DEVELOPMENT AND PSYCHOMETRIC TESTING OF IBADAN STROKE-SPECIFIC PAIN SCALE

OSUNDIYA, OLADUNNI CAROLINE

DEVELOPMENT AND PSYCHOMETRIC TESTING OF IBADAN STROKE-SPECIFIC PAIN SCALE

BY

OSUNDIYA, OLADUNNI CAROLINE

MSc (Neurological Phyiotherapy)

A Thesis in the Department of Physiotherapy Submitted to the Postgraduate School, University of Ibadan, in partial fulfilment of the requirements for the Degree of

DOCTOR OF PHILOSOPHY (NEUROLOGICAL PHYSIOTHERAPY)

of the

UNIVERSITY OF IBADAN

SEPTEMBER, 2014

CERTIFICATION

We certify that this research work was carried out by Mrs Oladunni C. Osundiya of the Department of Physiotherapy, College of Medicine, University of Ibadan under our supervision.

Supervisor

Professor T.K. Hamzat (PhD, Ib)
Department of Physiotherapy
College of Medicine
University of Ibadan
Ibadan

Co-supervisor

Dr M.O. Owolabi (MBBS; MSc; FMCP; Dr Med)
Department of Medicine
College of Medicine
University of Ibadan
Ibadan

DEDICATION

This work is specially dedicated to my dear OLUSEGUN and our lovely children: TOLUWALEYI, TOLUWALASE and TOLUWALOPE for their unequalled support throughout the course of this study.

ABSTRACT

Post-stroke pain is a common and multifaceted condition that significantly limits stroke survivors' potentials for functional recovery. Appropriate assessment of post-stroke pain is useful in evaluating the effectiveness of interventions aimed at controlling it. Generic pain scales are inadequate in capturing the peculiarities of post-stroke pain. Literature search revealed no stroke-specific pain scale. A stroke-specific pain rating scale, the 'Ibadan Stroke-Specific Pain Scale'(IbSSPS) was developed and psychometrically tested in this study.

Development and psychometric testing of the IbSSPS were carried out using qualitative and quantitative research designs respectively. Potential scale items were generated through four sessions of Focus Group Discussions (FGDs) involving 18 purposively selected individuals with stroke-related pain at the University College Hospital, Ibadan. Different aspects of post-stroke pain and its impact on their daily functioning were explored. Items generated from the FGDs were grouped into four themes based on the domains of interest namely: pain location and severity, psychosocial functioning, physical functioning, and signs and symptoms. The items of IbSSPS were reviewed by a panel of clinical experts and pre-tested among another 30 stroke survivors to rule out ambiguity, establish comprehension and endorsement. A four-domain, 36-item IbSSPS, with scores ranging from 0 to 116 (higher score indicating higher pain status) was subsequently developed. The IbSSPS was tested for reliability and responsiveness among 56 (27 males and 29 females) consecutive stroke survivors (Index Group) and 56 (27 males and 29 females) apparently healthy age and sex-matched counterparts (Control) for known-group validity. The categorised verbal descriptor pain scale was used for convergent validity. Also, the IbSSPS was administered after a two-hour interval to assess the test-retest reliability and after six weeks to test responsiveness. Data were analysed using Mann-Whitney U, Spearman correlation, intraclass correlation coefficient (ICC), Cronbach's alpha coefficient, Wilcoxon Sign rank test, standardised effect size and standardised response mean at p=0.05.

The baseline IbSSPS median total score for the index group (37.0; range: 2 to 82) was significantly higher than the control group (3.0; range: 0 to 15). The IbSSPS score for pain

location and severity domain was significantly correlated with the categorised verbal descriptor pain scale (r = 0.65). The other domains had weak to moderate correlations (r =0.29 to 0.58). The ICC ranged from 0.85 to 0.94 while Cronbach's alpha ranged from 0.64 to 0.90 for the four domains. At 6 weeks, the IbSSPS also detected changes in pain status for all the domains: pain location and severity (from 6.8 to 4.6), psychosocial functioning (from 10.2 to 7.9), physical functioning (from 20.8 to 17.7), signs and symptoms (from 3.5 to 2.3) and total score (from 41.5 to 32.4). The standardised effect size and standardised response mean ranged from 0.31 to 0.70 and 0.50 to 0.90 respectively.

The Ibadan Stroke-Specific Pain Scale is a reliable and responsive instrument for assessing post-stroke pain. The instrument is recommended for evaluating and tracking changes in pain experienced by stroke survivors.

Keywords: Post-stroke pain, stroke-specific pain scale, Psychosocial function

Word Count: 480

ACKNOWLEDGEMENT

l wish to express my sincere gratitude to all those who have contributed to the successful completion of this work. A special thanks to my long-suffering supervisor Prof. T. K. Hamzat who never gave up on me even when l almost gave up on myself. Thanks for all your advice and professional skills. Thanks for the insight you gave me into this area of stroke that became more interesting as l moved on with the work. I also want to greatly appreciate the immense contribution of my co-supervisor, Dr. M. O. Owolabi, a very busy man who never got tired of giving my work the desired time. Thanks for your professional input into this work and for those areas you stood your ground even when it appeared not workable.

My big thanks to Dr Aderonke O. Akinpelu, Dr B.O.A. Adegoke and Dr Oladapo O. Taiwo for their encouragement. My sincere gratitude goes to Prof. Aarinola Sanya, for her motherly role, encouragement and timely prodding which she was very generous with. At that critical moment that l gave up on the work, God used you to push me on. You will not be stranded in life.

To the experts who were of great help in this study, Dr M.O. Owolabi, Dr B. B. Osinaike, Dr A.O. Olaleye, Dr A.C. Odole, Dr Ekanem, Mrs N. A. Odunaiya, Mr R.O. Olaseinde, Mr A.O. Adejare. Thanks a lot. A big thanks to Dr J.O. Akinyemi for helping with the data analysis. My lovely friends, Mrs Akinwande and Mrs B.M.S. Tinubu, thanks for always being there. My aburos: Dr Faderera Adepoju and Mrs A. A. Osose, my lovely unit members, Mrs R. O. Anyakudo, Mrs O. F. Kehinde, Mrs K.O. Atobatele, Mr B. I. Uwumagbe, Mrs T. A. Adekanla, Mr A. O. Adepoju and Mr F. D. Akintola thanks for your support. Mr Ogunbowale Eze, I cannot forget to say thank you.

To all stroke survivors who patricipated in this study, l say a big thank you. lf you did not participate, there would have been no study. May you get relief from all your pains. My lovely siblings, Titi, Niyi, Deji and Wole, l appreciate your unequalled love and encouragement. My lovely sister Olanike, l didn't leave you out of this though you've gone ahead to rest in the bossom of the lord. l cannot forget your love. You kept

encouraging me till that particular week you decided to surrender to the will of God. Sleep on till we see on the resurrection day. To my father Pa Simeon Faleye and my mum Mrs Lydia Faleye both of blessed memories, thanks for the beautiful start you gave me in life. You were convinced beyond measure that l would get to great height in life and handled me as your true princess.

To my wonderful husband, friend, brother and daddy Olusegun, you are lovely. Who could have tolerated me as you did? Thank you for the peace of mind you gave me to do this work and all the support. And my lovely jewels: Toluwaleyi, Toluwalase and Toluwalope, l'm proud to be your mum. This will be the least height you will get to in life by the grace of God.

To the Almighty God, my creator, my strength, my help in ages past. Everything came to be because you allowed it. l bow my knees in adoration to you lord.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER ONE

INTRODUCTION

1.1 Introduction

Stroke is broadly classified as ischaemic and hemorrhagic types. 'Central nervous system infarction is defined as brain, spinal cord, or retinal cell death attributable to ischaemia, based on neuropathological, neuroimaging, and/or clinical evidence of permanent injury (Sacco et al, 2013). It occurs over a clinical spectrum: Ischaemic stroke specifically refers to central nervous system infarction accompanied by overt symptoms, while silent infarction by definition causes no known symptoms. Stroke also broadly includes intracerebral hemorrhage and subarachnoid hemorrhage'(Sacco et al, 2013). It is the leading cause of disability among adults, more than accidents or complications from Parkinson's or Alzheimer's diseases (Adamson et al, 2004; Krakauer, 2005; Fridriksson, 2010) with resulting significant impact on the independence, quality of life and productivity of the survivors (Obembe et al, 2014).

It is a common entity in African Nigerians and remains a significant cause of mortality at all times beyond the onset and the need for intensive care of patients with stroke has been emphasized (Ogun et al, 2005). It therefore appears to be a huge problem in Nigeria, placing a major financial burden on the inadequate health services in the country (Ogun et al, 2005).

The neurological insult following a stroke may leave the survivor with a chronic illness encompassing a lifetime of recovery (Vanhook, 2009), as well as a multitude of challenges to restore their highest quality of life within the limitations of residual impairment (Bays, 2001). The type of disability that follows a stroke depends upon which area of the brain is damaged, and may correlate to the patient's neurologic deficits with the expected sites of cortical compromise (Warlow et al, 2001). The recovery of patients with stroke represents a great challenge, not only

due to the complexity of the lost functions, but also the high incidence of pain, resulting in a negative impact during the rehabilitation process (Klotz et al, 2006).

Pain which is one of the most common and highly challenging medical problems in health care is one of the most frequently observed complications that occur after a stroke (Zorowitz et al, 2005). It is increasingly recognised as a consequence of stroke (Klit et al, 2011; Miller et al, 2013) and an important clinical factor that can limit movement at a joint and inhibit the functional use of a limb after a stroke (Hamzat and Osundiya, 2010). Post-stroke pain is seen in up to 50% of stroke survivors, hence necessitating that all patients should be asked if they are experiencing pain (Zorowitz et al, 2005). Pain after a stroke spans a spectrum: from irritating headaches, to crippling joint pain, to shoulder subluxation, to the difficult-to-treat central post- stroke pain (Jonsson et al, 2006).

Post-stroke pain may be nociceptive (neuromuscular or local pain) or neuropathic, that is, central post-stroke pain (CPSP) (Roosink et al, 2010). However, mixed pain is also common after stroke with peripheral nociceptive pain coinciding with symptoms characteristic of central post-stroke pain (Roosink et al, 2010). Many patients with CPSP have a combination of both inflammatory and neuropathic pain elements. When located in the same area, it can be difficult to differentiate them (Klit et al, 2009). For some patients, post-stroke pain may be serious enough to jeopardise their recovery by preventing them from participating in rehabilitation. Whatever the pain intensity, it compromises quality of life for patient and the caregiver alike (Jonsson et al, 2006). Recovery for the stroke survivor entails more than the return of function.

The aim of stroke rehabilitation is for the patient to regain the best level of health, activity and participation possible within the limits of any persisting stroke impairment (Vanhook, 2009). People who have suffered a stroke have reported needs for health care services that are to a large extent unmet, including post-stroke pain (Tistad et al, 2012). In a study by Tistad et al (2012) to assess the unfulfilled rehabilitation needs and dissatisfaction with care 12 months after a stroke, 33% reported unmet needs and 14% were dissatisfied with care received the first year after stroke. The Agency for Healthcare Policy Research Guidelines for Post-stroke Rehabilitation (AHCPR) recommends a pain management plan that includes assessment of likely (musculoskeletal and neuropathic); pain location, pain quality, quantity, duration and intensity

and what aggravates or relieves the pain (Duncan et al, 2005). Hence providers are enjoined to improve their performance with respect to pain management (Starck et al, 2001).

Inability to self report pain by stroke survivors has been found to be associated with measures of stroke severity, aphasia severity, and level of consciousness thereby making it more common for stroke survivors to be able to rate pain than previously thought (Smith et al, 2013). Assessment and evaluation is paramount to the treatment of any condition, hence the need for accurate assessment of pain in both clinical and research setting (Price et al, 1999). The choice of a pain scale should depend on the setting, the clinicians goal, and the patient's level of education. Also, disease-specific measures have been found to quantify the impact of a specific pain problem on function and can be used to track changes after an intervention (Garratt et al, 2001). However, patient preference is central to better clinician-patient communication (Clark et al, 2003). Self-report measures provide the "gold standard" in assessing pain outcomes because they reflect the inherently subjective nature of pain, but they should be supplemented by careful assessment (Karoly, 2001; Jensen, 2003).

1.2 Statement of the Problem

Health care providers have been enjoined to carry out pain assessment in stroke survivors in order to initiate proper referral and treatment (Zeferino and Haycocks, 2010). Assessment and measurement of pain are fundamental to the process of assisting in the diagnosis of the cause of a patient's pain, selecting an appropriate therapy and modifying that therapy according to a patient's response (Zeferino and Haycocks, 2010).

Developing an instrument takes considerable time, effort, and resources. Therefore, exploring existing measures is necessary (Turk et al, 2006). A literature review of available stroke assessment measures and studies on stroke revealed substantial evidence of the presence of pain following a stroke (Zorowitz et al, 2005; Hadianfard and Hadiafard, 2008; Hamzat and Osundiya, 2010; Smith, 2012).

Available outcome measures for assessment of neuropathic pain (a type of post-stroke pain) like the Leeds Assessment of Neuropathic Signs and Symptoms (LANSS) and the Neuropathic Pain

Scale are aimed at distinguishing between nociceptive and neuropathic pain which cannot be emphasised in post stroke pain evaluation. These measures do not capture the entire spectrum of pain experienced by stroke survivors. Most stroke patients experience more than one type of pain and that it involves more than one joint / location is a significant point of concern (Klit et al, 2009; Roosink et al, 2010). Other commonly used pain rating scales such as Visual Analogue Scale (VAS), Box numerical scale have not been found to be valid in the stroke population. Verbal Rating Scale (VRS) and Numerical rating scales tend to be preferred over the Visual Analogue Scale (VAS) by patients with respect to lost data from patients failing to complete the measure correctly, patient preference, and ease of data recording (Jensen and Karoly, 2010). The faces pain scale was preferred to VAS and Verbal rating scales (VRS) by people with left hemispheric stroke while those with right hemispheric stroke prefered the VAS. However, the sole use of the faces pain scale is not recommended in stroke patients. This is because of paucity of information on uses of faces pain scale in stroke patents for assessing changes in severity of pain over time (Benaim et al, 2007). Also, VAS is susceptible to some bias with some patients likely to give higher scores through a desire to please (Edwards et al, 2002).

The implication of the foregoing is that caution is needed when using the traditional scales to rate pain (a subjective health status) from stroke patients (with higher cortical deficits). The best way therefore to assess pain in such patients may be by using a tool that combines self report with physical examination (Williamson and Hoggart et al, 2005). However, there is no readily available stroke-specific pain measuring scale hence the need to develop a stroke-specific pain scale and psychometrically test the new instrument. Four important questions of adequate degree of construct validity, responsiveness and reliability would be relevant with regards the new instrument. The following questions were answered in this study:

i. Will the newly developed stroke-specific pain scale demonstrate adequate degree of validity?
ii. Will the newly developed stroke-specific pain scale demonstrate adequate degree of test-retest reliability?
iii. Will the newly developed stroke-specific pain scale demonstrate adequate degree of responsiveness?

iv. Will the newly developed stroke-specific pain scale demonstrate adequate degree of internal consistency?

1.3 Aims of the Study

The aims of this study were:

i. To develop a stroke-specific pain scale that can identify: Pain location / severity, associated symptoms, pain interference with physical functioning and psychosocial functioning.
ii. To determine the construct validity of the newly developed stroke-specific pain scale
iii. To determine the responsiveness of the newly developed stroke-specifc pain scale
iv. To determine the internal consistency and test-retest reliability of the newly developed stroke-specific pain scale.

1.4 Hypotheses

1.4.1 Major Hypothesis

The newly developed 'Ibadan Stroke-Specific Pain Scale -IbSSPS' will not be a valid, reliable or responsive instrument in assessing pain among stroke survivors.

1.4.2 Sub hypotheses.

1. There will be no significant difference between the scores on the IbSSPS obtained from post-stroke patients and their age/sex-matched apparently healthy counterparts (Known-group validity).
2. There will be no significant correlation between the scores obtained on the Categorized Verbal Descriptor pain scale and the IbSSPS by the same group of stroke survivors (Convergent validity).
3. There will be no significant difference between the IbSSPS score of the stroke survivors before and after 6 weeks of physiotherapy intervention (Responsiveness).
4. There will be no significant correlation between scores obtained on the IbSSPS by the same group of stroke survivors on two different occasions (Test-retest reliability)

1.5 Inclusion Criteria

a. Stroke survivors with first-incidence stroke of not longer than 12 months onset and who were experiencing pain at the time of the study.
b. Stroke survivors who could comprehend instructions in English language.

1.6 Exclusion Criteria

Stroke survivors with severe language and cognitive impairment were excluded from this study.

1.7 Limitation

A short-term test retest interval of two hours was used for ethical reasons which may introduce a measure of recall bias.

1.8 Significance of the Study

1. The outcome of this study has produced a valid, reliable, and responsive stroke-specific pain scale that is clinically useful, and which may facilitate a broader description of post-stroke pain thereby making it easier to track changes in intervention.
2. This new instrument is useful in detecting clinically relevant differences and meaningful comparisons among treatment options in pain management after a stroke.

1.9 Definition of Terms

1.9.1.0 Validity is generally described as the degree to which a study accurately reflects or assesses the specific concept that the researcher is attempting to measure (Terwee et al, 2007). It means an instrument fulfils it's function. Recent view of validity focuses on the interpretation and measuring of the scores derived from an instrument i.e. the extent to which theory and evidence support the proposed use of tests (Whiston, 2005).

1.9.1.1 Face Validity refers to the researcher's subjective assessments of the presentation and relevance of the measuring instrument as to whether the items in the instrument appear to be relevant, reasonable, unambiguous and clear. It is believed not to be a true indicatorof validity and hence should not be considered as one (Kaplan and Saccuzzo, 2005; Whiston, 2005)

1.9.1.2 Content Validity is the extent to which the concepts of interest are comprehensively represented by the items in the questionnaire (Mokkink et al, 2010). It is a theoretical concept that focuses on the extent to which the instrument of measurementshows evidence of fairly and comprehensive coverage of the domain of items that it purports to cover. It shows the degree to which a measure covers the range of meanings included within a concept (Babbie, 2007).

1.9.1.3 Criterion Validity refers to the extent to which scores on a particular instrument relate to a gold standard (Mokkink et al, 2010). It is a standard of judgement or an established standard against which other measure is compared (Kaplan and Saccuzzo, 2005). It covers correlations of the measure with another criterion measure, which is accepted as valid (Bowling, 2009)

1.9.1.4 Construct Validity refers to the extent to which scores on a particular instrument relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured (Terwee et al, 2007). It is based on the logical relationships among variables. It shows the degree to which inferences are legitimately made from the operationalisations in one's study to the theoretical constructs on which those operationalisations are based (Kaplan and Saccuzzo, 2005).

Convergent validity requires that the scores derived from the measuring instrument correlate with the scores derived from similar variables (Cooper and Schindler, 2001) i.e. whether the instrument is related to variables to which it should be related if the instrument were valid (Chou et al, 2005). However, *discriminant validity* suggests that the construct in question is different from other potentially similar construct (Cooper and Schindler, 2001). This means the measurement is unrelated to variables to which it should be unrelated if the instrument were valid (Chou et al, 2005). Also *known-group validity* , the two groups are expected to differ on the test i.e. the tests are expected to be able to discriminate between the two groups (Cooper and Schindler, 2001).

1.9.1.5 Factorial validity is a form of construct validity that is established through factor analysis. Factor analysis is a term that represents a large number of different mathematical procedures for analysing the interrelationships among a set of variables and for explaining these

interrelationships in terms of a reduced number of variables, called factors. A factor is a hypothetical variable that influences scores on one or more observed variables (Markovic et al, 2004)

1.9.2.0 Reliability is the degree of consistency with which an instrument measures a variable. Reliability concerns the degree to which patients can be distinguished from each other despite measurement error (Terwee et al, 2007).

1.9.2.1 Test-retest reliability refers to stability of scores over time in subjects whose condition has remained stable. It involves instrument self-completion on two occasions separated by a suitable time–period and assuming no change in the underlying health state. It measures the temporal stability of the score (Terwee et al, 2007).

1.9.2.2 Intra-rater and Inter-rater reliability testing is the process by which a measurement tool or method can be shown to give similar results when used by same raters at different times for the same group of subjects while inter-rater reliability is the extent of agreement of two measures by two examiners independent assessment of the same subect (Post et al, 2011; Kurande et al, 2013).

1.9.2.3 Internal Consistency Reliability is a measure of the extent to which items in a questionnaire (sub) scale are correlated (homogenous), thus measuring the same concept (Kurande et al, 2013). Internal consistency is an important measurement property for questionnaires that intend to measure a single underlying concept (construct) by using multiple items. For questionnaires in which the items are merely different aspects of a complex clinical phenomenon that do not have to be correlated, such as in the Apgar Scale, internal consistency is not relevant (Mokkink et al, 2010).

After determining the number of (homogenous) (sub) scales, Cronbach's alpha should be calculated for each (sub) scale separately. Cronbach's alpha is considered an adequate measure of internal consistency. A low Cronbach's alpha indicates a lack of correlation between the items in a scale which makes summarizing the items unjustified. A very high Cronbach's alpha indicates high correlations among the items in a scale, i.e, redundancy of one or more items. A

very high Cronbach's alpha is usually found for scales with a large number of items, because cronbach's alpha is dependent upon the number of items in a scale (Post et al, 2011).

1.9.3 Responsiveness is the ability of a measurement tool to detect meaningful changes over time (Terwee et al, 2007). The ability of a questionnaire to detect clinically important changes over time, even if these changes are small. lt is a measure of longitudinal validity. The instrument should be able to distinguish clinically important change from measurement error (Terwee et al, 2007; Mokkink et al, 2010).

