should be done as new students begin sessions'.* Three recommended that more illustrations be provided and greater emphasis on the practical aspects; *'can be improved by making it more practical', 'there should be graphical illustrations'.* Two suggested creating more awareness of the intervention. See table 17.

Table 17: Themes that emerged from suggestions to improve the intervention

Themes	frequency	%
Increase awareness for the intervention	**6**	**33.3**
'To involve more Hbss patients and a very practical help and assistance'		
'Ensuring people get high interest in participating in such interventions'		
'Create more awareness'		
'Increase awareness for the interventions'		
'More clients can be involved'		
'Make it more regular'		
Early commencement of intervention as students resume, ensure follow up	**7**	**38.8**
'The intervention should be done as new students begin sessions'		
'Ensure effective follow-up and provide support'		
'Regular seminars and follow-up to be organized'		
'Effective follow-up'		
'Follow up should be done'		
'A social media group for participant (whatsapp) '		
'To organise effective follow-ups to ensure that participants make use of the things taught'		
Increase duration of intervention and more practical sessions	**4**	**22.2**
'More practical sessions, like the relaxation techniques'		
'Can be improved by making it more practical'		
'There should be graphical illustrations'		
'It could be longer'		
The intervention is okay as it is	**1**	**5.6**
'Nothing, it is okay'		
Total	**18**	**100**

CHAPTER FIVE

DISCUSSION

The aim of this study was to evaluate the effect of a group-based CBT programme on quality of life, coping strategies and emotional well-being of young adults with sickle cell disease at the University of Ibadan. This was achieved through a pre and post study design. The intervention was associated with reduced depressive and anxiety symptoms, improved use of active and passive coping strategies, and social functioning. The intervention was well received as the participants rated many aspects of it highly. To my knowledge, this is the first study evaluating a cognitive behavioural intervention for people with sickle cell in Nigeria.

Socio-demographic and clinical characteristics of the study participants

The study participants were adolescents and young people living with sickle cell disease who are presently enrolled as undergraduates at the University of Ibadan. Their ages ranged from 16 to 24years, with the mean age being 19.83. This age range represents the normal expected for undergraduate students, as minimum age for admission at this university is 16 and for a four year course, age of graduation is expected to be about 20 years and a third of the participants were in 400level. This age distribution is similar to that reported in an unpublished study done among these same university undergraduates (Ekore 2015), where the mean age was 20.2 years, as well as other studies among undergraduates (Kulsoom and Afsar, 2015).

The participants were evenly distributed in terms of gender; half of them were males and the other half were females, there were more Christians than Muslims involved in this study, and the predominant ethnicity of participants was Yoruba, which is expected

since the university is located in the western part of Nigeria, where the predominant tribe is Yoruba; only 1 (5.6%) participant was Igbo.

The phenotypic distribution of the participants had 78% of them having the HBSS genotype and 22% HBSC, majority of them (78%) had visited the university health centre over the past 12 months between 1-5 times (one to five) while 22% had visited between 6-10 times. 56% of the participants had been admitted 1-3 times over the 12 months and 28% between 4-6 times. Their packed cell volume ranged between 15-35%, but majority (61%) had PCV values between 21-25%, and the higher values 26-35% was noted among those with the HBSC phenotype.

Anxiety and Depressive symptoms scores among participants

The participants (100%) all had clinically significant anxiety and depressive symptoms prior to the onset of the intervention, as this was a prerequisite for taking part in the study, the post intervention mean score for anxiety (M =5.00, SD =3.03) was significantly lower than the pre-intervention score of (M =9.22, SD = 1.67), and a paired sample t-test showed a statistically significant reduction in the anxiety score t =7.20, p = 0.001. The mean depressive symptoms score post intervention (M = 2.83, SD = 1.92) was also significantly lower than the mean pre-intervention score (M = 4.50, SD = 2.81), a paired sample t-test indicated a significant reduction in the depressive symptoms score t =2.64, p =0.02, the post intervention reduction in both anxiety and depressive symptoms is similar to that obtained by Ratanasiripong et al. (2015) among graduate nursing students and Elsami et al.(2016) among high school students, however the mean scores they obtained were significantly higher for both anxiety and depression pre and post intervention in both studies.

The differences noticed in this study could be attributed to the types of study instruments used in the other studies and also associated factors such as co-morbidities, stressful life events, self esteem, financial capabilities and socioeconomic status (Kader Maideen et al. 2015) and academic challenges as may be encountered amongst this study participants.

Intervention outcome

This study involved the use of a cognitive behavioural based intervention, which involved addressing thinking patterns as this has been shown to affect the individual's feelings which in turn affect their behaviour. This link between their thoughts, feelings and behaviour was explored. A change in the thinking (cognition) pattern characteristically described as 'automatic' or 'hot' thoughts, would affect how an individual felt about a particular situation and then determine how they behaved about it, thus potentially helping to promote positive methods of coping.

The intervention was associated with a significant reduction in both depressive and anxiety symptoms amongst the study participants at the end of 6 weeks. The mean score post intervention on HADS for anxiety was 5.00 (SD 3.03) compared to the pre-intervention mean of 9.22 (SD 1.67)

These results can be explained by the intervention giving the participants increased ability to cope with distressing symptoms and situations that would have produced these symptoms of psychological distress in them previously similar to that found by Elsami et al. (2016), who found out in their study among high school students that assertiveness intervention significantly reduces stress, anxiety and depressive symptoms among their study participants. The reduction of these symptoms might however not have been associated with a corresponding reduction in the chronic pain

that had produced them (Speckens et al. 1995). Nevertheless, this reduced distress alone might be of great significance both clinically and economically as these individuals would tend to perceive fewer symptoms, visit the hospitals less and save money by not procuring unnecessary medications and investigations (Speckens et al. 1995). Anxiety and depressive symptoms are usually perceived by their sufferers as symptoms of more serious underlying organic problems and this may make them pursue unnecessary diagnoses and this lifestyle would then produce more distressing symptoms in a vicious cycle. The intervention produced statistically significant improvement in both active coping skills ($t= 2.19$, $p = 0.04$) and passive coping skills ($t= -2.20$, $p = 0.04$). However no significant difference was noted in the affective coping domain ($p=0.58$). These values showed that there was an increase in the use of cognitive and behavioural skills among these study participants, this finding is similar to that obtained by Anie et al (2002). However in this study amongst children and adolescents with sickle cell disease by Anie and others, active coping skills utilization was associated with more hospital and emergency care utilization. This increase they considered to be part of the active coping strategies whereby the individual is taking charge of their lives, but on the contrary in another study, active coping skills utilization was associated with less utilization of the health facilities (Gil et al. 1993). This might be explained by the fact that the active coping skills alone might have been sufficient to handle or make the pain more bearable and hence reduce the need for hospital utilization. The relationship between coping strategy and hospital services utilization was not explored in this study. On the other hand passive coping skills have been associated with increased pain intensity (Anie et al. 2002), but again this relationship was not looked for in this study. It might be that as proposed by Anie et al (2002), the helplessness associated with this coping method might account for the

severity of the pain episode, and produce skills involved in passive coping, include resting, massaging, hot or cold shower, and all this may make the individual feel out of control and further worsen the pain perception.

Affective negative coping was not significantly affected by the intervention, and this is commendable as affective coping is more maladaptive in the long run and can worsen psychological distress. Negative affective coping has been noted to impair quality of life independent of other socio-demographic characteristics or severity of disease (Anie et al. 2002).

