

QUALITY OF LIFE AMONG PATIENTS WITH
LOWER LIMB OSTEOARTHRITIS IN HOSPITAL
UNIVERSITI SAINS MALAYSIA

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by

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LIST OF ABBREVIATIONS

ADLs	-	Activity Daily Livings
BMI	-	Body Mass Index
KOOS	-	Knee Injury and Osteoarthritis Outcome Score
NRS	-	Numerical Rating Scale
OA	-	Osteoarthritis
OAKHQOL	-	Osteoarthritis Knee and Hip Quality of Life
QOL	-	Quality of Life
SF-36	-	36-Item Short Form Survey
USM	-	Universiti Sains Malaysia
VAS	-	Visual Analogue Scale
WHO	-	World Health Organization
WOMAC	-	Western Ontario and McMaster Universities Osteoarthritis

**Kualiti Hidup dalam Kalangan Pesakit yang Mengalami Osteoarthritis Anggota
Bawah di Hospital Universiti Sains Malaysia**

ABSTRAK

Kualiti hidup adalah komponen penting dalam kesejahteraan pesakit, yang dianggap sebagai matlamat rawatan dalam penyakit kronik. Kajian keratan rentas telah dijalankan untuk mengenal pasti kualiti hidup dalam kalangan pesakit osteoarthritis anggota bawah di Hospital USM. Soal selidik yang digunakan dalam kajian ini ialah “*Osteoarthritis Knee and Hip Quality of Life*” (OAKHQOL) yang diadaptasi daripada Kadir et al. (2018). Seramai 100 pesakit di Hospital USM yang memenuhi kriteria inklusi dan pengecualian telah didekati untuk menyertai kajian ini. Data yang dikumpul dianalisis secara statistik menggunakan perisian SPSS versi 26.0. *Pearson Chi Square* digunakan untuk analisis data untuk perkaitan antara ciri sosiodemografi dan kualiti hidup. Bagi aktiviti fizikal, purata min ialah 40.45 (SD 23.03), kesihatan mental 22.33 (SD 19.77), sakit 25.46 (SD 11.07), fungsi sosial 26.78 (SD 3.21) dan sokongan sosial 27.56 (SD 2.16). Terdapat perkaitan yang signifikan antara umur dan jenis osteoarthritis dengan aktiviti fizikal ($p = 0.030$), tahap pendidikan dengan kesihatan mental ($p = 0.01$), umur dan Indeks Jisim Tubuh dengan kesakitan ($p = 0.001$). Akhir sekali, tidak terdapat perkaitan yang signifikan antara ciri sosiodemografi dengan sokongan sosial dan fungsi sosial. Kesimpulannya, dapatan kajian ini menunjukkan kualiti hidup dalam kalangan pesakit osteoarthritis anggota bawah adalah yang paling teruk dalam domain kesakitan dan yang terbaik dalam fungsi sosial.

Quality of Life among Patients with Lower Limb Osteoarthritis in Hospital

Universiti Sains Malaysia

ABSTRACT

Quality of life is an important component in patient's well-being, which considered as a goal of treatment in chronic illness. A cross-sectional study was carried out to identify the quality of life among the patients with lower limb osteoarthritis in Hospital USM. The questionnaire used in this study was Osteoarthritis Knee and Hip Quality of Life (OAKHQOL) which adapted from Kadir et al. (2018). A total of 100 patients in Hospital USM who fulfilled the inclusion and exclusion criteria were approached to participate in this study. Data collected were statistically analysed using the SPSS software version 26.0. Pearson's Chi Square were used for data analysis for the association between sociodemographic characteristics and quality of life. For physical activity, the average mean was 40.45 (SD 23.03), mental health 22.33 (SD 19.77), pain 25.46 (SD 11.07), social functioning 26.78 (SD 3.21) and social support 27.56 (SD 2.16). There is a significant association between age and types of osteoarthritis with physical activity ($p = 0.030$), level of education with mental health ($p = 0.01$), age and Body Mass Index with pain ($p = 0.001$). Lastly, there is no significant association between the sociodemographic characteristics with social support and social functioning. In conclusion, the findings of this study showed that the quality of life among patients with lower limb osteoarthritis was the worst in pain domain and the best in social functioning.

CHAPTER 1

INTRODUCTION

1.1 Background of the Study

Osteoarthritis (OA) represents failed repair of joint damage resulting from stresses initiated by any joint or periarticular tissue (Sharma, 2021). It is the most common form of arthritis in which the lower limb OA causes high levels of pain and disability (Willett et al., 2021). OA is one of the most frequent chronic diseases that can lead to loss of quality of life and increased prevalence and incidence due to increased life expectancy (Pereira et al., 2015). In addition, activity limitations have a negative influence on patients' social and psychological well-being, which also lowers the quality of life of patients (Vitaloni et al., 2019).

In terms of site-specific prevalence in 2019, OA of the knee, accounting for 60.6% of cases, was the most prevalent site globally. It was followed by OA of the hand, accounting for 23.7% of cases, other joint sites, 10.2%, and the hip, accounting for 5.5% of cases (Splete, 2022). The World Health Organization (WHO) has estimated that 80% of people with OA have movement limitations while 25% of them cannot perform their major daily activities, thus resulting in a decline of their nutritional status and quality of life (Zamri et al., 2021). The prevalence of knee OA is expected to rise due to the increased aging of the population, therefore, increased understanding of the effects of knee OA on multiple dimensions of health is pivotal for enhancing the quality of care in this population (Aree-Ue et al., 2019).

According to Long et al. (2022), using data derived from the Global Burden of Disease Study 2019 showed that prevalent cases of OA has increased globally, by 113.25%, from 247.51 million in 1990 to 527.81 million in 2019 respectively. In the

United States, 24% of all adults, or 58.5 million people have arthritis whereby the most common form of arthritis is OA (Centers for Disease Control and Prevention, 2021). Asia's highest amount of OA cases is in China, which also has the highest number worldwide. Therefore, Splete (2022) stated that China has the highest number of cases in 2019 which is 132.81 million, followed by India with 62.36 million, and the United States with 51.87 million of cases. Meanwhile, the prevalence of knee OA in Malaysia was estimated to be 10% to 20% of the elderly population (Ministry of Health Malaysia, 2013).

OA is often described as a chronic degenerative disease and thought by many to be an inevitable consequence of growing old (Anderson & Loeser, 2010). The prevalence of OA is increasing because of the growing aging of the population in developed and developing countries as well as an increase in risk factors leading to OA (Palazzo et al., 2016). Goetz et al. (2011) stated that it is predicted that by 2025, the proportion of elderly people in the world's population would increase to 27.4% of all people.

Globally, 1 in 6 people in the world will be aged 60 years or over by 2030 (World Health Organization, 2022b). OA is strongly associated with aging and Asian countries are aging rapidly (Zamri et al., 2019). Therefore, Asian elderly aged ≥ 65 years old had increased from 7% in 2008 and is predicted to achieve 16% in 2040 (Bureau et al., 2009). Meanwhile, Malaysia has become an ageing society with the percentage of the population aged 65 and over has increased from 7.0 percent to 7.3 percent for the same period (Department of Statistics Malaysia Official Portal, 2022). Therefore, in the general population, OA is anticipated to become the leading cause of disability by 2030 due to its high prevalence and primary relationship to ageing (Mathiessen & Conaghan, 2017).

1.2 Problem Statement

Patients with knee osteoarthritis have a low perception of their quality of life, especially in the fields functional capacity, functional limitations and pain (Kawano et al., 2015). Patients with OA will suffer physical disabilities that will interfere with their daily activities, which are essential for living an independent daily life. According to Stamm et al. (2016), OA was associated with a 68 % higher chance of a detracting of intense activity daily livings (ADLs), and with a 32 % higher chance of impairment in hand-focussed ADLs.

Some musculoskeletal conditions can be life-threatening and result in death if left untreated, along with higher mortality rates especially for people living with rheumatoid arthritis, osteoarthritis and those with sustained osteoporotic fracture (Briggs et al., 2016). According to Cleveland et al. (2019), rheumatic and musculoskeletal diseases, including OA, are associated with significant pain and functional limitations, as well as mortality rates up to 1.6-fold higher than in the general population. In contrast, long-term physical pain and movement inconvenience in the elderly will cause negative psychological effects, which will prevent them from going outside and preventing them from living normally (Xiaonan & Olsson, 2020).

Moreover, Yelin et al. (2016) stated that it remains true that conditions perceived to affect quality of life receive less attention. Subsequently, the symptoms of OA will have a substantial impact on a patient's quality of life, including their ability to engage in physical activity, maintain good mental health, sleep soundly, cope with fatigue, and other aspects. The quality of life and mental health of an individual can also be impacted by pain, poor treatment results, and increased pharmacotherapy (Sharma et al., 2016).

In addition, pain is the most common complaint and the most significant cause of decreased health-related quality of life among osteoarthritic patients (Shalhoub et al., 2022). Therefore, this study is focusing on young elderly patients with lower limb OA in Hospital USM in order to assess their quality of life for a better healthcare intervention, outcomes and overall life satisfaction. A survey will be done from hospital record of admission in orthopaedic clinic and I identify the case of the OA increased during 2019 – 2022.

1.3 Research Question

The research questions for this study are formulated as below:

- 1.3.1 What is the quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia?
- 1.3.2 Is there any association between socio-demographic characteristics and quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia?

1.4 Research Objective

1.4.1 General Objectives

The study is to determine the quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia.

1.4.2 Specific Objectives

The following specific objectives of this study are:

- i. To determine the quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia.
- ii. To determine the association between socio-demographic characteristics and quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia.

1.5 Hypothesis

Hypothesis 1:

Ho: There is no significant relationship between socio-demographic characteristics and quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia.

HA: There is a significant relationship between socio-demographic characteristics and quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia.

1.6 Conceptual and Operational Definitions

Table 1.1 : Conceptual and Operational Definitions

TERMS	CONCEPTUAL DEFINITION	OPERATIONAL DEFINITION
Quality of Life	An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns (World Health Organization, 2012.).	Quality of life in this study is referring to the perception of position in life among patients in Hospital Universiti Sains Malaysia, who are living with lower limb osteoarthritis by using OAKHQOL questionnaire.
Lower Limb Osteoarthritis	Defined as clinical knee and/or hip osteoarthritis (van Schoor et al., 2022), in which a degenerative joint disease that is typically the result of wear and tear and progressive loss of articular cartilage (Vad et al., 2022).	In this study, lower limb osteoarthritis is referring to the hip and knee osteoarthritis cases that will be conducted among patients in Hospital Universiti Sains Malaysia.
Physical Activity	Any bodily movement produced by skeletal muscles that requires energy expenditure (World Health Organization, 2022).	In this study, physical activity is referring to the one of the domains in the instrument in order to assess the respondent's quality of life.

Mental Health	A state of mental well-being that enables people to cope with the stresses of life, realize their abilities, learn well and work well, and contribute to their community (World Health Organization, 2022).	In this study, mental health is referring to the domain that affected in quality of life and was assessed in the instrument of this study.
Pain	An unpleasant signal that something hurts (National Institute of Neurological Disorders and Stroke, 2023).	Pain in this study refers to one of the variables on the questionnaire that measures the respondents' quality of life.
Social Functioning	A person's ability to engage effectively in social interactions, to maintain interpersonal relationships, to engage in work, and conduct everyday activities independently (Brissos et al., 2011).	In this study, social functioning refers to the domain that had an impact on quality of life and was also measured by the study's instrument.
Social Support	Social support refers to the psychological and physical resources provided by social networks that help individuals cope with stress (Hu et al., 2015).	Social support also one of the domains that was evaluated to determine the respondent's quality of life in this study.

1.7 Significance of the Study

Osteoarthritis is a representative degenerative disease that commonly occurs in synovial joints which has the highest incidence of all inflammatory diseases of the joints (Lee et al., 2020). Since the prevalence of OA is also increasing due to age, it will be more cases of OA in the future, considering the general population aging.

Therefore, the ability to do everyday activities, mental health conditions like depression and anxiety, and pain will all have an impact on the quality of life for the elderly patients with lower limb OA. In order to give patients the best care possible, nurses and other healthcare professionals can utilize the baseline information gathered in this study as a starting point. This is due to the fact that evaluating quality of life is crucial for assisting medical professionals in understanding how a patient's condition affects them personally and make health services more patient-centered (Zakaria et al., 2009).

Other than that, this study can also serve as a primary step for healthcare professionals to become aware with patients who have OA symptoms, not just in terms of prescribing medications but also in terms of providing holistic care that includes both physical and emotional support. Management strategies may be optimized by adapting to patient-specific needs with a multimodal personalized OA management plan grounded on evidence-based therapies for whole person care (Vitaloni et al., 2019).

Furthermore, because the results of the research addressing quality of life among young elderly patients with lower limb OA in Hospital Universiti Sains Malaysia are still limited, this study can be very useful and can be implemented as a benchmark for our healthcare professionals in hospitals in order to provide more effective interventions for the patients. Moreover, the outcomes of this research can also be used as a starting point for further research in more in-depth studies.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

In order to demonstrate the comprehension of quality of life among patients with lower limb osteoarthritis in greater detail from the prior research studies conducted internationally, a literature review will be performed in this chapter. The chosen conceptual framework for the study will next be described in detail to illustrate how the variables should be related to one another.

2.2 Review of literature

2.2.1 Quality of Life

Osteoarthritis (OA) is one of the most frequent chronic diseases that can lead to loss of quality of life and increased prevalence and incidence due to increased life expectancy (Shalhoub et al., 2022). Quality of life defined by World Health Organization (WHO) is an individual's perspective of their position in life in relation to their objectives, expectations, standards, and concerns, as well as the culture and value systems in which they live (World Health Organization, 2012). Individuals who are living with OA having a lower quality of life. According to Araujo et al. (2016), the significant drop of quality of life is resulted due to limited joint range and pain, daily living activities of these individuals are more compromised, which generates harm in work, leisure and social relationships. Therefore, quality of life assessment is essential in order to improve the effectiveness of nursing care.

Pain has a high impact on their quality of life, because it generates negative effects on their mood, their participation in social activities, recreation and even affects their sleep (Vargas & Grande, 2021). In addition, it was also documented that patients with

moderate to severe pain due to OA had a high impact on the quality of life, even using medications (Conaghan et al., 2021). Knee OA is characterized by the following symptoms such as pain, stiffness and limited motion of knee joint (Pang et al., 2015). In those patients in whom the disease progresses, pain is more continuous and begins to affect activities of daily living, eventually causing severe limitations in function (Sen & Hurley, 2022).