1.9.4 Sensitivity to change is the ability of a measure to show a statistically significant change irrespective of the relevance or meaningfulness of such change (Liang et al, 2002).

1.9.5 Interpretability of the Items is the degree to which one can assign qualitative meaning to quantitative score (Mokkink et al, 2010). Completing the questionnaire should not require reading skills beyond that of a 12-year old to avoid missing values and unreliable answers. The items should be short and simple, not consisting of two questions at the same time (Terwee et al, 2007).

CHAPTER TWO
LITERATURE REVIEW

2.1 Introduction

Stroke has been found to be associated with more individual domains of disability compared with other conditions and might be considered to be the most common cause of complex disability (Adamson et al, 2004). It is a leading cause of death and disability in low and middle income countries (Strong et al, 2009). It is a significant economic, social, medical problem all over the world (Ogun et al, 2005), a leading cause of morbidity and mortality worldwide which is likely to worsen in developing countries over the next two decades based on projections by the World Health Organization (Wahab, 2008).

The burden of stroke in africa is high and still increasing due to population growth and ageing (Adeloye, 2014). Nigeria, the most populous black nation in the world stands to risk the further straining of it's resources as a result of the increasing prevalence of stroke. The annual incidence rate of stroke is up to 316 per 100,000 with prevalence rate of up to 315 per 100,000 and a three year fatality of up to 84% in Africa (Owolabi, 2011). A recent meta-analysis puts the incidence rate of stroke in Africa for the year 2013 at 535 per 100,000 and a prevalence of 2.09 million (Adeloye, 2014).

Musculoskeletal pain has been found to be one of the most common complications after a stroke (Kuptniratsaikul et al, 2009; Kitisomprayoonkul et al, 2010). The exact mechanism is unclear, but the thalamus is thought to be involved, creating a hyper-excitable response to sensory stimulation (Fowler, 2001). Patients may misinterpret pain from another source as being due to arthritis; thus they may describe any musculoskeletal pain as arthritis pain (Smith et al, 2010). Pain after a stroke may be nociceptive (Roosink et al, 2010). However, mixed post-stroke pain and pre-existing pain are also common after a stroke (Roosink et al, 2010). Peripheral nociceptive pain after stroke might coincide with symptoms characteristic of central post stroke pain (Roosink et al, 2010). This

is because many patients with CPSP have a combination of both inflammatory and neuropathic pain elements (Klit et al, 2009). Routinely, all stroke patients should be assessed for shoulder pain and, when symptoms are present, prompt action should be implemented (Lindsay et al, 2008). Zeferino and Aycock (2010) also opined that health care providers are advised to assess stroke survivors for shoulder pain and to initiate proper referral and treatment. Post-stroke pain may include joint pain from spasticity, immobility, muscle weakness, headache, centrally mediated pain and shoulder pain. However, prevention, assessment, and treatment of pain should continue throughout rehabilitation care (Duncan et al, 2005).

2.2 Epidemiology of Post-Stroke Pain

Pain is prevalent in post-stroke patients (Chari and Tunks, 2010). It is an often neglected complication with prevalence ranging from 18.6% to 49% (Gyayeghran et al, 2012). The prevalence of shoulder pain, one of the most common sites of pain after a stroke, ranges from 11% to 40% (Langhorne et al, 2000; Gamble et al, 2002; Ratnasabapathy, 2003; Mclean, 2004) and of Central Post Stroke Pain, from 8% to 35% (Widar et al, 2002; Hanson, 2004). Although prevalence of pain after stroke has been found to decrease with time of onset, Jonsson et al (2006) found that after 16 months of stroke onset, 21% of the studied population had moderate to severe pain. The incidence of musculoskeletal pain among community-dwelling stroke survivors was investigated by Hamzat and Osundiya (2010) who reported that 79.4% of the studied population had pain symptoms, with 23.5% predating stroke onset, and so may not be stroke-related.

A study by Lolascon et al (2006) in a post-acute rehabilitation clinic, showed that pain was present in 33.3% of the 345 patients that were evaluated. Lindgren et al (2007) found that shoulder pain onset within four months after stroke was reported by 71 patients (22%). Another researcher postulated that 72% of stroke patients will experience at least one episode of shoulder pain during the first year after the stroke (Duncan et al, 2005). Jonsson et al (2006), focusing on the patients' perspective, found that approximately one-third of the patients studied had moderate-to-severe pain in the first few months after a first-ever stroke, decreasing to 21% one year later. The overall observed prevalence of pain in the study by Lundstrom et al (2008) was

49%, and for 21% of the participants the pain was considered to be stroke-related. Also, in a study of 63 patients with Wallenberg syndrome (lateral medullary wedge infarction with characteristic clinical features), 25% developed CPSP within 6 months of stroke onset. The pain was constant and severe (Kumar, 2009).

2.3 Pattern of Pain after Stroke

Pain after a stroke is very complex in nature and in some cases, it is difficult to determine whether pain is clearly stroke-related or not. The pain intensity could modify the existing pre-stroke pain. It has been demonstrated that pain is common in the first 30 days following stroke (Indredavik et al, 2008). Headache after stroke is more common in patients with a history of migraine (Nardi et al, 2008).

The upper limb is a common site for post-stroke pain, which is often regarded as a direct consequence of proximal motor impairment. However, clinical features unrelated to motor consequences of stroke can be useful for making a management plan for pain (Price, 2003). Zorowitz et al (2005) found that the head, leg, back, and shoulder are the most common sites of post stroke pain while Hamzat and Osundiya (2010) found that the joints of the upper limbs were more affected than those of the lower limbs. Pain begins in most stroke patients within 1-6 months after stroke (Bowsher, 1995). Widar et al (2002) found that half of the patients studied seemed to suffer pain continuously or almost continuously though they rated it differently on two different scales which may rate item as pain can "come and go" even though the pain is continuous. Pain location in decreasing frequency are arm, leg, trunk and face. The most common pattern is hemibody (Cowsher, 2005).

2.4 Types of Pain following a Stroke

It is important to differentiate between the various types of pain because of their different clinical pictures, risk factors and treatments (Gyayeghra et al, 2012). Classification of post-stroke pain is primarily based on neurological examination and pain assessment. Currently, distinct neurological and neurophysiological features of post-stroke pain subtypes are lacking (Roosink et al, 2008). Several methods have been reported for post-stroke pain classification, but no gold

standard has been found. Also, no discriminating somatosensory or nociceptive profiles of post-stroke pain subtypes has been detected and the relationship between the severity of dysfunction, pain severity and pain description remained unclear (Roosink et al, 2008). However, two major forms of pain have been distinguished: Central (neuropathic) pain arising from the vascular lesion defined as CPSP, and pain primarily triggered by peripheral mechanisms: Nociceptive pain (Widar et al, 2002; Seifert et al, 2013). However, it has been shown that some stroke patients may suffer from more than one type of pain (Widar et al, 2002).

2.4.1 Post-Stroke NociceptivePain

This is the most common type of post-stroke pain which can begin at any stage after the vascular accidents. However, it usually occurs during the subacute recovery phase e.g. hemiplegic shoulder pain and spasticity-related pain. Hemiplegic shoulder pain is a common sequela of stroke that can hamper functional recovery and subsequently lead to disability such as hemiplegic shoulder pain and spasticity-related pain. It can begin as early as 2 weeks post stroke but typically occurs within 2 to 3 months post stroke (Suethanapornkul et al, 2008). Shoulder pain is second only to depression among complications seen in stroke survivors (O'Donnell, 2010). The stability of the shoulder may be compromised with subsequent risk of damage to soft tissue structures (Smith, 2012) and eventual interference with the function of the upper extremities (Lee et al, 2012).

Rotator cuff tears and deltoid tendino-pathies are highly prevalent in post-stroke shoulder pain. However, their relationship to shoulder pain is uncertain with atrophy being less common but is associated with less severe shoulder pain (Shah et al, 2008). Increased prevalence of post-stroke shoulder pain has been linked to improper handling of patients (Hadianfard and Hadianfard, 2008). It has been reported that between 16% and 72% of post-stroke individuals develop hemiplegic shoulder pain (Hanukah et al, 1984). The incidence of shoulder pain following a stroke is high, with as many as 72% of adult stroke patients reporting at least one episode of shoulder pain within the first year after stroke (Lindsay et al, 2008).

Post stroke shoulder pain has been found to show significant association with increased light touch threshold, increased vibration threshold, communication disorder, age, temporary unconsciousness, anxiety and depression (Hadianfard and Hadianfard, 2008). It was concluded

from the above study that the severity of disabilities in the areas of physical activity, sensory disability and communication disorder in combination with low motivation for rehabilitation are the main predictors for upcoming hemiplegic shoulder pain (HSP) (Hadianfard and Hadianfard, 2008). However, patients with serious sensory and motor disability have more chance for hemiplegic shoulder pain symptoms after stroke with shoulder subluxation correlating with Brunnstrom's stage, proprioceptive loss and haemorrhagic type of stroke (Suethanapornkul et al, 2008). Also, patients with more severe paralysis of the arm are increasingly likely to develop shoulder pain (Smith, 2012).

2.4.2 Central Post Stroke Pain

Central Post Stroke Pain (CPSP) refers to pain resulting from a primary lesion or dysfunction of the central nervous system after a stroke (Misra et al, 2008). The CPSP was initially attributed to a thalamic lesion but is now also associated with extra-thalamic lesion (Hansson, 2004, Misra et al, 2008). It is probably the least recognized complication of stroke (Sulch et al, 2002; Jonsson et al, 2006). The CPSP is unique because of its diversity, which is reflected in its clinical picture, latency from the onset of stroke, pathophysiological mechanisms, and treatment options. It can result in disability, interfere with rehabilitation and adversely affect quality of life.

Central post stroke pain (CPSP) is a disabling morbidity occurring in 8% of patients with stroke (Kumar et al, 2009). The exact prevalence of CPSP is however not known, partly owing to the difficulty in distinguishing this syndrome from other pain types that can occur after stroke (such as shoulder pain, painful spasticity, persistent headache, and other musculoskeletal pain conditions). However, prevalence range between 8% and 35% has been reported (Hansson, 2004, Widar et al, 2002). Most patients with the CPSP appear to be younger than the general stroke population and usually have relatively milder motor affectation; thus they may live for many years giving a prevalence perhaps as high as 20% (Widar, 2002). It often begins shortly after the injury or damage that caused it, but may be delayed by months or even years. The character of the pain differs widely among individuals. It may affect a large portion of the body or may be more restricted to specific areas (Klit et al, 2009).

Central pain may be spontaneous, or evoked, and varies in intensity and quality. It tends to

improve with time and is associated with mild motor symptoms with relative sparing of joint position and vibration sensations (Kumar et al, 2009). This syndrome is characterised by pain and sensory abnormalities in the body parts that correspond to the brain territory that has been injured by the cerebro-vascular lesion (Klit et al, 2009). Spontaneous pain may be continuous or paroxysmal. Evoked pain may be precipitated by non-nociceptive or nociceptive stimuli (Kumar et al, 2009). Most CPSP patients complain of burning and other symptoms, including aching, pricking, lacerating, shooting, squeezing, and throbbing sensation or in various combinations which may be continous or intermittent. The pain may be aggravated by several stimuli, such as movement, touch, temperature, or stress (Cowsher, 2005). Allodynia, dysaesthesia and hyperalgesia are commonly associated with most patients with CPSP. Hyperalgesia or allodynia are important and perhaps essential parts of CPSP syndrome (Cowsher, 2005). Two thirds of patients with CPSP have impaired pinprick, temperature and touch sensation, whereas impairment of vibration and joint position occur less frequently with burning pain being more common than non burning pain in younger patients (Cowsher, 2005).

2.5 Pathophysiology of Post-Stroke pain

An association has been found between stroke–related pain and persisting neurologic impairments. The mechanism necessary for developing stroke–related pain require the presence of neurological deficits such as a sensory disturbance or a paresis of the spastic limb (Lundstrom et al (2008). When the nociceptive system is activated, physiologically, short lasting neuroplastic changes occur in the CNS. In neuropathic pains, there is damage to the somatosensory systems, causing peripheral and central neuroplastic changes that can sometimes be permanent (Lolascon, 2006). In inflammatory or simple nociceptive pain disorders, the somatosensory system is essentially intact, but it is in a state of heightened excitability that gradually returns to normal when the inflammation subsides (Bowsher, 1995).

Spasticity is not enough to account for stroke-related pain but sensory and motor impairments increase the risk for abnormal musculoskeletal loading which may lead to strain injuries and pain (Lundstrom et al, 2008). Heterotopic Ossification (HO) characterised by new bone formation in the periarticular regions of large joints, though frequently seen after spinal cord injury, traumatic

brain injury, burn and trauma but considered a rare complication of hemiplegia following stroke has been observed in patients post-stroke (Chari and Tunks, 2010; Gurcay et al, 2013). Hence, HO should be kept in mind in the differential diagnosis in stroke patients presenting with spontaneous joint limitation (Gurcay et al, 2013).

2.5.1 Nociceptive Post-Stroke Pain

Post-stroke nociceptive pain frequently results from abnormal posturing, immobilization, incorrect mobilization, or poor positioning, with the absence of normal active motion in the affected upper extremity (Gould and Barnes, 2009). Neurological impairment can result to direct degenerative complication in skeletal and soft tissues resulting from decreased muscle activity around a joint (Roy, 2004). Nociceptive post-stroke pain has been found to be associated with a variety of slow anatomical, physiological and biochemical changes (Schott, 2003).

Several possible mechanisms may link spasticity and pain (Lundstrom et al, 2008). Spasticity may cause an abnormal loading and strain on muscles and ligaments with a risk for nociceptive pain, pain may enhance spinal reflexes involved in spasticity, thirdly the neuronal networks involved in spasticity and pain at both spinal and cerebral levels may well overlap and thus be involved in the same nervous lesion. However, spasticity has not been identified as an independent risk factor for developing stroke-related pain (Lundstrom et al, 2008).

Speculations about the aetiology of hemiplegic shoulder pain have failed to establish a cause-and-effect relationship with a suspicion that subluxation, complex regional pain syndrome (CRPS), rotator cuff injury, and spastic muscle imbalance of the glenohumeral joint are contributory factors (Lundstrom et al, 2008). Hanger et al (2000) however concluded that the cause of post-stroke shoulder pain is multifactoral, with different factors contributing at different stages of recovery (i.e flaccidity contributing to subluxation and subsequent capsular stretch, abnormal tonal and synergy patterns contributing to rotator cuff or scapular instability). However, the stages are not mutually exclusive but instead can occur simultaneously in the affected limb. Once the brain injury occurs, the flaccid stage evolves with a state of areflexia with accompanying loss of muscle tone and volitional motor activity, variable sensory loss, and loss of muscle stretch reflexes (Hanger et al, 2000). The muscular support of the humeral head in the glenoid fossa by the supraspinatus and deltoid muscles is lost leading to downward and

outward subluxation of the humeral head, with the joint capsule being the only support (Gould and Barnes, 2009). The shoulder capsule is composed of 2 tissue layers: The inner synovial layer, (Stratum Synovium) which is highly vascular but poorly innervated, making it insensitive to pain but highly reactive to heat and cold. The outer layer (Stratum Fibrosum) is poorly vascularised but richly innervated, predisposing it to pain from stretch. For this reason, added capsular stretch in a flaccid shoulder may predispose the capsule to irreversible damage and the shoulder to pain (Gould and Barnes, 2009). Also, flaccidity of the trapezius, rhomboids and serratus anterior muscles result in depression, protraction, and downward traction of the scapula, which is believed to lead to significant angular changes of the glenoid fossa, subsequently contributing to subluxation (Cailliet, 1991). The spine also begins to flex laterally towards the hemiparetic side because of elimination of the righting reflex, further altering the scapulothoracic relationship. However, scapular position does not contribute as much to inferior subluxation as was originally thought (Gould and Barnes, 2009).

2.5.2 Central Post-stroke Pain

The precise cause of central post-stroke pain is unknown, although it may be due to hyperactivity of the autonomic nervous system whereby because the brain has been damaged, it feels pain when it should be feeling a sensation that is not painful. The pathophysiology of CPSP is not well understood, but central disinhibition, imbalance of stimuli and central sensitisation havebeen suggested (Kumar et al, 2009). The presence of sensory loss and signs of hypersensitivity in the painful area in patients with CPSP might indicate the dual combination of differentiation and the subsequent development of neuronal hyper excitability (Kumar et al, 2009).

The Central Post Stroke Pain was known as “thalamic syndrome” but early post mortem studies showed that many cases had extra-thalamic lesions and modern imaging methods have confirmed and extended these findings (Bowsher, 1995). Bowsher (1995) reported that Dejerine and Roussy in 1906 first described the thalamic syndrome, a condition which follows a thalamic stroke, with severe pain in the contralateral side. Central pain is produced within the brain as a result of the stroke. It does not stem from damage nerve ending rather, the body sends normal message to the brain in response to touch, warmth, cold, and other stimuli. The brain does not

understand these signals correctly; instead, it will register even slight sensation on the skin as painful (Bowsher, 1995).

The disinhibition theory, according to which injury to the lateral thalamus sets the medial thalamus free from its control was proposed by Head and Holmes in 1911 (Widar et al, 2002). Later, it was found that the lesion anywhere in the spinothalamocortical pathway leads to prominent over-activity of the lateral thalamus. In either situation, CPSP is associated with impaired sensation evoked by cotton wisp, vibration, heat and cold. The essential component of this hypothesis is that discriminate sensory deficit in CPSP results in disinhibition, which gives rise to spontaneous pain or allodynia (Widar et al, 2002). Earlier, partial sensory loss of spinothalamic modalities was considered necessary for the development of CPSP (Widar et al, 2002). This is however not sufficient, as spinothalamic deficit, manifested by loss of thermal sensation but without pain, is found in more than half of patients. Therefore it is not possible to predict the development of CPSP by documenting sensory loss (Widar et al, 2002).

Stroke anywhere in the spinothalamic pathway and its cortical projection may result in CPSP, although, in the past, thalamic pain was synonymous with thalamic stroke. Most CPSP patients have multiple lesionson their magnetic resonance imaging (MRI) and many of these are unrelated to pain (Kumar, 2009). The most severe pain is more likely in an extremity in supratentorial lesions and on the face in the infratentorial lesions. Unlike pain-free stroke patients, patients with CPSP due to supratentorial lesions have a deficit of sensation to sharpness or cold (predominantly mediated by A-delta fibres) than pain-free stroke patients. Whereas patients with infratentorial CPSP have a deficit of C-fibres mediated temperature sensation and heat pain (Kumar, 2009). Lateral medullary syndrome involves spinothalamic and trigeminothalamic pathyways, and medial medullary syndrome involves lemniscal pathways (Kumar, 2009).

A painful response to lightly stroking the skin with a finger or cotton wool is a sign of allodynia, or an exaggerated painful response to pin prick testing with a monofilament or sharp object confirm an altered pinprick threshold (hyperalgesia). A combination of characteristic painful symptoms and an area of altered sensation on bedside testing is usually enough to make a

diagnosis of neuropathic pain (Rolke et al, 2006). According to Dworkin et al (2007) and Gray (2008), the features in pain history that may suggest a diagnosis of neuropathic pain include:

a. Clinical circumstances associated with a high risk of pain descriptors such as burning, shooting and stabbing.
b. The paroxysymal or spontaneous nature of the pain, which may have no clear precipitating factors
c. The presence of dysaesthesia (spontaneous or evoked unpleasant abnormally painful stimulus), allodynia (pain due to a stimulus that does not normally evoke pain such as light touch), hyperalgesia or areas of hypoaesthesia.
d. Regional autonomic features (changes in colour, temperature and sweating).

However, Klit et al (2009) have proposed the mandatory criteria for the diagnosis of CPSP which include:

i. Pain within an area of the body corresponding to the abnormality of the CNS.
ii. History suggestive of a stroke and onset of pain at or after stroke onset.
iii. Confirmation of a CNS lesion by imaging, or negative or positive sensory signs confirmed to the area of the body corresponding to the lesion.
iv. Other causes of pain are excluded or considered highly unlikely.

Supportive Criteria may include:

a. No primary relation to movement, inflammation, or other local tissue damage.
b. Descriptions such as burning, painful cold, electric shocks, aching, pressing stinging and pins and needles.
c. Allodynia or dyesthesia to touch or cold (Klit et al, 2009).

2.6 Management of Post-Stroke Pain

Interest in management and treatment of patients with post-stroke pain has grown with increase in the elderly population (Kim et al, 2012). Appropriate and timely treatment of painful conditions results in maximum function and the ability to lead active lives (Zorowitz et al 2005). Most individuals with pain can assist in their own pain management, either by using verbal communication or with the assistance of a standardized pain assessment scale to express the type

and degree of pain they are experiencing (Merskey,1994). Women have been found to use spiritual and religious activities more as a coping strategy and they perceived their emotional state as the cause of the pain (Nogueira and Teixeira, 2012).

2.6.1 Management of Nociceptive Post-Stroke Pain

Good shoulder function is a prerequisite for effective hand function, as well as for performing multiple tasks involving mobility, ambulation, and activities of daily living (Gould and Barnes, 2009). Awareness of potential injuries to the shoulder joint reduces the frequency of shoulder pain after stroke. The multidisciplinary team, patients, and carers should be provided with instruction on how to avoid injuries to the affected limb (Walsh, 2001). Management should vary according to associated physical changes. In the flaccid stage, the shoulder is prone to inferior subluxation and vulnerable to soft-tissue damage. The arm should be supported at all times and functional electrical stimulation may reduce subluxation and enhance return of muscle activity (Turner Stokes and Jackson, 2002). While sitting or lying down, the paralysed arm should be supported on an arm rest or pillow to relieve shoulder pain from the arm's weight; the same should be done with a sling while walking (Walsh, 2001). Hot packs and range of motion exercises have been found useful (Walsh, 2001). In the spastic stage, movement is often severely limited. Relieving spasticity and maintaining range requires expert handling. Overhead exercise pulleys should not be used because it encourages uncontrolled abduction (Turner-Stokes and Jackson, 2002). Foam supports or shoulder strapping may be used to prevent shoulder painand over arm slings should be avoided (Walsh, 2001).