There was an improvement in the social functioning domain of the SF-36 post intervention but no significant differences in all the other domains of physical functioning, limitations in physical activity and emotional role, emotional wellbeing, energy and fatigue, pain and also general health. This could be attributed to the fact that the intervention might have focused on improving coping skills that would affect psycho-social functioning predominantly and hence the less significant impact on the other domains. Also the short duration of the study could be responsible for these results, since they are expected to still be in the process of practicing and mastering the skills learnt. One could expect that if this improvement in social functioning is sustained, it could eventually affect the other domains positively. Anie et al. (2002) noted in their study among adults with sickle cell disease that the use of appropriate pain coping skills may improve quality of life.

Following the intervention, there was a significant improvement in self-rated knowledge about coping skills, knowledge about change in thinking patterns, as well as an increase in confidence in using coping skills. Knowledge about inheritance of sickle cell was high; only about 17% of the participants had an incorrect knowledge about

this. Surprisingly since they have been living with this disease for a long time, a few of them had incorrect knowledge about management of SCD pain and the use of other forms of therapy in its management; most of them were not sure if they could predict the onset of a crises (55.6%), but the overall knowledge about sickle cell disease was high and the use of cognitive behavioural skills was 100%; this is not surprising considering they had just received intervention in it.

The participants' satisfaction with the intervention was rated to be high on both qualitative and quantitative measures. Almost two-thirds of them rated it as excellent and over a third said it was good. Most of them agreed that they got the help they needed from the intervention and almost all would recommend the intervention to their friends. On if they would participate in the intervention again, almost four out of five also said they would. Qualitative responses (open unstructured responses) were organised into themes and they generally followed the pattern of the quantitative measures. Majority of the participants were satisfied because of the knowledge transferred during the intervention. Specifically, more than a fifth was satisfied because of its interactive nature, one participant was satisfied because of the character of the trainer. While two-thirds of the participants had no reason to be dissatisfied with the intervention, one individual complained of the attitude of other participants, two complained about the short duration of the intervention, one complained about the lack of adequate illustrations and another complained that the intervention was coming too late in the course of their illness. Participants' suggestions on how to improve on the intervention were varied and included ensuring regularity of the intervention and effective follow-up, increasing awareness about the intervention beginning the intervention every session as new students are admitted into the university, improving on practical sessions and providing more graphical illustrations.

The level of satisfaction is encouraging especially amongst young adults who could be very difficult to get across to and engage, but one reason for this outcome could be the fact that such an intervention has never been made available in the past. It served as a forum for meeting other people who were going through similar challenges and learning from each other practical coping tips especially considering participants were all undergraduates facing the same academic challenges albeit in different departments. Similar satisfaction was noted amongst adolescents who had a behavioural intervention carried out for depression (Bella –Awusah et al. 2015).

Challenges and Adaptations of the intervention programme

The intervention took place during the first semester of the session and despite the initial enthusiasm of the participants, several changes in their individual time-tables presented some challenges. Some had lectures abruptly fixed for their weekends in other to make up for some lost time, some, especially final year students, had to spend extended time carrying out their research work or meeting with their supervisors, making some arrive late for the sessions, In order to meet up with their particular groups, we had to reschedule such missed sessions with the other groups as long as they had the sessions at the end. A few participants fell ill during the course of the intervention and had to be excluded for the period, special group sessions were then organized for them to enable their full benefit, one person however had to be admitted for a long period at the tertiary hospital and was scheduled to have surgery, hence was excluded from the final data analysis because of the inability to attend more than two (2) sessions.

Limitations of the study

Limitations of this study included the small sample size (N =18), which may make generalization of the study difficult, the short duration of the study (5 weeks), also provided some limitations as CBT sessions are usually conducted over a period of 12-18 weeks and more impact could have been noted if the duration was longer. The lack of a control group also meant that other factors unrelated to the content of the study may have accounted for some of the improvements noticed, factors like regression to the mean, socially desirable response by the participants, the enthusiasm of the session leader and other medical intervention, or health variables which were not monitored during the study.

Despite these limitations, this study provides important information on the feasibility of psychotherapeutic intervention for undergraduates living with sickle cell disease and should be replicated in a controlled trial to confirm efficacy.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

At the end of this interventional study, there is evidence that anxiety and depressive symptoms are prevalent amongst the sickle cell disease patients who were part of this study and that a cognitive behavioural based intervention appeared helpful in reducing it significantly, with an increase in their active and passive coping skills. Satisfaction with the intervention was high, however participants would require its onset to come early as they gain admission into the university and each intervention module to be longer, more practical, regular and have a wider coverage of participants.

Recommendations

These results show that group-based cognitive behavioural intervention is feasible in reducing anxiety and depressive symptoms, improving adaptive coping skills and improving social functioning in the quality of life of young people living with sickle cell disease in Nigerian universities. Based on these the following recommendations are made:

1. That the psychosocial aspects of sickle cell disease should be given priority and attention among university undergraduates in order to provide holistic care for this group as they pursue their higher degrees.
2. There should be effective collaboration between health care providers and university authorities to provide a conducive learning environment for them to increase their productivity.
3. Based on the suggestions of the students there should be a programme put in place specifically to provide mental health support to those living with sickle cell disease and other chronic illnesses in the university setting

4. This study while just looking at a small sample of the Nigerian population where sickle cell disease is most prevalent, provides a window to see that those living with sickle cell disease elsewhere, who have significant psychological distress, could benefit from a short form of cognitive behavioural therapy intervention.

REFERENCES

Abiodun A.O, (1994), A validity study of the Hospital Anxiety and Depression Scale in general hospital units and a community sample in Nigeria. Br J Psychiatry. Nov ;165 (5):669-72

Adeniyi, A.F., Okafor, N.C., Adeniyi,C.Y. (2011). Depression and physical activity in a sample of Nigerian adolescents: Levels, Relationships and Predictors. *Child and Adolescent Psychiatry and Mental Health* 5:16

Adewuya AO, Ola BA, Aloba OO, Mapayi BM, Oginni OO.(2006). Depression amongst Nigerian university students. Prevalence and sociodemographic correlates. Social Psychiatry and Psychiatric Epidemiology. Aug; 41(8):674-8

Alexander N, Higgs D, Dover G, Serjeant GR. (2004). Are there clinical phenotypes of homozygous sickle cell disease? British Journal of Haematology 126:606-11.

Almeida,A , Roberts, I., (2005). Bone involvement in sickle cell disease. British Journal of Haematology, 129: 482-490.

Ani .C, Mayordomo Aranda .A, Kinanee .J, Ola . B, Kramer,T (2012) ,Trainee-Teachers' Stigmatising attitude towards sickle cell disorder in Nigeria. European Journal of Educational Studies 4(3),

Anie KA, Egunjobi FE, Akinyanju OO. (2010) Psychosocial impact of sickle cell disorder: Perspectives from a Nigerian setting. Global. Health. 6(2):1–6. PMid:20181213, PMid:2829543

Anie KA, Steptoe A, Ball S, Dick M, Smalling BM. (2002). Coping and health service utilisation in a UK study of paediatric sickle cell pain. Archives of Disease in Childhood 86:325-9

Anie, K. A. & Green, J., (2015). Psychological therapies for sickle cell disease and pain. Cochrane Database Syst Rev, 5, Cd001916.

Anie, K. A. (2005). Psychological complications in sickle cell disease. British Journal of Haematology, 129, 723-9.