The WHO has estimated that 80% of people with OA have movement limitations while 25% of them cannot perform their major daily activities, thus resulting in a decline of their nutritional status and quality of life (Zamri et al., 2021). Approximately 40% of adults over 70 have OA, and 80% of the people with this disease suffer from some type of limitation when carrying out their daily activities (Santos et al., 2015). These disabilities, mainly related to pain, manifested by difficulty in walking, climbing stairs, to the performance of household chores or when sitting upright and change is accompanied by a decrease in quality of life and an important psychological impact (Mahir et al., 2016). In addition, activity limitations negatively impact social connectedness and psychological well-being, reducing the quality of life of patients (Vitaloni et al., 2019). Therefore, the risk of social isolation may be increased by these symptoms and indicators of OA, particularly joint pain and decreased function (Ethgen et al., 2004). Moreover, OA with its symptoms and potential physical disability can affect the patient's quality of life and may cause psychiatric problems such as anxiety, depression and despair in the elderly (Awatif et al., 2019).

Most people with OA experience mental health issues such as depression and anxiety which lead to diminish quality of life (Lee et al., 2020). According to Stubbs et al. (2014), the depressive symptoms were highlighted as a potential barrier to physical activity for people with osteoarthritis in a recent systematic review. In the other words,

anxiety and depression are interrelated with pain and physical limitation, the two key OA symptoms (Sharma et al., 2016). The World Health Organization estimates that approximately 280 million people suffer from depression, while over 700,000 people die because of suicide every year (World Health Organization, 2021). Depression is the most common mood disorders which involves 12% of men and 10 to 25% of women (Nazarinasab et al., 2017). In 2016, a systematic review discovered a combined prevalence of depressive symptoms among OA patients of 19.9%, whereas the prevalence among patients with mixed lower extremity and adult knee OA was 18.5% and 23.0%, respectively (Stubbs et al., 2016).

2.2.2 Lower Limb Osteoarthritis

Osteoarthritis (OA) is the most common debilitating disease, a leading cause of disability, and is characterized by chronic pain and whole arthropathies such as articular cartilage damage, synovitis, subchondral bone remodelling and osteophyte formation (Tong et al., 2022). It is the most common joint disease, affecting an estimated more than 240 million people worldwide, including an estimated more than 32 million in the US, which the most frequent reason for activity limitation in adults (Katz et al., 2021). OA usually occurs in knee, lumbar, cervical, hand, and hip joints, and because of the higher knee's vulnerability to direct (knocked) and indirect (twisted) trauma, along with the high load supported by this joint, the knee is seen as the most frequently affected joint by OA (Sun et al., 2019). In addition, among the 32 million US adults, the most common sites of their clinical OA are being knee and hip (Callahan et al., 2021).

Knee osteoarthritis is the most common arthritic location and the impact of its symptomatic form is estimated at 240/100,000 people per year (Mahir et al., 2016). It has been listed as the 11th largest contributor to global disability and the 38th highest contributor in terms of disability-adjusted life years (Bindawas et al., 2018). In the US, about 37% of the population aged above 60 present a diagnosis of knee osteoarthritis (Kawano et al., 2015). Meanwhile, most of the Asian populations reported to have knee OA in a range of 13.1% to 71.1% in various Asian countries (Zamri et al., 2019). In addition, according to the Arthritis Foundation of Malaysia (AFM), the most prevalent form of OA in adults 60 and older is knee OA, which affects about one in ten of them (Hatta & Hasan, 2019).

Furthermore, there are four stages of osteoarthritis which include minor, mild, moderate and severe. Stage 1 is the minor stage that will develop very minor wear & tear and bone spur growths at the end of the knee joints with very little pain or discomfort

likely to be experienced (Illinois Bone & Joint Institute, 2016). Stage 2 is the mild stage, when X-rays will start to show more noticeable bone spur growths, the growths that often develop where bones meet each other in the joint, as well as start to feel stiff after long, sedentary periods, and will become uncomfortable (Orthopaedic Specialty Group, 2016).

Stage 3 is the moderate stage, whereby the cartilage between bones shows obvious damage, and the space between the bones begins to narrow with feeling of joint stiffness for long periods of time or when waking up in the morning (Holland, 2021). Lastly, stage 4 is the severe stage where the joint space between the bones reduces considerably, and the bone spur becomes large in size, with apparent deformity of the bone ends and formation of a large area of connective tissue in the joint (HealthMatch, 2022). In addition, the breakdown of cartilage leads to a chronic inflammatory response, with decreased synovial fluid that causes friction, greater pain and discomfort when walking or moving the joint (Illinois Bone & Joint Institute, 2016).

2.2.3 Association between Socio-demographic Characteristics and Quality of Life among Patients with Lower Limb Osteoarthritis

Knee OA is a multifactorial disease, with many risk factors playing a role in symptomatic findings and disease progression (Natalie & Reed, 2021) which include modifiable (obesity, knee injury) and unmodifiable (age, sex) factors (Cui et al., 2020). OA affects both sexes equally, but it affects males more frequently than women before the age of 45 and women more frequently after the age of 45 (National Institute on Aging, 2017). Globally, among individuals aged more than 60 years, 9.6% of men and 18% of women suffer from symptomatic OA, with knee being most commonly affected joint (Valdes & Stocks, 2018). In addition, Zamri et al. (2019) also states that knee OA is more prevalent in females than males at 31.6% and 28.1%, respectively.

In the many studies investigating the risk factors of knee OA, overweight and obesity remain the most determinant even though they are considered modifiable (Raud et al., 2020). Knee OA accounts for almost four fifths of the burden of OA worldwide and increases with obesity and age (Cui et al., 2020). Obesity was once considered a risk factor for knee OA because it increases joint contact forces, the external knee adduction moment, and diurnal cartilage strain (Batushansky et al., 2022). In the US, 12% of adults between 40 and 59 years of age are severely obese, defined as a body mass index (BMI) greater than 40 (Landy et al., 2022). In addition, Wall et al. (2020) state that although the prevalence of osteoarthritis among all normal or underweight Americans is 16%, this number increases to 23% among overweight adults and to 31% for obese individuals.

OA is the most common joint disease, mainly affecting middle-aged and elderly persons (Stemberger & Schindl, 2013) with the major risk factors for OA is ageing (Valdes & Stocks, 2018). Anderson & Loeser (2010) reported that older persons are more likely to develop OA because additional OA risk factors are more likely to exist in

combination with the ageing alterations that have been observed in the cells and extracellular matrix of joint tissues. This combination likely increases the vulnerability of older adults to OA. It has been reported that knee OA is a rapidly growing health problem in people over 50 years of age and a significant cause of disability (Bindawas et al., 2018).

OA is highly prevalent and most common among elderly age more than 60 years as well as affect the healthy ageing (Valdes & Stocks, 2018). Furthermore, about one-third of people with the age of over than 65 years old experience symptomatic knee OA and about 18% of patients over 70 years old experience degenerative joint disease (Iwata et al., 2013). In addition, 10% of the world's population 60 years and older suffer with OA (Mistry et al., 2022), while the number of people aged 60 years and above is expected to double by 2050 and more than triple by 2100 (Jahan et al., 2017). At the same time, there is an estimated 22.9% of people worldwide who have knee osteoarthritis who are 40 years of age or older (Cui et al., 2020).

According to Bhandarkar et al. (2016), OA will be one of the most prevalent diseases in Asian countries in the next two to three decades due to the region's high population of elderly people. Since OA is strongly associated with aging and Asian countries are aging rapidly, the prevalence of knee OA is shown to be in the range of 13.8% to 71.1% across the Asian populations (Zamri et al., 2019). According to Gates (2018), the number of adults 65 and older is expected to grow significantly over the next 50 years in all across Asia, increasing by 314 percent, from 207 million in 2000 to 857 million in 2050. Subsequently, the point prevalence of knee OA in Malaysia today is estimated to be 10–20% of the total adult population (Ganasegeran et al., 2014). Therefore, the increasing number of age will result in an increase in the possibility that

they will develop OA, as ageing is one of the most prominent risk factors for OA (Greene & Loeser, 2015).

Other than that, lower education level is the component of socioeconomic status that most strongly related to higher prevalence of knee OA and knee symptoms (Lee et al., 2021). According to a study conducted by Alkan et al. (2014), a bad quality of life was experienced by this group of participants in the study, which comprised around 70% of those with low to middle education. Furthermore, in OA, low educational attainment is associated with greater reported pain and poorer health status outcomes independently of socioeconomic factors, such as income (Kouraki et al., 2022). It has also been reported that those with lower education have reduced access to self-management programs as treatment for OA (Wetterholm et al., 2016). It also may be because of the fact that individuals with lower education level frequently involved heavy physical activities or accessed to few the knowledge of prevention for knee OA (Cui et al., 2020). Furthermore, previous studies have shown that OA is associated with certain occupational risk factors, such as kneeling, squatting, climbing, heavy lifting, and vibration (Yucesoy et al., 2015). Compared to sedentary occupations, heavy manual work was associated with an increased risk of incident knee OA, particularly in men (Perry et al., 2020).

2.2.4 Instrumentations

There are several validated instruments used in order to evaluate the level of quality of life among patients with osteoarthritis from previous study such are Medical Outcomes Study-36 - Item Short -Form Health Survey (SF-36), Western Ontario and McMaster Universities Osteoarthritis (WOMAC), Knee Injury and Osteoarthritis Outcome Score (KOOS) and Osteoarthritis Knee and Hip Quality of Life (OAKHQOL).

SF-36 is a set of questionnaires consisting of 36 items which were clustered into eight health concepts which are meant to be measured (Musa et al., 2021). It is frequently used to evaluate quality of life, but as a generic instrument, it is not specifically for a particular disease like OA. This instrument was also found to have low response rate in population more than 65 years of age (Parker et al., 1998). WOMAC instrument questionnaire is a disease-specific instrument which is used to assess pain (5 questions), stiffness (2 questions) and physical function (17 questions) in patients with knee and hip OA. However, Bellamy & Buchanan (1986) stated that WOMAC only measure pain and functional disability but do not take other domains of quality of life into account such as mental, social and sexual.

Another instrument that has been extensively used in prior OA research is the self-administered questionnaire known as KOOS, which assesses five outcomes. However, this instrument is not limited to quality of life because it includes pain, other symptoms, activity of daily living, sports, and recreational activity measurements (Zulkifli et al., 2017). Therefore, OAKHQOL instrument will be chosen to use in this study because it is the first quality of life tool that specifically dedicated to lower-limb osteoarthritis, also meets psychometric requirements for validity and reliability (Anne Christine Rat et al., 2005). The major advantage of OAKHQOL is that it covers a significant number of International Classification of Functioning, Disability, and Health's (ICF) categories and captures specific aspects for patients with knee and/or hip osteoarthritis (Duruöz et al., 2022). In addition, this may be interpreted as the universality and comprehensiveness of the instrument (A. C. Rat et al., 2008).

2.3 Conceptual Framework of the Study

A health-related quality of life conceptual framework is utilized in this study which developed by Wilson and Cleary's in 1995. This model is revised by Ferrans, Zerwic, Wilbur, and Larson in 2005. They explicit the definitions for individual and environmental characteristics, and they simplified the depiction of the model by removing non-medical factors but five major domains of the original model were retained (Bakas et al., 2012). The major domains proposed in this model is a pathway of linkages between the five domains which are biophysiological status, symptoms, functional status, general health perception (i.e., patient-rated health), and quality of life (Lawson et al., 2018).

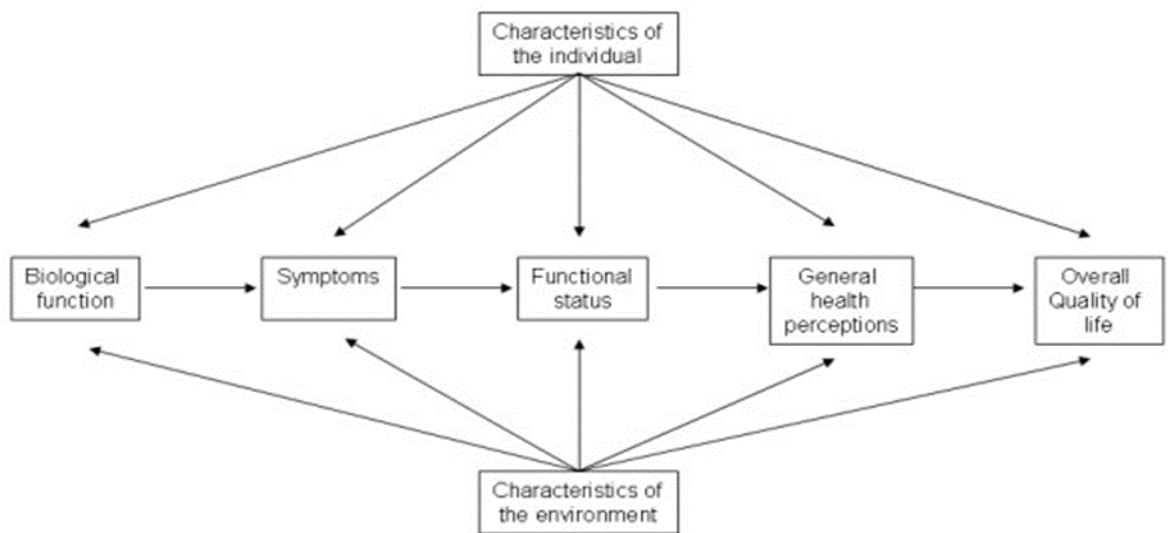


Figure 2.1 The Wilson and Cleary Model of Health-related Quality of Life (1995)

This model provides an excellent understanding of the concept of quality of life, which describes the interactions between factors that affect quality of life related to health. This conceptual framework describes how selected characteristics of individual such as age, gender, weight and educational level will influence the health-related quality of life. In the other words, this conceptual model suggests causal links among biological and physiological factors, symptoms, functional levels, general health perceptions and

overall quality of life (Rodríguez et al., 2013). Hence, this model demonstrated good features suitable for evaluating health-related quality of life in chronic diseases (Ojelabi et al., 2017).