Transcutaneous Electrical Nerve Stimulation (TENS) and Ultrasonic Therapy (UST) are both effective but TENS may be safer and superior to UST in the treatment of patients with post-stroke shoulder pain (Moniruzzaman et al, 2010). Positive outcomes have been noted with the use of corticosteroid injections and electrical stimulation. These have provided benefits in the treatment of shoulder pain (Viana et al, 2012). Local steroid injections should however be avoided unless there is clear evidence of an inflammatory lesion (Turner-Stokes and Jackson, 2002).

Acupuncture, which has been practiced for thousands of years and has been widely used in various conditions that include pain, musculoskeletal disorders, and several neurologic disorders

(Erst, 2010), can be considered as an adjuvant therapy in combination with exercise for rehabilitation of stroke patients who are suffering from shoulder pain (Lee et al, 2012). Floating acupuncture has been found to relieve shoulder pain of patients with post-stroke shoulder-hand syndrome promptly and effectively, and its effects on shoulder pain and the improvements of daily life activity are superior to that of the oral administration of Western medicine and local Chinese medicine (Wang et al, 2013). It has been recommended that efforts should be directed toward proper treatment of depression and anxiety to prevent and alleviate shoulder pain because heightened awareness of the risk factors of hemiplegic shoulder pain may lead to early prevention or improved management (Hadianfard and Hadianfard, 2008).

2.6.2 Management of Central Post-Stroke Pain

Central post-stroke pain is the most difficult type of central neuropathic pain to control with medical treatment (Kumar et al, 2009). It is also the least recognised complication of stroke and therefore often treated inadequately in daily practice (Lolascon et al, 2006). However, it is a treatable disorder (Flaster et al, 2013). The most effective approaches are those that target the increased neuronal hyper excitability (Lolascon et al, 2006). A start is to avoid things that can cause pain, such as hot baths, tight or easily bunched clothing and pressure on the side of the body affected by the stroke (Klit et al, 2009). The Pharmacological and non-pharmacological treatment of CPSP is challenging. The inadequacy and limitations of the present therapies have been reported (Kumar, 2009).

Pharmacological Treatment

Antidepressants: Amitriptyline has been found to be effective, safe, and well tolerated compared with placebo for treatment of CPSP (Class II, level B evidence) (Lampl et al, 2002). There is evidence that the sooner antidepressant treatment is begun, the more likely the patient is to respond. Time should not be wasted trying conventional analgesics, which rarely have any significant effect (Jonsson et al, 2006). Amitriptyline has been a first line treatment for neuropathic pain for many years. Though there are no supportive unbiased evidence for a beneficial effect, decades of successful treatment have been reported in many patients with neuropathic pain with no good evidence of a lack of effect (Moore et al, 2012). Fluroxamine at

least 125mg daily is effective (Class II, level B) in CPSP patients who had a stroke within 1year (Carnavero et al, 2002).

Anticonvulsants: Pregabalin has demonstrated efficacy in the management of neuropathic pain (Class I evidence)(Kim et al, 2011). Carbamazepine has been found to be minimally effective (better than placebo only) (Class II Level B). Lamotrigine is moderately effective and well tolerated dung for CPSP (Class I, level B evidence).

Gabapentin is well tolerated but not effective in CPSP (Class III).

Phenytoin, Topiramate and Zonisamide: There is inconclusive evidence for these in CPSP (Serpell, 2002).

N – Methyl –d-aspartate Antagonist: Ketamine may be tried in refractory patients with CPSP as a short measure (Class IV).

Dextromethorphan is not effective (Class III) (Serpell, 2002).

Opioids: Opioids like oral tramadol is effective at reducing pain levels in patients with CPSP and is a medication option for the treatment of CPSP (Tanei et al, 2013). Morphine is ineffective in CPSP and side effects are frequent Class II level B evidence. (Attal et al, 2002).

Nalaxone is ineffective in CPSP and causes more side effects (Class II, Level B).

Oral Levorphanol is not effective (Class III, level C).

(Rowbotham et al, 2003). Tramadol has been tried in I patient with CPSP Only one class IV study showed tramadol to be beneficial (Iranami et al, 2006).

Anaesthetic: Lidocaine may be effective for a short period in CPSP (Class I, ILevel B) (Attal et al, 2000). Propofol and Peritothal (Class III) may be effective for a short period in CPSP

2.7 Predisposing factors of Post-stroke Pain

Pain after stroke is multifactorial in origin: pre-stroke pain, post-stroke functional recovery, and mood disorders all contribute to pain status. However, vascular risk factors and stroke characteristics, besides stroke severity, do not seem to play an important role (Henon, 2006). Stroke-related pain has been found to be associated with sensory-motor impairments but not with spasticity on an independent variable (Lundstrom et al, 2009). In a large cohort study by O'Donnell et al (2013) involving patients with ischaemic stroke who did not have a history of

chronic pain before their stroke, predictors of post-stroke pain included increased stroke severity, female sex, alcohol intake, depressive symptoms, diabetes mellitus, antithrombotic regimen, and peripheral vascular disease. Also pattern of correlated risk factors such as location of the leison can help predict certain types of post-stroke pain syndromes (Ghyeghran et al, 2012), hence a multifactorial basis has been established for post-stroke pain (Naess et al, 2010).

Stroke-related pain has been found to be associated with sensorimotor impairments but not with spasticity on an independent variable (Lundstrom et al, 2009). Those with stroke who are generally elderly, often experience pain from chronic conditions such as arthritis and other musculoskeletal conditionswhile patients with sensory and motor disability have more chance for hemiplegic shoulder pain symptoms after stroke (Hadianfard and Hadianfard, 2008). Loss or impairment of motor function and high NIHSS score were predictors of shoulder pain (Lindgren et al, 2007).

2.8 Impact of Post-Stroke Pain on Functional Outcome

Post-stroke pain can importantly impact rehabilitation and long term outcomes (Seifert et al, 2013) and has been found to be negatively correlated with outcomes important to rehabilitation. Post–stroke chronic pain syndromes have been found to be associated with increased functional dependence and cognitive decline (O'Donnell et al, 2013) with likelihood of disability/ dependence at follow up and eventual long-term mortality (Naess et al, 2010). Among major impairments that cause disabilities in stroke survivors, pain plays an important role (Lolascon et al, 2006). It significantly interferes with the execution of activities of daily living, quality of life and mood. While some have relatively minor pain or functional limitation from these problems, for many, it distinctively impair their quality of life (Kendall, 2010; Jungehulsing et al, 2013).

Pain has a consistent detrimental impact on functioning across multiple QoL domains, even after controlling for multiple demographic and medical characteristics known to be associated with self-report QoL (Putzke et al, 2000). CPSP has been found to distinctively impair the quality of life (Jungehulsing et al, 2013). However, to what extent pain alters the quality of life in stroke survivors remain undetermined and should be evaluated in long term follow-up studies.

Considering the association between neuropathic pain condition and health-related quality of life (HRQoL), Jensen et al (2007) reviewed 52 studies in patients with six neuropathic conditions including post-stroke pain. The results showed strong evidence that the presence and severity of neuropathic pain are associated with greater impairment in a number of important HRQoL domain.

Shoulder pain which occurs in stroke can delay rehabilitation and functional recuperation, because the painful joint may mask improvement of motor function or may inhibit rehabilitation and limits the use of hand for wheelchair- ambulation (Duncan et al, 2005). Post stroke pain has been found to be associated with lower motor performance (Hamzat and Osundiya, 2010). Shoulder pain has also been found to restrict daily life often or constantly when dressing and ambulating (Lindgren et al, 2007). In a study by Jonsson et al (2006), it was observed that pain influences the quality of life of stroke survivors: pain is frequently described as constant over time, disturbing sleepin one half of patients, and requiring temporary rest, or a change in position in 25 – 50% of patients. Shoulder pain in stroke survivors has an important negative role in rehabilitation programme (Poenam et al, 2008).

Post-stroke shoulder pain is common and significantly impacts rehabilitation outcomes though the exact aetiology remains unknown (Shah et al, 2008). Spasticity and post-stroke shoulder pain have been found to be strongly associated and this may represent a cause and effect relationship (Lundstrom et al, 2008). Post-stroke pain can impact substantially on the patient's sense of well-being and quality of life. Shoulder pain can delay rehabilitation and recovery of function; the pain may mask improvement of function or may inhibit patient participation in rehabilitation activities such as therapy or activities of daily living (Lindsay et al, 2008). Pain can affect the course of stroke rehabilitation adversely, and it occasionally may be a cause for transfer back to an acute care hospital (Zorowitz et al, 2005).

2.9 Evaluation of Post-Stroke Pain

Pain is one of the most important, yet difficult construct to measure in clinical practice and research. Its definition underlies the complexity of its measurement (Krueger and Stone, 2008).

Pain is an individual and subjective experience modulated by physiological, psychological and environmental factors such as previous events, culture, prognosis, coping strategies, fear and anxiety (Moore et al, 2003). Therefore, most measures of pain are based on self report which lead to sensitive and consistent results if done properly (Moore et al, 2003). Though self reporting can be influenced by numerous factors e.g. mood, sleep disturbance and medication and may result in patient not reporting pain accurately, it is regarded as the gold standard of pain assessment as it provides the most valid measurement of pain (Peter and Walt–Watson, 2002).

There are no objective measures of pain intensity but associated factors such as hyperalgesia (e.g mechanical withdrawal threshold), the stress response (e.g plasma cortisol concentrations), behavioural responses (e.g facial expression), functional impairment (e.g ambulation, coughing) or physiological responses (e.g changes in heart rate) may provide additional information (Moore, 2003). However, in a study comparing psychometric properties of four established pain scales in a population of adult patients with varying levels of cognitive impairment, the ability of older, cognitively impaired patients to rate pain reliably and validly was established (Chibnall and Tait, 2001). No gold standard is presently available for post-stroke pain diagnosis, hence diagnosis is based on clinical judgement (Roosink et al, 2010). The essential elements of this process are to identify painful symptoms, altered sensation, and a clinical history that all match a neuroanatomical or dermatomal pattern (Cruccu et al, 2004).

Screening methods for neuropathic pain consist mostly of characteristic verbal descriptors, though some have single bedside tests in addition to clinical assessment. Examples are Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) pains scale or the pain DETECT questionnaire. They are however not intended to be diagnostic methods (Bennett et al, 2007). Bedside examination is straight forward and is aimed at identifying altered sensation in the painful area, and so responses should be compared with a non-painful situation (Bennett, 2001). Mixed pain and pre-existing pain are common after stroke. For this reason, peripheral nociceptive pain after stroke might coincide with symptoms characteristics of CPSP (Roosink et al, 2010). Pain is a complex experience that depends strongly on cognitive, emotional and educational influence, hence the pressing need for tools that can measure pain objectively (Cruccu and Truini, 2009).

Four different levels of objective assessment have been distinguished.

1. Laboratory tests that use quantitative tools and measure an objective response. Standard neurophysiological responses to electrical stimuli such as nerve conduction studies and somato sensory-evoked potentials can identify, locate, and quantify damage along the peripheral or central sensory pathways but they do not assess nociceptive pathway function (Cruccu et al,2004; Cruccuetal, 2008). However these do not measure pain intensity nor response to treatment (Cruccu and Truini, 2009).
2. Quantitative Sensory Testing analyses perception in response to external stimuli of controlled intensity. Detection and pain thresholds are determined by applying stimulus to the skin in ascending and descending order of magnitude. Mechanical sensitivity for tactile stimuli is measured withplastic filaments that produce graded pressure, such as a von Frey hair, pinprick sensation with weighted needle and vibration sensitivity with an electronic vibrameter. Thermal perception and thermal pain are measured using a thermode, or other device that operates on a thermoelectric effect (Cruccu and Truini, 2009).
3. Bedside examination: Abnormal sensory findings should be neuroanatomically compatible with a definite lesion site. Location, quality and intensity of pain should be assessed. Proper assessment requires a clear understanding of all possible types of negative (e.g. sensory loss) and positive (e.g. pain and paraesthesia) symptoms and signs.

   Sensory disorders should be recorded in detail, preferably on body sensory maps. Though this is difficult for the non-specialist and time consuming for everybody but it provides information. Tactile sense is best assessed with a piece of cotton wool, pinprick sense with a wooden cocktail stick, thermal sense with warm and cold object and vibration sense with a 128-Hz tuning fork (Cruccu et al, 2004).
4. Questionnaires: Several screening tools for distinguishing neuropathic from nociceptive pain have been validated (Bennet et al, 2007). Some of them like the Neuropathic Pain Questionnaire (NPQ) (Krause and Backonja, 2003) and pain DETECT (Freynhager et al, 2006) rely only on interview questions. The Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) scale (Bennet, 2001) and Doleur Neuropathique (DN4) questionnaire (Bouhassira et al, 2004) use both

interview, questions and critical test and achieve higher sensitivity and specificity than the screening tools that use only interview questions which emphasises the importance of clinical examination. Careful assessment is needed before pain can be labelled idiopathic or psychogenic. Though these tools help in diagnosing neuropathic pain and quantifying damage to the nociceptive pathways, they measure neither pain intensity nor response to treatment (Crucci and Truini, 2009).

Many patients with CPSP have a combination of both inflammatory and neuropathic pain elements. When located in the same area, it can be difficult to distinguish between them (Klit et al, 2009). In certain cases of post-stroke shoulder pain, the pain is clearly nociceptive but in other cases the pain mimics that seen when CNS structures are damaged. Patients with PSSP who have sensory abnormalities in the shoulder area corresponding to the lesion fulfill the proposed criteria for CPSP if there is no other obvious pathological abnormality in the shoulder that can fully explain the pain (Klit et al, 2009).

2.10 Types of Outcomes

Patient-Reported Outcomes (PROs) – document patient's perceptions of the impact of disease and treatment on health and functioning and include patients' evaluations of their health status, symptoms, adherence to treatment, satisfaction, and the impact of disease on functioning and well being (Acquadro et al, 2003; Willke et al, 2004). Patient-reported outcomes (PROs) are reports coming directly from patients about how they function or feel in relation to a health condition and its therapy, without interpretation of a patient's responses by a physician or anyone else (Valderas et al, 2008). Patient-Reported Outcomes are increasingly used in clinical research, but ascertaining the circumstances under which PROs are truly helpful beyond research settings remains a challenge (Guyatt et al, 2007). Clinician-Reported Outcomes (CROs) include outcomes either observed by a provider or requiring interpretation. It includes scales completed by a health care provider using information about the patient (Willke et al, 2004).

2.10.1 Benefits of Patient-Rated Outcomes

The benefits of PRO could lead to improvement in outcomes that are important to patients. These include the following:

a. It facilitates patient-clinician communication about issues that are important to patients, thereby promoting shared decision making.
b. It helps in monitoring disease progression and response to treatment.
c. It identifies vulnerable patients and enables continuous assessment of quality of care (Guyatt et al, 2007; Valderas et al, 2009).

2.10.2 Demerits of Patient-Rated Outcomes

The use of PROs may interfere with doctor-patient communication and patients may be concerned about who will review or use the information. Administering some of the currently available measures is already burdensome, and scores resources would be consumed in computing and reviewing PRO scores (Valderas et al, 2009; Guyatt et al, 2007).

2.10.3 Evidence of using PRO measures in clinical practice

There are limited number of systemic reviews that assessed the impact of PROs and its impact on the process of care (Valderas et al, 2008). Its less evident impact on health professionals has been shown to increase the frequency with which doctors discuss issues such as quality of life and symptoms with their patients, without an increase in the visit duration (Detmar et al, 2002; Velikova et al, 2004).

A meta-analysis also showed that PROs reports of mental health status in a variety of settings resulted in a higher likelihood of diagnostic notations recorded in patients' medical records (Espallargues et al, 2000).

2.10.4 Challenges for Implementing PRO measures in Clinical Practice.

The Systematic use of PRO instruments in Clinical practice has the potential to bring about significant improvements in a number of relevant areas of health care (Valderas et al, 2008).

However, possible barriers to implementation would need to be overcome, including:

1. Unfamiliarity with the interpretation of PRO information;
2. Paucity of direct face-to-face instrument comparisons
3. Costs of data collection
4. The need for rapid data manipulation and processing (Vanderas et al, 2008)
5.

2.11 Pain Scales

Pain rating scales are instruments used to qualify a patient's perception of the quality of their pain and to longitudinally monitor their response to analgesic therapy. The most widely used scales are verbal, numerical, observer or some combination of all three forms.

1. **Numeric rating scale:** numbers usually 0-10 where o-"no pain" and 10-worst pain" e.g Visual analogue scale (VAS spine score) developed by Knop, (2001).
2. **Verbal rating scales:** use words (descriptors) like mild, moderate, severe to qualify pain e.g. McGill pain scale developed by Melzack and Torgerson, (1971).
3. **Observer / Visual Scales: o**ften used with people who are unable to communicate their pain effectively. Observation – based scales offer objective measurements for pain. These include facial expression, muscle tone, blood pressure and heart rate. Examples of observer pain scales are Flacc scale, the Cries scale and the Comfort scale.

The Visual Analogue Scale (VAS) is a well studied method for measuring both acute and chronic pain, and its usefulness has been validated by several investigators (Cork et al, 2004). The relationship between pain scores obtained on the visual anaolgue scale (VAS), the Box Numerical Scale (BNS) and Verbal Rating Scale (VRS) were studied by Akinpelu and Olowe (2002). The three pain rating scales were found to measure the same construct and could be used for pain measurement in obstetric related conditions in this environment. However, VAS is comparatively time-consuming and requires ability to understand the abstract concept of the VAS line and then relate it to distance from a zero mark. It also requires the use of a paper and pen. As line length in VAS is the response continuum, many patients find it difficult to judge distance accurately. Therefore VAS has some practical limitations in a clinic setting (Cork et al, 2004).

TABLE 2.1

PAIN SCALES

SCALE	DESCRIPTION	DEVELOPER
Numerical Rating Scale	Pain rating from 0 to 10 (0 to 100)	Karoly and Jensen 1987
Pain Disability Index	Measures the impact of chronic pain on various daily activities	Tart et al, 1987
Pain Management Index	Compares the most potent analgesic with reported level of pain.	Cleeland et al, 1994
Pain Perception Profile	Measuring the affective, sensory and intensity dimensions of pain	Tursky1976
PatientOutcome Questionnaire	Measures pain severity, interference, satisfaction with pain control	AmericanPain Society, 1995
Unmet Analgesic Needs Questionnaire	Designed for cancer patients to measure prevalence and pain intensity. Identifies characteristic associated with unmet analgesic needs	Zhukorsky,1994
Verbal Rating Scale	There are many forms of verbal rating scales.	Lasagna,1988
Visual Analogue	They are 100mm lines with two words that anchor different end of the spectrum (e.g. pain as bad as it can be ……. No pain.	
West Haven-Yale Multi-dimensional Pain Inventory	A 52 item chronic pain inventory	Kerns,1985
Wisconsin Brief Pain Questionnaire	A self administered questionnaire which measures pain at its word, its least average, and right now. It also uses a checklist of adjectives to characterize the pain and information collected on impact of treatment and of pain impact on function.	Daut,1983

2.12 Development of Outcome Measure for Pain Clinical Trial

The lack of existing, well-validated measures that address the hypotheses being tested may necessitate the development of a new measure. However, the outcome measure must assess the domains of interest and the specific measures selected must be appropriate for the population for which the treatment is being considered, and must be reliable and valid with the minimum of patient burden possible (Turk et al, 2006). However, because instrument development takes considerable time, effort and resources, existing measures should be examined to determine whether a new measure is necessary in reviewing available measures. Attention should not only be given to the adequacy of the psychometric properties of the measure but also the availability of appropriate information to confirm the measure's psychometric properties for the population of interest (Turk et al, 2006). Once the need for a new measure is established, the formal process of instrument development can begin.

The development of outcome measures in clinical trials involves a series of sequential steps beginning with consideration of what construct (latent variable) or constructs will be assessed. Attention must be given to the specific goals of the measure, its intended uses, and the characteristics of the individuals to whom it will be administered.

i. **Identification of scientific approach:** This involves the overall question, the conceptual model and scope of assessment. It is incumbent on authors of any new measure to demonstrate whether a newly developed measure has incremental advantages including decreased participant burden or increased reliability or validity or requires less time for completion.

ii. **Establishment of a target population:** the factors or concepts to be included in the scale should be considered putting in view the specific goal of the outcome measure and specific traits. Also, a decision should be made whether there is a need for independent or overlapping subscales. People with particular diseases or symptoms have unique perspectives on the impact of the disease and its treatment on their everyday functi\oning and well-being and thus are of critical importance in developing a new measure (Kirwan et al, 2003).

iii. **Developing item pool:** A good literature review to critically explore existing measures. Focus groups and indepth interview with patients and experts. These

should be used to identity content domains that are considered important by patients. Relevant information that has intuitive value to patients is a key element in determining the content to be included in a measure. Focus groups should include individuals with a range of pain or symptom severity because this can influence the importance that is ascribed to the outcome (Casarett et al, 2001). The composition of the groups should also reflect the demographics of the patients to whom the measure will be applied because factors such as age, sex and ethnicity might affect priorities and preferences for different outcomes (Ganz, 2002). The format of the measure should also be determined i.e. individual items and scale properties. Also the scoring and eventual analysis.

iv. **Item Evaluation:** Once the overall content domain has been selected and specific items have been developed, attention must be given to the instructions, item wording, time frame, response categories, scale anchors and response format. The group in whom the measure is going to be used must be able to clearly understand the instructions and item wording.

v. **Instrument Evaluation:** This involves evaluating the psychometric properties in target population i.e. the reliability, validity and responsiveness. Once a preliminary set of items has been selected and instructions have been developed, pilot testing with cognitive interview should be conducted on a sample drawn from the study population to establish that the targeted patient group clearly understands the instructions, item wording, reference period, and response format. Pilot testing may reveal that there are insufficient items covering particular aspect of the construct. Test developers need to determine, in advance the appropriate sample size and representation of the sample that will be used to evaluate the psychometric properties of an instrument.

vi. **Complete Instrument Development:** This involves revision of the instrument of necessary and then finalizing the instrument and eventual development of user manual and instructions to respondents. Although the recommended sequence is presented as if it were a linear process, the development of measures is frequently an iterative process (Turk et al, 2006).