Anie, K. A., Steptoe, A., & Bevan, D. H. (2002). Sickle cell disease: Pain coping and quality of life in a study of adults in the UK. British Journal of Health Psychology, 7, 1–14

Ashley-Koch A, Yang Q, Olney RS,. (2000). Sickle hemoglobin (HbS) allele and sickle cell disease: a HuGE review. Am J Epidemiol. May 1;151(9):839-45.

Ataga, K.I., Sood, N., DeGent, G., Kelly, E., Henderson, A.G., Jones, S., Strayhorn, D., Lail, A., Lieff, S., Orringer, E.P.(2004) Pulmonary hypertension in sickle cell disease. American Journal of Medicine 1;117(9):665-9

Attkisson CC, Greenfield TK. The UCSF Client Satisfaction Scale: The Client Satisfaction Questionnaire 8. In M Maruish (Ed). The use of psychological testing for treatment planning and outcome assessment (3rd Ed). Mahwah MJ: Lawrence Erlbaum Associates. 2004; 799-811.

Bakare, M.O., Omigbodun, O.O., Kutevi, O.B., Meremikwu, M.M., & Agomoh, A.O. (2008) Psychological complications of childhood chronic physical illness in Nigerian children and their mothers: the implication for developing pediatric liaison services. Child and Adolescent Psychiatry Mental Health, 2(1), 34. doi:10.1186/1753-2000-2-34

Barakat, L., Patterson, C., Weinberger, B., Simon, K., Gonzalez, E. & Dampier, C. (2007). A prospective study of the role of coping and family functioning in health outcomes for adolescents with sickle cell disease. Journal of Paediatric Haematology Oncology, 29, 752-60.

Barbosa de Melo, M., 2014. An eye on sickle cell retinopathy; *Revista Brasileira de Hematologia e Hemoterapia, Volume 36, Issue 5, September–October 2014, 319-21*

Beck, J.S. (2011) Cognitive behaviour therapy:Basics and beyond (2nd Ed.)(pp.19-20).New York,NY:The Guilford Press.

Beers, Mark H., MD, and Robert Berkow, MD.,(2004). "Anemias Caused by Excessive Hemolysis: Sickle Cell Diseases." Section 11, Chapter 127 Merck Manual of Diagnosis and Therapy. Whitehouse Station, NJ: Merck Research Laboratories

Bella-Awusah T, Ani C, Ajuwon A, Omigbodun O. (2016). Effectiveness of a brief school-based, group cognitive behavioural therapy for depressed adolescents in south west Nigeria, Child and Adolescent Mental Health, 21, No.1,pp 44-50.

Berge, J,M., Patterson ,J,M., Goetz ,D., & Milla, C. (2007). Gender differences in young adults' perception of living with cystic fibrosis during the transition to adulthood: A qualitative investigation. Families, Systems, & Health, 25(2), 190-203

Bjelland I, Dahl A.A., Haug T.T., Neckelmann D. (2002) The validation of the Hospital Anxiety and Depression Scale. An updated literature review. J Psychosom Res 52:69-77. Doi:10.1016/S0022-3999(01)00296-3

Broderick, G.A.,(2012) Priapism and sickle cell anemia: diagnosis and non-surgical therapy, Journal of Sex Medicine, 9(1):88-103

Brousse V, Makani J, Rees D.C., (2014)Management of sickle cell disease in the community, BMJ 2014;348:g1765

Brown B, Okereke J, Lagunju I, Orimadegun A, Ohaeri J, Akinyinka O. (2010) Burden of health-care of carers of children with sickle cell disease in Nigeria. Health Soc Care Community;18:289–95

Brown, S. E., Weisberg, D. F. & Sledge, W. H. 2015. Family caregiving for adults with sickle cell disease and extremely high hospital use. J Health Psychol.

Burnes, DPR, Antle, BJ, Williams, CC & Cook, L. (2008). Mothers raising children with sickle cell disease at the intersection of race, gender, and illness stigma. Health & Social Work, 33 (3), 211-20.

Cohen J. (1988). Statistical power analysis for the behavioural sciences (2nd ed.). Hillsdale, NJ: Lawrence Erlbaum Associates.

Cohen LM, McChargue DE, Collins FL (2003). The health psychology handbook: Practical issues for the behavioural medicine specialist. Thousand Oaks, CA: Sage Publications

Constantinou, C., Payne, N., Inusa, B. 2015. Assessing the quality of life of children with sickle cell anaemia using self-, parent-proxy, and health care professional-proxy reports. Br J Health Psychol, 20, 290-304.

Constanza, R., Fisher B., Ali S., Beer C., Bond L., Boumans R., et al. (2008) An Integrative Approach to Quality of Life Measurement, Research, and Policy S.A.P.I.EN.S,1(1)

Cozzi L, Tryon WW, Sedlacek K. (1987) The effectiveness of biofeedback assisted relaxation in modifying sickle cell crises. Biofeedback Self Regul; 12 (1):51-61

Cully,J.A.,Teten, A.L. A Therapist Guide to Brief Cognitive Behavioral Therapy. 2008. Department of Veteran Affairs South Central MIRECC. Houston.

Daniels, S. 2015. Cognitive behavioral therapy in patients with sickle cell disease. Creat Nurs, 21, 38-46.

Davies SC, Cronin E, Gill M, et al. 2000, Screening for sickle cell disease and thalassaemia—a systematic review with supplementary research. Health Technol Assess;4:3.

De Santis Feltran L, de Abreu Carvalhaes J T, Sesso R 2002. Renal complications of sickle cell disease: managing for optimal outcomes. Paediatr Drugs. 4(1):29-36.

DeBaun MR, Telfair J; 2012 Transition and sickle cell disease. Pediatrics. Nov;130(5):926-35. doi: 10.1542/peds.2011-3049.

Drawz P, Ayyappan S, Nouraie M, Saraf S, Gordeuk V, Hostetter T, et al 2016, Kidney Disease among Patients with Sickle Cell Disease, Hemoglobin SS and SC. Clin J Am Soc Nephrol, (CJASN) vol. 11 no. 2 207-15.

Dyson, S., Atkin, K., Culley L.A., Dyson, S.E., Evans, H., & Rowley, D. T. (2010) Disclosure and sickle cell disorder: A mixed methods study of the young person with sickle cell at school. Social Science and Medicine, 70, 2036-44.

Edwards CL, Scales MT, Loughlin C, Bennett GG, Harris-Peterson S, De Castro LM, Whitworth E, Abrams M, Feliu M, Johnson S, Wood M, Harrison O, Killough A. 2005. A brief review of the pathophysiology, associated pain, and psychosocial issues in sickle cell disease. International Journal of Behavioral Medicine 12:171-9.

Edwards LK.Y., Edwards. C.L., (2010) Psychosocial Treatments in Pain Management of Sickle Cell Disease. J Natl Med Assoc. 2010;102:1084-94.

Ehigie B.O. (2003) Comparative analysis of the psychological consequences of the traumatic experiences of cancer, HIV/AIDS, and sickle cell anemia patients. IFE Psychologia. ;11(3):34-54

Frenette, P.S. (2004) Sickle cell vasoocclusion: heterotypic, multicellular aggregations driven by leukocyte adhesion. Microcirculation, 11, 167–77

Gatchel, Robert J.; Rollings, Kathryn H. (2008). "Evidence-informed management of chronic low back pain with cognitive behavioral therapy". The Spine Journal 8 (1): 40–4

Gil KM, Thompson RJ, Keith BR, et al. Sickle cell disease pain in children and adolescents: change in pain frequency and coping strategies over time. J Pediatr Psychol 1993;18:621–7.