In this study, this model will be customized in accordance with the research health concepts whereby the characteristics of individuals consist of age, gender, types of osteoarthritis and level of education. The respondents' Body Mass Index (BMI) will be included in biological function and pain is included in symptoms. Meanwhile, physical activity, mental health, social support and social function will be included in functional status but are not specifically studied in this study. Therefore, this model clearly helps to understand the relationship between all the health concepts and quality of life which is important for outcome measure in clinical trials and health research. This is because when knowing the proximate causes of health-related quality of life in a disease population will help target rather than just monitor the improvement of the health-related quality of life (Ojelabi et al., 2017).

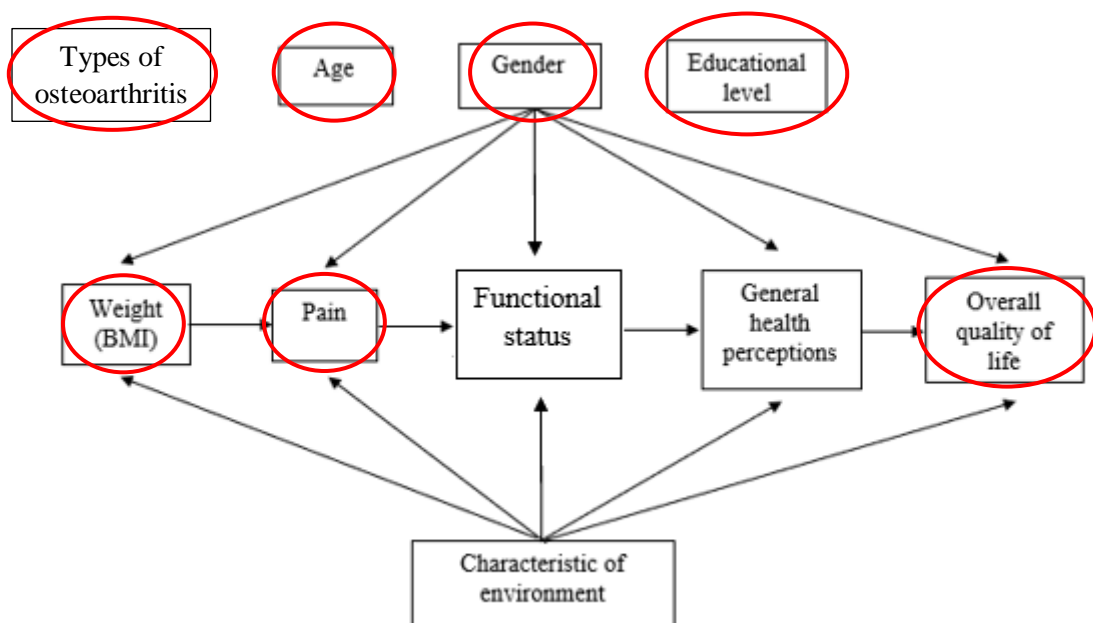


Figure 2.2 The Wilson and Cleary model of health-related quality of life among patients with lower limb osteoarthritis

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Introduction

In this section, research methodology such as research design, research duration, sampling plan, instrumentation, data analysis, expected outcome of study and ethical consideration was discussed.

3.2 Research Design

The study used a cross-sectional study design for data collection among patients with lower limb osteoarthritis.

3.3 Research Location

The location of this study was conducted in Outpatient Orthopaedic Clinic in Hospital Universiti Sains Malaysia (HUSM), Kubang Kerian, Kelantan. It was the main teaching hospitals for the undergraduates and postgraduates students of Universiti Sains Malaysia which consists of 723 beds (School of Medical Sciences, 2022).



3.4 Research Duration

From October 2022 until August 2023, this study was carried out. Data collecting was started once The Human Research Ethics Committee (HREC) of USM had given its ethical permission, which was anticipated to happen on January 2023 until April 2023.

3.5 Research Population

This study was conducted among patients with lower limb osteoarthritis who were attending the orthopaedic clinic throughout the data collection period and met the inclusion and exclusion criteria.

3.6 Subject Criteria

The data collection of this study only was conducted among participants who met the following inclusion and exclusion criteria:

3.6.1 Inclusion Criteria

Participants must meet the following criteria to be included in this study, based on previous study from Kadir et al. (2018):

- i. Have medical diagnosis of unilateral or bilateral knee or hip osteoarthritis.
- ii. Able to understand and respond in Malay or English language.

3.6.2 Exclusion Criteria

Participants were excluded if they:

- i. Have terminally ill condition (Pisters et al., 2014).
- ii. Have underlying neurological disorders (Kawano et al., 2015).
- iii. Have degenerative disease that could affect the quality of life such as heart disease, Parkinson's disease, renal failure, cancer and more (Kawano et al., 2015).

3.7 Sampling Plan

3.7.1 Sample Size Estimation

The sample size was calculated for each study objective. For the first and second objective, the sample size was calculated using the single proportion formula. Based on the previous study, the margin error was being set at 5% with the confidence level of 95% (Zamri et al., 2021).

$$n = \left[\frac{z}{\Delta} \right]^2 p(1 - p)$$

Where

n = Sample size

p = Anticipated population proportion

z = 95% of confidence interval (CI) = 1.96

Δ = Precision = 0.05

For the first objective, it is to determine the level of quality of life among young elderly patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia, the sample size was determined using a single proportion formula:

$$n = \left[\frac{z}{\Delta} \right]^2 p(1 - p)$$

Where

n = Sample size

p = Anticipated population proportion = 92.3% (Zamri et al., 2021)

z = 95% of confidence interval (CI) = 1.96

Δ = Precision = 0.05

Calculation:

$$n = \left[\frac{1.96}{0.05} \right]^2 0.923(1 - 0.923)$$

$n = 109$ respondents

The minimal sample size was 109 and after considering 10% of drop out, the calculated sample size is 120.

For second objective, to identify the level of pain among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia,

$$n = \left[\frac{z}{\Delta} \right]^2 p(1 - p)$$

Where

n = Sample size

p = Anticipated population proportion = 4.7% (Aw et al., 2022)

z = 95% of confidence interval (CI) = 1.96

Δ = Precision = 0.05

Calculation:

$$n = \left[\frac{1.96}{0.05} \right]^2 0.047(1 - 0.047)$$

n = 69 respondents

The minimal sample size was 69 and after considering 10% of drop out, the calculated

sample size is 76.

For the third objective, it is to identify the association between socio-demographic characteristics and the level of quality of life among elderly patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia, two proportion is used.

$$n = \frac{p1(1 - p1) + p2(1 - p2)(z\alpha + z\beta)^2}{(p1 - p2)^2}$$

Whereby,

n = Required sample size

p = Anticipated population proportion

$p1$: Patients with low educational level, 0.430 (Kawano et al., 2015)

$p2$: Patients with high educational level, 0.172 (Kawano et al., 2015)

$Z\alpha$ = Value of the standard normal distribution curve cutting off probability alpha in one tail for one-sided alternatives ($Z\alpha = 1.96$)

$Z\beta$ = Power of study, 80% ($Z\beta = 0.84$)

Calculation:

$$n = \frac{0.430(1 - 0.430) + 0.172(1 - 0.172)(1.96 + 0.84)^2}{(0.430 - 0.172)^2}$$

$n = 20$ respondents

The minimal sample size is 20, and after considering a 10% drop out, the sample size calculated is 22.

Therefore, based on three calculations of sample sizes, the sample size in objective 1 is convenience and realistic to do since bigger sample size helps produce a more significant result. Hence, the total number of participants of this study are 120.

3.7.2 Sampling Method

Convenience sampling method was used in this study to recruit sample. It is a non-probability sampling method where units are selected for inclusion in the sample because they are the easiest for the researcher to access (Nikolopoulou, 2022). Therefore, the researcher only approaches potential participants for the data collection who attend the Outpatient Orthopaedic Clinic at Hospital Universiti Sains Malaysia. Hence, the study participants who voluntarily agree to participate was given a set of questionnaires.

3.8 Research Instrument

3.8.1 Questionnaire

One set of questionnaires was used to obtain relevant data on the quality of life among patients with lower limb osteoarthritis in Hospital USM. The questionnaire was adopted from Kadir et al. (2018) named Osteoarthritis Knee and Hip Quality of Life Questionnaire (OAKHQOL), which has been translated and validated in Malay version. However, the original OAKHQOL instrument was developed by Rat et al. (2005). Therefore, permissions to use the instrument from both authors was obtained (Appendix B). The original instrument consists of five domains which are physical activity (Q1, Q2, Q3, Q4, Q5, Q6, Q7, Q8, Q9, Q18), pain (Q16, Q17, Q22, Q23), mental health (Q10, Q11, Q12, Q13, Q14, Q15, Q24, Q26), social support (Q25, Q27, Q28) and social functioning (Q19, Q20, Q21). Hence, the questionnaire only consists of 33 questions in three sections, Section A and Section B as follows:

Section A: Socio-demographic Information

This section consists of 5 questions of socio-demographic background which includes gender, age, types of osteoarthritis, height, weight (Body Mass Index) and level of education.

Section B: Quality of Life

This section consists of 28 close-ended questions regarding quality of life which covers 5 domains such as physical activity, mental health, pain, social functioning and social support. Each question was measured on a numerical rating scale from 0 to 10, which 0 determined not at all and 10 determined a great deal.

3.8.2 Validity and Reliability

The content of this questionnaire has been validated by the original authors. The reliability analysis showed that the Cronbach's alpha coefficient value for each construct was greater than 0.7 (Kadir et al., 2018). Furthermore, as the identical questionnaire had already been used in a prior study at the same clinic in the same hospital, there was no need to do a pilot study.

3.9 Variable

3.9.1 Variable Measurement

This study has identified two different variables which were dependent variable and independent variable. The variables were as followed:

Table 3.1 Dependent and Independent Variable

Dependent Variable	Quality of life of among patients with lower limb osteoarthritis
Independent Variable	Socio-demographic characteristics of patients with lower limb osteoarthritis in Hospital USM (age, gender, types of osteoarthritis, height and weight (BMI) and level of education).

3.9.2 Variable Scoring

The data was collected and computerized for analysis using IBM Statistical Package for the Social Sciences (SPSS) for Windows version 27.0. There are 33 items in the questionnaire instrument. 5 items were structured at socio-demographic data which is Section A, and 28 items in the instrument of Section B.

In Section A, the descriptive data frequency (n), percentage (%), mean and standard deviation will be presented. In Section B, the score was obtained by computing the mean of the item score for each domain and normalized to a scale from 0 (the worst) to 100 (the best). The final scores were the mean of scores of all the items in respective domains that ranged between 0 to 10 (Kadir et al., 2018).

3.10 Data Collection Plan

Data for this study were collected after obtaining ethical approval from the Human Research Ethical Committee (HREC) and permission to carry out this study in HUSM was obtained from the Director of Hospital USM. A day before the data collection in Outpatient Orthopaedic Clinic, the researcher had approached the staff nurses in charge at the clinic to get the list of patients who diagnosed with lower limb osteoarthritis that have appointments scheduled for the following day.

Each chosen patient received informational materials to read and briefed on the study, including an explanation of its objectives. After that, the researcher obtained an informed consent (refer Appendix C) from the respondents, which indicated whether they agree or reject to take part in the study. Then, they received a questionnaire survey to complete while seeking clarification from the researcher if necessary. If the respondents need assistance writing or reading the questionnaire, which should only take them about 15-20 minutes to complete, they had received it. After they have finished answering, the questionnaires were collected and used to collect data for this study. Figure 3.1 demonstrates that the overall flow of the data collection process.

3.10.1 Flow Chart of Data Collection

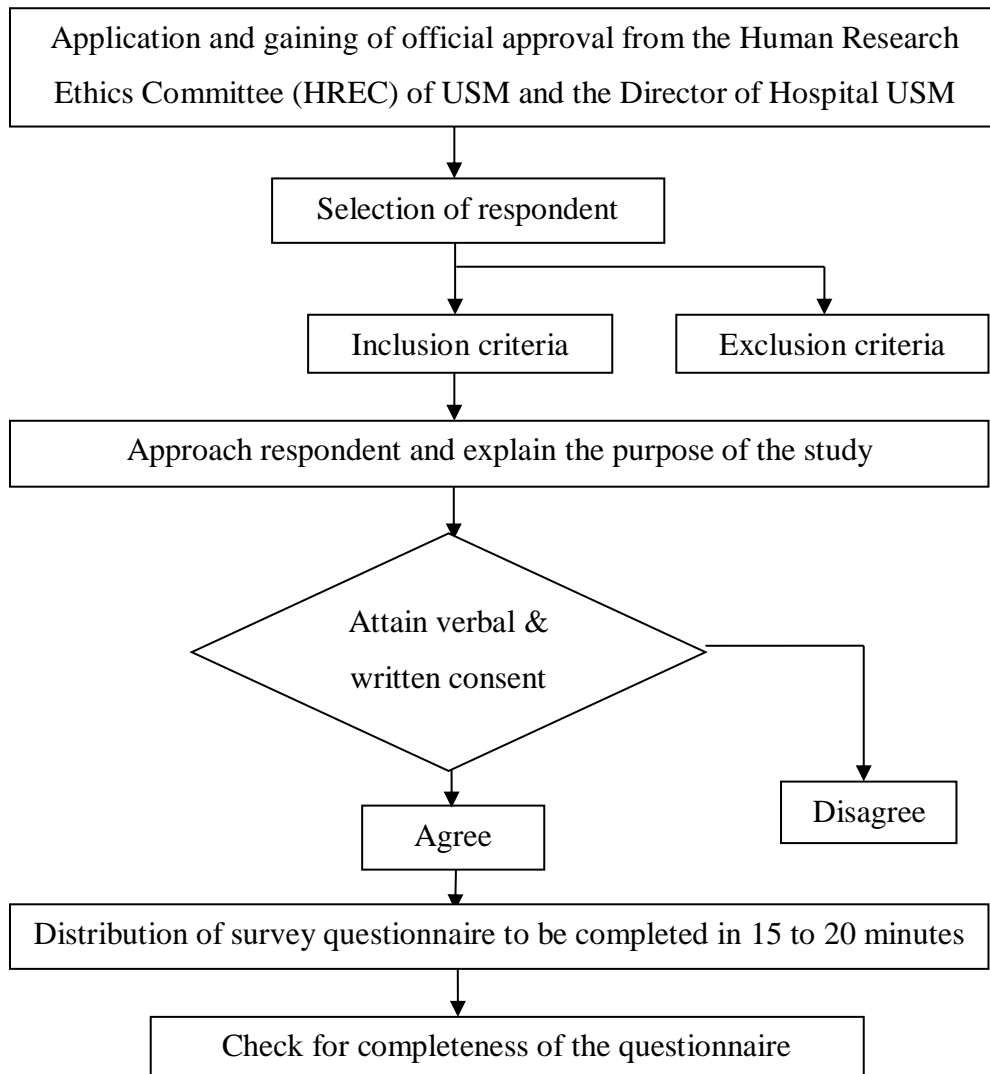


Figure 3.1 The flowchart of data collection for this study

3.11 Data Analysis

The data was collected and computerized for analysis using SPSS version 27.0 for Window. The data was screened and checked for accuracy, data errors, outliers, and inconsistencies prior analysis.