2.13 Focus Group Discussion (FGD)

Focus Group Discussion (FGD) is a rapid assessment, semi-structured data gathering method in which a purposively selected set of participants gather to discuss issues and concerns based on a list of key themes drawn up by the researcher (Kumar, 1987).

Purpose: the purpose of FGD is to obtain information about a group's beliefs and attitudes on a particular health issue or problem. Focus group can be used for idea generation, in conjunction with a quantitative method, or as a primary data collection method. However, if FGDs are used as a primary data-collection method, their results must be treated with caution. It gives room for interaction among all the members of the group (unlike individual interview) and permits participants to give detailed opinion on a topic which differentiates it from a survey (Kumar, 1987).

Description: FGD brings 6-12 people together for a discussion on a specific health topic. The participants usually have some characteristics in common such as sex and age. It is recommended that at least two FGDs be done with each group. It typically lasts from 1-2 hours, led by a facilitator and another person to take notes and should be recorded on audio tape for later transcription and analysis (Kumar, 1987).

2.14 Psychometric Properties of Measuring Scales

Psychometric Properties refers to the reliability and validity including responsiveness and sensitivity to change, of a measurement tool (Terwee et al, 2007; Kurande et al, 2013). To rate the quality of a questionnaire, authors should provide a clear description of the following aspects in the development of a questionnaire (Terwee et al, 2007). The Terwee quality criteria (Terwee et al, 2007) is a useful rule of thumb in determining psychometric properties of measurement tools. The criteria does not summate into one total quality score which is often done with trial methodological quality scales, such as the PEDro scale (Terwee et al, 2007). A total quality score presumes that the psychometric properties assess the same attribute and that each property is equally important, which may not be true (Terwee et al, 2007). Summed quality scores do not indicate the specific methodological problems that are most prevalent. Therefore, it is more informative to seperately consider each of the measurement properties (Terwee et al, 2007).

2.14.1 Validity

This is generally described as the degree to which a study accurately reflects or assesses the specific concept that the researcher is attempting to measure (Terwee et al, 2007). Nunnally and Bernstein (1994) say the term validity denotes the scientific utility of a measuring instrument, broadly stated in terms of how well it measures what it purports to measure. Validity usually is a matter of degree rather than an all or none property, and validation is an unending process. Validation is the process by which a test developed or test user collects evidence to support the types of inferences that are to be drawn from test scores.

Content Validity: examines the extent to which the concepts of interest are comprehensively represented by the items in the questionnaire. A positive rating is given for content validity if a clear description is provided of the measurement tool, the target population, the concepts that are being measured, and the item selection (Mokkink et al, 2010).

Criterion Validity: refers to the extent to which scores on a particular instrument relate to a gold standard. A positive rating is given for criterion validity if convincing arguments are presented that the used standard really is "gold" and if the correlation with the gold standard is at least 0.70 (Mokkink et al, 2010).

Construct Validity: refers to the extent to which scores on a particular instrument relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured. Construct validity should be assessed by testing predefined hypotheses (e.g., about expected correlations between measures or expected differences in scores between known groups). A positive rating is given when at least 75% of the results are in correspondence with these hypotheses, in (sub) groups of at least 50 patients (Terwee et al, 2007).

2.14.2 Interpretability of the Items.

This is the degree to which one can assign qualitative meaning toquantitative score (Mokkink et al, 2010). Completing the questionnaire should not require reading skills beyond that of a 12-

year old to avoid missing values and unreliable answers. The items should be short and simple, not consisting of two questions at the same time (Terwee et al, 2007).

2.14.3 Internal Consistency

This is a measure of the extent to which items in a questionnaire (sub) scale are correlated (homogenous), thus measuring the same concept (Kurande et al, 2013). Internal consistency is an important measurement property for questionnaires that intend to measure a single underlying concept (construct) by using multiple items. For questionnaires in which the items are merely different aspects of a complex clinical phenomenon that do not have to be correlated, such as in the Apgar Scale, internal consistency is not relevant (Mokkink et al, 2010). After determining the number of (homogenous) (sub) scales, Cronbach's alpha should be calculated for each (sub) scale separately. Cronbach's alpha is considered an adequate measure of internal consistency. A low Cronbach's alpha indicates a lack of correlation between the items in a scale which makes summarizing the items unjustified. A very high Cronbach's alpha indicates high correlations among the items in a scale, i.e, redundancy of one or more items. A very high Cronbach's alpha is usually found for scales with a large number of items, because cronbach's alpha is dependent upon the number of items in a scale (Post et al, 2011). Nunnally and Bernstein proposed a Criterion of 0.70 – 0.90 as a measure of good internal consistency. A positive rating is given for internal consistency when factor analysis was applied and Cronbach's alpha is between 0.7 and 0.95 (Terwee et al, 2007).

2.14.4 Reliability

This is the extent to which a self-reported outcome questionnaire or a scale is measuring something in a reproducible and consistent fashion. Reliability indicates the stability of a measure (Terwee et al, 2007). The degree to which repeated measurements in stable persons provide similar answers. Reliability concerns the degree to which patients can be distinguished from each other despite measurement error. Test-retest reliability involves instrument self-completion on two occasions separated by a suitable time–period and assuming no change in the underlying health state. It measures the temporal stability of the score (Terwee et al, 2007)

Intra-rater reliability testing is the process by which a measurement tool or method can be shown to give similar results when used by same raters at different times for the same group of subjects while inter-rater reliability is the extent of agreement of two measures by two examiners independent assessment of the same subect (Post et al, 2011; Kurande et al, 2013).

The intraclass correlation coefficient (ICC) is the most suitable and most frequently used method for test-retest for continuous data. The ICC is the variation in the population (inter-individual variation) divided by the total variation, expressed as a ratio between as a ratio between 0 and 1 (Terwee et al, 2007). The time period between the repeated administrations should be long enough to prevent recall, though short enough to ensure that clinical change has not occurred.The appropriateness of the time period is not specific, but only require that the time period is described and justified. A minimum of 0.70 is recommended as a standard for reliability.A positive rating is given for reliability when the ICC or weighted Kappa is at least 0.70 in a sample size of at least 50 patients.

2.14.5 Responsiveness

The ability of a questionnaire to detect clinically important changes over time, even if these changes are small. lt is a measure of longitudinal validity. The instrument should be able to distinguish clinically important change from measurement error (Terwee et al, 2007; Mokkink et al, 2010).

2.14.6 The Target population

The population for which the questionnaire was developed. This is important to judge the suitability of a questionnaire for a specific purpose. Relevant concepts can be defined in terms of symptoms, functioning (physical, psychological and social) general health perception, and overall quality of life. Adequate description of the target population is therefore important for judging the comprehensiveness and the applicability of the questionnaire in other populations. The target population should have been involved during item selection, as well as experts (Terwee et al, 2007).

TABLE 2.2

Quality Assessment for Psychometric Properties

Property	Definition	Quality Criteria
1. Content Validity	The extent to which the domain of interest is comprehensively sampled by the items in the questionnaire	+ A clear description is provided of the measurement arm, the target population and experts were involved in item generation and selection ? A clear description of the above is lacking Only target population is involved Doubtful design or method - No target population involvement 0 No information found on target population involvement
2.Construct Validity	The extent to which scores on a particular questionnaire relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured	+ Specific hypotheses were formulated AND at least 75% of the results are in accordance with these hypotheses ? Doubtful design or method (e.g. no hypotheses): _ Less than 75% of hypotheses were confirmed, despite adequate design and methods; 0 No information found on construct validity
3. Reliability	The extent to which patients can be distinguished from each other, despite measurement errors (relative measurement error)	+ ICC or Weighted Kappa ≥0.70 ? Doubtful design or method (e.g. time internal not mentioned) _ ICC or weighted Kappa <0.70, despite adequate design and method; 0 No information found on reliability

Property	Definition	Quality Criteria
4. Responsiveness	The ability of a questionnaire to detect clinically important changes over time	+ Smallest detectable change (SDC) > 1.96 or AVC ≥0.70 ? Doubtful design or method SDC ≤ 1.96 or AVC < 0.70 despite adequate design and methods 0 No information found on responsiveness
5. Internal Consistency	The extent to which items in a (Sub) Scale are inter correlated, thus measuring the same construct	+ Factor analysis performed on adequate sample size AND Cronbach's alpha is between 0.70 and 0.95 ? No factor analysis OR doubtful design or method - Cronbach's alpha <0.70 or > 0.95 No information found on internal consistency
6. Criterion Validity	The extent to which scores on a particular questionnaire relate to a gold standard	+ Convincing arguments that gold standard is "gold" AND correlation with gold Standard ≥ 0.70 ? No convincing arguments that gold standard is "gold" OR doubtful design or method - Correlation with gold standard <0.70, despite adequate design and method 0 No information found on criterion validity
SDC = Smallest detectable change ICC = Internal Consistency	+ = Positive rating ? = Indeterminate rating - = Negative rating 0 = No information available	Doubtful design or method = lack of a clear description of the design or methods of the study, sample size smaller than 50 subjects

Key: *+ = Positive rating*
? = Indeterminate rating
- =Negative rating
0= No information available
SDC = Smallest detectable change
ICC = Intraclass correlation coefficient

CHAPTER THREE
MATERIALS AND METHODS

3.1 Instrument Development Phase

The recommended process for development of outcome measures for pain clinical trials (Turk et al, 2006) was followed in developing this instrument. The stages were as follows:

3.1.1 Identification of Scientific Approach:

Pain assessment in stroke survivors was performed with emphasis on pain location/severity, patient's report on pain interference on their physical and psychosocial functioning, clinician report/assessment (associated signs and symptoms).

3.1.2 Conceptual Model of the Stroke-specific Pain Scale:

The conceptual model of the stroke-specific pain scale is based on the need for pain assessment following a stroke. Clinician-measured items were included so as to harmonise discrepant perceptions between patients and clinicians regarding health status, impact of disease, and treatment outcome priorities and preferences (Clinch et al, 2001; Hewlett et al, 2001). The IbSSPS combines both self-report and clinician-measured items. Also, self-report was included because people with particular diseases or symptoms have unique perspectives on the impact of the disease and its treatment on everyday functioning and well-being and thus are of critical importance in developing a disease specific measure (Garrat et al, 2001).

It has also been noted that outcome measures that directly assess the interference of pain on physical functioning will be more relevant and responsive to treatment benefits than measures that more generally assess physical limitations (Turk et al, 2006).

3.1.3 Devising Items

Four (4) sessions of Focus Group Discussion (FGD) were held to explore different aspects of post-stroke pain based on the domains of interest: pain location / severity, pain interference with physical functioning and psychosocial functioning, and signs and symptoms of post-stroke pain as recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) protocol (Turk et al, 2006).

Literature search was conducted in English Medical Databases: namely Cochrane, Pubmed, Google Scholar. Search items were: 'post-stroke pain', 'pain scales in stroke', 'types of post stroke pain', 'assessing pain after a stroke'. This was to identify possible areas of concern about post-stroke pain explored in literature which was used in developing the focus group discussion guide

3.1.3.1 Participants for the Focus Group Discussion (FGD)

Eighteen (18) stroke survivors (9 males, 9 females) of not longer than 12 months onset were recruited purposively from among patients attending the physiotherapy outpatient clinic of the University College Hospital for the focus group discussion. The four groups consisted of five, four, four and five participants each. The stroke survivors were recruited based on presence of pain and level of literacy in English language. These participants were excluded from the other parts of the study.

3.1.3.2 Procedure for Data Collection.

Ethical approval was obtained from UI/UCH Ethics Committee (Appendix III). The rationale and the procedure for the study were explained to the participants and their informed consent sought and obtained. The researcher moderated the proceedings. The subjects were informed of the need to record the proceedings. The FGD explored different aspects of post-stroke pain to know the common locations and the level of interference of the pain with physical and psychosocial functions. Two sessions were held for males and two for females with four to five participants per focus group. The participants were informed that some of the questions may make them feel uncomfortable, hence they could opt out or stop if they did not wish to continue.

The Focus Group sessions were held at the gymnasium of the Department of Physiotherapy, University of Ibadan. The place was comfortable for the subjects to interact and discuss the research topic. There were no distractions, the location was secure and private considering the personal and sensitive nature of some of the information. The discussions were kept anonymous while also limiting the types of identifiers in order to reduce the risk of identification. Participants were reminded of the need for the information discussed during the focus group to remain confidential.

The focus group session lasted between 1 hour and 1hour 30 minutes and it was a one-time visit. The participants were given transport fare, lunch and treated for their pain.

3.1.3.3 Data Management

The recording was transcribed and the texts categorised to find common themes while also considering the notes. Based on the domains of interest, the items were grouped into four.

3.1.4 Content Validity

3.1.4.1 Expert's Rating

Copies of the list of the devised item and details about the stroke-specific pain scale under development were sent to 8 experts for review (content relevance). Experts were chosen based on their research work and publications in the fields of neurology and scales development and/or clinical experience (≥10 years post qualification experience). These experts comprised:

5 Physiotherapists, 1 Neurologist, 1 Epidemiologist, 1 Anaesthetist

They were asked to rate the degree of relevance/importance of each item to the main theme (Post-Stroke Pain) on a Likert scale (5-Extremely important, 4-Very important, 3- Important, 2-Slightly important, 1-Not important). They also evaluated the appropriateness of the generated items.

3.1.5.1 Scaling Responses

1. The response scales for Section A (self-report) was adapted from Schaeffer and Pressure (2003). Five response categories (Likert scale of 0-4) was used

because this has been found reliable. It gives more stable results and provides better scales. Response for section B was zero for absent and 1 for present.

2. The items/questions were closed while using simple terms which have the same meaning to all stroke survivors. Attempt was made for the questions to be as brief as possible flowing smoothly from one to the next.

3.1.5.2 Experts Meeting

A meeting of the experts who did the initial review for content relevance was held to review the scale and clarify other issues such as wording and method of administration. The meeting was held on Wednesday 12th April 2012 between the hours of 11.00am and 1.00pm.

The proceeding of the experts' meeting was video-taped and pictures were taken.A concensus was reached on the following issues:

1. Section A to be self report and Section B clinician-administered.
2. Instructions for domains 2 and 3 to read: 'To what extent does your pain interfere or limit the following activities'
3. Domain I should not be represented by picture because of possible spatial neglect or hemianopia commonly experienced by stroke survivors.

3.1.5.3 Pretesting of the Draft of the Stroke-specific Pain Scale

The initial draft of the Instrument was pretested among 30 purposively selected stroke survivors receiving physiotherapy at the physiotherapy outpatient unit of University College Hospital and Adeoyo Maternity Hospital, Yemetu Ibadan (These subjects did not participate in the focus group sessions and psychometric testing phase). The aim of the pretest was to ensure that the items were comprehensible, unambiguous and not double-barrelled (i.e. ask only one question). It was also aimed at checking the relevance of the items to pain in the target population.

3.1.5.4 Item Elimination

Following the pre-testing, the frequency of endorsement of the items was calculated and items with endorsement rates between 0.2 and 0.8 were retained.This excluded the following items most of which were rated by more than one expert as not important were eliminated

Domain 1 - Head, Forearm

2 - Recreational activities, Enjoyment of life, Social life

3 - Sitting and caring for self

4 - Pain is referred and associated joint stiffness

3.1.6 Naming of the instrument

The initial draft of the instrument was named "Stroke-specific Pain Scale' to indicate its specificity to assessment of pain in stroke survivors. The final draft of the instrument was named "Ibadan Stroke-Specific Pain Scale (IbSSPS)' to give it a specific identity and reflect that it was developed at the University of Ibadan.

3.1.7 Description of the Ibadan Stroke-specific Pain Scale (IbSSPS)

The Ibadan Stroke-Specific Pain Scale is a disease-specific pain scale with 36 items.

Population: The IbSSPS was developed for use among stroke survivors with post-stroke pain

Purpose: To assess pain location and severity, impact of pain on psychosocial and physical functioning and the associated signs and symptoms.

Content: It contains two sections A- self report and section B is clinician report.

Section A has 3 domains namely:

a. Pain location /severity with 12 items.
b. Psychosocial functioning with 6 items
c. Physical functioning with 11 items

Section B has only one domain- signs and symptoms with 8 items

Administration: It is a combination of self and clinician report. Minimal instruction is needed.

Time to administer/ complete is approximately 15mins

Scoring: responses in section A are scored on a Likert scale of 0 to 4 using descriptors for all the items which correspond to an ordinal scale of 0 to 4

1. Pain location / severity with 12 items on a 5 point ordinal scale (0-4)(no pain, minimal pain, moderate pain, severe pain and extreme pain) and a maximum obtainable score of 48.

2. Psychosocial functioning with 6 items on a 5 point ordinal scale (0-4)((Not at all, a little, moderately, severely and extremely) and a maximum obtainable score of 24.
3. Physical functioning with 11 items on a 5 point ordinal scale (0-4)(Not limited by pain, minimally limited, moderately limited, severely limited and activity not possible because of pain) and a maximum obtainable score of 44.

The items are summed for each subscale resulting in the following ranges: Pain location/severity 0-48, Psychosocial functioning 0-24, Physical functioning 0-44, while a total IbSSPS score is created by summing the items for the 3 subscales in section A. The maximum obtainable score on IbSSPS is 116. However, section B is a disciminatory tool which categorizes nociceptive and neuropathic post-stroke pain.
The total score on IbSSPS was calculated as $\frac{\text{Score obtained X 100}}{116}$

This was adapted from the Oswestry Pain Disability Questionnaire in which the scoring for each participant was calculated as
$\frac{\text{Participants score}}{\text{Total possible score}}$ X 100 (Wright et al, 1998)

Interpretation: Higher scores on the IbSSPS indicate worse pain and more negative impact on physical and psychosocial functioning.

3.2 Psychometric Testing Phase

3.2.1 Study Design

This was a prospective design approved by the University of Ibadan/University College Hospital Ethics Committee

3.2.2 Participants

Based on the guidelines for scale development (recommending a minimum of 50 patients for validation) by Terwee et al, (2007), Sixty-four (33 females and 31 males) survivors experiencing pain receiving physiotherapy at the outpatient clinic of the University College Hospital, were consecutively recruited. Stroke patients with first incidence stroke, not > 12months onset, who were able to communicate effectively in English language and willing to participate in the study with the provision of informed consent were considered eligible.

Fifty six (29 females, 27 males) stroke survivors completed the study with fifty-six age (56) and sex-matched apparently healthy individuals recruited from among members of staff of UCH, and relations of members of staff who had no complaint of pain at the point of recruitment served as the control group.

3.2.3 Materials

1. The newly-developed Ibadan Stroke-Specific Pain Scale (IbSSPS) for assessing pain.
2. An open-ended questionnaire to obtain sociodemographic data and clinical history from the participants (Appendix V).
3. Verbal Descriptor Scale for global rating of pain. This is a 5 point unidimensional pain assessment tool that uses descriptive words rather than numbers to allow the patient to assign a value to his or her current pain experience from ‘no pain’ ‘mild pain, ‘moderate pain’, ‘severe pain’, or ‘very severe pain. It is self scoring with the ability to quickly and reliably screen for pain. It has good internal consistency,test-retest reliability from 0.52 to 0.83. A factor analysis has also found the scale valid (Herr et al, 2004).

3.2.4 Procedure for data collection

The rationale and procedure for the study were explained to the participants and their informed consent obtained. Sociodemographic data on age, sex, occupation, educational level, marital status, and clinical history: onset of pain, side of affectation were obtained from the participants and recorded. Cognitive ability was based on the ability to comprehend and execute 3-word command.

Convergent validity was assessed by comparison with the Verbal Descriptor Scale. The stroke survivors were asked to rate their pain globally on the categorized verbal descriptor scale i.e. a general assessment of the pain they are experiencing at that point in time to assess convergent validity. After this, a copy of the Ibadan Stroke-Speccific Pain scale (IbSSPS) was administered to each stroke survivor. Administration of IbSSPS was repeated 2 hours later to assess test-retest reliability. A short-term test-retest interval of 2 hours was chosen for ethical reasons. A shorter interval would have introduced recall bias while longer interval was not allowed because the participants were experiencing pain. The first copy of the scale was collected before presenting the second copy. The IbSSPS was administered to their age and sex-matched apparently healthy counterparts who served as the control group to determine known-group validity.

The stroke survivors received physiotherapy for their pain twice a week for 6 weeks after which the IbSSPS was administered again to assess responsiveness of the scale to physiotherapy intervention. Physiotherapy intervention for pain included use of hydrocollator pack, cryotherapy, mobilization exercises, as indicated for respective patient).