Grove J., Grove. O., Colin. M. (2013), The real effects of sickle cell disease on children and adolescents. The West London Medical Journal Vol 6 No 1 pp 11-7.

Gureje O, Lasebikan VO, Kola L. Makanjuola V a. Lifetime and 12-month prevalence of mental disorders in the Nigerian Survey of Mental Health and Well-Being. Br J Psychiatry. 2006;188:465–71. doi: 10.1192/bjp.188.5.46.

Hayes, Steven C.; Villatte, Matthieu; Levin, Michael; Hildebrandt, Mikaela (2011). "Open, Aware, and Active: Contextual Approaches as an Emerging Trend in the Behavioral and Cognitive Therapies". Annual Review of Clinical Psychology 7 (1): 141–68

Haywood C Jr, Beach MC, Lanzkron S, et al.(2009) A systematic review of barriers and interventions to improve appropriate use of therapies for sickle cell disease. J Natl Med Assoc. ;101(10):1022-33.

Holmes AP, Hatch J, Robinson GA (1992) A lay educator approach to sickle cell disease education. J Natl Black Nurses Assoc;5(2):26-36

Huck , J ,G. (1923). Sickle cell anaemia. Bull. Johns Hopkin Hosp. 35;335-34

Iloeje, S. (1991) Psychiatric morbidity among children with Sickle Cell Disease. Developmental Medicine and Child Neurology, 33, 1087-94.

Indexmundi.2015. Nigeria demographic profile 2014 (online), Available at http:www.indexmundi.com/Nigeria [Accessed 8 August 2016].

Innocent Ocheyana George, Peace Ibo Opara.(2011) Sickle Cell Anaemia: A survey of associated morbidities in Nigerian children. Afr J Haematol Oncol ;2:187-90

Jenerette, C. M. & Brewer, C.(2010). Health-related stigma in young adults with sickle cell disease. J Natl Med Assoc, 102, 1050-5

Jenerette, C., Brewer, C. A., Crandell, J. & Ataga, K. I. 2012. Preliminary validity and reliability of the Sickle Cell Disease Health-Related Stigma Scale. Issues Ment Health Nurs, 33, 363-9.

John-Olabode S, Awodele I, Oni O.(2015) Adolescents with sickle cell anaemia: Experience in a private tertiary hospital serving a tertiary institution. Niger Med J 2015;56:204-7

Kader Maideen, S. F., Mohd Sidik, S., Rampal, L., & Mukhtar, F. (2015). Prevalence, associated factors and predictors of anxiety: a community survey in Selangor, Malaysia. *BMC Psychiatry*, *15*, 262.

Kavanagh P., (2012).Mental health and learning needs in children with sickle cell disease, Sickle Cell Disease Association of America. www.sicklecelldisease.org/sicklecelldisease/uploads/file/2012 convention power point presentation.

Kelch-Oliver, K., Smith, C., Diaz, D., & Collins, M. (2007). Individuals and family contributions to depressive symptoms in African American children with sickle cell disease. Journal of Clinical Psychology Medical Setting, 14, 376-84.

Kessler, R, Avenevoli ,S., & Merikangas , K. (2001). Mood disorders in children and adolescents; an epidemiological perspective. Biological Psychiatry, *49*, 1002-14

Kim, S.K., Miller, J.H. (2002) Natural history and distribution of bone and bone marrow infarction in sickle hemoglobinopathies. Journal of Nuclear Medicine, 43, 896–900.

Kulsoom, B., Afsar, N. A. (2015). Stress, anxiety, and depression among medical students in a multiethnic setting. *Neuropsychiatric Disease and Treatment*, *11*, 1713–22. http://doi.org/10.2147/NDT.S83577

Levenson J.L., (2008). Psychiatric issues in Adults with sickle cell disease. Primary Psychiatry;15.(5): 45-9.

Levenson J.L., McClish D.K., Dahman B.A.et al (2008)Depression and anxiety in adults with sickle cell disease:the PiSCES project,PsychosomMed:70(2);192-6

Lin, S. M., Strouse, J. J., Whiteman, L. N., Anders, J. & Stewart, R. W. (2015). Improving Quality of Care for Sickle Cell Patients in the Pediatric Emergency Department. Pediatr Emerg Care.

Manwani, D., Frenette P.S., (2013). Vasooclusion in sickle cell disease, pathophysiology and novel targeted therapies: Hematology Am Soc Hematol Educ Prog; 2013:362-9.

Mbada, C.E., Adeogun, G.A., Ogunlana, M.O., Adedoyin, R.A., Akinsulore, A., Awotidebe, O.A.(2015) Health Qual Life Outcomes 13:141.doi: 10.1186/ s12955-015-0337-y

McClish DK, Penberthy LT, Bovbjerg VE, et al.(2005) Health related quality of life in sickle cell patients: the PiSCES project. Health Qual Life Outcomes.;3:50

Minniti C.T., Eckman J., Sebastiani, P., Steinberg, M.H., Ballas S.K.,(2010) leg ulcers in sickle cell disease, American journal of hematology; 85(10):831-3

Mirowsky, J., C.E. Ross. (2002). "Selecting outcomes for the sociology of mental health:Issues of measurement and dimensionality. "Journal of Health and Social Behavior no:43:152-70.

Moos, R. H., Schaefer, J.A., (1984) .The crisis of physical illness: An overview and conceptual approach in coping with physical illness: New Perspectives. Volume 2. Edited by Moos RH. New York: Plenum Press;::3-3

Mostafa A.A., Tarek T.A., Omar A.A.,(2011) Health Related Quality of Life among adolescents with sickle cell disease in Saudi Arabia The Pan African Medical Journal 2011;8:10. doi:10.11604/pamj.2011.8.10.488

Ogunfowora OB, Olanrewaju DM, Akenzua GI. (2005) A comparative study of academic achievement of children with sickle cell anaemia. J Natl Med Assoc. ;97:405–8.

Ohaeri, J. U. & Shokunbi, W. A. (2001). Attitudes and beliefs of relatives of patients with sickle cell disease. East Afr Med J, 78, 174-9.

Ohene-Frempong. K, Weiner. S.J., Sleeper. L.A., Miller. S.T., Embury.S., Moohr.J.W.,(1998) Cerebrovascular accidents in sickle cell disease:rates and risk factors. Blood journal 91(1):288-94.

Okpala, I., Tawil, A. (2002).Management of pain in sickle cell disease. Journal of the Royal Society of Medicine, 95(9), 456-8.

Ola, B. A., Coker, A. O, Ani, C. (2013). School children's stigmatizing attitude towards peers with sickle cell disease among secondary school students in Nigeria. International Journal of Child, Youth and Family Studies (2013) 4: 391–402

Olujohungbe, A.B., Adeyoju, A., Yardumian, A., Akinyanju, O., Morris, J., Westerdale, N., et al (2011) A prospective study of stuttering priapism in adolescents and young men with sickle cell anemia: report of an international randomized control trial- The Priapism in Sickle Cell Study. J Androl.32(4):375-82.

Palermo,T., Schwartz, L., Drotar D., McGowan, K. (2002). Parental report of health-related quality of life in children with sickle cell disease. J Behav Med. Jun;25(3):269-83.

Panepinto, J.A., Pajewski, N.M., Foerster, L. M., Sabnis, S., Hoffmann, R.G.(2009). Impact of family income and sickle cell disease on the health related quality of life of children. Quality of Life Research,18,5-13.doi:10.1097/MPH.0b013e31817e4a44

Pereira, S. A., Brener, S., Cardoso, C. S. & Proietti, A. B. (2013). Sickle Cell Disease: quality of life in patients with hemoglobin SS and SC disorders. Rev Bras Hematol Hemoter, 35, 325-31.