Table 3.2 Measurement of Data Analysis

No.	Research Objectives	Test
1.	To identify the quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia.	Frequency, percentage, mean and standard deviation (SD).
2.	To identify the association between socio-demographic characteristics and the quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia.	Pearson Chi-square test

3.12 Ethical Consideration

3.12.1 Permission to Conduct the Study

Permission to conduct the study was gained from the Human Research Ethics Committee (HREC), USM. Approval of study location was obtained from Director of Hospital USM to gain the access of the study population, the patients with lower limb osteoarthritis in HUSM.

3.12.2 Permission to Use the Instrument from the Original Author

The permission to use the original questionnaire had been approved by original author through email (Appendix B).

3.12.3 Subject Vulnerability

All subjects had the option to participate in this study voluntarily. The participants were informed that the study was voluntary and that they had the right to reject it or refuse to participate. Respondents' written informed consent was obtained and all the procedures were explained to them so they could agree to participate in this study (Appendix C). Prior to the data collection, each participant was given information on the purpose, scope, and importance of the study as well as the importance of their participation. Additionally, this study was not threatened or subjected to any physical or biological harm to the respondents involved.

3.12.4 Declaration of Absence of Conflict of Interest

This study had no conflicts of interest which were absence from any influence that have potential to effect or compromise professional judgement in research.

3.12.5 Privacy and Confidentiality

There were no patient identifications in the survey results, which were considered private. All throughout the study, subject data was kept private and confidential and utilised exclusively for academic and research purposes only.

3.12.6 Community Sensitivities and Benefits

This research was concerned with quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia. The researchers therefore concluded that the outcomes were necessary for healthcare professionals to provide a holistic care and effective interventions for the patients from this quality-of-life measurement.

3.12.7 Honorarium and Incentives

The participants were informed that the survey was self-supported. Hence, there was no honorarium or incentives given to participants.

CHAPTER 4: RESULTS

4.1 Introduction

This chapter presents the results of the study among patients with lower limb osteoarthritis in Hospital USM. The findings discussed in this chapter are according to the objective of the study as below:

4.2.1 Sociodemographic Characteristics

Table 4.1 summarized the sociodemographic data among patients in Hospital USM. A total of 109 patients were invited to participate in this study. However, only 100 number of responses were obtained at the end of data collection. Most of the respondents' age in this study were 51-65 years old. The majority of the respondents were identified as females (69.0%). Almost all the respondents were diagnosed with knee osteoarthritis (81.0%). Most of the respondents have the highest body mass index which is overweight (49.0%) and about half of the respondents were experiencing secondary school educational level (56.0%). Table 4.1 summarised all the socio-demographic characteristics among lower limb OA patients in Hospital USM.

Table 4.1 Socio-demographic Characteristics among Patients with Lower Limb Osteoarthritis in Hospital USM (n=100)

Variables	n	%
Age (Years old)		
20-35	5	5.0
36-50	18	18.0
51-65	46	46.0
66-80	31	31.0
Gender		
Male	31	31.0
Female	69	69.0
Type of osteoarthritis		
Knee osteoarthritis	81	81.0
Hip osteoarthritis	19	19.0
Body Mass Index		
<18.5	1	1.0
18.5 – 24.9	18	18.0
25 – 29.9	49	49.0
≥30	32	32.0
Level of education		
Primary School	16	16.0
Secondary School	56	56.0
Higher Education	28	28.0

4.2.2 Quality of Life

Table 4.2 depicts the overall frequency and percentage of quality of life in each domain among patients with lower limb osteoarthritis in Hospital USM. The result has shown that the pain domain had the lowest and worst quality of life (25.46 ± 11.07) while the social functioning scored the highest quality of life (26.78 ± 3.21). The characteristics of respondents were outlined in detail in the table below:

Table 4.2 The Overall Score Quality of Life among Patients with Lower Limb Osteoarthritis in Hospital USM (n=100)

Domain	Quality of Life (QOL)		
	Frequency (%)		mean \pm SD
	Worst QOL	Best QOL	
Physical activity	48 (48.0%)	52 (52.0%)	40.45 \pm 23.03
Mental health	40 (40.0%)	60 (60.0%)	22.33 \pm 19.77
Pain	59 (59.0%)	41 (41.0%)	25.46 \pm 11.07
Social functioning	31 (31.0%)	69 (69%)	26.78 \pm 3.21
Social support	45 (45.0%)	55 (55.0%)	27.56 \pm 2.16

Table 4.3 described the quality of life among patients with lower limb osteoarthritis in Hospital USM. The results have shown that overall quality of life.

Table 4.3 Respondents' quality of life among patients with lower limb osteoarthritis in Hospital USM (n=100)

Variables	Frequency (%)	Percentage (%)
1. I have difficulty walking.		
0 (Not at all)	4	4.0
1	2	2.0
2	4	4.0
3	12	12.0
4	8	8.0
5	19	19.0
6	14	14.0
7	12	12.0
8	9	9.0
9	9	9.0
10 (A great deal)	7	7.0
2. I have difficulty bending down or straightening up.		
0 (Not at all)	5	5.0
1	4	4.0
2	5	5.0
3	7	7.0
4	9	9.0
5	20	20.0
6	12	12.0
7	8	8.0
8	9	9.0
9	9	9.0
10 (A great deal)	12	12.0
3. I have difficulty going down the stairs.		
0 (Not at all)	3	3.0
1	6	6.0
2	5	5.0
3	7	6.0
4	0	0.0
5	22	22.0
6	7	7.0
7	18	18.0
8	13	13.0
9	6	6.0

10 (A great deal)	13	13.0
4. I have difficulty climbing stairs.		
0 (Not at all)	3	3.0
1	4	4.0
2	3	3.0
3	9	9.0
4	2	2.0
5	17	17.0
6	11	11.0
7	15	15.0
8	15	15.0
9	6	6.0
10 (A great deal)	15	15.0
5. I have difficulty taking a bath.		
0 (Not at all)	56	56.0
1	14	14.0
2	8	8.0
3	7	7.0
4	5	5.0
5	5	5.0
6	2	2.0
7	0	0.0
8	2	2.0
9	0	0.0
10 (A great deal)	1	1.0
6. I have difficulty getting dressed.		
0 (Not at all)	37	37.0
1	11	11.0
2	6	6.0
3	8	8.0
4	8	8.0
5	12	12.0
6	4	4.0
7	4	4.0
8	3	3.0
9	4	4.0
10 (A great deal)	3	3.0
7. I have difficulty cutting my toenails.		
0 (Not at all)	35	35.0
1	8	8.0
2	9	9.0
3	8	8.0
4	6	6.0
5	14	14.0
6	5	5.0
7	3	3.0

8	4	4.0
9	5	5.0
10 (A great deal)	3	3.0
8. I have difficulty getting in and out of a car.		
0 (Not at all)	30	30.0
1	8	8.0
2	12	12.0
3	7	7.0
4	8	8.0
5	10	10.0
6	10	10.0
7	2	2.0
8	6	6.0
9	6	6.0
10 (A great deal)	1	1.0
9. I have difficulty using public transport.		
0 (Not at all)	42	42.0
1	7	7.0
2	9	9.0
3	5	5.0
4	2	2.0
5	10	10.0
6	5	5.0
7	3	3.0
8	7	7.0
9	7	7.0
10 (A great deal)	3	3.0
10. My spirits are low because of the pain.		
0 (Not at all)	42	42.0
1	12	12.0
2	8	8.0
3	7	7.0
4	3	3.0
5	10	10.0
6	3	3.0
7	2	2.0
8	2	2.0
9	5	5.0
10 (A great deal)	6	6.0
11. I worry about being disabled.		
0 (Not at all)	58	58.0
1	7	7.0
2	5	5.0
3	2	2.0
4	0	0.0
5	8	8.0

6	5	5.0
7	2	2.0
8	0	0.0
9	6	6.0
10 (A great deal)	7	7.0
12. I feel embarrassed when people look at me.		
0 (Not at all)	60	60.0
1	10	10.0
2	7	7.0
3	5	5.0
4	1	1.0
5	2	2.0
6	0	0.0
7	1	1.0
8	2	2.0
9	4	4.0
10 (A great deal)	8	8.0
13. I am anxious.		
0 (Not at all)	39	39.0
1	13	13.0
2	8	8.0
3	10	10.0
4	2	2.0
5	8	8.0
6	2	2.0
7	4	4.0
8	3	3.0
9	3	3.0
10 (A great deal)	8	8.0
14. I am depressed.		
0 (Not at all)	39	39.0
1	9	9.0
2	7	7.0
3	11	11.0
4	2	2.0
5	11	11.0
6	2	2.0
7	5	5.0
8	2	2.0
9	4	4.0
10 (A great deal)	8	8.0
15. I feel my family life is being affected.		
0 (Not at all)	62	62.0
1	5	5.0
2	4	4.0
3	7	7.0

4	0	0.0
5	5	5.0
6	1	1.0
7	5	5.0
8	3	3.0
9	1	1.0
10 (A great deal)	7	7.0
16. I have pain (describe frequency).		
0 (Not at all)	0	0.0
1	2	2.0
2	19	19.0
3	34	34.0
4	6	6.0
5	2	2.0
6	1	1.0
7	6	6.0
8	8	8.0
9	8	8.0
10 (A great deal)	14	14.0
17. I have pain (describe intensity).		
0 (Not at all)	1	1.0
1	6	6.0
2	14	14.0
3	29	29.0
4	11	11.0
5	2	2.0
6	2	2.0
7	2	2.0
8	5	5.0
9	12	12.0
10 (A great deal)	16	16.0
18. I need help for things like housework and shopping.		
0 (Not at all)	32	32.0
1	9	9.0
2	8	8.0
3	7	7.0
4	3	3.0
5	12	12.0
6	9	9.0
7	5	5.0
8	6	6.0
9	0	0.0
10 (A great deal)	9	9.0

19. I am able to plan projects for the long term.		
0 (Not at all)	0	0.0
1	2	2.0
2	0	0.0
3	0	0.0
4	0	0.0
5	6	6.0
6	2	2.0
7	6	6.0
8	17	17.0
9	41	41.0
10 (A great deal)	26	26.0
20. I get out of the house as much as I like.		
0 (Not at all)	0	0.0
1	0	0.0
2	0	0.0
3	0	0.0
4	0	0.0
5	4	4.0
6	3	3.0
7	5	5.0
8	22	22.0
9	37	37.0
10 (A great deal)	29	29.0
21. I entertain at home as much as I like.		
0 (Not at all)	0	0.0
1	0	0.0
2	1	1.0
3	0	0.0
4	0	0.0
5	0	0.0
6	0	0.0
7	2	2.0
8	6	6.0
9	19	19.0
10 (A great deal)	72	72.0
22. I have difficulty getting to sleep or getting back to sleep because of pain.		
0 (Not at all)	1	1.0
1	16	16.0
2	20	20.0
3	17	17.0
4	7	7.0
5	7	7.0
6	1	1.0
7	6	6.0
8	9	9.0

9	11	11.0
10 (A great deal)	5	5.0
23. I wake up because of pain.		
0 (Not at all)	1	1.0
1	21	21.0
2	18	18.0
3	18	18.0
4	5	5.0
5	3	3.0
6	6	6.0
7	6	6.0
8	7	7.0
9	10	10.0
10 (A great deal)	5	5.0
24. I wonder what will become of me.		
0 (Not at all)	32	32.0
1	13	13.0
2	11	11.0
3	6	6.0
4	6	6.0
5	8	8.0
6	3	3.0
7	2	2.0
8	6	6.0
9	1	1.0
10 (A great deal)	12	12.0
25. I feel others understand the difficulties I have because of my arthritis.		
0 (Not at all)	0	0.0
1	0	0.0
2	0	0.0
3	0	0.0
4	0	0.0
5	0	0.0
6	0	0.0
7	0	0.0
8	1	1.0
9	15	15.0
10 (A great deal)	84	84.0
26. I am embarrassed to ask for help if I need it.		
0 (Not at all)	56	56.0
1	13	13.0
2	4	4.0
3	2	2.0
4	2	2.0

5	6	6.0
6	2	2.0
7	4	4.0
8	0	0.0
9	3	3.0
10 (A great deal)	8	8.0

27. I feel supported by people close to me.

0 (Not at all)	0	0.0
1	0	0.0
2	0	0.0
3	0	0.0
4	0	0.0
5	1	1.0
6	0	0.0
7	0	0.0
8	9	9.0
9	22	22.0
10 (A great deal)	68	68.0

28. I feel supported by those around me.

0 (Not at all)	0	0.0
1	0	0.0
2	0	0.0
3	0	0.0
4	3	3.0
5	8	8.0
6	5	5.0
7	14	14.0
8	21	21.0
9	20	20.0
10 (A great deal)	29	29.0

4.2.3 The Association between Sociodemographic Factors and Quality of Life

This objective was focused on all the variables of demographic data. The association between sociodemographic factors and level of quality of life were determined according to each domain respectively. Table 4.6, 4.7, 4.8, 4.9 and 5.0 outline the overall association between sociodemographic factors in each domain by using Pearson Chi-square test. The characteristics of respondents were outlined in detail in the tables below:

Table 4.6 summarised the overall association between sociodemographic characteristics and physical activity. P-value ≤ 0.05 is considered to be statistically significant. Thus, there is a statistically significant association between the age ($p = 0.030$) and types of osteoarthritis ($p = 0.013$), tested using Pearson's Chi-Square test. There is no statistically significant association between gender ($p = 0.703$), body mass index ($p = 0.153$) and level of education ($p = 0.333$).