The use of the hydrocollator was explained to the participants to get his/her consent while also ensuring that there are no contraindications to the use of local heat. The area to be treated was checked visually to see what the participants' skin looks like before treatment. The gel pack was wraped in a large towel to protect the participants' skin from burning and prevent the pack from cooling fast and wraped round the painful parts. The participants were warned during the course of the treatment (Be sure you tell me right away if it feels too hot). The skin was checked every 3mins for the first 10mins

3.2.5 A Priori Statements

i. To establish known-group validity, stroke survivors are expected to have significantly higher IbSSPS score than the apparently healthy controls.

ii. To establish convergent validity, correlations above 0.6 reflects a strong association (McDowell and Newell, 1996).

iii. A moderate correlation (0.4< r< 0.6) is expected between the Categorized Verbal Descriptor Scale andthe IbSSPS while a strong correlation is expected with the pain location and severity domain and lower correlation (r<0.4) with the other three domains.

iv.The IbSSPS will be responsive to change in the pain status of the stroke survivors after 6 weeks of physiotherapy intervention.

3.2.6 Data Analyses

i. Data analysis were performed using the Statistical Package for Social Science (SPSS) software

ii. Descriptive statistics of mean and standard deviation was used to summarize the data.

iii. Mann-Whitney–U test was used to compare the IbSSPS scores of the stroke survivors and their age and sex-matched apparently healthy counterparts (Known-group validity).

iv. Spearman's rho correlation was used for the correlation between the categorized verbal descriptor scale and the Ibadan stroke–specific pain scale (Convergent validity).

v. Intraclass correlation coefficient was used to determine the correlation between the IbSSPS scores obtained by stroke survivors on two different occasions.

vi. Factor analysis was performed while internal consistency reliability was tested through Cronbach's alpha statistics.

vii. Responsiveness (sensitivity to change) was determined by examinig the standardized effect size (SES) and the standardised response mean (SRM). The SES is equal to the mean change in score from the baseline to 6 weeks, divided by the standard deviation of the baseline score while the standardised response mean is calculated as the mean change in score from the baseline to

6 weeks, divided by the standard deviation of the change in the score (Liang et al, 1990).

viii. The Wilcoxon signed rank test was also used to compare the scores obtained on the IbSSPS by stroke survivors before and after 6 weeks of physiotherapy.

ix. Level of significance was set at 0.05

CHAPTER FOUR

RESULTS AND DISCUSSION

4.1 RESULTS

4.1.1 Clinical and Demographic Characteristics of Participants

Fifty-six stroke survivors (27 males, 28 females) and 56 age and sex-matched apparently healthy adults without history of stroke participated in the psychometric testing phase of this study. The duration of pain onset for the stroke survivors ranged between 2 and 16 weeks while those whose pain began between 3 and 8 weeks after stroke constituted 89.1% of the sample as shown in table 4.1.

Sixty-eight percent (19 males and 19 females) of the stroke survivors had left-sided hemiplegia while 32% (7 males and 11 females) had right-sided hemiplegia (Figure 4.1). The educational level of the participants (stroke survivors and apparently healthy individuals stroke survivors) is shown in Figures 4.2 and 4.3. There was significant difference between the mean age of the Stroke Survivor Group (SSG) (56 ± 11.08, range=33 - 74 years) and that of the Apparently Healthy Control (AHC) (57± 11.07, range=34-76years). The characteristics of the participants showed the homogeneity of the groups.

TABLE 4.1

Pain Onset of Stroke survivors (N= 56)

	Pain onset post-stroke	
Duration (weeks)	**N**	**%**
2	1	1.8
3	10	17.9
4	11	19.6
5	3	5.3
6	13	23.2
7	4	7.1
8	9	16.0
9	1	1.7
10	1	1.8
11	2	3.6
12	2	3.6
16	1	1.8

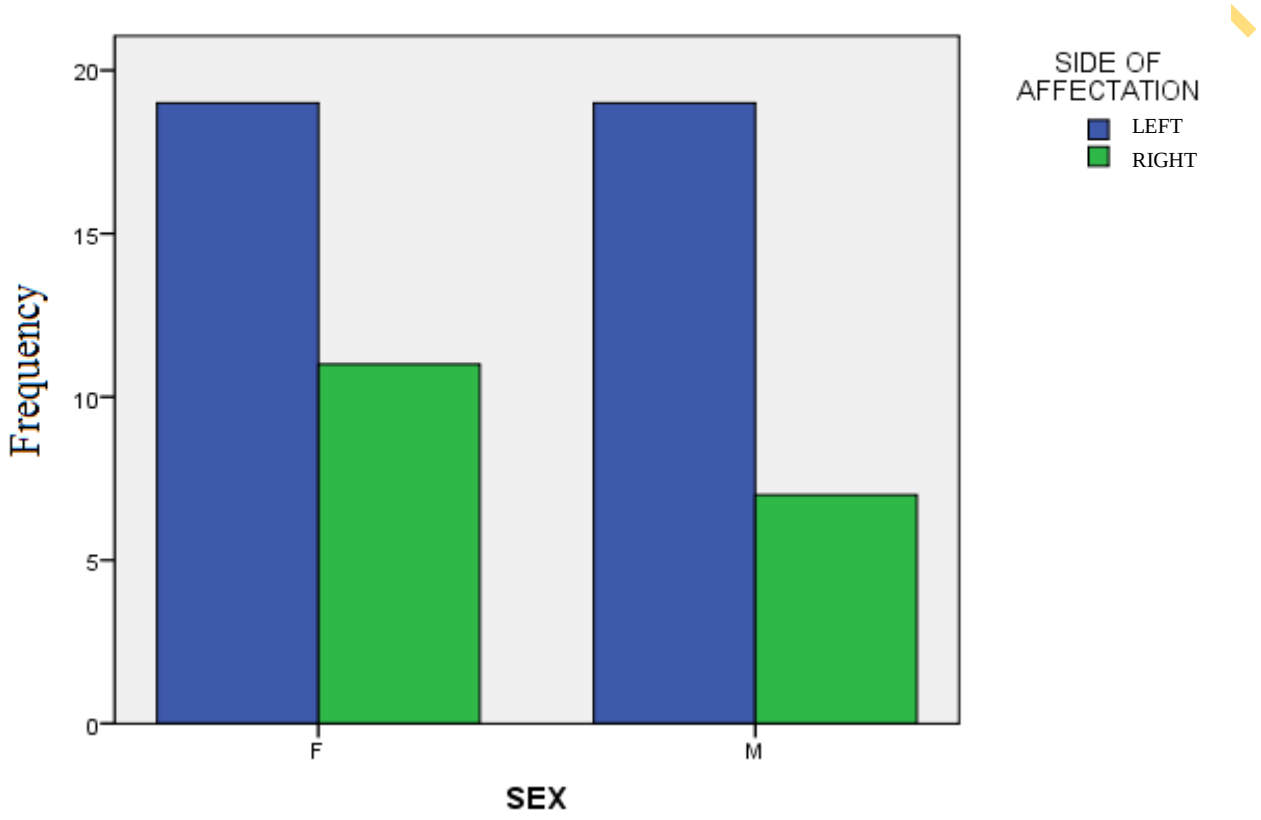

Figure 4.l : Side of Affectation of Stroke Survivors

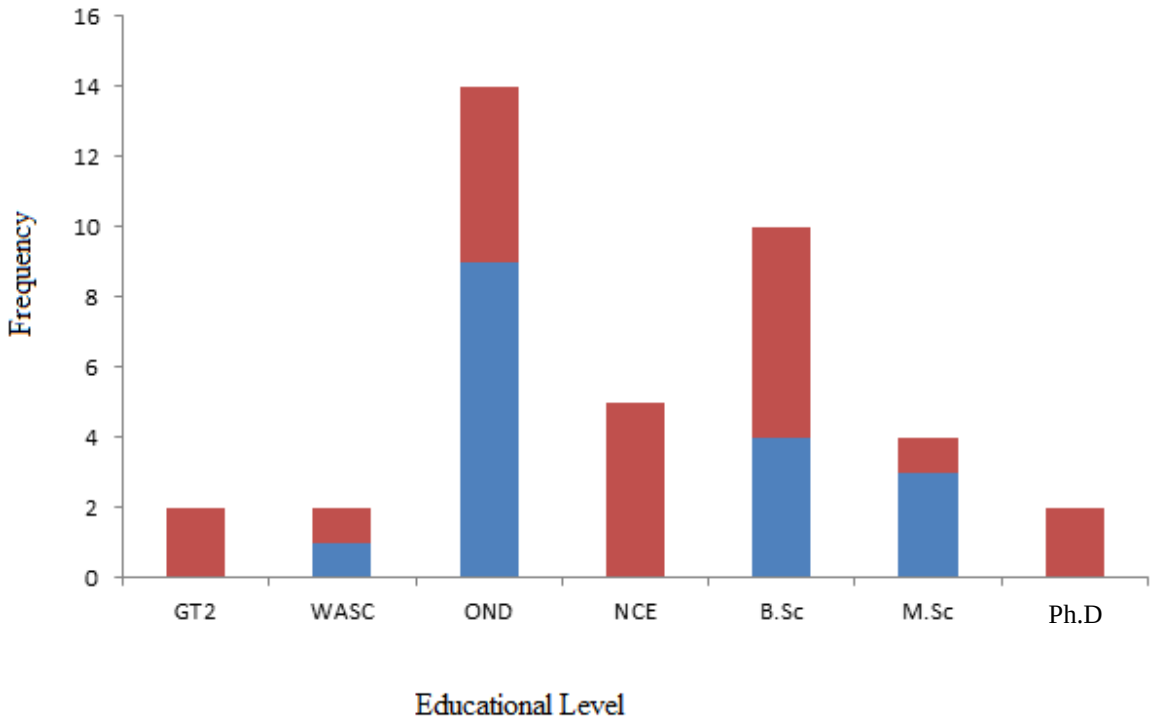

Figure 4.2: Educational level of Stroke Survivors (N= 56)

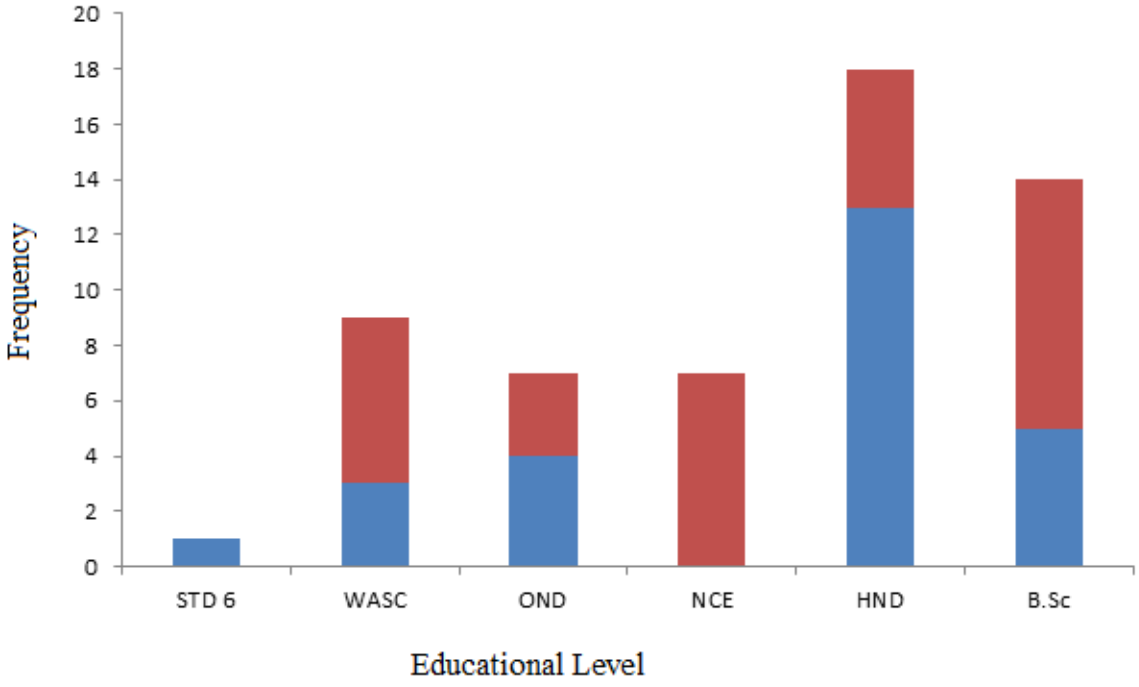

Figure 4.3: Educational Level of Apparently Healthy Controls (N= 56)

4.1.2 Themes based on the domains of interest generated from the FGDs

Theme 1: Parts of the body where pain is felt

According to respondents:

'I feel pain in my neck, in my joints: shoulder, elbow, fingers, and wrist.

In, fact, my upper arm and forearm pain me'

(A male stroke patient FGD/UCH)

Another asserted that:

My hip and my knee pain me

'To say the truth, every part of the arm and leg affected give me pain'

(Female stroke patient /FGD/UCH)

Theme 2: Area of your life/ well being that the pain affects.

A respondent in his own submission noted thus:

'In fact, my mood, my sleep and even my willingness to interact with people is affected negatively'

(Female stroke patient/FGD/UCH)

Others emphasized that

Religious activities, sexual activities which seemed to be improving became hindered by the pain l'm experiencing

(Male stroke patient /FGD/UCH)

'My own pain is minimal, I can still cope well with life'

(Male stroke patient/FGD/UCH)

'Actually, the interference with my well-being is moderate but I still need attention'

(Female stroke patient/FGD/UCH)

Theme 3: Interference of pain experienced on activities of daily living

A respondent said:

'Actually, there are somethings that I can now do which I couldn't do before but this pain has been preventing me again since it started'

For example, combing my hair, tying my scarf.

'Even my walking was better until this pain started in my hip and knee'

(Female stroke patient/FGD/UCH)

Another respondent said:

I feel this pain when I stand, even when I'm trying to walk. I think my muscles are stronger but I want this pain to go. It is almost giving me more problem than the stroke because, it affects almost everything I want to do.

(Male stroke patient/FGD/UCH)

Theme 4: Pain description characteristics, associated symptoms

Respondents in the FGD sessions described their pain gets worse when that part of their body is touched or pressed. Also when that part of their body is moved.

Pain is there most times

Sometimes, I feel the place is stiff

I don't know if it is the pain that also causes the swelling

In fact, the pain worsens when my clothes scratch the painful part

The pain burns say like hot water.

(Male & Female stroke patients/FGD/UCH)

4.1.3 Outlined items based on responses from FGD

The following items were then outlined based on the responses from the FGD.

A. Pain location

i. Head
ii. Neck
iii. Shoulder
iv. Upper arm

v. Elbow
vi. Forearm
vii. Wrist
viii. Fingers
ix. Low back
x. Hip
xi. Thigh
xii. Knee
xiii. Leg
xiv. Ankle
xv. Toes

B. Psychosocial Functioning

i. Recreational activities
ii. Sleep
iii. Mood
iv. Work in and outside the house
v. Sexual activities
vi. Enjoyment of life
vii. Social life
viii. Interacting with friends and relations
ix. Religious activities

C. Physical Functioning

i. Bathing
ii. Walking
iii. Standing
iv. Lifting object
v. Caring for self
vi. Dressing up
vii. Wearing cap/tying head gear

viii. Feeding self
ix. Combing hair
x. Rolling in bed
xi. Sitting
xii. Squatting
xiii. Climbing stairs

3. Signs and Symptoms

i. Pain at rest
ii. Pain on palpation
iii. Pain is localized
iv. Pain is referred
v. Painful area sensitive to touch/clothing
vi. Feels pins and needles sensation
vii. Swelling
viii. Pain aggravated by movement
ix. Associated joint stiffness
x. Feels burning sensation

4.1.4 Convergent Validity of the Ibadan Stroke-specific Pain Scale

The lbSSPS showed a moderate correlation with the Verbal Categotical Pain Scale with a coefficient value of 0.58. However, across the domains, there was a range of 0.29 to 0.47 except the Pain location and severity domain with a strong correlation of 0.65 as shown in Table 4.2.

4.1.5 Known-group Validity of the Ibadan Stroke-Specific Pain Scale

The mean IbSSPS Total score of the Stroke survivor group (34.04±18.58) was statistically higher than that of their apparently healthy controls (3.11±3.48) (Table 4.3). The significant difference showed a higher trend for the stroke survivors across all the four domains. This reflects the ability of the IbSSPS to differentiate between stroke survivors with post-stroke pain and those without.

TABLE 4.2

Correlation between Categorized Verbal Descriptor Scale and Ibadan Stroke-specific Pain Scale (IbSSPS) (N=56)

Domain on IbSSPS	Spearman Rho	P –value
Pain location/Severity	0.65	0.01*
Psychosocial functioning	0.39	0.01*
Physical functioning	0.47	<0.001*
Signs and Symptoms	0.29	0.28
Total (IbSSPS)	0.58	<0.001*

IbSSPS: Ibadan Stroke-specific Pain Scale

***** significant at p< 0.01

TABLE 4.3

Comparison of Ibadan Stroke-Specific Pain Scale scores for Stroke Survivors (SSV) and their Apparently Healthy Controls (AHC) Using Mann Whitney-U test (N=56)

	SSV		AHC			
	$\bar{X}$ ± SD		$\bar{X}$ ± SD		Z	P
Pain location/Severity	6.80	5.2	1.11	1.37	-8.01	<0.001
Psychosocial functioning	10.16	6.2	1.02	1.68	-7.69	<0.001
Physical functioning	20.79	11.36	0.98	1.21	-8.45	<0.001
Signs & Symptoms	3.48	1.18	1.84	1.82	-5.47	<0.001
TOTAL Score	38.04	18.58	3.11	3.48	-8.57	<0.001

SSV: Stroke Survivors

AHC: Apparently Healthy Control

Significant at $p \leq 0.01$

4.1.6 Test-retest Reliability of the IbSSPS

The Intra Class Coefficient (ICC) for the IbSSPS was high (0.93). The ICC of the domains ranged between 0.85 and 0.94, the highest being pain location and severity (0.94) and the lowest, being both the Physical functioning, Signs and symptoms domains as shown in Table 4.4.

4.1.7 Internal Consistency Reliability

Tables 4.5, 4.6, 4.7 and 4.8 shows the proportion of each variable's variance that can be explained by the factors. The factor loadings were presented as correlation coefficients revealing adequate loading of each of the items in each of the domains. Tables 4.9, 4.10, 4.11 and 4.12 shows the rotated factor loadings (factor pattern matrix) representing the correlation between the variables and the factors. The internal consistency of the domains of the IbSSPS ranged from good to excellent between 0.64 and 0.90. The highest being the physical functioning domain and the lowest the signs and symptoms domain as shown in Table 4.13. This reflects the homogeneity of the items within the psychosocial and physical functioning domains while that of the pain location and severity and the signs and symptoms domains were weakly correlated.

4.1.8 Responsiveness

A significant decrease was observed ($p< 0.05$) in the mean IbSSPS score for the stroke survivors before (41.52 ± 18.86) and after (32.41 ± 15.31) physiotherapy intervention to manage the pain.

Across the 4 domains, there was significant reduction in the IbSSPS scores of the participants after physiotherapy showing good sensitivity. The response to physiotherapy was more evident with the pain location and severity domain (Tables 4.14 and 4.15). The standardized effect size for the domains ranged between 0.59 and 0.70 revealed a mild to moderate degree of responsiveness. The standardized response mean also ranged between 0.5 and 0.9 thereby demonstrating moderate to high degree of responsiveness. This difference conotes the ability of the lbSSPS to pick clinically relevant changes in the pain status.