Poillon WN, Kim BC, Castro O. (1998). Intracellular hemoglobin s polymerization and the clinical severity of sickle cell anemia. Blood 91:1777-83

R. S. Lazarus & S. Folkman, (1984), Stress, Appraisal, and Coping p.141

Rho, Y. I., Lee, S. A., Yim, S. B., Chu, M., Park, H. M., Lee, G. H., Park, S. P. & Jung, D. S. (2010). Factors contributing to Korean adolescents' perceptions of stigma with respect to epilepsy. Epilepsy Behav, 19, 627-30.

Sansom-Daly, U. M., Peate, M., Wakefield, C. E., Bryant, R. A. & Cohn, R. J. (2012). A systematic review of psychological interventions for adolescents and young adults living with chronic illness. Health Psychol, 31, 380-93.

Schatz, J. (2004). Brief report: Academic attainment in children with sickle cell disease. Journal of Pediatric Psychology, 29(8), 627–33.

Schnog JB, Duits AJ, Muskiet FA, ten Cate H, Rojer RA, Brandjes DP (2004). Sickle cell disease; a general overview. Neth J Med. Nov; 62(10):364-74.

Schwartz LA, Radcliffe J, Barakat LP. (2007). The development of a culturally sensitive paediatric pain management intervention for African American adolescents with sickle cell disease. Child Health Care;36(3):267-83

Silber, T. J. (1983). Chronic illness in adolescents: a sociological perspective. Adolescence, 18, 675-7.

Simon, K., Barakat, L., Patterson, C., & Dampier, C. (2009). Symptoms of depression and anxiety in adolescents with sickle cell disease: The role of intrapersonal characteristics and stress processing variables. Child Psychiatry, 40, 317-30.

Smith WR, Bovbjerg VE, Penberthy LT, Mcclish DK, Levenson JL, Roberts JD, Gil K, Roseff SD, Aisiku IP. (2005). Understanding pain and improving management of sickle cell disease: The pisces study. Journal of the National Medical Association 97:183-93Speckens AE, van Hemert AM, Spinhoven P, Hawton KE, Bolk JH, Rooijmans HG. Cognitive behavioural therapy for medically unexplained symptoms: A randomized controlled trial. BMJ 1995; 311: 1328-33

Thaniel, Lisa N., (2013). "A Case-Control Study: The Psychosocial Functioning and Academic Achievement in Siblings with and without Sickle Cell Disease" (Doctorate in Social Work (DSW) Dissertations. Paper 43

Theofilou, P. (2013) Quality of Life: Definition and Measurement. Europe's Journal of Psychology,9(1),150-62

Thomas, V. J., Taylor, L. M. (2002). The psychosoc ial experience of people with sickle cell disease and its impact on quality of life: Qualitative findings from focus groups. Br J Health Psychol, 7, 345-63.

Thomas, V.J., Dixon, A.L., Milligan, P., Thomas, N.,(2010). Cognitive-behaviour therapy for the management of sickle cell disease pain: An evaluation of a community-based intervention. Br J Health Psychol, 4, 209-29.

Tripette J, Alexy T, Hardy-Dessources M-D, Mougeneld D, Beltan E, Chalabi T., (2009). Red blood cell aggregation, aggregate strength and oxygen transport potential of blood are abnormal in both homozygous sickle cell anemia and sickle-hemoglobin C disease. Haematologica; 94:1060-5.

Vichinsky EP, Neumayr LD, Earles AN, (2000). Causes and outcomes of the acute chest syndrome in sickle cell disease. National Acute Chest Syndrome Study Group, N Engl J Med 2000;342:1855–65.

Wade A (1999). Statistics and Research Methodology London: Institute of Child Health

Ware, J. E., & Sherbourne, C. (1992). Quality of Life (QOL) – measured with the 36 item Short Form Questionnaire. The MOS 36 item short-form health survey (SF-36) 1: Conceptual framework and item selection. Medical Care, 30, 473–83.

WHO, international disaster report/5517

WHO,(1997), WHOQOL Measuring Quality of Life, p (1).

World Health Organisation. (2006) Sickle cell anaemia. Fifty-Ninth World Assembly A59/9, Geneva. http://apps.who.int/gb/ebwha/pdf_files/WHA59/A59_9-en.pdf (accessed 18th July 2015).

World Medical Association. (2013), World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. *JAMA*;310(20):2191-2194. doi:10.1001/jama.2013.281053

Zeltzer L, Dash J, Holland JP (1979) Hypnotically induced pain control in sickle cell anaemia. Pediatrics'; 64(4):533-6.

Zigmond AS, Snaith P. The hospital anxiety and depression scale (1983) Acta Psychiatr Scand.67:361-70. Doi:10.111/j.1600-0447.1983.tb09716.x.

APPENDIX 1

THE EFFECT OF A COGNITIVE BEHAVIOURAL INTERVENTION ON COPING SKILLS, QUALITY OF LIFE AND EMOTIONAL WELLBEING OF UNDERGRADUATES WITH SICKLE CELL DISEASE IN THE UNIVERSITY OF IBADAN

INFORMED CONSENT FORM

My name is Dr. Alero Adegbolagun, with the University Health Services (Jaja Clinic); I am carrying out a study on the effect of a coping skills intervention on the quality of life and emotional well-being among young adults with sickle cell disease.

The purpose is to identify your experiences coping with sickle cell disease and how it affects your mental and emotional well being and to teach effective coping methods.

Please, be assured that all information provided shall be kept confidential. Feel free to refuse to take part in this research, and you have a right to withdraw from the programme at any point in time. Refusal to take part in this research or withdrawal at any time shall not be against you in any way. However, I will greatly appreciate your full participation in the study.

Consent:

Now that the study has been well-explained to me and I fully understand its content, I am willing to participate.

Signature of Respondent…… Date.....

SECTION I:

DEMOGRAPHIC DATA

Instruction: Please tick in the appropriate box

1. Age : _____ years
2. Sex : (a) male( ) (b) female ( )
3. Religion : (a) Christianity ( ) (b) Islam ( ) (c) Others :(please specify)_____
4. Tribe: (a) Yoruba ( ) (b) Igbo ( ) (c) Hausa ( ) Others: (please specify)_____
5. Level: _____
6. Department: _____
7. No of years in the university _____
8. Current CGPA_____

CLINICAL DATA

9. Haemoglobin phenotype (a) HBSS ( ) (b) HBSC ( )
10. Visit to the emergency clinic in the last 12months_____
11. Emergency room admissions in the last 12 months _____
12. Duration of admission in the last 12 months (maximum) _____
13. Mean packed cell volume (PCV) in the last 12 months _____

SECTION II (HOSPITAL ANXIETY AND DEPRESSION SCALE)

Please give an immediate response and don't think too long about your answers.