Table 4.4 Association between Sociodemographic Characteristics and Physical Activity

Variables	PHYSICAL ACTIVITY		p value
	Level of Quality-of-Life n(%)		
	Worst	Best	
Age			
20 – 35 years	3 (60.0)	2 (40.0)	0.030
36 – 50 years	4 (22.2)	14 (77.8)	
51 – 65 years	21 (45.7)	25 (54.3)	
66 – 80 years	20 (64.5)	11 (35.5)	
Gender			
Male	14 (45.2)	17 (54.8)	0.703
Female	34 (49.3)	35 (50.7)	
Types of Osteoarthritis			
Knee Osteoarthritis	34 (42.0)	47 (58.0)	0.013
Hip Osteoarthritis	14 (73.7)	5 (26.3)	

Body Mass Index (BMI)

< 18.5	0 (0.0)	1 (100)	
18.5 – 24.9	8 (44.4)	10 (55.6)	0.153
25 – 29.9	20 (40.8)	29 (59.2)	
≥ 30	20 (62.5)	12 (37.5)	

Level of Education

Primary School	10 (62.5)	6 (37.5)	
Secondary School	27 (26.9)	29 (51.8)	0.333
Higher School	11 (39.3)	17 (60.7)	

Table 4.7 summarised the overall association between sociodemographic characteristics and mental health. P-value ≤ 0.05 is considered to be statistically significant. Thus, there is a statistically significant association between the level of education ($p = 0.001$), tested using Pearson's Chi-Square test. There is no statistically significant association between age ($p = 0.074$), gender ($p = 0.537$), types of osteoarthritis ($p = 0.466$) and body mass index ($p = 0.707$).

Table 4.5 Association between Sociodemographic Characteristics and Mental Health

MENTAL HEALTH			
Variables	Level of Quality-of-Life n(%)		p value
	Worst	Best	
Age			
20 – 35 years	3 (60.0)	2 (40.0)	0.074
36 – 50 years	11 (61.1)	7 (38.9)	
51 – 65 years	18 (39.1)	28 (60.9)	
66 – 80 years	8 (25.8)	23 (74.2)	
Gender			
Male	11 (35.5)	20 (64.5)	0.537
Female	29 (42.0)	40 (58.0)	
Types of Osteoarthritis			
Knee Osteoarthritis	31 (38.3)	50 (61.7)	0.466
Hip Osteoarthritis	9 (47.4)	10 (52.6)	
Body Mass Index (BMI)			
< 18.5	1 (100.0)	0 (0.0)	0.707
18.5 – 24.9	8 (44.4)	10 (55.6)	
25 – 29.9	19 (38.8)	30 (61.2)	
≥ 30	12 (37.5)	20 (62.5)	
Level of Education			
Primary School	7 (43.8)	9 (56.3)	0.001
Secondary School	30 (53.6)	26 (46.4)	
Higher School	3 (10.7)	25 (89.3)	

Table 4.8 summarised the overall association between sociodemographic characteristics and pain. P-value ≤ 0.05 is considered to be statistically significant. Thus, there is a statistically significant association between the age ($p = 0.006$) and body mass index ($p = 0.001$), tested using Pearson's Chi-Square test. There is no statistically significant association between gender ($p = 0.755$), types of osteoarthritis ($p = 0.148$) and level of education ($p = 0.442$).

Table 4.6 Association between Sociodemographic Characteristics and Pain

Variables	PAIN		p value
	Level of Quality-of-Life n(%)		
	Worst	Best	
Age			
20 – 35 years	5 (100)	0 (0.0)	0.006
36 – 50 years	8 (44.4)	10 (55.6)	
51 – 65 years	22 (47.8)	24 (52.2)	
66 – 80 years	24 (77.4)	7 (22.6)	
Gender			
Male	19 (61.3)	12 (38.7)	0.755
Female	40 (58.0)	29 (42.0)	
Types of Osteoarthritis			
Knee Osteoarthritis	45 (55.6)	36 (44.4)	0.148
Hip Osteoarthritis	14 (73.7)	5 (26.3)	
Body Mass Index (BMI)			
< 18.5	1 (100.0)	0 (0.0)	0.001
18.5 – 24.9	9 (50.0)	9 (50.0)	
25 – 29.9	22 (44.9)	27 (55.1)	
≥ 30	27 (84.4)	5 (15.6)	
Level of Education			
Primary School	11 (68.8)	5 (31.3)	0.442
Secondary School	34 (60.7)	22 (39.3)	
Higher School	14 (50.0)	14 (50.0)	

Table 4.9 summarised the overall association between sociodemographic characteristics and social functioning. P-value ≤ 0.05 is considered to be statistically significant. Thus, there is a statistically significant association between the types of osteoarthritis ($p = 0.023$), tested using Pearson's Chi-Square test. There is no statistically significant association age ($p = 0.446$), gender ($p = 0.516$), body mass index ($p = 0.297$) and level of education ($p = 0.160$).

Table 4.7 Association between Sociodemographic Characteristics and Social Functioning

SOCIAL FUNCTIONING			
Variables	Level of Quality-of-Life n(%)		p value
	Worst	Best	
Age			
20 – 35 years	0 (0.0)	5 (100.0)	0.446
36 – 50 years	5 (27.8)	13 (72.2)	
51 – 65 years	16 (34.8)	30 (65.2)	
66 – 80 years	10 (32.3)	21 (67.7)	
Gender			
Male	11 (35.5)	20 (64.5)	0.516
Female	20 (29.0)	49 (71.0)	
Types of Osteoarthritis			
Knee Osteoarthritis	21 (25.9)	60 (74.1)	0.023
Hip Osteoarthritis	10 (52.6)	9 (47.4)	
Body Mass Index (BMI)			
< 18.5	0 (0.0)	1 (100.0)	0.297
18.5 – 24.9	3 (16.7)	15 (83.3)	
25 – 29.9	19 (38.8)	30 (61.2)	
≥ 30	9 (28.1)	23 (71.9)	
Level of Education			
Primary School	8 (50.0)	8 (50.0)	0.160
Secondary School	14 (25.0)	42 (75.0)	
Higher School	9 (32.1)	19 (67.9)	

Table 5.0 summarised the overall association between sociodemographic characteristics and social support. P-value ≤ 0.05 is considered to be statistically significant. Thus, there is no statistically significant association between the age ($p = 0.330$), gender ($p = 0.680$), types of osteoarthritis ($p = 0.458$), body mass index ($p = 0.592$) and level of education ($p = 0.947$), tested using Pearson's Chi-Square test.

Table 4.8 Association between Sociodemographic Characteristics and Social Support

SOCIAL SUPPORT			
Variables	Level of Quality-of-Life n(%)		p value
	Worst	Best	
Age			
20 – 35 years	2 (40.0)	3 (60.0)	0.330
36 – 50 years	5 (27.8)	13 (72.2)	
51 – 65 years	21 (45.7)	25 (54.3)	
66 – 80 years	17 (54.8)	14 (45.2)	
Gender			
Male	13 (41.9)	18 (58.1)	0.680
Female	32 (46.4)	37 (53.6)	
Types of Osteoarthritis			
Knee Osteoarthritis	35 (43.2)	46 (56.8)	0.458
Hip Osteoarthritis	10 (52.6)	9 (47.4)	
Body Mass Index (BMI)			
< 18.5	1 (100.0)	0 (0.0)	0.592
18.5 – 24.9	7 (38.9)	11 (61.1)	
25 – 29.9	21 (42.9)	28 (57.1)	
≥ 30	16 (50.0)	16 (50.0)	
Level of Education			
Primary School	7 (43.8)	9 (56.3)	0.947
Secondary School	26 (46.4)	30 (53.6)	
Higher School	12 (42.9)	16 (57.1)	

CHAPTER 5: DISCUSSIONS

5.1 Introduction

This chapter presents a discussion of the study findings. This study mainly focused to determine the level of quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia. Therefore, the discussion in this chapter is grouped under subheadings:

- i. Sociodemographic of respondents
- ii. The quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia.
- iii. The association between socio-demographic characteristics (age, gender, type of osteoarthritis, body mass index and level of education) and the quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia.

5.2 Sociodemographic of Respondents

There were 100 total number of respondents who participated in this study. The mean age of respondents were 58.83 (SD 11.632) years with the majority of respondents were age between 51 to 65 years old. These findings are supported by a previous research report that subjects aged 50 years and above are more vulnerable to OA compared to those younger than 50 years old (Zamri et al., 2019). A previous study conducted by Mahmoud et al. (2019) in Egypt showed the mean age of patients that participate in the study were 54.6 (SD 10.4) years while Ouédraogo et al. (2014) showed the mean age was 55 (SD 10.4) in Africa.

As expected, majority of our respondents in this study were female (69.0%). This result similar to a previous study in Terengganu conducted by Zamri et al. (2021) which

found that the female respondents were the majority 80.9%, followed by the study by Zakaria et al. (2009) which consisted of 78.8% of female respondents in majority. It is not surprising at all since women are more affected and burdened by osteoarthritis of the knee compared to men (Hame & Alexander, 2013).

Furthermore, more than half of the respondents in this study were diagnosed with knee osteoarthritis (81.0%) and it was similar with a study in Spain, conducted by Bernad-Pineda et al. (2014) that consisted of knee osteoarthritis (61.5%) as the majority of the respondents while a study by Ackerman et al. (2015) stated that 59.0% of their respondents were diagnosed with knee osteoarthritis.

Other than that, almost half of the respondents 49.0% (49) had body mass index in the overweight category, followed by 32.0% (32) who were obesity, 18.0% (18) normal and 1.0% (1) underweight. This study was slightly different from a study conducted by Fekete et al. (2020) whereby the highest BMI (48.0%) was in the highest category. However, at study from Indonesia conducted by Naqib & Dewati (2018) revealed a similar finding, with the biggest proportion of their respondents (60.5%) falling into the overweight category.

In term of level of education, more than half of the respondents in this present study was secondary school (56.0%), which higher than a study by Kawano et al. (2015) who showed that the secondary school was 37 (SD 39.8) among their respondents.

5.3 Quality of Life

In this present study, the most affected domain was pain (25.46 ± 11.07). This finding was similar to a study conducted by Ouédraogo et al. (2014) using the OAKHQOL questionnaire which reported that the pain domain had the lowest standardized score (60.6 ± 20). In addition, a study reported by Mahmoud et al. (2019) also stated that the pain domain had the lowest quality of life among their respondents (49.8 ± 15.4).

However, the highest quality of life was attained from social functioning (26.78 ± 3.21). This finding was consistent with those of other similar studies reported by Zamri et al. (2021) among osteoarthritis patients in Terengganu and by Ouédraogo et al. (2014) among osteoarthritis patients in Burkina Faso with mean score of 41.25 (SD 27.16) and 75.6 (SD 20.1) respectively. Zakaria et al. (2009) also reported that the highest domain among their respondents was falling into the social functioning (93.62 ± 15.06).

Furthermore, the mean score of physical activity in this present study was 40.45 (SD 23.03), which considered as lower quality of life. The mean score was slightly similar to a study by Zamri et al. (2021), with mean score of 41.6 (SD 22.81). This physical activity results showed relatively lower score as compared to mental health results. However, the lower score in physical activity component compared to the mental component were consistent with other studies such as from Ouédraogo et al. (2014) and Mahmoud et al. (2019). The mental health status was better than the physical health status probably due to the patients' ability to cope and adapt to their illness (Awatif et al., 2019).

In the mental health domain, the mean score was 22.33 ± 19.77 which considered as towards a better quality of life. In contrast, the results of present study was similar to other studies such as in Brazil conducted by Kawano et al. (2015) which revealed that

mental health was interpreted as a better quality with mean score of 60.1 (SD 27.3) while Zakaria et al. (2009) reported that the mean score of mental health domain was 85.0 (SD 14.79). The mental health domain was found to be the least affected due to better coping mechanisms and adaptation to the chronic disease Zamri et al. (2021). The results in this present study were also similar to other study in Egypt that showed mental health domain had higher normalized score which indicated as a better mental health among the respondents (Mahmoud et al., 2019).

The social support showed the mean score of 27.56 (SD 2.16), which interpreted as lower than a study in Morocco that consisted of 59.4 (SD 24.0) but slightly higher than a study in Terengganu by Zamri et al. (2021), with mean score of 21.32 (SD 18.70). In contrast, the social support components significantly affected QOL scores (Awatif et al., 2019). A study in Malaysia, China and Spain also reported a high level of social support. The reason may be that the elderly have more time and energy to communicate with their friends and family after retirement, express their feelings, and get responses from others, thereby increasing their social support (Tan et al., 2022).

5.5 Association between Socio-demographic Characteristics and the Quality of Life

5.5.1 Physical Activity

In physical activity, the significant associated characteristics that affecting the domain were age and types of osteoarthritis among patients with lower limb osteoarthritis. The association between the age and quality of life was similar to a study from Palestine by Arrospide et al. (2019). This could be due to the effect of OA on physical activity, along with the social withdrawal associated with advanced age, which will negatively affect their HRQOL (Kawano et al., 2015).

In terms of gender, there was no significant association between the domains. It was similar with a study conducted by Awatif et al. (2019) in Kedah, Malaysia. They reported that male patients had better scores in all QOL domains, however none of the domains were significant with gender.

There was no statistically significant between all the domains and body mass index (BMI). It was also similar with the study by Fekete et al. (2020) from Hungary which stated that the significant difference was not proved between physical activity and BMI. A study from Awatif et al. (2019) who used SF-12 questionnaires also reported that there was no significant correlation between BMI and QOL scores except for General Health. This was different from other studies where patients with $BMI \geq 30$ had lower QOL score in all domains except social functioning (Awatif et al., 2019).

5.5.2 Mental Health

In mental health, the only significant associated characteristics was level of education. In this study, higher educated respondents showed fewer negative effects on their mental health. This was similar to a study by Zakaria et al. (2009) who stated that a relatively higher score in the mental component in their study showed that mental health

was less affected by knee OA. Therefore, low educational attainment may be the cause for these patients' poor quality of life, as there is little information available about osteoarthritis prevention and treatment, and more exhausting and demanding work activities may expose an individual to osteoarthritis risk factors.

The education level is an important factor in OA patients that some studies show that patients with the higher education level may decrease the severity of the disease and improve their quality of the life (Thabit & Al-Qazaz, 2022). However, they also reported that although there were studies reported that more years of education were associated with better physical function, none of the studies reviewed reported any association between education levels with mental health.