TABLE 4.4

Test-retest Reliability of Ibadan Stroke Specific Pain Scale Using Intraclass Correlation Coefficient (N=56)

	Intraclass CC	Lower bound	Upper bound	Significance
Pain location/severity	0.94	0.90	0.97	<0.001*
Psychosocial functioning	0.88	0.80	0.93	<0.001*
Physical functioning	0.85	0.76	0.91	<0.001*
Signs & Symptoms	0.85	0.76	0.91	<0.001*
TOTAL Score	0.93	0.89	0.96	<0.001*

Key

* significant at $p < 0.01$

TABLE 4.5

Communalities for Pain location/severity domain

Item	Extraction
Neck	0.72
Shoulder	0.67
Upper arm	0.76
Elbow	0.77
Wrist	0.58
Fingers	0.80
Low back	0.73
Hip	0.67
Thigh	0.42
Knee	0.76
Ankle	0.70
Toes	0.67

***** Acceptable value ≥ 0.4

TABLE 4.6

Communalities for Psychosocial functioning Domain

Item	Extraction
Sleep	0.67
Mood	0.73
Work in and outside the home	0.74
Interaction with friends and relations	0.63
Sexual activities	0.70
Religious activities	0.65

*Acceptable value ≥ 0.4

TABLE 4.7

Communalities for Physical functioning Domain

Item	Extraction
Bathing	0.62
Walking	0.77
Lifting	0.69
Standing	0.75
Dressing up	0.70
Tying head gear/wearing cap	0.81
Feeding self	0.87
Combing hair	0.72
Rolling in bed	0.64
Squatting	0.76
Stairs climbing	0.71

*Acceptable value ≥ 0.4

TABLE 4.8

Communalities for Signs and Symptoms Domain

Item	Extraction
Swelling	0.70*
Pain on palpation	0.78*
Pain is localize	0.77*
Painful area sensitive to touch/clothing	0.62*
Feels pins/needles/burning sensation	0.81*
Pain at rest	0.64*
Pain on passive/active movement	0.81*

* Acceptable value ≥ 0.4

TABLE 4.9

Rotated Component Matrix for Pain location and Severity domain

Item	Component				
	1	2	3	4	5
Shoulder	0.62				
Wrist	0.68				
Fingers	0.84				
Ankle	0.62				
Toes	0.69				
Neck		0.77			
Elbow		0.78			
Low-back		0.62			
Knee			0.86		
Hip				0.69	
Upper arm					0.84
Thigh					0.54

*Acceptable value ≥ 0.4

TABLE 4.10

Rotated Component Matrix for Psychosocial Functioning Domain

Item	Component	
	1	2
Sexual activities	0.83	
Work in and outside the house	0.78	
Religious activites	0.79	
Interaction with friends and relations		0.69
Mood		0.62
Sleep		0.80

*Acceptable value ≥ 0.4

TABLE 4.11

Rotated Component Matrix for Physical Functioning domain

Item	Component		
	1	2	3
Walking	0.83		
Rolling in bed	0.65		
Standing	0.75		
Squatting	0.85		
Stairs climbing	0.74		
Bathing		0.66	
Lifting objects		0.74	
Dressing up		0.73	
Tying head		0.88	
gear/wearing cap			
Feeding self			0.89
Combing hair			0.68

*Acceptable value ≥ 0.4

TABLE 4.12

Rotated Component Matrix for Signs and Symptoms Domain

Item	Component			
	1	2	3	4
Swelling	0.78			
Pain at rest	0.72			
Feels pins & needles/ burning sensation		0.81		
Pain on passive / active movement			0.90	
Pain on palpation				0.25
Pain is localized				0.85
Painful area sensitive to touch				0.59

*Acceptable value ≥ 0.4

TABLE 4.13

Internal consistency for the Domains of Ibadan Stroke-specific Pain Scale

Domain	Cronbach's Alpha	No of Items
Pain location/severity	0.65	12
Psychosocial functioning	0.79*	6
Physical functioning	0.90*	11
Signs and Symptoms	0.64	7

*Acceptable value ≥ 0.7

TABLE 4.14

Comparison of Ibadan Stroke-Specific Pain Scale scores before and after 6-weeks of Physiotherapy using the Wilcoxon-signed rank test (N=56)

	Pre		Post			
	X ± SD		X ± SD		Z	p
Pain location/severity	6.80	5.21	4.63	3.69	-5.40	<0.001*
Psychosocial functioning	10.16	6.21	7.87	4.94	-5.22	<0.001*
Physical functioning	20.79	11.36	17.69	9.92	-3.72	<0.001*
Signs & Symptoms	3.48	1.18	2.32	1.65	-3.94	<0.001*
TOTAL	41.51	18.86	32.41	15.31	-4.98	<0.001*

Significant at < 0.01

TABLE 4.15

Responsiveness of Ibadan Stroke-Specific Pain Scale

Domain	SES	SRM
Pain location/severity	0.59	0.9
Psychosocial functioning	0.47	0.8
Physical functioning	0.31	0.5
Signs and Symptoms	0.70	0.6

SES – Standardized Effect Size

SRM – Standardised Response Mean

4.2 Discussion

4.2.1 Development of the Ibadan Stroke-specific Pain Scale

Pain after a stroke is an often neglected matter in clinical practice. Pain scales that are useful in other population of patients have been found to be invalid in the stroke population hence the need for a pain assessment tool to help stroke survivors communicate effectively about their pain to the clinician. This is more important considering the fact that stroke is a disease often with life-long consequences (Vanhook, 2009).

Assessment or evaluation is paramount to the treatment of any clinical condition. However, it is a widely held view that disease-specific measures of health may identify different, yet complimentary aspects of an individual's health status. The availability of a scale for assessing pain in stroke survivors will meet the need to assess all stroke survivors for pain because disease-specific measures have been found to describe better the impact of a disease on functioning.

4.2.2 Content Validity

The Ibadan Stroke-Specific Pain Scale showed excellent content validity, which is an assessment of how well the domains of interest are sampled poosibly because it was developed with the target population distinctively defining the domains. The comprehensive and multi-dimentional nature of the scale, that is covering four (4) domains of the same construct makes the instrument suitable for singular usage in clinical trials of intervention for post-stroke pain. This is similar to the experience of Williams et al (1999) with the stroke-specific quality of life and Owolabi (2011b) in the development and validation of the shortened version of the Stroke-specific health-related quality of life-(HRQOLISP-26).

4.2.3 Known-group's Validity

The observed higher IbSSPS score in the apparently healthy group is an indication that IbSSPS is able to differentiate between individuals with, and those without symptoms of

post-stroke pain. This provides evidence that IbSSPS has adequate construct validity. The proposed construct was that IbSSPS would be able to differentiate between patients with post-stroke pain and those without.

A measure is said to be valid only if it measures what it is supposed to measure and not something else. This earns the IbSSPS a positive rating for construct validity. The good construct validity demonstrated by the IbSSPS, reveals its qualities also as a disease-specific measure with precise responses which captures the uniqueness of pain in a stroke suvivor. This would make it very useful in the stroke population like other Stroke-specific measures like the Health Related Quality of Life in Stroke Patients (HRQOLISP) (Owolabi, 2011b) in its ability to tap disease-specific concepts and assess the worst and best health states possible.

4.2.4 Convergent Validity

Convergent validity reflects the extent to which two measures capture a common construct (Kevin et al, 2012). The Pain location/Severity domain of the IbSSPS was strongly correlated to the Categorized Verbal Descriptor pain scale revealing that this domain truly measures pain severity. However, the moderate correlation of the IbSSPS total score to the categorized verbal descriptor pain scale suggests that the IbSSPS is a composite of several components measuring the same construct. This means that the two scales are related rather than being totally distinct (Storch et al, 2004). This was demonstrated through testing a priori hypothesis comparing the lbSSPS with an instrument measuring the same construct (pain), the Categorized Verbal Descriptor scale. Correlations above 0.6 reflects a strong association (McDowell and Newell, 1996). High coefficients were not expected across the other domains as these would indicate strong similarities between the measures. Conversely, lower coefficients would indicate that the measures were assessing different constructs. A moderate correlation ($0.4 < r < 0.6$) was expected with the total IbSSPS while a strong correlation was expected with the pain location and severity domain and lower correlation ($r<0.4$) with the other three domains as they do not directly measure pain but its advserse effects and impact on functioning.

The categorized verbal descriptor pain scale is a product of pain intensity scores derived from multiple tools that were equated and categorised into 'no pain', 'mild pain', 'moderate pain' and 'severe pain,' 'pain as bad as it could be' has been found useful in guiding treatment decisions and evaluation of treatment (Jones et al, 2007). It was used because there is no formally recognised gold standard for the assessment of pain either in stroke survivors nor in neurological patients.

4.2.5 Test-retest Reliability

The lntraclass correlation coefficient (ICC) for the subscales and the total score for the lbSSPS were very high, ranging from 0.85 to 0.94. This indicates that IbSSPS is a reliable measurewith consistent results from one time of use to the next. Intraclass Correlation Coefficient lower than 0.4 represents poor reliability, between 0.4 and 0.75 represents moderate reliability, 0.75 to 0.90 represents substantial reliability while values higher than 0.90 represents excellent reliability (Nunnally and Bernstein, 1994) . This is similar to the findings of Bouhassira et al (2004) in the evaluation of the Neuropathic Pain Scale which was greater than 0.90 for all the items. This is likely evident for reasons of usage of words (verbal descriptors) rather than figures in the development of the instrument. For patients with cortical deficits like stroke, it has been suggested that words are better comprehended than figures or pictures even in a state of mild to moderate cognitive deficits (Chibnall and Tait, 2001).

The high level of reliability found with the IbSSPS fulfilled Nunnally's criterion which considers an lCC value of 0.7 as acceptable The findings of this study also meet the Terwee criterion which gives a positive rating for reliability when Intraclass Correlation Coefficient is at least 0.7 in a sample of at least 50 patients (Terwee et al, 2007).

4.2.6 Factorial Validity and Internal Consistency Reliability

A factor loading of ≥ 0.4 is considered appropriate for inclusion of an item in a scale (Field, 2000). All the items loaded adequately in their respective domains. However, the rotated factor matrix did not reveal unidimensionality showing that some of the items did not load on the same factor. This may be expected because pain location and severity

cannot load on the same factor because pain in one part of the body would not necessarily imply pain in another part of the body. Also, the signs and symptoms domain is designed to discriminate neuropathic and nociceptive pain just like the Leeds Assessment of Neuropathic Signs and Symptoms (LANSS) scale (Bennett, 2001). The items are therefore not expected to load on the same factor. Internal consistency is a measurement property that tests if the items of an instrument (or subscales of the instrument) are correlated/homogeneous i.e. if multiple items of an instrument measure the same construct.

Cronbach's alpha value of ≥ 0.7 is considered acceptable, from 0.7 to 0.9 as good and values greater than 0.9 is considered to be excellent. However, values > 0.9 may indicate redundancies in the scale (Post et al, 2011). The internal consistency was within the 'good range' of 0.7 to 0.9 for the Pain location and severity, Psychosocial functioning and Physical functioning domain. This is consistent with the findings of Owolabi (2011b) (0.81 to 0.89) in the validation of the HRQOLISP-26. However the Cronbach's alpha for the fourth domain (Signs and symptoms) (0.65) was low. It is a discriminative sub-scale assessing different types of post-stroke pain.

However, the items in the IbSSPS showed moderate item-to-item correlation. Nunnally and Bernstein (1994) proposed a criterion of 0.7 to 0.9 as a measure of good internal consistency while a positive rating is given for internal consistency when factor analysis is applied and internal consistency ranges between 0.7 and 0.95 all of which the IbSSPS fulfilled.

4.2.7 Responsiveness

The newly developed Ibadan Stroke-specific Pain Scale (IbSSPS) showed good responsiveness (sensitivity to clinically relevant changes). This is indicative of the extent to which the scores on the scale reflects changes in the patient's condition, which is expected to be in line with the direction of the pain status. These changes were related to the subjective improvement or alteration of pain after 6 weeks of physiotherapy

intervention. The ability of an instrument to be sensitive to within-patient change is very important in clinical trial.

By convention, standardized effect size scores of less than 0.2 were considered non-responsive, 0.2 to 0.5 as mildly responsive, 0.51 to 0.7 while values greater than 0.7 are considered to be markedly responsive to change (Cohen, 1977). Based on the results obtained in this study, the lbSSPS demonstrates a good attribute of a disease-specific measure to be able to detect small improvements and deteriorations. This will make it a useful tool in assessing the impact of therapeutic and rehabilitative interventions in stroke patients, that can compete favourably as a stroke-specific instrument by being able to assess meaningful changes.

Although preferential or selective therapeutic effect was not demonstrated, the observed changes after intervention were evident for both total and sub-scores. This is contrary to the findings of Bouhassira et al (2004) in the validation of Neuropathic Pain Scale. They found the Neuropathic. Pain Scale to be responsive to changes but the changes were only evidenced for the total score not for the five subscores. Responsiveness, though a component of validity, has been considered a separate attribute of outcome measures because of its pivotal role in clinical trials (Terwee et al, 2007).

CHAPTER FIVE

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.1 Summary

Pain has been found to occur as a secondary comorbid condition or complication of neurological disease at a high prevalence rate. This is very evident among stroke survivors where pain has been found to be a strong limiting factor which prolongs the rehabilitation. Acceptance, recognition and assessment of pain as a risk factor at an early stage is key to preventing the chronicity process of pain especially in stroke where it may be a lifelong issue. However, pain scales otherwise useful in the non-stroke population have been found deficient in assessing pain after a stroke. This report describes the development of a stroke-specific pain scale, the Ibadan Stroke-Specific Pain Scale (IbSSPS) for assessing pain in stroke survivors and provides evidence for its validity, reliability and responsiveness.

Literature review was focused on the epidemiology of stroke, types of post-stroke pain, impact of post-stroke pain, pain evaluation in stroke survivors, review of existing pain measures and steps in scale development. This revealed the reality of post-stroke pain, its evident negative impact on the survivor's recovery, paucity of clinical trials on post-stroke pain and the inability of available pain rating scales in capturing the peculiarities of post-stroke pain.

Recommendations in literature were followed in order to develop a valid, reproducible scale that is capable of detecting changes. The initial scale was developed through the Focus Group Discussion (FGD) process consisting of a small discussion group coordinated by a facilitator which was aimed at suggesting important items for the scale. For the size of the FGD, a small number (5-12) was followed. Four FGDs were conducted with a total of 18 stroke survivors (9 males and 9 females). The discussions were recorded and the researcher took notes. The items were analysed by a group of experts.

The psychometric testing of construct validity (Known group and convergent), test-retest reliability and responsiveness for the final draft of the instrument involved fifty-six stroke survivors experiencing pain. They comprised 29 (51.8%) females and 27 (48.2%) males and 56 age, and sex-matched apparently healthy counterparts without stroke who were consecutively recruited through a purposive sampling technique. Descriptive statistics of mean and standard deviation was used to summarise the data. The scores between the stroke survivors and their apparently healthy controls were compared using the Mann-Whitney U test and the Spearman's rho was used to study the correlation between the Categorical Verbal Rating Scale and the IbSSPS. Intra Class Correlation Coefficient was used to determine the correlation between the IbSSPS scores obtained on two different occassions while the differences between the scores before and after intervention were compared with the Wilcoxon signed rank test.

Results showed the psychometric properties of the IbSSPS fulfilled the quality Criteria for the Psychometric Properties of Health Status Questionnaires developed by Terwee et al (2007) .

Each Psychometric property was rated using the following grades:

+ = Positive rating, indicated that adequate methods and results were used.

? = indeterminate rating, indicated doubtful methods and results were used.

0 = no information available

The known group were found satisfactory with significant difference between IbSSPS scores for stroke survivors (34.04±18.58) and their age and sex matched apparently healthy counterparts (3.11±3.48). The content validity of the IbSSPS was found to be good. The frequency of endorsement being within acceptable range (20%-80%) shows that all the items on the scale are relevant due to the involvement of the target population in the item selection. The Intraclass Correlation Coefficient (ICC) for the 4 domains wehre statistically significant. Also, there was a significant reduction in the domain and total score after physiotherapy intervention (41.51± 18.86 vs 32.42 ± 15.31 z = -5.171). The questionnaire is evaluative and the items are valid for pain assessment in the target population (stroke survivors).

5.2. Conclusions

Based on the findings of this study, the following conclusions were drawn:

1. The Ibadan Stroke-specific Pain Scale has good content and construct validity.
2. lt demonstrated satisfactory test-retest and internal consistency reliability.
3. It is responsive making it a suitable outcome measure for clinical trials.

5.3 Recommendations

The following recommendations are hereby made:

1. Physiotherapists and others concerned with stroke management should consider this new instrument in assessing pain among stroke survivors.
2. The Ibadan Stroke-specific Pain Scale should be translated into Nigerian languages to facilitate usage by patients who do not understand English language.
3. The inter-rater reliability of the Signs and Symptoms domain should be investigated in further studies.

REFERENCES

Adamson,J., Beswick, A., Ebrahim, S. 2004. Is stroke the most common cause of disability? *Journal of Stroke and Cerebrovascular Diseases* 13.4:171-177

Acquadro, C., Berzon, R., Dubois, D., Leidy, N.K.,Marquis, P., Revicki, D., Rothman, M. 2003. Incorporating the patient's perspective into drug development and communication: an ad hoc task force report of the Patient-Reported Outcomes (PRO) Harmonization Group meeting at the Food and Drug Administration, February 16, 2001.*Value Health* 6.5:522-531

Akinpelu, A.O., Olowe, O.O. 2002. Correlative study of 3 pain rating scales among obstetric patients. *African Journal of Medicine and Medical Science* 31.2: 123-126

Alstadhaug, K.B., Prytz, J.F. 2012. Pure sensory syndromes and post – stroke pain secondary to bilateral thalamic lacunar infarcts: a case report.*Journal of Medical Case Report* 6.1: 359

Adeloye, D. 2014. An estimate of the Incidence and Prevalence of Stroke in Africa: A Systemic Review and Meta-Analysis. PloS ONE 9.6:e100724

Appelros, P. 2006. Prevalence and predictors of pain and fatigue after stroke: a population-based study *International Journal of Rehabilitation Research* 29.4: 329-333

Arnstein, P. Assessment of Nociceptive versus Neuropathic pain in older Adults. *Best Practices in Nursing Care to Older Adults* Issue Number SPI 2010

Atkinson, J.H., Chandler, J., Cleeland, C., Cowan, P., Dimitrova, R., Dionne R., Farrar J.T., Haythornthwaite J.A., Hertz S., Jadad A.R., Jensen M.P., Kellstien D., Kerns R.D., Manning D.C., Martins S., Max M.B., McDdermott M.P., McGrath P., Moulin D.E, Nurmikko T., Quessy S., Raja S., Rappaport B.A., Rauschkolb C, Robinson J.P., Royal M.A., Simon L., Stauffer J.W., Stucki G., Toolet J., Stein T.V, Wallace M.S., Wernnicke J., White R.E., Williams A,C., Witter J., Wyrwich

K.W. 2006. Developing patient-reported outcome measures for pain clinical trials: IMMPACT recommendations. *Pain*125: 208-215

Attal N, Guarrimand F, Brassenz L, Gande V, Chauvin M, Bonhassira D. 2002. Effects of IV Morphine in central pain: a randomized placebo-controlled study. *Neurology* 58:554-63

Babbie, E. 2007. The Practice of Social Research (11th edition) Belmont, USA: Thomson High Education.

Backonja, M., Stacey, B. 2004. Neuropathic Pain Symptoms Relative To overall Pain Rating. *The Journal of Pain* 5.9: 491-497

Bays, C.L. 2001. Quality of life stroke survivors: A Research Synthesis. *Journal of Neuroscience Nursing.* 33:310-316

Bellamy, N., Buchanan,W.V., Goldsmith, C.H., Campbell, J., Stitt, L.W. 1988. Validity of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with Osteoarthritis of hip and knee *Journal of Rheumatology* 15:1833-1840

Bennett, M. I., Attal, N., Backenja, M.M., Baron, R. Bouhassira, D., Cholz, J., Tolle, T.R., Wittchen, H., Jensen, T.S., Freynhangen, R. 2007. Using screening tools to identify neuropathic pain (topical review) *Pain*127: 199 – 203

Bennett, M.2001. The LANSS pain scale: Leeds Assessment of Neuropathic Symptoms and Signs. *Pain* 92: 147 – 157

Benaim, C., Froger, J., Cazottes, C., Gueben, D., Porte, M. Desnuelle, C. Pelissier, J.Y.2007. Use of Faces Pain Scale By Left And Right Hemisphere Stroke Patients.*Pain* 128.1:52-58

Berlin, R.C., Mendora, T.R., Nakamura, Y., Edwards, K., Cleeland, C.S. 1995. When is Cancer pain mild Moderate or Severe? Grading pain Severity by its interference with function.*Pain* 61:277-284

Bouhassira, D., Attal, N., Fermanian, J., Alchaar, H., Gautron, M.,Masquelier, E., Rostaing, S., Lanteri-Minet, M.,Collin, E., Grisart, J., Boureau, F. 2004. Development and Validation of the Neuropathic Pain Symptom Inventory. *Pain 108.3.248-257*

Bowsher, D., Leijon, G., Thomas, K.A. 1998. Central pos-tstroke pain: correlation of MRI with clinical pain characteristics and sensory abnorrmalitiies. *Neurology* 51: 1352-1358

Breivik, E.K., Bjornsson, G.A., Skorlund, E. 2000. A comparison of Pain Rating Scales by Sampling from Clinical Trial Data *Clinical Journal of Pain*. 16.1:22-28

Breivick, H., Colleh, B., Ventafriddo, V. Cohen, R., Gallacher, D. 2006. Survey of Chronic pain in Europe : Prevalence, impact on daily life and treatment. *European Journal of Pain* 10.4: 287-333

Bodian, C.A., Freedam, G., Hossain, S., Ersenkraft, J.B., Beilin, Y. 2001. The Visual Analogne Scale for pain: Clinical Significance in post Operative Patients. *Anesthesiology* 95.6: 1356-1361

Bonnifer and Anderson 2003. Application of constraint-induced therapy for an individual with severe chronic upper-extremityhemiplegia. Physical Therapy 83:384-398

Bowling, A. 2009. Research Methods in Health: Investigative Health and Health Services (3rd edition) New York: McGraw-Hill 162-176

Bowsher, M. 1995. The management of central post stroke pain. *Postgraduate Medical Journal* 71:598-604

Bowsher, D. 2005. Allodynia in relation to lesion site in central post-stroke pain. *Journal of pain* 6:736-40

Boyle, G.J. 1983. Critical review of state-trait curiosity development. *Motivation and Emotion* 7:377-379

Cailliet R. The shoulder in the hemiplegic patient In: Shoulder Pain. 3rd edition F A Davis; 1991: 193 – 226

Canavero S, Bonicalzi V, Paolotti R. 2002. Reboxetime for central parn: a single blind prospective study. *Clinical Neuropharmacology* 25: 238-9

Casarett D, Karlawish J, Sankar P, Hirschmark K, Asch D. 2001. Designing pain research from the patients perspective: what trial endpoints are important to patients with chronic pain? *Pain Medication* 2:309-316

Chae, J., Bethoux, F., Bohine, T. 2005. Muscular electrical stimulation for hemiplegic shoulder pain: a 12-month follow-up of a multiple – centre, randomized clinical trial. *American Journal of Physical Medicine and Rehabilitation* 84.11:832 – 842

Chari, V., Tunks, E. 2010.Post – stroke pain – but multiple pain mechanisms. Pain Research and Management 15.1: 24 – 26

Clark, P. Lavielle, P., Martinez, H. 2003. Learning from Pain Scales: Patient's Perspective. *The Journal of Rheumatology* 30.7: 1584-1588

Clark, W.C., Yang, J.C., Tsui Ng, K., Clark, S.B.2002. Unidimensional painrating scales: a Multidimensional Affect and Pain Survey (MAPS) analysis of what they really measure. *Pain* 98.3: 241-247

Chen, F., Tao, W., Li, Y. 2008.Advances in brain imaging of neuropathicpain. *Chinese Medical Journal* 121.7:653-657

Chibnall, J.T., Tait, R.C. 2001: Pain assessment in cognitively impaired and unimpaired older adults: a comparison of four scales. *Pain* 92.1: 173-186

Chou, K.L., Jun, L.W., Chi, I. 2005. Assessing Chinese older adult's suicidal ideation: chinese version of the Geriatric Suicide Ideation Scale. *Aging and Mental Health* 9:167-171

Clinch J, Tugwee P, Wells G, Shea B. 2001. lndividualized functional priority approach to

the assessment of health related quality of life in Rheumatology. Journal of Rheumatology 28:445-451

Cohen, J. 1977. Statistical power analysis for the behavioural sciences. New York, NY: Academic Press

Collins, S.l., Edwards, J., Moore, R.A. 2001. Seeking a simple measure of analgesia for mega-trials: is a single global assessment good enough? *Pain* 91.12: 189-194

Cooper, D.C., Schindler, P.C. 2001. Business Research Methods (7th Dition) New York: McGraw-Hill.