1. I feel tense or nervous
   (3) Most of the time (2) A lot of the time (1) From time to time, occasionally (0) Not at all

2. I still enjoy the things I used to enjoy
   (0) definitely as much (1) Not quite as much (2) Only a little (3) Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen
   (3) Very definitely and quite badly (2) Yes, but not too badly (1) A little, but it doesn't worry me (0) Not at all

4. I can laugh and see the funny side of things
   (0) As much as I always could (1) Not quite so much now (2) Definitely not so much now (3) Not at all

5. Worrying thoughts go through my mind
   (3) A great deal of the time (2) A lot of the time (1) From time to time (0) Only occasionally

6. I feel cheerful
   (3) Not at all (2) Not often (1) Sometimes (0) Most of the time

7. I can sit at ease and feel relaxed
   (0) Definitely (1) Usually (2) Not often (3) Not at all

8. I feel as if I am slowed down
   (3) Nearly all the time (2) Very often (1) sometimes (0) Not at all

9. I get a sort of frightened feeling like "butterflies" in the stomach
   (0) Not at all (1) Occasionally (2) Quite often (3) Very often

10. I have lost interest in my appearance
    (3) Definitely (2) I don't take as much care as I should (1) I may not take quite as much care (0) I take just as much care as ever

11. I feel restless as I have to be on the move
    (3) Very much indeed (2) Quite a lot (1) Not very much (0) Not at all

12. I look forward with enjoyment to things
    (0) As much as I ever did (1)Rather less than I used (2) Definitely less than I used to (3) Hardly at all

13. I get sudden feelings of panic
    (3) Very often indeed (2) Quite often (1) Not very often (0) Not at all

14. I can enjoy a good book or radio or TV program
    (0) Often (1) Sometimes (2) Not often (3)Very seldom

COPING STRATEGIES QUESTIONNAIRE

SECTION III

Individuals who experience pain have developed a number of ways to cope or deal with their pain. These include saying things to themselves when they experience pain, or engaging in different activities.

Below is a list of things that patients have reported doing when they feel pain. For each activity, I want you to indicate, using the scale below, how much you engage in that activity when you feel pain where:

0	**1**	**2**	**3**	**4**	**5**	**6**
NEVER DO THAT			SOMETIMES DO THAT			ALWAYS DO THAT

Remember, you can use any point along the scale.

s/n		**0**	**1**	**2**	**3**	**4**	**5**	**6**
1.	I try to get some sleep							
2.	I imagine that the pain is outside of my body							
3.	I take a hot or cold bath							
4.	I think of things I enjoy doing							
5.	I try to think years ahead, what everything will be like after I've gotten rid of the pain							
6.	I read							
7.	I avoid pain							
8.	I realize that most people don't really care							
9.	I don't like to be with people							
10	I try to think of something pleasant							
11	I drink twice as much as I usually do							
12	I rub the parts of my body that hurt							
13	I increase my fluid intake							
14	I tell myself it doesn't hurt							
15	It is awful and I feel that it overwhelms me							
16	I try to drink some water or juice every hour							
17	I think it is not fair that I have to live this way							
18	I do something I enjoy, such as watching TV or listening to music							
19	I try to drink a lot of water							
20	I worry that I am having a heart attack or some other physical problems							
21	It is terrible and I feel it is never going to get any better							

22	I take a hot or cold shower							
23	I think no one wants to hear about my problems							
24	I go off by myself							
25	I go to bed							
26	I try to be alone							
27	I rely on my faith in God							
28	I count numbers in my head or run a song through my mind							
29	I worry that my disease is getting worse							
30	I know I need to get away from everyone							
31	I pretend it is not a part of me							
32	I massage painful areas							
33	I use ice packs to help relieve the pain							
34	I play mental games with myself to keep my mind off the pain							
35	I go to a quiet place where I won't be bothered							
36	I think of people I enjoy doing things with							
37	Although it hurts, I just keep on going							
38	I think that if I can't be healthy then no one else should be							
39	I tell myself that I can overcome the pain							
40	I try to be around other people							
41	I ignore it							
42	I have faith in doctors that someday there will be a cure for my pain							
43	I think that I don't deserve this							
44	I just go on as if nothing happened							
45	I tell myself to be brave and carry on despite the pain							
46	I worry all the time whether it will end							
47	I just think of it as some other sensation, such as numbness							
48	I know others don't understand							
49	I don't pay any attention to it							
50	I drink five or more glasses of water or juice a day							
51	I worry that I am really going to get sick							
52	I relax my muscles							
53	I do anything to get my mind 0ff the pain							
54	I am afraid I am going to die							

55	I lay down on the bed or couch in order to relax							
56	I try not to think of it as my body but rather as something separate from me							
57	I feel I can't go on							
58	I pretend it is not there							
59	I pray to God it won't last long							
60	I feel I can't stand it anymore							
61	I replay in my mind pleasant experiences in the past							
62	I do something active, like household chores or projects							
63	I try to feel distant from the pain, almost as if the pain was in somebody else's body							
64	I drink as much juice or water as I can							
65	I know I'll have to go to the hospital or see my doctor							
66	I spend time resting							
67	I know someday someone will be here to help me and it will go away for a while							
68	I don't think about the pain							
69	I leave the house and do something, such as going to the movies or shopping							
70	I try to relax							
71	I am sure there is something wrong							
72	No matter how bad it gets, I know I can handle it							
73	I tell myself I can't let the pain stand in the way of what I have to do							
74	I use a heating pad							
75	I see it as a challenge and don't let it bother me							
76	I feel my life isn't worth living							
77	I pray for the pain to stop							
78	I don't think of it as pain but rather as a dull or warm feeling							

79. Based on all the things you do to cope or deal with your pain, on an average day, how much control do you feel you have over it? Please circle the appropriate number.

Remember, you can circle any number along the scale.

0	**1**	**2**	**3**	**4**	**5**	**6**

No control — Some control — Complete control

80. Based on all the things you do to cope or deal with your pain, on an average day, how much control are you able to decrease it? Please circle the appropriate number.

Remember, you can circle any number along the scale.

0	**1**	**2**	**3**	**4**	**5**	**6**

Can't decrease it at all — Can decrease it somewhat — Can decrease it completely

SF-36 QUESTIONNAIRE

Please answer the 36 questions of the **Health Survey** completely, honestly, and without interruptions.

GENERAL HEALTH

1 In general, would you say your health is

1. Poor 2.Fair 3. Good 4.Very good 5.Excellent

2 Compared to one year ago, how would you rate your health in general now?

5. Much worse than one year ago
4. Somewhat worse now than one year ago
3. About the same
2. Somewhat better now than one year ago
1. Much better now than one year ago

LIMITATIONS OF ACTIVITIES:

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(3) No, Not Limited at all (2) Yes, Limited a Little (1) Yes, Limited a lot

		1	2	3
1	Vigorous activities, such running, lifting heavy objects, participating in strenuous sports			
2	Moderate activities, such as moving a table, p a vacuum cleaner, bowling, or playing golf			
3	Lifting or carrying groceries			
4	Climbing several flights of stairs			
5	Climbing one flight of stairs			
6	Bending, kneeling or stooping			
7	Walking more than 2km			
8	Walking several streets			
9	Walking one street			
10	Bathing or dressing yourself			

PHYSICAL HEALTH PROBLEMS

During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of your physical health?

s/n		1 Yes	2 No
1	Cut down the amount of time you spent on work or other activities		
2	Accomplishing less than you would like		
3	Were limited in the kind of work or other activities		
4	Had difficulty performing the work or other activities (for example, it took extra effort)		

EMOTIONAL HEALTH PROBLEMS

During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

s/n		**1 Yes**	**2 No**
1.	Cut down the amount of time you spent on work or other activities		
2	Accomplishing less than you would like		
3	Didn't do work or other activities as carefully as usual		

SOCIAL ACTIVITIES:

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbour, or groups?