There was no statistically significant between the domain and the gender. It was similar with a study conducted by Subrat et al. (2016) stated that their results also demonstrated a statistically non-significant difference between both genders after comparing all the domains of SF 36 scores among males and females with OA knee using unpaired t test. In addition, Zamri et al. (2021) noted that results of the effect of oestrogen therapy have been conflicting because oestrogen usage is connected to a healthy lifestyle and osteoporosis, which can reduce the risk of OA. This is true even though there has been a significant increase in OA in females around the time of menopause in other previous studies.

5.5.3 Pain

In this domain, the significant associated characteristics that affecting the domain were age and body mass index (BMI). In this study, the increasing of age showed the decreasing of quality of life in level of pain. Thus, it was similar with the study by Ouédraogo et al. (2014) which reported that the dimension above 60 years of age alters

the quality of life in the dimensions of pain. In addition, some authors reported significant correlation between age and pain domain (Mahmoud et al., 2019).

Furthermore, BMI also a significant characteristic affecting lower limb osteoarthritis respondents in our study. This finding indicated that when BMI increased, the quality of life for people with pain decreased. It was similar to other studies where patients with BMI ≥ 30 had lower QOL score in all domains except social functioning (Awatif et al., 2019).

Moreover, there was no statistically significant between the education level and the pain domain. The findings in this study was contrary with the study by Kawano et al. (2015) using the SF-36 pain domain which their results was statistically significant and showed that a better quality of life in those with higher education.

5.5.4 Social Functioning

In this study, none of the variable listed have any significant correlation with the social functioning domain of quality of life except for types of osteoarthritis. However, the result were consistent with other studies such as Kawano et al. (2015) and Zakaria et al. (2009). They reported that none of the variable in their study (without OA at any site) were significantly affecting social functioning domain. These proved that none of the variable studied were significantly affecting social functioning in osteoarthritis patients (Faizal, 2017).

5.5.5 Social Support

There was no significant correlation between sociodemographic characteristics with social support domain of quality of life. Awatif et al. (2019) stated there was no significant correlation between social support and QOL score in their study. However, it was contrary with a study by Ethgen et al. (2004) who stated that social support

components were significantly account for health-related quality of life. Hence, older adults with more social support were likely to have less loneliness and depression (Kang et al., 2018).

5.6 Strength and Limitation of Study

This study has strengths and limitations that can be improved upon by other researchers in subsequent studies. First and foremost, the strength of this study is it is composed of a high validity and reliability of item questionnaires, Osteoarthritis Knee and Hip Quality of Life (OAKHQOL) which has been adapted into Malay version by Kadir et al. in 2018. Therefore, this questionnaire is easy to understand and answered by the target population, regardless of who they are. Other than that, OAKHQOL is the first quality of life tool that specifically dedicated to lower-limb osteoarthritis.

Moreover, the authors of this questionnaire are the experts in Family Medicine from Universiti Sains Malaysia Health Campus, who consist of associate professors, philosophy doctor and medical doctor. As a result, the quality of this questionnaire is of the highest possible standard. Furthermore, the findings from this study may contribute to a better adaptation in quality of life among the patients particularly in Hospital USM. This is because the healthcare professionals may be more concerned regarding this issue and provide the patients with the best, most comprehensive and holistic care possible all at once.

However, the limitations of this study also need to be considered when conducting the study. The respondents of this study were not completely enough due to a very short time frame for the data collection. However, the total respondents who participated had achieved more than 70% of total study populations. Therefore, the data will be more substantial as a bigger sample size will help to produce a more significant result. Apart from that, as the targeted area for this study was only in Hospital USM, the result from

this study population does not represent all the quality of life among patients with lower limb osteoarthritis in Kelantan. Furthermore, the study only consists of single ethnic only which is Malay. Consequently, it is impossible to determine the way the outcomes varied in the present study.

CHAPTER 6: CONCLUSION

This research study highlighted how important the quality of life is among lower limb osteoarthritis patients in Hospital USM. The results have been reported in chapter 4 while the implications have been discussed in chapter 5. The summary of the study's results, implications for nursing practise and education, suggestions for future research, and study conclusion were all covered in this chapter.

6.1 Summary of the Study Finding

This cross-sectional study was done at Hospital Universiti Sains Malaysia to identify the quality of life among patients with lower limb osteoarthritis. This research included a total of 100 patients, with 31 males and 69 females from Orthopaedics Clinic. According to the findings of the study, the quality of life of the patients differs with the domains. For physical activity, the average mean was 40.45 (SD 23.03), mental health 22.33 (SD 19.77), pain 25.46 (SD 11.07), social functioning 26.78 (SD 3.21) and social support 27.56 (SD 2.16).

The level of pain from pain domain in this study showed that most of the patients were having severe pain in pain frequency, pain intensity, difficulty to sleep because of pain and wake up from sleep because of pain. There is a significant association between age and types of OA with physical activity, level of education with mental health, age and BMI with pain. However, the result of this present study also revealed that there is no significant association between the sociodemographic characteristics with social support and social functioning.

6.2 Implications and Recommendations

6.2.1 Nursing Practice

Nurses are the ones who responsible for taking care of the patients by providing their best and holistic care that encompasses both physical and emotional support for them. In this situation, the results from this study can be implemented by our nurses to know that how affected the quality of life is among the osteoarthritis patients especially in terms of pain and physical activity. Therefore, new interventions can be applied in order to provide the care as best as possible. Additionally, the quality of life for patients can improve significantly while they are receiving therapy or being hospitalised.

6.2.2 Nursing Education

The finding of the study can be helpful in the planning of nursing education for the students either in theoretically or practically. The study's findings can be useful in both theoretical and practical planning for students' nursing education. It will be more beneficial and make the students aware of how crucial it is to create a positive nurse-patient relationship while offering the patients excellent holistic care. It is because their quality of life can be affected from the disease itself and also people surrounding. A good quality of life can indicate a good healing process.

6.2.3 Recommendation

The recommendation for future research is sociodemographic questions that can be added into the future study such as unilateral or bilateral knee or hip osteoarthritis and the stages of osteoarthritis. So that, the results outcome will be more detail and specific. Furthermore, it can be added more than one ethnic in this study such as Chinese and Indian since some of them are also affected with OA. Thus, the result of quality of life will be different.

6.3 Conclusion

The findings of this study showed that the quality of life among patients with lower limb osteoarthritis was the worst in pain domain and the best in social functioning. The mental health and social support of the patients also considered as a good quality of life. However, the physical activity was in between, which is almost equally in both poor and good quality of life. These findings need to be concerned healthcare professionals in order to improve patients' quality of life.

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8.0 APPENDIX

8.1 Appendix A: Instrument

SOAL SELIDIK (VERSI MELAYU)

KUALITI HIDUP DALAM KALANGAN PESAKIT YANG MENGALAMI OSTEOARTRITIS ANGGOTA BAWAH DI HOSPITAL UNIVERSITI SAINS MALAYSIA

KOD: _____

SEKSYEN A : DATA CIRI-CIRI SOSIO-DEMOGRAFIK

Arahan: Soalan berikut bertujuan untuk menilai ciri-ciri sosio-demografik anda. Sila tanda (√) pada kotak yang sesuai dengan respon anda dan/ atau isi di ruangan yang disediakan.

- 1) Umur (Sila nyatakan: _____ tahun)
- 2) Jantina
 - Lelaki
 - Perempuan
- 3) Jenis Osteoartritis
 - Osteoartritis Lutut
 - Osteoartritis Paha
- 4) Berat Badan (Sila nyatakan: _____ kg)
Tinggi (Sila nyatakan: _____ cm)
Indeks Jisim Tubuh (BMI): _____
- 5) Tahap Pendidikan:
 - Peringkat Rendah
 - Peringkat Menengah

SEKSYEN B: TAHAP KUALITI HIDUP

Arahan: Soalan berikut bertujuan untuk menilai tahap kualiti hidup anda. Sila tanda (√) pada kotak yang sesuai dengan respon anda bermula dari skala 1 (tidak sama sekali) hingga skala 10 (sangat kerap).

	Tidak sama sekali										Sangat kerap
1) Saya mengalami kesusahan untuk berjalan.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
2) Saya mengalami kesusahan untuk tunduk atau meluruskan badan/bangun semula.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
3) Saya mengalami kesusahan untuk menuruni tangga.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
4) Saya mengalami kesusahan untuk menaiki tangga.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
5) Saya mengalami kesusahan untuk mandi.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
6) Saya mengalami kesusahan untuk berpakaian lengkap (seperti memakai stoking, kasut, seluar dan sebagainya).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
7) Saya mengalami kesusahan untuk memotong kuku kaki.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
8) Saya mengalami kesusahan untuk masuk dan keluar daripada kereta.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10

- 9) Saya mengalami kesusahan untuk menggunakan kenderaan awam (bas, teksi dsb).
0 1 2 3 4 5 6 7 8 9 10
- 10) Saya kurang bersemangat disebabkan sakit
0 1 2 3 4 5 6 7 8 9 10
- 11) Saya risau menjadi tidak berkemampuan
0 1 2 3 4 5 6 7 8 9 10
- 12) Saya merasa malu apabila orang melihat saya
0 1 2 3 4 5 6 7 8 9 10
- 13) Saya berasa gelisah
0 1 2 3 4 5 6 7 8 9 10
- 14) Saya berasa tertekan
0 1 2 3 4 5 6 7 8 9 10
- 15) Saya merasakan kehidupan keluarga saya terjejas
0 1 2 3 4 5 6 7 8 9 10
- 16) Saya mengalami kesakitan (kekerapan)
0 1 2 3 4 5 6 7 8 9 10
- 17) Saya mengalami kesakitan (keterukan)
0 1 2 3 4 5 6 7 8 9 10
- 18) Saya memerlukan pertolongan untuk membuat sesuatu seperti kerja rumah dan membeli belah
0 1 2 3 4 5 6 7 8 9 10
- 19) Saya mampu/boleh merancang projek/program untuk jangkamasa yang panjang
0 1 2 3 4 5 6 7 8 9 10
- 20) Saya keluar rumah sekerap mana yang saya suka
0 1 2 3 4 5 6 7 8 9 10

- 21) Saya melayan tetamu di rumah sebanyak
mana yang saya suka
- 0 1 2 3 4 5 6 7 8 9 10
- 22) Saya mengalami kesukaran untuk tidur atau
tidur semula kerana sakit
- 0 1 2 3 4 5 6 7 8 9 10
- 23) Saya terjaga disebabkan sakit
- 0 1 2 3 4 5 6 7 8 9 10
- 24) Saya tertanya-tanya apa yang bakal
berlaku/kan terjadi kepada saya
- 0 1 2 3 4 5 6 7 8 9 10
- 25) Saya merasakan orang lain faham tentang
kesusahan yang saya alami disebabkan
penyakit sendi (arthritis) saya
- 0 1 2 3 4 5 6 7 8 9 10
- 26) Saya merasa malu untuk meminta
bantuan/pertolongan jika perlu
- 0 1 2 3 4 5 6 7 8 9 10
- 27) Saya rasa saya diberi sokongan oleh orang
yang rapat dengan saya (pasangan dan
keluarga)
- 0 1 2 3 4 5 6 7 8 9 10
- 28) Saya rasa saya diberi sokongan oleh orang
yang berada di sekeliling saya (kawan dan
jiran)
- 0 1 2 3 4 5 6 7 8 9 10

SURVEY QUESTIONNAIRE (ENGLISH VERSION)

**QUALITY OF LIFE AMONG PATIENTS WITH LOWER LIMB
OSTEOARTHRITIS IN HOSPITAL UNIVERSITI SAINS MALAYSIA**

CODE: _____

SECTION A : SOCIO-DEMOGRAPHIC CHARACTERISTICS

Instruction: The following questions are intended to assess your socio-demographic characteristics. Please fill in the blank and tick () the appropriate answer box that best response to you.

- 1) Age (Please state: _____ years)
- 2) Gender
 - Male
 - Female
- 3) Types of Osteoarthritis
 - Knee Osteoarthritis
 - Hip Osteoarthritis
- 4) Body Weight (Please state: _____ kg)
Height (Please state: _____ cm)
Body Mass Index (BMI): _____
- 5) Educational Level:
 - Primary School
 - Secondary School
 - Higher Education

SECTION B: LEVEL OF QUALITY OF LIFE

Instruction: The following questions are intended to assess your level of quality of life.

Please tick (✓) the appropriate answer box that best response to you which ranging from

0 (not at all) to 10 (a great deal).


	Not at all											A great deal										
1) I have difficulty walking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10
2) I have difficulty bending down or straightening up	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10
3) I have difficulty going down stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10
4) I have difficulty climbing stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10
5) I have difficulty taking a bath	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10
6) I have difficulty getting dressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10
7) I have difficulty cutting my toe-nails	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10
8) I have difficulty getting in and out of a car	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10
9) I have difficulty using public transport	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10
10) My spirits are low because of the pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	0	1	2	3	4	5	6	7	8	9	10	0	1	2	3	4	5	6	7	8	9	10

	0	1	2	3	4	5	6	7	8	9	10
11) I worry about being disabled	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
12) I feel embarrassed when people look at me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
13) I am anxious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
14) I am depressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
15) I feel my family life is being affected	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
16) I have pain (describe frequency)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
17) I have pain (describe intensity)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
18) I need help for things like housework and shopping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
19) I am able to plan projects for the long term	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
20) I get out of the house as much as I like	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
21) I entertain at home as much as I like	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
22) I have difficulty getting to sleep or getting back to sleep because of pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
23) I wake up because of pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10
24) I wonder what will become of me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	0	1	2	3	4	5	6	7	8	9	10

- 25) I feel others understand the difficulties I have because of my arthritis
0 1 2 3 4 5 6 7 8 9 10
- 26) I am embarrassed to ask for help if I need it
0 1 2 3 4 5 6 7 8 9 10
- 27) I feel supported by people close to me
0 1 2 3 4 5 6 7 8 9 10
- 28) I feel supported by those around me
0 1 2 3 4 5 6 7 8 9 10

Permission from the Author

11/5/22, 3:32 PM Gmail - Request and Permission to Use Questionnaire Tool

 Nuranis Milani Ahmad Nazeri <nuranismilani@gmail.com>

Request and Permission to Use Questionnaire Tool
4 messages

Nuranis Milani Ahmad Nazeri <nuranismilani@gmail.com> Fri, Oct 21, 2022 at 12:35 AM
To: francis.guillemine@chu-nancy.fr

Dear Dr. Francis Guillemin,

I am Nuranis Milani, an undergraduate student in Bachelor of Nursing from Universiti Sains Malaysia (USM) writing my Final Year Project titled Quality of Life Among Elderly Patients with Lower Limb Osteoarthritis in Hospital Universiti Sains Malaysia (HUSM).