Cork, R.C., Isaac, I., Elsharydah, A., Saleemi, S., Zavisca, F. Alexander, L. 2004. A comparison of the Verbal Scale and The Visual Analogue Scale for Pain Assessment. *The Internet Journal of Anesthesiology* 8.1:1092-406

Cruccu, G., Aminoff, M.J., Curio, G., Gueri, J.M, Kasigi, R. 2008. Recommendations for the Clinical use of Somato sensory evoked potentials. *Clinical Neurophysiology* 19: 1705-1719

Cruccu, G., Anand, P., Ahal, N., Garcia – Larreal, L., Haanp, S.S. M., Jirum. 2004. EFNS guidelines on neuropathric pain assessment. *European Journal of Neurology* 153 – 162

Cruccu,G., Truini, A. 2009. Tools for assessing neuropathic pain PloS Medical 6.4:e1000045

De Oliveira, R.A., de Andrade, D.C., Machado, A.G., Teixeira, M.J. 2012. Central post stroke pain: somato-sensory abnormalities and the presence of associated myofascial pain syndrome. *Biomedical Central Neurology* 12:89

Detmar S.B., Muller M.Jo, Schornagel J.H. 2002. Health-related quality of life in routine oncology practice improves communication and patient well-being: a randomized clinical trial. *Journal of Clinical Oncology* 22:714-724

Duncan, P.W., Lai, M., van Culin, V., Huang, L. Clausen, D., Wallace, D.1999. Development of a comprehensive assessment tool box for stroke. *Clinical Geriatric Medicine* 15:885-915

Duncan, P.W., Zorowitz, R., Bates, B., Choi, J.Y., Glasberg, J.J., Graham, G.D.Katz, R.C., Lamberty, K. Reker, D. 2005. Management of Adult Stroke Rehabilitation Care. A Clinical Practice Guldeline. *Stroke* 36: e100-e143

Dromerick, A. W., Edwards, D. F., Kumar, A.P. 2008. Hemiplegics shoulder pain syndrome: Frequency and characteristics during inpatient stroke rehabilitation. *Archives of Physical Medicine and Rehabilitation* 89: 1589-1593

Dromerick, A., Redeng, M. 1994. Medical and neurologic complications of stroke during Inpatient rehabilitation. *Stroke* 25.2: 358-361

Dworkin, R.H., Backonja, M., Rowbotham, M.C., Allen, R.R., Argoff, C.R., Bennett, G.J. 2003. Advances in neuropathic Pain: diagnosis, mechanisms and treatment recommendations. *Archives of Neurology* 60:1524-1534

Dworkin, R.H., Jensen, M.P., Gammaitomi, A.R.. 2007. Symptoms profiles differ in patients with neuropathic versus non-neuropathic pain. *Journal of Pain* 8.2: 118-126

Edwards, S.G.M., Playford, E.D., Hobart, J.C., Thompson A.J.2002. Comparison of Physician Outcome Measures and Patients Perception of Benefits of Inpatient Neurorehabilitation. *British Medical Journal* 324:14

Erdek, M. A., Pronovost, P.J. 2004. Improving Assessment And Treatment of Pain In The Critically. *International Journal for Quality in Health Care* 16: 59-64

Espallargies M., Vladoras J.M., Alonso J. 2000. Provision of feedback on perceived health status to health care professionals: a systematic review of its impact. *Medcare* 38:175-186

Ernst, E. 2010. Acupuncture *The Lancet Oncology* 11.1:20

Farrar, J.T.,Young Jr, J.P., LaMoreaux, L. Werth, J.L., Poole, R.M. 2001. Clinical Importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale *Pain* 94.2: 149-158

Field, A. 2000. Discovering Statistics using SPSS. Advanced techniques for the beginner. London-Thousand oaks – New Delhi. Sage Publications

Flaster, M., Meresh, E., Rao, M., Biller, J. 2013. Central post-stroke pain: current diagnosis and treatment *Topics in Stroke Rehabilitation* 20.2: 11 – 123

Fleiss, J. 1986. The design and analysis of clinical experimentised New York: Wiley

Fowler, S. 2001. Treating post-stroke pain *Journal of Neuroscience Nursing*

Frese A, HusstedtIW, Ringelstein EB, Evers, S. 2006. Pharmacolgic treatment of central post-stroke pain. *Clinical Journal of Pain* 22:252-60

Freynhagen, R., Bennett, M.I. 2009. Diagnosis and management of neuropathic pain – Clinical Review. *British Medical Journal* 339 : b3002

Fridriksson J. 2010. Evidence of Post–Stroke Brain Recovery Discovered. *Journal of Neuroscience* 30.35: 11558

Gamble, G.E., Barberan, E., Laasch, H.U. 2002. Post-stroke Shoulder pain: a prospective study of the association and risk factors in 152 patients from a consecutive cohort of 205 patients presenting with stroke. *European Journal of Pain* 6: 467-74

Ganz P.A. 2002. What outcomes matter to patients. A Physician-researcher point of view. *Medical Care 40* (Suppl lll): 11-19

Garratt, A. M., Klaber, M. J., Farrin, A.J. 2001. Responsiveness of generic and specific measures of health outcome in low back pain. *Spine* 26.1:71-77

Ghayeghran, A.R., Bakhshayesh, E.B., Hosseini, N.M., Azari, P., Kazem, N.E. 2012. Survey of Various Post Stroke Pain Syndromes and the Related Risk Factors. *Journal of Guilan University of Medical Sciences* 21.82:1-7

Gould, R., Barnes, S. 2009.Shoulder and Hemiplegia Retrieved August 2011 from http://emedicine.com/pmr/topic 132.htm#section-introduction

Gordon, D.B., Dahl, J. L., Miaskowski, et al 2005. American pain society recommendations for improving the quality of acute and cancer pain management: American Pain Society Quality of Care Task force. *Archives of Internal Medicine* 165(14): 1574-1580.

Gray, P. 2008 Acute neuropathic pain: diagnosis and treatment. *Current Opinion in Anaesthesiology* 21(5): 590-595

Gurcay, E., Ozturk, E.A., Erdem, T., Gurcay, A.G., Cakci, A. 2013. Heterotopic Ossification as rare complication of hemiplegia following stroke: Two cases. Brain Injury.

Guyatt,G.H., Feeny,D.H., Patrick,D.L. 1993. Measuring health related quality of life. *Annals of Internal Medicine 118:622e9*

Guyatt G.H., Ferrans C.E., Halyard M.V. 2007. Clinical significance Consensus Meeting Group.Explorations of the value of health-related quality-of-life information from clinical research and into clinical practice. *Mayo clinic Procedure* 82: 1229-1239

Haines, R., Blair, A., Osbourn, M.1997. The Challenges of Assessing Outcome in Chronic Pain. *International Journal of Health care Quality Assurance.* 10. 4: 149-152

Hadianfard, H., Hadianfard, M.J. 2008. Predictor factor of hemiplegic shoulder pain in a group of stroke patients. *Iranian Red Crescent Medical Journal. 10.3:*218-222

Hamzat, T.K., Osundiya, O.C. 2010. Musculoskeletal pain and its impact on motor performance among stroke survivors. *Hong Kong Physiotherapy Journal* 28:11-15.

Hanger, H.C., Whitewood, P., Brown, G. 2000. A randomized controlled trial of strapping to prevent post–stroke shoulder pain. *Clinical Rehabilitation* 14.4:370-380.

Hansson, P. 2004. Post stroke pain case study: Clinical characteristics, therapeutic options and long term follow-up. *European Journal of Neurology* 11(Suppl):22-30.

Hanukah, A., Sashimi, H., Ohkawa, T. 1984. Orthographic findings in hemiplegics shoulders. *Archives of Physical Medicine and Rehabilitation.* 46: 23-26.

Harden, N., Cohen, M. 2003. Unmet needs in the management of Neuropathic Pain. *Journal of Pain and Symptom Management* 25.55: 512-517

Henon, 2006. Pain after stroke: a neglected issue *Journal of Neurology, Neurosurgery & Psychiatry with Practical Neurology* 77:569.

Herr, K. A., Spratt, K., Mobily, P.R., Richardson,G. 2004. Pain Intensity Assessment in Older Adults: Use of Experimental pain to compare. Psychometric Properties and usability of Selected Pain Scales withYounger Adults. *Clinical Journal of Pain* 20.4: 207-219.

Hewlett, S., Smith A.P, Kirwan J.R. 2001. Values for function in rheumatoid arthritis: patients, professional, and public Annals of Rheumatology Disorders 60:928-33

Horbart, J., Cano,S., Zajicek, J., Thompson, A. 2007. Rating scales as outcome measures for clinical trials in neurology: problems, solutions and recommendations *Lancet* 6:1094-1105

House, A., Demis, M., Hawtonk, Warlow, C.1989. Methods of identifying mood disorders in stroke patients experience in the Oxfordshire Community stroke project. *Age and Ageing* 18:317-379

Iranami, H., Yamazaki, A. 2006. Tramadol Challenges for relief of intractable central post stroke pain *Mayo Clinic Procedure* 81:566-9

Iridredavik, B., Rohweder, G., Naalsund, E., Lydersen, S.2008. Medical Complications in a Comprehensive Stroke Unit and an Early Supported Discharge Service. *Stroke* 39.2: 414 – 420

Jensen, M.P., Chen, C., Brugger, A.M. 2003. Interpretation of visual analogue scale ratings and change scores: a reanalysis of two clinical trials of post-operative pain *Journal of Pain* 4.7:407-414

Jensen, M.P., Chodroff, M.J., Dworkin, R.H. 2007. The Impact of Neuropathic pain on Health–Related Quality Of Life: Review and Implications. *Neurology* 68: 1178 – 1182

Jensen, T. S., Compbell, J.N., Crunch, G., Dostoevsky, J. O., Griffin, J.W., Hansson, P., Hughes, R., Nurmikko, T., Serra, J. 2008. Neuropathic pain: Redefinition and a grading system for clinical and Research purposes. *Neurology* 70:1630-1635

Jensen, M.P., Karoly P. 2008. Self report scales and procedures for assessing pain in adults In: Dworkin, R.H., Jensen, M.P., Gammaitomi, A.R.. 2007. Symptoms profiles differ in patients with neuropathic versus non-neuropathic pain. *Journal of Pain* 8.2: 118-126

Jonsson, A.C., Lindgren, I. Hallstrom, B., Norrving, B., Lindgren, A.2006. Prevalence and Intensity of pain after Stroke: a population based study focusing on patients persepectives. *Journal of Neurology, Neurosurgery and Psychiatry* 77: 590-595

Jonnes, K.R., Vojir, C.P., Hutt, E., Fink, R. 2007. Determining mild, moderate and severe pain equivalency across pain-intensity tools in nursing home residents. *Journal of Rehabilitation, Research and Development 44.2:305-314*

Jungehulsing, G.J., Israel, H., Safar, N., Taskin, B., Nolte, C.H., Brunecker, P., Wernecke, K.D., Villringer, A. 2013.Levetiracetam in patients with central neuropathic post-stroke pain– a randomized, double blind, placebo-controlled trial. *Europe Journal of Neurology* 20.2: 331 – 337

Kahl, C., Cleland, J. 2005. Visual Analogue Scale, Numeric Pain Rating Scale and the Mcgill Pain Questionnaire: An Overview of Psychometric Properties. *Physical Therapy Reviews* 10.2:123-128

Kaplan, R.M., Saccuzzo, D. P. 2005. Psychological testing: Principles, applications and issues(6th edition) Thomson Wadsworth 132-154

Kasner, S. (2006): Clinical interpretation and use of stroke scales. *The Lancet Neurology* 5.7: 603-612

Kehayia, E., Korner-Bitensky, N., Singer, F., Becker, R., Lamarche, M., Georges, P., Retik, S. 1997. Differences in pain medication use in stroke patients with Aphasia and without Aphasia. *Stroke* 28: 1867-1870

Kendall, R. 2010. Musculoskeletal Problems in stroke survivors. *Topics in Stroke Rehabilitation.* 19.3: 173 – 178

Carlson, K.D., Herdman, A.O. 2012. Understanding the Impact of Convergent Validity on Research results. *Organizational Research Methods* 15.1:17-32

Kim, G.S. 2009 Post stroke pain *Expert Review* of *Neurotherapeutic* 9.5:711-721

Kim J.S. 2007. Sensory abnormalities in cortical stroke, evidence for a dichotomized sensory system. *Neurology* 68:174-80

Kim, J.S., Bashford, G., Murphy, T.K., Martin, A., Dror,V., Cheung, R. 2011. Safety and efficacy of Pregabalin in patients with central post-stroke pain *Pain* 152.5:1018-1023

Kim, J.P., Chang, W.S., Park, W.S., Chang, J.W. 2012. Impact of Ventralis Caudalis deep brain stimulation combined with stereotactic bilateral cingulotomy for treatment of post – stroke pain. *Stereotacic and Functional Neurosurgery* 90.1:9–15

Kirwan J, Heiberg T, Hewlett S, Hughes R,Kvien T, Ahlmen M. 2003. Outcomes from the patient perspective workshop ar OMERACT 6. *Journal of Rheumatology* 30:868-872

Kitisomprayoonkul, W., Sungkapo, P., Taveemanoon, S., Chaiwanichsiri, D. 2010. Medical Complications during Inpatient Stroke Rehabilitation in Thailand: A Prospective Study *Journal of Medical Association of Thailand* 93.5: 594-600

Klit, H., Finnerup, N.B., Jensen, T.S. 2009. Central post stroke pain: Clinical characteristics, pathophysiology, and management. *The Lancet Neurology* 8.9:857-868

Klit, H., Finnerup. H., Jensen, T.S. 2010. Defining post-stroke pain: diagnostic challenges –Authors reply. *The Lancet Neurology* 9.4:344-345

Klit, H., Finnerup, N.B., Overrad, K., Anderson, G., Jensen, T. S. 2011. Pain following stroke: a population – based follow up study. *The Lancet Neurology 6.11:e27607*

Kollen, B., Kwakkel G., Lindeman, E. 2006. Functional Recovery ater Stroke: A Review of Current Developments in Stroke Rehabilitation Research. *Reviews on Recent Clinical Trials* 1: 75-80 Best Practice 27 April (2010): Issue 27 Care of stroke survivors

Klotz, T., Borges, H.C., Monteiro, V.C., Chamlian, T.R., Masiero, D. 2006. Physiotherapy treatment in hemiplegic shoulder pain in stroke patients-Literature Review *Acta Fisiatr* 13.1:12-16

Kuptiniratsaikul, V., Kovidha, A., Suethanapornkul, S., Manimmanakorn, N., Archongka, Y. 2009. Complications during the rehabilitation period in Thai patients with Stroke: a multicentre prospective study. *American Journal of Physical Medicine and Rehabilitation* 88: 92-99

Kumar K. 1987. Conducting focus group interviews in developing countries. A.I.D. Program Design and Evaluation Methodology Report No. 8. Washington, D.C.: U.S. Agency for International Development

Kumar, B., Kalita, J., Kumar, G., Misra, U.K. 2009. Central post-stroke pain: a review of pathophysiology and treatment. Anesthesia Analgesia 108.5: 1645-1657

Kumar, G., G., Soni, C. 2009. Central Post–Stroke Pain: Current evidence. *Journal of Neurological Science* 284.1-2: 10 – 17

Kurande, V.H., Waagepetersen, R., Toft, E., Prasad, R. 2013. Reliability studies of diagnostic methods in Indian traditional Ayurveda medicine: An overview *Journal of Ayurveda Integrated Medicine* 2.4:67-76

Krause, S.J., Backonja, M. 2003. Development of a Neuropathic Pain Questionnaire *Clinical Journal of Pain* 19.5: 306-314

Krueger, A.B., Stone, A.A. 2008. Assessment of pain: a community-based diary survey in the USA. *Lancet* 3.371:1519-1525

Lamplc, Yazdi K, Roper C, 2002. Amitriptyline in the prophylaxis of central post-stroke pain preliminary results of 39patients in a place bo – controlled, long term study *Stroke* 33:3030 - 2

Langhorne, P. 2000. Medical Complication after stroke: a multicenter study. *Stroke* 31:1223-1229

Lee, J., Park, S., Hwang, P.W., Lim, S.M., Kook, S.,Choi, K., Kang, K.S. 2012. Acupuncture for ShoulderPain after Stroke: A Systematic Review. *The Journal of Alternative and Complementary Medicine* 18.9: 818 – 823

Leijon, G., Boivie, J., Johansson, I.1989. Central post stroke pain-Neurological Symptoms and characteristics. *Pain* 36:13-25

Liang, M.H., Fossel, A.H., Larson, M.G. 1990. Comparisons of five health status instruments for orthopaedic evaluation. *Medical Care* 28:632-642

Lindgren, R.P.T., Jonsson, A.C., Norrving, B., Lindgren, A. 2007. Shoulder pain after stroke: A prospective population based study. *Stroke* 38:343

Lindsay, P., Bayley, M., Hellings, C., Hill, M., Woodbury, E., Phillip, S. 2008. Selected topics in stroke Management.shoulder pain assessment and treatment. In *Canadian Best Practice Recommendations for Stroke Care*. CMAJ Dec 2:179 .12 Suppl : E70-2

Langhorne, P., Legg, L. 2003. Evidence behind stroke rehabilitation. *Journal of Neurology Neurosurgery and Psychiatry* 7.4:18-21

Lolascon, G., Gimigliano, R. 2006. Pain in Stroke Survivors: Epidemiology and impact on functional outcome

Lundstrom, E., Smiths, A., Terent, A., Borg, J.2008. Risk factors for stroke-related pain 1 year after first-ever stroke *European Journal of Neurology* 1111.10:1468-1331

Lindgren, I., Jonsson, A., Norrving, B., Lindgren, A. 2007. Shoulder Pain after Stroke: A prospective population-Based Study. *Stroke* 38:343

Lindsay, P., Bayley, M., Hellings, C., Hill, M.,Woodbury , E., Philips, S. 2008. Canadian best practice recommendations for stroke care (updated 2008). *Canadian Medical Association Journal* 179.12:70-72

Markovic, G., Dizdar, D., Jukik, I., Cardinale, M. 2004. Reliability and Factorial Validity of Squat and Counter-movement jump tests *Journal of Strength and Conditioning Research*

Mclean, D.E. 2004. Medical Complications experienced by a cohort of stroke survivors during inpatient, tertiary-level stroke rehabilitation *Archives of Physical Medicine and Rehabilitation.* 85:466-9

Merskey, H. 1994. Logic, truth and language in concepts of pain. *Quality of Life Research.* 3.1: 569-576

McDowell, I., Newell, C. 1996. Measuring health: a guide to rating scales and questionnaires. 2nd Edition, New York: Oxford University Press Page 523

Miller, K.K., Combs. S.A., Van Rymbroeck, M., Altenburger, P.A., Kean, J., Dierks, T.A., Schmid, A.A. 2013. Fatigue and pain: relationships with physical performance and patient beliefs after stroke. Topics in Stroke Rehabilitation 20.4: 347 – 355

Misra, U.K., Kalita, J., Kumar, B. 2008. A study of clinical MRI and somatosensory evoked potential in central post stroke pain. *Journal of Pain* 9:1116-1122

Mokkink, L.B., Terwee, C.B., Knol, D.L., Stratford, P.W., Alonso, J.,Patrick, D.L., Bouter, L.M., de Vet, H.C. 2010. The COSMIN checklist for evaluating the methodological quality of studies on measurement properties: A clarification of it's content BMC *Medical Research Methodology* doi:10. 1186 / 1471-2288-10-22

Moniruzzaman, M., Salek, K.M., Shakoor, M.A., Mia, B.A., Moyeenuzzaman, M. 2010. Effects of therapeutic modalities on patients with post stroke shoulder pain. *Mymensingh Medical Journal* 19.1:48-53

Moore, R.A., Derry, S., Aldington, D., Cole, P., Wiffen, P.J. 2012. Amitriptyline for neuropathic pain and fibromyalgia in adults. *Cochrane Database Systematic Review* 12:CD008242

Moore, A., Edwards, J., Barden, J. 2003. Bandolier's little Book of Pain. Oxford, Oxford University Press

Nadler, S.F., Weingand, K.,Kruse, R.J. 2004. The Physiologic Basis and Clinical Applications of Cryotherapy and Thermotherapyfor the Pain Practitioner. 7:395-399

Naess, H., Lunde, L., Brogger, J., Waje-Andreassen, U. 2010. Post-stroke pain on long-term follow-up: the Bergen stroke study. *Journal of Neurology* 257. 9:1446 – 1452

Nardi, K., Parnetti, L., Pieri, M.L., Eusebi, P., Calabresi, P., Sarchielli, P. 2008. Association between migrane and headache attributed to stroke: a case 0 control study. *Headache: The Journal of Head & Face Pain* 48.10:1468 – 1475

Nogueira, M., Teixeira, M.J. 2012. Central Pain due to stroke: cognitive representation and coping according to gender. *Archives of Neuropsychiatry* 70.2:125 – 128