(1) Not at all (2) Slightly (3) Moderately (4) Severe (5) Very severe

PAIN:

s/n		1	2	3	4	5	6
1	How much bodily pain have you had during the past 4 weeks?	none	Very mild	Mild	moderate	severe	Very severe
2	During the past weeks, how much pain interfere with Your normal v (including both v outside and home housework)?	Not at all	A little bit	moderately	Quite a bit	Extremely	

ENERGY AND EMOTIONS:

These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

(6) None of the time (5) A little bit of the time (4) Some of the time (3)A good bit of time

(2) Most of the time (1) All of the time

s/n		1	2	3	4	5	6
1.	Did you feel full of life (cheerful happy)?						
2	Have you been a very nervous person						
3	Have you felt so down in your spirit t Nothing could cheer you up?						
4	Have you felt calm and peaceful?						
5	Did you have a lot of energy?						
6	Have you felt downhearted and sad?						
7	Do you feel extremely tired exhausted						
8	Have you been a happy person?						
9	Did you feel tired?						

SOCIAL ACTIVITIES

(1)All of the time (2) Most of the time (3) some of the time
(4)A little bit of the time (5) none of the time

	1	2	3	4	5
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc)?					

GENERAL HEALTH:

How true or false is each of the following statements for you?

Please tick (√)

(1) Definitely true (2) Mostly true (3) Don't know (4) Mostly false (5) definitely false

s/n		1	2	3	4	5
1	I seem to get sick a little easier than other people					
2	I am as healthy as anybody I know					
3	I expect my health to get worse					
4	My health is excellent					

KNOWLEDGE QUESTIONNAIRE

(1) Sickle cell disease can be acquired by other means apart from being inherited from both parents? (a) True [ ] (b) Not sure [ ] (c) False [ ]

(2) The onset of every sickle cell crises can be predicted? (a) True [ ] (b) Not sure [ ] (c) False [ ]

(3) No other treatment can make sickle cell pain better apart from medication? (a) True [ ] (b) Not sure [ ] (c) False [ ]

(4) When a person has pain from sickle cell they have to stop doing enjoyable activities? (a) True [ ] (b) Not sure [ ] (c) False [ ]

(5) Doing enjoyable activities including physical exercises can help cope with sickle cell disease? (a) True [ ] (b) Not sure [ ] (c) False [ ]

(6) The way we think about a situation can affect how we feel? (a) True [ ] (b) Not sure [ ] (c) False [ ]

(7) Deep slow breathing can help us feel relaxed? (a) True [ ] (b) Not sure [ ] (c) False [ ]

(8) Assertiveness is the best way of communicating in order to get optimum care? (a)True [ ] (b) Not sure [ ] (c) False [ ]

Please circle the number 0 - 10 that apply to you about this intervention:

1. How much did you know about positive coping strategies for sickle cell before the intervention?

(No knowledge) 0 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 (very knowledgeable)

2. How much do you now know about coping strategies for sickle cell?

(No knowledge) 0 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 (very knowledgeable)

3. How much did you know about the importance of changing the way we think to change the way we feel before the intervention?

(No knowledge) 0 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 (very knowledgeable)

4. How much do you now know about the importance of changing the way we think as a way of changing how we feel after the intervention?

(No knowledge) 0 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 (very knowledgeable)

5. How confident did you feel about coping with sickle cell before the intervention?

(Not confident) 0 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 (very confident)

6. How confident do you feel now about coping with sickle cell after the intervention?

(Not confident) 0 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 (very confident)

7. How much of the things you learnt from the intervention have you started putting into practice?

(None) 0 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 (a lot)

9. Overall how much new things did you learn about sickle cell and positive coping strategies?

(None) 0 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 (a lot)

CLIENT SATISFACTION QUESTIONNAIRE

(1) How would you rate the intervention?

_____4 _____3 _____2 _____1

Excellent Good Fair Poor

(2) Did you get the kind of help you wanted?

_____1 _____2 _____3 _____4_____

Not at all not really Yes generally Yes definitely

(3) If a friend had a similar problem, would you recommend the intervention to him/her?

_____1 _____ 2 _____ 3_____ 4_____

Definitely not No, probably not Yes Probably Yes definitely

(4) How satisfied are you with the help you received?

_____1 _____2 _____ 3 _____ 4_____

Very dissatisfied quite dissatisfied Mostly satisfied Very satisfied

(5) Has the intervention helped you to cope better with your sickle cell?

_____4 _____3 _____2 _____1_____

Yes a lot Yes a little No it didn't really help No things even got worse

(6) Overall, how satisfied are you with the intervention?

_____4 _____3 _____2 _____1_____

Very satisfied Mostly satisfied Not very satisfied Very dissatisfied

(7) If you were to need help again, would you come back to the intervention?

_____1 _____2 _____ 3 _____ 4_____

No definitely not No probably not Yes probably Yes definitely

(8) What I liked best about the intervention is _____

(9) What I didn't like about the intervention is _____

(10) My suggestions to improve the intervention are:_____

APPENDIX 2

The Short Form Health Survey Questionnaire (SF-36)

INTRODUCTION

The RAND 36-Item Health Survey (Version 1.0) taps eight health concepts: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions. It also includes a single item that provides an indication of perceived change in health. These 36 items, presented here, are identical to the MOS SF-36 described in Ware and Sherbourne (1992). They were adapted from longer instruments completed by patients participating in the Medical Outcomes Study (MOS), an observational study of variations in physician practice styles and patient outcomes in different systems of health care delivery (Hays & Shapiro, 1992; Stewart, Sherbourne, Hays, et al., 1992). A revised version of the RAND 36-Item Health Survey (Version 1.1) that differs slightly from Version 1.0 in terms of item wording is currently in development.

SCORING RULES FOR THE RAND 36-ITEM HEALTH SURVEY (Version 1.0)

We recommend that responses be scored as described below. A somewhat different scoring procedure for the MOS SF-36 has been distributed by the International Resource Center for Health Care Assessment (located in Boston, MA). Because the scoring method described here (a simpler and more straightforward procedure) differs from that of the MOS SF-36, persons using this scoring method should refer to the instrument as the RAND 36-Item Health Survey 1.0.

Scoring the RAND 36-Item Health Survey is a two-step process. First, precoded numeric values are recoded per the scoring key given in Table 1. Note that all items are scored so that a high score defines a more favorable health state. In addition, each item is scored on a 0 to 100 range so that the lowest and highest possible scores are set at 0 and 100, respectively. Scores represent the percentage of total possible score achieved. In step 2, items in the same scale are averaged together to create the 8 scale scores. Table 2 lists the items averaged together to create each scale. Items that are left blank (missing data) are not taken into account when calculating the scale scores. Hence, scale scores represent the average for all items in the scale that the respondent answered.

Example: Items 20 and 32 are used to score the measure of social functioning. Each of the two items has 5 response choices However, a high score

(response choice 5) on item 20 indicates extreme limitations in social functioning, while a high score (response choice 5) on item 32 indicates the absence of limitations in social functioning. To score both items in the same direction, Table 1 shows that responses 1 through 5 for item 20 should be recoded to values of 100, 75, 50, 25, and 0, respectively. Responses 1 through 5 for item 32 should be recoded to values of 0, 25, 50, 75, and 100, respectively. Table 2 shows that these two recoded items should be averaged together to form the social functioning scale. If the respondent is missing one of the two items, the person's score will be equal to that of the nonmissing item.

Table 3 presents information on the reliability, central tendency and variability of the scales scored using this method.

References

1. Ware, J.E., Jr., and Sherbourne, C.D. "The MOS 36-Item Short-Form Health Survey (SF-36): I. Conceptual Framework and Item Selection," *Medical Care*, 30:473-483, 1992.