In relation to the aforementioned subject above, I would like to ask for permission to use the questionnaire from your article "OAKHQOL: A New Instrument To Measure Quality of Life in Knee and Hip Osteoarthritis" because I feel it will be very beneficial to me and will raise the standard of my research study's execution.

Thank you so much for your help and encouragement. I appreciate your time and look forward to hearing from you soon.

Sincerely,
Nuranis Milani,
Degree of Nursing Student,
University Sains Malaysia (USM),
16150 Kubang Kerian, Kelantan, Malaysia.

GUILLEMIN Francis <francis.guillemine@chru-nancy.fr> Fri, Oct 21, 2022 at 12:39 AM
To: Nuranis Milani Ahmad Nazeri <nuranismilani@gmail.com>

Dear Nuranis Milani,

I appreciate your interest in this instrument, of which you certainly know that a Malay version has been validated : Adaptation and Validation of the Malay Version of the Osteoarthritis Knee and Hip Quality of Life Questionnaire among Knee Osteoarthritis Patients
Azidah Abdul Kadir<https://pubmed.ncbi.nlm.nih.gov/?sort=date&term=Abdul+Kadir+A&cauthor_id=29955601> 1<<https://pubmed.ncbi.nlm.nih.gov/29955601/#affiliation-1>>, Mohd Faizal Mohd Arif<https://pubmed.ncbi.nlm.nih.gov/?sort=date&term=Mohd+Arif+MF&cauthor_id=29955601> 1<<https://pubmed.ncbi.nlm.nih.gov/29955601/#affiliation-1>>, Azlina Ishak<https://pubmed.ncbi.nlm.nih.gov/?sort=date&term=Ishak+A&cauthor_id=29955601> 1<<https://pubmed.ncbi.nlm.nih.gov/29955601/#affiliation-1>>, Intan Idiana Hassan<https://pubmed.ncbi.nlm.nih.gov/?sort=date&term=Hassan+I&cauthor_id=29955601> 2<<https://pubmed.ncbi.nlm.nih.gov/29955601/#affiliation-2>>, Norhayati Mohd Noor<https://pubmed.ncbi.nlm.nih.gov/?sort=date&term=Mohd+Noor+N&cauthor_id=29955601> 1<<https://pubmed.ncbi.nlm.nih.gov/29955601/#affiliation-1>> Biomed Res Int. 2018 May 31;2018:4329751. doi: 10.1155/2018/4329751. eCollection 2018.

I grant you permission to use it for your study, in which I recommend you quote the publication

With best wishes

Francis Guillemin

CIC 1433 Epidémiologie clinique
Inserm, CHRU, Université de Lorraine
CHRU de Nancy-Hopitaux de Brabois
9 allée du morvan
54505 Vandoeuvre-les-Nancy



Nuranis Milani Ahmad Nazeri <nuranismilani@gmail.com>

Request and Permission to Use Questionnaire Tool

2 messages

Nuranis Milani Ahmad Nazeri <nuranismilani@gmail.com>

Thu, Oct 27, 2022 at 10:20 PM

To: drzalinakk@usm.my

Dear Dr. Azlina Ishak,

I am Nuranis Milani, an undergraduate student in Bachelor of Nursing from Universiti Sains Malaysia (USM) writing my Final Year Project titled Quality of Life Among Young Elderly Patients with Lower Limb Osteoarthritis in Hospital Universiti Sains Malaysia (HUSM).

In relation to the aforementioned subject above, I would like to request permission to adopt the questionnaire from your article "Adaptation and Validation of the Malay Version of the Osteoarthritis Knee and Hip Quality of Life Questionnaire among Knee Osteoarthritis Patients" for my final year project because I feel it will be very beneficial to me and will raise the standard of my research study's execution.

Your assistance and support are highly appreciated. Thank you so much for your help and encouragement. I appreciate your time and look forward to hearing from you soon, Dr.

Sincerely,
Nuranis Milani,
Degree of Nursing Student,
University Sains Malaysia (USM),
16150 Kubang Kerian, Kelantan, Malaysia.

Azlina Ishak <drzalinakk@usm.my>

Thu, Oct 27, 2022 at 10:57 PM

To: Nuranis Milani Ahmad Nazeri <nuranismilani@gmail.com>

Dear Nuranis,

I am glad you are interested in using the questionnaire.

I am happy to assist you by granting permission to use it.

Thank you.

Dr Azlina Ishak
Family Medicine Department,
School of Medical Sciences,
USM Health Campus,

From: Nuranis Milani Ahmad Nazeri <nuranismilani@gmail.com>

Sent: Thursday, October 27, 2022 10:20 PM

To: Azlina Ishak <drzalinakk@usm.my>

Subject: Request and Permission to Use Questionnaire Tool

[Quoted text hidden]

8.2 Appendix B: Research Information

LAMPIRAN A

MAKLUMAT KAJIAN

Tajuk Kajian: Kualiti Hidup dalam Kalangan Pesakit yang Mengalami Osteoarthritis Anggota Bawah di Hospital Universiti Sains Malaysia

Nama Penyelidik: Nuranis Milani Binti Ahmad Nazeri

Penyelidik Bersama: Dr. Zakira Binti Mamat @ Mohamed

PENGENALAN

Anda adalah dipelawa untuk menyertai satu kajian penyelidikan mengenai kualiti hidup dalam kalangan pesakit yang mengalami osteoarthritis anggota bawah di Hospital Universiti Sains Malaysia secara sukarela. Kajian ini adalah berkaitan penilaian tahap kualiti hidup demi menyediakan pesakit dengan penjagaan yang lebih baik dan rawatan yang holistik merangkumi sokongan fizikal dan mental. Hal ini kerana kualiti hidup boleh menjejaskan keupayaan seseorang untuk melakukan aktiviti hidup seharian, terutama sekali golongan warga tua jika ianya tidak diambil berat dan dipandang serius oleh kakitangan kesihatan. Oleh itu, penilaian maklumat pesakit tentang kualiti hidup mereka secara tidak langsung akan dapat membantu kakitangan kesihatan memahami bagaimana keadaan seseorang pesakit itu mampu memberi kesan terhadap mereka di samping dapat membantu menyediakan perawatan yang berkesan untuk mereka.

Adalah penting bagi anda membaca dan memahami maklumat kajian sebelum anda bersetuju untuk menyertai kajian penyelidikan ini. Sekiranya anda menyertai kajian ini, anda akan menerima satu salinan borang ini untuk simpanan anda.

Penyertaan anda di dalam kajian ini dijangka mengambil masa 15 hingga 20 minit sahaja. Seramai 120 orang dijangka akan menyertai kajian ini.

TUJUAN KAJIAN

Kajian ini bertujuan untuk mengenal pasti kualiti hidup terhadap pesakit yang mengalami osteoarthritis anggota bawah di Hospital Universiti Sains Malaysia. Kajian ini juga bertujuan untuk menentukan hubungan antara ciri sosio-demorafik terpilih dan kualiti hidup pesakit yang mengalami osteoarthritis anggota bawah di Hospital Universiti Sains Malaysia.

KELAYAKAN PENYERTAAN

Salah seorang kakitangan kajian akan membincangkan kelayakan untuk menyertai kajian ini. Adalah penting anda berterus terang dengan kakitangan tersebut tentang maklumat yang diperlukan termasuklah sejarah kesihatan anda.

Kajian ini akan melibatkan individu yang:

- Mengalami diagnosis perubatan sebelah atau kedua-dua belah osteoarthritis lutut dan peha.

- Mampu memahami dan menjawab dalam Bahasa Melayu atau Inggeris

Kajian ini tidak akan melibatkan individu yang:

- Mempunyai sakit tenat
- Mempunyai masalah mental
- Mempunyai penyakit degeneratif yang menjejaskan kualiti hidup seperti penyakit jantung, penyakit Parkinson, kegagalan buah pinggang, kanser dan sebagainya.

PROSEDUR-PROSEDUR KAJIAN

Sekiranya anda bersetuju untuk menyertai kajian ini, anda perlu menjawab soalan kaji selidik yang diedarkan oleh penyelidik. Masa yang diperlukan untuk menyiapkan soalan kaji selidik ini lebih kurang 15 hingga 20 minit sahaja.

Soalan ini terdiri daripada dua seksyen. Seksyen A merangkumi 5 soalan berkaitan ciri-ciri sosio-demografik manakala Seksyen B terdiri daripada 28 soalan untuk menilai tahap kualiti hidup berkenaan osteoarthritis anggota bawah.

RISIKO

Kajian ini berbentuk soalan. Justeru, tiada prosedur invasif yang perlu dilakukan. Responden mungkin merasakan sedikit jemu dan penat semasa menjawab soalan. Walaubagaimanapun, sila maklumkan kepada kakitangan kajian sekiranya anda menghadapi sebarang masalah atau mempunyai sebarang maklumat penting yang mungkin mengubah persetujuan anda untuk terus menyertai kajian ini.

MELAPORKAN PENGALAMAN KESIHATAN

Sila hubungi kakitangan berikut pada bila-bila masa sekiranya anda mengalami sebarang masalah kesihatan, samada berkaitan atau tidak berkaitan dengan kajian ini secepat mungkin:

Nuranis Milani Binti Ahmad Nazeri di talian 011-61668252

PENYERTAAN DALAM KAJIAN

Penyertaan anda dalam kajian ini adalah secara sukarela. Anda berhak menolak untuk menyertai kajian ini atau menamatkan penyertaan anda pada bila-bila masa, tanpa sebarang kehilangan manfaat yang sepatutnya anda perolehi.

Penyertaan anda juga mungkin boleh diberhentikan oleh kakitangan kajian ini tanpa persetujuan anda sekiranya anda didapati tidak sesuai untuk meneruskan kajian ini berdasarkan protokol kajian. Kakitangan kajian akan memaklumkan anda sekiranya anda perlu diberhentikan dari menyertai kajian ini.

MANFAAT YANG MUNGKIN

Prosedur kajian ini akan diberikan kepada anda tanpa kos. Sekalung penghargaan diberi atas kesudian anda menyertai kajian ini. Hasil kajian ini diharapkan, dapat memberi manfaat kepada masyarakat umum sebagai kesedaran untuk menjaga kesihatan mereka sementara penuaan semakin meningkat kerana terdapat pelbagai aspek yang akan terjejas

melibatkan kualiti hidup seperti aktiviti fizikal, kesihatan mental, fungsi sosial dan sebagainya. Ia juga sangat berguna sebagai penanda aras dan maklumat tambahan kepada kakitangan kesihatan terutama sekali jururawat, untuk meningkatkan mutu penjagaan kepada pesakit dari segi fizikal dan mental. Maklum balas anda sangat bermanfaat untuk kami sentiasa mengambil perhatian terhadap kesihatan anda di samping membantu menyediakan servis kesihatan yang lebih baik. Sementara itu, anda tidak akan menerima sebarang pampasan kerana menyertai kajian ini.

PERSOALAN

Sekiranya anda mempunyai sebarang soalan mengenai prosedur kajian ini atau hak-hak anda, sila hubungi;

Nuranis Milani Binti Ahmad Nazeri

Program Kejururawatan
Pusat Pengajian Sains Kesihatan
Kampus Kesihatan
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan
No. Tel: 01161668252
E-mail: nuranismilani@gmail.com

Dr. Zakira Binti Mamat @ Mohamed

Program Kejururawatan
Pusat Pengajian Sains Kesihatan
Kampus Kesihatan
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan
No. Tel: 0199326335
E-mail: zakira@usm.my

Sekiranya anda mempunyai sebarang soalan berkaitan kelulusan etika atau sebarang pertanyaan dan masalah berkaitan kajian ini, sila hubungi;

En. Mohd Bazlan Hafidz Mukrim
Setiausaha Jawatankuasa Etika Penyelidikan (Manusia) USM
Bahagian Penyelidikan dan Inovasi (P&I)
USM Kampus Kesihatan.
No. Tel: 09-767 2354 / 09-767 2362
Email: bazlan@usm.my

KERAHSIAAN

Maklumat yang anda berikan akan dirahsiakan oleh kakitangan kajian. Ianya tidak akan dedahkan secara umum melainkan jika ia dikehendaki oleh undang-undang.

Data yang diperolehi dari kajian ini tidak akan mengenalpasti anda secara perseorangan. Hasil kajian mungkin akan diterbitkan untuk tujuan perkongsian ilmu.

Semua borang kajian dan data yang anda berikan mungkin akan disemak oleh pihak penyelidik, Lembaga Etika kajian ini dan pihak berkuasa regulatori bagi tujuan mengesahkan prosedur dan/atau data kajian klinikal. Maklumat anda akan disimpan dalam komputer dan hanya kakitangan kajian yang dibolehkan sahaja dibenarkan untuk mendapatkan dan memproses data tersebut.

Dengan menandatangani borang persetujuan ini, anda membenarkan penelitian rekod, penyimpanan maklumat dan pemprosesan data seperti yang dihuraikan di atas.

TANDATANGAN

Untuk dimasukkan ke dalam kajian ini, anda atau wakil sah anda mesti menandatangani serta mencatatkan tarikh halaman tandatangan.

ATTACHMENT B

RESEARCH INFORMATION

Research Title: Quality of Life among Patients with Lower Limb Osteoarthritis in Hospital Universiti Sains Malaysia
Researcher's Name: Nuranis Milani Binti Ahmad Nazeri
Co-Researcher's Name: Dr. Zakira Binti Mamat @ Mohamed

INTRODUCTION

You are invited to take part voluntarily in research studying quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia. This research is about assessing quality of life in order to provide patients with better care and holistic treatment that encompasses both physical and emotional support. This is because quality of life can impair someone's ability to do daily life activities (ADLs), especially if they fall into the elderly category if it is not being concerned and taken seriously by healthcare professionals. As a result, assessing patients' information about their quality of life can help healthcare providers better comprehend how a patient's condition may affect them individually and can offer an effective possible treatment for them.