Nunally, J.C., Bernstein, L.H. 1994. Psychometric Theory 3rd Edition New York: McGraw-Hill

O'Donnell, M.J., Diener, H., Sacco, R.L., Panju, A.A., Vinisko, R., Yusuf, S. 2013. Chronic Pain Syndromes after Ischemic Stroke PRoFESS Trial *Stroke* AHA 111.671.008

Ogun, S.A., Ojini, F.I., Ogungbo, B., Kolapo, K.O., Danesi, M.A. 2005. Stroke in south-west Nigeria.A 10-year review. *Stroke* 36: 1120-1122

Ojini, F.I., Danesi, M.A.2003. Pattern of neurological admissions at the Lagos University Teaching hospital. *Nigerian Journal of Clinical Practice* 5: 38 – 41

Osuntokun, B.O., Bademosi, O., Akinkugbe, O.O., Oyediran, A.B., Carlisle, R. 1979. Incidence of Stroke In An African City: Result From the Stroke Registry Ibadan, Nigeria. 1973 – 1975 *Stroke* 10: 205 – 207

Owolabi, M.O. 2010. Which is more valid for stroke patients: generic or stroke-specific quality of life measures? *Neuroepidemiology* 34.1:8-12

Owolabi, M.O. 2011a. Taming the Burgeoning Stroke Epidermic in Africa: Stroke Quadrangle to the Rescue *West Indian Medical Journal* 60.4:412-421

Owolabi, M.O. 2011b. HRQOLISP-26: A Concise Multiculturally Valid, Multidimensional, Flexible and Reliable Stroke-Specific Measure *ISRN Neurology*

10.5402

Poenarn, D., Cinteza, D., Posescu, S. Lonita, L., Mateescu, M. 2008. Shoulder pain management in stroke medical. *A Journal of Clinical Medicine* 3.3:

Poissant,L., Mayo, N.E., Wood-Dauphinee, S., Clarke, A.E. 2003. The development and preliminary validation of a oreference-Based Stroke Index (PBSI) *Health and Quality of Life Outcomes* 1.43:1-15

Portenoy, R.K. 2006. Cancer pain: Epidemiology and Syndromes *Cancer* 11.63:2298-2307

Post, M.W.M., Boosman, H., Van Zandroot, M., Passier, P.E., Rinkel, G.J., Visser-Meily, J.M. 2011. Development and validation of a short version of the 'Stroke-Specific Quality of Life Scale' *Journal of Neurology, Neurosurgery and Psychiatry* 3.82:283-286

Price, C.I.M., Curless, R.H., Rodgers, H. 1999. Can Stroke patients use Visual Analogue Scale? *Stroke* 30:1357-1361

Price, C.I.M. 2004. Treatment of shoulder and upper limb pain after stroke: an obstacle course for evidence-based practice *Stroke* 13.4:321-333

Putzke, J.D., Richards, J.S., Dowler, R.H. 2000.The impact of pain in spinal cord injury.A Case-control Study. *Rehabilitation Psychology* 45.4:386-401

Raffaeli W., Minella, C.E., Magnani, F.Sarti, D. 2013 Population – based study of central post stroke pain in Rimini district, Italy. *Journal of Pain Research* 6:705 – 711

Ratnasabapathy, Y., Broad J., Basket J.2003. Shoulder pain people with a stroke :a population based study. *Clinical Rehabilitation* 17:304-11

Richards, J.S. 1992. Chronic pain and spinal cord injury: Review and comment. *Clinical Journal of Pain* 8:119-122

Roosink, K. M., Geurts, A.C.H., Ijzerman, M.J. 2010: Defining post stroke pain: diagnostic challenges. *The Lancet Neurology* 9.4:344

Roosink, M., Renzenbrink, G.J., Dongen.Van, R.T.M., Buitenweg, J.R., Geutits,A.C.H., IJzerman, M.J. 2008. Diagnostic Uncertainties in Post-Stroke Pain.12thWorld Congress on Pain 17-22 Aug 2008, Glasgow, Scotland.

Roosink, K.M., Geurts, A.C.H., Ijzerman, M.J. 2010. Defining post-stroke pain: Diagnostic Challenges. *The Lancet Neurology 9.4:344*

Roosink, K.M., Van Dongen, R.T. Renzenbrink, G.J., Ijzerman, M.J. 2011. Classifying post-stroke shoulder pain can the DN4 be helpful. *European Journal of Pain 15.1:99-102*

Roy, C.W. 1988. Shoulder pain in hemiplegia: a Literature review. *Clinical Rehabilitation* 2: 35-44

Roy,O. 2004.Musculoskeletal complications of neurological conditions. *Advances in Clinical Neuroscience and Rehabilitation* 4.4:32-34

Rolke, R., Baron, R., Maier, C., Talle, T.R.., Treede, R..D., Beyer, A., Binder, A. 2006. Quantitative sensory testing in the German research Network on Neuropathic pain (DFNS): standardized protocol and reference values. *Pain* 123: 231- 243

Rowbotham, M.C, Twilling L, Davies P. S, Reisner L, Taylor K., Mohr D. 2003. Oral opiod therapy for chronic peripheral and central neuropathic pain *New England Journal of Medicine* 348: 1223-32

Sacco, R. L., Kasner, S. E., Broderick, J. P., Caplan, L. R., Connors, J. J., Culebras, A., Elkind, M. S., George, M. G., Hamdan, A. D., Higashida, R. T., Hoh, B. L., Janis, L.S., Kase, C. S., Kleindorfer, D. O., Lee, J. M., Moseley, M. E., Peterson, E. D., Turan, T. N., Valderrama, A. L., Vinters, H. V. 2013. An Updated definition of stroke for the 21st century: a statement for healthcare professionals from the

American Heart Association and American Stroke Association *Stroke* 44.7:2064-2089

Sahin, N., Bodur, S., Salli, A., Ugurlu, H.2010. Reliability and Validity of the Turkish Version of the pain Quality Assessment Scale in Patients with Carpal Tunnel Syndrome. *Nobel Medicine* 6.1:26-33

Salter, K., Jutar, M. 2005. Issues For Selection Of Outcome Measures In Stroke Rehabilitation: ICF Participation *Disability and Rehabilitation* 27.9:507-528

Schott, G.D. 2001. Delayed onset and resolution of pain- some observations and implications. *Brain-A Journal of Neurology* 124:1067

Seghirer, M.L., Lazeyras, F., Vuilleumier, P., Schnider, A., Carota, A. 2005. Functional Magnetic Resonance Imaging and Diffusion Tensor Imaging in a case of central Post stroke Pain. *The Journal of Pain.* 6:208-212

Seifert, C.L., Mallar, C.M., Sprenger, T. 2013. The complexities of pain after stroke-a review with a focus on central post – stroke pain.*Panminerva Medical* 55.1:1-10

Serpell. 2002. Neuropathic pain study group. Gabapentin in neuropathic pain syndrome: a randomized, double-blind, placebo – controlled trial *Pain* 99.3:557-566

Shah, R.R., Haghpanah, S., Elovic, E. P., Flanagon, S. R., Behnegar, A. Nguyen, V., Page, S.J., Fang, Z., Chae, J. 2008. MRI findings in the painful post-stroke shoulder *Stroke* 39(6):1808-1813

Smith, M. 2012. Management of Hemiplegic shoulder pain following stroke. *Nursing Standard.* 26. 44:35-44

Smith, J.H., Botlemiller, K.L., Michael, G.F., Strand, E.A. 2013. Inability to self report pain after a stroke: a population – based study *Pain* 154.8:1281 – 1286

Smith, A.K., Cenzer, I.S., Knight, S.J., Puntillo, K. A., Widdera, E., Williams, B.A., Boscardin, W. J., Covinsky, K.E. 2010. The Epidemiology of Pain During the last

2years of life *Annals of Internal Medicine* 153:563-569

Sprenger, T., Seifert, C.L., Valet, M., Andreon, A.P., Foerschler, A., Zimmer, C., Collins, D.L., Goadsby, P.J., Tolle, T.R., Chakravarty, M.M. 2012. Assessing the risk of central post-stroke pain of thalamic origin by lesion mapping. Brain 135.8:2536 – 2545

Stark, S.L., Edwards, D.F., Hollingsworth, H., Gray,D.B.2005. Validation of the Reintegration to Normal Living Index in a population of Community-Dwelling People with Mobility Limitations. Archive of Physical Medicine and Rehabilitation 86.2:344-345

Streiner, D.L., Norman,G.R. 2003. Health measurement scales. A pratical guide to their development and use. New York: Oxford University Press

Strong, K., Mathers C, Bonita, R. 2007 Preventing Stroke:Saving lives around the world *Lancet Neurology* 6:182-187

Strong, K., Mathers, C., Bonita, R. 2007. Preventing Stroke: saving lives around the world. *Lancet Neurology.* 6:182-187

Storch, E.A., Roberti, J.W., Roth, D.A. 2004. 'Factor strucure, concurrent validity, and internal consistency of the Beck Depression Inventory-Second Edition in a sample of college students'. *Depression and Anxiety* 19.3:187-189

Sudlow, C. L.M., Warlow, C.P. 1996. Comparing Stroke Incidence Worldwide: What Makes Studies Comparable? *Stroke* 27: 550 – 558

Suethanapornkul, S., Kuptniratsaikul, P.S., Kuptisiratsaikul, V., Uthensut, P., Dajpratha, P, Wongwiseth Karn, J. 2008. Post stroke shoulder subuluxation and shoulder pain: a conort multicenter study. *Journal of Medical Association Thailand.* 91.12: 1885 – 1892

Sulch D, Melbourn A, Perez I, Kalra L. 2002. Integrated care pathways and quality of life on a stroke reliabilitation unit. *Stroke* 33:1600 – 4

Tanei,T., Kajita,Y., Takebayashi, S., Hirano, M., Nakahara, N., Wakabayashi, T. 2013. Efficacy of tramadol/ acetaminophen medication for central post–stroke pain *No Shinkei Geka* 41.8:679 – 685

Terwee C.B.,Bota D.M., de Boera, M.R., Van der Windta, D. A.W.M., Kuola, D.L., Dekkera, J.,Boutera, L.M., de Veta, H.C.W. 2007. Ouality Criteria proposed for Measurement properties of Health Status Questionnaire. *Journal of Clinical Epidemiology 60:34e42*

Tistad, M., Tham, Koch, L.,YHerberg, C. 2012.Unfulfilled rehabilitation needs and dissatisfaction with care 12 months after a stroke: an explorative observational study. *Biomedical Central Neurology* doi: 10.1186 / 1471-2377-12-40

Turk, D.C., Dworkin, R.H., Allen, R.R., Bellamy, N., Brandenburg, N., Carr, D.B., Cleeland, C., Dionne, R., Farrar, J.T., Galer, B.S., Hewitt, D.J., Jadad, A.R., Katz, N.P., Kramer, L.D., Manning,.D.C., McCormink, C.G., McGrath, P., Quessy, S., Rappaport,, B.A., Robinson, J.P., Royal, M.A., Simon, L., Stauffer, J.W., Stein, W., Tollett, J., and Witter, J. 2003. Core Outcome Domains for Chronic Pain Clinical Trials: IMMPACT Recommendations. *Pain* 106: 337-345

Turk, D.C., Dworkin, R.H., Burke, L.B., Atkinson, J.H., Chandler, J., Cleeland, C., Cowan, P., Dimitrova, R., Farrar, J.T., Haythornthwaite, J.A., Hertz, S., Jadad, A.R., Jensen, M.P., Kellstien, D., Kerns, R.D., Manning, D.C.,Martins, S., Max, M.B., McDermott, M.P., McGrath, P., Moulin, D.E., Nurmikko, T., Quessy, S., Raja, S., Rappaport, B.A., Rauschkolb, C., Robinson, J.P>, Royal,M.A., Simon, L., White, R.E., Williams, A.C., Witter, J., and Wyrwich, K.W. 2006. Developing patient-reported outcome measures for pain clinical trials: IMMPACT recommendations *Pain* 125: 208-215

Turner-Stokes, L., Jackson, D. 2002. Shoulder Pain after Stroke: A Review of the Evidence Base To Inform The Development Of An Integrated Care Pathway. *Clinical Rehabilitation* 16.3:276-298

Valderas J.M, Alonso J., Guayatt G.H. 2008. Measuring Patient – reported outcomes moving from clinical trials into clinical practice. *Medical Journal of Australia* 189.2:93-94

Vanhook P. 2009. The domains of stroke recovery: A synopsis of the literature. *Journal of Neuroscience Nursing* 41.1:6-17

Velikova, G., Booth, L., Smith, A.B., Lynch, P., Brown, J.M., Selby, P.J. 2004. Measuring QoL in routine oncology practice improves communication and patient's well-being: A randomised controlled trial. *Journal of Clinical Oncology* 22:714-724

Viana, R., Pereira, S., Mehta, S., Miller, T., Teasell, R. 2012. Evidence for therapeutic interventions for hemiplegic shoulder during the chronic stage of stroke: a review. *Topics on Stroke Rehabilitation* 19.6:514–522

Wahab, K.W. 2008. The burden of stroke in Nigeria. *International Journal of Stroke* 3.4:290-292

Walsh, K. 2001. Management of shoulder pain patients with stroke. *Postgraduate Medical Journal* 77:645-649

Wang, J., Cui, X., Ni, H.H., Huang, C. S., Zhou, C.X., Wu, J., Shi, J.C., Wu, Y. 2013. Observation on the Clinical efficacy of shoulder pain in post – stroke shoulder – hand syndrome treated with floating acupuncture and rehabilitation training. *Zhongguo Zhen Jiu* 33.4: 294 – 298

Wanklyn, P., Forester, A., Young, J.1996. Hemiplegia Shoulder pain (HSP): natural history and investigation of associated features. *Disability and Rehabilitation* 18:497-501

Warlow, C.P., Dennis, M.S., van Gijn, J. 2001.Stroke. A Practical Guide to Management. 2nd edition. Blackwell Press.

Watt-Watson, J.B. 2001. Relationship between nurses knowledge and pain management outcomes for their post operative cardiac patient *Journal of Advanced Nursing* 36.4: 535 – 545

Whiston, S.C. 2005. Principles and Applications of Assessment in Counselling 2nd edition Thomson Brooks/Cole 43-74

Widar, M., Samuelsson, L., Karlsson-Tivenius, S., Ahlstrom, G.2002. Long-term Pain Conditions after a Stroke. *Journal of Rehabilitation Medicine* 34:165-170

Widar, M., Ahlstrom, G. 2004. Coping with Long-Term Pain after a Stroke *Stroke* 27.3: 215-225

Williams, L.S.,Weinberger, W., Harris, L.E.,Clark, D.O., Biller,J. 1999. Development of a Stroke-specific quality of life scale *Stroke* 30.7:1362-1369

Williams, A. 2003. How to write and analyze a questionnaire. *Journal of Orthodontics* 30.3:245-252

Williamson, A., Hoggart, B. 2005. Pain: a review of three commonly used pain rating scales *Journal of Clinical Nursing.* 14:798-804

Willke, R.J., Burke, L.B., Erickson, P. 2004. Measuring treatment impact: a review of patient reported outcomes and other efficacy endpoints in approved product labels. *Controlled Clinical Trials* 25:535-552

Winstein, C., Miller, J., Blanton, S., Morris, D., Uswante, G., Taub, E., Nichols, D., Wolf, S. 2003. Methods for a multi-site randomized trial to investigate the effect of constrain-induced movement movement therapy in improving upper extremity function among adults recovering from cerebrovascular stroke. *Neurorehabilitation and Neural Repair* 17:137-152

Wolfe, C. D. 2000. The Impact of Stroke. *British Medical Bulletin* 56:275-286

Zeferino, S. I., Aycock, D.M. 2010. Post stroke shoulder pain: Inevitable or Preventable? *Rehabilitation Nursing* 35:4

Zorowitz, R.D., Gross, E., Polinski, D.M. 2002. The stroke survivor. *Disability and Rehabilitation* 24.13: 666-679

Zorowitz, R.D., Smout, R.J., Gassaway, J.A., Horn, S.D. 2005. Usage of Pain Medicationsduring Stroke Rehabilitation: The Post-Stroke Rehabilitation Outcomes Project. *Topics in Stroke Rehabilitation.* 12.4:37-49

APPENDIX I

Ibadan Stroke-Specific Pain Scale

1. Pain location/ Severity

	Pain Location	No pain	Minimal pain	Moderate pain	Severe pain	Extreme pain
1	Neck					
2	Shoulder					
3	Upper arm					
4	Elbow					
5	Wrist					
6	Fingers					
7	Low back					
8	Hip					
9	Thigh					
10	Knee					
11	Ankle					
12	Toes					

2. Psychosocial Functioning

To what extent does your pain interfere with the following activities:

Activities	Not at all	A little	Moderately	Severely	Extremely
1.Your sleep					
2.Your mood					
3.Your work in and outside the house					
4.Your interaction with friends and relations					

5.Your sexual activities					
6.Your religious activities					

3. Physical Functioning

To what extent does your pain limit the following activities.

Functions	Activity not possible because of pain	Severely limited	Moderately limited	Minimally limited	Not limited by pain
1.Bathing					
2.Walking					
3.Standing					
4.Lifting objects					
5.Dressing up					
6.Tying head gear/Wearing cap					
7.Feeding self					
8.Combing hair					
9.Rolling in bed					
10.Squatting					
11.Stairs climbing					

4. Symptoms associated with post-stroke pain (To be completed by the clinician)

   Please indicate the presence/absence of the following signs and symptoms.

Signs & Symptoms	Present=1	Absent=0		
Swelling				
Pain on palpation				
Pain is localized				
Painful area sensitive to touch or clothing				
Feels pins and needles / burning sensation				
Pain at rest				
Pain on passive/active movement				

APPENDIX II

INFORMED CONSENT FORM

My name is Oladunni Caroline Osundiya. I am a post graduate student of the Department of Physiotherapy, College of Medicine, University of Ibadan, Ibadan.

The study is on a Stroke specific pain scale which is a means of evaluation the effectiveness of Physiotherapy treatment in people experiencing pain after a stroke.

I have been given the following information.

i. That the research is been carried out to find out if the compiled questions will measure what is supposed to measure.

ii. That I will have to go through physiotherapy treatment for 6 weeks as often as twice per week.

iii. That the questionnaire will be used to determine my pain location, pattern and pain interference before and after 6 weeks of treatment.

iv. That the information obtained during the programme will be treated as privileged and confidential. However, the information may be used for statistical or scientific purpose with my right of privacy retained.

CONSENT- Now that the study has been well explained to me. I fully understand the content of the study process. I am willing to take part in the programme

_____	_____	_____
Signature / thumb print of the participant	Signature / thumb print of the interviewer	Signature / thumb print of the witness

APPENDIX III

Ethical Approval

INSTITUTE FOR ADVANCED MEDICAL RESEARCH AND TRAINING (IAMRAT)
COLLEGE OF MEDICINE, UNIVERSITY OF IBADAN. IBADAN, NIGERIA.
Director: **Prof. A. Ogunniyi,** B.Sc(Hons), MBChB, FMCP, FWACP, FRCP (Edin), FRCP (Lond)
Tel: **08023038583, 08038094173**
E-mail: **aogunniyi@comui.edu.ng**

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

NOTICE OF EXPEDITED REVIEW AND APPROVAL

Re: Development and Validation of a Stroke-Specific Pain Scale

UI/UCH Ethics Committee assigned number: UI/EC/12/0106

Name of Principal Investigator: **Oladunni C. Osundiya**

Address of Principal Investigator: Department of Physiotherapy,
College of Medicine,
University of Ibadan, Ibadan

Date of receipt of valid application: 08/05/2012

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 and other participant information materials have been reviewed and *given expedited approval by the UI/UCH Ethics Committee.*

This approval dates from 19/12/2012 to 18/12/2013. 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
19 DEC 2012
APPROVED
COLLEGE OF MEDICINE U.I.

Professor A. Ogunniyi
Director, IAMRAT
Chairman, UI/UCH Ethics Committee
E-mail: uiuchirc@yahoo.com

APPENDIX IV

Focus Group Discussion Guide

Introduction

The purpose of this study is to find out the degree to which pain after a stroke affects different areas of a stroke survivors' life, activities of daily living, the specific parts of the body the pain is felt and the characteristics of this pain. We would like you to state your honest feelings about the topic. Everything that you say here will be kept confidential, and your names and any other identifying information will not be used in any report coming from this research.

We will like to manage our time well so as not to keep you longer than needed, so you might be interrupted from time-to-time to keep things moving.

Opening Question:

'Could you please tell me what your experiences have been as regards the pain you have been experiencing following the stroke you had?

Introductory question: What exactly is unique about this pain bearing in mind that you've had other forms of pain before'?

Key questions:

'How exactly does the pain you are experiencing feel?

What specific areas of your life does this pain affect?

What parts of your body do you feel the pain?

What are the things you want to do that the pain prevents you despite the functional improvement you have had?'

Ending questions:

'What are the most important concerns about this pain and stroke?

What would you like to be done about it?'

Debriefing: 'I would like to thank you for your participation'

I also want to restate that what you have shared with me is confidential. No part of our discussion that includes names or other identifying information will be used in any

reports, displays, or other publicly accessible media coming from this research. Once again, thank you for your participation.

APPENDIX V

QUESTIONNAIRE FOR SOCIODEMOGRAPHIC DATA

Name:

Age in years:

Gender: Male ( ) Female ( )

Marital Status: Married ( ) Single ( ) Widowed ( ) Seperated ( )

Educational Status: WASC ( ) OND ( ) NCE ( ) BSc ( ) MSc ( ) PhD ( )
Others.....

When did you have the stroke ? .....

What parts of your body was affected : Right ( ) Left ( )

When did you start experiencing the pain ? .....