2. Hays, R.D., & Shapiro, M.F. "An Overview of Generic Health-Related Quality of Life Measures For HIV Research," *Quality of Life Research,* 1: 91-97, 1992.

3. Stewart, A. L., Sherbourne, C., Hays, R. D., et al. "Summary and Discussion of MOS Measures," In A. L. Stewart & J. E. Ware (eds.), *Measuring Functioning and Well-Being: The Medical Outcome Study Approach* (pp. 345-371). Durham, NC: Duke University Press, 1992.

Table 1

STEP 1: RECODING ITEMS

ITEM NUMBERS	Change original response category [a]	To recoded value of:
1,2,20,22,34,36	1 ---------->	100
	2 ---------->	75
	3 ---------->	50
	4 ---------->	25
	5 ---------->	0
3,4,5,6,7,8,9,10,11,12	1 ---------->	0
	2 ---------->	50
	3 ---------->	100
13,14,15,16,17,18,19	1 ---------->	0
	2 ---------->	100
21,23,26,27,30	1 ---------->	100
	2 ---------->	80
	3 ---------->	60
	4 ---------->	40
	5 ---------->	20
	6 ---------->	0
24,25,28,29,31	1 ---------->	0
	2 ---------->	20
	3 ---------->	40
	4 ---------->	60
	5 ---------->	80
	6 ---------->	100
32,33,35	1 ---------->	0
	2 ---------->	25
	3 ---------->	50
	4 ---------->	75
	5 ---------->	100

(a) Precoded response choices as printed in the questionnaire.

Table 2

STEP 2: AVERAGING ITEMS TO FORM SCALES

Scale	Number Of Items	After Recoding Per Table 1, Average The Following Items:
Physical functioning	10	3 4 5 6 7 8 9 10 11 12
Role limitations due to physical health	4	13 14 15 16
Role limitations due to emotional problems	3	17 18 19
Energy/fatigue	4	23 27 29 31
Emotional well-being	5	24 25 26 28 30
Social functioning	2	20 32
Pain	2	21 22
General health	5	1 33 34 35 36

Table 3

RELIABILITY, CENTRAL TENDENCY AND VARIABILITY OF SCALES IN THE MEDICAL OUTCOMES STUDY

Scale	Items	Alpha	Mean	SD
Physical functioning	10	0.93	70.61	27.42
Role functioning/physical	4	0.84	52.97	40.78
Role functioning/emotional	3	0.83	65.78	40.71
Energy/fatigue	4	0.86	52.15	22.39
Emotional well-being	5	0.90	70.38	21.97
Social functioning	2	0.85	78.77	25.43
Pain	2	0.78	70.77	25.46
General health	5	0.78	56.99	21.11
Health change	1	----	59.14	23.12

Note: Data is from baseline of the Medical Outcomes Study (N = 2471), except for Health change, which was obtained one-year later.

Statistics and Research Methodology

Statistics and Research Methodology

Angie Wade
Institute of Child Health
1999

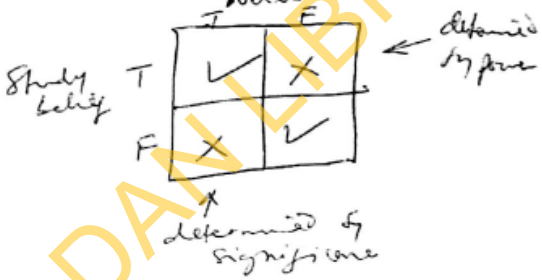
FORMULAE FOR DEMONSTRATING A SIGNIFICANT EFFECT

The first step is to decide on appropriate values for the significance level and power. From these we obtain a value F from the following table.

		Power required :- 80%	90%	95%	99%
SIGNIFICANCE LEVEL required (p-value) :-	0.100	6.18	8.56	10.82	15.77
	0.050	7.85	10.51	12.99	18.37
	0.025	9.51	12.41	15.10	20.86
	0.010	11.68	14.88	17.81	24.03

E.g. For a sample adequate to detect a difference significant at 5% (2-sided) with a power of 90% choose F=10.51. I.e. With F taken to be 10.51 we expect to obtain a false positive result (saying there is a difference when none exists) 5% of the time and to detect a difference, if one actually exists, 90% of the time.

Let **d** be the smallest difference considered to be of clinical or scientific importance.



ONE SAMPLE

5. Mean : σ Standard deviation of the values

$$n > \frac{F\sigma^2}{d^2} = F\left(\frac{\sigma}{d}\right)^2$$

6. Proportion or percentage : p Proportion or $p_{\%}$ Percentage

$$n > \frac{Fp(1-p)}{d^2} \quad \text{or} \quad n > \frac{Fp_{\%}(100-p_{\%})}{d^2}$$

TWO SAMPLES

- Calculated n is the requirement for EACH sample

7. Difference between two means : σ Standard deviation of each of the samples

$$n > \frac{2F\sigma^2}{d^2} = 2F\left(\frac{\sigma}{d}\right)^2$$

8. Difference between two proportions or percentages :

p_1, p_2 Proportions or $p_1^{\%}$, $p_2^{\%}$ Proportions

$$n > \frac{F[p_1(1-p_1)+p_2(1-p_2)]}{d^2} \quad \text{or} \quad n > \frac{F[p_1^{\%}(100-p_1^{\%})+p_2^{\%}(100-p_2^{\%})]}{d^2}$$

APPENDIX 4

INSTITUTE FOR ADVANCED MEDICAL RESEARCH AND TRAINING (IAMRAT)
College of Medicine, University of Ibadan, Ibadan, Nigeria.

Director: **Prof. Catherine O. Falade,** *MBBS (Ib), M.Sc, FMCP, FWACP*
Tel: 0803 326 4593, 0802 360 9151
e-mail: cfalade@comui.edu.ng lillyfunke@yahoo.com

UI/UCH EC Registration Number: **NHREC/05/01/2008a**

NOTICE OF FULL APPROVAL AFTER FULL COMMITTEE REVIEW

Re: The Effect of Cognitive Behavioural Intervention on Coping, Quality of Life and Emotional Wellbeing in undergraduates of the University of Ibadan with Sickle Cell Disease

UI/UCH Ethics Committee assigned number: UI/EC/16/0018

Name of Principal Investigator: **Dr. Alero Adegbolagun**
Address of Principal Investigator: Department of Psychiatry
College of Medicine,
University of Ibadan, Ibadan

Date of receipt of valid application: 18/01/2016

Date of meeting when final determination on ethical approval was made: **N/A**

This is to inform you that the research described in the submitted protocol, consent form, and other participant information materials have been reviewed and *given full approval by the UI/UCH Ethics Committee.*

This approval dates from **09/03/2016 to 08/03/2017.** If there is delay in starting the research, please inform the UI/UCH Ethics Committee so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of these dates. *All informed consent forms used in this study must carry the* UI/UCH EC *assigned number and duration of* UI/UCH EC *approval of the study.* It is expected that you submit your annual report as well as an annual request for the project renewal to the UI/UCH EC early in order to obtain renewal of your approval to avoid disruption of your research.

The National Code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the Code including ensuring that all adverse events are reported promptly to the UI/UCH EC. *No changes are permitted in the research without prior approval by the* UI/UCH EC *except in circumstances outlined in the Code. The* UI/UCH EC *reserves the right to conduct compliance visit to your research site without previous notification.*

UI/UCH EC
09 MAR 2016
APPROVED
COLLEGE OF MEDICINE, UI

Professor Catherine O. Falade
Director, IAMRAT
Chairperson, UI/UCH Ethics Committee
E-mail: uiuchec@gmail.com