It is important that you read and understand this research information before agreeing to participate in this study. You will receive a copy of this form to keep for your records if you agree to participate.

Your participation in this study is expected to last 15 to 20 minutes. This study is estimated to include up to 120 participants.

PURPOSE OF THE STUDY

The purpose of this study is to identify the quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia. This study is also to determine the association between socio-demographic characteristics and quality of life among patients with lower limb osteoarthritis in Hospital Universiti Sains Malaysia.

PARTICIPANTS CRITERIA

The research team members will discuss your eligibility to participate in this study. It is important that you are completely truthful with the researcher regarding the wanted information including your health history.

This study will include individuals who are:

- Having medical diagnosis of unilateral or bilateral knee or hip osteoarthritis.
- Able to understand and respond in Malay or English language.

This study will not include individual who are:

- Having terminally ill condition.
- Have underlying mental disorders.
- Have degenerative disease which affect the quality of life such as heart disease, Parkinson's disease, renal failure, cancer and more.

STUDY PROCEDURES

If you agree to participate in the study, you will need to respond to a survey questionnaire distributed by the researcher. The time taken to complete the questionnaire will be approximately 15 - 20 minutes.

This questionnaire consists of two sections. Section A consists of 5 questions related to socio-demographic characteristics while Section B consists of 28 questions that assess the level of quality of life regarding lower limb osteoarthritis.

RISKS

This research is in questionnaire, no invasive procedure will be done. Respondent may feel tired or boring when answer the question. However, please inform the researcher if you are facing any problem or have any importance information that may change your agreement to continue participate in this study.

REPORTING HEALTH EXPERIENCES.

Please contact, at any time, the following researcher if you experience any health problem either directly or indirectly related to this study:

Nuranis Milani Binti Ahmad Nazeri at 011-61668252

PARTICIPATION IN THE STUDY

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation in the study at any time, without any penalty or loss of benefits to which you are otherwise entitled. Your participation also may be stopped by the research team without your consent if in any form you have violated the study eligibility criteria. The research team member will discuss with you if the matter arises.

POSSIBLE BENEFITS

You may not receive benefits directly from this study. However, a small token of appreciation will be given to you for your participations. This study finding may benefit the community as an awareness to take care of their health as ageing becomes rising since there are many aspects can be affected to their quality of life such as physical activity, mental health, social functioning and many more. It also can be very useful as a benchmark and additional information for our healthcare providers especially nurses to improve their quality care for the patients physically and mentally. Your response will

benefit us to understand and aware of your condition in order to help you receive a better healthcare service. You will not receive any compensation from this study.

QUESTIONS

If you have any question about this study or your rights, please contact:

Nuranis Milani Binti Ahmad Nazeri

Program of Nursing
School of Health Science
Health Campus
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan
Tel. No.: 01161668252
E-mail: nuranismilani@gmail.com

Dr. Zakira Binti Mamat @ Mohamed

Program of Nursing
School of Health Science
Health Campus
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan
Tel. No.: 0199326335
E-mail: zakira@usm.my

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact:

Mr. Mohd Bazlan Hafidz Mukrim

Secretary of Human Research Ethics Committee USM
Division of Research & Innovation (R&I)
USM Health Campus
Tel. No.: 09-767 2354 / 09-767 2362
Email: bazlan@usm.my

CONFIDENTIALITY

Your information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the study procedures and/or data. Your information may be held and processed on a computer. Only research team members are authorized to access your information.

By signing this consent form, you authorize the record review, information storage and data process described above.

SIGNATURES

To be entered into the study, you or a legal representative must sign and date the signature page.

8.3 Appendix C: Subject Information and Consent Form

LAMPIRAN S

Borang Keizinan Peserta (Halaman Tandatangan)

Tajuk Kajian: Kualiti Hidup dalam Kalangan Pesakit yang Mengalami Osteoarthritis Anggota Bawah di Hospital Universiti Sains Malaysia

Nama Penyelidik: Nurani Milani Binti Ahmad Nazeri

Penyelidik Bersama: Dr. Zakira Binit Mamat @ Mohamed

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini. Dengan menandatangani mukasurat ini, saya mengesahkan yang berikut:

- Saya telah membaca semua maklumat dalam Borang Maklumat dan Keizinan Pesakit ini termasuk apa-apa maklumat berkaitan risiko yang ada dalam kajian dan saya telah pun diberi masa yang mencukupi untuk mempertimbangkan maklumat tersebut.
- Semua soalan-soalan saya telah dijawab dengan memuaskan.
- Saya, secara sukarela, bersetuju menyertai kajian penyelidikan ini, mematuhi segala prosedur kajian dan memberi maklumat yang diperlukan kepada doktor, para jururawat dan juga kakitangan lain yang berkaitan apabila diminta.
- Saya boleh menamatkan penyertaan saya dalam kajian ini pada bila-bila masa.
- Saya telah pun menerima satu salinan Borang Maklumat dan Keizinan Peserta untuk simpanan peribadi saya.

Nama Peserta

No. Kad Pengenalan Peserta

Tandatangan Peserta atau Wakil Sah
(Masa jika perlu)

Tarikh (dd/MM/yy)

Nama & Tandatangan Individu yang Mengendalikan
Perbincangan Keizinan

Tarikh (dd/MM/yy)

Nama Saksi dan Tandatangan

Tarikh (dd/MM/yy)

Nota:

i) Semua peserta yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

**Subject Information and Consent Form
(Signature Page)**

Research Title: Quality of Life among Patients with Lower Limb Osteoarthritis in Hospital Universiti Sains Malaysia
Researcher's Name: Nuranis Milani Binti Ahmad Nazeri
Co-Researcher's Name: Dr. Zakira Binti Mamat @ Mohamed

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form including any information regarding the risk in this study and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at any time.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

Participant Name

Participant I.C No

Signature of Participant or Legal Representative

Date(dd/MM/yy)

**Name & Signature of Individual
Conducting Consent Discussion**

Date(dd/MM/yy)

Name & Signature of Witness

Date (dd/MM/yy)

Note: i) All participants who are involved in this study will not be covered by insurance.

8.4 Appendix D: Institutional Approval (Permission to conduct the study)



HOSPITAL UNIVERSITI SAINS MALAYSIA
KAMPUS KESIHATAN, USM
16150 KUBANG KERIAN, KELANTAN

BORANG PERMOHONAN PENGUNAAN DATA PESAKIT, PERKHIDMATAN MAKMAL DAN LAIN-LAIN DI HOSPITAL USM

BAHAGIAN A : MAKLUMAT PEMOHON

NAMA : NURANIS MILANI BINTI AHMAD NAZERI

NO. KAD PENGENALAN : 990703036786

ALAMAT/JABATAN : PROGRAM KEJURURAWATAN, PUSAT PENGAJIAN SAINS KESIHATAN,
UNIVERSITI SAINS MALAYSIA KAMPUS KESIHATAN,
16150 KOTA BHARU, KELANTAN.

PROGRAM AKADEMIK : JAJAH SARJANA MUDA KEJURURAWATAN

PUSAT PENGAJIAN : PUSAT PENGAJIAN SAINS KESIHATAN

NO. TELEFON : 01 161 668252 EMAIL : nuranismilani@student.usm.my

TAJUK PENYELIDIKAN / AKTIVITI (jika berkaitan: beside teaching/peperiksaan professional)
QUALITY OF LIFE AMONG PATIENTS WITH LOWER LIMB OSTEOARTHRITIS IN HOSPITAL UNIVERSITI
SAINS MALAYSIA

JENIS & NOMBOR AKAUN GERAN (jika berkaitan: FRGS, RU, Jangka pendek, insentif dll)
.....

TEMPOH PENYELIDIKAN / AKTIVITI : OKTOBER 2022 HINGGA OGOS 2023

**SILA SENARAIKAN NAMA PAKAR/PENSYARAH/STAF/PELAJAR JIKA PERMOHONAN MELIBATKAN
PENYELIDIKAN, PROJEK INOVASI, LATIHAN INDUSTRI & PEMBELAJARAN.**

PENYELIDIK UTAMA/KETUA KUMPULAN/PENYELIA UTAMA:

..NURANIS MILANI BINTI AHMAD NAZERI

PENYELIDIK BERSAMA/AHLI KUMPULAN (jika berkaitan):

1. DR. ZAKIRA BINTI MAMAT @ MOHAMED

2.

3.

4.

PELAJAR SELIAAN/KUMPULAN PELAJAR (jika berkaitan):

1.

2.

3.

(JIKA LATIHAN INDUSTRI, SILA NYATAKAN TEMPAT ASAL PENGAJIAN/KERJA PELAJAR)
.....

BAHAGIAN B : PERMOHONAN PENGGUNAAN DATA PESAKIT, PERKHIDMATAN MAKMAL DAN LAIN-LAIN

(sila tanda (/) diruang yang disediakan)

MAKLUMAT DIPERLUKAN

PENGGUNAAN DATA PESAKIT

Tujuan Pengajaran dan pembelajaran

Penyelidikan

Projek inovasi

Latihan industri

Tarikh Mula : OKTOBER 2022.....

Tarikh Tamat : OGOS 2023.....

Penerangan DATA PESAKIT YANG DIPERLUKAN ADALAH DI KLINIK ORTOPEDIK PESAKIT LUAR SAHAJA.

PERKHIDMATAN MAKMAL

MAKMAL PATOLOGI KIMIA

MAKMAL FARMAKOKINETIK

MAKMAL ENDOKRIN

MAKMAL FARMAKOLOGI (TOKSIKOLOGI)

MAKMAL HEMATOLOGI

MAKMAL TRANSFUSI PERUBATAN

MAKMAL MIKROBIOLOGI

PUSAT GENOM

MAKMAL HISTOPATOLOGI

NEURO SAINS

MAKMAL IMUNOLOGI

PERKHIDMATAN RADIOLOGI

Tujuan Pengajaran dan pembelajaran

Penyelidikan

Projek inovasi

Latihan industri

Tarikh Mula :

Tarikh Tamat :

Penerangan :

LAIN-LAIN PERKHIDMATAN

ASET MUDAH ALIH (ventilator, ultrasound, SPO2, x-ray dll)

Sila senaraikan :

.....
.....

INFRASTRUKTUR (ruang/wad/bilik rawatan/klinik dll) :

Sila senaraikan :

.....
.....

IVENTORI (peralatan pejabat/ict/perabot/alat gunahabis)

Sila senaraikan :

.....
.....

SUMBER MANUSIA (Jururawat, Pembantu Perawatan Kesihatan, Houseman dll)

Sila senaraikan :

.....
.....

Tujuan Pengajaran dan pembelajaran

Penyelidikan

Projek inovasi

Latihan industri

Tarikh Mula :

Tarikh Tamat :

Penerangan :

.....

BAHAGIAN C : PENGESAHAN KETUA JABATAN/ PENYELIA

Dengan ini saya mengesahkan / tidak mengesahkan maklumat yang di pohon memenuhi keperluan Pengajaran & Pembelajaran, Penyelidikan dan Projek Inovasi


NUR ADIBAH BINTI SOLIHIN SULAIMAN
Pemangku Pengerusi Program Kejururawatan
Busek Pengajaran Sains Kesihatan
(Tandatangan & Cop Rasmi)
Universiti Sains Malaysia

6 Disember 2022

(Tarikh)

BAHAGIAN D : KEGUNAAN PEJABAT

Diperakukan Tidak Diperakukan

Ulasan / Komen :

.....

(Tandatangan & Cop Rasmi)


MOHD SABERI BIN MOHD YUSOFF

TIMBALAN PENDAFTAR KANAN

BAHAGIAN E : KELULUSAN PENGARAH HOSPITAL USM

Diluluskan Tidak Diluluskan

Ulasan / Komen :

.....

(Tandatangan & Cop Rasmi)


PROF. DATO DR. NIK HASMUDDIN NIK AB. RAHMAN

No. MPM : 32959

Pengarah

Hospital Universiti Sains Malaysia

(Tandatangan & Cop Rasmi) Kerian, Kelantan


7/2/23
(Tarikh)

Nota :

1. Maklumat ini hanya dibenarkan bagi tujuan Pengajaran & Pembelajaran, Penyelidikan dan Projek Inovasi secara dalaman sahaja tanpa melibatkan pembentangan dan penerbitan luar.
2. Sila lampirkan ringkasan projek pengajaran & pembelajaran, penyelidikan dan projek inovasi yang diperakukan oleh Penyelia.
3. Sila kemukakan satu salinan borang ini ke Jawatankuasa Etika Penyelidikan Manusia (JPeM)

Edisi Semakan : 01
Tarikh : 31 Okt. 2018

8.5 Appendix E: Ethical Approval



Jawatankuasa Etika
Penyelidikan Manusia USM (JEPeM)
Human Research Ethics Committee USM (HREC)

9th February 2023

Miss Nuranis Milani Ahmad Nazeri
Undergraduate Student (Nursing)
School of Health Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

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Kampus Kesihatan
16150 Kubang Kerian, Kelantan, Malaysia.
Tel. : +609 - 767 3000/2354/2362
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Email : jepem@usm.my
Laman Web : www.jepem.kk.usm.my
www.usm.my

JEPeM Code : USM/JEPeM/22120799

Protocol Title: Quality of Life among Patients with Lower Limb Osteoarthritis in Hospital Universiti Sains Malaysia.

Dear Miss.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/22120799**, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from **9th February 2023** until **8th February 2024**.

Study Site: Hospital Universiti Sains Malaysia.

The following researchers are also involved in this study:

1. Dr. Zakira Mamat @ Mohamed

The following documents have been approved for use in the study.

1. Research Proposal

In addition to the above mentioned document, the following technical documents were included in the review on which this approval was based:

1. Patient Information Sheet and Consent Form (English version)
2. Patient Information Sheet and Consent Form (Malay version)
3. Survey Questionnaire (English version)
4. Survey Questionnaire (Malay version)

While the study is in progress, we request you to submit to us the following documents:

1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2019: Continuing Review Application Form**.
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form**.
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form**.
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2019: Adverse Events Report**.
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2019**.
6. Any event which may have ethical significance.



7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2019: Final Report Form.**

Please note that forms may be downloaded from the JEPeM-USM website:
www.jepem.kk.usm.my

JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

“BERKHIDMAT UNTUK NEGARA”

Sincerely,



ASSOC. PROF. DR. AZLAN HUSIN
Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia